IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. DIANA ESPINOSA, *et al.*, Defendants.	No. 21-cv-1479 (DLF)

NOTICE OF FILING JOINT APPENDIX OF ADMINISTRATIVE RECORD

Pursuant to Local Civil Rule 7(n) and the Court's Minute Order of June 16, 2021, the parties have conferred and Defendants hereby submit a joint appendix, agreed upon by the parties, containing the excerpts from the certified administrative record that were cited by the parties in briefing their cross-motions for summary judgment.[1] Attached hereto is (i) an index of the contents of the joint appendix and (ii) the four-part joint appendix.

Dated: July 16, 2021

Respectfully submitted,

BRIAN D. NETTER
Deputy Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director

/s/ Jody D. Lowenstein
JODY D. LOWENSTEIN
Mont. Bar No. 55816869
KATE TALMOR
RACHAEL L. WESTMORELAND
Trial Attorneys
United States Department of Justice
Civil Division, Federal Programs Branch

[1] If an excerpt of the certified administrative record was cited by either party in briefing their cross-motions for summary judgment and was inadvertently omitted from the joint appendix, the parties have agreed that the joint appendix should be supplemented with the omitted excerpt.

1100 L Street NW
Washington, D.C. 20005
Phone: (202) 598-9280
Email: jody.d.lowenstein@usdoj.gov

Attorneys for Defendants

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Resources and Services Administration
Rockville, MD 20857

May 17, 2021

Mr. Dan Lopuch
Managed Market Finance
Novartis Pharmaceuticals Corporation
One Health Plaza, 135/4110F
East Hanover, NJ 07936

Dear Mr. Lopuch:

The Health Resources and Services Administration (HRSA) has completed its review of Novartis Pharmaceuticals Corporation's (Novartis) policy that places restrictions on 340B pricing to covered entities that dispense medication through pharmacies, unless the covered entities provide claims data to a third-party platform. After review of this policy and an analysis of the complaints HRSA has received from covered entities, HRSA has determined that Novartis' actions have resulted in overcharges and are in direct violation of the 340B statute.

Section 340B(a)(1) of the Public Health Service (PHS) Act requires that manufacturers "shall…offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." This requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. Nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities. Furthermore, the 340B statute does not permit manufacturers to impose conditions on covered entities' access to 340B pricing, including the production of claims data. Section 340B(a)(1) of the PHS Act also requires manufacturers that have signed a Pharmaceutical Pricing Agreement (PPA) and PPA addendum to comply with these requirements. Novartis is bound by the terms of the PPA and must ensure that the 340B ceiling price is available to all covered entities.

Also consistent with section 340B(a)(1) of the PHS Act, manufacturers are expected to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs. This extends to the manner in which 340B drugs are made available to covered entities (e.g., access to 340B ceiling prices through wholesalers that make products available at non-340B ceiling prices).[1] The 340B Program Ceiling Price and Civil Monetary Penalties Final Rule (CMP final rule)[2] further specifies that a manufacturer's failure to provide 340B ceiling prices through the manufacturer's distribution agreements with wholesalers may violate a manufacturer's obligation under the 340B statute. HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor such purchases regardless of the dispensing mechanism.

[1] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017); 42 C.F.R. §10.11(b)(2)
[2] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017)

Novartis purports that the rationale for its restrictive action is to prevent diversion and duplicate discounts. The 340B statute provides a mechanism by which a manufacturer can address these concerns. Specifically, the manufacturer must (1) conduct an audit and (2) submit a claim through the Administrative Dispute Resolution process as described in section 340B(d)(3)(A) of the PHS Act. The 340B statute does not permit a manufacturer to impose industry-wide, universal restrictions.

For the reasons set forth above, Novartis must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy. Novartis must comply with its 340B statutory obligations and the 340B Program's CMP final rule and credit or refund all covered entities for overcharges that have resulted from Novartis' policy. Novartis must work with all of its distribution/wholesale partners to ensure all impacted covered entities are contacted and efforts are made to pursue mutually agreed upon refund arrangements.

Continued failure to provide the 340B price to covered entities utilizing contract pharmacies, and the resultant charges to covered entities of more than the 340B ceiling price, may result in CMPs as described in the CMP final rule. The CMP final rule states that any manufacturer with a PPA that knowingly and intentionally charges a covered entity more than the ceiling price for a covered outpatient drug may be subject to a CMP not to exceed $5,000 for each instance of overcharging.[3] Assessed CMPs would be in addition to repayment for an instance of overcharging as required by section 340B(d)(1)(B)(ii) of the PHS Act. The Department of Health and Human Services will determine whether CMPs are warranted based on Novartis' willingness to comply with its obligations under section 340B(a)(1) of the PHS Act.

HRSA requests that Novartis provide an update on its plan to restart selling, without restriction, 340B covered outpatient drugs at the 340B price to covered entities with contract pharmacy arrangements by **June 1, 2021**, to 340Bpricing@hrsa.gov.

Thank you for your commitment to the 340B Program.

Sincerely,

/Diana Espinosa/

Diana Espinosa
Acting Administrator

[3] Note, the Department of Health and Human Services publishes inflation-adjusted increases for various CMPs annually. The 2020 inflation adjusted penalty for 340B overcharging violations is $5,883. 85 Fed. Reg. 2,869, 2,873 (Jan. 17, 2020).

United States Code Annotated
Title 42. The Public Health and Welfare
Chapter 6A. Public Health Service (Refs & Annos)
Subchapter II. General Powers and Duties
Part D. Primary Health Care
Subpart VII. Drug Pricing Agreements

42 U.S.C.A. § 256b

§ 256b. Limitation on prices of drugs purchased by covered entities

Currentness

(a) Requirements for agreement with Secretary

(1) In general

The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2). Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the "ceiling price"), and shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.

(2) "Rebate percentage" defined

(A) In general

For a covered outpatient drug purchased in a calendar quarter, the "rebate percentage" is the amount (expressed as a percentage) equal to--

(i) the average total rebate required under section 1927(c) of the Social Security Act with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by

(ii) the average manufacturer price for such a unit of the drug during such quarter.

(B) Over the counter drugs

(i) In general

For purposes of subparagraph (A), in the case of over the counter drugs, the "rebate percentage" shall be determined as if the rebate required under section 1927(c) of the Social Security Act is based on the applicable percentage provided under section 1927(c)(3) of such Act.

(ii) "Over the counter drug" defined

The term "over the counter drug" means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law).

(3) Drugs provided under State Medicaid plans

Drugs described in this paragraph are drugs purchased by the entity for which payment is made by the State under the State plan for medical assistance under title XIX of the Social Security Act.

(4) "Covered entity" defined

In this section, the term "covered entity" means an entity that meets the requirements described in paragraph (5) and is one of the following:

(A) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act).

(B) An entity receiving a grant under section 256a of this title.

(C) A family planning project receiving a grant or contract under section 300 of this title.

(D) An entity receiving a grant under subpart II of part C of subchapter XXIV (relating to categorical grants for outpatient early intervention services for HIV disease).

(E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV.

(F) A black lung clinic receiving funds under section 937(a) of title 30.

(G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act.

(H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.

(I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

(J) Any entity receiving assistance under subchapter XXIV (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).

(K) An entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2) of this title (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).

(L) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act) that--

(i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this subchapter;

(ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act; and

(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

(M) A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act, or a free-standing cancer hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v) of the Social Security Act, that would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, if the hospital were a subsection (d) hospital as defined by section 1886(d)(1)(B) of the Social Security Act.

(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act), and that meets the requirements of subparagraph (L)(i).

(O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act, or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.

(5) Requirements for covered entities

(A) Prohibiting duplicate discounts or rebates

(i) In general

A covered entity shall not request payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act.

(ii) Establishment of mechanism

The Secretary shall establish a mechanism to ensure that covered entities comply with clause (i). If the Secretary does not establish a mechanism within 12 months under the previous sentence, the requirements of section 1927(a)(5)(C) of the Social Security Act shall apply.

(B) Prohibiting resale of drugs

With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

(C) Auditing

A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs [1] (A) or (B) with respect to drugs of the manufacturer.

(D) Additional sanction for noncompliance

If the Secretary finds, after audit as described in subparagraph (C) and after notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs [1] (A) or (B), the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in subparagraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.

(6) Treatment of distinct units of hospitals

In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this subsection.

(7) Certification of certain covered entities

(A) Development of process

Not later than 60 days after November 4, 1992, the Secretary shall develop and implement a process for the certification of entities described in subparagraphs (J) and (K) of paragraph (4).

(B) Inclusion of purchase information

The process developed under subparagraph (A) shall include a requirement that an entity applying for certification under this paragraph submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs in the preceding year so as to assist the Secretary in evaluating the validity of the entity's subsequent purchases of covered outpatient drugs at discounted prices.

(C) Criteria

The Secretary shall make available to all manufacturers of covered outpatient drugs a description of the criteria for certification under this paragraph.

(D) List of purchasers and dispensers

The certification process developed by the Secretary under subparagraph (A) shall include procedures under which each State shall, not later than 30 days after the submission of the descriptions under subparagraph (C), prepare and submit a report to the Secretary that contains a list of entities described in subparagraphs (J) and (K) of paragraph (4) that are located in the State.

(E) Recertification

The Secretary shall require the recertification of entities certified pursuant to this paragraph on a not more frequent than annual basis, and shall require that such entities submit information to the Secretary to permit the Secretary to evaluate the validity of subsequent purchases by such entities in the same manner as that required under subparagraph (B).

(8) Development of prime vendor program

The Secretary shall establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs. If a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution.

(9) Notice to manufacturers

The Secretary shall notify manufacturers of covered outpatient drugs and single State agencies under section 1902(a)(5) of the Social Security Act of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of paragraph (5) or that are no longer certified pursuant to paragraph (7).

(10) No prohibition on larger discount

Nothing in this subsection shall prohibit a manufacturer from charging a price for a drug that is lower than the maximum price that may be charged under paragraph (1).

(b) Other definitions--

(1) In general

In this section, the terms "average manufacturer price", "covered outpatient drug", and "manufacturer" have the meaning given such terms in section 1927(k) of the Social Security Act.

(2) Covered drug

In this section, the term "covered drug"--

(A) means a covered outpatient drug (as defined in section 1927(k) (2) of the Social Security Act); and

(B) includes, notwithstanding paragraph (3)(A) of section 1927(k) of such Act, a drug used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section.

(c) Repealed. Pub.L. 111-152, Title II, § 2302(2), Mar. 30, 2010, 124 Stat. 1083

(d) Improvements in program integrity

(1) Manufacturer compliance

(A) In general

From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by manufacturers with the requirements of this section in order to prevent overcharges and other violations of the discounted pricing requirements specified in this section.

(B) Improvements

The improvements described in subparagraph (A) shall include the following:

(i) The development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities, which shall include the following:

(I) Developing and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection.

(II) Comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary.

(III) Performing spot checks of sales transactions by covered entities.

(IV) Inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies.

(ii) The establishment of procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers, including the following:

(I) Providing the Secretary with an explanation of why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued.

(II) Oversight by the Secretary to ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered outpatient drugs.

(iii) The provision of access through the Internet website of the Department of Health and Human Services to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary in accordance with this section, in a manner (such as through the use of password protection) that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure.

(iv) The development of a mechanism by which--

(I) rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of covered outpatient drugs to covered entities are reported to the Secretary; and

(II) appropriate credits and refunds are issued to covered entities if such discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter for the drugs involved.

(v) Selective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program under this section.

(vi) The imposition of sanctions in the form of civil monetary penalties, which--

(I) shall be assessed according to standards established in regulations to be promulgated by the Secretary not later than 180 days after March 23, 2010;

(II) shall not exceed $5,000 for each instance of overcharging a covered entity that may have occurred; and

(III) shall apply to any manufacturer with an agreement under this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1).

(2) Covered entity compliance

(A) In general

From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount provision and other requirements specified under subsection (a)(5).

(B) Improvements

The improvements described in subparagraph (A) shall include the following:

(i) The development of procedures to enable and require covered entities to regularly update (at least annually) the information on the Internet website of the Department of Health and Human Services relating to this section.

(ii) The development of a system for the Secretary to verify the accuracy of information regarding covered entities that is listed on the website described in clause (i).

(iii) The development of more detailed guidance describing methodologies and options available to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A).

(iv) The establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered outpatient drugs under this section, including the processing of chargebacks for such drugs.

(v) The imposition of sanctions, in appropriate cases as determined by the Secretary, additional to those to which covered entities are subject under subsection (a)(5)(D), through one or more of the following actions:

(I) Where a covered entity knowingly and intentionally violates subsection (a)(5)(B), the covered entity shall be required to pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under subsection (a)(5)(D), such interest to be compounded monthly and equal to the current short term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable.

(II) Where the Secretary determines a violation of subsection (a)(5)(B) was systematic and egregious as well as knowing and intentional, removing the covered entity from the drug discount program under this section and

disqualifying the entity from re-entry into such program for a reasonable period of time to be determined by the Secretary.

(III) Referring matters to appropriate Federal authorities within the Food and Drug Administration, the Office of Inspector General of Department of Health and Human Services, or other Federal agencies for consideration of appropriate action under other Federal statutes, such as the Prescription Drug Marketing Act (21 U.S.C. 353).

(3) Administrative dispute resolution process

(A) In general

Not later than 180 days after March 23, 2010, the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(C), of violations of subsections[2] (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B).

(B) Deadlines and procedures

Regulations promulgated by the Secretary under subparagraph (A) shall--

(i) designate or establish a decision-making official or decision-making body within the Department of Health and Human Services to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price described in subsection (a)(1), and claims by manufacturers that violations of subsection (a)(5)(A) or (a)(5)(B) have occurred;

(ii) establish such deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously;

(iii) establish procedures by which a covered entity may discover and obtain such information and documents from manufacturers and third parties as may be relevant to demonstrate the merits of a claim that charges for a manufacturer's product have exceeded the applicable ceiling price under this section, and may submit such documents and information to the administrative official or body responsible for adjudicating such claim;

(iv) require that a manufacturer conduct an audit of a covered entity pursuant to subsection (a)(5)(C) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity;

(v) permit the official or body designated under clause (i), at the request of a manufacturer or manufacturers, to consolidate claims brought by more than one manufacturer against the same covered entity where, in the judgment of such official or body, consolidation is appropriate and consistent with the goals of fairness and economy of resources; and

(vi) include provisions and procedures to permit multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding, and permit such claims to be asserted on behalf of covered entities by associations or organizations representing the interests of such covered entities and of which the covered entities are members.

(C) Finality of administrative resolution

The administrative resolution of a claim or claims under the regulations promulgated under subparagraph (A) shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction.

(4) Authorization of appropriations

There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for fiscal year 2010 and each succeeding fiscal year.

(e) Exclusion of orphan drugs for certain covered entities

For covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M)), (N), or (O) of subsection (a)(4), the term "covered outpatient drug" shall not include a drug designated by the Secretary under section 360bb of Title 21 for a rare disease or condition.

CREDIT(S)

(July 1, 1944, c. 373, Title III, § 340B, as added Pub.L. 102-585, Title VI, § 602(a), Nov. 4, 1992, 106 Stat. 4967; amended Pub.L. 103-43, Title XX, § 2008(i)(1)(A), June 10, 1993, 107 Stat. 212; Pub.L. 111-148, Title II, § 2501(f)(1), Title VII, §§ 7101(a) to (d), 7102, Mar. 23, 2010, 124 Stat. 309, 821, 823; Pub.L. 111-152, Title II, § 2302, Mar. 30, 2010, 124 Stat. 1082; Pub.L. 111-309, Title II, § 204(a)(1), Dec. 15, 2010, 124 Stat. 3289.)

Notes of Decisions (4)

Footnotes

1 So in original. Probably should be "subparagraph".
2 So in original. Probably should be "subsection".

42 U.S.C.A. § 256b, 42 USCA § 256b
Current through P.L. 116-259. Some statute sections may be more current, see credits for details.

End of Document

H.R. REP. 102-384(II), H.R. REP. 102-384, H.R. Rep. No. 384(II), 102ND Cong., 2ND Sess. 1992, 1992 WL 239341 (Leg.Hist.)
THE MEDICAID DRUG REBATE AMENDMENTS OF 1992
P.L. 102-585, *1 VETERANS HEALTH CARE ACT OF 1992
DATES OF CONSIDERATION AND PASSAGE
House: August 4, October 5, 1992
Senate: October 1, 8, 1992
Cong. Record Vol. 138 (1992)
House Report (Veterans' Affairs Committee) No. 102-714, July 24, 1992 (To accompany H.R. 5193)
Senate Report (Veterans' Affairs Committee) No. 102-401, Sept. 15, 1992 (To accompany S. 2575)
RELATED REPORTS
House Report (Veterans' Affairs Committee) No. 102-384(I), Nov. 24, 1991 (To accompany H.R. 2890)
House Report (Energy and Commerce Committee) No. 102-384(II), Sept. 22, 1992 (To accompany H.R. 2890)
House Report (Veterans' Affairs Committee) No. 102-622, June 26, 1992 (To accompany H.R. 5192)
Senate Report (Veterans' Affairs Committee) No. 102-409, Sept. 17, 1992 (To accompany S. 2973)
Senate Report (Veterans' Affairs Committee) No. 102-400, Sept. 15, 1992 (To accompany S. 2974)

HOUSE REPORT NO. 102–384(II)

September 22, 1992
[To accompany H.R. 2890 which on July 15, 1991, was referred jointly to the Committee on Veterans' Affairs and the Committee on Energy and Commerce]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 2890) to establish limits on the prices of drugs procured by the Department of Veterans Affairs, and for other purposes, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

CONTENTS

The amendments are as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Medicaid Drug Rebate Amendments of 1992".

*2 SEC. 2. TREATMENT OF PRESCRIPTION DRUGS PROCURED BY DEPARTMENT OF VETERANS AFFAIRS OR PURCHASED BY CERTAIN CLINICS AND HOSPITALS.

(a) Exclusion of Prices From Calculation of Best Prices for Medicaid Rebate Agreements.–Section 1927(c)(1)(C) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(C)) is amended by striking "(excluding" and inserting "(excluding any prices charged to the Indian Health Service or a covered entity described in subsection (a)(5)(D), any prices charged under the Federal Supply Schedule of the General Services Administration, or any prices used under a State pharmaceutical assistance program by reference to prices charged to the Department of Veterans Affairs, and excluding".

(b) Agreements Required to Receive Payment.–

(1) In general.–The first sentence of section 1927(a)(1) of such Act (42 U.S.C. 1396r–8(a)(1)) is amended by striking "manufacturer)." and inserting "manufacturer) and an agreement described in paragraph (5) (with respect to drugs purchased by a covered entity on or after October 1, 1992), and must meet the requirements of paragraph (6).".

(2) Agreements described.–Section 1927(a) of such Act (42 U.S.C. 1396r–8(a)) is amended by adding at the end the following new paragraphs:

"(5) Limitation on prices of drugs procured by covered entities.–

"(A) Agreement with secretary.–An agreement described in this paragraph is an agreement between a manufacturer and the Secretary that provides that the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in subparagraph (C)) procured by a covered entity (as defined in subparagraph (D)) does not exceed an amount equal to the average manufacturer price for the drug under this title in the preceding calendar quarter, reduced by the rebate percentage described in subparagraph (B).

"(B) Rebate percentage defined.–For a covered outpatient drug procured in a calendar quarter, the 'rebate percentage' is the amount (expressed as a percentage) equal to–

"(i) the average total rebate required under subsection (c) with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by

"(ii) the average manufacturer price for such a unit of the drug during such quarter.

"(C) Exception for drugs provided under state plans.–Drugs described in this subparagraph are drugs procured by the entity for which payment is made by the State under the State plan.

"(D) Covered entity defined.–In this subsection, the term 'covered entity' means an entity that meets the requirements described in subparagraph (E) and is one of the following:

"(i) A Federally-qualified health center (as defined in section 1905(l)(2)(B)).

"(ii) A family planning project receiving a grant or contract under section 1001 of the Public Health Service Act.

"(iii) An entity receiving a grant under subpart II of part C of title XXVI of the Public Health Service Act (relating to categorical grants for outpatient early intervention services for HIV disease).

"(iv) A State-operated AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the Public Health Service Act.

"(v) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act.

"(vi) A subsection (d) hospital (as defined in section 1886(d)(1)(B)) that the Secretary certifies–

"(I) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII or eligible for assistance under the State plan under this title;

"(II) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment ***3** percentage (as determined under section 1886(d)(5)(F)) greater than 12.5 percent or was described in section 1886(d)(5)(F)(i)(II); and

"(III) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

"(E) Requirements for covered entities.–

"(i) Prohibiting duplicate rebates.–A covered entity shall not request payment under the State plan for medical assistance described in section 1905(a)(12) with respect to a drug that is subject to an agreement under this paragraph if the drug is subject to the payment of a rebate to the State under this section.

"(ii) Prohibiting resale of drugs.–With respect to any covered outpatient drug that is subject to an agreement under this paragraph, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

"(iii) Auditing.–A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this paragraph with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in clauses (i) or (ii) with respect to drugs of the manufacturer.

"(iv) Additional sanction for noncompliance.–If the Secretary finds, after notice and hearing, that a covered entity is in violation of a requirement described in clause (i) or clause (ii), the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in subparagraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.

"(F) Treatment of distinct units of hospitals.–In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this paragraph.

"(G) Notice to manufacturers.–The Secretary shall notify manufacturers of covered outpatient drugs of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of subparagraph (E).

"(6) Requirements relating to drugs procured by department of veterans affairs.–

"(A) In general.–A manufacturer meets the requirements of this paragraph and applicable provisions of title 38, United States Code, if–

"(i) for each quarter beginning on or after January 1, 1993, the manufacturer makes available for procurement on the Federal Supply Schedule of the General Services Administration each drug or product of the manufacturer which–

"(I) is an innovator multiple source drug,

"(II) would be an innovator multiple source drug but for the application of the first sentence of subsection (k)(3), or

"(III) is a covered drug (as defined in subparagraph (D)(ii)); and

"(ii) with respect to each covered drug of the manufacturer (as defined in subparagraph (D)(ii)) procured by the Department of Veterans Affairs on or after October 1, 1992, the manufacturer has entered into and has in effect an agreement with the Secretary of Veterans Affairs under which–

"(I) in the case of a drug purchased under the depot contracting system or listed on the Federal Supply Schedule, the price charged may not exceed 76 percent of the non-Federal average manufacturer price (less the amount of any additional discount required under subparagraph (B)); and

"(II) the manufacturer is required to meet applicable requirements relating to reporting information to the Secretary of Veterans Affairs on drug prices and the Secretary's authority to audit the manufacturer's records.

"(B) Additional discount.–With respect to any covered drug the price of which is determined in accordance with an agreement under this paragraph, ***4** the manufacturer shall provide a discount in an amount equal to the amount by which–

"(i) the change in non-Federal price (as determined under subparagraph (D)(i)); exceeds

"(ii) the product of–

"(I) the non-Federal average manufacturer price of the drug during the 3-month period that ends one year before the last day of the month preceding the month during which the agreement goes into effect (or, in the case of a covered drug for which sufficient data for determining the non-Federal average manufacturer price during such period is not available, during such period preceding the month during which the agreement goes into effect as the Secretary of Veterans Affairs considers appropriate); and

"(II) the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) between the last month of the period described in subclause (I) and the last month preceding the month during which the agreement goes into effect.

"(C) Application of survey requirements and sanctions.–The provisions of subparagraphs (B) and (C) of subsection (b)(3) shall apply to covered drugs and the Secretary of Veterans Affairs in the same manner as such provisions apply to covered outpatient drugs and the Secretary of Health and Human Services under such subparagraphs, except that references in such subparagraphs to prices or information reported or required under 'subparagraph (A)' shall be deemed to refer to information reported to the Secretary of Veterans Affairs pursuant to applicable requirements relating to reporting information to the Secretary of Veterans Affairs on drug prices.

"(D) Definitions.–In this paragraph:

"(i) Change in non-federal price.–The term 'change in non-Federal price' means, with respect to a covered drug that is subject to an agreement under this paragraph, an amount equal to–

"(I) the non-Federal average manufacturer price of the drug during the 3-month period that ends with the month preceding the month during which the agreement goes into effect (or, in the case of a covered drug for which sufficient data for determining the non-Federal average manufacturer price during such period is not available, during such period as the Secretary of Veterans Affairs considers appropriate); minus

"(II) the non-Federal average manufacturer price of the drug during the 3-month period that ends one year before the end of the period described in subclause (I) (or, in the case of a covered drug for which sufficient data for determining

the non-Federal average manufacturer price during such period is not available, during such period preceding the period described in subparagraph (A) as the Secretary of Veterans Affairs considers appropriate).

"(ii) Covered drug.–The term 'covered drug' means a drug or product which–

"(I) is a single source drug (as defined in subsection (k)(7)(A)(iv));

"(II) would be a single source drug but for the application of the first sentence of subsection (k)(3);

"(III) is a biological product identified under section 600.3 of title 21, Code of Federal Regulations; or

"(IV) is insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act.

"(iii) Depot.–The term 'depot' means a storage system operated by an agency of the Federal Government or by an entity with which such an agency contracts, through which drugs from various manufacturers are received, stored, and held for distribution to multiple health care facilities of an agency of the Federal Government. The term includes any warehousing and distribution arrangement whether Government-owned and operated, Government-owned and privately operated, or privately-owned and operated.

"(iv) Non-federal average manufacturer price.–The term 'non-Federal average manufacturer price' means, with respect to a covered drug and a period of time (as determined by the Secretary of Veterans Affairs), the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers to the manufacturer, taking into ***5** account any cash discounts or similar price reductions during that period, but not taking into account any prices paid by the Federal Government.

"(v) Weighted average price.–The term 'weighted average price' means, with respect to a covered drug and a period of time (as determined by the Secretary of Veterans Affairs) an amount equal to–

"(I) the sum of the products of the average price per unit of each quantity of the drug sold during the period and the number of units of the drug sold during the period; divided by

"(II) the total number of units of the drug sold during the period.".

(3) Confidentiality of information.–Section 1927(b)(3)(D) of such Act (42 U.S.C. 1396r–8(b)(3)(D)) is amended–

(A) by striking "this paragraph" and inserting "this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii)"; and

(B) by striking "Secretary" each place it appears and inserting "Secretary or the Secretary of Veterans Affairs".

(4) Study of treatment of certain clinics as covered entities eligible for prescription drug discounts.–

(A) Study.–The Secretary of Health and Human Services shall conduct a study of the feasibility and desirability of including entities described in subparagraph (C) as covered entities eligible for limitations on the prices of covered outpatient drugs under section 1927(a)(5) of the Social Security Act (as added by paragraph (2)).

(B) Report.–Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit a report to Congress on the study conducted under subparagraph (A), and shall include in the report–

(i) a description of the entities that are the subject of the study;

(ii) an analysis of the extent to which such entities procure prescription drugs; and

(iii) an analysis of the impact of the inclusion of such entities as covered entities under section 1927(a)(5) of the Social Security Act on the quality of care provided to and the health status of the patients of such entities.

(C) Entities described.–An entity described in this subparagraph is an entity–

(i) receiving funds from a State for the provision of mental health or substance abuse treatment services under subparts I or II of part B of title XIX of the Public Health Service Act or under title V of such Act;

(ii) receiving funds under section 318 of the Public Health Service Act (relating to treatment of sexually transmitted diseases) or section 317(j)(2) of such Act (relating to treatment of tuberculosis) through a State or unit of local government; or

(iii) receiving funds from a State under title V of the Social Security Act for the provision of maternal and child health services that are furnished on an outpatient basis.

(c) Budget Neutrality Adjustment.–Section 1927(c)(1)(B) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(B)) is amended–

(1) in clause (i), by striking "January 1, 1993," and inserting "October 1, 1992,";

(2) by striking "and" at the end of clause (i); and

(3) by striking clause (ii) and inserting the following:

"(ii) for quarters (or other periods) beginning after September 30, 1992, and before January 1, 1994, the greater of–

"(I) 15.7 percent of the average manufacturer price for the drug, or
"(II) the difference between the average manufacturer price for the drug and the best price (as defined in subparagraph (C)) for such quarter (or period) for such drug;
"(iii) for quarters (or other periods) beginning after December 31, 1993, and before January 1, 1995, the greater of–

"(I) 15.4 percent of the average manufacturer price for the drug, or
"(II) the difference between the average manufacturer price for the drug and the best price (as defined in subparagraph (C)) for such quarter (or period) for such drug;
"(iv) for quarters (or other periods) beginning after December 31, 1994, and before January 1, 1996, the greater of–

***6** "(I) 15.2 percent of the average manufacturer price for the drug, or
"(II) the difference between the average manufacturer price for the drug and the best price (as defined in subparagraph (C)) for such quarter (or period) for such drug; and
"(v) for quarters (or other periods) beginning after December 31, 1995, the greater of–

"(I) 15.1 percent of the average manufacturer price for the drug, or
"(II) the difference between the average manufacturer price for the drug and the best price (as defined in subparagraph (C)) for such quarter (or period) for such drug.".

(d) Reports on Best Price Changes and Payment of Rebates.–

(1) In general.–Not later than 180 days after the expiration of each calendar quarter that begins on or after October 1, 1992, and ends on or before December 31, 1995, the Secretary of Health and Human Services shall submit a report to Congress that contains the following information relating to prescription drugs dispensed in the quarter (subject to paragraph (2)):

(A) With respect to single source drugs and innovator multiple source drugs (as such terms are defined in section 1927(k)(7) of the Social Security Act)–

(i) the percentage of such drugs whose best price (as reported to the Secretary under section 1927(b) of the Social Security Act) increased compared to the best price during the previous calendar quarter;
(ii) the percentage of such drugs whose best price (as so reported) decreased compared to the best price during the previous calendar quarter;
(iii) the percentage of such drugs whose best price (as so reported) was the same as the best price during the previous calendar quarter;
(iv) the median and mean percentage increase (or decrease) in the best price of such single source drugs (as so reported) compared to the best price during the previous calendar quarter;

(v) the median and mean percentage increase (or decrease) in the best price of such innovator multiple source drugs (as so reported) compared to the best price during the previous calendar quarter; and

(vi) the median and mean percentage increase (or decrease) in the best price of all such drugs (as so reported) compared to the best price during the previous calendar quarter.

(B) With respect to all drugs for which manufacturers are required to pay rebates under section 1927(c) of the Social Security Act, the Secretary's estimate, on a State-by-State and a national aggregate basis, of–

(i) the total amount of all rebates paid under such section during the quarter, broken down by the portions of such total amount attributable to rebates described in paragraphs (1), (2), and (3) of such section;

(ii) the percentages of such total amount attributable to rebates described in paragraphs (1), (2), and (3) of such section; and

(iii) the amount of the portion of such total amount attributable to the rebate described in paragraph (1) of such section that is attributable to the application of clauses (i)(II) or (ii)(II) of such paragraph.

(2) Limitation on drugs subject to report.–No report submitted under paragraph (1) shall include any information relating to any prescription drug unless the Secretary finds that expenditures for the drug are significant expenditures under the medicaid program. In the previous sentence, expenditures for a drug are "significant" if the drug was one of the 1,000 drugs for which the greatest amount of the Federal financial assistance attributable to prescription drugs was paid under section 1903(a) of the Social Security Act during calendar year 1991.

(3) Special rule for initial report.–For purposes of the first report required to be submitted under paragraph (1)–

(A) the Secretary shall submit the report not later than July 1, 1993; and

(B) the information contained in the report shall include information on prescription drugs dispensed during each calendar quarter that began on or after January 1, 1991, and ended on or before December 31, 1992.

(e) Effective Date.–The amendments made by this section shall apply with respect to payments for calendar quarters (or periods) beginning on or after January 1, 1993 (without regard to whether or not regulations to carry out such amendments have been promulgated by such date).

Amend the title so as to read:

***7** A bill to amend title XIX of the Social Security Act to establish limits on the prices of prescription drugs procured by the Department of Veterans Affairs or purchased by certain clinics and hospitals, and for other purposes.

PURPOSE AND SUMMARY

The purpose of H.R. 2890 is to enable the Department of Veterans Affairs and certain Federally-funded clinics to obtain lower prices on the drugs that they provide to their patients.

Under current law, no Federal Medicaid matching funds are available for State spending on any of a manufacturer's outpatient prescription drugs unless the manufacturer agrees to provide a rebate on each drug to the State and the Federal government. With respect to single source drugs (drugs for which there is no generic competition) and innovator multiple source drugs (drugs that were once single source for which there is generic competition), the required rebate is the sum of (1) a basic rebate plus (2) an additional rebate. During calendar year 1992, the basic rebate is the greater of (1) 12.5 percent of the average manufacturer price (AMP) of the drug, or (2) the largest discount the manufacturer gives any U.S. purchaser as reflected in this "best price," so long as this discount does not exceed 50 percent of the AMP. In calculating the "best price," the Secretary must take into account the prices charged to the Department of Veterans Affairs and other agencies purchasing drugs from the Federal Supply

Schedule. Beginning in calendar year 1993, the 12.5 percent minimum percentages will increase to 15.0 percent, and the 50 percent maximum discount will no longer apply.

The additional rebate applicable to single source and innovator multiple source drugs under current law is, through calendar year 1993, the difference between the AMP for the drug and the AMP for that drug on October 1, 1990, increased by the percentage increase in the consumer price index. Beginning in calendar year 1994, the additional rebate will be calculated on the basis of the weighted AMP for all of a manufacturer's single source and innovator multiple source drugs.

With respect to generic drugs (a copy of a single source drug that has been approved for marketing by the Food and Drug Administration), the required rebate is 10 percent of the AMP for a drug through calendar year 1993, and 11 percent thereafter.

Under the Committee bill, no Federal Medicaid matching funds would be available for State spending on any of a manufacturer's covered outpatient prescription drugs unless the manufacturer (1) lists each of its drugs on the Federal Supply Schedule and (2) enters into, and complies with, an agreement with the Secretary of the Department of Veterans Affairs (DVA). Under this agreement, the Secretary may require that the price charged to DVA by a manufacturer for any single source drug not exceed 76 percent of the non-Federal average manufacturer price, less an additional discount to offset any price increases in excess of the increase in the consumer price index. The manufacturer would also have to meet reporting and auditing requirements specified in Title 38 of the U.S. Code. The bill would also exclude prices charged under the Federal Supply Schedule to the DVA (or any other Federal purchaser, including the Department of Defense and the Federal ***8** Bureau of Prisons) from the calculation of "best price" for purposes of determining the Medicaid basic rebate for single source and innovator multiple source drugs.

The Committee bill would also protect the following Federally-funded clinics and public hospitals: (1) Federally qualified health centers (FQHCs); (2) family planning programs; (3) Ryan White Act early intervention programs; (4) State AIDS drug purchase programs; (5) hemophilia treatment centers; and (6) certain public "disproportionate share" hospitals. Under the bill, Federal Medicaid matching funds would not be available for State spending on any of a manufacturer's covered outpatient prescription drugs unless the manufacturer enters into, and complies with, an agreement with the Secretary of HHS under which these protected purchasers would pay the same amount for a covered outpatient drug that Medicaid pays (after the basic and additional rebates have been deducted from the drug's average manufacturer price). The Secretary would have the discretion to determine the mechanism (rebate, point-of-purchase discount, or otherwise) for assuring this price reduction, which would apply only to drugs for which payment is not made separately to the clinic or other protected purchaser by a State Medicaid program. The Committee bill would prohibit these protected purchasers from reselling or transferring drugs to individuals other than their patients and would give the Secretary and manufacturers access to directly pertinent records for audit purposes.

Exclusion of the prices charged to the DVA and other protected purchasers from the calculation of "best price" would result in a cost to the Federal government if no change is made in current law. In order to maintain budget neutrality, the Committee bill would raise the minimum rebate which manufacturers must pay on single source and innovator multiple source drugs to 15.7 percent during the last quarter of calendar year (CY) 1992 and all of CY 1993; to 15.4 percent during CY 1994; to 15.2 percent during CY 1995; and to 15.1 percent during CY 1996 and thereafter. The additional rebates required under current law with respect to single source and innovator multiple source drugs, as well as the current law rebate percentages applicable to generic drugs, would remain unchanged.

The Committee bill directs the Secretary to report, on a quarterly basis, information relating to (1) changes in the Medicaid "best prices" of the top (by Medicaid expenditures) 1,000 single source and innovator multiple source drugs and (2) total Medicaid rebates paid by all manufacturers, broken down by the amounts attributable to the basic rebate (both the amounts attributable to the minimum percentage and the amounts attributable to "best price"), to the additional rebate, and to the generic rebate. The first report, covering CY 1991 and 1992, would be due July 1, 1993.

BACKGROUND AND NEED FOR THE LEGISLATION

CURRENT LAW

Medicaid is a Federal-State means-tested entitlement program that purchases basic health care and long-term care services on behalf of over 30 million low-income women, children, and elderly ***9** and disabled individuals. In FY 1993, the Federal government will spend an estimated $80 billion on Medicaid, matching about $60 billion in State Medicaid expenditures.

Medicaid is the Nation's largest single purchaser of prescription drugs, paying for between 12 and 20 percent of all retail prescriptions in the U.S. In 1993, the Federal and State governments will spend an estimated $7.4 billion on outpatient prescription drugs, with Federal spending representing 57 percent, or about $4.2 billion of that total.

The Department of Veterans Affairs operates a health care system composed of 172 hospitals, some 350 outpatient clinics, and 127 nursing homes that deliver health and long-term care services to some 3 million veterans. In FY 1993, the DVA will spend an estimated $975 million, or 6.7 percent of its projected operating budget of $14.6 billion, purchasing prescription drugs. Because the DVA health system gives the products of manufacturers exposure to about half of the Nation's physicians-in-training, and because each medical center in the DVA system is urged to carefully limit its formulary to the most cost-effective drugs available, the DVA has negotiating leverage vis-a-vis manufacturers of competing products. Prior to the enactment of the Medicaid drug rebate program in 1990, this negotiating leverage enabled the DVA to receive deep discounts on prescription drugs, varying from 22 percent to 90 percent of the average wholesale price (AWP) of single source products and 39 to 93 percent of AWP on multiple source drugs.

Under the terms of the Budget Summit agreement between the President and the Congress in September, 1990, the Committee on Energy and Commerce was directed to report changes in Medicaid law that would achieve savings of $1.6 billion over 5 years in the purchase of prescriptions drugs. This Committee responded by reporting legislation that imposed a rebate requirement on manufacturers of single source, innovator multiple source, and generic drugs. Under this proposal, which was included by the Committee in that year's budget reconciliation bill and estimated by CBO to save $2.1 billion over 5 years, a manufacturer could not receive Federal Medicaid matching funds on any of its covered outpatient drugs in any State unless it agreed to give rebates to all States on each of its drugs. The rebates for single source and innovator multiple source drugs were to be based on the "best price" given to any purchaser in the U.S. on each drug as of September 1, 1990. For purposes of calculating the rebate, this "best price" could not increase more than the percentage increase in the consumer price index (CPI–U, all items). The purpose of this indexing provision was to protect the savings to the Medicaid program against future price increases by manufacturers.

In the House-Senate conference on the Omnibus Budget Reconciliation Act (OBRA) of 1990, where the current Medicaid drug rebate program was crafted, the indexing provision was deleted. As a result, a rebate program was created under which manufacturers may have a disincentive to offer lower "best prices" on covered outpatient drugs that Medicaid patients use in any significant volume. If Medicaid represents, say, 20 percent of a manufacturer's sales on a particular drug, the manufacturer knows that a "best price" that is lower than 87.5 percent of the AMP for a drug will result in a ***10** rebate to the Medicaid program for that product which is greater than the minimum rebate percentage which the manufacturer would have to pay under current law. The lower the "best price" to that purchaser, the greater the rebate to Medicaid.

However, the disincentive created by the Medicaid rebate program is only one of many factors that manufacturers may take into account when they set prices for their products, and it may not necessarily determine a manufacturer's pricing strategy with respect to any particular drug. For example, a manufacturer may pursue a "best price" strategy irrespective of the Medicaid rebate program in order to maintain its share in a competitive market.

The Subcommittee on Health and Environment heard testimony that many manufacturers did in fact respond to the potential disincentive in the Medicaid drug rebate program enacted in OBRA 90. Chairman Montgomery of the Committee on Veterans' Affairs testified that manufacturers deleted numbers of drugs from the Federal Supply Schedule (FSS), a DVA-administered

list of drugs available to Federal purchasers at prices negotiated by DVA authorities, and by raising FSS prices for many other drugs. "Overall, VA data showed a net increase in its post-OBRA pharmaceutical prices of 21 percent ... Factoring out 'normal' inflation, VA calculated OBRA's impact on an already fiscally-starved system to be $93 million annually," he stated.

The DVA is not the only Federal purchaser that has experienced price increases since the enactment of OBRA 90. Federally-funded clinics and public hospitals serving large numbers of low-income patients also testified to the loss of "best prices." The Director of an Association which represents the 28 community and migrant health centers in Texas that serve 270,000 low-income and uninsured patients testified that, since the enactment of OBRA 90, drug prices to the centers, which purchase drugs through a buying group, have risen "dramatically." He gave the example of glyburide, an oral antidiabetic usually prescribed to adults who develop diabetes after age 30 and who do not require insulin. Health centers in Texas have been paying $153 for the 5 mg., 1,000 count of glyburide; they will spend nearly $108,000 this year for this size and strength of glyburide. The centers have been informed by the manufacturer that next year, the price for this size and strength will increase nearly 89 percent to $287; this would result in an expenditure of $202,000 by the centers for this same size and strength next year, which translates into nearly 2,800 clinic visits.

Testimony presented by the Chief Operating Officer of the Parkland Memorial Hospital in Dallas, Texas, describes the adverse impact of drug price increases on public hospitals which serve large numbers of low-income and uninsured patients. A detailed study of the most widely used outpatient drugs at 5 public hospitals, conducted by researchers at New York University, found that, after OBRA 90, manufacturers "promptly cancelled discount contracts, terminated special-price practices, and raised the prices they charged public hospitals." Hospital costs for the drugs included in the study increased, on average, by 32 percent, far in excess of the historical 5 to 9 percent annual increases in drug prices experienced by public hospitals.

***11** Hard evidence on the effect of OBRA 90 on prescription drug prices is still being compiled. The testimony received by the Subcommittee is not dispositive as to the impact of the OBRA 90 Medicaid rebate program. There is still uncertainty as to the extent to which manufacturers have raised prices to purchasers other than Medicaid, and the extent to which such increases were due to the provisions of OBRA 90. But two points seem clear. Prices paid for outpatient drugs by the DVA, and some Federally-funded clinics and public hospitals, have increased substantially over the last two years. Those price increases have in turn reduced the level of services and the number of individuals that these hospitals and clinics are able to provide with the same level of resources.

While there is substantial disagreement about the effects of OBRA 90, there is no dispute that the Medicaid rebate program has generated significant savings for the State and Federal governments, and is expected to continue to do so. According to the Congressional Budget Office, the rebate program will reduce Federal Medicaid outlays by about $5.2 billion over the next 5 years.

It is evident that OBRA 90 has achieved its objective of generating savings for the Medicaid program. However, other entities–notably the DVA, Federally-funded clinics, and public hospitals, have continued to experience substantial increases in their outpatient drug costs. The Committee is persuaded that, without intervention, the DVA and Federally-funded clinics may continue to experience substantial drug price increases as manufacturers try to limit their rebates to Medicaid. In the view of the Committee, the Federal government simply cannot continue to allow the DVA, Federally-funded clinics, and their patients to remain unprotected against manufacturer price increases.

With respect to the DVA, the Committee bill attempts to restore a market environment in which the DVA can again negotiate effectively for favorable prices on prescription drugs, while offering manufacturers the assurance that, by giving DVA at least the discount specified (or providing a deeper discount), those favorable prices will not affect the calculation of Medicaid rebates. To accomplish this, the Committee bill would make three major changes.

First, the bill would require a manufacturer, as a condition of the availability of Medicaid matching funds with respect to its covered outpatient drugs, to make available for procurement on the Federal Supply Schedule (FSS) of the General Services

Administration after December 31, 1992, each of its single source and innovator multiple source drugs, whether administered on an outpatient or inpatient basis. This will assure that the DVA has access to all the drugs that its patients may need, and will prevent manufacturers from refusing to negotiate or give discounts on particular drug products.

Second, the bill would exclude from the calculation of "best price" for determining the amount of the Medicaid rebate any prices charged under the FSS, thereby excluding all prices to the DVA. In doing so, the bill would further the economies which the DVA-administered FSS permits such Federal health care providers as the Department of Defense and the Bureau of Prisons, which also purchase drugs through the FSS. In addition, the Committee bill would clarify that prices paid under State pharmaceutical assistance ***12** programs such as that operating in the State of New York, which use DVA of FSS prices as a basis for determining rebates or discounts, are also excluded from the calculation of "best price."

Finally, the Committee bill would also condition the availability of Federal matching funds with respect to any covered outpatient drug of a manufacturer on the agreement of the manufacturer to provide the DVA a minimum discount on each drug and to comply with applicable reporting and auditing requirements. In the case of single source drugs (outpatient or inpatient) purchased under the DVA's depot contracting system or listed on the FSS, the DVA may not be charged more than 76 percent of the non-Federal average manufacturer price (less an additional discount to offset price increases in excess of inflation). The 24 percent discount represents the median "best price" rebate under the Medicaid program for the first quarter of 1991, which was the last quarter before manufacturers began substantially increasing prices to the DVA. The use of this percentage is intended to capture what the Committee on Veteran's Affairs believes to be the level of discounts the DVA was receiving before the Medicaid rebate program went into effect. The Committee bill requires that an additional discount be paid on a drug when the increase in the non-Federal AMP exceeds the increase that would have occurred if the CPI had been applied to the non-Federal AMP (measured in the 3-month period ending one year before the end of the 3-month period for which the discount is calculated).

The Committee bill also provides protection from drug price increases to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans. Like the prices charged to the DVA, prices charged to these "covered entities" would be exempt from the calculation of the Medicaid "best price" for purposes of determining the Medicaid rebate. The Committee expects that this exemption will remove any disincentive that the Medicaid rebate program creates to discourage manufacturers from providing substantial voluntary or negotiated discounts to these clinics, programs, and hospitals.

In addition, manufacturers, as a condition of receiving Federal Medicaid matching funds on their covered outpatient drugs, would have to enter into an agreement with the Secretary of HHS to provide price reductions (whether through a discount, rebate, or other mechanism) to these "covered entities" on covered outpatient drugs. These price reductions would be at least as great as those which Medicaid receives under the rebate program. They would be implemented, at the discretion of the Secretary, either by a point-of-purchase discount, a rebate, or other mechanism. "Covered entities" receiving these price reductions would be prohibited from obtaining payment for these drugs under Medicaid or from reselling or transferring the drugs to individuals other than their patients, and they would be subject to audit to verify compliance with these requirements. In giving these "covered entities" access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.

***13** The Committee bill specifies 6 types of "covered entities":

(1) Federally qualified health centers (FQHCs), a category which includes approximately 1,500 Community Health Center sites, 425 Migrant Health Center sites, and 300 Health Care for the Homeless sites, as well as those clinic sites recognized by the Secretary as "look-alikes";

(2) Family planning clinics receiving Federal funds under Title X of the Public Health Service (PHS) Act, a category which includes approximately 85 grantees, encompassing almost 5,000 sites for delivery of services;

(3) AIDS early intervention sites receiving Federal funds under title XXVI of the PHS Act, a category which includes approximately 120 grantees (some of which are also Federally qualified health centers or Federally funded hemophilia treatment programs);

(4) State-operated AIDS drug purchasing assistance programs receiving Federal funds under title XXVI of the Public Health Service Act, a category which includes 54 programs;

(5) Comprehensive hemophilia diagnostic treatment centers receiving funds under the "Federal set-aside" in the Maternal and Child Health Block Grant, a category that includes a network of centers that are direct recipients of grant under this section, as well as nearly 150 facilities with which they subcontract; and

(6) Certain public hospitals that for the most recent cost reporting period had a Medicare disproportionate share adjustment greater than 12.5 or received more than 30 percent of their inpatient revenues from State or local indigent care funds, a category that encompasses approximately 90 hospitals.

With respect to clinics providing mental health, substance abuse treatment, maternal and child health, sexually transmitted disease treatment, or tuberculosis treatment services with Federal block grant funds, the bill directs the Secretary to report to the Congress within a year of enactment on the feasibility and desirability of treating these programs as "covered entities."

SECTION-BY-SECTION ANALYSIS AND DISCUSSION

SECTION 1. SHORT TITLE

The short title of the bill is the "Medicaid Drug Rebate Amendments of 1992."

SECTION 2. TREATMENT OF PRESCRIPTION DRUGS PROCURED BY THE DEPARTMENT OF VETERANS^AFFAIRS OR PURCHASED BY CERTAIN CLINICS AND HOSPITALS

(a) Exclusion of prices from calculation of best prices for Medicaid rebate agreements

The Committee bill would exclude from the calculation of "best price" for purposes of determining the Medicaid basic rebate with respect to single source or innovator multiple source drugs any of the following: (1) prices charged to the Department of Veterans Affairs (DVA), the Department of Defense, the Federal Bureau of Prisons, or any other purchaser under the Federal Supply Schedule of the General Services Administration; (2) prices charged to the ***14** Indian Health Service; (3) prices used under a State pharmaceutical assistance program by reference to prices charged to the DVA; and (4) prices charged to a "covered entity." For this purpose, a "covered entity" means (a) a Federally-qualified health center; (b) a family planning project receiving a grant or contract under section 1001 of the Public Health Service (PHS) Act; (c) an entity receiving a categorical grant to provide outpatient early intervention services for HIV disease under title XXVI of the PHS Act; (d) a State-operated AIDS drug purchasing assistance program receiving Federal funds under title XXVI of the PHS Act; (e) a comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act; and (5) a "disproportionate share" hospital that meets certain requirements. As defined under current Medicaid law, a Federally-qualified health center includes entities receiving Federal funds through the Community Health Center, Migrant Health Center, and Health Care for the Homeless programs under the PHS Act, as well as certain entities which do not actually receive Federal funds but are certified by the Secretary meet the requirements for doing so, and outpatient programs or facilities operated by Indian tribes or tribal organizations. In order to qualify as a "covered entity," a clinic, program, or project falling into one of these five categories must also meet requirements relating to the prohibition of duplicate rebates, the prohibition of resale of drugs, and auditing.

The requirements that a hospital must meet in order to be a "covered entity" are as follows. First, the hospital must meet the definition of a hospital set forth in section 1886(d)(1)(B) of the Social Security Act, which in general excludes psychiatric,

rehabilitation, children's, chronic care, and cancer treatment or research hospitals. Second, the hospital must be owned or operated by a unit of State or local government. The Committee recognizes that some "public" hospitals are not owned or operated by a unit of State or local government. The bill would therefore also extend "covered entity" status to a public or private nonprofit corporation which is formally granted governmental powers by a unit of State or local government, and to a private nonprofit hospital which has a contract with a State or local government health care to low-income individuals who are not eligible for Medicaid or Medicare. The Committee does not intend to extend "covered entity" status to a private nonprofit hospital that has a minor contract to provide indigent care which represents an insignificant portion of its operating revenues. Third, the hospital, for the most recent cost reporting period ending before the calendar quarter involved, must have had a Medicare disproportionate share adjustment percentage greater than 12.5 percent or, in the alternative, be located in an urban area, have 100 or more beds, and receive more than 30 percent of its inpatient care revenues (excluding Medicare and Medicaid payments) from State and local government payments for indigent care.

Finally, a hospital may not be a "covered entity" under the Committee bill if it obtains covered outpatient drugs through a group purchasing organization or other group purchasing arrangement. The Committee recognizes that the public disproportionate share hospitals which the Committee is seeking to protect from high drug ***15** prices may participate in, or themselves maintain, group purchasing arrangements for a variety of purposes, including the purchase of supplies and equipment as well as pharmaceuticals. The Committee does not intend to disturb these arrangements or to require the withdrawal of these hospitals from these organizations or arrangements. However, the Secretary may not certify a hospital as a "covered entity" for purposes of the Committee bill if the hospital purchases any covered outpatient drug through a group purchasing organization or other group purchasing arrangement during the period for which certification is sought.

The Committee emphasizes that, in defining "covered entities" for purposes of both the exclusion from "best price" and the receipt of price reductions under manufacturer agreements with the Secretary, the bill does not require the receipt of any specified amount of Federal funding. In the case of "look alike" FQHCs and public hospital, an entity need not receive any Federal grants funds to qualify as a "covered entity." With respect to the other categories of "covered entity," the level of Federal grant funds that the entity receives is immaterial to a determination of its status as a "covered entity."

(b) Agreements required to receive payment

Under the Committee bill, in order for Federal Medicaid matching funds to be available for a manufacturer's covered outpatient drugs, the manufacturer must have entered into, and have in effect, an agreement with the Secretary of DVA, and a separate agreement with the Secretary of HHS, relating to the prices charged for drugs to the DVA and to certain Federally-funded clinics. These agreements are independent of, and additional to, the agreement into which manufacturers must enter into with the Secretary of HHS under current law regarding the provision of rebates to States for drugs purchased by Medicaid.

Limitation on prices of drugs procured by "covered entities"

In order to receive Federal Medicaid matching funds with respect to its covered outpatient drugs, a manufacturer must enter into an agreement with the Secretary of HHS that provides that the amount required to be paid to the manufacturer for covered outpatient drugs procured by a "covered entity" (as described above) does not exceed a specified amount. That amount is equal to the average manufacturer price for the drug in the preceding calendar quarter, reduced by an amount (expressed as a percentage) equal to the average total rebate (both basic and additional rebates) required under the Medicaid rebate program during the preceding calendar quarter, divided by the AMP for the drug (for a unit of the dosage form and strength involved). Thus, if the average manufacturer price for a unit of a drug (of a particular dosage form and strength) is $1.00, and the average Medicaid basic rebate for that unit of the drug is 17 cents, and the average Medicaid additional rebate is 3 cents, then no "covered entity" may be required to pay an amount in excess of 80 cents in the following quarter for that unit of the drug. The Committee bill does not preclude either the Secretary, on behalf of "covered entities," or "covered entities" ***16** themselves, from negotiating greater price reductions with manufacturers on one or more covered outpatient drugs.

The Committee emphasizes that the bill does not limit the amount of drugs that a "covered entity" may procure for purposes of receiving price reductions under this agreement. Unlike the general treatment of entities under the CDC-administered consolidated purchase price for vaccines, a "covered entity" under this bill is not limited to purchasing drugs with its Federal grant funds. Instead, it may use any revenues or funds available to it to procure drugs. The Committee bill does not authorize the Secretary to limit in any way the volume of purchases that can be made at the price reduction provided under the Secretary's agreements with manufacturers.

The Committee bill does not specify whether "covered entities" would receive these favorable prices through a point-of-purchase discount, through a manufacturer rebate, or through some other mechanism. A mechanism that is appropriate to one type of "covered entity," such as community health centers, may not be appropriate to another type, such as State AIDS drug purchasing programs. The Committee expects that the Secretary of HHS, in developing these agreements, will use the mechanism that is the most effective and most efficient from the standpoint of each type of "covered entity." The Committee further expects that if, in order to implement these agreements, the Secretary finds it necessary to disclose to a contractor any confidential information provided to the Secretary by a manufacturer, the Secretary shall take such steps as may be necessary to prevent re-disclosure of such information by the contractor.

In order to assure that manufacturers that enter into these agreements with the Secretary do not extend price discounts on the same unit of the same drug twice–once to the "covered entity" in the form of a discount and again to the State Medicaid program in the form of a rebate–the Committee bill specifies that drugs procured by a "covered entity" for which payment is made by a State under the Medicaid program are not subject to the limitation on prices provided under this agreement. (The manufacturer would still owe a rebate on such a drug to the State Medicaid agency).

The Committee bill imposes three requirements on "covered entities" to assure the integrity of the drug price limitation program under these agreements. First, the Committee bill prohibits a "covered entity" from billing Medicaid separately for a prescription drug dispensed to a Medicaid patient if that unit of the drug was obtained by the "covered entity" for an amount specified under the manufacturer's agreement with the Secretary and if that unit of the drug would be subject to payment of a rebate under the Medicaid program. However, the Committee emphasizes that the bill does not prohibit the entity from dispensing a drug procured under the terms of this agreement in connection with a clinic visit and including the drug in the cost of the clinic visit for which the clinic bills the State Medicaid program. Because the State receives no separate claim for reimbursement for the prescription, the State will not claim a rebate on that unit of the drug from the manufacturer under the Medicaid rebate agreement, and the manufacturer ***17** is not required to make a price reduction twice on the same unit of drug.

Second, the Committee bill prohibits "covered entities" from reselling or otherwise transferring a drug subject to this agreement to a person who is not a patient of the entity. If the Secretary finds, after notice and hearing, that a "covered entity" is in violation of either the prohibition against billing Medicaid separately for a drug subject to price limitation under this agreement or the prohibition against transfer or resale, the Committee bill provides that the "covered entity" is liable to the manufacturer for an amount equal to the price reduction for the drug which the entity received under the agreement.

Finally, the Committee bill requires that a "covered entity" permit the Secretary and the manufacturer of a covered outpatient drug subject to this agreement to audit, at the Secretary's or the manufacturer's expense, the records of the entity that directly pertain to its compliance with the prohibitions against duplicate rebates and against resale or transfer with respect to the drugs of the manufacturer. The audits are to be conducted in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits. The Committee expects that, in developing these procedures, the Secretary will make every effort to minimize the administrative and financial burdens that these audits impose on "covered entities," and to limit the allowable scope of these audits to records directly pertinent to a determination of compliance with the specific prohibitions. The Committee emphasizes that participation by a "covered entity" in the price reductions under these agreements is completely at the option of each entity.

Requirements relating to drugs procured by Department of Veterans Affairs

In order to receive Federal Medicaid matching funds with respect to its covered outpatient drugs, a manufacturer must, effective January 1, 1993, make available for procurement on the Federal Supply Schedule of the General Services Administration each drug or product which is (1) a single source drug (whether administered on an outpatient or inpatient basis), (2) a biological product described in 21 C.F.R. section 600.3, (3) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act, or (4) an innovator multiple source drug (whether administered on an outpatient or inpatient basis). In addition, the manufacturer must enter into, and have in effect, an agreement with the Secretary of DVA relating to "covered drugs" procured by the DVA on or after October 1, 1992. For purposes of this agreement, the term "covered drug" means (1) a single source drug (whether administered on an outpatient or inpatient basis) and (2) a biological product described in 21 C.F.R. section 600.3.

Under this agreement, the price charged by a manufacturer to the DVA with respect to a "covered drug" purchased under the DVA depot contracting system or listed on the Federal Supply Schedule may not exceed 76 percent of the non-Federal average manufacturer price, less the amount of any "additional discount" required. The "additional discount" with respect to a drug is an ***18** amount equal to the amount by which the change in the non-Federal price exceeds the product of (1) the non-Federal average manufacturer price of the drug during the 3-month period that ends one year before the last day of the month during which the agreement goes into effect and (2) the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) between the last month of the 3-month period and the last month preceding the month during which the agreement goes into effect. The non-Federal average manufacturer price is defined as the weighted average price of a single form and dosage unit of a "covered drug" that is paid (during a period of time specified by the Secretary of DVA) by wholesalers to the manufacturer, taking into account any cash discounts or similar price reductions, but not taking into account any prices paid by the Federal Government.

The Committee bill also requires that, under this agreement, the manufacturer meeting applicable requirements (under Title 38 of the U.S. Code) relating to reporting information on drug prices to the Secretary of DVA and to the Secretary's authority to audit the manufacturer's records. The Secretary of DVA is authorized to survey wholesalers and manufacturers that directly distribute their "covered drugs" to verify manufacturer prices reported to the Secretary of DVA. The Secretary of DVA is authorized to impose a civil monetary penalty of up to $100,000 on a wholesaler, manufacturer, or direct seller of a "covered drug" that refuses a request for information about charges or prices by the Secretary, or that knowing provides false information to the Secretary. Manufacturers with an agreement with the Secretary of DVA that fail to provide information relating to prices of "covered drugs" to the Secretary of DVA on a timely basis are subject to an increase in the civil monetary penalty that the Secretary imposes of $10,000 per day in which the information is not provided. A manufacturer with an agreement with the Secretary of DVA that knowingly provides false information is subject to a civil money penalty of up to $100,000 for each item of false information.

Under the Committee bill, information disclosed by a manufacturer or a wholesaler under an agreement with the Secretary of DVA is confidential and shall not be disclosed by the Secretary of DVA (or a contractor with the DVA) in a form which discloses the identify of a specific manufacturer or wholesaler, except as the Secretary of DVA determines to be necessary to carry out this section and to permit the Comptroller General to review the information provided.

Study of treatment of certain clinics as "covered entities"

The Committee bill directs the Secretary of HHS to report to Congress, within one year after enactment, on the feasibility and desirability of allowing the following entities to qualify as "covered entities" an receive manufacturer discounts or rebates on covered outpatient drugs under the terms of the agreement with the Secretary of HHS: (1) entities receiving Federal funds from a State for the provision of mental health or substance abuse treatment services under titles V or XIX of the Public Health Service (PHS) Act; (2) entities providing treatment for sexually transmitted diseases or tuberculosis and receiving Federal funds

through a State or unit of *19 local government under section 317(j) or 318 of the PHS Act; and (3) entities receiving Federal funds from a State under the Title V Maternal and Child Health Block Grant for the provision of maternal and child health services furnished on an outpatient basis. The report is to include a description of these entities, an analysis of the extent to which they procure prescription drugs, and an analysis of the impact of the inclusion of such entities as "covered entities" on the quality of care provided to, and the health status of, the patients of such entities.

(c) Budget neutrality adjustment

Under current law, the basic rebate which a manufacturer must pay on single source and innovator multiple source drugs is a minimum of 12.5 percent of the average manufacturer price (AMP) for a drug in CY 1992, and 15 percent in CY 1993 and thereafter. To assure that the exclusion of prices charged under the Federal Supply Schedule and prices charged to "covered entities" will not increase Federal Medicaid outlays, the Committee bill raises these minimum percentages to 15.7 percent for the period October 1, 1992, through December 31, 1993; to 15.4 percent for quarters during CY 1994; to 15.2 percent for quarters during CY 1995; and to 15.1 percent for quarters during CY 1996 and thereafter.

(d) Reports on best price changes and payment of rebates

The Committee bill would direct the Secretary of HHS to submit reports to the Congress, on a quarterly basis, regarding the trends in "best prices" for single source and innovator multiple source drugs and the relative contribution that "best prices" make to the total rebates received by States. This reporting requirement is designed to give Congress the information necessary to determine whether the "best price" method of calculating the Medicaid basic rebate will continue to generate significant savings for the Federal and State governments over time, or whether the use of a flat percentage rebate would yield greater savings.

The Congressional Budget Office, working with the prices of a sample of the 100 single source and innovator multiple source drugs representing the largest Medicaid expenditures, found that the median "best price" discount–i.e., the percentage by which "best price" is below the average manufacturer price for a drug–fell from 24 percent in the first quarter of 1991 to 18 percent in the first quarter of 1992. CBO expects "best price" discounts to continue to decline until, by 1997, most will fall below the level of the minimum rebate (15.0 percent of AMP under current law, 15.1 percent under the Committee bill).

The National Governors Association and State Medicaid Directors do not share this assumption. They make 3 arguments in opposition to the CBO analysis. First, the NGA argues that the CBO analysis is based on a faulty assumption that "best prices" will disappear over time. Working from that assumption in a circular fashion, the NGA argues, CBO has arrived at estimates showing that the portion of Medicaid rebates attributable to "best price" will disappear. Second, the NGA argues that not enough information is available at this point to draw a firm conclusion regarding the future of "best prices." Third, the State Medicaid Directors point *20 out that rebate revenues to the States increased between 1991 and 1992 to an extent they believe cannot be fully explained by increased utilization or inflation. The quarterly reports required under the Committee bill will enable the Congress and the States to determine whether the CBO projection is accurate, and, if so, whether a change in the methodology for calculating the basic rebate would be appropriate.

Each quarterly report must contain the following information relating to the 1,000 drugs for which the greatest amount of Federal Medicaid matching payments were made during calendar year 1991. With respect to single source and innovator multiple source drugs among this group, the report must provide (1) the percentage of such drugs the "best price" of which increased from the previous calendar quarter; (2) the percentage of such drugs the "best price" of which decreased from the previous calendar quarter; (3) the percentage of such drugs the "best price" of which did not increase or decrease from the previous calendar quarter; (4) the median and mean percentage increase (or decrease) in the "best price" of the single source drugs within this group of 1,000 from the previous quarter; (5) the median and mean percentage increase (or decrease) in the "best price" of the innovator multiple source drugs within this group of 1,000 from the previous quarter; and (6) the median and mean percentage increase (or decrease) in the "best price" of the entire group of 1,000 from the previous quarter.

Each quarterly report must also contain information with respect to the total amount of rebates which the Secretary estimates will be received by each State (and the District of Columbia), and by the Medicaid program nationally, on all covered outpatient drugs (currently about 45,000 drug products are covered under rebate agreements). These estimates must include the total amount of rebates paid in the quarter, as well as the percentages of the total paid, broken down by the portion attributable to the basic rebate, the additional rebate, and the generic rebate, respectively. The amounts attributable to the basic rebate must be further broken down by the amounts attributable to the minimum rebate percentage and the amounts attributable to the "best price."

The first of these reports would be due on July 1, 1993, and would apply to drugs dispensed during the 8 quarters in calendar years 1991 and 1992. Reports relating to subsequent quarters would be due no later than 180 days after the close of the quarter. The Committee expects that each of these reports will be made available to it and the other committees of jurisdiction in a timely manner.

(e) Effective date

The amendments made by the Committee bill would apply to Medicaid payments made on or after January 1, 1993, whether or not regulations to implement these amendments have been proposed or published in final form by such date. Thus, the requirements that manufacturers enter into agreements with the Secretary of DVA and the Secretary of HHS would be effective on January 1, 1993, although the agreements with the Secretary of HHS would apply to drugs purchased by "covered entities" on or after October 1, 1992, and the agreements with the Secretary of DVA ***21** would apply with respect to drugs procured on or after October 1, 1992. The requirement that manufacturers list all their single source and innovator multiple source drugs on the Federal Supply Schedule would apply January 1, 1993.

HEARINGS

On September 11, 1991, the Subcommittee on Hospitals and Health Care of the Committee on Veterans' Affairs held a hearing on H.R. 2890 and received testimony from representatives of the Department of Veterans Affairs and pharmaceutical manufacturers (Ser. No. 102–21).

On July 31, 1992, the Subcommittee on Health and the Environment held a hearing on legislative proposals to reform the Medicaid drug rebate program: H.R. 2890; H.R 3405, introduced by Mr. Wyden and Mr. Cooper; and H.R. 5614, introduced by Mr. Slattery. Testimony was received from Senators Kennedy, Pryor, and Rockefeller; Mr. Slattery; Chairman Montgomery and Representative Stump on behalf of the Committee on Veterans' Affairs; five veterans' organizations; representatives of community health centers, public hospitals, and State AIDS drug purchasing programs; representatives of Governors and State Medicaid agencies; representatives of group purchasing organizations; representatives of brand name drug manufacturers; and representatives of generic drug manufacturers.

COMMITTEE CONSIDERATION

The bill H.R. 2890 was introduced on July 15, 1991 by Mr. Montgomery, Mr. Stump, and Mr. Hammerschmidt. It was jointly referred to the Committee on Veterans' Affairs and the Committee on Energy and Commerce. On November 13, 1991, the Committee on Veterans' Affairs ordered reported H.R. 2890 without amendment, by voice vote.

On September 15, 1992, the Subcommittee on Health and the Environment of the Committee on Energy and Commerce met in open session and ordered reported the bill H.R. 2890, as amended, by voice vote, a quorum being present.

On September 17, 1992, the Committee on Energy and Commerce met in open session and ordered reported the bill H.R. 2890, as amended, by voice vote, a quorum being present.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 2(l)(3)(A) of rule XI of the Rules of the House of Representatives, the Subcommittee on Health and the Environment has made no oversight findings on the operation of the Medicaid drug rebate program or its impact on the Department of Veterans Affairs.

COMMITTEE ON GOVERNMENT OPERATIONS

Pursuant to clause 2(l)(3)(D) of rule XI of the Rules of the House of Representatives, no oversight findings on the subject of the Medicaid drug rebate program or its impact on the Department of Veterans *22 Affairs have been submitted to the Committee by the Committee on Government Operations.

COMMITTEE COST ESTIMATE

In compliance with clause 7(a) of rule XXIII of the Rules of the House of Representatives, the Committee agrees with the Congressional Budget Office that no cost will be incurred by the Federal Government in carrying out the Committee bill in fiscal years 1993 through 1997.

INFLATIONARY IMPACT STATEMENT

Pursuant to clause 2(l)(4) of rule XI of Rules of the House of Representatives, the Committee states that the enactment of this bill into law will not have an inflationary impact on prices and costs in the operation of the national economy. The bill will give the Department of Veterans Affairs and certain Federally-funded clinics and public hospitals the ability to obtain the same (or lower) prices on covered outpatient drugs as Medicaid (net of rebates) receives. This will reduce the costs of operation of these providers. If drug manufacturers respond to these changes by increasing their prices to other customers that the bill does not protect, such as hospital and HMO group purchasing organizations, then these entities may experience an increase in their costs of operation. However, the Committee has no evidence that the bill will cause the prices of covered outpatient drugs overall to rise faster than they would have increased in its absence.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

U.S. Congress,
Congressional Budget Office,
Washington, DC, September 21, 1992.

Hon. John D. Dingell,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 2890, the Medicaid Drug Rebate Amendments of 1992, as ordered reported by the House Committee on Energy and Commerce on September 17, 1992.

The bill would affect direct spending or receipts and thus would be subject to pay-as-you-go procedures under section 252 of the Balanced Budget and Emergency Deficit Control Act of 1985. As a result, the estimate required under clause 8 of House Rule XXI also is enclosed.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

James L. Blum
(For Robert D. Reischauer.)

Enclosure.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: H.R. 2890.

***23** 2. Bill title: Medicaid Drug Rebate Amendments of 1992.

3. Bill status: As ordered reported by the House Committee on Energy and Commerce on September 17, 1992.

4. Bill purpose: H.R. 2890 would amend title XIX of the Social Security Act to make amendments to the prescription drug rebate portion of the Medicaid program and for other purposes.

5. Estimated cost to the Federal Government:

TABULAR OR GRAPHIC MATERIAL SET FORTH AT THIS POINT IS NOT DISPLAYABLE
The costs of the bill fall within budget function 550.

Basis of estimate

Direct spending

The Omnibus Budget Reconciliation Act of 1990 (OBRA–90) required that pharmaceutical manufacturers give rebates to the state Medicaid programs for the purchase of outpatient prescription drugs. The rebates are calculated as the product of the rebate percentage, the average manufacturer price (AMP), and the total number of units of the drug purchased by Medicaid. For single-source and innovator multiple-source drugs (SS/IMS), the rebate percentage is the greater of the minimum rebate percentage, and the percentage by which the so-called best price for the drug is lower than the AMP. The minimum rebate percentage is set at fifteen percent for SS/IMS drugs sold in 1993 and thereafter. The best price of a drug is the lowest price for which the drug is available to any purchaser in the United States during the calendar quarter.

H.R. 2890 would affect the prescription drug rebates collected by state Medicaid programs in two ways. First, the minimum rebate percentage for SS/IMS drugs would be increased to the following levels: 15.7 percent for the last quarter in 1992 and all of 1993, 15.4 percent in 1994, 15.2 percent in 1995, and 15.1 percent thereafter.

Second H.R. 2890 would exempt certain prices from the calculation required by current law to determine the best price. OBRA–90 already has exempted prices received by agencies of the federal government through depot arrangements and single-award contract prices, as well as prices negotiated by individual state Medicaid plans. H.R. 2890 would exempt prices on the Federal Supply Schedule (FSS), which is an important drug purchasing mechanism used primarily by the Department of Veterans Affairs (VA) and the Department of Defense (DoD), from the calculation of the best price. The bill also would exempt prices paid by certain entities that receive grants under the Public Health Service Act and under Maternal and Child Health Block grants. Finally, H.R. 2890 would exempt prices paid by public hospitals that treat a disproportionate ***24** share of the poor and that do not purchase outpatient drugs through a buying group.

To estimate the costs of the bill, CBO has assembled a data base consisting of information about the 100 SS/IMS drugs on which Medicaid spends the most. The Inspector General's Office of the Health and Human Services Department (IG) provided the list of 100 drugs. The IG, based on its survey of drug use in the Medicaid program during the first quarter of 1991, estimated that these 100 drugs accounted for about half of all Medicaid spending for outpatient drugs. In addition, the Health Care Financing Administration (HCFA), provided manufacturer pricing data, including the AMP, the best price, and the unit rebate amount. Finally, the VA provided FSS price information, although not all of our sample drugs were included on the FSS.

In addition to the data described in the previous paragraph, CBO used information gathered in interviews with health industry experts to estimate the costs of the bill. We estimate that the loss in rebates from exempting certain prices from the best price calculation would be offset by the increase in rebates from the higher minimum rebate percentages. Therefore, we estimate that H.R. 2890 would have no net effect on direct spending.

Other effects

This bill also would establish a mechanism to control the prices paid by federal agencies to purchase drugs and biologicals from the Federal Supply Schedule (FSS). In general, the FSS price paid for a brand name drug would be limited to 76 percent of the average price paid by wholesalers. The FSS price would be further reduced to reflect the extent to which drug price increases exceed increases in the Producer Price Index. Drug manufacturers would be required to enter into pricing agreements complying with this formula in order to receive payment for drugs or biological under the Medicaid program or to sell drugs or biologicals to VA, the DoD, the Public Health Service (PHS), or any entity that receives funds from the PHS.

CBO is unable to provide a precise estimate of the savings in the pharmaceutical costs of VA, DoD, and PHS that would result from this measure because of limitations on the data available to compare current federal drug prices to wholesale prices. Based on a comparison of 1991 FSS prices and wholesale prices for a sample of 24 drugs commonly used by VA, it is estimated that savings could amount to $40–60 million a year for VA and $30–40 million annually for DoD. Nevertheless, spending on pharmaceuticals for these agencies is financed through appropriations and net federal savings from this provision would only occur if future appropriation levels are reduced in response to the reduction in pharmaceutical costs.

6. Pay-as-you-go considerations: The Budget Enforcement Act of 1990 set up pay-as-you-go procedures for legislation affecting direct spending or receipts through 1995. The pay-as-you-go effects of the bill are as follows.

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*25 7. Estimated cost to State and local government: None.

8. Estimate comparison: None.

9. Previous CBO estimate: None.

10. Estimate prepared by: Scott Harrison and K.W. Shepherd.

11. Estimate approved by: C.G. Nuckols, Assistant Director for Budget Analysis.

CONGRESSIONAL BUDGET OFFICE ESTIMATE [1]

The applicable cost estimate of this Act for all purposes of sections 252 and 253 of the Balanced Budget and Emergency Deficit Control Act of 1985 shall be as follows:

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AGENCY VIEWS

No views were received from the Department of Health and Human Services.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3 of Rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

SECTION 1927 OF THE SOCIAL SECURITY ACT

PAYMENT FOR COVERED OUTPATIENT DRUGS

Sec. 1927. (a) Requirement for Rebate Agreement.–

(1) In general.–In order for payment to be available under section 1903(a) for covered outpatient drugs of a manufacturer the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a [manufacturer).] ***26** manufacturer) and an agreement described in paragraph (5) (with respect to drugs purchased by a covered entity on or after October 1, 1992), and must meet the requirements of paragraph (6). Any agreement between a State and a manufacturer prior to April 1, 1991, shall be deemed to have been entered into on January 1, 1991, and payment of such manufacturer shall be retroactively calculated as if the agreement between the manufacturer and State had been entered into on January 1, 1991. If a manufacturer has not entered into such an agreement before March 1, 1991, such an agreement, subsequently entered into, shall not be effective until the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into

* * * * * * *

(5) Limitation on prices of drugs procured by covered entities.–

(A) Agreement with secretary.–An agreement described in this paragraph is an agreement between a manufacturer and the Secretary that provides that the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in subparagraph (C)) procured by a covered entity (as defined in subparagraph (D)) does not exceed an amount equal to the average manufacturer price for the drug under this title in the preceding calendar quarter, reduced by the rebate percentage described in subparagraph (B).

(B) Rebate percentage defined.–For a covered outpatient drug procured in a calendar quarter, the "rebate percentage'' is the amount (expressed as a percentage) equal to–

(i) the average total rebate required under subsection (c) with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by

(ii) the average manufacturer price for such a unit of the drug during such quarter.

(C) Exception for drugs provided under state plans.–Drugs described in this subparagraph are drugs procured by the entity for which payment is made by the State under the State plan.

(D) Covered entity defined.–In this subsection, the term "covered entity" means an entity that meets the requirements described in subparagraph (E) and is one of the following:

(i) A Federally-qualified health center (as defined in section 1905(l)(2)(B)).

(ii) A family planning project receiving a grant or contract under section 1001 of the Public Health Service Act.

(iii) An entity receiving a grant under subpart II of part C of title XXVI of the Public Health Service Act *27 (relating to categorical grants for outpatient early intervention services for HIV disease).

(iv) A State-operated AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the Public Health Service Act.

(v) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act.

(vi) A subsection (d) hospital (as defined in section 1886(d)(1)(B)) that the Secretary certifies–

(I) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII or eligible for assistance under the State plan under this title;

(II) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F))) greater than 12.5 percent or was described in section 1886(d)(5)(F)(i)(II); and

(III) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

(E) Requirements for covered entities.–

(i) Prohibiting duplicate rebates.–A covered entity shall not request payment under the State plan for medical assistance described in section 1905(a)(12) with respect to a drug that is subject to an agreement under this paragraph if the drug is subject to the payment of a rebate to the State under this section.

(ii) Prohibiting resale of drugs.–With respect to any covered outpatient drug that is subject to an agreement under this paragraph, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

(iii) Auditing.–A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this paragraph with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in clauses (i) or (ii) with respect to drugs of the manufacturer.

(iv) Additional sanction for noncompliance.–If the Secretary finds, after notice and hearing, that a covered entity is in violation of a requirement described *28 in clause (i) or clause (ii), the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in subparagraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.

(F) Treatment of distinct units of hospitals.–In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this paragraph.

(G) Notice to manufacturers.–The Secretary shall notify manufacturers of covered outpatient drugs of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of subparagraph (E).

(6) Requirements relating to drugs procured by department of veterans affairs.–

(A) In general.–A manufacturer meets the requirements of this paragraph and applicable provisions of title 38, United States Code, if–

(i) for each quarter beginning on or after January 1, 1993, the manufacturer makes available for procurement on the Federal Supply Schedule of the General Services Administration each drug or product of the manufacturer which–

(I) is an innovator multiple source drug,

(II) would be an innovator multiple source drug but for the application of the first sentence of subsection (k)(3), or

(III) is a covered drug (as defined in subparagraph (D)(ii)); and

(ii) with respect to each covered drug of the manufacturer (as defined in subparagraph (D)(ii)) procured by the Department of Veterans Affairs on or after October 1, 1992, the manufacturer has entered into and has in effect an agreement with the Secretary of Veterans Affairs under which–

(I) in the case of a drug purchased under the depot contracting system or listed on the Federal Supply Schedule, the price charged may not exceed 76 percent of the non-Federal average manufacturer price (less the amount of any additional discount required under subparagraph (B)); and

(II) the manufacturer is required to meet applicable requirements relating to reporting information to the Secretary of Veterans Affairs on drug prices and the Secretary's authority to audit the manufacturer's records.

(B) Additional discount.–With respect to any covered drug the price of which is determined in accordance with an agreement under this paragraph, the manufacturer ***29** shall provide a discount in an amount equal to the amount by which–

(i) the change in non-Federal price (as determined under subparagraph (D)(i)); exceeds

(ii) the product of–

(I) the non-Federal average manufacturer price of the drug during the 3-month period that ends one year before the last day of the month preceding the month during which the agreement goes into effect (or, in the case of a covered drug for which sufficient data for determining the non-Federal average manufacturer price during such period is not available, during such period preceding the month during which the agreement goes into effect as the Secretary of Veterans Affairs considers appropriate); and

(II) the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) between the last month of the period described in subclause (I) and the last month preceding the month during which the agreement goes into effect.

(C) Application of survey requirements and sanctions.–The provisions of subparagraphs (B) and (C) of subsection (b)(3) shall apply to covered drugs and the Secretary of Veterans Affairs in the same manner as such provisions apply to covered outpatient drugs and the Secretary of Health and Human Services under such subparagraphs, except that references in such subparagraphs to prices or information reported or required under "subparagraph (A)" shall be deemed to refer to information reported to the Secretary of Veterans Affairs pursuant to applicable requirements relating to reporting information to the Secretary of Veterans Affairs on drug prices.

(D) Definitions.–In this paragraph:

(i) Change in non-federal price.–The term "change in non-Federal price" means, with respect to a covered drug that is subject to an agreement under this paragraph, an amount equal to–

(I) the non-Federal average manufacturer price of the drug during the 3-month period that ends with the month preceding the month during which the agreement goes into effect (or, in the case of a covered drug for which sufficient data for determining the non-Federal average manufacturer price during such period is not available, during such period as the Secretary of Veterans Affairs considers appropriate); minus

(II) the non-Federal average manufacturer price of the drug during the 3-month period that ends one year before the end of the period described in subclause (I) (or, in the case of a covered drug for which sufficient data for determining the non-Federal average manufacturer price during such ***30** period is not available, during such period preceding the period described in subparagraph (A) as the Secretary of Veterans Affairs considers appropriate).

(ii) Covered drug.–The term "covered drug" means a drug or product which–

(I) is a single source drug (as defined in subsection (k)(7)(A)(iv));

(II) would be a single source drug but for the application of the first sentence of subsection (k)(3);

(III) is a biological product identified under section 600.3 of title 21, Code of Federal Regulations; or

(IV) is insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act.

(iii) Depot.–The term "depot" means a storage system operated by an agency of the Federal Government or by an entity with which such an agency contracts, through which drugs from various manufacturers are received, stored, and held for

distribution to multiple health care facilities of an agency of the Federal Government. The term includes any warehousing and distribution arrangement whether Government-owned and operated, Government-owned and privately operated, or privately-owned and operated.

(iv) Non-federal average manufacturer price.–The term "non-Federal average manufacturer price" means, with respect to a covered drug and a period of time (as determined by the Secretary of Veterans Affairs), the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers to the manufacturer, taking into account any cash discounts or similar price reductions during that period, but not taking into account any prices paid by the Federal Government.

(v) Weighted average price.–The term "weighted average price" means, with respect to a covered drug and a period of time (as determined by the Secretary of Veterans Affairs) an amount equal to–

(I) the sum of the products of the average price per unit of each quantity of the drug sold during the period and the number of units of the drug sold during the period; divided by

(II) the total number of units of the drug sold during the period.

(b) Terms of Rebate Agreement.–

(1) ***

* * * * * * *

(3) Manufacturer provision price information.–

(A) ***

* * * * * * *

*31 (D) Confidentiality of information.–Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under [this paragraph] this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii) is confidential and shall not be disclosed by the Secretary or the Secretary of Veterans Affairs or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except as the Secretary or the Secretary of Veterans Affairs determines to be necessary to carry out this section and to permit the Comptroller General to review the information provided.

* * * * * * *

(c) Amount of Rebate.–

(1) Basic rebate for single source drugs and innovator multiple source drugs.–With respect to single source drugs and innovator multiple source drugs, each manufacturer shall remit a basic rebate to the State medical assistance plan. Except as otherwise provided in this subsection, the amount of the rebate to a State for a calendar quarter (or other period specified by the Secretary) with respect to each dosage form and strength of single source drugs and innovator multiple source drugs shall be equal to the product of–

(A) ***

(B)(i) for quarters (or periods) beginning after December 31, 1990, and before [January 1, 1993,] October 1, 1992, the greater of–

(I) the difference between the average manufacturer price (after deducting customary prompt payment discounts) and 87.5 percent of such price for the quarter (or other period), or

(II) the difference between the average manufacturer price for a drug and the best price (as defined in paragraph (2)(b)) for such quarter (or period) for such drug (except that for calendar quarters beginning after December 31, 1990, and

ending before January 1, 1992, the rebate shall not exceed 25 percent of the average manufacturer price, and for calendar quarters beginning after December 31, 1991, and ending before January 1, 1993, the rebate shall not exceed 50 percent of the average manufacturer price); [and]
[(ii) for quarters (or other periods) beginning after December 31, 1992, the greater of–

[(I) the difference between the average manufacturer price for a drug and 85 percent of such price, or
[(II) the difference between the average manufacturer price for a drug and the best price (as defined in paragraph (2)(B)) for such quarter (or period) for such drug.]
(ii) for quarters (or other periods) beginning after September 30, 1992, and before January 1, 1994, the greater of–

***32** (I) 15.7 percent of the average manufacturer price for the drug, or
(II) the difference between the average manufacturer price for the drug and the best price (as defined in subparagraph (C)) for such quarter (or period) for such drug;
(iii) for quarters (or other periods) beginning after December 31, 1993, and before January 1, 1995, the greater of–

(I) 15.4 percent of the average manufacturer price for the drug, or
(II) the difference between the average manufacturer price for the drug and the best price (as defined in subparagraph (C)) for such quarter (or period) for such drug;
(iv) for quarters (or other periods) beginning after December 31, 1994, and before January 1, 1996, the greater of–

(I) 15.2 percent of the average manufacturer price for the drug, or
(II) the difference between the average manufacturer price for the drug and the best price (as defined in subparagraph (C)) for such quarter (or period) for such drug; and
(v) for quarters (or other periods) beginning after December 31, 1995, the greater of–

(I) 15.1 percent of the average manufacturer price for the drug, or
(II) the difference between the average manufacturer price for the drug and the best price (as defined in subparagraph (C)) for such quarter (or period) for such drug.
(C) For the purposes of this paragraph, the term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer to any wholesaler, retailer, nonprofit entity, or governmental entity within the United States [(excluding] (excluding any prices charged to the Indian Health Service or a covered entity described in subsection (a)(5)(D), any prices charged under the Federal Supply Schedule of the General Services Administration, or any prices used under State pharmaceutical assistance program by reference to prices charged to the Department of Veterans Affairs, and excluding depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government). The best price shall be inclusive of cash discounts, free goods, volume discounts, and rebates (other than rebates under this section) and shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package, and shall not take into account prices that are merely nominal in amount;

* * * * * * *

1 An estimate of H.R. 2890, the Medicaid Drug Rebate Amendments of 1992, as ordered reported by the House Committee on Energy and Commerce on September 17, 1992. This estimate was transmitted by the Congressional Budget Office on September 21, 1992

H.R. REP. 102-384(II), H.R. REP. 102-384, H.R. Rep. No. 384(II), 102ND Cong., 2ND Sess. 1992, 1992 WL 239341 (Leg.Hist.)

End of Document

Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau OMB No. 0915-0327; Expiration Date: 08/31/2019

General Instructions for Completing the Pharmaceutical Pricing Agreement (PPA)

In accordance with the guidance found in the May 7, 1993, *Federal Register*, (link here) Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement (the "Agreement") with the Secretary of Health and Human Services (the "Secretary") in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed the average manufacturer price ("AMP") decreased by a rebate percentage.

Manufacturer is defined in the guidance listed above, as follows:
The term "Manufacturer" has the meaning as set forth in section 1927(k)(5) of the Social Security Act and includes all entities engaged in –

> (1) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or
>
> (2) the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. A manufacturer must hold legal title to or possession of the NDC number for the covered outpatient drug. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

"Manufacturer" also includes any entity, described in (1) or (2) above, that sells outpatient drugs to covered entities, whether or not the manufacturer participates in the Medicaid rebate program. Furthermore, the Pharmaceutical Pricing Agreement provides that the term also includes any contractor who fulfills the responsibilities pursuant to the PHS drug pricing agreement.

Please print the attached Pharmaceutical Pricing Agreement (PPA) in its entirety and have it signed by a corporate officer, such as the Chief Executive Officer. The form utilizes Adobe Acrobat Reader in an interactive format allowing you to input all applicable information on the computer. However, the form cannot be saved with your information for future use. You must print the form to submit it to the Office of Pharmacy Affairs Branch (OPA).

If your organization would like to receive a signed original, please ensure that you submit TWO signed originals to the OPA. Otherwise, the OPA will send you a copy of the document once it is counter-signed by the Associate Administrator, Healthcare Systems Bureau, Health Resources and Services Administration.

If you have any questions, please contact the 340B Prime Vendor at 1-888-340-2787 or via email at ApexusAnswers@340BPVP.com.

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PHARMACEUTICAL PRICING AGREEMENT

(hereinafter referred to as the "Agreement")
Between
THE SECRETARY OF HEALTH AND HUMAN SERVICES
(hereinafter referred to as the "Secretary") and
THE MANUFACTURER
Identified in Section IX of this Agreement
(hereinafter referred to as the "Manufacturer")

The Secretary, on behalf of the Department of Health and Human Services, and the Manufacturer for purposes of section 602 of the Veterans Health Care Act of 1992, Public Law No. 102-585, which enacted section 340B of the Public Health Service Act (hereinafter referred to as "the Act"), 42 U.S.C. 256b, hereby agree to the following:

I. Definitions

The terms defined in this section will, for the purposes of this agreement, have the meanings specified in the Act and section 1927(k) of the Social Security Act, as interpreted and applied herein:

(a) **"Average Manufacturer Price (hereinafter referred to as the "AMP")"** means the average unit price paid to the Manufacturer for the drug in all States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is labeled under the distributor's national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. AMP includes cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Social Security Act), which reduce the actual price paid. It is calculated as a weighted average of each drug of prices for all the Manufacturer's package sizes for each calendar quarter. Specifically, it is calculated as net sales divided by the numbers of units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements). For bundled sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangements. The AMP for a calendar quarter must be adjusted by the Manufacturer, if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(b) **"Best Price"** has the meaning given it in section 1927(c)(1)(C) of the Social Security Act, and section I(d) of the Medicaid Rebate Agreement.

(c) **"Bundled Sale"** refers to the packaging of drugs of different types where the total price for the package is less than the purchase price of the drugs, if purchased separately.

(d) **"Covered Drug"** means an outpatient drug as set forth in section 1927(k) of the Social Security Act. For purposes of coverage under the Agreement, all covered outpatient drugs are identified by the NDC number.

(e) **"Covered Entity"** means:

(1) certain Public Health Service grantees, "look-alike" Federally Qualified Health Centers and disproportionate share hospitals as described in section 340B(a)(4) of the Act; and

(2) in the case of a covered entity that is a distinct part of a hospital, the hospital itself shall not be considered a covered entity unless it meets the requirements of section 340B(a)(4)(L) of the Act, as determined by the Secretary.

(f) **"Manufacturer"** has the meaning as set forth in section 1927(k)(5) of the Social Security Act except that, for purposes of the Agreement, it shall also mean the entity holding legal title to or possession of the NDC number for the covered outpatient drug. The term includes:

(1) any Manufacturer who sells covered outpatient drugs to covered entities, whether or not the Manufacturer participates in the Medicaid rebate program; and

(2) any contractors which fulfill the responsibilities pursuant to the Agreement, unless excluded by the Secretary.

(g) **"Centers for Medicare and Medicaid Services (CMS) (formerly the Health Care Financing Administration)"** means the agency of the Department of Health and Human Services having the delegated authority to administer the Medicaid and Medicare Programs.

(h) **"Medicaid Rebate Program and Medicaid Rebate Agreement"** mean, respectively, the program, and a signed agreement between the Secretary and the Manufacturer, to implement the provisions of section 1927 of the Social Security Act.

(i) **"National Drug Code (NDC)"** means the identifying drug number maintained by the Food and Drug Administration (FDA). For purposes of the Agreement, the NDC number will be used including labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specified product or formulation), and package size code when reporting requested information.

(j) **"Over the Counter Drug"** means a drug that may be sold without a

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prescription and which is prescribed by a physician (or other persons authorized to prescribe such drugs under State law).

(k) **"Quarter"** means a calendar quarter unless otherwise specified.

(l) **"Rebate Percentage"** means an amount (expressed in a percentage) equal to the average total rebate required under section 1927(c) of the Social Security Act with respect to each dosage, form, and strength of a single source or innovator multiple source drug during the preceding calendar quarter; divided by the AMP for such a unit of the drug during such quarter.

(m) **"the Secretary"** means the Secretary of Health and Human Services, or any successor thereto, or any officer or employee of the Department of Health and Human Services or successor agency to whom the authority to implement this agreement has been delegated.

(n) **"Unit of the Drug"** means a drug unit in the lowest identifiable amount (e.g., tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the unit associated with each covered outpatient drug, as part of the submission of data, in accordance with the Secretary's instructions provided pursuant to Section II of the Agreement.

(o) **"Wholesaler"** means any entity, having a wholesale distributor's license, to which a Manufacturer sells the covered outpatient drug, but which does not relabel or repackage the covered outpatient drug.

II. MANUFACTURER'S RESPONSIBILITIES

Pursuant to requirements under section 340B of the Act, the Manufacturer agrees to the following:

(a) for single source and innovator multiple source drugs, to charge covered entities a price for each unit of the drug that does not exceed an amount equal to the AMP for the covered outpatient drug reported (or which would have been reported had the Manufacturer participated in the Medicaid rebate program) to the Secretary in accordance with the Manufacturer's responsibilities under section 1927(b)(3) of the Social Security Act, reduced by the rebate percentage;

(b) for multiple source, noninnovator multiple source, and over the counter drugs, the AMP is reduced by 11%, as described in 1927(c)(3)(B)(ii) of the Social Security Act;

(c) for those Manufacturers that do not have a reporting requirement under section 1927(b)(3) of the Social Security Act for covered outpatient drugs, to submit to the Secretary upon request, a list of such covered outpatient drugs, and the AMP,

baseline AMP, and the Best Price of such covered outpatient drugs;

(d) to retain all records that may be necessary to provide the information described in paragraph (c) of this section for not less than 3 years from the date of their creation;

(e) to afford the Secretary or his designee reasonable access to records of the Manufacturer relevant to the Manufacturer's compliance with the terms of the Agreement;

(f) to permit CMS to share AMP and unit rebate amount submitted under the Medicaid Rebate Agreement on covered outpatient drugs with the Secretary or his designee for purposes of carrying out the Agreement; and

(g) to participate in the HRSA Prime Vendor Program as provided by section 340B(a)(8) of the Act unless otherwise agreed to by the Secretary.

III. SECRETARY'S RESPONSIBILITIES

Pursuant to the requirements under section 340B of the Act, the Secretary agrees to the following:

(a) to make available a list of covered entities on the HRSA Office of Pharmacy Affairs web site (http://www.bphc.hrsa.gov/opa/), or otherwise, for access by participating Manufacturers, covered entities, State Medicaid agencies, and the general public. This information will be updated, to the extent practicable, on a quarterly basis;

(b) with respect to a covered entity that bills Medicaid using a cost basis for drug purchases, to require the entity to submit its pharmacy Medicaid provider number. The Secretary shall provide respective State Medicaid agencies with the list of such entities and their Medicaid provider numbers. Based on these provider numbers, the State agencies will create an exclusion file which will exclude data from these entities when generating Medicaid rebate requests.

(c)to require each covered entity to retain purchasing and dispensing records of covered outpatient drugs under the Agreement and of any claims for reimbursement submitted for such drugs under Title XIX of the Social Security Act for not less than 3 years.

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IV. DISPUTE RESOLUTION

(a) If the Manufacturer believes that a covered entity has violated the prohibition against resale or transfer of covered outpatient drugs, section 340B(a)(5)(B), or the prohibition against duplicate discounts or rebates, section 340B(a)(5)(A), the Manufacturer can access the elective dispute resolution process in the following manner:

(1) The Manufacturer shall attempt in good faith to resolve the matter with the covered entity.

(2) If unable to resolve the dispute, the Manufacturer may provide written notice of the discrepancy to the Secretary.

(3) The Secretary, at his discretion, will initiate an informal dispute resolution process.

(4) If the Secretary finds, after conclusion of the dispute resolution process, that the entity is in violation of such prohibitions, the entity shall be liable to the Manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug as described in section II(a) of the Agreement. Pursuant to section 340B(a) (4) and (5) a covered entity also could be removed from the list of eligible entities.

(b) The Manufacturer may challenge the presence of an entity on the list of eligible entities issued by the Secretary. Upon presentation of appropriate information documenting the entity's ineligibility, the Secretary shall take such steps as necessary to carry out his responsibilities under paragraph III(a) of the Agreement.

(c) If the Secretary believes that the Manufacturer has not complied with the provisions of the Agreement, or has refused to submit reports, or has submitted false information pursuant to the Agreement, the Secretary, at his discretion, may initiate the informal dispute resolution process. If so found, the Secretary may require the Manufacturer to reimburse the entity for discounts withheld and can also terminate the Agreement. A Manufacturer who does not have an agreement with the Secretary pursuant to the Act, will no longer be deemed to meet the requirements of section 1927(a)(5)(A) of the Social Security Act.

(d) A covered entity's failure to comply with the audit requirement pursuant to section 340B(a)(5)(C) of the Act shall be cause for the Manufacturer to notify the Secretary or his designee and for the Secretary to initiate the informal dispute resolution process. Such action will not relieve the Manufacturer from its obligation to conform to the pricing requirements as provided in section 340B(a) of

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the Act and the Agreement.

(e) Nothing in this paragraph shall preclude the Manufacturer or the Secretary from exercising such other remedies as may be available by law.

V. CONFIDENTIALITY PROVISIONS

(a) Information disclosed by the Manufacturer in connection with the Agreement, except as otherwise required by law, will not be disclosed by the Secretary or his designee in a form which reveals the Manufacturer, except as necessary to carry out the provisions of section 340B of the Act, and to permit review by the Comptroller General.

(b) The Manufacturer will hold audit information obtained from the covered entities confidential. If the Manufacturer receives further information on such data, that information shall also be held confidential. Nothing in this paragraph shall preclude the Manufacturer from making such information available to the Secretary to enable the Secretary to carry out the provisions of section 340B of the Act.

VI. NONRENEWAL AND TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of the Agreement, the Agreement shall be effective for an initial period of 1 year, beginning on the date specified in section X of the Agreement. It shall be automatically renewed for additional successive terms of 1 year unless the Manufacturer gives written notice of intent not to renew the Agreement at least 90 days before the end of the applicable period.

(b) The Manufacturer may terminate the Agreement for any reason. Such termination shall become effective the later of the first day of the first calendar quarter beginning 60 days after the Manufacturer gives written notice requesting termination, and the ending date of the term of the Agreement, if notice has been given 90 days before the end of the term.

(c) The Secretary may terminate the Agreement for a violation of the Agreement or other good cause upon 60 days prior written notice to the Manufacturer of the existence of such violation or other good cause. The Secretary shall provide the Manufacturer, upon request, the opportunity to participate in an informal dispute resolution process concerning the termination, but such a process shall not delay the effective date of the termination. Disputes arising under a contract between a Manufacturer and a covered entity should be resolved according to the terms of that contract. Actions taken by the parties in such disputes are not grounds for termination of the Agreement with the Secretary, except to the extent that there is a violation of the provisions of the Agreement.

(d) If the Agreement is not renewed or is terminated, the Manufacturer is prohibited from entering into another Agreement as provided in section 340B of the Act until a period of one complete calendar quarter has elapsed from the effective date of the termination, unless the Secretary finds good cause for earlier reinstatement.

(e) Any nonrenewal or termination will not affect the ceiling price under paragraph II(a) for any covered outpatient drug purchased before the effective date of termination.

VII. GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of the Agreement will be sent in writing.

(1) Notice to the Secretary will be sent to:

Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane Mail
Stop 8W03A
Rockville, Maryland 20857

(2) Notice concerning data transfer and information systems issues is to be sent to the same address as listed above (section VII(a)(1) of this Agreement).

(3) Notice to the Manufacturer will be sent to the address as provided with the Agreement and updated upon Manufacturer notification to the Secretary at the address in the Agreement.

(b) The Manufacturer will be permitted to audit the records of each covered entity

(1) that directly pertain to the entity's compliance with the prohibition on

(A) the resale or other transfer of covered outpatient drugs to persons not patients of the entity, section 340B(a)(5)(B), and

(B) duplicate discounts pertaining to the rebate under section 1927 of the Social Security Act, section 340B(a)(5)(A);

(2) in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits; and

(3) at the Manufacturer's expense.

(c)No provision in the Agreement shall prohibit the Manufacturer from charging a price

for a drug that is lower than the ceiling price as described in section II(a) of the Agreement.

(d) In the event of a transfer in ownership of the Manufacturer, the Agreement is automatically assigned to the new owner.

(e) Nothing in the Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of the Agreement is found to be invalid by a court of law, the Agreement will be construed in all respects as if any invalid or unenforceable provisions were eliminated, and without any effect on any other provision.

(f) Nothing in the Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Secretary under the Constitution, the Act, or Federal laws, or State laws.

(g) The Agreement shall be construed in accordance with Federal common law, and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme.

(h) Except for changes of addresses, the Agreement will not be altered except by an amendment in writing signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Secretary and the Manufacturer.

(i) In the event that a due date falls on a weekend or Federal holiday, items will be due on the first business day following that weekend or Federal holiday.

VIII. EFFECTIVE DATE

The Agreement will be effective upon signing but will in no way alter the effective date upon which drug discounts were to be given to covered entities under any previously signed Pharmaceutical Pricing Agreement between the Secretary and the Manufacturer.

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IX. SIGNATURES

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By:_____ Date: _____

Title: Associate Administrator
Healthcare Systems Bureau
Health Resources and Services Administration

ACCEPTED FOR THE MANUFACTURER

I certify that I have made no alterations, amendments, or other changes to this pricing agreement.

By: _____ Printed Name: _____
(Signature)

Title: _____ Date: _____

Phone Number: _____ Ext. _____ FAX Number: _____

e-Mail Address:_____

Manufacturer Labeler Code(s): _____

Name of Manufacturer: _____

Manufacturer Address: _____

_____

Contact Person: _____

Title: _____

Phone Number: _____ Ext._____FAX Number: _____

e-Mail Address:_____

Public Burden Statement: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0327. Public reporting burden for this collection of information is estimated to average 0.5 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 10C- 03I, Rockville, Maryland, 20857.

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General Instructions for Completing the 340B Drug Pricing Program Pharmaceutical Pricing Agreement – Addendum

Section 340B(a)(1) of the Public Health Service Act (PHS Act) provides that the Secretary of Health and Human Services (the Secretary) will enter into a pharmaceutical pricing agreement (the Agreement) with each manufacturer of covered outpatient drugs in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed the average manufacturer price decreased by a rebate percentage. Section 7102(b) of the Affordable Care Act amended section 340B(a)(1) of the PHS Act to add two new requirements for inclusion in the Agreement with the manufacturer:

1. The Agreement "shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug"; and
2. The Agreement "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."

Section 7102 of the Affordable Care Act also amended section 340B(d)(1)(B)(i)(II) of the PHS Act, which requires HRSA to develop a system to verify the accuracy of manufacturer-submitted quarterly pricing data with ceiling price data calculated by the Secretary.

Section 340B(d)(1)(B)(v) of the PHS Act, as amended by section 7102 of the Affordable Care Act, requires HRSA to develop a 340B ceiling price validation system to calculate and verify 340B ceiling prices for covered outpatient drugs as compared to the manufacturers' 340B prices offered to a covered entity. This system will enable HRSA to receive pricing information directly from manufacturers, which will allow HRSA to more efficiently identify discrepancies among the ceiling price variables and resolve them with minimal burden on the industry. As part of HRSA's oversight of the 340B Program, this Addendum to the Agreement will help to ensure that the requirements of the statute are met, including that manufacturers provide HRSA with their calculated prices for the pricing validation system, and the provision to offer covered entities drugs for purchase at or below the applicable ceiling price if such drugs are made available to any other purchaser at any price.

Please print the attached Addendum and have it signed by a corporate officer, such as the Chief Executive Officer. The form utilizes Adobe Acrobat Reader in an interactive format allowing you to input all applicable information on the computer. However, the form cannot be saved with your information for future use. You must print the form to submit it to the Office of Pharmacy Affairs (OPA).

If your organization would like to receive a signed original, please ensure that you submit TWO signed originals to the OPA. Otherwise, the OPA will send you a copy of the signed document.

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PHARMACEUTICAL PRICING AGREEMENT ADDENDUM

Between
THE SECRETARY OF HEALTH AND HUMAN SERVICES
(hereinafter referred to as the "Secretary")
and
THE MANUFACTURER
Identified in "Signatures" Section of this Addendum
(hereinafter referred to as the "Manufacturer")

This is an Addendum to the Pharmaceutical Pricing Agreement (the "Agreement") between the Secretary and the Manufacturer. The following terms are hereby incorporated as part of the Agreement:

1) Manufacturer shall furnish the Secretary with reports, on a quarterly basis, that include the price of each covered outpatient drug that is subject to the Agreement, that according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this addendum as the "ceiling price").

2) Manufacturer shall offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price, if such drug is made available to any other purchaser at any price.

Signatures

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By: _____ **Date:** _____

Title: Associate Administrator, Healthcare Systems Bureau
Health Resources and Services Administration

ACCEPTED FOR THE MANUFACTURER

By: _____ **Date:** _____
(Signature)

Printed Name: _____ **Title:** _____

Phone Number: _____ **Email Address:** _____

Name of Manufacturer: _____

Manufacturer Address: _____

_____

Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

V. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 20, 2016.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.434, revise the entry for "avocado" in the table under paragraph (b) to read as follows:

§ 180.434 Propiconazole; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ revocation date
Avocado	10	12/31/19
* * * * *		

* * * * *

[FR Doc. 2016–31827 Filed 1–4–17; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 10

RIN 0906–AA89

340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation

AGENCY: Health Resources and Services Administration, Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Health Resources and Services Administration (HRSA) administers section 340B of the Public Health Service Act (PHSA), referred to as the "340B Drug Pricing Program" or the "340B Program." This final rule will apply to all drug manufacturers that are required to make their drugs available to covered entities under the 340B Program. This final rule sets forth the calculation of the 340B ceiling price and application of civil monetary penalties (CMPs).

DATES: This rule is effective March 6, 2017.

FOR FURTHER INFORMATION CONTACT: CAPT Krista Pedley, Director, Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), HRSA, 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857, or by telephone at 301–594–4353.

SUPPLEMENTARY INFORMATION:

I. Background

Section 602 of Public Law 102–585, the "Veterans Health Care Act of 1992," enacted section 340B of the PHSA, "Limitation on Prices of Drugs Purchased by Covered Entities," codified at 42 U.S.C. 256b. The 340B Program permits covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. REP. No. 102–384(II), at 12 (1992). Eligible covered entity types are defined in section 340B(a)(4) of the PHSA. Section 340B of the PHSA instructs HHS to enter into a pharmaceutical pricing agreement (PPA) with certain drug manufacturers. When a drug manufacturer signs a PPA, it is opting into the 340B Program and it agrees to the statutory requirement that the prices charged for covered outpatient drugs to covered entities will not exceed defined 340B ceiling prices, which are based on quarterly pricing data obtained from the Centers for Medicare & Medicaid Services (CMS). Section 7102 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) as amended by section 2302 of the Health Care and Education Reconciliation Act (Pub. L. 111–152) (HCERA) (hereinafter referred to as the "Affordable Care Act"), added section 340B(d)(1)(B)(vi) of the PHSA, which provides for the imposition of sanctions in the form of civil monetary penalties, which—

(I) shall be assessed according to standards established in regulations to be promulgated by the Secretary;

(II) shall not exceed $5,000 for each instance of overcharging a covered entity that may have occurred; and

(III) shall apply to any manufacturer with an agreement under Section 340B of the PHSA that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection 340B(a)(1).

The Affordable Care Act also added section 340B(d)(1)(B)(i)(I) of the PHSA, which requires "[d]eveloping and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices . . ." CMPs provide a critical enforcement mechanism for HHS if manufacturers do not comply with statutory pricing obligations under the 340B Program. HHS is also finalizing this rule to provide increased clarity in the marketplace for all 340B Program

stakeholders as to the calculation of the 340B ceiling price.

Since 1992, HHS has administratively established the terms and certain elements of the 340B Program through guidelines published in the **Federal Register**, typically after publication of a notice in the **Federal Register** and opportunity for public comment. In September 2010, HHS published an advanced notice of proposed rulemaking (ANPRM) in the **Federal Register**, "340B Drug Pricing Program Manufacturer Civil Monetary Penalties" (75 FR 57230, September 20, 2010). After consideration of the comments received on the ANPRM, HHS published a notice of proposed rulemaking (NPRM) in the **Federal Register** (80 FR 34583, June 17, 2015) entitled, "340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation" to implement CMPs for manufacturers who knowingly and intentionally charge a covered entity more than the 340B ceiling price for a covered outpatient drug and to provide increased clarity on the requirements of manufacturers to calculate the 340B ceiling price on a quarterly basis. The public comment period closed on August 17, 2015, and HHS received approximately 35 comments. HHS reopened the comment period (81 FR 22960, April 19, 2016) to invite additional comment on several specific areas of the NPRM: 340B ceiling price calculations that result in a ceiling price that equals zero (penny pricing), the methodology that manufacturers utilize when estimating the ceiling price for a new covered outpatient drug, and the definition of the knowingly and intentionally standard for manufacturer CMPs. The additional comment period closed on May 19, 2016, and HHS received approximately 70 comments during this additional comment period. The following section presents a summary of the comments received, grouped by subject, and a response to each grouping. All comments on the proposals included in the NPRM and the reopening Notice were considered in developing this final rule, and changes were made as described. Other changes were also made to improve clarity and readability.

II. Summary of Proposed Provisions and Analysis and Responses to Public Comments

The revisions to 42 CFR part 10 of the final rule are described according to the applicable section of the final rule. This final rule replaces § 10.1, § 10.2, § 10.3, and § 10.10, adds a new § 10.11, and eliminates § 10.20 and § 10.21.

General Comments

Comments received during both comment periods addressed general issues. We have summarized those comments and have provided a response below.

Comment: Several commenters urge HHS to specify that the effective date of the final rule be prospective and at least two quarters after the final rule's publication in the **Federal Register**. In addition, the commenters urge HHS to build in a significant grace period with respect to manufacturer compliance to give manufacturers sufficient time to put the necessary system capabilities in place. Other commenters asked HHS to revise the effective date of the final rule to 180 days after March 23, 2010, which would allow HHS to impose CMPs retroactively.

Response: The final rule is effective March 6, 2017. HHS recognizes that the effective date falls in the middle of a quarter. As such, HRSA plans to begin enforcing the requirements of this final rule at the start of the next quarter, which begins April 1, 2017. Manufacturers that offer 340B ceiling prices as of the quarter beginning April 1, 2017, must comply with the requirements of this final regulation. HHS believes that this timeframe provides manufacturers sufficient time to adjust systems and update their policies and procedures. HHS disagrees that the rule should be implemented retroactively. An attempt to apply the final rule retroactively would be administratively burdensome and difficult to implement for all stakeholders.

Comment: Several commenters urge HHS to defer the final rule pending the issuance of additional substantive program guidance. The commenters state that the issuance of substantive guidance first is more consistent with fundamental fairness in a civil penalty enforcement context, inasmuch as program stakeholders should understand their substantive obligations prior to any enforcement activity. The commenters also request that HHS finalize the information collection request (ICR) and gain experience first with administering the 340B ceiling price reporting system.

Response: HHS does not believe that the issuance of additional guidance is needed in order to implement this final rule. The provisions of this final rule will be effectively implemented independent of other programmatic regulations and guidances. Current policies under the 340B Program provide stakeholders with sufficient guidance regarding programmatic compliance. Regarding the ICR, HHS submitted an ICR pertaining to the collection of information for the 340B ceiling price reporting system in compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995. The Office of Management and Budget (OMB) approved the ICR on September 28, 2015, after a formal notice and comment process (80 FR 22207, April 21, 2015). This final rule contains specific information related to the calculation of the 340B ceiling price and the imposition of CMPs against manufacturers who knowingly and intentionally overcharge a covered entity; therefore, it is not necessary to implement the 340B ceiling price reporting system prior to finalizing this rule.

Comment: A commenter requests that HHS provide login credentials to state Medicaid staff to facilitate dissemination of 340B ceiling price information. Alternatively, HHS could develop a different means of providing states with quarterly updates of 340B ceiling price calculations (*e.g.,* via designated state technical contacts).

Response: We appreciate the commenters concern, and HRSA and CMS are jointly working on alternative ways to share this information with states.

Comment: Several commenters argue that HHS does not have rulemaking authority to issue a binding ceiling price regulation, as it does not have general rulemaking authority with respect to the 340B Program. Regarding 340B ceiling prices, commenters point out that Congress directed HHS under section 340B(d)(1)(B)(i)(I) of the PHSA to establish "precisely defined standards and methodology for the calculation of ceiling prices" via "an appropriate policy or regulatory issuance." They argue, however, that in other parts of the statute, Congress more clearly directs HHS to issue regulations. For instance, under section 340B(d)(1)(B)(vi)(I), Congress directed HHS to implement civil monetary penalties pursuant to "standards established in regulations." Commenters argue that Congress intended to confer a different level of authority and did not give HHS authority to issue regulations in this area.

Response: HHS has the statutory authority under section 340B(d)(1)(B)(i)(I) of the PHSA to develop and publish through appropriate policy or a regulatory issuance, such as this final rule, the precisely defined standards and methodology for the calculation of 340B ceiling prices. The fact that Congress limited HHS to proceed by rulemaking

with regard to other authorities in the statute does not negate the choice that Congress expressly provided to HHS in section 340B(d)(1)(B)(i)(I) to proceed through either policy or regulation.

Comment: Some commenters suggest that the rule should require manufacturers to provide background information to HHS regarding 340B sales, including information such as the identity of the 340B covered entity billed for a given drug and the shipping location of the drug.

Response: HHS appreciates these comments; however, they are beyond the scope of this final rule.

Comment: Commenters noted that the rule only addressed one of the 340B Program integrity improvements required by the Affordable Care Act—CMPs for manufacturers. They suggested that HHS should not finalize this rule and should instead issue a new, comprehensive NPRM that addresses all the improvements as required by the Affordable Care Act. For instance, the commenters opposed the implementation of CMP procedures absent HHS's creation of an Administrative Dispute Resolution (ADR) process.

Response: HHS is choosing to issue separate rulemakings for the different areas of the 340B Program integrity improvements that the Affordable Care Act mandates and for which HHS has rulemaking authority. HHS is addressing the administrative dispute resolution process and issued an NPRM August 12, 2016, in the **Federal Register** (81 FR 53381). HHS anticipates finalizing the administrative dispute resolution regulation after the comments have been reviewed and considered.

Comment: Commenters note that the Affordable Care Act requires manufacturers to report to HHS the 340B ceiling price each quarter as well as any prior period lagged price concessions that could affect prior quarter 340B ceiling prices by changed average manufacturer price (AMP), Best Price, and unit rebate amounts (URA). The commenter further notes that the proposed rule did not address this circumstance. They suggested that HHS establish a secure protocol to submit pricing and publish for comment its proposed process for manufacturer reporting of such submissions.

Response: Section 340B(d)(1)(B) of the PHSA requires HHS to develop a system to verify the accuracy of 340B ceiling prices calculated by manufacturers and charged to covered entities. HHS recognizes the utility of the type of policy mentioned in the comments and plans to publish guidance on the particular components of the 340B ceiling price reporting system.

Subpart A—General Provisions

A. Purpose and Summary of 340B Drug Pricing Program—§ 10.1 and § 10.2

Section 10.1 and § 10.2 of the rule provide general information concerning section 340B of the PHSA, "Limitation on Prices of Drugs Purchased by Covered Entities." Section 10.1 provides the purpose of part 10 and § 10.2 provides a summary of section 340B of the PHSA, which instructs the Secretary of Health and Human Services to enter into agreements with manufacturers of covered outpatient drugs under which the amount to be paid to manufacturers by certain statutorily defined covered entities does not exceed the 340B ceiling price. Manufacturers participating in the 340B Program are required to provide these discounts on all covered outpatient drugs sold to participating 340B covered entities. HHS did not receive any comments with respect to these sections and is finalizing these sections as proposed.

B. Definitions—§ 10.3

In the proposed rule, HHS sought to define several terms that were used throughout the regulation. These terms included: "340B Drug," "Average Manufacturer Price," "Ceiling price," "CMS," "Covered entity," "Covered outpatient drug," "Manufacturer," "National Drug Code," "Pharmaceutical Pricing Agreement," "Quarter," "Secretary," and "Wholesaler." HHS did not receive comment on the following terms, which are finalized in this rule as proposed: "Average Manufacturer Price," "Ceiling Price," "CMS," "National Drug Code," "Pharmaceutical Pricing Agreement," and "Secretary." For the remaining terms, HHS received specific comments and have summarized those comments below.

1. 340B Drug

Proposed § 10.3 set forth a definition of the term "340B drug" as a covered outpatient drug, as defined in section 1927(k) of the Social Security Act (SSA), purchased by a covered entity at or below the 340B ceiling price required pursuant to a PPA with the Secretary. Based on the comments received, HHS is removing this definition from the final rule, as HHS believes that the definition is unnecessary. HHS received the following comment regarding the definition of a 340B drug.

Comment: Several commenters suggest that HHS remove the proposed definition of a "340B drug" as the term is not used in the 340B statute or proposed regulations and as drafted could lead to confusion and uncertainty. The proposed definition also narrowly defines the circumstances under which a 340B covered entity can acquire the drug.

Response: After consideration of the comments received with respect to this definition and in light of the definition of covered outpatient drug as set forth in section 1927(k) of the SSA, which is also defined in this final rule, HHS does not believe the definition is necessary and is, therefore, removing the definition of a 340B drug from this final rule.

2. Covered Entity

The proposed rule defined the term covered entity as an entity that is listed in section 340B(a)(4) of the PHSA, meets the requirements under section 340B(a)(5) of the PHSA, and is registered and listed in the 340B database. HHS received several comments regarding the proposed definition of covered entity and have summarized them below.

Comment: Several commenters supported the proposed definition of "covered entity" as it included both registration and database listing requirements. They explain that HHS's proposal will improve the integrity of the Program, assist manufacturers in meeting their obligations, and strengthen manufacturer Medicaid compliance. Commenters urge HHS to include in the definition of covered entity that an organization must both: (1) Be in compliance with the duplicate discount and diversion prohibitions; and (2) be registered and appear on the 340B database as a participating entity during the quarter in which the transaction is made.

Response: The term covered entity is defined, in accordance with section 340B(a)(4) of the PHSA, to mean an entity that is listed in the statute and meets all of the requirements in section 340B(a)(5) pertaining to diversion and duplicate discounts. As the definition imposed in this final rule already includes that a covered entity must comply with section 340B(a)(5), it is not necessary for the definition to specify compliance with the requirements pertaining to diversion and duplicate discounts The process for appearing on the 340B database is separate and distinct from compliance with the requirements in section 340B(a)(5), and all covered entities listed on the 340B database are expected to be in compliance with this provision of the statute.

3. Covered Outpatient Drug

The term covered outpatient drug was defined in the proposed rule as having the meaning set forth in section 1927(k) of the SSA. HHS received several comments on the proposed definition and has summarized them below.

Comment: A few commenters recommended that HHS limit the definition of "covered outpatient drug" to only the definition at section 1927(k)(2) of the SSA, and not include the "limiting definition" of covered outpatient drugs in section 1927(k)(3) of the SSA to prevent manufacturers from limiting 340B pricing to drugs that are reimbursed separately, as opposed to those reimbursed under bundled payment methodologies. Commenters note that CMS is increasingly moving towards the use of bundled payments and other types of value-based purchasing models with the goal of 50 percent of all Medicaid payments being made under alternative payment models by 2018. Therefore, they argue, it is highly likely that an increasing number of covered entities will no longer be eligible for 340B pricing for Medicaid patients if section 1927(k)(3) of the SSA is incorporated into this regulation. Commenters urge the development of a definition of "covered outpatient drug" that is specific to the 340B Program and does not track with the Medicaid statute, which is limited to the Medicaid Drug Rebate Program (MDRP).

Response: Section 340B(b)(1) of the PHSA states that the term "covered outpatient drug" has the meaning set forth in section 1927(k) of the SSA. Section 1927(k) includes the limiting definition and HHS does not believe that the interpretation of covered outpatient drug is contrary to the purpose of the 340B Program. We disagree that covered entities will not be eligible for the 340B Program as a result of this provision.

4. Manufacturer

HHS defined the term manufacturer in the proposed rule as having the meaning set forth in section 1927(k) of the SSA. HHS received several comments on the proposed definition and has summarized them below.

Comment: For the term "manufacturer," commenters urge HHS to incorporate its long-standing guidance that a manufacturer "must hold legal title to or possession of the national drug code (NDC) for the covered outpatient drugs." The commenter explains that the PPA has reflected this provision. This is important because there could be distinct legal entities that own distinct NDCs and are different manufacturers for purposes of the 340B Program.

Response: Section 340B(b)(1) of the PHSA defines the term as having the meaning set forth in section 1927(k) of the SSA. Given the 340B statute's direct reference to section 1927(k) of the SSA, HHS does not believe that this term needs to be further defined in this final rule. However, for 340B Program purposes, a manufacturer would be the entity holding legal title or possessing the NDC in question.

Comment: Commenters urged HHS to clarify the distinction between "manufacturers" and "wholesalers." They suggest HHS specify that "traditional" wholesale distribution operations and contract packaging and repackaging operations do not make an entity a "manufacturer" that can be subject to CMPs.

Response: The definition of "manufacturer" is finalized at § 10.3. To the extent that a wholesale distributor meets the definition of "manufacturer," it would need to meet the requirements for manufacturers as defined in this rule.

5. Quarter

The term quarter is defined in the proposed rule as a calendar quarter, unless otherwise specified. HHS received several comments on this term, which are summarized below.

Comment: Several commenters support that 340B ceiling prices are calculated based on calendar quarters. However, the commenters argue that the proposed rule does not recognize the two-quarter lag between when a sales transaction occurs and when the applicable 340B ceiling price becomes effective. They urge HHS to clarify that 340B ceiling price calculations are based on sales transactions from two prior calendar quarters. They feel this is supported because calculating the 340B ceiling price for a particular calendar quarter in the immediate preceding quarter is not possible because AMP and Best Price for the quarter are not calculated and reported to CMS until 30 days after the end of a quarter.

Response: HHS agrees with the commenters. HHS notes that the 340B ceiling price is calculated based on data received from CMS that incorporates the quarterly pricing lag. For purposes of this final rule, HHS is interpreting the 340B ceiling price calculation provision at section 340B(a)(1) to be the AMP reported from the preceding calendar quarter minus the URA. Section 10.10(a) of this final rule, pertaining to the calculation of the 340B ceiling price, has been modified to align with the 340B statute pertaining to AMP calculations made in the preceding calendar quarter. For instance, the pricing data from the first quarter in any given year is not due to be reported to CMS until 30 days into the second quarter. Therefore, the pricing data from the first quarter cannot be used to price drugs until the third quarter. The definition of quarter will be finalized as proposed.

6. Wholesaler

The proposed rule defines wholesaler as the term as set forth in 42 U.S.C. 1396r–8(k)(11). HHS received several comments, which are summarized and responded to below.

Comment: Commenters suggest that HHS uniformly refer to the applicable sections of the SSA (as opposed to the reference to the United States Code) for purposes of consistency and to avoid any potential confusion. Other commenters note that the term "wholesaler" as defined in section 1927(k)(11) of the SSA is focused on the distribution to retail community pharmacies, which are entities that cannot qualify as 340B covered entities. They state further that while retail community pharmacies may serve as contract pharmacies, not all 340B covered entities maintain contract pharmacy arrangements. The commenters do not think it is appropriate to utilize a definition that focuses on drug distribution and retail community pharmacies. In addition, commenters urge HHS to ensure that specialty pharmacies, including radio pharmacies and nuclear pharmacies, are not included in the term "manufacturer" or "wholesaler" and, therefore, that the 340B ceiling price is not required to be offered by specialty pharmacies, although they may elect to do so. Unlike "specialty distribution," which can be an entity that performs the same function as a wholesaler, specialty pharmacies are pharmacies that receive, rather than distribute drugs.

Response: After consideration of the comments received on the term wholesaler, HHS is removing this term from the final rule. The term "wholesaler" as defined at section 1927(k)(11) of the SSA is not appropriate for 340B Program purposes for the reasons cited by commenters and it is not necessary to define this term in the final rule. With respect to "specialty distribution" or "specialty pharmacy," HHS notes that it is the manufacturer's responsibility to ensure compliance with 340B Program requirements, including the requirements set forth in this final rule.

Comment: Commenters urge HHS to clarify that (1) traditional wholesale

distribution operations (*e.g.,* purchasing or holding for resale or distribution) and (2) contract packaging and repackaging operations (*i.e.,* where the product does not bear the repackages labeler code) will not cause an entity to be a "manufacturer" that is potentially subject to CMPs. Instead, manufacturers subject to the 340B Program's pricing obligations (and potentially CMPs) should be limited to entities whose NDC labeler code appears on a drug product, as this approach is consistent with CMS and the MDRP.

Response: Although HRSA recognizes that wholesalers often act as independent entities, a manufacturer's failure to ensure that covered entities receive the 340B ceiling price through its distribution arrangements with wholesalers may be grounds for assessment of civil monetary penalties as set forth in this final rule.

Subpart B—340B Ceiling Price

A. Ceiling Price for a Covered Outpatient Drug—Calculation of 340B Ceiling Price—§ 10.10(a)

In the proposed rule, HHS recognized that the 340B ceiling price for a covered outpatient drug is equal to AMP minus the URA, and will be calculated using six decimal places. HRSA proposed to publish the 340B ceiling price rounded to two decimal places.

HHS received numerous comments on this provision in the proposed rule. In this final rule, HHS has decided to remove the terms "package size" and "case package size" and plans to address these operational elements concerning the 340B ceiling price calculation in future guidance associated with the 340B Program ceiling price reporting system. HHS has addressed specific comments with respect to this issue below.

Comment: Several commenters expressed concern that the terms "package size" and "case package size" are confusing and not in the 340B statute. Commenters argue that "case package size" is not a metric tabulated or reported under other price reporting programs or currently used by manufacturers. Commenters suggest HHS clarify the terms to assist stakeholders in understanding how 340B ceiling prices are calculated and to ensure consistency in the methodology used by manufacturers to calculate 340B ceiling prices. Commenters also urge HHS to refrain from introducing new variables without analysis and an understanding of the overall ceiling price calculation. Other commenters stated that case/package size was proposed in an effort to assist HHS in providing sales prices for an 11-digit NDC; however if the unit type and units per package are consistent with the units in the 11-digit NDC, then the sales price can be derived without using any other value.

Response: After consideration of the comments received, HHS has decided to remove "package size" and "case package size" from the final rule as the statute only speaks to the 340B ceiling price calculation as being AMP minus URA. HHS does plan to further elaborate on the manner that the terms relate to the 340B ceiling price calculation, and its use by the market, in future guidance associated with the 340B Program ceiling price reporting system.

Comment: Some commenters noted that the proposed rule would require calculation of the ceiling price to six decimal points and that the necessity of this added complexity is unclear. They suggested that the ceiling prices be reported and calculated in dollars and cents with two decimal places. Several commenters support and appreciate that HHS plans to publish the ceiling price rounded to two decimal places, which makes it easier for covered entities to determine if manufacturers are charging them appropriately.

Response: HHS has concluded that the data utilized for the 340B ceiling price calculation should be in the same format as reported to CMS. CMS has indicated in Manufacturer Release No. 82 (November 1, 2010) that when AMP is submitted to the Drug Data Reporting for Medicaid (DDR) system, it should be rounded to six decimal places. In Manufacturer Release No. 46 (April 18, 2000), CMS modified the rounding methodology for the URA and required manufacturers to round URA calculations to four digits and because the field codes require six digits, CMS "pads" positions five and six with zeros. HRSA receives both the AMP and URA data from CMS at six decimal places. For the purposes of calculating the 340B ceiling price, HHS has decided that data utilized for the calculation of the 340B ceiling price will be rounded to six decimal places in an effort to ensure an accurate 340B ceiling price. HHS will then make the 340B ceiling price available in the secure 340B ceiling price system rounded to two decimal places in an effort to ensure certainty in the market place.

Comment: Some commenters urge HHS to clarify in the final rule that the ceiling price calculation is based on the quarterly AMP as opposed to a monthly AMP.

Response: AMP is described in section 340B(a)(1) of the PHSA as the AMP for the drug under title XIX of the SSA in the preceding calendar quarter. The AMP used for the calculation of the 340B ceiling price is a quarterly AMP sent to HRSA by CMS on a quarterly basis. We agree with the commenters and have modified the final rule to clarify that the 340B ceiling price is based on quarterly AMP data.

Comment: Commenters argue that the ceiling price calculation mechanics are unclear given that HHS has not yet implemented the ceiling price verification mechanism and Web site for covered entities. Other commenters request that HHS provide a detailed, standardized 340B ceiling price methodology, including a written formula.

Response: With respect to the 340B ceiling price calculation, HHS has determined that this final rule will be limited to the elements necessary to calculate the 340B ceiling price as defined at section 340B(a)(1) of the PHSA. This final rule sets forth the 340B ceiling price calculation as AMP minus URA. The development of the 340B ceiling price reporting system is proceeding under a separate ICR process that is operational in nature and is not contingent upon the specific provisions contained in this final rule. This ICR was submitted and approved by OMB on September 28, 2015, after a formal notice and comment process (80 FR 22207, April 21, 2015, OMB No. 0915–0327).

Comment: Some commenters encourage HHS to require both manufacturers and CMS to report URA values to HHS for verification and resolution of anomalies or discrepancies.

Response: The reporting obligations of manufacturers and HRSA's receipt of pricing information from CMS are outside the scope of this rule.

B. Ceiling Price for a Covered Outpatient Drug—Exception—§ 10.10(b)

Where the URA equals the AMP for a drug, the section 340B ceiling price formula would result in a ceiling price of zero. The statute, however, clearly contemplates a payment to a manufacturer and the act of purchasing covered outpatient drugs. Setting a zero dollar ceiling price would run counter to the statutory scheme and lead to unintended consequences, including operational challenges. For example, some information technology systems are not able to generate invoices for any prices less than $0.01 and manufacturers may not be able to generate an electronic data interchange price update for an item that does not have a price of at least $0.01. The NPRM

therefore proposed that when the 340B ceiling price calculation resulted in an amount less than $0.01, a manufacturer charge a $0.01 per unit of measure.

In light of the comments received on this particular policy (when ceiling price calculations result in a ceiling price that equals a zero, or "penny pricing"), HHS reopened the comment period (81 FR 22960, April 19, 2016) to solicit additional comment and determine whether or not alternatives raised in the comments regarding the penny pricing policy would be more appropriate. HHS also sought to provide the public with adequate opportunity to comment on alternatives to penny pricing.

The specific alternatives raised by commenters on the NPRM included the Federal Ceiling Price (FCP), the most recent positive 340B ceiling price from previous quarters, and nominal price. Some commenters stated that the FCP, which is the basis for certain Federal government program drug purchases, would be a viable alternative. Other commenters suggested that charging a ceiling price from previous quarters in which the ceiling price was greater than $0.00 would be reasonable. Finally, several commenters suggested that nominal pricing, which is a term used in the MDRP, would be more appropriate. Other commenters suggested that manufacturers should be able to utilize any reasonable pricing methodology that they choose.

In the reopening of the comment period published in the **Federal Register**, HHS received numerous comments supporting and opposing the alternatives to penny pricing. Several commenters opposed to the alternatives expressed that any alternatives to penny pricing would violate the 340B ceiling price formula and would reward manufacturers for raising prices faster than inflation. In addition, commenters opposed to the alternatives explained that they would directly conflict with the intent of the 340B Program by increasing costs for covered entities. Other commenters opposing the penny pricing policy suggested that the policy would result in drug shortages, stockpiling, diversion, harm to patients and abuse. Among support for several of the alternatives, these commenters recommended that HHS allow manufacturers to select a reasonable pricing methodology in accordance with their duty of good faith under the PPA.

After consideration of the comments received, HHS is finalizing the penny pricing policy as proposed. This long-standing policy reflects a balance between the equities of different stakeholders and establishes a standard pricing method in the market. Specific comments are addressed below.

Comment: Several commenters support the maintenance of the current HHS penny pricing proposal, believing it is the best approach for calculating the 340B ceiling price, that it is well-established and effective, and that it is consistent with HHS' existing policy. Many commenters were concerned that any alternatives to penny pricing would be inconsistent with the statute. Commenters encouraged HHS to consider the unintended impact that changing the penny pricing policy would have on the covered entities and the vulnerable populations they serve and supported finalizing the original penny pricing proposal. Commenters recommended that if alternate proposals were considered, HHS put forward more detailed models for thorough review and analysis of impact on covered entities.

Response: HHS agrees with the commenters supporting the current policy and is finalizing the penny pricing policy as proposed. HHS has established the penny pricing policy that allows for the next positive price ($0.01) when the calculation of the 340B ceiling price is zero. This policy is consistent with the timing of the 340B ceiling price calculation (preceding calendar quarter), and it appropriately aligns with the requisite data points (*i.e.,* AMP and URA) for the 340B ceiling price as set forth in section 340B(a)(1) of the PHSA. HHS believes that the proposed alternatives to penny pricing would be inconsistent with the 340B ceiling price formula established in section 340B(a) of the PHSA and would raise 340B ceiling prices above the statutory formula in ways that would be inconsistent with the statutory scheme. HHS believes that the penny pricing policy best effectuates the statutory scheme.

Comment: Some commenters stated that the inflationary penalty used to calculate the URA was established to discourage manufacturers from raising the price of drugs faster than inflation (*i.e.,* the rebate percentage increases when a manufacturer increases the price of a brand-name drug). Further, commenters believed that any alternative policy to penny pricing would reward manufacturers for raising prices faster than inflation. Commenters stated that the inflationary penalty used to calculate the URA was intentionally established by Congress to discourage manufacturers from raising the price of drugs faster than the rate of inflation and that any alternative to penny pricing would ignore this core component of the pricing formula established by Congress.

Response: Under the MDRP, CMS indexes quarterly AMPs to the rate of inflation (Consumer Price Index adjusted for inflation-urban). Section 1927(c)(2)(A) of the SSA provides that if the AMP increases at a rate faster than inflation, the manufacturer pays an additional rebate amount which is reflected in an increased URA. Historically, because of the basic rebate and the inflation factor, section 1927(c)(2)(A) of the SSA could increase the rebate amount manufacturers must pay to the States, and result in negative 340B ceiling prices. Due to the provision in section 1927(c)(2)(D) of the SSA that limits the unit rebate amount to 100 percent of the AMP, effective January 1, 2010, an increase in the basic rebate and inflation factor would not result in a negative 340B price, but could result in a zero 340B ceiling price. The methodologies proposed as alternatives to penny pricing would decrease the effect of the inflationary component of the statutory formula established by Congress (AMP increasing faster than inflation).

Comment: Commenters acknowledged HHS' authority and obligation to define the term "ceiling price," but argued that a literal interpretation of the statutory text that would result in a calculated 340B ceiling price of zero dollars is an absurd outcome.

Response: The calculation of the 340B ceiling price is defined in section 340B(a)(1) of the PHSA as AMP minus URA. Under the MDRP, CMS indexes quarterly AMPs to the rate of inflation (Consumer Price Index adjusted for inflation-urban). Section 1927(c)(2)(A) of the SSA provides that if AMP increases at a rate faster than inflation, the manufacturer pays an additional rebate amount which is reflected in an increased URA, which could result in a 340B ceiling price of zero. Although infrequent, HHS notes that there are instances when the 340B ceiling price does calculate to a zero price. For example, in the first calendar quarter of 2016, approximately 1 percent of all drugs listed under the 340B program for that quarter resulted in a zero price.

For the reasons described in the previous responses, HHS does not believe that it is consistent with the statutory scheme to set the price at zero. In this circumstance, HHS is therefore requiring that manufacturers charge a $0.01 for the drug, which we believe best effectuates the statutory scheme by requiring a payment.

Comment: Several commenters stated that the 340B statute does not address situations where the 340B ceiling

pricing calculation results in zero and therefore the PPA should govern. Commenters argued that while the PPA does not directly address what should occur when the 340B pricing formula results in zero, it provides that the agreement "shall be construed in accordance with Federal common law" which requires the parties "gap fill" by negotiating ambiguous requirements in good faith. Other commenters offered criteria under which the duty of good faith would be met by a reasonable pricing methodology to include that the policy is readily and objectively verifiable, is statutorily supported, and represents a favorable discount to covered entities.

Response: The U.S. Supreme Court has stated that PPAs are not transactional, bargained for contracts, and that "PPAs simply incorporate statutory obligations and record the manufacturers' agreement to abide by them" (*Astra USA* v. *Santa Clara County,* 563 U.S. 110, 118 (2011)). Moreover, the PPA indicates that any ambiguities shall be interpreted in a manner that best effectuates the statutory scheme, not that any ambiguities should be negotiated between the parties. 340B Program requirements are based on the manner in which the Department interprets the statute, and are not subject to a contractual negotiation process. For the reasons previously stated, the Department has determined that penny pricing is the policy that best effectuates the statutory scheme.

Comment: Commenters suggested that HHS institute a similar policy to address zero prices as the Veterans Administration (VA) uses to implement the Master Agreement for FCP prices given to certain Federal purchasers pursuant to the Veterans Health Care Act of 1992, the same legislation that created the 340B Program. They state that the VA interprets its program, which is similar to the 340B Program, to require a good faith negotiation to set a reasonable price in the event of a negative or zero FCP.

Response: Contrary to the commenters' position, the approach utilized by the VA under its separate Prime Vendor Program supports the penny pricing policy. Similar to this final rule, the VA sets the price of a negative or zero priced FCP at $0.01. The VA's assumption for these drugs is, therefore, that prices are set at $0.01. While the VA also has an additional mechanism through which manufacturers can request nominal increases in the prices of drugs (Department of Veterans Affairs, Dear Manufacturer Letter, February 24, 1993), the VA's ability to increase prices by a nominal amount above this default is based on statutory authority that does not apply to the 340B Program. Title 38 U.S.C. 8126(a)(2) states that prices may nominally exceed the statutory formula if the VA determines it "to be in the best interests of the Department or such Federal agencies." There is no similar authority in the 340B statute to exceed the basic price calculation, and therefore HHS does not have the same ability to adjust the pricing formula set by statute.

Comment: Many commenters strongly objected to the penny pricing policy. They argued that HHS did not articulate a non-arbitrary, non-capricious reason as to why a $0.01 price is reasonable. Some commenters stated that there is no material difference between zero and $0.01, and since HHS has already stated that zero is not reasonable, $0.01 is also not reasonable. They also argued that the price of zero or one penny fails to cover the costs of goods sold, so cannot be considered the "purchase" of product. Commenters argued that the penny pricing policy would result in an illegal taking of private property by the government. They also argued the policy would result in "arbitrary" or "confiscatory" price controls.

Response: The longstanding penny pricing policy attempts to strike a balance that best effectuates the statutory scheme while ensuring that a zero ceiling price does not result. There is no requirement in the statute that the price paid must cover the costs of the drug. Reading such a requirement into the statute would require the evaluation of the costs of not only zero priced drugs, but any drug with a 340B ceiling price that is only a nominal amount. HHS does not believe that such a system is consistent with the statute. The sale of a drug for a cost less than manufacturing costs still constitutes a "purchase" and does not result in the taking of private property.

HHS disagrees with commenters that there is no material difference between setting the price at zero and $0.01. Setting the price at $0.01 requires a payment and therefore ensures that there is a purchase within the meaning of the statute and, as a practical matter, between the buyer and seller. Setting the price at zero rather than $0.01 would lead to operational challenges. We understand, for instance, that some information technology systems are not able to generate invoices for any prices less than $0.01 and manufacturers may not be able to generate an electronic data interchange price update for an item that does not have a price of at least $0.01.

Manufacturer participation in the 340B Program is also voluntary, albeit required in order to participate in the MDRP. Moreover, it is important to note that a manufacturer controls when a product reaches a zero 340B ceiling price through its own pricing decisions. If a manufacturer does not wish to offer a zero 340B ceiling price, the manufacturer may choose not to participate in the 340B Program or may alter its drug pricing practices so as not to cause a zero 340B ceiling price. For example, when AMP increases more quickly than the rate of inflation, the manufacturer must pay a greater Medicaid rebate, which can also cause a zero 340B price. A manufacturer can control AMP by adjusting the prices that it charges for drugs.

Comment: Some commenters stated the penny pricing proposal is likely to result in and/or increase the potential for drug shortages and diversion, requiring manufacturers to adopt burdensome and costly "alternate allocation procedures" to correct for the market-distorting effect of HHS' policies. Commenters further stated the continuation of penny pricing policy would further exacerbate drug shortages, particularly for generic drugs, given that in the first quarter 2017 generic drugs will be subject to an additional rebate in the URA formula if the AMP for such drugs rises faster than inflation. Given this, the penny pricing provision would result in potential of stockpiling, diversion, harm to patients, and abuse of controlled substances. Commenters were also concerned that there could be an increase in risk evaluation and mitigation strategy (REMS) drugs and drugs for which there is a grey or black market.

Response: The penny pricing policy has been in place for many years and HHS does not have evidence that the policy causes significant risks of stockpiling, diversion, harm to patients, and abuse of controlled substances. HHS has existing policy with regard to manufacturer limited distribution plans for sales of covered outpatient drugs to eligible 340B entities under the 340B Program. Manufacturers may address any resultant market distribution challenges by developing and executing a plan for limited distribution to all purchasers of the affected drug, including 340B covered entities when penny pricing occurs. Manufacturers are currently able to develop appropriate limited distribution protocols. HHS will be sensitive to plans to address drug shortages, stockpiling, and oversupplying of drugs subject to abuse or with REMS warnings.

Comment: Many commenters stated their desire for the flexibility to use any or all of the alternative methods to penny pricing proposed. Manufacturer flexibility and discretion to adopt reasonable approaches to setting the 340B ceiling price when the ceiling price calculates to zero allows manufacturers to recover their costs while providing a discounted rate commensurate with the intent of the 340B statute.

Response: HHS believes it is most appropriate to establish a standard price calculation in this circumstance, as it is not practical to allow all manufacturers to choose from a variety of methods that could result in pricing variations that could create market disruption and uncertainty. Therefore, we are finalizing the penny pricing policy as proposed.

Comment: Some commenters were in favor of utilizing nominal pricing (less than 10 percent of AMP in the same quarter for which the AMP is computed) as an alternative to penny pricing. Commenters also noted that the MDRP uses this methodology, and that nominal price is a term that appears nine times in the Medicaid statute. They stated further that Congress has demonstrated support for applying this concept by listing 340B covered entities first among the six potential recipients to whom manufacturers may extend a nominal price without impacting best price. Commenters stated that nominal price addressed HHS' concern that "prices must be based on the immediately preceding calendar quarter."

Response: While the term nominal price appears in the Medicaid drug rebate statute, it is entirely absent from the 340B statute. Covered entities can receive a nominal price without impacting a manufacturers' best price for purposes of Medicaid calculations; however, nominal pricing is unrelated to the statutorily-mandated 340B Program pricing calculation. Although the nominal pricing alternative is based on the calendar quarter in which AMP is calculated, consistent with the timing of the 340B ceiling price calculation, it does not appropriately align with the requisite data points (*i.e.,* AMP and URA) for the 340B ceiling price as set in section 340B(a)(1) of the PHSA. HHS will therefore finalize penny pricing as proposed.

Comment: Some commenters favored the utilization of the most recent positive AMP or the last positive, non-zero ceiling price as an alternative to penny pricing. This approach would result in a significant discount to covered entities and would be analogous to the process under MDRP where manufacturers are required to report the most recent positive AMP if AMP equals zero. Carrying forward the most-recent, positive quarterly 340B ceiling price would have the practical effect of establishing a realistic covered entity purchase price, and would reduce the risk of diversion posed by penny pricing.

Response: The MDRP and the 340B Program are authorized under different statutes. While the commenter attempts to draw a comparison between the Medicaid AMP policy and the 340B penny pricing policy, AMP is not the only component of the 340B ceiling pricing formula, as the calculation also includes the URA.

In addition, utilizing the AMP calculation from the last positive quarter would not align with the statutory requirement at section 340B(a)(1) of the PHSA that the 340B ceiling price be based on the preceding calendar quarter's data and could encourage manufacturers to manipulate pricing data. In addition, this method ignores the portion of the congressionally mandated pricing formula regarding the inflation adjustment. Therefore, HHS has determined that this alternative is not an adequate alternative and will finalize this rule as proposed.

Comment: Many commenters were in favor of utilizing the FCP as an alternative to penny pricing. Commenters also suggested the FCP offers an objectively verifiable benchmark and conveys a significant discount to covered entities without driving stockpiling and diversion.

Response: The FCP has some similarities in intent and price-setting methodology to the 340B ceiling price. However, the FCP is generally computed once each calendar year and does not align with the requirement that 340B ceiling prices be calculated on a quarterly basis. Additionally, the FCP is not computed using the required calculation points of AMP and URA. Moreover, there is no mention of the FCP in the 340B statute. Therefore, HHS has determined that FCP is not an adequate alternative and will finalize this rule as proposed.

Comment: Some commenters requested an exception to the penny pricing policy for orphan drugs. They suggest that when 340B sales volume exceeds a given threshold (*e.g.,* 15 percent), a manufacturer should be permitted to utilize an alternative 340B price, such as its lowest commercial price.

Response: When an orphan drug meets the definition of a covered outpatient drug, it would be subject to the requirements as set forth in this final rule. Further, the statue does not contemplate an alternative pricing methodology for orphan drugs.

C. Ceiling Price for a Covered Outpatient Drug—New Drug Price Estimation—§ 10.10(c)

In general, calculation of the current quarter 340B ceiling price for each covered outpatient drug is based on pricing data from the immediately preceding calendar quarter. For new drugs, there is no sales data from which to determine the 340B ceiling price. HHS published guidelines in 1995 describing ceiling price calculations for new drugs (60 FR 51488, October 2, 1995) and the final rule will replace these guidelines.

In the NPRM, HHS proposed that manufacturers estimate the 340B ceiling price for a new covered outpatient drug as of the date the drug is first available for sale, and provide HHS an estimated 340B ceiling price for each of the first three quarters the drug is available for sale. HHS also proposed that, beginning with the fourth quarter the drug is available for sale, the manufacturer must calculate the 340B ceiling price as described in proposed 42 CFR 10.10(a). Under the proposed rule, the actual 340B ceiling price for the first three quarters would also have been calculated and manufacturers would have been required to provide a refund or credit to any covered entity that purchased the covered outpatient drug at a price greater than the calculated 340B ceiling price. HHS proposed that any refunds or credits owed to a covered entity would be provided by the end of the fourth quarter.

HHS received comments supporting and opposing the various components of its proposal on new drug price estimation. Commenters requested clarification on de minimis refunds under the proposed policy, price estimation methodologies, and whether refund policies stated in this regulation apply to all refunds, not just those corresponding to new drugs. Several commenters supported a specific methodology for calculating new drug prices, which included setting the price of the new covered outpatient drug as wholesale acquisition cost (WAC) minus the applicable rebate percentage (*i.e.,* 23.1 percent for most single-source and innovator drugs, 17.1 percent for clotting factors and drugs approved exclusively for pediatric indications, and 13 percent for generics). Commenters argued that this price would eliminate the need to estimate the price for the first three quarters and would result in a reasonable 340B ceiling price. Given the comments

received regarding setting a specific methodology, when HHS reopened the comment period, HHS sought comment on this issue. HHS specifically requested comment on setting the estimation at WAC minus the applicable rebate percentage.

After consideration of the comments received, HHS is modifying the final rule to require that manufacturers estimate, using a standardized methodology, the 340B ceiling price for a new covered outpatient drug until there is AMP data available to calculate an actual 340B ceiling price as set forth in 340B(a)(1) of the PHSA. The methodology set forth in this final rule for the estimated 340B ceiling price is WAC minus the appropriate rebate percentage. Once the AMP is known, and no later than the fourth quarter that the drug is available for sale, manufacturers would be required to calculate the actual 340B ceiling price based on AMP for the time under which the 340B ceiling price was estimated. The manufacturer is then required to offer a repayment to the covered entity the difference between the estimated 340B ceiling price and the actual 340B ceiling price within 120 days of the determination by the manufacturer that an overcharge occurred.

For example, if a manufacturer with a PPA has a new drug approved for sale in February, and that drug meets the definition of covered outpatient drug, the 340B price estimation requirements would apply for at least one full calendar quarter. During that time, the manufacturer would estimate the 340B ceiling price at WAC minus the appropriate rebate percentage until the manufacturer can calculate an AMP for the product, resulting in an actual 340B ceiling price based on that AMP. The estimation can occur for up to the first three calendar quarters of availability, at which point the manufacturer will have the necessary pricing data to calculate the 340B ceiling price based on section 340B(a)(1) of the PHSA.

Since manufacturers must offer repayments as set forth in this section, it is incumbent on them to contact affected covered entities as part of that process. During initial contact, a manufacturer and a covered entity may both determine that a given overcharge is not significant, or agree to other payment options such as netting or crediting. In these instances, both parties are free to pursue mutually agreed-upon alternative refund arrangements. HHS has summarized and provided a response to the comments below.

Comment: HHS received comments generally supporting and opposing the proposal to price new covered outpatient drugs at WAC minus the Medicaid minimum discount rebate percentages (*i.e.*, 23.1 percent for most single-source and innovator drugs, 17.1 percent for clotting factors and drugs approved exclusively for pediatric indications, and 13 percent for generics) until an AMP derived ceiling price can be identified after the third full quarter in which the drug became available. In addition, commenters suggested that HHS should not require subsequent pricing revisions or a refund once the actual price is determined. The commenters stated that such an approach would be simpler, while resulting in reasonable proxies for the final 340B ceiling prices.

Response: The 340B ceiling price is calculated based upon AMP minus URA data supplied by CMS that is reported by manufacturers under the MDRP. Given that the AMP for a new covered outpatient drug may not be known for a period of time after the drug comes to market, HHS sought a balance between a standardized and universally applicable interim pricing requirement, while also ensuring that covered entities ultimately receive the 340B ceiling price as defined by the statute. Therefore, we have added to the final rule that new covered outpatient drugs should be estimated and sold to 340B participating covered entities using a standardized formula for the estimation at WAC minus the applicable Medicaid drug rebate percentage until an actual 340B ceiling price can be determined based on AMP. HHS believes a standardized formula for the calculation of the estimation will create stability in the market and provide transparency and consistency in the process. While the commenter's suggested approach may be feasible, HHS does not believe that it is reflective of statutory intent. In addition, HHS has maintained in the final rule that once an actual 340B ceiling price can be determined, manufacturers will be obligated to refund any difference between the estimated 340B price and the actual 340B ceiling price. If a manufacturer refuses to refund covered entities after it has been determined covered entities were overcharged during the time the 340B ceiling price was estimated, that could meet the knowingly and intentionally standard to apply a CMP. This has been clarified in § 10.11 of this final rule.

Comment: HHS received several comments from covered entity groups expressing concern that the proposed new drug price estimation method, based on WAC minus the appropriate rebate percentage, would result in prices that are significantly higher than estimates derived from other methods. Commenters stated that WAC-derived pricing is often 30 percent higher than prices available to group purchasing organizations and that 340B ceiling prices are typically much lower than this estimation.

Response: HHS believes that the final rule ensures that covered entities will be able to receive the 340B ceiling price as defined in statute by requiring manufacturers to offer a refund to covered entities after the estimation period and within 120 days of determining there was an overcharge.

Comment: Several commenters suggested that the 340B Program follow Medicaid policy towards rebates for new drugs, whereby prices are determined from the beginning by AMP (rather than WAC) minus the applicable discount percentage. The commenters argued that policy alignment with Medicaid would greatly simplify rebate program administration, and minimize the need for future reconciliation of overcharges. Commenters also suggested that HHS should reevaluate such a formula for new drug pricing to see how closely it aligns with AMP derived pricing after the initial estimation period.

Response: The CMS Medicaid Covered Outpatient Drug Rule (81 FR 5270, February 1, 2016) refers to AMP-based pricing only when a new version of an existing drug comes to market. In the case of a new drug, the Medicaid program does not utilize AMP-based pricing, as there are no prior sales data to base it on. Therefore, initial prices must be based on another price point. HHS believes that using a standardized formula, WAC minus the appropriate rebate percentage, to estimate 340B ceiling prices prior to an AMP being available is the most appropriate way to implement pricing requirements with regards to new drugs.

Comment: Regarding the timeframe for new drug price calculations, several commenters suggested that new drug pricing follow the VA policy, whereby manufacturers are required to provide an initial (provisional) FCP statutory discount percentage to the WAC for 30 days, followed by a temporary pricing period predicated on the first 30 days of commercial sales, and permanent ceiling pricing taking effect after the first quarter by applying the statutory discount to the non-Federal AMP as it becomes available. Commenters cited the VA timeframe, whereby an estimated (WAC-based) price is used for the first month that a new drug is available, followed by a switch to a temporary (AMP-based) price.

Response: HHS believes that it is appropriate to minimize any restatements of pricing that occur as a new 340B drug comes to market. The VA timeframe does not correlate to the quarterly pricing that occurs in the 340B Program. Therefore, HHS has finalized the rule to estimate drug pricing as WAC minus the appropriate rebate percentage until an actual 340B ceiling price can be computed based on AMP.

HHS also notes that a provisional FCP is not required by the VA, it is optional. In addition, if a provisional FCP is established, it is not valid for just the first 30 days. It remains valid until the first temporary FCP comes due or is established, which could be up to 75 days from launch.

Comment: Commenters suggested that new drug calculations should not be subject to the two-quarter lag typical of other price calculations. These commenters recommended establishing an "interim" (WAC minus the appropriate rebate percentage) ceiling price through the first full quarter, followed by pricing based on the AMP, which can be established with one quarter of data. Other commenters suggested establishing provisional 340B ceiling prices for new drugs based on MDRP statutory discounts applied to an available U.S. sales reference price (*e.g.,* WAC reduced by estimates for quarterly URA values), thus eliminating the need for restatements at a later date.

Response: The 340B ceiling price is set by the statute and manufacturers are required to charge covered entities that ceiling price. Therefore, manufacturers are required to issue refunds if it is determined that a covered entity paid a price higher than the 340B ceiling price. HHS has also decided to standardize the pricing estimation during the period for which there is not an AMP available to calculate an actual 340B ceiling price. HHS believes that WAC minus the rebate percentage serves is a fair and reasonable estimated 340B ceiling price.

Comment: Commenters among the drug manufacturer community stated that it is not necessary to provide price estimates past the first full quarter, so that less time will elapse where a new drug ceiling price is estimated instead of being based on actual market data. Others stated that two quarters was sufficient to calculate prices based off the first quarter's sales data. Commenters argued that a shorter estimate period would reduce administrative burdens, and lessen the need for retroactive refunds.

Response: HHS agrees that an AMP for a new covered outpatient drug may be established after one full quarter has elapsed. Under the final rule, once the AMP is known, and no later than the fourth quarter that the drug is available for sale, manufacturers would be required to calculate the actual 340B ceiling price based on the AMP for the time under which the ceiling price was estimated. The estimation can occur for up to the first three calendar quarters of availability, at which point the manufacturer will have the necessary pricing data to calculate the 340B ceiling price based on section 340B(a)(1) of the PHSA. The manufacturer must offer to refund or credit the covered entity the difference between the estimated ceiling price and the actual 340B ceiling price within 120 days of the determination by the manufacturer that an overcharge occurred.

Comment: Commenters were concerned that the proposed timeframe for manufacturers to issue refunds or credits is too short. Commenters requested that the refund process for overestimated new drug prices follow the Medicaid approach of allowing 12 quarters for price restatements, followed by 2 quarters for the refund to occur. Other commenters wrote in support of the proposed fourth quarter standard.

Response: The NPRM proposed that refunds or credits be provided to entities by the end of the fourth quarter. HHS agrees additional time may be necessary to issue refunds. Therefore, HHS has changed the NPRM's fourth quarter standard in the final rule. In addition, the final rule states that manufacturers must offer to refund or credit the covered entity the difference between the estimated 340B ceiling price and the actual 340B ceiling price within 120 days of the determination by the manufacturer that an overcharge occurred. HHS believes that 120 days allows the manufacturer and the covered entity an opportunity to first determine whether the overcharge is significant, and if not, whether to make repayment options such as crediting or netting.

Comment: Commenters argued that the proposed refund procedure is inconsistent with the 1995 guidance (60 FR 51488, October 2, 1995) where covered entities are responsible for initiating the refund process, and must do so without a third-party intermediary and that the refund requests should be made by the end of the fourth full quarter after a new drug comes to market.

Response: Manufacturers are required by statute to provide covered entities the statutorily defined 340B ceiling price. Therefore, once a manufacturer determines there is an overcharge related to new drug price estimation as set forth in this final rule, manufacturers must notify covered entities affected and appropriately refund them accordingly. This final rule replaces the 1995 guidance in its entirety.

Comment: Commenters stated that requiring refunds following ceiling price recalculations would be inconsistent with the 340B statute because such refunds would impose an undue cost on manufacturers.

Response: In accordance with section 340B(a)(1) of the PHSA, 340B ceiling prices for covered entities must "not exceed an amount equal to the average manufacturer price for the drug under title XIX of the SSA in the preceding calendar quarter, reduced by the rebate percentage" outlined in section 340B(a)(2)(A) of the PHSA. Since the necessary predicate of an AMP cannot be known until a drug has been on the market for a preceding calendar quarter, we have determined that using a reasonable, standardized estimate in the interim, followed by refunds as the AMP is calculated, achieves the programmatic goal of assuring that covered entities receive refunds owed in both a timely and a complete manner. Regarding the cost to manufacturers, this policy involves using similar mechanisms currently in use for other refunds routinely issued by manufacturers, and does not represent a significant added cost.

Comment: Commenters requested clarification on what is meant by the "expected" versus the "actual" price, in addition to requests for clarification on methods for developing expected or estimated prices for new drugs.

Response: For the purposes of this rule, "expected" can be understood as the initial (estimated) 340B ceiling price that is charged to a covered entity when there is not yet an AMP to use in the 340B ceiling price calculation. HHS has added to this final rule a standardized formula to the new drug price cost estimation, which is WAC minus the appropriate rebate percentage. The "actual" 340B ceiling price is the price of a new drug once there is an AMP in place that is used to calculate the 340B ceiling price per statute.

Comment: Commenters requested clarification on the potential role of wholesalers and distributors in the refund process, specifically in identifying covered entities entitled to a refund based on new drug price estimation.

Response: The role of wholesalers and distributors is dependent on how individual manufacturers contract with these third parties to distribute 340B drugs. Whether wholesalers and distributors play a role in the refund process is determined by individual

manufacturers and their business operations with these stakeholders. The requirement to refund a covered entity as outlined in the final rule rests with the manufacturers. A manufacturer may use a third party to assist in ensuring they meet those requirements.

Comment: Several commenters requested that there be an exemption for de minimis refund amounts resulting from differences between initial ceiling price estimates and the establishment of a retroactive actual ceiling price after the first three quarters that a new drug becomes available. Commenters cited administrative burden in issuing refunds for all overcharges, regardless of their significance. Commenters representing both the manufacturer and the covered entity communities were broadly supportive of a defined threshold, as well as a stated timeframe for refunds to be issued.

Response: Manufacturers are obligated to offer repayments within 120 days of the determination that an overcharge occurred. HHS does not agree that the final rule should set a materiality threshold, and believes this is best approached by marketplace arrangements and in good faith negotiation between the parties. To the extent that a manufacturer and covered entity agree that a de minimis threshold for refunds should be established, such a threshold can be established through mutual agreement between the manufacturer and covered entity.

Comment: Regarding overcharges resulting from differences between estimated and actual ceiling prices, a number of commenters requested that overcharges be netted in a manner similar to MDRP regulations. The commenters stated that the MDRP permits manufacturers to aggregate the impact of restated prices on each sale to determine the net amount due after pricing restatements and that states are not permitted to retain excess rebate amounts paid upon recalculations. Commenters suggested that because the MDRP and 340B Program are closely intertwined, they should be consistently administered and allow a similar netting approach as to minimize administrative and financial burden of refunding 340B covered entities.

Response: To the extent there is an agreement between the manufacturer and covered entity, HHS does not intend to prevent manufacturers from using the industry's practice of netting overcharges and undercharges, or to restate ceiling prices based on pricing data submitted to CMS. However, the 340B statute is specific to ensuring each covered outpatient drug is offered at or below the 340B ceiling price. Once it is determined that an overcharge occurred, a manufacturer and a covered entity, in good faith, may both determine that a given overcharge is not significant, or agree to other payment options such as netting or crediting. In these instances, both parties are free to pursue mutually agreed-upon alternative refund arrangements.

Comment: Many commenters suggested that covered entities be held liable for undercharges that occur during a new drug's estimated pricing period.

Response: Given the nature of the standardized estimated 340B ceiling price calculation described in this final rule, HHS views the likelihood of undercharges to be low. Because WAC is typically higher than the 340B ceiling price and the estimation for new drugs finalized in this rule is based on that amount, we believe that new estimation undercharges will be minimal. Section 340B(a)(10) of the PHSA states that there is no prohibition on larger discounts being offered to covered entities. In addition, the statute is specific in addressing when a manufacturer overcharges a covered entity and it does not address refunds by covered entities if the manufacturer provides a price below the 340B ceiling price. Therefore, it will not be addressed in the final rule.

Comment: Commenters requested clarification on whether the refund policy described in this rule would apply to all overcharges identified during price restatements, and not just those that occur as sales data can be applied to new drug pricing. Commenters also requested that HHS codify a formal refund procedure in regulation and that the Affordable Care Act requires the 340B Program to develop a refund mechanism.

Response: The refund requirements as set forth in this final rule apply as it relates to new drug price estimations. Specific procedures for refunds are outside the authority of this final rule and will be addressed in future guidance. HHS is finalizing this refund requirement as proposed and continues to believe that an instance of overcharging may occur at the time of initial purchase or when subsequent ceiling price recalculations resulting from pricing data submitted to CMS occur.

Comment: Commenters requested that HHS define "new drug" in this rule, suggesting the use of NDC–11 or package size as criteria. Commenters suggested a clarification that a new package size is not a new drug, suggesting that new prices can be derived off known unit prices, with any subsequent refunds occurring under the existing reconciliation process. Commenters suggested a clarification that a new package size of an existing drug should not be considered a new drug for purposes of this rule and that the 340B ceiling price should use the per unit pricing data (NDC–9) from the existing package sizes already in the market.

Response: For the purposes of this final rule, a new covered outpatient drug is any drug that does not have a previous quarter AMP calculation from which a price can be derived. HHS does not believe this distinction needs to be clarified in the final rule, and additional policy on this issue may be developed if the need arises.

D. Manufacturer Civil Monetary Penalties General—§ 10.11(a)

Section 340B(d)(1)(B)(vi) of the PHSA provides for the imposition of civil monetary penalties on manufacturers that knowingly and intentionally charge a covered entity a price for a 340B drug that exceeds the ceiling price. At § 10.11(a) of the NPRM, HHS proposed that any manufacturer with a PPA that knowingly and intentionally charges a covered entity more than the 340B ceiling price, as defined in § 10.10, for a covered outpatient drug, may be subject to a civil monetary penalty not to exceed $5,000 for each instance of overcharging a covered entity. As indicated in the NPRM, pursuant to a delegation of authority, OIG will have authority to impose a CMP. The initial release of the NRPM did not define the term "knowing and intentional," but based on comments received, HHS reopened the NPRM comment period (81 FR 22960, April 19, 2016) to seek comment on the definition of the knowing and intentional standard for purposes of HHS' CMP authority. HHS offered possible options on how the term should be defined. HHS understands that intent is difficult to define, therefore, input was solicited on circumstances in which the requisite intent should and should not be inferred. In particular, HHS solicited comment on the concept that manufacturers would not be considered to have the requisite intent in the following circumstances:

- The manufacturer made an inadvertent, unintentional, or unrecognized error in calculating the ceiling price;
- A manufacturer acted on a reasonable interpretation of agency guidance; or
- When a manufacturer has established alternative allocation procedures where there is an inadequate

supply of product to meet market demand, as long as covered entities are able to purchase on the same terms as all other similarly situated non-340B covered entities.

HHS received numerous comments recommending the terms knowingly and intentionally be further defined in the final rule. Commenters generally supported the listed examples of circumstances where the requisite intent is not demonstrated, and a number of commenters suggested additional examples. Commenters also raised concern over ensuring the terms knowingly and intentionally are not overly prescriptive such that they limit the use of a CMP. In the final rule, HHS sought balance between a clear and enforceable definition and the need to approach each instance of an overcharge with a full view of the surrounding circumstances. Given these two goals, HHS is finalizing the rule as proposed and has provided additional examples of conduct that would not be considered to meet the threshold of "knowing and intentional" action in this supplementary information section in response to comments. In addition, as a general principle, HHS will defer to OIG to determine whether a given situation constitutes a 'knowing and intentional' 340B drug overcharge based on the specific case being investigated. HHS believes this will provide the flexibility necessary to evaluate an instance of overcharging on a case-by-case basis. Below is a summary of the comments received, and HHS' responses.

Comment: Commenters provided additional examples to be considered as not meeting the knowing and intentional threshold, such as periods of estimations for new drugs.

Response: HHS agrees that the period of time for which a manufacturer is estimating a 340B ceiling price for new drugs as set forth in this final rule may not meet the knowingly and intentionally standard, as long as the manufacturer also ensures that the covered entities are refunded according to § 10.10(c). However, if a manufacturer does not offer to refund a covered entity per § 10.10(c) of the final rule, that may constitute a knowing and intentional overcharge. The final rule has been modified accordingly. Examples of circumstances where HHS would assume that a manufacturer did not "knowingly and intentionally" overcharge a covered entity are:

- The manufacturer made an isolated inadvertent, unintentional, or unrecognized error in calculating the 340B ceiling price;
- The manufacturer sells a new covered outpatient drug during the period the manufacturer is estimating a price based on this final rule, as long as the manufacturer offers refunds of any overcharges to covered entities within 120 days of determining an overcharge occurred during the estimation period;
- When a covered entity did not initially identify the purchase to the manufacturer as 340B-eligible at the time of purchase; or
- When a covered entity chooses to order non-340B priced drugs and the order is not due to a manufacturer's refusal to sell or make drugs available at the 340B price.

We note that these examples are not exhaustive, and are intended to provide an indication of some types of actions that would not be considered "knowing and intentional" overcharges. In the NPRM, the last two examples above were included in the text of the regulation defining instances of overcharging. Upon consideration of public comments, HHS believes that the last two examples above should be construed as particular circumstances under which an instance of overcharging did not occur as opposed to examples of what would constitute an instance of overcharging. As a result, HHS is not including these two examples in the final regulatory text defining an instance of overcharging, but rather providing them here as examples of instances where overcharging did not occur. As a general principle, HHS will defer to OIG to determine whether a given situation constitutes a 'knowing and intentional' overcharge based on the specific case being investigated.

Comment: Some commenters suggested that HHS adopt the definition of "knowingly" from the HHS OIG CMP regulations. Under these regulations, the term "knowingly" is defined as "a person, with respect to information, has actual knowledge of information, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of the truth or falsity of the information, and that no proof of specific intent to defraud is required" (42 CFR 1003.102 (e)). A few commenters noted that under the canons of statutory construction, agencies must assume Congress intended each word or phrase to have a distinct meaning.

Response: HHS does not believe it is appropriate to incorporate additional language over and above the statutory language "knowingly and intentionally" that would limit OIG further in applying this penalty. Each factual case is different and will be evaluated separately to determine if it may warrant a penalty as set forth in this final rule. After consideration of the comments received, HHS has decided not to define these terms and to allow OIG the necessary flexibility to evaluate each instance of overcharge on a case-by-case basis.

Comment: Commenters offered specific definitions of the term "intentionally." Several commenters requested that "intentionally" be defined as "not due to a mathematical miscalculation, clerical oversight, or similar inadvertent error." A few commenters requested that the term "intentionally" be defined as "consciously committing an act or omission that results in an overcharge." Commenters requested that, when defining the terms "knowingly" and "intentionally," HHS incorporate definitions such as "actual knowledge by the manufacturer, its employees, or its agents of the instance of overcharge" or "acting consciously and with awareness of the acts leading to the instance of overcharge." Commenters interpreted the statute to say that it must be "knowing and intentional" on the part of the manufacturer both that the amount charged exceeds the ceiling price and that the entity charged is in fact a covered entity.

Response: HHS appreciates commenters' proposed definitions of "knowingly and intentionally," and also acknowledges commenters' concerns about HHS' proposed definitions. HHS agrees that in cases where a manufacturer established that the overcharge in question was as a result of an isolated act of simple negligence or inadvertent math error, then the penalty would not typically apply. However, the facts and circumstances of each case would need to be taken into account. For example, if a manufacturer inadvertently developed an unreliable process that resulted in negligent errors, but later there is knowledge of such systematic failures that results in errors in the 340B ceiling price calculation that causes overcharges, this could be sufficient to meet a knowingly and intentionally standard. After consideration of the comments received, HHS has decided not to define these terms and to allow OIG the necessary flexibility to evaluate each instance of overcharge on a case-by-case basis.

Comment: Several commenters believed that the statute's requirement that conduct must be both "knowing" and "intentional" to impose CMPs sets up a specific and demanding standard and some covered entities were concerned that the proposed definitions set the bar so high as to have little practical value in ensuring that they receive appropriate prices under the

340B Program. They stated that the intent standard is contrary to Congress' intent to give HHS a meaningful enforcement tool, and it will not deter manufacturers from overcharging under the 340B statute. Further, they noted that the Supreme Court wrote that through CMP provisions "Congress thus opted to strengthen and formalize HHS' enforcement authority" (*Astra USA* v. *Santa Clara County,* 563 U.S. 110, 121–22 (2011)). Other commenters were concerned that the proposed definitions would not amount to the heightened threshold for intent outlined in the statute, meaning that the proposed definitions would capture lesser forms of misconduct than Congress had intended.

Response: While HHS agrees that the use of the terms knowingly and intentionally as set forth in the statute set a high standard for imposing penalties, HHS believes it will serve as an enforcement tool to ensure manufacturers are charging covered entities at or below the 340B ceiling price. HHS appreciates commenters' proposed definitions of "knowingly and intentionally," and also acknowledges commenters' concerns about HHS' proposed definitions. HHS has decided not to define these terms and to allow OIG the necessary flexibility to evaluate each instance of overcharge on a case-by-case basis.

Comment: HHS provided several possible definitions for knowing and intentional when it reopened the comment period: (1) Actual knowledge by the manufacturer, its employees, or its agents of the instance of overcharge; (2) willful or purposeful acts by, or on behalf of, the manufacturer that lead to the instance of overcharge; (3) acting consciously and with awareness of the acts leading to the instance of overcharge; and/or (4) acting with a conscious desire or purpose to cause an overcharge or acting in a way practically certain to result in an overcharge. HHS received a number of comments on the proposed definitions.

Response: HHS has decided not to define these terms and to allow OIG the necessary flexibility to evaluate each instance of overcharge on a case-by-case basis.

Comment: With respect to the language in the notice of reopening of comment period (81 FR 22960, April 6, 2016) that "manufacturers do not need to intend specifically to violate the 340B statute; but rather to have knowingly and intentionally overcharged the 340B covered entity," several commenters expressed concern that this is inconsistent with the statutory text. These commenters argued that in order to be subject to CMPs, the manufacturer must specifically intend to violate the 340B statute, not solely intend to charge a price that is higher than the 340B ceiling price.

Response: HHS agrees that CMPs will be applied to a manufacturer that knowingly and intentionally overcharges a covered entity. The specific intent to violate the 340B statute is not necessarily required to be shown to warrant an application of the penalty provision.

Comment: Commenters expressed concern that any further definition of the terms "knowing" and "intentionally" will constrain HHS' ability to judge whether a CMP is appropriate in a given instance. If HHS determines that further definition is necessary, they suggested using an exclusionary approach, stating specific actions that do not rise to the level of requisite intent, rather than an approach that names only specific actions that will be considered "knowing and intentional" in this context. Commenters generally supported the listed examples of circumstances where the requisite intent is not demonstrated and requested that the examples be explicitly characterized as non-exhaustive. Several commenters suggested adding a catch-all provision to the list of examples, such as "other situations in which it is reasonable not to infer that a manufacturer acted 'knowingly and intentionally,'" or "any other situation not presenting circumstances of a deliberate effort to disobey the law with regard to the 340B program."

Response: HHS agrees with the commenter's approach. Therefore, instead of defining these terms in an inclusive manner, HHS has chosen to provide OIG the flexibility to determine what constitutes "knowingly" and "intentionally" overcharging a covered entity in a particular instance. In addition, HHS provides examples above regarding circumstances that would not meet the threshold of knowingly and intentionally overcharging a covered entity.

Comment: With respect to the proposed example "the manufacturer made an inadvertent, unintentional, or unrecognized error in calculating the ceiling price," one commenter suggested including an error "identifying the eligibility of an entity to receive the 340B discount."

Response: HHS did not include the suggestion to include an error in "identifying the eligibility of an entity to receive the 340B discount" in the final rule to retain flexibility that the penalty be applied only where appropriate. However, it should be noted that 340B covered entities are listed on the 340B public database, and those listed are entitled to the 340B ceiling price.

Comment: Regarding the proposed example "a manufacturer acted on a reasonable interpretation of agency guidance," a commenter was concerned that the example was overly broad, since manufacturers may decide what is reasonable, and this, therefore, may create a loophole for manufacturers to avoid CMPs. They recommended, at a minimum, clarifying that this is an objective reasonableness standard, as determined by HHS and/or OIG. Several other commenters suggested adding exceptions for reasonable interpretations of laws, regulations, and the pharmaceutical pricing agreement. Further, one commenter stated that in circumstances where the statute and agency guidance conflict, it is reasonable for the manufacturer to adopt practices consistent with the statute.

Response: HHS agrees that the proposed example that, "a manufacturer acted on a reasonable interpretation of agency guidance," was overly broad. OIG would need to consider each circumstance of a 340B drug overcharge on a case by case basis to determine if that circumstance constitutes a "knowing and intentional action.

Comment: With respect to the proposed example, "when a manufacturer has established alternative allocation procedures where there is an inadequate supply of product to meet market demand, as long as covered entities are able to purchase on the same terms as all other similarly-situated providers," commenters were concerned that this is overly broad. They recommended that HHS only provide a safe harbor for manufacturers with valid limited distribution plans, and revise § 10.11 of the final rule to address other situations where a manufacturer fails to make 340B drugs available to covered entities to the same extent as to non-340B providers. They argued that the statute states CMPs are issued when manufacturers "knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum available price under subsection (a)(1)." Section 340B(a)(1) of the PHSA requires that "the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such a drug is made available to any other purchaser at any price." Therefore, if a manufacturer does not comply with the nondiscrimination provision in subsection (a)(1), this constitutes an overcharge for purposes

of the CMP provision. Other commenters recommended that HHS delete this example, because it would allow any manufacturer to develop alternative allocation procedures to disregard the ceiling price whenever demand exceeds supply.

Response: HHS agrees that the proposed example, "when a manufacturer has established alternative allocation procedures where there is an inadequate supply of product to meet market demand, as long as covered entities are able to purchase on the same terms as all other similarly-situated providers," was overly broad. OIG would need to consider each circumstance of a 340B drug overcharge on a case by case basis to determine if that circumstance constitutes a "knowing and intentional" action.

Comment: Commenters suggested that the proposed example, "when a manufacturer has established alternative allocation procedures where there is an inadequate supply of product to meet market demand, as long as covered entities are able to purchase on the same terms as all other similarly-situated providers," a manufacturer would not have the requisite intent if a covered entity chooses to purchase the manufacturer's product through a channel other than the subset of distributors through which the 340B ceiling price is available. Another commenter suggested that the example read instead, ". . . as long as the manufacturer offers covered entities the opportunity to purchase on terms consistent with those offered to other similarly-situated entities in the same class of trade."

Response: In general, HHS agrees that the penalty provisions typically would not be appropriate in a case where a covered entity chooses to purchase a covered outpatient drug knowing that the price charged exceeds the 340B ceiling price. However, in the case where there was sufficient evidence to conclude that this result was due to actions by the manufacturer that were knowing and intentional, a penalty may be appropriate. Although it may be reasonable to believe that such a circumstance is extremely unlikely to arise, HHS does not believe it is appropriate or necessary to exclude a possibility that may occur.

Comment: A number of commenters suggested additional examples of situations that they believe do not meet the "knowing and intentional" standard. Some of the examples suggested by commenters include, but are not limited to, the following:

- Instances of intentional failure to issue refunds to covered entities, because HHS has not yet established procedures for issuing refunds;
- A case where a manufacturer was not aware it was selling to a covered entity;
- A case where a distributor failed to give a covered entity a 340B price through no fault of the manufacturer;
- Situations where there is a reasonable disagreement and no established law or agency guidance or circumstances where the manufacturer acted based on reasonable assumptions in the absence of (or in the face of conflicting) guidance, provided such assumptions are consistent with the requirements and intent of section 340B of the PHSA and any implementing regulations, and a written or electronic record outlining these assumptions is maintained; and
- When a manufacturer has established a uniformly applied limited distribution system or risk evaluation and mitigation strategy ("REMS").

Response: HHS appreciates the efforts commenters made in enumerating conduct they believed should be exempt from examples of knowingly and intentionally selling a drug above its 340B ceiling price. OIG will review these circumstances on a case-by-case basis along with the facts for each instance. Rather than try to anticipate every circumstance that might occur, HHS believes it more appropriate to retain flexibility. To the extent that manufacturers identify situations where uncertainty results in unnecessary costs, HHS will respond as such circumstances arise and may provide additional guidance in the future.

Additionally, since manufacturers are named in statute as being responsible for setting appropriate 340B ceiling prices, they must be responsible for the conduct of business partners with whom they have contracted. Nevertheless, inadvertent clerical errors, as long as they are corrected as soon as identified, would not be considered to be a "knowing and intentional" overcharge.

Comment: Commenters recommended including as an exemption from being considered an overcharge and meeting the knowing and intentional threshold when a manufacturer acted on credible evidence that a covered entity is engaged in diversion of 340B drugs. They stated that if a manufacturer has evidence a covered entity is improperly diverting a drug, it should be able to charge the covered entity a price above the 340B ceiling price. It is argued that this option would create a check on 340B drug diversion, since manufacturers have better and timelier access to sales data than does HHS.

Response: HHS does not believe that unilaterally overcharging a covered entity based upon suspicion of diversion is warranted under the statutory language. Manufacturers cannot condition the sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity. Manufacturers that suspect diversion are encouraged to work in good faith with the covered entity, conduct an audit per the current audit guidelines, or contact HHS directly.

E. Manufacturer Civil Monetary Penalties—Instance of Overcharging—§ 10.11(b)

At § 10.11(b) of the proposed rule, HHS defined an instance of overcharging for the purpose of imposing a CMP as any order for a certain covered outpatient drug, by NDC, which results in a covered entity paying more than the 340B ceiling price. An instance of overcharging is considered at the NDC level and may not be offset by other discounts provided on any other NDC or discounts provided on the same NDC on other transactions, orders, or purchases. HHS also proposed that manufacturers have an obligation to ensure that the 340B ceiling price is provided through distribution arrangements made by the manufacturer. An instance of overcharging may occur at the time of initial purchase or at subsequent ceiling price recalculations. The recalculations are due to pricing data submitted to CMS that results in a covered entity paying more than the ceiling price due to failure or refusal to refund or credit a covered entity. Finally, HHS proposed that a manufacturer's failure to provide the 340B ceiling price is not considered an instance of overcharging when a covered entity did not initially identify the purchase to the manufacturer as 340B-eligible at the time of purchase. Covered entity orders of non-340B priced drugs will not subsequently be considered an instance of overcharging unless the manufacturer refuses to sell or makes drugs available at the 340B ceiling price.

HHS received comments supporting and opposing the proposed § 10.11(b). Some commenters opposed certain components of the proposed definition, including the proposal to (1) define the term based on orders; (2) require manufacturers to ensure 340B pricing regardless of distribution arrangements; (3) prohibit offsets; (4) consider as an instance of overcharging when a manufacturer fails or refuses to provide funds at the time of initial purchases or during subsequent ceiling price

recalculation; and (5) clarify that a manufacturer's failure to provide the 340B ceiling price if a covered entity did not initially identify such purchases as 340B eligible or that covered entity orders of non-340B drugs will not be subsequently considered an instance of overcharging unless the manufacturers refuses or makes drugs available at the 340B ceiling price. These commenters claimed that HHS does not have the statutory authority to define the term as such or that such definition does not meet the "knowingly and intentionally" standard. At the same time, other commenters supported these components of the proposed definitions as they ensure that covered entities have access to covered outpatient drugs under the 340B Program. Specific comments are addressed below.

Comment: Commenters wrote in opposition to the definition of an instance of overcharging as any order for a covered outpatient drug, by NDC, which results in a covered entity paying more than the ceiling price. Some commenters asked HHS to define an instance of overcharging more restrictively and on a per-unit basis rather than a per-order basis. Doing so would allow OIG to impose penalty amounts commensurate with the severity of the violation.

Response: HHS has determined to finalize the definition of instance as proposed. An instance of overcharging is any order for a certain covered outpatient drug, by NDC, which results in a covered entity paying more than the 340B ceiling price, as defined in § 10.3 of this final rule, for a covered outpatient drug. Each order for an NDC will constitute a single instance, regardless of the number of units of each NDC in that order. This includes any order placed with a manufacturer or through a wholesaler, authorized distributor, or agent. A single order may contain one or more NDCs; thus a violation of this provision may constitute more than one instance depending on the number of NDCs in the order. HHS believes that changing the definition to a per-unit basis is restrictive and overly burdensome as current purchasing occurs at the 11-digit NDC versus a per-unit basis. Finalizing the rule as proposed strikes the right balance in applying the appropriate penalties.

Comment: Commenters asked HHS to clarify that the "order" is the single purchase order, rather than separate line items within a single purchase order. Commenters claimed that defining an instance of overcharging based on "orders" may be interpreted to include situations in which estimated 340B ceiling prices for new drugs were too high and the manufacturer did not issue refunds to covered entities in the time that the rule would require.

Response: Each order for an NDC will constitute a single instance, regardless of the number of units of each NDC in that order. If a covered entity orders a single bottle of a covered outpatient drug four times in a month, it would be considered four instances of overcharging. A single order may contain one or more NDCs; thus a violation of this provision may constitute more than one instance depending on the number of NDCs in the order. With regards to new drug price estimation and refunds to a covered entity, HHS addresses those requirements in § 10.10 of this final rule. If refunds in this circumstance are not offered to covered entities within 120 days of the determination by the manufacturer that an overcharge occurred, it may be considered as meeting the definition of knowingly and intentionally overcharging the covered entity and the definition of instance would apply. This is in alignment with the statute that requires manufacturers to provide covered entities the 340B ceiling price.

Comment: Some commenters suggested that an instance of overcharging be defined as each product ceiling price reported by a manufacturer to HRSA that contains a price that the manufacturer knows and intends to be in excess of the price as calculated. Other comments recommended further defining the term to add details related to the instance. For example, some recommended inclusion of the following language: all mispriced purchases within a quarter on a particular drug to a particular customer, intentionally incorrect ceiling prices reported to HRSA that actually result in overcharges to one or more registered covered entities, and incorrect treatment by a manufacturer of a registered covered entity as an organization ineligible for the 340B ceiling price. Other commenters asked HHS to include in the definition of instance of overcharging, a manufacturer's failure to offer a covered outpatient drug to a covered entity to the same extent that the drug is offered to other purchasers.

Response: HHS declines to include additional language as raised by the commenters. While the examples provided may result in a covered entity being charged above the 340B ceiling price, they relate more to defining the knowing and intentional standard, which will be determined by OIG on a case-by-case basis. HHS believes it is important to provide the necessary flexibility for OIG to determine the facts surrounding a specific case. HHS also notes that it is the actual sale of the covered outpatient drug above the 340B ceiling price by the manufacturers to the covered entity that is the subject of the overcharge per the statute.

Comment: Commenters opposed the proposed extension of the manufacturer's responsibility to ensure that covered entities have access to 340B pricing for covered outpatient drugs sold by wholesalers and distributors. They contend that manufacturers should not be responsible for the conduct of their agents, since an agent's actions are not knowing and intentional on the part of the manufacturer and since these actions are not within the manufacturers' control. A number of commenters pointed out that manufacturers may provide wholesalers and distributers the 340B pricing but covered entities may not purchase drugs at 340B pricing because wholesalers and distributers may add fees that may raise the price of drugs above the 340B ceiling price. Clarification was requested related to when actions by a wholesaler would be attributed to manufacturers when assessing CMPs, and whether a distribution fee charged by a wholesaler could cause an overcharge.

Response: Manufacturers are ultimately responsible for ensuring a covered entity receives a drug at or below the 340B ceiling price as stated in the statute and per this final rule. Manufacturers also have control over the distribution of covered outpatient drugs, including those distributed by wholesalers, distributers, and agents wherein the terms and conditions of the sales set through these distribution arrangements are set by the manufacturer via a contract agreed to and between the manufacturer and the distributors. This final rule applies solely to manufacturers, even though other third parties have a role in ensuring the covered entity receives a drug at or below the 340B ceiling price. Manufacturers must consider the wholesaler role in this process and work out issues in good faith and in normal business arrangements regarding the assurance that the covered entity is receiving the appropriate prices. Failure to ensure the covered entities are receiving the 340B ceiling prices through a third party may be grounds for the assessment of CMPs under this final rule. HHS does clarify, however, that fees charged directly by a wholesaler or other distributor are not considered part of the 340B ceiling price

and would not be considered as part of assessing an instance of an overcharge.

Comment: Commenters asked for a clarification that specialty pharmacies are not considered "specialty distribution or wholesalers" and thus are not required to provide 340B pricing. Other commenters claimed that the requirements set forth under this section are not consistent with the non-discrimination policy, which allows manufacturers to establish alternate allocation procedures. Commenters requested clarification that CMPs would not apply in a situation where a covered entity purchased product in the marketplace when the manufacturer was employing a distribution system compliant with HRSA's non-discrimination guidance (340B Program Notice Release No. 2011–1.1 (May 23, 2012)). Some commenters asked HHS to clarify that a refusal by the covered entity to purchase drugs through a limited distribution arrangement should not be interpreted as the manufacturer's refusal to sell or make drugs available at the 340B price for purposes of CMPs.

Response: All requirements as set forth in this final rule for offering the 340B ceiling price to covered entities apply regardless of the distribution system. If a manufacturer is using a specialty pharmacy to distribute covered outpatient drugs, it must ensure the covered entity is not overcharged if drugs are accessed through that pharmacy. As to comments suggesting that the rule is inconsistent with the current non-discrimination policy, HHS does not believe that is the case. Consistent with section 340B(a)(1) of the PHSA, manufacturers are expected to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs when such drugs are sold through limited distributors or specialty pharmacies. Manufacturers may continue to develop limited distribution procedures provided that those arrangements follow HHS established policy. HHS will take into consideration whether a manufacturer has submitted an alternate allocation plan to HHS when a manufacturer is being investigated for a possible overcharge, whether this plan is compliant with the 340B non-discrimination policy, and whether the manufacturer is following its plan.

Comment: Commenters argued that HHS is attempting to interpret and apply the "shall offer" provision through this rule. Some commenters claimed that CMPs do not apply to a shall offer provision until a manufacturer signs a PPA that includes that provision.

Response: Section 340B(a)(1) of the PHSA provides that a manufacturer shall offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price. This particular provision of section 340B(a)(1) is separate and distinct from the provision pertaining to the calculation of 340B ceiling prices. Because this final rule is applicable to the provision of section 340B(a)(1) pertaining to the calculation of the 340B ceiling price, the language in the statute regarding "shall offer" will not be addressed in this final rule.

Comment: Commenters asked HHS not to finalize the proposed rule provision that an instance of overcharging would be considered at the NDC level and may not be offset by other discounts provided on any other NDC or discounts provided on the same NDC on other transactions, orders, or purchases. They argue that offsetting is an industry practice and should not meet the knowing and intentional standard. Still other commenters pointed out that HHS has not developed a process for refunds and without such a standardized refund process, the use of offsets should be allowed. For these reasons, the commenters asked that HHS finalize the regulation to allow for offsets. Commenters also claimed that if finalized, HHS would make the offering of sub-ceiling prices mandatory rather than voluntary. Calculating refunds based only on restatements that lower the ceiling price, without accounting for restatements that raise the ceiling price, would transform the voluntary nature of offering sub-ceiling prices into a requirement. Other commenters favored allowing offsetting but providing covered entities a mechanism to contest the offsets.

Response: As proposed, and finalized in this rule, an instance of overcharging is considered at the 11-digit NDC level and may not be offset by other discounts provided on any other NDC or discounts provided on the same NDC on other transactions, orders, or purchases. The 340B statute is specific to ensuring each covered outpatient drug is offered at or below the 340B ceiling price. However, HHS does not intend to prevent manufacturers from using the industry's practice of netting overcharges and undercharges, or from restating ceiling prices based on pricing data submitted to CMS, to the extent that there is agreement between the manufacturer and covered entity.

In regards to comments based on the refund process, HHS has finalized that an instance of an overcharge may occur at the time of initial purchase or when subsequent ceiling price recalculations occur and the manufacturer refuses to refund or issue a credit to a covered entity. HHS has clarified in the final rule that this would include refusal to refund covered entities according to § 10.10(c) of the final rule with regards to new drug price estimation and would include refusal to refund a covered entity after restatements to CMS. If a covered entity is not refunded when there is an overcharge, the covered entity, in essence paid above the 340B ceiling price. While HHS has finalized in this rule the requirement to refund if there is an overcharge, the specific refund procedures will be addressed under separate guidance. Until there is final guidance in place regarding refund procedures, manufacturers and covered entities should work in good faith and refund in a reasonable manner that is documented by the parties involved.

Regarding the statement that not allowing offsets would force manufacturers to sell below 340B ceiling prices, the statute is specific in addressing when a manufacturer overcharges a covered entity and it does not address refunds by covered entities if the manufacturer provides a price below the 340B ceiling price. Therefore, it will not be addressed in the final rule.

Comment: Some commenters asked HHS not to finalize the rule as proposed related to penalizing a manufacturer for failure or refusal to refund or credit a covered entity. They pointed out that HHS has not developed a mechanism to provide such subsequent price recalculations and has not established or operationalized a mechanism to retroactively revise 340B pricing based on revised Medicaid metrics. Other commenters stated that finalizing the rule is premature since HHS has not developed a process for credits and refunds.

Response: HHS has finalized that an instance of an overcharge may occur at the time of initial purchase or when subsequent ceiling price recalculations occur and the manufacturer refuses to refund or issue a credit to a covered entity. This would include refusal to refund covered entities according to § 10.10(c) of the final rule with regards to new drug price estimation and would include refusal to refund a covered entity after restatements to CMS. If a covered entity is not refunded when there is an overcharge, the covered entity, in essence paid above the 340B ceiling price. The final rule requires a refund if there is an overcharge and specific refund procedures will be addressed under separate guidance. HHS does not believe that the requirements of this rule are dependent

on the separate issue of how to operationalize a refund process. Until there is final guidance in place regarding the refund procedures, manufacturers and covered entities should work in good faith and refund in a reasonable manner that is documented by the parties involved.

Comment: Some commenters supported the rule as proposed but asked HHS to allow covered entities time to request a reclassification of prior purchases as 340B eligible. They asked that HHS finalize the rule to require manufacturers to honor a covered entity's request to reclassify a purchase from non-340B to 340B and to issue a corresponding refund if a covered entity requests such a reclassification within 365 days of purchase.

Response: HHS continues to maintain the decision that a manufacturer's failure to provide the 340B ceiling is not considered an overcharge if the covered entity did not initially identify the purchase to the manufacturer as 340B eligible at the time of purchase. HHS does not authorize covered entities to reclassify a purchase as 340B eligible after the fact. Therefore, HHS has removed this example from the final regulation and instead includes it as an example of what would not be considered an instance of overcharging in the preamble to this rule. Covered entities participating in the 340B Program are responsible for requesting 340B pricing at the time of the original purchase. If a covered entity wishes to reclassify a previous purchase as 340B, covered entities should first notify manufacturers and ensure all processes are fully transparent with a clear audit trail that reflects the actual timing and facts underlying a transaction. The covered entity retains responsibility for ensuring full compliance and integrity of its use of the 340B Program.

Comment: Commenters supported the proposal that it could be considered an instance of overcharging when a manufacturer's documented refusal to sell or make drugs available at the 340B price results in the covered entity purchasing at the non-340B price. However, some commenters asked HHS to clarify the term "documented refusal" mentioned in the preamble. They suggested that the following examples not constitute a documented refusal:

- Communications between a manufacturer (or a wholesaler) and a covered entity relating to verifying eligibility for 340B prices prior to a sale, or
- A manufacturer's failure to provide the 340B ceiling price to a covered entity that has violated the prohibition against diversion or duplicate discounting.

Response: Covered entity orders of non-340B priced drugs will not subsequently be considered an instance of overcharging unless the manufacturer's documented refusal to sell or make drugs available at the 340B price resulted in the covered entity purchasing at the non-340B price. When a manufacturer's documented refusal to sell or make drugs available at the 340B ceiling price results in the covered entity purchasing at the non-340B price, a manufacturer's sale at the non-340B price could be considered an instance of overcharging. An example of "documented refusal" would include any type of manufacturers' written communication related to reasons a manufacturer is not providing 340B ceiling prices to either a single covered entity or group of covered entities. HHS does not agree that a manufacturer could consider not selling a 340B drug at the 340B ceiling price to a covered entity based on possible non-compliance with program requirements. Regarding verifying the eligibility of a covered entity, the 340B public database lists all covered entities eligible to purchase 340B drugs in any given quarter. The 340B public database should be used by all stakeholders to determine and verify covered entity eligibility. In addition to the example provided above as "documented refusal," OIG would also review information related to such a circumstance on a case-by-case basis to determine if a manufacturer has overcharged a covered entity and whether the threshold is met to apply CMPs. HHS notes that we are removing this specific example from the final regulation and include it as an example of what would not be considered an instance of overcharging in the preamble to this rule.

Comment: Some commenters requested that HHS not require that an act be "intentional" when imposing CMPs and that the penalty be higher than $5,000.

Response: Section 340B(d)(1)(B)(vi) of the PHSA provides for the imposition of civil monetary penalties on manufacturers that knowingly and intentionally charge a covered entity a price for purchase of a drug that exceeds the 340B ceiling price. Additionally, section 340B(d)(1)(B)(vi)(II) of the PHSA states that CMPs "shall not exceed $5,000 for each instance of overcharging." Therefore, HHS has no authority to modify the standard of intent, and any CMPs assessed will be done in accordance with the amount specified in the 340B statute, as adjusted annually for inflation pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114–74).

Comment: A few commenters stated that when imposing CMPs, certain documentation should be required to establish that there was a "knowing and intentional" overcharge. They suggested that evidence should include documentation that the manufacturer received a request for the ceiling price by the covered entity, and either refused in writing to provide the ceiling price, or failed to execute a ceiling price transaction within a specified period of time.

Response: The OIG will determine, upon review of the case, the appropriate documentation and other information that may be required to determine if a CMP should be applied.

Comment: Commenters requested that the rule specify that HHS should not attempt to recover any penalties until at least 60 days after the end of any appeal or judicial review. It was also requested that, should a party seek data in relation to a CMP proceeding from a third party, such as a wholesaler or software vendor, the party seeking data may compensate the third party for their assistance, and that the third party may require that compensation. Commenters also recommended that the rule provide for confidentiality requirements in CMP proceedings, in order to ensure the confidentiality of 340B pricing.

Response: HHS understands the importance of maintaining the confidentiality of 340B ceiling price data and will handle such data accordingly. More broadly, the pertinent procedures outlined in 42 CFR parts 1003 and 1005 will be followed in matters involving the imposition of CMPs and any appeals therefrom.

Comment: Several commenters suggested that the funds collected from CMPs should be directed to OIG to support the enforcement of CMPs, to the HRSA Office of Pharmacy Affairs, and for HHS to create a 340B ceiling price database.

Response: While HHS appreciates these comments, they are beyond the statutory authority of the 340B Program and this final rule.

Comment: Several commenters supported HHS delegating the authority to levy CMPs to OIG, and recommended that the delegation of authority to OIG be explicitly stated in the regulation, rather than mentioned in the preamble. Additionally, several commenters were also concerned that at proposed § 10.11(a), in the sentence "This penalty will be imposed pursuant to the procedures at 42 CFR part 1003 and

1005" the term "procedures" may be read to not encompass definitions and standards for CMPs. Therefore, they suggested modifying the sentence to state, "Pursuant to a delegation of authority, the HHS Office of Inspector General (OIG) will have the authority to bring CMP actions utilizing the definitions, standards, and procedures applied to civil monetary penalties under 42 CFR parts 1003 and 1005." It was also suggested to add a definition of "knowingly and intentionally" to section 1003.101 of the OIG regulations.

Response: HHS does not believe it necessary to add the delegation of authority to OIG in the regulatory text. HHS believes that pursuant to a separate delegation of authority, OIG has the authority to handle CMP actions utilizing the definitions, standards, and procedures applied to civil monetary penalties under 42 CFR parts 1003 and 1005, as applicable. Consistent with the proposed rule, we have finalized the regulatory text indicating that CMPs will be imposed pursuant to the procedures contained at 42 CFR part 1003. No further rulemaking is required to apply the procedures at 42 CFR part 1003 to the imposition of CMPs. HHS will monitor activities relating to the evaluation and pursuit of CMPs and, if necessary, will consider issuing additional guidance about procedures applicable to such actions.

Comment: A few commenters were concerned about the decision to delegate CMP actions to OIG. They stated that HHS has not identified a specific delegation, and that 42 CFR parts 1003 and 1005 only provide for the imposition of CMPs under specific statutory authorities, which do not include the 340B statute's CMP provisions. They argued that unless OIG amends their regulations to apply them to a 340B proceeding, HHS will need to develop, take comments on, and ultimately finalize a new proposal setting out procedures for seeking and imposing CMPs against manufacturers. A few commenters noted that some portions of 42 CFR parts 1003 and 1005 are inapplicable in a 340B context.

Response: As noted above, a delegation of authority to OIG for a CMP from the Secretary of HHS is sufficient. HHS does not perceive there to be any conflict between the procedural aspects of 42 CFR part 1003 and the imposition of CMPs. HHS notes that 42 CFR part 1005 applies to appeals of exclusions and civil monetary penalties and assessments and would not be directly relevant to the initial imposition of a CMP. Accordingly, HHS finalized the regulatory text indicating that CMPs will be imposed pursuant to the applicable procedures contained at 42 CFR part 1003. No further rulemaking is required to apply the procedures at 42 CFR part 1003 to the imposition of CMPs. HHS will monitor activities relating to the evaluation and pursuit of CMPs and, if necessary, will consider issuing additional guidance about procedures applicable to such actions.

III. Regulatory Impact Analysis

HHS has examined the effects of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 8, 2011), the Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999).

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866, emphasizing the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year), and a "significant" regulatory action is subject to review by the Office of Management and Budget (OMB).

This final rule will not have economic impacts of $100 million or more in any 1 year, and, therefore, has not been designated an "economically significant" rule under section 3(f)(1) of Executive Order 12866. The 340B Program as a whole creates significant savings for entities purchasing drugs through the program, with total savings estimated to be $6 billion in CY 2015.[1] However, this final rule would not significantly impact the Program. This final rule codifies current policies, some of which have been modified, regarding calculation of the 340B ceiling price and manufacturer civil monetary penalties. HHS does not anticipate that the imposition of civil monetary penalties would result in significant economic impact.

The 340B Program uses information that already must be reported under Medicaid to calculate the statutorily defined 340B ceiling price as required by this final rule. Because the components of the 340B ceiling price are already calculated by the manufacturers under the MDRP and reported to CMS, HHS does not believe this portion of the final rule would have an impact on manufacturers. The impact on manufacturers would also be limited with respect to calculation of the 340B ceiling price as defined in this final rule due to the fact that manufacturers regularly calculate the 340B ceiling price and have been doing so since the program's inception.

Separate from calculation of the 340B ceiling price, manufacturers are required to ensure they do not overcharge covered entities, and a civil monetary penalty could result from overcharging if it met the standards in this final rule. HHS envisions using these penalties in rare situations. Since the Program's inception, issues related to overcharges have been resolved between a manufacturer and a covered entity and any issues have generally been due to technical errors in the calculation. For the penalties to be used as defined in the statute and in this rule, the manufacturer overcharge would have to be the result of a knowing and intentional act. Based on anecdotal

[1] In CY 2015, 340B covered entities spent approximately $12 billion on the total purchases of 340B drugs under the 340B Program. This data was obtained from the 340B Prime Vendor Program. This amount represents 2.6 percent of the overall prescription drug market. Assuming covered entities pay 25 to 50 percent less than non-340B prices, HHS calculated the estimated total savings in CY 2015 to be approximately $6 billion.

information received from covered entities, HHS anticipates that this would occur very rarely if at all.

This rulemaking also proposes that a manufacturer charge a $0.01 per unit of measure for a drug with a 340B ceiling price below $0.01. A small number of manufacturers have informed HRSA over the last several years that they charge more than $0.01 for a drug with a ceiling price below $0.01. However, this is a long-standing HRSA policy, and HRSA believes the majority of manufacturers currently follow the practice of charging a $0.01. Therefore, this portion of the regulation would not result in a significant impact. This final regulation would allow HRSA to enforce the policy in a manner that would require the manufacturer to charge a $0.01, and it is likely that manufacturers would charge $0.01 in order to avoid the imposition of a civil monetary penalty for overcharging a covered entity. HRSA believes manufacturers that currently do not comply will come into compliance, which will result in the covered entity paying less for these drugs. There will be a cost transfer from the covered entity to the manufacturer.

HHS recognizes that certain administrative costs would be incurred for compliance with this final rule. HHS does not collect data related to such administrative costs, and compliance costs are expected to vary significantly. HHS believes it is reasonable to assume that manufacturers would use one-half to one full-time compliance officer to ensure compliance with the requirements in this final rule. According to the Bureau of Labor Statistics, the mean annual wage for a pharmaceutical compliance officer (NAICS 325400, occupation code 13–1041) is $80,170 in 2015. Inclusion of benefits and overhead (resulting in a total labor cost of 1.5 times mean annual wage) yields a total annual cost of $120,255 for one compliance officer. Thus, the estimated annual cost for labor across all 600 manufacturers is between $36,067,500 and $72,153,000.

We received the following comments on the anticipated impacts on drug manufacturers:

Comment: Regarding the proposed rule's regulatory impact analysis, some commenters disagree that the proposed rule is "not likely to have an economic impact of $100 million or more in any 1 year" and objects to its failure to designate the proposed rule as economically significant. They argue that resources that would be required to comply with the obligations of this proposed rule would extend beyond a compliance officer and would include the re-writing and implementation of new policies and procedures, and the training of staff.

Response: The proposed rule and the policies finalized herein codify several current policies, some of which have been modified, regarding the calculation of the 340B ceiling price and introduce manufacturer civil monetary penalties. HHS reviewed the comments submitted in response to the NPRM, and has attempted to minimize burden for both manufacturers and covered entities in its formulation of the final rule, specifically regarding the policy of estimating new drug prices (see § 10.10(c)). With the modification made in this final rule, we believe that stakeholders' administrative burdens' with respect to this policy will be minimal. Through the comments that HHS received during both comment periods on the estimation of new drug prices, commenters expressed support for this approach and maintained that it created an even playing field across all stakeholders as the calculation of the 340B ceiling price is easily verifiable by covered entities and reduces administrative burden. HHS also understands that based on the comments received, the methodology for calculating new drugs as set forth in this final rule is already taking place in the marketplace and will thus not create any additional burden.

Manufacturers have always been required to ensure that they do not overcharge covered entities per the section 340B(d)(1). This final rule incorporates a penalty for knowingly and intentionally overcharging covered entities, as discussed in subsequent sections of this final rule (see § 10.11(a)). Under current practice, HHS encourages manufacturers and covered entities to work in good faith to resolve any pricing discrepancies. HHS anticipates this practice to continue and anticipates that the imposition of penalties to occur only on a rare basis. The remaining policies in the proposed rule and finalized in this rule reflect current 340B Program policy and should not result in significant economic impacts.

Comment: Commenters note that manufacturers would have to build into their systems the capacity to identify all sales transactions with covered entities at the originally charged price, as well as any recalculated price, for up to three full years after the original transaction. They explain that these prices along with issuing the actual refunds to the covered entities could easily exceed $100 million per year.

Response: We note that the 340B Program uses data that manufacturers already report to CMS under the MDRP (AMP, URA) to calculate the statutorily defined 340B ceiling price. As these components of the 340B ceiling price are already calculated by manufacturers under the MDRP, HHS does not believe that this will cause additional burden on manufacturers.

The Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require HHS to analyze options for regulatory relief of small businesses. If a rule has a significant economic effect on a substantial number of small entities, the Secretary must specifically consider the economic effect of the rule on small entities and analyze regulatory options that could lessen the impact of the rule. HHS will use an RFA threshold of at least a three percent impact on at least five percent of small entities.

The final rule would affect drug manufacturers (North American Industry Classification System code 325412: Pharmaceutical Preparation Manufacturing). The small business size standard for drug manufacturers is 750 employees. Approximately 600 drug manufacturers participate in the 340B Program. While it is possible to estimate the impact of this final rule on the industry as a whole, the data necessary to project changes for specific manufacturers or groups of manufacturers is not available, as HRSA does not collect the information necessary to assess the size of an individual manufacturer that participates in the 340B Program.

This final rule clarifies statutory requirements for manufacturers, including small manufacturers, and codifies current ceiling price calculation policies in regulation. HHS is unaware of small manufacturers who do not follow the ceiling price policies finalized by this regulatory action. The specific elements required as part of the calculation of the ceiling price are elements that manufacturers are already required to utilize as part of their participation in the 340B Program. HHS expects that these elements would continue to be available. Therefore, calculation of the ceiling price would not result in an economic impact or create additional administrative burden on these businesses.

HHS has determined, and the Secretary certifies that this final rule will not have a significant impact on the operations of a substantial number of small manufacturers; therefore, we are not preparing an analysis of impact for the purposes of the RFA. HHS, estimates

that the economic impact on small manufacturers will be minimal and less than three percent.

Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year." In 2015, that threshold level is approximately $144 million. HHS does not expect this final rule to exceed the threshold.

Executive Order 13132—Federalism

HHS has reviewed this final rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have "federalism implications." This final rule would not "have substantial direct effects on the States, or on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." The provisions in this final rule would not adversely affect the following family elements: Family safety, family stability, marital commitment; parental rights in the education, nurture, and supervision of their children; family functioning, disposable income or poverty; or the behavior and personal responsibility of youth, as determined under Section 654(c) of the Treasury and General Government Appropriations Act of 1999.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that OMB approve all collections of information by a Federal agency from the public before they can be implemented. This final rule is projected to have no impact on current reporting and recordkeeping burden for manufacturers under the 340B Program. Changes finalized in this rulemaking would result in no new reporting burdens.

List of Subjects in 42 CFR Part 10

Biologics, Business and industry, Diseases, Drugs, Health, Health care, Health facilities, Hospitals, 340B Drug Pricing Program.

Dated: October 3, 2016.

James Macrae,

Acting Administrator, Health Resources and Services Administration.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

■ For the reasons set forth in the preamble, the Department of Health and Human Services revises 42 CFR part 10 to read as follows:

PART 10—340B DRUG PRICING PROGRAM

Subpart A—General Provisions

Sec.

Subpart B—340B Ceiling Price

Authority: Sec. 340B of the Public Health Service Act (42 U.S.C. 256b) (PHSA), as amended.

Subpart A—General Provisions

§ 10.1 Purpose.

This part implements section 340B of the Public Health Service Act (PHSA) "Limitation on Prices of Drugs Purchased by Covered Entities."

§ 10.2 Summary of 340B Drug Pricing Program.

Section 340B of the PHSA instructs the Secretary of Health and Human Services to enter into agreements with manufacturers of covered outpatient drugs under which the amount to be paid to manufacturers by certain statutorily-defined covered entities does not exceed the 340B ceiling price.

§ 10.3 Definitions.

For the purposes of this part, the following definitions apply:

Average Manufacturer Price (AMP) has the meaning set forth in section 1927(k)(1) of the Social Security Act, as implemented in 42 CFR 447.504.

Ceiling price means the maximum statutory price established under section 340B(a)(1) of the PHSA and this section.

CMS is the Centers for Medicare & Medicaid Services.

Covered entity means an entity that is listed within section 340B(a)(4) of the PHSA, meets the requirements under section 340B(a)(5) of the PHSA, and is registered and listed in the 340B database.

Covered outpatient drug has the meaning set forth in section 1927(k) of the Social Security Act.

Manufacturer has the meaning set forth in section 1927(k) of the Social Security Act, as implemented in 42 CFR 447.502.

National Drug Code (NDC) has the meaning set forth in 42 CFR 447.502.

Pharmaceutical Pricing Agreement (PPA) means an agreement described in section 340B(a)(1) of the PHSA.

Quarter refers to a calendar quarter unless otherwise specified.

Secretary means the Secretary of the Department of Health and Human Services and any other officer of employee of the Department of Health and Human Services to whom the authority involved has been delegated.

Subpart B—340B Ceiling Price

§ 10.10 Ceiling price for a covered outpatient drug.

A manufacturer is required to calculate the 340B ceiling price for each covered outpatient drug, by National Drug Code (NDC) on a quarterly basis.

(a) *Calculation of 340B ceiling price.* The 340B ceiling price for a covered outpatient drug is equal to the Average Manufacturer Price (AMP) from the preceding calendar quarter for the smallest unit of measure minus the Unit Rebate Amount (URA) and will be calculated using six decimal places. HRSA will publish the 340B ceiling price rounded to two decimal places.

(b) *Exception.* When the ceiling price calculation in paragraph (a) of this section results in an amount less than $0.01 the ceiling price will be $0.01.

(c) *New drug price estimation.* A manufacturer must estimate the 340B ceiling price for a new covered outpatient drug as of the date the drug is first available for sale. That estimation should be calculated as wholesale acquisition cost minus the appropriate rebate percentage until an AMP is available, which should occur no later than the 4th quarter that the drug is available for sale. Manufacturers are required to calculate the actual 340B ceiling price as described in paragraph (a) of this section and offer to refund or credit the covered entity the difference between the estimated 340B ceiling price and the actual 340B ceiling price within 120 days of the determination by the manufacturer that an overcharge occurred.

§ 10.11 Manufacturer civil monetary penalties.

(a) *General.* Any manufacturer with a pharmaceutical pricing agreement that knowingly and intentionally charges a covered entity more than the ceiling price, as defined in § 10.10, for a covered outpatient drug, may be subject

to a civil monetary penalty not to exceed $5,000 for each instance of overcharging, as defined in paragraph (b) of this section. This penalty will be imposed pursuant to the applicable procedures at 42 CFR part 1003. Any civil monetary penalty assessed will be in addition to repayment for an instance of overcharging as required by section 340B(d)(1)(B)(ii) of the PHSA.

(b) *Instance of overcharging.* An instance of overcharging is any order for a covered outpatient drug, by NDC, which results in a covered entity paying more than the ceiling price, as defined in § 10.10, for that covered outpatient drug.

(1) Each order for an NDC will constitute a single instance, regardless of the number of units of each NDC ordered. This includes any order placed directly with a manufacturer or through a wholesaler, authorized distributor, or agent.

(2) Manufacturers have an obligation to ensure that the 340B discount is provided through distribution arrangements made by the manufacturer.

(3) An instance of overcharging is considered at the NDC level and may not be offset by other discounts provided on any other NDC or discounts provided on the same NDC on other transactions, orders, or purchases.

(4) An instance of overcharging may occur at the time of initial purchase or when subsequent ceiling price recalculations due to pricing data submitted to CMS or new drug price estimations as defined in § 10.10(c) result in a covered entity paying more than the ceiling price due to failure or refusal to refund or credit a covered entity.

[FR Doc. 2016–31935 Filed 1–4–17; 8:45 am]

BILLING CODE 4165–15–P

FOR FURTHER INFORMATION CONTACT: William Freas or Pearline Muckelvene, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–594–1054.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 15, 1994, FDA announced that a meeting of the Biological Response Modifiers Advisory Committee would be held on May 25 and 26, 1994. On page 18135, in the third column, under "*Type of meeting and contact person*" and "*Open committee discussion*" portions of the agenda are amended to read as follows:

Type of meeting and contact person. Open public hearing, May 25, 1994, 10:30 a.m. to 11:15 a.m., unless public participation does not last that long; open committee discussion, 11:15 a.m. to 5:30 p.m.; open public hearing, May 26, 1994, 8 a.m. to 8:45 a.m., unless public participation does not last that long; open committee discussion, 8:45 a.m. to 3 p.m.; William Freas or Pearline Muckelvene, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–594–1054.

Open committee discussion. The committee will discuss issues related to the safety and efficacy of hematopoietic support regimens in the setting of myelotoxic chemotherapy.

Dated: May 9, 1994.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

[FR Doc. 94–11641 Filed 5–12–94; 8:45 am]

BILLING CODE 4160–01–F

Public Health Service

Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines

AGENCY: Public Health Service, HHS.

ACTION: Final notice.

INFORMATION: Section 602 of Public Law 102–585, the "Veterans Health Care Act of 1992," enacted section 340B of the Public Health Service Act, "Limitation on Prices of Drugs Purchased by Covered Entities." Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must agree to charge a price that will not exceed the amount determined under a statutory formula. The purpose of this notice is to inform interested parties of final program guidelines regarding eligible covered entities.

FOR FURTHER INFORMATION CONTACT: Marsha Alvarez, R.Ph., Director, Drug Pricing Program, Bureau of Primary Health Care, Health Resources and Services Administration, East West Towers rm 10–3A1, Bethesda, Maryland 20814, Phone: (301) 594–4353.

EFFECTIVE DATE: June 13, 1994.

SUPPLEMENTARY INFORMATION:

(A) Background

Proposed entity guidelines were announced in the **Federal Register** at 58 FR 68922 on December 29, 1993. A comment period of 30 days was established to allow interested parties to submit comments. The Office of Drug Pricing received 7 letters with comments concerning confidential drug pricing information, retroactive discounts,drug diversion, audit requirements, entity participation, group purchasing, purchasing agents, manufacturer contracts, and 4 general comments.

The following section presents a summary of all major comments, grouped by subject, and a response to each comment. All comments were considered in developing this final notice. Changes were also made to increase clarity and readability.

(B) Comments and Responses

Confidential Drug Pricing Information

Comment: Establish specific sanctions for entities which knowingly make unauthorized disclosures.

Response: No change. The quoted price or the actual price given by the manufacturer to the covered entity is not confidential. Covered entities do not have access to confidential drug pricing information (i.e., average manufacturer price and best price).

Eligibility for Retroactive Discounts

Comment: Do not impose a deadline on requesting retroactive discounts.

Response: No change. It is a reasonable administrative decision to establish a time limit for requesting refunds. Manufacturers were given sufficient time in which to implement the discount program, and entities were given an adequate opportunity to elect whether to participate in the program. An entity may preserve its right to retroactive discounts, after the deadline, by sending each manufacturer a letter requesting such refunds and providing adequate documentation of drug purchases.

Comment: Exclude from eligibility for retroactive discounts any disproportionate share hospital (DSH) which purchased its outpatient drugs through a group purchasing organization (GPO).

Response: No change. The Office of Drug Pricing considers the outpatient drug purchases of DSHs bought through a GPO or any group purchasing arrangement ineligible for retroactive discounts.

Comment: Allow covered entities to request an extension of the deadline for retroactive discounts for good cause (e.g., offsite DSH clinics whose eligibility has not yet been determined).

Response: We have amended part 3 of the notice to permit a DSH outpatient clinic which was not participating in a GPO or any group purchasing arrangement during the period for which it is requesting retroactive discounts to preserve its right by sending manufacturers a letter requesting such refunds and providing adequate documentation of purchases.

Comment: Extend the deadline for those manufacturers which have refused to give PHS pricing to the date on which the manufacturer begins discounting its covered outpatient drugs in accordance with the law.

Response: No change. At every opportunity, the Office of Drug Pricing has communicated its willingness to assist entities with problems of accessing PHS pricing. It has responded to all entity complaints dealing with manufacturer noncompliance. We believe that one year is a reasonable time in which to have resolved any difficulty with pricing access.

Comment: Require manufacturers to respond within 30 days to requests for retroactive discounts, even if the response is just a request for additional information, or face possible termination from the Medicaid program.

Response: No change. Because this issue deals with manufacturer guidelines, it is beyond the scope of this notice. However, should a covered entity have difficulty obtaining retroactive discounts, we encourage the entity to contact the Office of Drug Pricing for assistance.

Comment: Establish that a DSH, which did not submit its Medicaid provider number for the period for which it is requesting retroactive discounts, would be ineligible for the refund.

Response: No change. A DSH which did not submit its Medicaid provider number may still be eligible for retroactive discounts if it (1) did not bill Medicaid for the drugs, (2) billed for covered outpatient drugs using an all-inclusive rate, or (3) has adequate documentation proving that drugs for which retroactive discounts are being requested did not generate Medicaid rebates.

Drug Diversion

Comment: Develop and publish a mechanism whereby manufacturers can report to the Office of Drug Pricing when they suspect an entity of diversion.

Response: No change. The Office of Drug Pricing has currently developed a proposed dispute resolution process which will be published in the **Federal Register** with a public comment period.

Comment: Require PHS preclearance of all safeguard systems developed by entities to deter diversion and require this information to be supplied to the manufacturers upon request.

Response: No change. Guidelines concerning separate purchasing accounts and dispensing records are quite specific, and procedures in these areas need no prior approval. If a manufacturer believes that a covered entity is involved in drug diversion, it has the statutory authority to audit the entity records that directly relate to drugs of that manufacturer purchased at PHS pricing. Proposed audit guidelines have been developed and will be published in the **Federal Register** with a public comment period.

Comment: Issue criteria for measuring the adequacy of the safeguards.

Response: No change. If a manufacturer believes that a covered entity has established inadequate safeguards and is involved in drug diversion, then the manufacturer can either audit the entity or file a complaint with the Office of Drug Pricing.

Comment: Develop a broad definition of "patient" to include all necessary services provided to individuals served by the covered entities.

Response: No change. The notice does not address the definition of patient. The Office of Drug Pricing is in the process of developing a definition of patient, which will be published in the **Federal Register**. Public comment will be invited, and this comment will be considered at that time.

Comment: Do not require separate inventories, as this would place a hardship on most hospitals.

Response: No change. There is no requirement for separate inventories.

Comment: Do not permit entities to develop alternate tracking systems or develop criteria for these systems by March 1, 1994.

Response: No change. It is essential that the Office of Drug pricing maintain some flexibility during this period of implementation. Because these alternate tracking systems require prior approval from the Office of Drug pricing before they can be implemented, sufficient control is maintained. The Office will develop criteria at a later date and welcomes all suggestions.

Audit Requirements

Comment: Specify the statutory basis for the Secretary to authorize manufacturer audit guidelines.

Response: We have amended part 5 of the notice to include a reference to section 340B(a)(5)(C) of the PHS Act, which gives the Secretary the authority to establish procedures relating to the number, duration, and scope of manufacturer audits.

Comment: Move quickly to develop procedures to allow manufacturers to audit records of entities' purchases of covered outpatient drugs and of Medicaid claims for reimbursement for such drugs.

Response: No change. The Office of Drug Pricing is developing proposed audit guidelines which will be published in the **Federal Register** with public comment invited. All comments regarding suggested audit procedures, currently received, will be considered at that time.

Entity Participation

Comment: An entity should be viewed as not participating in the program (and therefore as ineligible to receive its discounts) if it has not given its Medicaid provider number of the Office of Drug Pricing.

Comment: We have amended part 2 of the notice to require entities to provide one of the following: (1) A pharmacy Medicaid number (the number which the entity uses to bill Medicaid for medications), or (2) their all-inclusive Medicaid number (e.g., "FQ" number), or (3) notification that it does not bill Medicaid for all outpatient drugs. These numbers will be posted on the electronic bulletin board (Electronic Data Retrieval System or EDRS), maintained by the Office of Drug Pricing, to indicate which covered entities have elected to participate in the program. For access to the EDRS call (301) 549–4992.

Comment: All covered entities should be required to notify manufacturers 30 days before they wish to access PHS pricing.

Response: We have amended part 6 of the notice to provide that entities will be added to or deleted from the eligibility list on a quarterly basis only. The Office of Drug Pricing will update the list 2 weeks before each calendar quarter, giving lead time for pricing changes and appropriate communications with wholesalers, GPOs, and purchasing agents.

Group Purchasing Arrangements

Comment: Allow eligible DSHs to continue GPO participation for manufacturers who are not offering PHS pricing and prohibit GPO participation with respect to all complying manufacturers.

Response: No change. Generally, we have found that entities are receiving PHS pricing. The Office of Drug Pricing has, at every opportunity, communicated its willingness to assist entities when there are problems with accessing PHS pricing. The Office has investigated all complaints of manufacturer noncompliance immediately and was and is willing to take appropriate enforcement action if necessary. This is the proper course for dealing with any manufacturer non-compliance, rather than attempting to compensate for continued non-compliance by disregarding the statutory GPO provisions.

Purchasing Agents

Comment: Distinguish clearly between a purchasing agent and a GPO for purposes of the DSH/GPO prohibition, only.

Response: We have amended part 8 of the notice to distinguish a purchasing agent from a group purchasing arrangement for purposes of the DSH/GPO prohibition. A purchasing agent would not be considered operating as a group purchasing arrangement if the following conditions are met: (1) the purchasing agent is not associated with a group purchasing organization; (2) no collective bargaining by a group of hospitals occurs; (3) the negotiations of PHS pricing are separate activities for each individual DSH; (4) a separate agreement with each DSH is executed; (5) as part of the agreement, there will be no sharing or pricing information; and (6) all final decisions concerning product and price acceptance will be made by each individual DSH.

Comment: Do not require manufacturers to sell directly to a purchasing agent, a GPO, or a contract pharmacy, but solely to covered entities and their wholesalers.

Response: No change. It is a customary business practice for manufacturers to sell to intermediaries as well as directly to the entity. Entities often use purchasing agents or contract pharmacies, or participate in GPOs. By placing such limitations on sales transactions, manufacturers could be discouraging entities from participating in the program.

Manufacturers may not single out covered entities from their other customers for restrictive conditions that

would undermine the statutory objective.

Manufacturer Contracts Which Require Entity Compliance

Comment: Permit a manufacturer to require the covered entities to sign a contract containing only the manufacturer's normal business policies (e.g., routine information necessary to set up and maintain an account) if this is a usual business practice of the manufacturers.

Response: We have amended part 11 of the notice to state that this prohibition against a contract between a manufacturer and a covered entity regarding entity compliance with section 340B provisions or the Office of Drug Pricing program guidelines does not encompass entity/manufacturer contracts that contain provisions relating to normal business activities, requests for standard information, or other appropriate contract provisions.

Comment: Declare null and void provisions in manufacturer contracts signed by entities pursuant to section 340B which deal with assurances of entity compliance with section 340B.

Response: No change. While the Office of Drug Pricing has no legal authority to declare null and void provisions of contracts between covered entities and manufacturers, it is our position that manufacturers may not enforce such provisions.

General

Comment: Post Medicaid provider numbers of all eligible DSH outpatient clinics on the electronic bulletin board.

Response: No change. The Office of Drug Pricing has developed proposed criteria to determine the eligibility of DSH outpatient clinics. These criteria will be published in the **Federal Register**, and the public will be invited to comment.

Comment: Might certain activity generate a new Medicaid Best Price?

Response: No change. Because the Health Care Financing Administration (HCFA) Medicaid Rebate Program deals with Best Price calculations, the Office of the Drug Pricing will refer all Best Price questions to the agency. For further information in this regard, please call Al Beachley, Branch Chief, Medicaid Drug Rebate Operations Branch, HCFA, at (410) 966–3225.

Comment: Establish a procedure whereby manufacturers will be able to determine which purchasing groups are eligible to purchase on behalf of covered entities and receive the PHS pricing.

Response: We have amended part 7 of the notice to require any group which purchases covered outpatient drugs at OHS pricing on behalf of an eligible covered entity to have written authority from the entity to purchase its covered outpatient drugs. The purchasing group must provide documentation of this purchase authority to the manufacturer upon request. This rule does not supersede the statutory limitations regarding DSH participation in GPOs or group purchasing arrangements.

Comment: Establish a prime vendor program designating certain wholesalers to service PHS covered entities similar to programs established with the Department of Veterans Affairs (VA), Department of Defense (DOD), and the Bureau of Prisons (BOP).

Response: No change. The Office of Drug Pricing is in the early stages of developing a pilot prime venter program and has considered, among others, the various programs of VA, DOD, and BOP.

(C) Revised Entity Guidelines

Set forth below are the final entity guidelines, revised based on the analysis of the comments described above.

(1) Confidential Drug Pricing Information

"Confidential drug pricing information" includes both "best price" and "average manufacturer price." The quoted price and the actual price given by the manufacturer to the covered entity are not confidential.

(2) Duplicate Discount/Rebate Potential

First, a covered entity billing on a cost basis for drug purchases must provide the Office of Drug Pricing with a pharmacy Medicaid number (the number which the entity uses to bill Medicaid for medications). Second, a covered entity using an all-inclusive rate (either per encounter or visit) must submit its all-inclusive Medicaid number (e.g., "FQ" number). Third, if a covered entity does not bill Medicaid for outpatient drugs, then the entity must notify the Office of this decision. Fourth, a large facility which houses many different clinics, only several of which are eligible, must obtain a separate Medicaid provider number for the eligible clinics. For those States which cannot generate additional Medicaid provider numbers for entities, covered entities must discuss an alternative arrangement with the States to accomplish this objective.

This information will be posted on the Electronic Data Retrieval System (EDRS), maintained by the Office of Drug Pricing, to indicate which covered entities have elected to participate in the program. For access to the EDRS call (301) 594–4992.

If a drug is purchased by or on behalf of a Medicaid beneficiary, the amount billed may not exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with the Veterans Health Care Act of 1992, plus a reasonable dispensing fee established by the State Medicaid agency.

(3) Eligibility for Retroactive Discounts

Until 30 days after publication of this notice, eligible covered entities included on the initial eligibility list may request retroactive discounts (discounts, rebates, or account credit) for covered outpatient drugs purchased retroactive to December 1, 1992. Entities added to the eligibility list at a later date may only request discounts retroactive to the date of their inclusion on the list. Of the entities listed on the eligibility list, only the following may request these discounts: The covered entity that—(1) has billed for covered outpatient drugs using an all-inclusive rate (either per visit or per encounter), or (2) has not billed Medicaid for covered outpatient drugs since December 1, 1992, (or since its inclusion on the eligibility list), or (3) has submitted its Medicaid provider number and is requesting refunds for subsequent periods, or (4) has adequate documentation proving that drugs for which a retroactive discount is being requested have not generated Medicaid rebates.

A DSH is not eligible for retroactive discounts for covered outpatient drugs purchased through a group purchasing organization (GPO) or any group purchasing arrangement. Any DSH outpatient clinic which is or will be eligible for retroactive discounts may preserve its rights by sending manufacturers a letter requesting such refunds and providing adequate documentation of purchases.

(4) Entity Guidelines Regarding Drug Diversion

Covered entities are required not to resell or otherwise transfer outpatient drugs purchased at the statutory discount to an individual who is not a patient of the entity. There are several common situations in which this might occur. First, if individuals other than patients of the covered entity obtain covered outpatient drugs from its pharmaceutical dispensing facility, the entity must develop and institute adequate safeguards to prevent the transfer of discounted outpatient drugs to individuals who are not eligible for the discount (e.g., separate purchasing accounts and dispensing records). Second, a larger institution which

contains an eligible entity within its structure is required to establish separate purchasing accounts and maintain separate dispensing records for the eligible entity. Third, the covered entity itself may not use the covered outpatient drug in excluded services (e.g., inpatient services). If an entity offers services excluded from the drug discount program, the entity must develop a separate method for purchasing and dispensing drugs for excluded services.

The covered entity may, at its option, develop an alternative system, short of tracking each discounted drug through the purchasing and dispensing process, by which it can prove compliance. If an alternate system of tracking is proposed to be used, this system must be approved by the Drug Pricing Program. The Office will develop criteria for alternative systems at a later date and welcomes all suggestions.

(5) Audit Requirement

All entities receiving statutory prices are required to maintain records of purchases of covered outpatient drugs and of any claims for reimbursement submitted for such drugs under title XIX of the Social Security Act. The entity must permit HHS and the manufacturer to audit any record of a covered drug purchase that was subject to the discount, as provided by section 340B(a)(5)(C) of the PHS Act. Manufacturer audits will be conducted in accordance with procedures developed by the Secretary of HHS. The Office of Drug Pricing is developing proposed audit guidelines which will be published in the **Federal Register** with public comment invited. The notice will address only audits related to purchases as a covered entity; it does not address other audit requirements related to participation in State Medicaid programs or receipt of Federal funding.

(6) Entity Participation

Covered entity participation in the section 340B drug discount program is voluntary. Once an entity has elected to participate in the program, it must wait to enter or withdraw from the program until the next official updating of the eligible entity list. The Office of Drug Pricing will update this list two weeks before each calendar quarter. The entity must comply with all program guidelines until the date it is removed from the eligibility list.

(7) Group Purchasing

A DSH may participate in a group purchasing arrangement for inpatient drug use without affecting its eligibility to purchase section 340B discounted drugs. If a DSH participates in a GPO or other group purchasing arrangement for covered outpatient drugs, the DSH will no longer be an eligible covered entity and cannot purchase covered outpatient drugs at the section 340B discount prices.

States, or other groups, which purchase drugs for covered entities (other than disproportionate share hospitals) are not included on the list of covered entities; however, they are eligible to purchase at the section 340B discount if the following requirements are met: (1) the group purchasing arrangement must be comprised of only covered entities, (2) if group purchasing arrangements contain entities which are not eligible for the discount, separate purchasing accounts and dispensing/distribution must be maintained, and (3) the purchasing group has written authority from the covered entity to purchase covered outpatient drugs on its behalf.

(8) Purchasing Agents

A covered entity is permitted to use a purchasing agent without forfeiting its right to the section 340B drug discounts. If a purchasing agent is used, the arrangement must be in writing and the terms of the agent's relationship with the entity must be clearly defined. The entity and the agent should decide whether the agent simply negotiates the drug purchasing contracts on behalf of the entity or actually receives drug shipments for distribution to the entity. If the latter, the transfer of purchased pharmaceuticals from an agent to the entity would not be viewed as drug diversion.

For purposes of the DSH/GPO prohibition only, a purchasing agent may be distinguished from and would not be considered operating as a GPO or other group purchasing arrangement if the following conditions are met: (1) the purchasing agent is not associated with a GPO or other purchasing arrangement; (2) no collective bargaining by a group of hospitals occurs; (3) the negotiations for PHS pricing are separate activities for each individual DSH; (4) a separate agreement with each DSH is executed; (5) as part of the agreement, there will be no sharing of pricing information; and (6) all final decisions concerning product and price acceptance will be made by each individual DSH.

(9) Definition of Covered Outpatient Drug

Section 1927(k)(2) of the Social Security Act defines "covered outpatient drug" to include most drugs and biologicals which may be dispensed only by prescription and which require approval by the Food and Drug Administration or a license under section 351 of the PHS Act. Section 1927(k)(3) limits the definition of "covered outpatient drug" to exclude certain settings (e.g., such services as emergency room, hospice, dental, physician, nursing facilities, x-ray, lab, and renal dialysis) in some instances. In these settings, if a covered drug is included in the per diem rate (i.e., bundled with other payments in an all-inclusive, per visit, or an encounter rate), it will not be included in the section 340B discount program. However, if a covered drug is billed and paid for instead as a separate line item as an outpatient drug in a cost basis billing system, this drug will be included in the program.

(10) Dealing Direct or Through a Wholesaler

If a manufacturer has customarily dealt directly with a particular covered entity, then requiring the manufacturer to continue this form of purchasing with the covered entity is reasonable. When dealing directly with a covered entity, manufacturers must offer covered outpatient drugs at or below the section 340B discount prices. If a manufacturer customarily uses a wholesaler as a means of distribution, then requiring the manufacturer to continue this form of purchasing with covered entities is also reasonable. If the manufacturer's drugs are available to covered entities through wholesalers, the discount must be made available through that avenue. Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective. Manufacturers must not place limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program.

(11) Manufacturer's Contracts Requiring Entity Compliance

A manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions. Covered entity assurances regarding the following activities may not be required: (1) eligibility to participate in the program; (2) utilization of covered outpatient drugs only in authorized services; (3) maintaining the confidentiality of the drug pricing information; (4) permitting the manufacturers to audit purchase, inventory, and related records prior to the publication of approved PHS guidelines; and (5) submitting information related to drug acquisition,

purchase, and inventory systems. Entities are not required to sign agreements assuring manufacturers of their compliance with section 340B provisions. (If a manufacturer asks a covered entity whether the entity is in fact participating in the section 340B discount program, the entity must supply the manufacturer with this information). This prohibition does not include provisions that address customary business practice, request standard information, or include other appropriate contract provisions.

Dated: May 9, 1994.

John H. Kelso,

Acting Administrator, Health Resources and Services Administration.

[FR Doc. 94-11643 Filed 5-12-94; 8:45 am]

BILLING CODE 4160-15-P-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Community Planning and Development

[Docket No. N-94-1917; FR-3350-N-83]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

ADDRESSES: For further information, contact Barbara Richards, room 7262, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410; telephone (202) 708-4300; TDD number for the hearing- and speech-impaired (202) 708-2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1-800-927-7588.

SUPPLEMENTARY INFORMATION: In accordance with 56 FR 23789 (May 24, 1991) and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88-2503-OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Judy Breitman, Division of Health Facilities Planning, U.S. Public Health Service, HHS, room 17A-10, 5600 Fishers Lane, Rockville, MD 20857; (301) 443-2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to defer to the interim rule governing this program, 56 FR 23789 (May 24, 1991).

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable..

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1-800-927-7588 for detailed instructions or write a letter to Barbara Richards at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), and the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.*, acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: U.S.Navy: John J. Kane, Deputy Division Director, Dept. of Navy, Real Estate Operations, Naval Facilities Engineering Command, 200 Stovall Street, Alexandria, VA 22332-2300; (703) 325-0474; GSA: Leslie Carrington, Federal Property Resources Services, GSA, 18th and F Streets NW., Washington, DC 20405; (202) 208-0619; U.S. Air Force: Bob Menke, Area-MI, Bolling AFB, 172 Luke Avenue, suite 104, Washington, DC 20332-5113; (202) 767-6235; Dept. of Transportation: Ronald D. Keefer, Director, Administrative Services & Property Management, DOT, 400 Seventh St. SW., room 10319, Washington, DC 20590; (202) 366-4246; Corps of Engineers: Pete Digel, Headquarters, Army Corps of Engineers, Attn: CERE-MC, room 4224, 20 Massachusetts Ave. NW., Washington, DC 20314-1000; (202) 272-1753; Dept. of Interior: Lola D. Knight, Property Management Specialist, Dept of Interior, 1849 C St. NW., Mail stop 5512-MIB, Washington, DC 20240; (202) 208-4080; (These are not toll-free numbers).

Dated: May 6, 1994.

Jacquie M. Lawing,

Deputy Assistant Secretary for Economic Development.

Title V, Federal Surplus Property Program Federal Register Report for 05/13/94

Suitable/Available Properties

BUILDINGS (by State)

Arkansas

Murray Overlook & Info. Center
McClellan-Kerr Arkansas River Navigation Project
Little Rock Co: Pulaski AR 72203-
Landholding Agency: GSA
Property Number: 549410007
Status: Excess
Comment: 1003 sq. ft.; 1 story with basement; bldg. on 4.80 acres includes paved parking concrete; needs rehab.; most recent use—info. center/observation area
GSA Number: 7-D-AR-548

Respondents	No. of respondents	No. of responses/respondents	Avg. burden/response (in hrs.)	Total burden (in hrs.)
Initial Contact of Potential Candidates	1,600	1	0.16	267
Scheduling Interview	400	1	0.08	33
Telephone Interview	400	1	2	800
Total				1,108

5. State-Based Evaluation of Trends and Risk Factors in Morbidity and Mortality from Sickle Cell Disease after Newborn Screening—New—Children with sickle cell disease are at increased risk for mortality and morbidity, especially in the first three years of life. The need for early diagnosis and preventive medical intervention is the rationale for newborn hemoglobinopathy screening programs, now operating in more than 40 states. Although clinical trials have clearly demonstrated the efficacy of early medical intervention, more information is needed regarding the actual utilization of available therapies and preventive measures in large populations, health statuses of children identified by newborn screening programs, and risk factors for adverse health outcomes. Potential risk factors include extent of medical care follow-up, location of treatment, the use of penicillin prophylaxis, immunization patterns, as well as parental social, demographic and educational factors. In FY 1995, CDC awarded $150,000 to three state health departments to assist in their efforts to ascertain health status and risk factors for young children with sickle cell disease. States will be using these funds to obtain information about individual children through structured questionnaires directed toward their parents and physicians. There are no costs to the respondents.

Respondents	No. of respondents	No. of responses/respondent	Avg. burden/response (in hrs.)	Total burden (in hrs.)
Parents	3,000	1	1.5	4.5
Physicians	4,500	1	1	4.5
Total				9

Dated: October 26, 1995.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95-27056 Filed 10-31-95; 8:45 am]

BILLING CODE 4163-18-P

National Institute for Occupational Safety and Health; Meeting

The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Breast Cancer Incidence Among Occupational Cohorts Exposed to Ethylene Oxide and Polychlorinated Biphenyls.

Time and Date: 9 a.m.–3:30 p.m., December 13, 1995.

Place: Hubert Humphrey Building, Room 800, 200 Independence Avenue, SW., Washington, DC 20201.

Status: Open to the public, limited only by the space available. The room accommodates approximately 50 people.

Purpose: The purpose of this meeting is to obtain expert advice regarding technical and scientific aspects of the study "Breast Cancer Incidence Among Occupational Cohorts Exposed to Ethylene Oxide and Polychlorinated Biphenyls" being conducted at NIOSH. Participants on the Science Advisory Panel will review the study protocol and provide advice on the conduct of the study.

Viewpoints and suggestions from industry, labor, academia, other government agencies and the public are invited.

Contact Person for Additional Information: Teresa Schnorr, Ph.D., NIOSH, CDC, Mailstop R-13, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513/841-4587.

Dated: October 25, 1995.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 95-27030 Filed 10-31-95; 8:45 am]

BILLING CODE 4163-19-M

Public Health Service

Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Contracted Pharmacy Services

AGENCY: Public Health Service, HHS.

ACTION: Notice.

SUMMARY: Section 602 of Public Law 102-585, the "Veterans Health Care Act of 1992" (the "Act"), enacted section 340B of the Public Health Service Act ("PHS Act"), "Limitation on Prices of Drugs Purchased by Covered Entities." Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible (covered) entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services (HHS) in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

The purpose of this notice is to inform interested parties of the following proposed guidelines regarding contracted pharmacy services. Public comment is invited.

DATES: The public is invited to submit comments on the proposed guidelines by December 1, 1995. After consideration of the comments submitted, the Secretary will issue the final guidelines.

FOR FURTHER INFORMATION CONTACT: Marsha Alvarez, R. Ph., Director, Drug Pricing Program, Bureau of Primary Health Care, 4350 East-West Highway, Bethesda, MD 20814, Phone (301) 594-4353, FAX (301) 594-4982.

SUPPLEMENTARY INFORMATION: The Health Resources and Services Administration, Bureau of Primary Health Care, acting through the Office of Drug Pricing, has developed contracted pharmacy service guidelines to facilitate

program implementation. For covered entities that wish to utilize contracted pharmacy services to dispense section 340B outpatient drugs, the Office of Drug Pricing is proposing a contracted pharmacy service agreement between the covered entity and the pharmacy which would include the following provisions:

(a) The covered entity will purchase the drug. A "ship to-bill to" procedure may be used in which the covered entity purchases the drug, the manufacturer bills the covered entity for the drugs that it purchased but ships the drugs directly to the contracted pharmacy.

(b) The contractor will provide all pharmacy services (e.g., dispensing, record keeping, drug utilization review, formulary maintenance, patient profile, counseling). Each facility which purchases its covered outpatient drugs has the option of individually contracting for pharmacy services with the pharmacy of its choice. The limitation of one pharmacy contractor per facility does not preclude the selection of a pharmacy contractor with multiple pharmacy sites, as long as only one site is used for the contracted services. [The Office of Drug Pricing will be evaluating the feasibility of permitting these facilities to contract with more than one site and contractor.]

(c) If the patient does not elect to use the contracted service, the patient may obtain the prescription from the pharmacy provider of his/her choice.

(d) The contractor may provide the covered entity services, other than pharmacy, at the option of the covered entity (e.g., home care, reimbursement services).

(e) The contractor and the covered entity will adhere to all Federal, State, and local laws and requirements. Additionally, all PHS grantees will adhere to all rules and regulations established by the grant funding office.

(f) The contractor will provide the covered entity quarterly financial statements, a detailed status report of collections, and a summary of receiving and dispensing records.

(g) The contractor will establish and maintain a tracking system suitable to prevent diversion of section 340B discounted drugs to individuals who are not patients of the covered entity.

(h) Both parties agree that they will not resell or transfer a drug purchased at section 340B pricing to an individual who is not a patient of the covered entity. *See* section 340B(a)(5)(B). If a contract pharmacy is found to have violated this prohibition, the pharmacy will pay the entity the amount of the discount in question so that the entity can reimburse the manufacturer.

(i) A covered entity using contracted pharmacy services will not use drugs purchased under section 340B to dispense Medicaid prescriptions unless the contract pharmacy and the state medicaid agency have established an arrangement which will prevent duplicate discounts/rebates.

(j) Both parties understand that they are subject to audits (by the PHS and participating manufacturers) of records that directly pertain to the entity's compliance with the drug resale or transfer prohibition and the prohibition against duplicate Medicaid rebates and PHS discounts. *See* section 340B(a)(5).

(k) Upon request, a copy of this contracted pharmacy service agreement will be provided to a participating manufacturer which sells covered outpatient drugs to the covered entity. All confidential propriety information may be deleted from the document.

Covered entities which elect to utilize this contracted pharmacy mechanism must submit to the Office of Drug Pricing a certification that they have signed an agreement with the contracted pharmacy containing the aforementioned provisions.

Dated: August 18, 1995.

Ciro V. Sumaya,

Administrator, Health Resources and Services Administration.

[FR Doc. 95–27032 Filed 10–31–95; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–3971–N–02]

The Performance Review Board

AGENCY: Department of Housing and Urban Development.

ACTION: Notice of appointments.

SUMMARY: The Department of Housing and Urban Development announces the appointments of Linda S. Reid and Karen A. Miller as members of the Departmental Performance Review Board. The address is: Department of Housing and Urban Development, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Persons desiring any further information about the Performance Review Board and its members may contact Earnestine Pruitt, Deputy Director, Executive Personnel Management Division, Department of Housing and Urban Development, Washington, DC 20410, telephone (202) 708–1381. (This is not a toll free number.)

Dated: October 25, 1995.

Dwight P. Robinson,

Acting Deputy Secretary, Department of Housing and Urban Development.

[FR Doc. 95–27027 Filed 10–31–95; 8:45 am]

BILLING CODE 4210–32–M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Notice of Intent To Prepare an Environmental Impact Statement for a Proposed Lease To Construct and Operate an Integrated Waste Management Facility on the Cortina Indian Rancheria, Colusa County, CA

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of Intent and Public Scoping Meeting.

SUMMARY: This notice advises the public that the Bureau of Indian Affairs, in cooperation with the Cortina Indian Rancheria of Wintun Indians, intends to prepare an Environmental Impact Statement (EIS) for a proposed lease to construct and operate an integrated waste management facility on the Cortina Rancheria of the Cortina Band of Wintun Indians in Colusa County, California. A description of the proposed project, location, and environmental issues to be addressed in the EIS are provided below (supplementary information). In addition to this notice, a public meeting will be held to describe the proposed action and to receive public comments regarding the scope of the EIS. The public will be invited to participate in the scoping process, review of the draft EIS, and a public meeting.

This notice is published in accordance with the National Environmental Policy Act (NEPA) regulations found in 40 CFR 1501.7. The purpose of this notice is to solicit suggestions and information from other agencies and the public on the scope of issues to be addressed in the EIS. Comments and participation in this scoping process are encouraged.

DATES: Comments should be received by November 29, 1995. A public scoping meeting will be held on November 16, 1995.

ADDRESSES: Comments should be addressed to Mr. Ronald Jaeger, Area Director, Sacramento Area Office, 2800 Cottage Way, Room W–2550, Sacramento, California 95825. A public scoping meeting will be held on November 16, 1995, at 7:30 p.m. at the Cortina Indian Rancheria Satellite Office

businesses and organizations receiving grants from HHS; *Total Number of Respondents:* 25; *Frequency of Response:* monthly; *Average Burden per Response:* 15 minutes; *Estimated Annual Burden:* 75 hours.

The PMS–272, Federal Cash Transactions Report, is used to monitor Federal cash advances to grantees and obtain Federal cash disbursement data. It serves in place of the SF–272. *Respondents:* State and local governments, profit and nonprofit businesses and institutions receiving grants from HHS; *Total Number of Respondents:* 11,050; *Frequency of Response:* Quarterly; *Average Burden per Response:* 4 hours; *Estimated Annual Burden:* 176,800 hours.

Total Burden: 176,875 hours.

Send comments to Douglas F. Mortl, PSC Reports Clearance Officer, Room 17A08, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: August 19, 1996.

Lynnda M. Regan,

Director, Program Support Center.

[FR Doc. 96–21530 Filed 8–22–96; 8:45 am]

BILLING CODE 4160–17–M

Health Resources and Services Administration

RIN 0905–ZA96

Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final notice.

SUMMARY: Section 602 of Public Law 102–585, the "Veterans Health Care Act of 1992" (the "Act"), enacted section 340B of the Public Health Service Act ("PHS Act"), "Limitation on Prices of Drugs Purchased by Covered Entities." Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible (covered) entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services (HHS) in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

The purpose of this notice is to inform interested parties of final guidelines regarding contract pharmacy services.

FOR FURTHER INFORMATION CONTACT: Annette Byrne, R. Ph., M.S., Director, Drug Pricing Program, Bureau of Primary Health Care, Health Resources and Services Administration, 4350 East West Highway, 10th Floor, Bethesda, MD 20814, Phone (301) 594–4353, FAX (301) 594–4982.

EFFECTIVE DATE: August 23, 1996.

SUPPLEMENTARY INFORMATION:

(A) Background

Proposed guidelines for contract pharmacy services were announced in the **Federal Register** at 60 FR 55586 on November 1, 1995. A comment period of 30 days was established to allow interested parties to submit comments. The Health Resources and Services Administration, Bureau of Primary Health Care, acting through the Office of Drug Pricing (ODP), received eleven letters including comments concerning the scope of the 340B Program, contractor certification, contractor and entity penalties for drug diversion, creation of an agency relationship between the entity and the contractor, entity responsibilities including price establishment, reimbursement, inventory control, and the like.

Although some manufacturers expressed concerns regarding the potential for drug diversion, the Department has received no evidence of diversion that has required an official Departmental investigation. This includes the various drug distribution systems, among them those using contract pharmacy services. However, in response to manufacturers' concerns, the Department intends to study the use of contracted pharmacy services for accessing 340B drugs to determine if there is evidence of drug diversion. In particular, the Department will examine closely documented complaints, including the results of manufacturers' audits, will use other analyses as deemed appropriate, and will consider whether additional safeguards are necessary.

We received some very positive comments in support of the mechanism. These comments discussed the many covered entities which do not operate their own licensed pharmacies; therefore, the guidelines encourage these entities to participate in the program. Because these covered entities provide medical care for many individuals and families with incomes well below 200% of the Federal poverty level and subsidize prescription drugs for many of their patients, it was essential for them to access 340B pricing. Covered entities could then use savings realized from participation in the program to help subsidize prescriptions for their lower income patients, increase the number of patients whom they can subsidize and expand services and formularies. One commenter described the guidelines as straightforward, clear and consistent with section 340B. Another commenter stated that the "use of contract pharmacies by covered entities is fundamental to the success of the VHCA [Veterans Health Care Act] drug pricing program." The commenter supported the guidelines and urged the Department to expedite their completion, as the importance of the contract pharmacy option to their members could not be overstated.

The following section presents a summary of all major comments, grouped by subject, and a response to each comment. All comments were considered in developing this final notice, with changes made to increase clarity and readability. In addition, to provide further technical assistance and guidance to covered entities interested in using this mechanism, examples of report contents, a suggested system to ensure an adequate drug tracking system, and a method to ensure patient eligibility are included. Various commenters, and in particular drug manufacturers, suggested the need for detailed systems. The National Association of Community Health Centers suggested some of the specific examples.

(B) Comments and Responses

(1) General

Comment: The use of contract pharmacy services is inconsistent with section 340B of the PHS Act and results in an unauthorized expansion of the program.

Response: Section 340B, which established the Drug Pricing Program, requires manufacturers to sell to covered entities at or below a ceiling price determined by a statutory formula. The statute is silent as to permissible drug distribution systems. There is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself. It is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities.

It has been the Department's position that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price. If the entity directs the drug shipment to its contract pharmacy, we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise

exempts the manufacturer from statutory compliance. However, the entity must comply, under any distribution mechanism, with the statutory prohibition on drug diversion.

During the early period of program implementation, it became apparent that only a very small number of the 11,500 covered entities used in-house pharmacies (approximately 500), although additional entities participated by buying drugs for their physician dispensing activities. In addition, many of the larger groups of covered entities, including community and migrant health centers, hemophilia clinics and most of the Ryan White HIV service programs (e.g., State AIDS Drug Assistance Programs) depend upon outside pharmacy services. Yet, because the delivery of pharmacy services is central to the mission of (and a legal mandate in some instances for) these providers, they rely on outside pharmacies to fill the need. It would defeat the purpose of the 340B program if these covered entities could not use their affiliated pharmacies in order to participate in the 340B program. Otherwise, they would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or forego participation in the program altogether. Neither option is within the interest of the covered entities, the patients they serve, or is consistent with the intent of the law.

As early as 1993, several covered entity groups and a home care company came forward to assist the Department in developing a workable mechanism to use outside pharmacies under arrangements which would decrease the drug diversion potential. The result was the November 1 proposed notice, which articulates a voluntary model agreement. Currently, contract pharmacies are used by a number of large organizations, such as the American Red Cross, several community health centers, and the New York Blood Consortium.

It must be understood that the use of contract services is *only* providing those covered entities (which would otherwise be unable to participate in the program) a process for accessing 340B pricing. The mechanism does not in any way extend this pricing to entities which do not meet program eligibility. However, it has permitted more eligible entities to participate in the program with a reasonable assurance that the potential for drug diversion is eliminated.

Comment: The guidelines were proposed without a comprehensive notice and comment period.

Response: During the early months following enactment, it became clear that there were many gaps in the legislation and some form of program structure was necessary to move the program forward. There were approximately 11,500 eligible entities, 500 participating manufacturers, numerous wholesalers and many Federal programs affected by this legislation and all seeking guidance. It was incumbent upon the Department to implement this difficult Congressional mandate in an expeditious manner.

Interpretive rules and statements of policy were developed to provide necessary program guidance. The Department has published these guidelines in the **Federal Register**, used a Federal clearance process (including the Office of Management and Budget's clearance) and provided a public comment period to obtain both Federal as well as public input into guideline development. The Department considered all comments in developing these final guidelines.

The guidelines explain how the Department intends to administer the 340B, further explain the statutory language by clarifying the meaning given by the Department to particular words or phrases, and do not exceed the purpose of 340B or conflict with any of its provisions. We believe that these guidelines create no new law and create no new rights or duties; therefore, they are not subject to the Administrative Procedure Act's requirement of notice and comment. Nevertheless, the Department chose to solicit and respond to public comment.

Comment: As a matter of State law, entities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients. As a general rule, a person or entity privileged to perform an act may appoint an agent to perform the act unless contrary to public policy or an agreement requiring personal performance. Restatement of Agency 2d § 17 (1995). Hence, even in the absence of Federal guidelines, covered entities have the right to contract with retail pharmacies for the purpose of dispensing 340B drugs. By issuing guidelines in this area, ODP is not seeking to create a new right but rather is simply recognizing an existing right that covered entities enjoy under State law.

Response: We agree. However, entities, under any distribution system, must comply with the statutory prohibition against diversion of 340B drugs to individuals who are not patients of the covered entities. Further, the dispensing of drugs, purchased with a 340B discount, must not result in the generation of a Medicaid rebate.

Comment: Participation in the contract pharmacy mechanism by hemophilia treatment centers funded under the Maternal and Child Health Block Grant Program would contravene the central goals of that program and could result in grant termination or non-renewal.

Response: Block grant funds are designed for formula allocation to the States to meet specific defined needs in the legislation. Congress recognized that the Maternal and Child Health Bureau (MCHB) had other needs that should be met more flexibly; therefore, fifteen percent of the appropriation is a discretionary set-aside. These funds are not subject to the specific parameters of block grant funds but instead are used to fulfill other goals within the MCHB mission. This includes the provision of services (including pharmaceuticals) to individuals with hemophilia disorders and their families. Therefore, the purchase of pharmaceuticals by hemophilia centers does not contravene grant principles.

Comment: The contract pharmacy mechanism contravenes Federal and State laws and regulations (e.g., Prescription Drug Marketing Act and the Anti-kickback Statute).

Response: We found no indication that the guidelines contravene Federal or State law. Regarding allegations that the guidelines contravene the Prescription Drug Marketing Act (PDMA), it is clear that the guidelines fall squarely within the PDMA resale exception that allows the dispensing of a prescription drug purchased by a health care entity when dispensing is pursuant to a prescription. See 21 U.S.C. 353(c)(3)(B)(v). Under the guidelines, the contract pharmacy would dispense 340B drugs to patients of the covered entity pursuant to a prescription. The contract pharmacy would act as an agent of the covered entity, in that it would not resell a prescription drug but rather distribute the drug on behalf of the covered entity. This situation is akin to a covered entity having its own pharmacy. Moreover, the guidelines include controls intended to prevent diversion and provide for accountability of drug stocks. For these reasons, the guidelines are consistent with both the letter and the spirit of the PDMA.

We believe it necessary to ensure that covered entities contracting with pharmacies to dispense 340B drugs are aware of the requirements of the Federal anti-kickback statute and the way in

which such requirements could apply to their arrangements with contracting pharmacies. To this end, we inserted into the guidelines a discussion of the statute's requirements and its potential application in this type of contracting situation.

In addition, provision (e) of the guidelines provides that the "contractor and the covered entity will adhere to all Federal, State, and local laws and requirements." As a general matter, we found it impossible to discuss each State's laws and regulations regarding drug purchase, distribution, and dispensing in relation to the many different types of entities and their individual needs. We believe it appropriate that the guidelines include a provision that requires each entity and contractor to be responsible for ensuring that their particular contracting arrangements and operations conform to the requirements of all applicable laws and regulations.

Comment: The ODP should develop a uniform contractual agreement and distribute this agreement to covered entities for use without modification.

Response: The guidelines propose a model format only. The Department has included in the guidelines provisions necessary to ensure that covered entities and contract pharmacies understand and agree not to violate 340B provisions. Because of the wide diversity of covered entities (including hemophilia clinics, large hospitals, migrant health clinics, family planning service programs and State AIDS drug assistance programs), it would be impossible to include provisions responsive to the needs of all entities.

Comment: ODP should keep a list of all acceptable contract pharmacies.

Response: Any pharmacy licensed by a State Board of Pharmacy is acceptable.

Comment: Some State laws require that manufacturers ensure that a buyer is licensed to purchase pharmaceuticals. Covered entities that do not have pharmacy operations would not be licensed, and thus, in some States, manufacturers could not receive from the covered entity the assurance required by State law.

Response: Provision (e) provides that the covered entity will adhere to all Federal, State and local laws and requirements. Accordingly, if State X requires an entity to be licensed to purchase drugs and a covered entity subject to the laws of State X does not have a pharmacy license, it may not be able to purchase drugs. However, if State X permits a covered entity to use contract pharmacy services to purchase drugs on its behalf, the entity could presumably use this mechanism. To the extent the guidelines may be inconsistent with a State's distributor licensing requirements, this same reasoning would apply.

Comment: Covered entities may bill insurers for 340B drugs at the usual price, resulting in the savings not being passed on to the patients.

Response: Section 340B does not limit the pricing behavior of covered entities. It is our understanding that covered entities have a variety of drug pricing approaches. While some may pass all or a significant part of the discount to their patients, others may set the price slightly higher than the actual acquisition cost plus a reasonable dispensing fee, using the savings to reach more eligible patients and provide more comprehensive services. The Department intends to examine the section 340B drug pricing activities of covered entities to determine the various approaches used and the rationale for these approaches. However, until it completes its examination of this issue, the Department notes that a modest section 340B price markup, with saving realized from the discounts used by covered entities only for purposes of the federal program (including certain disproportionate share hospitals) which provides its section 340B eligibility does not appear to be inconsistent with the drug pricing program.

Comment: There should be a limitation to only those covered entities that do not have the capability under State pharmacy law to purchase and dispense prescription drugs.

Response: The guidelines have been revised to read that the "mechanism is designed to facilitate program participation for those eligible covered entities that do not have access to an appropriate 'in-house' pharmacy services." However, this is not a bar to the use of the mechanism by any covered entity.

Comment: A covered entity should use only one form of participation, and if it purchases in its own right for some patients, it should not use a contractor for others.

Response: Some covered entities may receive nominal pricing directly from a manufacturer (e.g., family planning) for specific drugs, may obtain certain drugs through promotional discounts, or have a manufacturer-specific indigent free drug program which could necessitate the procurement of other pharmaceuticals from a retail pharmacy. The statute does not limit the covered entities' access to these avenues of drug purchasing.

Comment: The Department should establish criteria that a contractor and a covered entity must meet in order to be in compliance with section 340B provisions and receive 340B pricing.

Response: The contracted pharmacy mechanism does establish these criteria in that it includes provisions for purchasing only by the entity and not contractor, identifies customary and adequate records that can provide an audit trail, preclusion of the filling of Medicaid prescriptions (thus preventing duplicate discounting), and three provisions related to the potential for drug diversion (agreement not to divert with specified penalties, customary drug tracking systems, and an agreement to permit manufacturer and HHS audits).

Comment: The reference to "facility" in provision (b) should be changed to "entity" for clarification.

Response: The guidelines were revised accordingly.

Comment: The Department should review all contracts between covered entities and pharmacies or develop a procedure for certifying that each contract pharmacy arrangement meets the mechanism criteria.

Response: The Department has added a provision to the guidelines which suggests that covered entities utilizing contract pharmacy services submit to the ODP a certification that they have signed and have in effect an agreement with the pharmacy contractor containing provisions (a) through (k) as outlined in the guidelines. For the convenience of participating drug manufacturers, the names of covered entities which submit a certification, or have submitted an alternate mechanism to reduce the potential for drug diversion which has been approved by ODP, will be placed on the program electronic bulletin board (EDRS) for public access.

Comment: Covered entities should be permitted to contract with more than one site and contractor. Although we understand that the limitation of one contractor (with multiple sites) was intended to address drug diversion concerns, covered entities will have the incentive of directing their patients to the contract pharmacy site participating in the program, even though there may be several nonparticipating sites of contractors that would be more convenient for the patients.

Response: Covered entities are unlikely to select a contract pharmacy that is not convenient for their patients. See also the discussion of patient choice, below.

Comment: PHS is moving from a direct purchase discount program to an indirect charge-back contracting system.

Response: All 340B drugs will be sold to covered entities; therefore, there are no additional charge backs involved.

(2) Patient Choice

Comment: Provision (c) provides that the patient may obtain the prescription from the pharmacy provider of his or her choice. Pharmacy providers cannot provide prescriptions, as only a physician can write a prescription. The guidelines should permit the patient to obtain the prescription from the covered entity physician and then be able to fill that prescription at the pharmacy of his or her choice. Further, the covered entity physician should inform each patient that he or she has the freedom to choose any pharmacy to fill the prescription.

Response: The use of the word "prescription" may be somewhat confusing. We have revised this provision to read "may obtain the prescription from the covered entity and then obtain the drug(s) from the pharmacy provider of his or her choice." In addition, a provision is added to address the responsibility of the covered entity physician to inform the patient of his or her freedom of choice.

Comment: Wording should be added to provision (c) to make it clear that when a patient obtains a drug from a retail pharmacy other than the entity's contract pharmacy, the manufacturer does not have to offer this drug at 340B pricing.

Response: The guidelines were revised accordingly.

(3) Bill to/Ship to

Comment: The type of "bill to, ship to" arrangement proposed in the notice is not a "purchase" by the covered entity.

Response: Please note provision (a) of the notice which states "the covered entity will purchase the drug." The contract pharmacy does not purchase the drug. Title to the drugs passes to the covered entity.

Comment: A "ship to, bill to" arrangement may not be lawful in many States (e.g., state distributor licensing requirements).

Response: The Department obtained information from both the American Pharmaceutical Association and the National Association of Boards of Pharmacy which suggests that no State would consider this type of activity unlawful.

Comment: If the "ship to, bill to" procedure is implemented through wholesalers, there are no procedures in place that can enable a manufacturer to conduct an adequate audit.

Response: The guidelines provide that the covered entity will verify, using the contractor's (readily retrievable) customary business records, that a tracking system exists which will ensure that drugs purchased under the Act are not diverted to individuals who are not patients of the covered entity. These records will be maintained for the period of time required by the State law and regulations. The guidelines provide that the contractor will provide the covered entity with reports consistent with normal business practices as well as maintain records separate from it's own operation. In addition, the contractor will agree to be subject to audits by both the manufacturers and the Department. In light of these provisions, audits will be possible, regardless of whether drugs are shipped by manufacturers or wholesalers.

Comment: A "ship to, bill to" procedure could interfere with marketing arrangements that an individual manufacturer may have established as part of its usual business practices.

Response: Because the manufacturer is still selling to the covered entities, we can see no interference with marketing arrangements. The manufacturer will be using its usual business practices. Only the delivery of the drug will be altered.

Comment: The covered entity (not its contractor) will place all orders for drugs based upon its projections of the needs of its patients.

Response: Because the covered entity will have no knowledge of the inventory levels of the pharmacy, it would be unrealistic to include a provision that the covered entity will order 340B drugs.

Comment: The covered entity, consistent with customary business practices in wholesale purchases, should make timely payment of invoices for drugs shipped to the contractor pursuant to the entity's order.

Response: We have included this concept in the guidelines, Section 1 of Appendix.

(4) Penalties

Comment: The penalty for the contract pharmacy which violates the agreement not to resell or transfer a drug purchased at 340B pricing is inadequate. Knowing violators should be fined beyond their unjust profit and criminal and fraud penalties should be imposed.

Response: The Department has no statutory authority to assess additional penalties beyond the authority provided in section 340B. However, to the extent the Department is aware that improper action by an entity or a contract pharmacy may be a violation of law, we will refer such cases to appropriate authorities.

(5) Potential Drug Diversion

Comment: PHS should conduct an annual audit of each contract pharmacy to ensure compliance with all Departmental rules and regulations.

Response: Subject to the availability of funds, the Department intends to conduct a study of the contract pharmacy mechanism. Depending upon the results of this analysis and the availability of funds, further study may result. Annual audits of each contract pharmacy situation would be burdensome and are not feasible.

Comment: Contract pharmacies will be motivated to identify patients other than those of the covered entity whose drug usage can afford the contractor a profit opportunity. The covered entity should be responsible to the manufacturer for any diversion by the contractor of 340B drugs to individuals who are not patients of the covered entity.

Response: The guidelines contains provision (h), in which both parties agree to not "resell or transfer a drug purchased at section 340B prices to an individual who is not a patient of the covered entity." In addition, this provision provides that if diversion has occurred, the contractor will pay the amount of the discount in question so that the covered entity can reimburse the manufacturer, as required by section 340B(a)(5)(D).

Comment: The mechanism should include provisions for ensuring that the agreement will, in fact, be enforced.

Response: The Department does have the authority to remove a covered entity from the eligibility list if it (or its contract pharmacy) is found to have diverted 340B drugs to individuals who are not patients of the entity. To this end, the Department has developed a mechanism to receive and investigate complaints concerning drug diversion. This mechanism was published in the **Federal Register** for notice and comment on June 10, 1994 (59 FR 30021). In addition, the Department, at various public meetings concerning the implementation of 340B, has requested documentation of any covered entity drug diversion. To date, the Department has received no indication of drug diversion in relation to drugs purchased at 340B discount pricing that has required an official Departmental investigation.

Comment: The manufacturer appears to bear the sole risk arising from abuses of the program and has no recourse if such abuse occurs. The manufacturer

has limited ability to verify an arrangement between the covered entity and the contract pharmacy. Under the statute, the manufacturer's only remedy is to demand an audit; however, the lack of final audit guidelines has effectively prevented manufacturers from undertaking this type of activity. PHS should make arrangements for injunctive relief to prevent damages from ongoing violations of the statute, or provisions for terminating the participation of covered entities or their contractors.

Response: The manufacturer has sufficient remedies available to detect and eliminate abuse of the program. First, the manufacturer may audit the entity. Although the audit guidelines were not published in final form, we consider the proposed guidelines, published in the **Federal Register**, a sufficient statement of Department guidelines to allow manufacturers to proceed with an entity audit. Second, the Department has developed a dispute resolution process to provide parties with an informal mechanism to bring before the Department allegations of behavior that is in violation of 340B. Third, the contract pharmacy guidelines provide that if the covered entity or its contractor is found to have violated the 340B prohibition against drug diversion (and duplicate discounting), the covered entity could be removed from the list of covered entities and could no longer access 340B pricing.

Comment: The covered entity should establish a process for a quarterly reconciliation of its prescribing records with the contractor's inventory and dispensing records to provide for early detection of diversion and remediation of irregularities.

Response: We have included a provision that covered entity will establish a process for a quarterly random (sample) comparison of its prescribing records with the contractor's dispensing records to detect potential irregularities.

Comment: The covered entity should establish prior authorization protocol, assuring that the individual's status as a patient of the entity is confirmed by the entity in advance of product dispensing.

Response: The contractor should have some type of assurance that the patient to whom the contractor is dispensing the 340B drug is a patient of a covered entity participating in the 340B Program. To that end, we have added a provision to the guidelines stating that the covered entity and the contractor will develop a system to verify patient eligibility (e.g., eligible patient list or a validated prescription). Additionally, we have included a suggested contract provision which states, "(pharmacy) will dispense covered drugs only in the following circumstances: (1) Upon presentation of a prescription bearing the (covered entity's) name, the eligible patient's name, a designation that the patient is an eligible patient, and the signature of a legally qualified health care provider affiliated with the (covered entity); or (2) receipt of a prescription ordered by telephone on behalf of an eligible patient by a legally qualified health care provider affiliated with the (covered entity) who states that the prescription is for an eligible patient. The (covered entity) should provide a list to the (pharmacy) of all such qualified health care providers and will update the list of providers to reflect any changes, which is consistent with customary business practice."

Comment: The contract agreement should restrict pharmacy services to only those patients who receive their medical care from the covered entity.

Response: Provision (g) of the guidelines provides that the contractor will not resell or transfer a 340B drug to an individual who is not a patient of the entity. The Department issued proposed guidelines to define the word "patient" in a **Federal Register** notice on August 3, 1995. See 60 FR 39762. Provision (2) of the definition provides that an individual is a patient of a covered entity if, among other requirements, the "individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that the responsibility for the care provided remains with the covered entity." Currently, the Department is analyzing the comments received in response to that notice and is developing final guidelines.

It must be noted that the covered entity is responsible for any diversion of its drugs to ineligible individuals; therefore, it must make every effort to thoroughly scrutinize the contractor's dispensing records, to determine if the 340B drugs were dispensed to only eligible recipients. If a manufacturer believes that a covered entity contractor is diverting 340B drugs to ineligible recipients, the manufacturer should immediately contact the Department with this information and submit all supporting documentation so that a thorough investigation can be initiated.

Comment: PHS should oversee contractors' compliance with the contracts regarding the 340B prohibition against drug diversion and duplicate discounting.

Response: Because the covered entity purchases the drug, retaining title, and directs shipment to its contractor, it retains responsibility for the drug. If the drug generates a Medicaid rebate or is diverted to an individual who is not a patient of the covered entity, the entity will be responsible for such activity. The Department and a participating manufacturer have the authority to audit the records of the covered entity and the contractor that directly relate to that manufacturer's drugs and to the 340B prohibitions against drug diversion and duplicate discounting. See proposed Audit Guidelines, 59 FR 30021, June 10, 1994. Further, the Department has proposed a dispute resolution process in which a manufacturer may bring a claim against an entity for drug diversion or duplicate discounting. See Dispute Resolution, 59 FR 30023. If the entity (or its contractor) is found to have violated such prohibitions, the entity is required by 340B(a)(5)(D) to pay the manufacturer the amount of the discount in dispute, and, pursuant to 340B(a)(4), the Department may determine that the entity is no longer a "covered entity" eligible to access 340B pricing.

We have added several suggested contract provisions that are consistent with normal business practices to the guidelines (Appendix) to provide further technical assistance in this area. One provision concerning potential discrepancies in ordering and shipping states, "the pharmacy will compare all shipments received to the orders and inform the covered entity of any discrepancy within five (5) business days of receipt." Concerning an appropriate tracking system to prevent drug diversion, another provision states, "prior to the pharmacy providing pharmacy services pursuant to this agreement, the (covered entity) will have the opportunity, upon reasonable notice and during business hours, to examine the tracking system and may require (the pharmacy) to make any modifications to such system as the (covered entity) may, in its sole discretion, require. Such a system may include sample quarterly comparisons of eligible patient prescriptions to the dispensing records and a six (6) month comparison of 340B drug purchasing and dispensing records. The (pharmacy) will permit the (covered entity) or its duly authorized representatives to have reasonable access to (pharmacy's) facilities and records during the term of this agreement in order to make periodic checks regarding the efficacy of such tracking systems. (Pharmacy) agrees to

make any and all adjustments to the tracking system which (covered entity) advises are reasonably necessary to prevent diversion of covered drugs to individuals who are not patients of the (covered entity)."

Comment: There should be a process for excluding from the 340B Program those contractors that are in violation of the statute and the guidelines should explicitly note that the pharmacy contractor will be subject to additional civil or criminal penalties if violation of the guideline involves a violation of State or Federal law.

Response: Covered entities which are found to have violated the prohibitions of section 340B(a)(5) can be excluded from the 340B Program, after an appropriate opportunity to be heard. See Dispute Resolution Guidelines in 59 FR 30023, June 10, 1994. However, if the program finds that the pharmacy contractor has violated these statutory prohibitions, it cannot bar this pharmacy from dispensing 340B drugs for a covered entity. Nevertheless, the program intends to alert any entity which submits a certification with this particular pharmacy listed as the contractor as to this pharmacy's past activities. If the covered entity insists upon using this pharmacy, the Department will carefully scrutinize its activities. An additional provision was added to address the potential for civil or criminal penalties if the contractor violates Federal or State law.

Comment: The agreement should appoint the pharmacy contractor to be the agent of the covered entity and discuss the duties to be performed by the agent on behalf of the covered entity and the agent's rights.

Response: We believe that the relationship between the covered entity and the contract pharmacy is one of agency. However, the form of the relationship will be dictated by the terms of the contract; therefore, it is not essential to characterize the relationship as meeting or not meeting the standards which would serve under applicable law to establish an agency relationship. The contract terms address the relative duties of the parties in relation to section 340B and diversion and duplicate discount concerns that have been raised by the commenters. Accordingly, we have concluded that it is unnecessary to label the relationship between the covered entity and the contract pharmacy.

Comment: The contract pharmacy is fully accountable for maintaining the security of the PHS inventory.

Response: There is no requirement for a separate (physical) inventory for drugs purchased at a 340B discount, because a separate data system will be used to verify appropriate dispensing.

Comment: Contract pharmacies are most likely Medicaid pharmacy providers, while the covered entity likely is not. Because State Medicaid programs are unlikely to issue pharmacy numbers to anyone other than licensed pharmacies, covered entities that are not licensed pharmacies will not be able to bill Medicaid for prescriptions dispensed by the contract pharmacies. This task will be completed by the contract pharmacy. The mechanism excludes Medicaid drugs; therefore, the contract pharmacy must have two Medicaid numbers (i.e., 340B exclusion package and one to bill Medicaid for its regular customers). However, PHS has not required the contract pharmacy to do so. Moreover, neither the pharmacy nor the State has any incentive to "make arrangements" to carry out the statute, since both may gain from inadequate enforcement.

Response: The mechanism requires the parties to comply with the prohibition on filling Medicaid prescriptions with drugs purchased at 340B pricing. Neither the covered entity nor the contract pharmacy will bill Medicaid for 340B drug reimbursement; therefore, there will be no need for two Medicaid numbers. The 340B drugs will not generate Medicaid rebates.

Comment: As the owner of the drug, the covered entity should be responsible for establishing the price for each drug sold to a patient of the entity (effectively preventing the contractor from charging whatever price it chooses) and assuming full responsibility for such prices under the terms of the PHS grant and any applicable consumer protection laws.

Response: Even though it is clearly stated in the guidelines that the covered entity must purchase the drug (not the contractor), which would give to the covered entity title to and responsibility for the drug, we have added the following clarifying language to provision (a): "* * * will purchase the drug and will assume full responsibility for establishing its price, pursuant to terms of a PHS grant (if applicable) and any applicable consumer protection laws."

(6) Records

Comment: The contractor should assure that all pertinent reimbursement accounts and dispensing records maintained by the contractor for the covered entity are separate from the contractor's own operations and are accessible to the covered entity, PHS, and the manufacturers in the event of an audit. The contractor should provide these records to the manufacturer upon request.

Response: We have added the concept of separate records to provision (j) to assure the availability of these records in the case of an audit by the manufacturer. However, a manufacturer has statutory authority to access these entity records by performing an audit; therefore, to require the entity to submit records upon demand would be unduly burdensome.

Comment: ODP should establish standards for reporting that will ensure consistency of the information and approve whatever "record-keeping" system is used.

Response: Any reasonable system which will provide an adequate audit trail will be acceptable. However, reporting should be consistent with State pharmacy laws and other reporting mechanisms. As stated earlier in this section, sample contract provisions are suggested which describe such records and reports (e.g., prescription files, velocity reports, and records of ordering and receipt).

Comment: Reporting requirements should include some record or report that assures that only patients of the covered entity were served.

Response: Provision (f) provides that the contractor will provide the covered entity with reports as deemed appropriate using normal and customary business records.

Comment: The agreement should require that the pharmacy contractor maintain separate inventories and separate records for patients of the PHS entity contracting for pharmacy services.

Response: The guidelines have been changed to include a provision for separate dispensing records for patients of the covered entity. However, the requirement for a separate inventory of 340B drugs is unnecessary, because the covered entity is required to monitor dispensing and inventory records. In addition, these records are also subject to Department and manufacturer audits. A separate inventory is a wasteful concept with respect to time, space and money. Further, it provides little if any additional security, as a separate inventory only speaks to what is currently on the shelf and not what should be on the shelf. On the other hand, dispensing and other records will accurately indicate use of 340B drugs.

Comment: The covered entity is responsible for making arrangements to seek reimbursement from third parties for 340B drugs used in treating patients of the entity. If the covered entity receives a PHS grant, it would lose its

grant eligibility for failing to make appropriate arrangements.

Response: Since the entity purchases the drugs, it has the option of seeking reimbursement from third parties itself or contracting for this service. However, to the extent that a covered entity (or its contract pharmacy acting on its behalf) fails to comply with grant conditions, the entity may be subject to grant penalties.

Comment: To the extent that the covered entity makes arrangements for the pharmacy contractor to submit claims for third party reimbursement, the covered entity should assume full responsibility under State consumer protection laws, insurance, fraud, and State and Federal health care laws with respect to any false claims charges or allegations of consumer or insurance fraud.

Response: The ODP is not authorized to enforce or interpret such laws. If we become aware of possible violations of such laws, we will refer these cases to appropriate authorities.

(C) Contract Pharmacy Services Revised Final Mechanism

Covered entities that wish to utilize contract pharmacy services to dispense section 340B outpatient drugs are encouraged to sign and have in effect a contract pharmacy service agreement between the covered entity and the pharmacy. This mechanism is designed to facilitate program participation for those eligible covered entities that do not have access to appropriate "in-house" pharmacy services. *See* Appendix for suggested contract provisions.

(1) The following is a suggested model agreement format:

(a) The covered entity will purchase the drug and assume responsibility for establishing its price, pursuant to the terms of a PHS grant (if applicable) and any applicable consumer protection laws.

A "ship to, bill to" procedure may be used in which the covered entity purchases the drug, the manufacturer bills the entity for the drug that it purchased, but ships the drug directly to the contract pharmacy. *See* section 1 of Appendix.

(b) The contractor will provide all pharmacy services (e.g., dispensing, record keeping, drug utilization review, formulary maintenance, patient profile, counseling). Each covered entity which purchases its covered outpatient drugs has the option of individually contracting for pharmacy services with the pharmacy of its choice. The limitation of one pharmacy contractor per entity does not preclude the selection of a pharmacy contractor with multiple pharmacy sites, as long as only one site is used for the contracted services. [The ODP will be evaluating the feasibility of permitting these covered entities to contract with more than one site and contractor.]

(c) The covered entity health care provider will inform the patient of his or her freedom to choose a pharmacy provider. If the patient does not elect to use the contracted service, the patient may obtain the prescription from the covered entity and then obtain the drug(s) from the pharmacy provider of his or her choice.

When a patient obtains a drug from a retail pharmacy other than the entity contract pharmacy, the manufacturer is not required to offer this drug at 340B pricing.

(d) The contractor may provide the covered entity services, other than pharmacy, at the option of the covered entity (e.g., home care, reimbursement services). Regardless of the services provided by the contractor, access to 340B pricing will always be restricted to only patients of the covered entity.

(e) The contractor and the covered entity will adhere to all Federal, State, and local laws and requirements. Additionally, all PHS grantees will adhere to all rules and regulations established by the grant funding office.

Both the covered entity and the contract pharmacy are aware of the potential for civil or criminal penalties if the covered entity and/or the contract pharmacy violate Federal or State law. [The Department reserves the right to take such action as may be appropriate if it determines that such a violation has occurred.]

(f) The contractor will provide the covered entity with reports consistent with customary business practices (e.g., quarterly billing statements, status reports of collections and receiving and dispensing records). See Section 2 of Appendix.

(g) The contractor, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of section 340B discounted drugs to individuals who are not patients of the covered entity. Customary business records may be used for this purpose. The covered entity will establish a process for a periodic random (sample) comparison of its prescribing records with the contractor's dispensing records to detect potential irregularities. See Section 3 of Appendix.

(h) The covered entity and the contract pharmacy will develop a system to verify patient eligibility. [The Department's draft guidance defining covered entity "patient" is set forth in an August 3, 1995, **Federal Register** notice. See 60 FR 39762.]

Both parties agree that they will not resell or transfer a drug purchased at section 340B pricing to an individual who is not a patient of the covered entity. See section 340B(a)(5)(B). The covered entity understands that it can be removed from the list of covered entities because of its participation in drug diversion, a 340B(a)(5) prohibition, and no longer be eligible for 340B pricing. See Section 4 of Appendix.

(i) Both parties will not use drugs purchased under section 340B to dispense Medicaid prescriptions, unless the contract pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounting.

(j) Both parties understand that they are subject to audits (by the Department and participating manufacturers) of records that directly pertain to the entity's compliance with the drug resale or transfer prohibition and the prohibition against duplicate Medicaid rebates and 340B discounts. See section 340B(a)(5).

The contractor will assure that all pertinent reimbursement accounts and dispensing records, maintained by the contractor, will be separate from the contractor's own operations and will be accessible to the covered entity, the Department, and the manufacturer in the case of a manufacturer audit.

(k) Upon request, a copy of this contract pharmacy service agreement will be provided to a participating manufacturer which sells covered outpatient drugs to the covered entity. All confidential propriety information may be deleted from the document.

(2) Certification

Under section 340B, we believe that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price. If the entity directs the drug shipment to its contract pharmacy, we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance. However, the entity must comply, under any distribution mechanism, with the statutory prohibition on drug diversion and duplicating discounting.

To provide ODP and manufacturers with assurance that the covered entity has acted in a manner which limits the potential for drug diversion, the covered entity is encouraged to submit to ODP a certification that it has signed and has in effect an agreement with the contract pharmacy containing the aforementioned provisions. However, ODP will review any alternative mechanism which is designed to reduce the potential for drug diversion. The names of those covered entities which submit a certification, or an alternate mechanism approved by ODP, will be placed on the EDRS for the convenience of participating drug manufacturers.

(3) Anti-kickback Statute

Contractors and covered entities must be aware of the potential for civil or criminal penalties if the contractor violates Federal or State law. In negotiating and executing a contracted pharmacy service agreement pursuant to these guidelines, contractors and covered entities should be aware of and take into consideration the provisions of the Medicare and Medicaid anti-kickback statute, 42 U.S.C. 1320a–7b(b). This statute makes it a felony for a person or entity to knowingly and willfully offer, pay, solicit, or receive

remuneration with the intent to induce, or in return for the referral of, Medicare or a State health care program business. State health care programs are Medicaid, the Maternal and Child Health Block Grant program, and the Social Services Block Grant program. Apart from the criminal penalties, a person or entity is also subject to exclusion from participation in the Medicare and State health care programs for a knowing and willful violation of the statute pursuant to 42 U.S.C. 1320a–7(b)(7).

The anti-kickback statute is very broad. Prohibited conduct covers not only remuneration intended to induce referrals of patients, but also includes remuneration intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or a State health care program. The statute specifically identifies kickbacks, bribes, and rebates as illegal remuneration, but also covers the transferring of anything of value in any form or manner whatsoever. This illegal remuneration may be furnished directly or indirectly, overtly or covertly, in cash or in kind and covers situations where there is no direct payment at all, but merely a discount or other reduction in price or the offering of a free good(s).

Arrangements between contractors and covered entities that could violate the anti-kickback statute would include any situation where the covered entity agrees to refer patients to the contractor in return for the contractor agreeing to undertake or furnish certain activities or services to the covered entity at no charge or at a reduced or below cost charge. These activities or services would include the provision of contracted pharmacy services, home care services, money or grants for staff or service support, or medical equipment or supplies, and the remodeling of the covered entity's premises. For example, if a contractor agreed to furnish covered outpatient drugs in return for the covered entity referring its Medicaid patients to the contractor to have their prescriptions filled, the arrangement would violate the anti-kickback statute. Similarly, if the contractor agreed to provide billing services for the covered entity at no charge in return for the covered entity referring its patients to the contractor for home or durable medical equipment, the statute would be violated.

Pursuant to the authority in 42 U.S.C. 1320a–7b(b)(3), the Secretary of HHS has published regulations setting forth certain exceptions to the anti-kickback statute, commonly referred to as "safe harbors." These regulations are codified at 42 CFR 1001.952. Each of the safe harbors sets forth various requirements which may be met in order for a person or entity to be immune from prosecution or exclusion.

(D) Appendix—Suggested Contract Provisions

(1) "The covered entity will order covered drugs directly from the manufacturer, from a designated sales representative, or a drug wholesaler and arrange to be billed directly for such drugs. The covered entity will arrange for shipment of such drugs directly to the pharmacy. The pharmacy will compare all shipments received to the orders and inform the covered entity of any discrepancy within five (5) business days of receipt. The covered entity will make timely payments for such drugs delivered to the (pharmacy) pursuant to the entity's order."

(2) "The covered entity will verify, using the contractor's (readily retrievable) customary business records, that a tracking system exists which will ensure that drugs purchased under the Act are not diverted to individuals who are not patients of the covered entity. Such records can include: prescription files, velocity reports, and records of ordering and receipt. These records will be maintained for the period of time required by State law and regulations."

(3) "Prior to the pharmacy providing pharmacy services pursuant to this agreement, the covered entity will have the opportunity, upon reasonable notice and during business hours, to examine the tracking system. For example, such a tracking system may include quarterly sample comparisons of eligible patient prescriptions to the dispensing records and a six (6) month comparison of 340B drug purchasing and dispensing records as is routinely done in other reconciliation procedures. The pharmacy will permit the covered entity or its duly authorized representatives to have reasonable access to pharmacy's facilities and records during the term of this agreement in order to make periodic checks regarding the efficacy of such tracking systems. The pharmacy agrees to make any and all adjustments to the tracking system which covered entity advises are reasonably necessary to prevent diversion of covered drugs to individuals who are not patients of the covered entity."

(4) "The pharmacy will dispense covered drugs only in the following circumstances: (a) Upon presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the patient is an eligible patient, and the signature of a legally qualified health care provider affiliated with the covered entity; or (b) receipt of a prescription ordered by telephone on behalf of an eligible patient by a legally qualified health care provider affiliated with the covered entity who states that the prescription is for an eligible patient. The covered entity will furnish a list to the pharmacy of all such qualified health care providers and will update the list of providers to reflect any changes. If a contract pharmacy is found to have violated the drug diversion prohibition, the pharmacy will pay the entity the amount of the discount in question so that the entity can reimburse the manufacturer."

Dated: August 14, 1996.

Thomas G. Morford,

Acting Administrator, Health Resources and Services Administration.

[FR Doc. 96–21485 Filed 8–22–96; 8:45 am]

BILLING CODE 4160–15–P

National Institutes of Health

National Heart, Lung, and Blood Institute; Proposed Collection; Comment Request the Framingham Study

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on the proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

PROPOSED COLLECTION: Title: The Framingham Study. Type of Information Collection Request: Extension of a currently approved collection (OMB No. 0925–0216). Need and Use of Information Collection: This project involves physical examination and testing of the surviving members of the original Framingham Study cohort and the surviving members of the offspring cohort. Investigators will contact doctors, hospitals, and nursing homes to ascertain participants' cardiovascular events occurring outside the study clinic. Information gathered will be used to further describe the risk factors, occurrence rates, and consequences of cardiovascular disease in middle aged and older men and women. Frequency of Response: The cohort participants respond every two years; the offspring participants respond every four years. Affected Public: Individuals or households; Businesses or other for profit; Small businesses or

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
106.100	5	10	50	4,000	200,000
107.50(c)(3)	3	10	30	3,000	90,000
Total					290,000

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

In compiling these estimates, FDA consulted its records of the number of infant formula submissions received in the past. The figures for hours per response are based on estimates from experienced persons in the agency and in industry.

Dated: January 8, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–331 Filed 1–11–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: Section 340B of the Public Health Service Act implements a drug pricing program in which manufacturers who sell covered outpatient drugs to covered entities must agree to charge a price that will not exceed an amount determined under a statutory formula. The purpose of this notice is to inform interested parties of proposed guidelines regarding contract pharmacy services that will allow covered entities to utilize contract pharmacy services arrangements previously limited to the Alternative Methods Demonstration Project program.

DATES: The public is invited to comment on the proposed guidelines by March 13, 2007. After consideration of the submitted comments, the Health Resources and Services Administration (HRSA) will issue the final guidelines.

ADDRESSES: Address all comments to Mr. Bradford R. Lang, Public Health Analyst, Office of Pharmacy Affairs (OPA), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mr. Jimmy Mitchell, Director, OPA, HRSA, 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, MD 20857, or by telephone through the Pharmacy Services Support Center at 1–800–628–6297.

SUPPLEMENTARY INFORMATION:

A. Background

Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service Act, Limitation on Prices of Drugs Purchased by Covered Entities. Previous guidelines pertaining to contract pharmacy services for the 340B drug pricing program (61 FR 43549, Aug. 23, 1996) stated that a covered entity could contract with only one pharmacy to provide all pharmacy services for any particular site of the covered entity. Furthermore, if the contract pharmacy had multiple locations, the covered entity site had to choose one, and only one, contract pharmacy location for provision of these services.

In 2001, HRSA established Alternative Methods Demonstration Projects (AMDPs) which allowed covered entities that applied and were approved by HRSA to pursue alternatives to contracting with a single pharmacy. These alternative models included the following: (1) The use of multiple contract pharmacy service sites, (2) the utilization of a contract pharmacy to supplement in-house pharmacy services, and/or (3) the development of a network of 340B covered entities. The intent was to allow community health centers and other 340B safety-net providers to develop new ways to improve access to 340B prescription drugs for their patients. From the time of the program's inception until the end of April 2006, a total of 18 AMDPs were approved. Of those, 11 utilize a multiple contract pharmacies model, four establish a network of 340B covered entities, one is a combination of the network model and the multiple contract pharmacies model, one utilizes a contract pharmacy to supplement an in-house pharmacy, and one utilizes multiple contract pharmacies to supplement an in-house pharmacy. All but one of the projects is currently ongoing. A condition of AMDP approval is the requirement that the approved demonstration project be audited annually by an independent, outside auditor for drug diversion and duplicative discounts under Medicaid. The results of the audits are required to be reported to the Office of Pharmacy Affairs (OPA). To date, there has been no evidence of drug diversion or duplicate manufacturer's discounts on 340B drugs in the AMDP program.

HRSA, acting through OPA, is proposing new guidelines that would allow covered entities to utilize multiple contract pharmacy service sites and the utilization of a contract pharmacy to supplement in-house pharmacy services that were previously limited to approved AMDPs. This proposed change is due to the success of the AMDPs, and the urging of safety net providers who wish to utilize alternatives to the single entity site/single pharmacy location contractor model to provide broader access to 340B discounted drugs to eligible patient populations. Other than permitting these specified models, HRSA is not proposing other substantive changes to the contract pharmacy guidelines. The AMDP process will continue for those covered entities wishing to develop 340B networks of covered entities. OPA will continue to review the utilization of network demonstration projects and consider adapting the rules to include them in the future. Of particular importance is the continued requirement that appropriate procedures be in place to prevent diversion of 340B drugs or a duplicative 340B drug discount and a Medicaid rebate on the same drug, which are prohibited under the statute.

These proposed guidelines replace all sections of previous 340B Program guidance documents addressing non-network contract pharmacy services, including, but not limited to, the "Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services," 61 FR

43549 and any individual correspondence issued by HRSA on the subject. Demonstration projects previously approved under the multiple contract pharmacy model, the supplement to in-house pharmacy model, or a combination of the two models when this Federal guidance goes into effect, would be governed by this guidance and would no longer be subject to expiration of AMDPs, interim reporting or annual audits currently mandatory for all demonstration projects (this guidance only applies to audits required under the AMDP and leaves unchanged audit requirements under any other authority or program). While annual audits will no longer be required to be provided to OPA annually, covered entities are required to maintain fully auditable records and OPA expects covered entities to include appropriate sampling of multiple contract pharmacy arrangements in the course of routine annual audits. Demonstration projects previously approved to utilize the network model would continue to be subject to all program requirements and conditions set up under the AMDP. Any covered entity wishing to utilize a network model would still be required to seek approval under the AMDP and may not do so without formal approval.

B. Contract Pharmacy Services Mechanism

(1) Basic Requirements for Utilization of Contract Pharmacy Arrangements

Covered entities that wish to utilize contract pharmacy services to dispense section 340B outpatient drugs must have a written contract in place between themselves and a pharmacy. This mechanism is designed to facilitate program participation for those covered entities that do not have access to available or appropriate "in-house" pharmacy services, those covered entities who have access to "in-house" pharmacy services but who wish to supplement these "in-house" services, and covered entities that wish to utilize multiple contract pharmacies to increase patient access to 340B drugs. The covered entity has the responsibility to: ensure against illegal diversion and duplicate discounts, maintain readily auditable records, and meet all other 340B Drug Pricing Program requirements. OPA has provided a model agreement format below as guidance for the type of contractual provisions expected in such agreements as well as suggested contract provisions in the Appendix. All covered entities utilizing a contract pharmacy must comply with the certification requirements described in (4) below.

(2) Potential Alternatives to Single Location, Single Pharmacy Model

In addition to contracting with a single pharmacy for each clinical site, covered entities may pursue more complex arrangements that include multiple pharmacies only if: (a) There is a written agreement and procedures meeting the basic requirements outlined in (1) above between the covered entity and each pharmacy; (b) the operation continues to meet all 340B Drug Pricing Program requirements and does not create unlawful diversion or duplicate discounts; and (c) the arrangements are one of the two following models individually or in combination: (i) The use of multiple contract pharmacy service sites, and/or (ii) the utilization of a contract pharmacy (ies) to supplement in-house pharmacy services. The use of multiple contract pharmacy service sites refers to any arrangement wherein a covered entity site seeks to provide drugs at 340B discounted prices for its patients at more than one pharmacy location. Supplementing in-house pharmacy services with a contract pharmacy refers to any arrangement wherein a covered entity site seeks to purchase drugs at 340B discounted prices for its patients at both an in-house pharmacy and at least one additional contract pharmacy location.

(3) Model Agreement Provisions

The following are suggested provisions for a model agreement:

(a) The covered entity will purchase the drug, maintain title to the drug and assume responsibility for establishing its price, pursuant to the terms of a HHS grant (if applicable) and any applicable state and local laws and consumer protection laws.

A "ship to, bill to" procedure is used in which the covered entity purchases the drug; the manufacturer/wholesaler must bill the covered entity for the drug that it purchased, but ships the drug directly to the contract pharmacy (Section 1 of Appendix.) In cases where a covered entity has more than one site, it may choose between having each site billed individually or designating a single covered entity billing address for all 340B drug purchases.

(b) The contract pharmacy will provide comprehensive pharmacy services (e.g., dispensing, recordkeeping, drug utilization review, formulary maintenance, patient profile, patient counseling, and medication therapy management services). Each covered entity which purchases its covered outpatient drugs has the option of individually contracting for pharmacy services with a pharmacy(ies) of its choice.

(c) The covered entity health care provider will inform the patient of his or her freedom to choose a pharmacy provider. If the patient does not elect to use the contracted service, the patient may obtain the prescription from the covered entity and then obtain the drug(s) from the pharmacy provider of his or her choice.

When a patient obtains a drug from a retail pharmacy other than a covered entity's contract pharmacy, the manufacturer is not required to offer this drug at the 340B price.

(d) The contract pharmacy may provide other services to the covered entity at the option of the covered entity (e.g., home care, delivery, reimbursement services). Regardless of the services provided by the contract pharmacy, access to 340B pricing will always be restricted to only patients of the covered entity.

(e) The contract pharmacy and the covered entity will adhere to all Federal, State, and local laws and requirements. Additionally, all HHS grantees, disproportionate share hospitals and FQHC Look-Alikes will adhere to all rules and regulations that apply to them as grantees or otherwise eligible entities.

Both the covered entity and the contract pharmacy are aware of the potential for civil or criminal penalties if the covered entity and/or the contract pharmacy violate Federal or State law. [The Department reserves the right to take such action as may be appropriate if it determines that such a violation has occurred.]

(f) The contract pharmacy will provide the covered entity with reports consistent with customary business practices (e.g., quarterly billing statements, status reports of collections and receiving and dispensing records). *See* Section 2 of Appendix.

(g) The contract pharmacy, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of section 340B drugs to individuals who are not patients of the covered entity. Customary business records may be used for this purpose. The covered entity will establish a process for a periodic comparison of its prescribing records with the contract pharmacy's dispensing records to detect potential irregularities. *See* Section 3 of Appendix.

(h) The covered entity and the contract pharmacy will develop a system to verify patient eligibility, as defined by HRSA guidelines.

Both parties agree that they will not resell or transfer a drug purchased at section 340B prices to an individual who is not a patient of the covered entity. *See* 42 U.S.C. 256a(a)(5)(B). The covered entity understands that it can be removed from the list of covered entities because of its participation in drug diversion and no longer be eligible for 340B pricing. *See* Section 4 of Appendix.

(i) Neither party will use drugs purchased under section 340B to dispense Medicaid prescriptions, unless the covered entity, the contract pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounts. Any such arrangement shall be reported to the Office of Pharmacy Affairs by the covered entity.

(j) Both parties understand that they are subject to audits (by the Department and participating manufacturers) of records that directly pertain to the entity's compliance with the drug resale or transfer prohibition and the prohibition against duplicate discounts. *See* 42 U.S.C § 256a(a)(5).

The contract pharmacy will assure that all pertinent reimbursement accounts and dispensing records, maintained by the pharmacy, will be accessible separately from the pharmacy's own operations and will be made available to the covered entity, the Department, and the manufacturer in the case of an audit.

(k) Upon written request to the covered entity, a copy of this contract pharmacy service agreement will be provided to a participating manufacturer which sells covered outpatient drugs to the covered entity. All confidential or proprietary information may be deleted from the document.

(4) Certification

Under section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price. If the entity directs the drug shipment to its contract pharmacy(ies), we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance. However, the entity must comply, under any distribution mechanism, with the statutory prohibition on drug diversion and duplicate discounting.

To provide OPA and manufacturers with assurance that the covered entity has acted in a manner which limits the potential for drug diversion, the covered entity is required to submit to OPA a certification that it has signed and has in effect an agreement with the contract pharmacy(ies) containing the aforementioned provisions (see 3 above). However, if a covered entity wishes to utilize an agreement with provisions different from those listed above that it believes meets 340B requirements; OPA will review the proposed agreement provisions for sufficiency. The names of those covered entities which submit a certification, or an alternate mechanism approved by OPA, will be listed on the OPA Web site for the convenience of participating drug manufacturers and wholesaler distributors.

In addition, any covered entity that has opted to utilize any pharmacy arrangement described in (2) must specify which arrangement or combination of arrangements it is utilizing, the names and 340B identification numbers of all covered entities participating, and the names of any pharmacies participating.

(5) Anti-Kickback Statute

Contract pharmacies and covered entities should be aware of the potential for civil or criminal penalties if the contract pharmacy violates Federal or State law. In negotiating and executing a contract pharmacy service agreement pursuant to these guidelines, contract pharmacies and covered entities should be aware of and take into consideration the provisions of the Medicare and Medicaid anti-kickback statute, 42 U.S.C. 1320a–7b(b). This statute makes it a felony for a person or entity to knowingly and willfully offer, pay, solicit, or receive remuneration with the intent to induce, or in return for the referral of, Medicare or a State health care program business. State health care programs are Medicaid, the Maternal and Child Health Block Grant program, and the Social Services Block Grant program. Apart from the criminal penalties, a person or entity is also subject to exclusion from participation in the Medicare and State health care programs for a knowing and willful violation of the statute pursuant to 42 U.S.C. 1320a–7(b)(7).

The anti-kickback statute is very broad. Prohibited conduct covers not only remuneration intended to induce referrals of patients, but also includes remuneration intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or a State health care program. The statute specifically identifies kickbacks, bribes, and rebates as illegal remuneration, but also covers the transferring of anything of value in any form or manner whatsoever. This illegal remuneration may be furnished directly or indirectly, overtly or covertly, in cash or in kind and covers situations where there is no direct payment at all, but merely a discount or other reduction in price or the offering of a free good(s).

Arrangements between contract pharmacies and covered entities that could violate the anti-kickback statute would include any situation where the covered entity agrees to refer patients to the contract pharmacy in return for the contract pharmacy or an entity owned or controlled by the contract pharmacy agreeing to undertake or furnish certain activities or services to the covered entity at no charge or at a reduced or below cost charge. These activities or services would include the provision of contract pharmacy services, home care services, money or grants for staff or service support, or medical equipment or supplies, or the remodeling of the covered entity's premises. For example, if a contract pharmacy agreed to furnish covered outpatient drugs in return for the covered entity referring its Medicaid patients to the contract pharmacy to have their prescriptions filled, the arrangement would violate the anti-kickback statute. Similarly, if the contract pharmacy agreed to provide billing services for the covered entity at no charge in return for the covered entity referring its patients to the contract pharmacy for home or durable medical equipment, the statute would be violated.

Pursuant to the authority in 42 U.S.C. 1320a–7b(b)(3), the Secretary of HHS has published regulations setting forth certain exceptions to the anti-kickback statute, commonly referred to as "safe harbors." These regulations are codified at 42 CFR 1001.952. Each of the safe harbors sets forth various requirements which must be met in order for a person or entity to be immune from prosecution or exclusion under the safe harbors.

C. Appendix—Suggested Contract Provisions

(1) "The covered entity owns covered drugs and arranges to be billed directly for such drugs. The pharmacy will compare all shipments received to the orders and inform the covered entity of any discrepancy within five (5) business days of receipt. The covered entity will make timely payments for such drugs delivered to the (pharmacy)."

(2) "The covered entity will verify, using the contract pharmacy's (readily retrievable) customary business records, that a tracking system exists which will

ensure that drugs purchased under the 340B Drug Pricing Program are not diverted to individuals who are not patients of the covered entity. Such records can include: prescription files, velocity reports, and records of ordering and receipt. These records will be maintained for the period of time required by State law and regulations.''

(3) ''Prior to the contract pharmacy providing pharmacy services pursuant to this agreement, the covered entity will have the opportunity, upon reasonable notice and during business hours, to examine the tracking system. For example, such a tracking system may include quarterly sample comparisons of eligible patient prescriptions to the dispensing records and a six (6) month comparison of 340B drug purchasing and dispensing records as is routinely done in other reconciliation procedures. The contract pharmacy will permit the covered entity or its duly authorized representatives to have reasonable access to contract pharmacy's facilities and records during the term of this agreement in order to make periodic checks regarding the efficacy of such tracking systems. The contract pharmacy agrees to make any and all adjustments to the tracking system which the covered entity advises are reasonably necessary to prevent diversion of covered drugs to individuals who are not patients of the covered entity.''

(4) ''The pharmacy will dispense covered drugs only in the following circumstances: (a) Upon presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the patient is an eligible patient of the covered entity, and the signature of a legally qualified health care provider affiliated with the covered entity; or (b) receipt of a prescription ordered by telephone or other means of electronic transmission that is permitted by State or local law on behalf of an eligible patient by a legally qualified health care provider affiliated with the covered entity who states that the prescription is for an eligible patient. The covered entity will furnish a list to the pharmacy of all such qualified health care providers and will update the list of providers to reflect any changes. If a contract pharmacy is found to have violated the drug diversion prohibition, the contract pharmacy will pay the covered entity the amount of the discount in question so that the covered entity can reimburse the manufacturer.''

Dated: December 22, 2006.

Elizabeth M. Duke,

Administrator.

[FR Doc. E7–334 Filed 1–11–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of ''Patient''

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: Section 602 of Public Law 102–585, the ''Veterans Health Care Act of 1992,'' enacted Section 340B of the Public Health Service (PHS) Act ''Limitation on Prices of Drugs Purchased by Covered Entities.'' Section 340B provides that in order to obtain Medicaid reimbursement for its covered outpatient drugs, a manufacturer must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price to covered entities for outpatient drugs that will not exceed an amount determined under a statutory formula. Section 340B is administered as the ''340B Drug Pricing Program'' and is commonly referred to as ''the 340B Program.''

Section 340B states that it is illegal for covered entities to sell medications purchased under the 340B Program to persons who are not considered ''patients'' of the covered entity. The purpose of this notice is to inform interested parties of proposed clarifications to the definition of ''patient'' for whom the covered entity can purchase discounted pharmaceuticals under the 340B Program. This clarification is necessary to protect the integrity of the 340B Program and to assist covered entities and other participants in their compliance efforts.

DATES: The public is invited to submit comments on the proposed guidelines by March 13, 2007. After consideration of the comments submitted, the Secretary will issue final guidelines.

ADDRESSES: Address all comments to Mr. Bradford R. Lang, Public Health Analyst, Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mr. Jimmy Mitchell, Director, OPA, HSB, HRSA, 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, MD 20857, or by telephone through the Pharmacy Services Support Center at 1–800–628–6297.

SUPPLEMENTARY INFORMATION:

Introduction

Section 340B(a)(4) of the PHS Act and section 1927(a) of the Social Security Act list the various types of organizations eligible to participate in and purchase discounted drugs under the 340B Program. Eligibility for participation in the 340B Program is strictly limited to the specific categories of entities specified in these statutes.

Section 340B(a)(5)(B) of the PHS Act prohibits entities from selling (or otherwise transferring) drugs purchased under the 340B Program to anyone who is not a patient of the covered entity. Responsibility for ensuring compliance with this provision rests with the covered entity. Congress did not define the term ''patient'' in Section 340B, and initial HRSA guidelines implementing the 340B Program directed covered entities to ''develop and institute adequate safeguards to prevent the transfer of discounted outpatient drugs to individuals who are not eligible for the discount'' in order to prevent diversion. To accomplish this, entities were encouraged to utilize a separate purchasing account and separate dispensing records (See 59 FR 25110).

As covered entities, manufacturers, and others began to implement the 340B Program, it became apparent that additional clarification of the patient definition was needed and on October 24, 1996, HRSA issued additional guidelines regarding the definition of a covered entity ''patient'' (61 FR 55156). These guidelines stated that the following definition of patient would apply for the purposes of the 340B Program:

An individual is a ''patient'' of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if:

1. *The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and*

2. *The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity; and*

3. *The individual receives a health care service or range of services from the covered entity which is consistent with the service or*

republished in its entirety; and amended on September 28, 2009 to provide targeted liability protections for pandemic countermeasures to enhance distribution and to add provisions consistent with other declarations and republished in its entirety. This Declaration incorporates all amendments prior to the date of its publication in the **Federal Register**. Any future amendment to this Declaration will be published in the **Federal Register**, pursuant to section 319F–2(b)(4) of the Act.

X. Definitions

For the purpose of this Declaration, including any claim for loss brought in accordance with section 319F–3 of the PHS Act against any covered persons defined in the Act or this Declaration, the following definitions will be used:

Administration of a Covered Countermeasure: As used in section 319F–3(a)(2)(B) of the Act includes, but is not limited to, public and private delivery, distribution, and dispensing activities relating to physical administration of the countermeasures to recipients, management and operation of delivery systems, and management and operation of distribution and dispensing locations.

Authority Having Jurisdiction: Means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.*, city, county, Tribal, State, or Federal boundary lines) or functional (*e.g.*, law enforcement, public health) range or sphere of authority.

Covered Persons: As defined at section 319F–3(i)(2) of the Act, include the United States, manufacturers, distributors, program planners, and qualified persons. The terms "manufacturer," "distributor," "program planner," and "qualified person" are further defined at sections 319F–3(i)(3), (4), (6), and (8) of the Act.

Declaration of Emergency: A declaration by any authorized local, regional, State, or Federal official of an emergency specific to events that indicate an immediate need to administer and use pandemic countermeasures, with the exception of a Federal declaration in support of an emergency use authorization under section 564 of the FDCA unless such declaration specifies otherwise.

Pandemic influenza A viruses and those with pandemic potential: Animal and/or human influenza A viruses, except those included in seasonal influenza vaccines and/or covered under the National Vaccine Injury Compensation Program, that are circulating in wild birds and/or domestic animals, that cause, or have significant potential to cause, sporadic or ongoing human infections, or historically have caused pandemics in humans, or have mutated to cause pandemics in humans, and for which the majority of the population is immunologically naïve.

Pandemic Phase: The following stages, as defined in the National Strategy for Pandemic Influenza: Implementation Plan (Homeland Security Council, May 2006): (4) First Human Case in North America; and (5) Spread Throughout United States.

Pre-pandemic Phase: The following stages, as defined in the National Strategy for Pandemic Influenza: Implementation Plan (Homeland Security Council, May 2006): (0) New Domestic Animal Outbreak in At-Risk Country; (1) Suspected Human Outbreak Overseas; (2) Confirmed Human Outbreak Overseas; and (3) Widespread Human Outbreaks in Multiple Locations Overseas.

Dated: February 26, 2010.

Kathleen Sebelius,

Secretary.

APPENDIX

I. List of U.S. Government Contracts—Covered H5N1, H2, H6, H7, H9, and 2009–H1N1 Vaccine Contracts

1. HHSN266200400031C
2. HHSN266200400032C
3. HHSN266200300039C
4. HHSN266200400045C
5. HHSN266200205459C
6. HHSN266200205460C
7. HHSN266200205461C
8. HHSN266200205462C
9. HHSN266200205463C
10. HHSN266200205464C
11. HHSN266200205465C
12. HHSN266199905357C
13. HHSN266200300068C
14. HHSN266200005413C
15. HHSO100200600021C (formerly 200200409981)
16. HHSO100200500004C
17. HHSO100200500005I
18. HHSO100200700026I
19. HHSO100200700027I
20. HHSO100200700028I
21. HHSO100200600010C
22. HHSO100200600011C
23. HHSO100200600012C
24. HHSO100200600013C
25. HHSO100200600014C
26. HHSO100200600022C (formerly 200200511758)
27. HHSO100200600023C (formerly 200200410431)
28. CRADA No. AI–0155 NIAID/MedImmune
29. HHSO100200700029C
30. HHSO100200700030C
31. HHSO100200700031C
32. All present, completed and future Government H5N1, H2, H6, H7, H9, and 2009–H1N1 vaccine contracts not otherwise listed.

[FR Doc. 2010–4644 Filed 3–4–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final notice.

SUMMARY: Section 602 of Public Law 102–585, the "Veterans Health Care Act of 1992" enacted Section 340B of the Public Health Service Act (PHS). Section 340B implements a drug pricing program by which manufacturers who sell covered outpatient drugs to particular covered entities listed in the statute must agree to charge a price that will not exceed the amount determined under a statutory formula. The purpose of this Final Notice is to inform interested parties of final guidelines regarding the utilization of multiple contract pharmacies and suggested contract pharmacy provisions, which had been previously limited to the Alternative Methods Demonstration Project program.

FOR FURTHER INFORMATION CONTACT: Mr. Jimmy Mitchell, Director, Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, Maryland 20857 or by telephone through the Pharmacy Services Support Center at 1–800–628–6297.

DATES: *Effective Date:* April 5, 2010.

SUPPLEMENTARY INFORMATION:

A. Background

Proposed guidelines for contract pharmacy services were announced in the **Federal Register** at 72 FR 1540 on January 12, 2007. A comment period of 60 days was established to allow interested parties to submit comments. HRSA, HSB, acting through the OPA, received 32 comments concerning the proposal.

In 1996, HRSA issued guidelines that permitted covered entities participating in the 340B Drug Pricing Program to contract with a pharmacy to provide services to the covered entity's patients (61 FR 43549, August 23, 1996). Those guidelines permitted a covered entity to use a single point for pharmacy services, either an in-house pharmacy or an

individual contract pharmacy. Since 2001, covered entities that have wanted to use other types of arrangements, or to blend the method of providing services (*e.g.* contract pharmacy to supplement an in-house pharmacy) have needed to apply to the OPA for an Alternative Methods Demonstration Project (AMDP) and secure approval in order to proceed.

It is important for all covered entities to keep in mind that use of a contract pharmacy arrangement (single, multiple or AMDP) does not lessen a covered entity's duty to ensure that the 340B program is being administered in compliance with the statute and HRSA guidelines. The covered entity has, and continues to bear, full responsibility and accountability for compliance with all requirements to prevent diversion of covered drugs to individuals other than patients of the covered entity, and to prevent situations in which a drug is subject to both the 340B discount and a Medicaid Rebate claim. Covered entities will be permitted to use multiple pharmacy arrangements as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition. Auditable records must be maintained to demonstrate compliance with those requirements. Such records must be maintained for as long as required by Federal, State and local law. Additionally, compliance with 340B requirements and guidelines does not excuse individual providers, covered entities, pharmacies, wholesale distributors or manufacturers from adherence to all other local, State or Federal requirements.

Covered entities should also be mindful that use of a contract pharmacy is voluntary. Covered entities are not required to use multiple contract pharmacies or any contract pharmacy at all. Each covered entity should conduct its own business review and patient assessment to determine what level of pharmacy services is needed, and the appropriate delivery mechanism for those services.

We received many comments in support of the proposal. Many of these came from covered entities that participate in 340B and highlighted how their delivery of patient care would be enhanced with a multiple contract pharmacy option. According to these comments, some patients currently face transportation barriers or other obstacles that limit their ability to fill their prescriptions. It would be a significant benefit to patients to allow the use of more easily accessible, multiple contract pharmacy arrangements by covered entities. This would permit covered entities to more effectively utilize the 340B program and create wider patient access by having more inclusive arrangements in their communities which would benefit covered entities, pharmacies and patients served.

Comments raised a number of issues: Audits; protecting against diversion; network models; limits on the number or location of contract pharmacies; and the need for model agreement provisions and certification procedures. Also addressed was the potential impact on manufacturers, pharmacies, covered entities and patients. Additional comments challenged the sufficiency of the data used to justify the changes, and questioned whether the proposed notice was in compliance with the Administrative Procedure Act.

The following section presents a summary of all major comments, grouped by subject, and a response to each grouping. All comments were considered in developing this Final Notice, and changes were made accordingly. Other changes were made to improve clarity and readability.

B. Comments and Responses

(1) Administrative Procedure Act (APA) Compliance

Comment: The proposed revisions represent a substantive rulemaking under the APA because they constitute new obligations and burdens on manufacturers. They also create new rights for covered entities under the law.

Response: HRSA disagrees. This guidance neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law. HRSA has used interpretive guidance and statements of policy to provide guidance since the inception of the program and to create a working framework for its administration. Contract pharmacy service guidelines have been considered by HRSA to be "interpretative rules and statements of policy" exempt from notice and comment rulemaking under the APA. Nonetheless, HRSA has published these guidelines in the **Federal Register** and provided a public comment period to obtain input into guideline development. The present guidelines used this same process. HRSA has considered all comments, both Federal and public, in developing the Final Guidelines.

Comment: Eleven demonstration projects out of a total of 12,000 covered entities do not give HRSA enough data to expand the scope of the contract pharmacy model. An additional demonstration project, with not less than 100 sites, should be the next step to further evaluate risks and benefits of the expanded model.

Response: At the time of publication of the proposed guidance there had been 18 demonstration projects. HRSA realizes that only a small percentage of covered entities have gone through the AMDP process. HRSA is working with the data that exists, which was overwhelmingly supportive of the guidelines. Although there have been a limited number of AMDPs approved, some of the approved projects included a large number of health care sites and contract pharmacies. The number of participating health care sites exceeded 50 and the number of contract pharmacy sites was over 170. The results of the AMDP are not the only basis for issuing this guidance. The circumstances surrounding pharmacy practice and the resources available to track transactions have changed substantially over the past decade. The AMDP provides concrete examples of the ability of covered entities to utilize multiple contract pharmacies without sacrificing program integrity. Upon review of the evidence and current circumstances, HRSA does not find sufficient basis to continue limiting contract pharmacies to a single site. The restriction has imposed its own costs by restricting the flexibility of covered entities in meeting the needs of their patients. Furthermore, pharmacy and inventory management processes are available that make utilization of more than one pharmacy readily feasible for many covered entities without increasing the risk of diversion. The use of multiple contract pharmacies is not appropriate for all covered entities; however, we do not find a blanket restriction on all covered entities to be justified.

(2) Audits

Many commenters presented varying perspectives on the topic of audits. Multiple comments from drug manufacturers argued that manufacturers should be given the ability to audit covered entities that use multiple pharmacy contracting services due to the heightened risk of drug diversion and duplicate discounts. Other comments focused on HRSA audit requirements, arguing that they should be identical to the current standards required for the AMDP. Finally, some comments supported not having an audit requirement, arguing that audits would be burdensome and costly for the covered entities.

Comment: The audit requirements from the AMDP process should be applied to multiple contract pharmacies. There is no evidence of diversion and duplicate discounts

because of the audit requirements. Their elimination may lead to increased diversion and duplicate discounts. Some commenters recommended retaining the audit requirements for at least a few years until a track record of compliance with multiple contract pharmacies can be created. Audits should include a full compliance review of all mandatory contract terms/requirements including implementation of tracking system, patient status verification, and providing information about other pharmacy options.

Response: Although HRSA does not believe that precisely the same procedures are appropriate as utilized under the AMDP, HRSA agrees that independent audits can play an important role in ensuring program integrity. The guidelines have been revised to state that the covered entity must have sufficient information to meet its obligation of ensuring ongoing compliance and the recognition of any problem. Furthermore, the guidelines have been revised to indicate that it is the expectation of HRSA that covered entities will fulfill their ongoing obligation by the utilization of independent audits. However, HRSA leaves it up to covered entities to determine how to meet their compliance responsibilities. The guidelines intentionally do not specify the precise method, personnel or items for ensuring sufficient information is obtained by the covered entity. As long as covered entities comply with their obligations under the guidelines, HRSA prefers to leave the method of compliance to the judgment of the covered entities.

To the extent that any internal compliance activity or audit performed by a covered entity indicates that there has been a violation of 340B program requirements, it is HRSA's expectation that such finding be disclosed to HRSA along with the covered entity's plan to address the violation.

Comment: A copy of the audits conducted by covered entities should be submitted to OPA. The results of such audit should be made available to manufacturers.

Response: HRSA does not feel there is a need for the automatic submission of audits conducted by covered entities. HRSA believes that there are already appropriate safeguards in place. Covered entities are required to maintain auditable records sufficient to demonstrate continued compliance with 340B requirements; and, to the extent that a situation warrants, HRSA will request copies of any internal compliance documents of covered entities.

Comment: Covered entities should be required to conduct audits of their contract pharmacies and be required to terminate the contract with pharmacies found to be in violation.

Response: As noted earlier, HRSA agrees that audits can play an important role in ensuring integrity, and that covered entities are required to have sufficient information to ensure against diversion and duplicate discounts. The extent to which an audit of the contract pharmacy or other arrangement is necessary to satisfy that obligation will depend upon the individual circumstances. Covered entities have the responsibility to have agreements with contract pharmacies and procedures in place sufficient to enable the covered entity to meet its obligations under the law, including the prohibition on diversion and duplicate discounts. While an audit capability and various grounds for termination are terms that could be included in such contracts, there is no requirement in the guidelines for such terms. However, covered entities are reminded that they retain ultimate responsibility for compliance with the 340B program. Covered entities may be well-served by ensuring that compliance terms are included in their pharmacy contracts. To the extent that covered entities uncover these problems, the appropriate response is to report those problems to HRSA and ensure that they are properly addressed.

Comment: Manufacturers should be permitted to audit covered entities that use multiple contract pharmacy services. No reasonable cause should be required, due to heightened risk of diversion.

Response: We do not agree that utilization of more than one contract pharmacy creates automatic cause to suspect diversion. The issue as to whether additional audits by an outside manufacturer are permitted is addressed in the guidance published in the **Federal Register** on that issue (61 FR 65406, December 12, 1996). To the extent a manufacturer believes there is a reasonable basis to conclude that a covered entity is in breach of program requirements, it may audit a covered entity consistent with these guidelines. Additionally, HRSA has developed a dispute resolution process to provide parties with an informal mechanism to bring before the Department allegations of behavior that are in violation of 340B. For further guidance on the audit and dispute resolution process *see* 61 FR 65406 (December 12, 1996). As indicated in this guidance, covered entities and contract pharmacies must retain auditable records of 340B covered drug transactions sufficient to demonstrate compliance with the requirements to ensure against diversion to non-patients and against duplicate discounts.

Comment: It would be burdensome for covered entities to provide reports and data for audits. It is unclear who would be required to construct the actual components of the audit, what would be included, and who would pay for it.

Response: HRSA would like to remind all 340B stakeholders that it is an option for covered entities to voluntarily enter into contract pharmacy arrangements. Each covered entity is encouraged to conduct its own analysis of the costs and benefits of implementing or expanding their pharmacy services. It is the responsibility of the covered entity to ensure against diversion and duplicate discounts. Covered entities may determine how to best meet that responsibility: By performing a separate audit, including spot audits as part of pre-existing auditing responsibilities, or via other mechanisms. HRSA believes that including these issues as part of an independent audit is the best but not necessarily the only approach to meet covered entities' ongoing responsibility to know that their covered outpatient drugs are being appropriately ordered and distributed to their patients.

(3) Diversion

Comment: The proposed guidelines do not adequately describe safeguards that will combat drug diversion and duplicate discounts. There should be more severe penalties for violations, especially duplicate discounts. Reimbursement of any inappropriate discounts is insufficient and will not deter bad behavior. A covered entity should be excluded from 340B if it continues to use a pharmacy found to be in violation of the program.

Response: HRSA believes that there are appropriate safeguards in place, based on the parameters of the program. HRSA has the ability to exclude covered entities that abuse the program. HRSA has no statutory authority to assess additional penalties beyond the authority provided in section 340B. However, to the extent HRSA is aware that an action by a covered entity or contract pharmacy may be a violation of the law, such cases are referred to appropriate authorities.

Comment: The proposed guidance appears to limit the need to segregate records for easy accessibility by auditors rather than for purposes related to ensuring there is no diversion. Is this intended, or is segregation, virtual or

otherwise, still expected to be used by the contract pharmacy as a method of showing that diversion has not occurred?

Response: All covered entities are required to have auditable records sufficient to fully demonstrate compliance with all 340B requirements. Any covered entity that chooses to utilize a contract pharmacy must ensure that any such contract fully addresses that requirement and has the responsibility to ensure that the contract is actually performed and administered in compliance with those requirements. Inventory and record segregation is one of many methods that can be used to ensure compliance with the program guidelines. HRSA does not intend to limit the methods covered entities may use in order to remain in compliance with the guidelines. As noted previously, covered entities and contract pharmacies must retain auditable records of 340B covered drug transactions sufficient to demonstrate compliance with the requirements to ensure against diversion to non-patients as well as duplicate discounts.

Comment: Covered entities should be required to maintain and provide to HRSA and manufacturers written policies and procedures for preventing diversion and duplicate discounts in their contract pharmacy services.

Response: The ultimate responsibility for compliance with all aspects of the 340B program lies with each covered entity. The contract arrangements between covered entities and outside pharmacies will have various terms and procedures, which are acceptable as long as there are no violations of the program. It is expected that all covered entities will have written policies and procedures for preventing diversion and duplicate discounts as part of their obligations to prevent diversion and duplicate discounts. They are also required to maintain auditable records. HRSA will not automatically require covered entities to submit such policies and procedures for HRSA review.

(4) Contract Pharmacy Services Mechanism—Potential Alternatives to Single Location/Single Pharmacy Model

Comment: HRSA should permit separate covered entity sites to enter into one comprehensive agreement between the sites and a single contract pharmacy, instead of requiring a separate agreement for each site. Additionally, HRSA should permit a covered entity to enter into one comprehensive agreement with a chain pharmacy binding on multiple locations of the chain, instead of requiring a separate agreement for each contract pharmacy site.

Response: Each covered entity retains its own responsibility for compliance with the program. With respect to a covered entity with multiple sites, HRSA agrees that a single covered entity may contract for sites that are integral parts of the covered entity and for which it has legal control of so long as all of the requirements are met in the contract. This approach maintains and recognizes the central responsibility of the covered entity. In the case of agreements with "chain pharmacies," there appears to be potential for loss of accountability without a clearly established relationship between the actual pharmacy site and the covered entity. Covered entities are not precluded from entering into agreements with chain pharmacies, however, each participating pharmacy location must be listed on the contract and comply with the requirements.

Comment: One comment suggested that HRSA should clarify the definition of "multiple." The commenter interprets "multiple" to mean that an FQHC could contract with more than one pharmacy, including more than one site of a chain pharmacy, more than one independent pharmacy, or a combination of chain sites and independent pharmacies. Additionally, the commenter interprets "multiple" to mean that a covered entity with an in-house pharmacy could use any acceptable contract pharmacy arrangement to supplement the in-house pharmacy. The commenter encourages OPA to adopt this interpretation in the final guidance.

Response: HRSA agrees with the comment about the meaning of "multiple" and believes that the Final Notice is clear with respect to this meaning.

Comment: Does a covered entity that currently has an agreement with only one contract pharmacy need to revise its agreement with that pharmacy if the entity subsequently enters into agreements with additional pharmacies?

Response: The covered entity may need to revise its existing contract, depending on the terms that it contains. There is no requirement in the guidelines to revise contracts, as long as they meet the criteria outlined. All entities are encouraged to seek competent counsel to assess their needs.

Comment: The proposed guidelines do not provide cautionary language about possible negative results of implementing a multiple contract pharmacy model. Some small pharmacies that currently contract with covered entities may be hurt by implementation of the guidance due to reduced business. More guidance and decision analysis tools should be provided to guide the process of deciding whether to implement.

Response: HRSA notes that participation in any multiple contract pharmacy models is completely voluntary. All stakeholders are encouraged to conduct a full business analysis to determine whether to implement a multiple contract pharmacy model before moving forward. HRSA also provides free technical assistance for covered entities, including assistance with business analysis, to help navigate these issues. Ultimately, the decisions and responsibility for those decisions lies with the covered entity.

(5) Network Models

Comment: Multiple commenters proposed that network arrangements (*i.e.* arrangements involving a network of more than one covered entity) should be permitted under the guidelines without prior approval from HRSA. They argued that network arrangements would decrease the burden on covered entities and contract pharmacies by simplifying the contracting process and maintaining multiple inventory records. They also made the point that networks would also encourage parties to participate in 340B and therefore, expand access to eligible patients.

Response: HRSA understands the comments that a network model might potentially ease the administrative burden for participants in some cases. However, due to ongoing concerns about maintaining the integrity of the program with such complex arrangements, at this time, we decline to include network models in the guidelines without the added scrutiny of the AMDP process. HRSA will reassess the appropriateness of the utilization of networks outside the AMDP process as sufficient experience with them is gained in the future.

Comment: Some comments urged HRSA not to permit networks of multiple covered entities outside the framework of the AMDP process and requested confirmation that under the new guidance the development of a network of 340B covered entities will remain subject to the entire process now applicable to the AMDPs.

Response: HRSA agrees that covered entity networks should remain under the AMDP process, as indicated in the response to the prior comment.

Comment: "All covered entities participating" language is unclear. Does it mean a covered entity with multiple sites, a network model, or a DSH would need to name each covered entity that

has an agreement with a pharmacy under contract with the covered entity? If so, that would be burdensome on the entity, which would need to research and identify other covered entities that may contract with a particular pharmacy. What is the justification for requiring a covered entity to specify the names and 340B ID numbers of other participating covered entities?

Response: If a covered entity wants to use any alternative to a single location/single pharmacy model, it must submit its name and 340B identification number, and the names of all participating pharmacies to HRSA. Network models will still need to go through the AMDP process. The commenter is correct that the "all covered entities participating" language is unclear, because such arrangements only apply to a single covered entity. The language has been changed in response to this comment.

Comment: The guidelines should limit the numbers and geographical locations (not over State lines) for contract pharmacy relationships. Perhaps contract pharmacies should only be added one at a time. Monitoring various sites by the covered entity may be extremely difficult unless safeguards are in place.

Response: HRSA understands the commenter's concerns, but at this point, HRSA declines to limit the number of arrangements, as long as each arrangement meets our guidelines. Each covered entity retains the obligation to ensure its program remains compliant with the guidelines. HRSA does not intend to prescribe the methods covered entities use to run their programs or to ensure compliance at this time. Each covered entity and contract pharmacy is responsible for ensuring that its particular contracting arrangements and operations conform to the requirements of all applicable Federal, State and local laws and regulations.

(6) Model Agreement Provisions/Covered Entity Compliance Elements

In the final guidelines the phrase "Model Agreement Provisions" has been changed to "Covered Entity Compliance Elements" to better reflect the purpose of the elements and to distinguish them from model contract provisions.

Comment: Covered entities with multiple contract pharmacy arrangements should have written contracts with each pharmacy, including procedures to ensure against drug diversion and duplicate discounts, to maintain records available for audit, and to meet all other 340B requirements. Covered entities should submit these contracts and procedures to HRSA.

Response: HRSA agrees in part, which is why the guidelines do require a covered entity to have a contract that specifies all participating pharmacy locations. Such contracts must include adequate terms to ensure compliance with all aspects of the 340B program as listed in the Covered Entity Compliance Elements. However, at this time, HRSA does not have the need, or the resources to collect and review each contract. The covered entity bears responsibility for compliance with the program and will be held accountable in the event of non-compliance.

Comment: HRSA should create a single list of model contract terms, add suggested language on duplicate discount prohibition, and require covered entities to certify that their contracts use these terms or apply to HRSA for approval to use alternative terms.

Response: The Appendix of the guidelines does include a list of suggested contract provisions. HRSA has included provisions necessary to ensure that covered entities and contract pharmacies understand and agree not to violate 340B provisions. Because of the wide diversity of covered entities, it would be impossible to include provisions that would respond to the needs of all covered entities.

Comment: Manufacturers should be allowed to request copies of the contracts between the covered entities and contract pharmacies.

Response: Manufacturers are certainly permitted to request copies of such contracts, however, HRSA declines to mandate that covered entities must provide copies of contracts upon any request. In the event a manufacturer demonstrates a reasonable need for the copy of a contract and its request for a copy of the contract has been denied, the manufacturer may ask OPA to obtain a copy. The suggested Covered Entity Compliance Elements include providing a copy of the contract pharmacy service agreement upon the request of the Office of Pharmacy Affairs.

Comment: The Appendix provisions impose additional requirements not discussed in Section (3) of the proposed guidance and the suggested provisions in Section (3) do not appear in the Appendix. The Appendix does not mention the 340B prohibition on duplicate discounts.

Response: The Suggested Contract Provisions, found in the Appendix of the Guidelines, are not meant to be comprehensive, exhaustive, or required. They offer a model format and sample provisions, but are not intended to be used as the complete terms of the contract.

Comment: Covered entities should not be permitted to use alternative mechanisms other than the model agreement provisions. The use of alternatives would increase OPA's oversight responsibilities, which may lead to different standards or the potential for abuse. A commenter also cited GAO/OIG reports on lack of oversight of the program to support his/her assertion that the model provisions should be required.

Response: The Covered Entity Compliance Elements are not intended to be required contract provisions. All covered entities must certify that all of the elements have been addressed; however, HRSA gives the covered entities the discretion to negotiate contract provisions suitable to their individual circumstances and jurisdictions. The various complexities of covered entities and the pharmacies with whom they will contract led HRSA to permit flexibility between the parties in designing their contract terms. HRSA does not intend to review contracts. As under the previous guidelines, the covered entity is ultimately responsible for assuring full compliance with 340B.

HRSA disagrees with the comment that recent reports by the GAO and the OIG would support the creation of a standard uniform contract. HRSA has worked diligently to implement the recommendations of both the GAO and the OIG, and HRSA does not believe that dictating to covered entities specific contract language that must be used in all contracts regardless of individual circumstances would assist in those efforts at this time.

(7) Miscellaneous Comments

Comment: Anti-kickback provisions may prohibit pharmacies from offering Medication Therapy Management and Pharmacy by Mail activities that would be beneficial to 340B and patients.

Response: Covered entities are not exempt from anti-kickback provisions. Section 340B does not authorize HRSA to grant any exceptions whether beneficial or not. It is recommended that covered entities get competent professional legal advice when appropriate.

Comment: In section B(3)(c), the proposal states that the manufacturer is not required to offer the 340B drug price if the patient declines to use the contract pharmacy. If however, the manufacturer does extend the 340B price in this case, please clarify whether this extension sets a new best price for the drug.

Response: The 340B drug pricing program does not restrict the prices that manufacturers voluntarily choose to offer to patients outside the parameters of the program. Whether such actions serve to set a new best price for a drug is beyond the scope of this guidance. We encourage anyone with specific best price questions to consult with the Centers for Medicare & Medicaid Services.

Comment: To prevent drug diversion, an additional contract requirement should be added that the contract pharmacy may not fill or refill a prescription using 340B medications until the covered entity confirms that the individual is a patient of the entity at the time the prescription is filled. There should also be an independent, annual audit to review the covered entity's policies and procedures for patient verification.

Response: The program guidelines for 340B make it clear that only individuals who are patients of the covered entity are eligible for drugs purchased under the program. Like all other program requirements, responsibility for compliance lies with the covered entity, which must structure agreements and systems appropriately to ensure that diversion does not occur. Technical assistance may be available for help with implementation and compliance for the 340B program, and maximizing the value of comprehensive pharmacy services for their patients. However, HRSA has chosen not to require time-of-services verification as suggested in the comment.

Comment: Pharmacy records from contract pharmacies should be made available to covered entities to ensure patient safety and continuity of care.

Response: HRSA agrees that this might be beneficial for patient care and encourages the parties to include such terms in their contract agreements. However, this is a decision which will be left to the contracting parties. In any case, the covered entity must have sufficient records or direct access to records for the covered entity to meet its responsibility to ensure compliance and to provide a complete audit trail to verify that there is no diversion or duplicate discounts.

Comment: HRSA should include in its final guidance and suggested contract provisions, language to reinforce that all savings from the 340B program should remain with the covered entity. Without written guidance, all savings will not be returned to the covered entity.

Response: HRSA agrees that the intent of the 340B program was to permit the covered entities to stretch scarce Federal resources, and that the benefit of the program was intended to accrue to the covered entities. However, the covered entity is free to negotiate how it chooses to use any such funds as it sees fit. For example, the covered entity is free to choose to use those dollars to pay contract pharmacies for their services or for extra services such as delivery.

C. Contract Pharmacy Services Mechanism

These final guidelines replace all previous 340B Program guidance documents addressing non-network contract pharmacy services, including, but not limited to, the "Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services," (61 FR 43549) and any individual correspondence issued by HRSA on the subject.

(1) Basic Compliance Issues in Utilization of Pharmacy Services Contracts

A covered entity that wishes to utilize contract pharmacy services to dispense section 340B outpatient drugs must have a written contract in place between itself and a specified pharmacy. A single covered entity that has more than one 340B eligible site at which it provides health care may have individual contracts for each such site or include multiple sites within a single pharmacy services contract. This mechanism is designed to facilitate program participation for those covered entities that do not have access to available or appropriate "in-house" pharmacy services, those covered entities that have access to "in-house" pharmacy services but wish to supplement these services; and covered entities that wish to utilize multiple contract pharmacies to increase patient access to 340B drugs. The covered entity has the responsibility to: Ensure against illegal diversion and duplicate discounts; maintain readily auditable records; and meet all other 340B Drug Pricing Program requirements (*See: http://www.hrsa.gov/opa/introduction.htm*). HRSA has provided essential covered entity compliance elements below as guidance for the type of contractual provisions expected in such agreements. Suggested contract provisions are also in the Appendix. All covered entities utilizing a contract pharmacy must comply with the certification requirements described in (5) below.

(2) Potential Alternatives to Single Location/Single Pharmacy Model

In addition to contracting with a single pharmacy for each clinical site, covered entities may pursue more complex arrangements that include multiple pharmacies only if: (a) There is a written agreement and procedures that meet the requirements outlined above in (1) between the covered entity and each pharmacy; (b) the written agreement includes, and fully addresses, all of the essential elements outlined in (3) and (4) below and a full listing of all pharmacy locations that may be utilized under that agreement; (c) the operation under the contract continues to meet all 340B Drug Pricing Program requirements and does not create diversion of covered drugs or duplicate discounts; (d) the arrangements are one of the two following models either individually or in combination: (i) The use of multiple contract pharmacy service sites, and/or (ii) the utilization of a contract pharmacy(ies) to supplement in-house pharmacy services (the use of multiple contract pharmacy service sites refers to any arrangement wherein a covered entity site seeks to provide drugs at 340B discounted prices for its patients at more than one pharmacy location). Supplementing in-house pharmacy services with a contract pharmacy refers to any arrangement wherein a covered entity site purchases drugs at 340B discounted prices for its patients at both an in-house pharmacy and at least one additional contract pharmacy location; and (e) the arrangement involves a single identifiable 340B covered entity and does not include a network, or other similar arrangement, of more than one covered entity unless specifically authorized in writing by HRSA through an AMDP or by other official written authorization.

(3) Essential Covered Entity Compliance Elements

The following are essential elements to address in contract pharmacy arrangements: (a) The covered entity will purchase the drug, maintain title to the drug and assume responsibility for establishing its price, pursuant to the terms of an HHS grant (if applicable) and any applicable Federal, State and local laws.

A "ship to, bill to" procedure is used in which the covered entity purchases the drug; the manufacturer/wholesaler must bill the covered entity for the drug that it purchased, but ships the drug directly to the contract pharmacy. *See* Section 1 of Appendix. In cases where a covered entity has more than one site, it may choose between having each site billed individually or designating a single covered entity billing address for all 340B drug purchases.

(b) The agreement will specify the responsibility of the parties to provide comprehensive pharmacy services (*e.g.*,

dispensing, recordkeeping, drug utilization review, formulary maintenance, patient profile, patient counseling, and medication therapy management services and other clinical pharmacy services). Each covered entity has the option of individually contracting for pharmacy services with a pharmacy (ies) of its choice. Covered entities are not limited to providing comprehensive pharmacy services to any particular location and may choose to provide them at multiple locations and/or "in-house."

(c) The covered entity will inform the patient of his or her freedom to choose a pharmacy provider. If the patient does not elect to use the contracted service, the patient may obtain the prescription from the covered entity and then obtain the drug(s) from the pharmacy provider of his or her choice.

When a patient obtains a drug from a pharmacy other than a covered entity's contract pharmacy or the covered entity's in-house pharmacy, the manufacturer is not required to offer this drug at the 340B price.

(d) The contract pharmacy may provide other services to the covered entity or its patients at the option of the covered entity (*e.g.,* home care, delivery, reimbursement services). Regardless of the services provided by the contract pharmacy, access to 340B pricing will always be restricted to patients of the covered entity.

(e) The contract pharmacy and the covered entity will adhere to all Federal, State, and local laws and requirements.

Both the covered entity and the contract pharmacy are aware of the potential for civil or criminal penalties if either violates Federal or State law. [The Department reserves the right to take such action as may be appropriate if it determines that such a violation has occurred.]

(f) The contract pharmacy will provide the covered entity with reports consistent with customary business practices (*e.g.,* quarterly billing statements, status reports of collections and receiving and dispensing records). *See* Section 2 of Appendix.

(g) The contract pharmacy, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of section 340B drugs to individuals who are not patients of the covered entity. Customary business records may be used for this purpose. The covered entity will establish a process for periodic comparison of its prescribing records with the contract pharmacy's dispensing records to detect potential irregularities. *See* Section 3 of Appendix.

(h) The covered entity and the contract pharmacy will develop a system to verify patient eligibility, as defined by HRSA guidelines. The system should be subject to modification in the event of change in such guidelines.

Both parties agree that they will not resell or transfer a drug purchased at section 340B prices to an individual who is not a patient of the covered entity. See 42 U.S.C. 256b(a)(5)(B). The covered entity understands that it may be removed from the list of covered entities because of its participation in drug diversion and no longer be eligible for 340B pricing. *See* Section 4 of Appendix.

(i) Neither party will use drugs purchased under section 340B to dispense Medicaid prescriptions, unless the covered entity, the contract pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounts. Any such arrangement shall be reported to the OPA, HRSA, by the covered entity.

(j) The covered entity and contract pharmacy will identify the necessary information for the covered entity to meet its ongoing responsibility of ensuring that the elements listed herein are being complied with and establish mechanisms to ensure availability of that information for periodic independent audits performed by the covered entity.

(k) Both parties understand that they are subject to audits by outside parties (by the Department and participating manufacturers) of records that directly pertain to the entity's compliance with the drug resale or transfer prohibition and the prohibition against duplicate discounts. *See* 42 U.S.C. 256b(a)(5)(c).

The contract pharmacy will assure that all pertinent reimbursement accounts and dispensing records, maintained by the pharmacy, will be accessible separately from the pharmacy's own operations and will be made available to the covered entity, HRSA, and the manufacturer in the case of an audit. Such auditable records will be maintained for a period of time that complies with all applicable Federal, State and local requirements.

(l) Upon written request to the covered entity, a copy of the contract pharmacy service agreement will be provided to the Office of Pharmacy Affairs.

(4) Ongoing Responsibility of Covered Entity To Ensure Compliance

Covered entities are responsible for ensuring that the system of distribution chosen fully meets statutory obligations of ensuring against diversion to non-patients or creating a situation that results in a State Medicaid Program seeking a rebate on a discounted drug. The covered entity remains responsible at all times for the disposition of covered outpatient drugs it purchases through a contract pharmacy. Annual audits performed by an independent, outside auditor with experience auditing pharmacies are expected, although the exact method of ensuring compliance is left up to the covered entity. The covered entity must have sufficient information to ensure it is meeting that responsibility. Independent audits are particularly valuable where the covered entity utilizes multiple pharmacy options. They should follow standard business practices for audits, including audit trails provided by the entity to the auditor, and use of standard reports. The precise methodology utilized to ensure compliance and obtain the necessary information is up to the covered entity given its particular circumstances and, for example, might include spot audits where the system in place permits. Drug diversion and duplicate discounts are a significant concern of HRSA and all efforts to avoid these problems should be well documented. In the event a covered entity determines that drug diversion or duplicate discounts have occurred or that it is otherwise unable to comply with its responsibility to reasonably ensure compliance, then it must take immediate remedial action to assure compliance and notify the OPA about such compliance problems and actions taken to remedy those problems.

(5) Certification

Under section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price. If the covered entity directs the drug shipment to its contract pharmacy or pharmacies, the covered entity must comply, under any distribution mechanism, with the statutory prohibition on drug diversion and duplicate discounting.

To provide HRSA and manufacturers with assurance that the covered entity has acted in a manner which limits the potential for drug diversion, covered entities should submit to OPA a certification that it has signed and has in effect an agreement with the contract pharmacy or pharmacies that satisfies both (3) and (4) above (*i.e.* that the contract(s) fully address the issues listed in (3) and that the covered entity has a

plan to meet its ongoing responsibilities to ensure compliance). The names of those covered entities which submit a certification, or an alternate mechanism approved by OPA, will be listed on the OPA Web site for the convenience of participating drug manufacturers and wholesaler distributors.

In addition, any covered entity that has opted to utilize any pharmacy arrangement described in (2) must specify which arrangement or combination of arrangements it is utilizing and the names of any pharmacies participating when registering. Covered entities seeking to materially change this arrangement that entail changes in the covered entity database should notify OPA of any such proposed changes and be aware that some changes may require advanced notice to manufacturers and wholesalers as part of quarterly updates to the database.

In order to ensure accuracy, integrity and transparency, the OPA may conduct a recertification process periodically (most likely annually) where covered entities affirmatively certify as to their ongoing compliance with 340B requirements. It is currently expected that the annual process would include certification by a duly authorized official: (1) That all information listed on the database for that covered entity is complete, accurate, and correct; (2) that the covered entity met the 340B eligibility requirements throughout the prior year and continues to do so; (3) that any contract pharmacy arrangement was actually performed in accordance with specified requirements including, but not limited to, that the covered entity obtained sufficient information from the contractor to ensure compliance with applicable policy and legal requirements; and (4) the methodology utilized to ensure compliance (*e.g.* through independent audit or other mechanism).

(6) Anti-Kickback Statute

Contract pharmacies and covered entities should be aware of the potential for civil or criminal penalties if the contract pharmacy violates Federal or State law. In negotiating and executing a contract pharmacy service agreement pursuant to these guidelines, contract pharmacies and covered entities should be aware of and take into consideration the provisions of the Medicare and Medicaid anti-kickback statute, 42 U.S.C. 1320a–7b(b).

D. Appendix—Suggested Contract Provisions

The following suggested contract provisions are included for illustrative purposes and are not intended to be comprehensive, exhaustive or required. They offer sample provisions for consideration, but are not intended to be used as the complete terms of the contract. Given the variances among many jurisdictions and among the numerous types of covered entities, HRSA has decided at this time not to include a complete model contract in this notice.

(1) "The covered entity owns covered drugs and arranges to be billed directly for such drugs. The pharmacy will compare all shipments received to the orders and inform the covered entity of any discrepancy within five (5) business days of receipt. The covered entity will make timely payments for such drugs delivered to the pharmacy."

(2) "The covered entity will verify, using the contract pharmacy's (readily retrievable) customary business records, that a tracking system exists which will ensure that drugs purchased under the 340B Drug Pricing Program are not diverted to individuals who are not patients of the covered entity. Such records can include: Prescription files, velocity reports, and records of ordering and receipt. These records will be maintained for the period of time required by State law and regulations."

(3) "Prior to the contract pharmacy providing pharmacy services pursuant to this agreement, the covered entity will have the opportunity, upon reasonable notice and during business hours, to examine the tracking system. For example, such a tracking system may include quarterly sample comparisons of eligible patient prescriptions to the dispensing records and a six (6) month comparison of 340B drug purchasing and dispensing records as is routinely done in other reconciliation procedures. The contract pharmacy will permit the covered entity or its duly authorized representatives to have reasonable access to contract pharmacy's facilities and records during the term of this agreement in order to make periodic checks regarding the efficacy of such tracking systems. The contract pharmacy agrees to make any and all adjustments to the tracking system which the covered entity advises are reasonably necessary to prevent diversion of covered drugs to individuals who are not patients of the covered entity."

(4) "The pharmacy will dispense covered drugs only in the following circumstances: (a) Upon presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the patient is an eligible patient of the covered entity, and the signature of a legally qualified health care provider affiliated with the covered entity; or (b) receipt of a prescription ordered by telephone or other means of electronic transmission that is permitted by State or local law on behalf of an eligible patient by a legally qualified health care provider affiliated with the covered entity who states that the prescription is for an eligible patient. The covered entity will furnish a list to the pharmacy of all such qualified health care prescribers and will update the list of prescribers to reflect any changes. If a contract pharmacy is found to have violated the drug diversion prohibition, the contract pharmacy will pay the covered entity the amount of the discount in question so that the covered entity can reimburse the manufacturer."

Dated: March 2, 2010.

Mary K. Wakefield,

Administrator.

[FR Doc. 2010–4755 Filed 3–4–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–3070 and CMS–416]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of*

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Resources and Services Administration
Healthcare System Bureau
Office of Pharmacy Affairs

U.S. Department of Health and Human Services
HRSA
Health Resources and Services Administration

Date: May 23, 2012

340B DRUG PRICING PROGRAM NOTICE
Release No. 2011-1.1
(Replaces No. 2011-1 dated November 21, 2011)

CLARIFICATION OF NON-DISCRIMINATION POLICY

This policy release is being issued to restate the Health Resources and Services Administration's (HRSA) policy with regard to manufacturer limitations or conditions on sales of covered outpatient drugs to eligible 340B entities (discrimination against 340B covered entities) under the 340B Drug Pricing Program (340B Program).

Background

Section 602 of Public Law 102-585, the "Veterans Health Care Act of 1992," enacted section 340B of the Public Health Service Act, "Limitation on Prices of Drugs Purchased by Covered Entities." Manufacturers who participate in Medicaid are required under the 340B statute to enter into an agreement with the Secretary under which the manufacturer must agree to charge a price that will not exceed the amount determined under a statutory formula when selling covered outpatient drugs to particular covered entities listed in the statute. This agreement, known as the Pharmaceutical Pricing Agreement (PPA), must be signed by a manufacturer as a condition for participating in Medicaid. Signing the PPA does not prohibit a manufacturer from charging a price for a covered outpatient drug that is lower than the 340B ceiling price. A manufacturer may not condition the offer of 340B discounts upon a covered entity's assurance of compliance with section 340B provisions.

Alternate Allocation Procedures

HRSA has policy in place to ensure that manufacturers have the ability to develop alternate allocation procedures during situations when the available supply of a covered drug is not adequate to meet market demands. These allocation procedures, however, must demonstrate that 340B providers are treated the same as non-340B providers. The 1994 guideline (59 Fed. Reg. 25110 (May 13, 1994)) states that "manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective" and that "manufacturers must not place limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program." This policy is consistent with section 340B(a)(1) of the Public Health Service Act which requires manufacturers to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."

In order to reduce the potential for disputes and ensure alternate allocation procedures are transparent to all stakeholders, the Office of Pharmacy affairs (OPA) requests manufacturers to provide notification to OPA in writing (e.g., email, mail, or facsimile) prior to actual implementation. Where feasible, this information should be submitted at least four weeks before the implementation date, with a plan that includes:

- A description of product information (Drug Name, Dosage, Form and NDC)
- Details for a non-discriminatory practice for restricted distribution to all purchasers, including 340B covered entities, which includes each of the following components:
    - Explanation of product's limited supply and rationale for restricted distribution among all purchasers

- How manufacturers will impose restrictions on non-340B purchasers
- Specific details of the drug allocation plan, including a mechanism that incorporates potential 340B sales to covered entities and sales to non-340B covered entities that may not have a previous history of purchasing the restricted drug
- Dates the restricted distribution begins and concludes
- Plan for notification of wholesalers and 340B covered entities

When submitted in a timely fashion, OPA will publish all submitted allocation plans on its website (www.hrsa.gov/opa) on the date of implementation. If OPA has concerns about the allocation plan, it will work with the manufacturer to incorporate mutually agreed upon revisions to the plan prior to posting the plan on the HRSA/OPA website. Covered entities that have concerns regarding the manner in which a particular plan is implemented are first encouraged to resolve them in good faith with manufacturers. Where such issues are not resolved, covered entities should contact OPA for appropriate action or involvement of other federal agencies (e.g., Office of Inspector General, Department of Justice) to bring the issue to resolution. Although prior notification by manufacturers is not currently required, HRSA believes that voluntarily providing OPA with timely notification will benefit manufacturers as well as covered entities by reducing the chance for misunderstandings about the requirements of the 340B Program and lessen the potential for disputes.

Manufacturers must comply with federal and state requirements regarding the distribution and sale of drugs. Accordingly, this policy does not require manufacturers to offer drugs to a covered entity under circumstances that would violate federal or state law.

From: Laura Murphy
To: HRSA HSB 340B Pricing
Subject: 340B Pricing Refusal - Documentation for DSH20033
Date: Wednesday, January 6, 2021 3:58:32 PM
Attachments: HRSA Reporting - Manufacturer Refusal of 340B Pricing October 2020.pdf
HRSA Reporting - Manufacturer Refusal of 340B Pricing December 2020.pdf
HRSA Reporting - Manufacturer Refusal of 340B Pricing November 2020.pdf

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Good Afternoon HRSA Team,

Please see attached for our documentation of several Manufacturers' refusal to provide 340B pricing at the contract pharmacy level for Beverly Hospital.

Please let me know if you have any questions,
We appreciate everything you are doing to help us and hope that this documentation is useful.

Best,
Laura Murphy

--
Laura E. Murphy, CPhT
Pharmacy Purchasing, Inventory, Contract & 340B Manager

Beverly Hospital
85 Herrick Street, 01915

E: Laura.E.Murphy@lahey.org
P: 978.816.3625
F: 978.921.7006

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Purpose: This tool can be used to report the following types of issues for covered outpatient drugs, to the Health Resources and Services Administration (HRSA):

- Table 1: Unavailable at a 340B ceiling price and/or
- Table 2: Incorrect 340B ceiling price (overcharge)

Instructions: Enter data in each field describing the issue. Before completing and submitting the tool, the stakeholder should contact the wholesaler and manufacturer directly to determine the reason for unavailability and/or to document incorrect pricing. HRSA investigates allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. If HRSA determines additional information is needed from the covered entity or manufacturer, it may extend the time for follow-up. If the tool is unable to capture all details, **please attach additional documentation as necessary.** HRSA may reach out to the person submitting this notification for additional information.

This completed tool, including copies of communications with manufacturer and/or wholesaler and any responses, should be emailed to HRSA at: 340Bpricing@hrsa.gov

Entity Name: Beverly Hospital **340B ID:** DSH220033

Please list the product(s) affected (*you may list multiple drugs as long as the labeler codes are the same; the labeler code is the first five digits of an NDC. If multiple labeler codes are represented you will need to submit multiple forms*).

	11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
1		see attached	sheet for full list of			October 2020	
2.						omissions	
3.							

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug ☐ Yes ☐ No > see attached
- The issue reported is limited to a contract pharmacy purchase ■ Yes ☐ No
- If shortage-related, is this a recurrent/intermittent availability issue? ☐ Yes ■ No
- If shortage-related, is this due to a local/regional/national or global shortage? no shortages

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

AVAILABILITY ISSUE: If you are unable to purchase the product at a 340B price, fill out the information below.

Reason for lack of 340B access (*check all that apply*):

- ☐ Drug shortage
- ☐ Drug subject to limited distribution or specialty pharmacy plan
- ☒ Other (*please describe*): manufacturer refusing 340B pricing
- ☐ Unknown

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ☒ Verified the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data and signed PPA with labeler code active in 340B OPAIS, contacted manufacturer for confirmation, etc.)

  For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.
- ☒ Confirmed shortage issues by reviewing validated resources*
- ☒ Contacted wholesaler and/or manufacturer to confirm unavailability
- ***For hospitals subject to Group Purchasing Organization (GPO) Prohibition:*** purchased product on an GPO account, after exhausting all measures for obtaining drug at a non-GPO price (please list all measures taken, including which NDC was purchased instead due to unavailability)

  not applicable / WAC for Contract Pharmacy pricing

- ☒ Other (*please describe issue*):

  Manufacturer is deliberately withholding 340B pricing for the attached products

Date issue first observed: 10·1·20

Date drug last available at 340B price (enter NEVER if has never been available): see attatched

*Recommended Drug shortage resources:
FDA: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
ASHP: https://www.ashp.org/drug-shortages/current-shortages
Wholesaler catalog information

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

PRICING ISSUE: The drug can be purchased on the 340B account but price is greater than the price in the OPAIS Pricing System.

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- [x] Determined if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturersearch), and check the Medicaid Drug Rebate Program labeler code (https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data)

  Note: *For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs*

- [x] Validated the ceiling price using the 340B OPAIS pricing system on (date): 10.31.20
  - Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS
  - The OPAIS Pricing Database displays the 340B ceiling price at the unit level; the covered entity may need to multiply the ceiling price by the package size (this might be the total number of mL, tablets, capsules, grams, etc.) in the package purchased
  - For Prime Vendor participants, verify the selling price by visiting the password-protected Prime Vendor Program Catalog or 340B & PVP Product Selling Price Lookup tool. Package size information is available.
  - Adjust the purchase price for your wholesaler distribution charge/markdown
- [x] Attempted to work with the entity's wholesaler and directly with the manufacturer to resolve the pricing issue
- [x] Other (*please describe issue*):

Manufacturer(s) deliberately refusing 340B Price

Price paid by the covered entity (including package size): See attached

Date issue first observed: 10.1.20

Date product last available at correct price (enter NEVER if has never been available): September 2020

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

HRSA may reach out to the following contact person from the covered entity to help resolve the issue in question. By signing below the submitter consents/acknowledges that this information may be used in correspondence with Manufacturers and other Federal Agencies.

Contact Name (printed): Laura E. Murphy **Phone**: (978) 816-3625

Email Address: Laura.E.Murphy@lahey.org

Contact Role/Organization: 340B and Purchasing Manager

Contact Signature: [signature] **Date**: 10-31-20

Beverly Hospital - DSH220033
Manufacturer 340B Pricing Refusals in the Contract Pharmacy Setting
October 2020

11 digit NDC	Drug Name and Strength	Manufacturer	Package Size	Case Package Size	Unit of Measure	CE Wholesaler	Is This a Specialty Drug?	340B Price/unit	WAC Price/unit	Savings Lost
00024-5925-05	ADMELOG SOLO INJ 100U/ML 3ML PENS	SANOFI	5	5	pens	Cardinal	No		$235.50	
00002-6145-27	BAQSIMI TWO POW 3MG/DOSE SINGLE DOSE PENS	LILLY	2	2	pens	Cardinal	No		$261.93	
00002-7715-59	BASAGLAR INJ 100UNIT 3ML PENS	LILLY	5	5	pens	Cardinal	No		$60.89	
00186-0777-60	BRILINTA TAB 90MG	ASTRAZENECA LP	60	60	tablets	Cardinal	No		$377.62	
00310-6524-01	BYETTA INJ 10MCG PEN	ASTRAZENECA	1	1	pen	Cardinal	No		$725.55	
00310-0095-30	DALIRESP TAB 500MCG	ASTRAZENECA	30	30	tablets	Cardinal	No		$369.62	
00024-5914-01	DUPIXENT INJ 300/2ML PEN	SANOFI	2	2	pens	Cardinal	Yes		$1,516.17	
00002-8400-01	FORTEO SOL 600/2.4	LILLY	1	1	pen	Cardinal	Yes		$3,683.28	
00002-8031-01	GLUCAGON KIT 1MG	LILLY	1	1	kit	Cardinal	No		$261.93	
00002-7510-01	HUMALOG INJ 100/ML 10 ML VIAL	LILLY	1	1	vial	Cardinal	No		$256.24	
00002-7714-59	HUMALOG JR INJ 100/ML 3 mL PEN	LILLY	5	5	pens	Cardinal	No		$98.95	
00002-8799-59	HUMALOG KWIK INJ 100/ML 3 ML PEN	LILLY	5	5	pens	Cardinal	No		$98.95	
00002-8797-59	HUMALOG MIX INJ 75/25KWP PEN	LILLY	5	5	pens	Cardinal	No		$98.95	
00002-7511-01	HUMALOG MIX SUS 75/25 10 ML VIAL	LILLY	1	1	vial	Cardinal	No		$265.57	
00002-8147-01	HUMATROPE INJ 6MG CARTRIDGE	LILLY	1	1	cartridge	Cardinal	Yes		$822.98	
00002-8715-01	HUMULIN INJ 70/30 10 ML VIAL	LILLY	1	1	vial	Cardinal	No		$138.71	
00002-8805-59	HUMULIN N INJ U-100KWP 3 ML PEN	LILLY	5	5	pens	Cardinal	No		$87.93	
00002-8501-01	HUMULIN R INJ U-500 20 ML VIAL	LILLY	1	1	vial	Cardinal	No		$1,387.07	
00002-8824-27	HUMULIN R INJ U-500 3 ML PEN	LILLY	2	2	pens	Cardinal	No		$267.81	
00088-2220-33	LANTUS INJ 100/ML 10 ML VIAL	SANOFI	1	1	vial	Cardinal	No		$264.50	
00088-2219-05	LANTUS SOLOS INJ 100/ML 3 ML PEN	SANOFI	5	5	pens	Cardinal	No		$79.35	
00169-6339-10	NOVOLOG INJ FLEXPEN 3 ML PEN	NOVO NORDISK	5	5	pens	Cardinal	No		$104.26	
72733-5901-02	PRALUENT INJ 75MG PEN	SANOFI US	2	2	pens	Cardinal	No		$219.38	
00186-0370-20	SYMBICORT AER 160-4.5 INHALER	ASTRAZENECA LP	1	1	inhaler	Cardinal	No		$346.68	
00186-0372-20	SYMBICORT AER 80-4.5 INHALER	ASTRAZENECA LP	1	1	inhaler	Cardinal	No		$303.30	
00024-5871-02	TOUJEO MAX INJ 300IU/ML 3 ML PEN	SANOFI	2	2	pens	Cardinal	No		$241.74	
00024-5869-03	TOUJEO SOLO INJ 300IU/ML 1.5 ML PEN	SANOFI	3	3	pens	Cardinal	No		$120.87	
00002-1433-80	TRULICITY INJ 0.75/0.5 ML PEN	LILLY	4	4	pens	Cardinal	No		$196.91	
00002-1434-80	TRULICITY INJ 1.5/0.5 ML PEN	LILLY	4	4	pens	Cardinal	No		$196.91	
							Total Savings Loss October		$126,508.55	

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Purpose: This tool can be used to report the following types of issues for covered outpatient drugs, to the Health Resources and Services Administration (HRSA):

- Table 1: Unavailable at a 340B ceiling price and/or
- Table 2: Incorrect 340B ceiling price (overcharge)

Instructions: Enter data in each field describing the issue. Before completing and submitting the tool, the stakeholder should contact the wholesaler and manufacturer directly to determine the reason for unavailability and/or to document incorrect pricing. HRSA investigates allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. If HRSA determines additional information is needed from the covered entity or manufacturer, it may extend the time for follow-up. If the tool is unable to capture all details, **please attach additional documentation as necessary.** HRSA may reach out to the person submitting this notification for additional information.

This completed tool, including copies of communications with manufacturer and/or wholesaler and any responses, should be emailed to HRSA at: 340Bpricing@hrsa.gov

Entity Name: Beverly Hospital **340B ID:** DSH220033

Please list the product(s) affected (*you may list multiple drugs as long as the labeler codes are the same; the labeler code is the first five digits of an NDC. If multiple labeler codes are represented you will need to submit multiple forms*).

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
1	See attached sheet for full list of				December 2020	
2.					omissions	
3.						

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug ☐ Yes ☐ No - see attached
- The issue reported is limited to a contract pharmacy purchase ☒ Yes ☐ No
- If shortage-related, is this a recurrent/intermittent availability issue? ☐ Yes ☒ No
- If shortage-related, is this due to a local/regional/national or global shortage? no shortage

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

AVAILABILITY ISSUE: If you are unable to purchase the product at a 340B price, fill out the information below.

Reason for lack of 340B access (*check all that apply*):

- ☐ Drug shortage
- ☐ Drug subject to limited distribution or specialty pharmacy plan
- ☑ Other (*please describe*): Manufacturer refusal of 340B Pricing
- ☐ Unknown

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ☑ Verified the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data and signed PPA with labeler code active in 340B OPAIS, contacted manufacturer for confirmation, etc.)

  For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.
- ☑ Confirmed shortage issues by reviewing validated resources*
- ☑ Contacted wholesaler and/or manufacturer to confirm unavailability
- ☐ ***For hospitals subject to Group Purchasing Organization (GPO) Prohibition:*** purchased product on an GPO account, after exhausting all measures for obtaining drug at a non-GPO price (please list all measures taken, including which NDC was purchased instead due to unavailability)

  _____

  _____
- ☑ Other (*please describe issue*):

  _____

  _____

  Manufacturers deliberately withholding 340B Pricing

  _____

  _____

  _____

  _____

Date issue first observed: 10.1.20

Date drug last available at 340B price (enter NEVER if has never been available): September 2020

*Recommended Drug shortage resources:
FDA: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
ASHP: https://www.ashp.org/drug-shortages/current-shortages
Wholesaler catalog information

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

PRICING ISSUE: The drug can be purchased on the 340B account but price is greater than the price in the OPAIS Pricing System.

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- [x] Determined if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturersearch), and check the Medicaid Drug Rebate Program labeler code (https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data)

  Note: *For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs*

- [x] Validated the ceiling price using the 340B OPAIS pricing system on (date): 12.31.20
  - Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS
  - The OPAIS Pricing Database displays the 340B ceiling price at the unit level; the covered entity may need to multiply the ceiling price by the package size (this might be the total number of mL, tablets, capsules, grams, etc.) in the package purchased
  - For Prime Vendor participants, verify the selling price by visiting the password-protected Prime Vendor Program Catalog or 340B & PVP Product Selling Price Lookup tool. Package size information is available.
  - Adjust the purchase price for your wholesaler distribution charge/markdown
- [x] Attempted to work with the entity's wholesaler and directly with the manufacturer to resolve the pricing issue
- [x] Other (*please describe issue*):

Manufacturer refusing 340B Pricing

Price paid by the covered entity (including package size): See attached

Date issue first observed: 10.1.20

Date product last available at correct price (enter NEVER if has never been available): ~~NEVER~~ September 2020

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

HRSA may reach out to the following contact person from the covered entity to help resolve the issue in question. By signing below the submitter consents/acknowledges that this information may be used in correspondence with Manufacturers and other Federal Agencies.

Contact Name (printed): Laura E. Murphy **Phone:** (978) 816-3625

Email Address: Laura.E.Murphy@lahey.org

Contact Role/Organization: 340B and Purchasing Manager

Contact Signature: [signature] **Date:** 1.5.21

Beverly Hospital - DSH220033
Manufacturer 340B Pricing Refusals in the Contract Pharmacy Setting
December 2020

11 digit NDC	Drug Name and Strength	Manufacturer	Package Size	Case Package Size	Unit of Measure	CE Wholesaler	Is This a Specialty Drug?	340B Price/unit	WAC Price/unit	Savings Lost
00024-5925-05	ADMELOG SOLO INJ 100U/ML	SANOFI	5	5	pens	Cardinal		[redacted]	$235.50	[redacted]
00002-7715-59	BASAGLAR INJ 100UNIT	LILLY	5	5	pens	Cardinal			$60.89	
00186-0777-60	BRILINTA TAB 90MG	ASTRAZENECA LP	60	60	tablets	Cardinal			$377.62	
00310-0095-30	DALIRESP TAB 500MCG	ASTRAZENECA	30	30	tablets	Cardinal			$369.62	
00024-5914-01	DUPIXENT INJ 300/2ML	SANOFI	2	2	pens	McKesson	Yes		$1,516.17	
00310-6210-30	FARXIGA TAB 10MG	ASTRAZENECA	30	30	tablets	Cardinal			$497.03	
00002-8400-01	FORTEO SOL 600/2.4	LILLY	1	1	pen	McKesson	Yes		$3,683.28	
00002-8031-01	GLUCAGON KIT 1MG	LILLY	1	1	kit	Cardinal			$261.93	
00002-7510-01	HUMALOG INJ 100/ML	LILLY	1	1	vial	Cardinal			$256.24	
00002-8799-59	HUMALOG KWIK INJ 100/ML	LILLY	5	5	pens	Cardinal			$98.95	
00002-8797-59	HUMALOG MIX INJ 75/25KWP	LILLY	5	5	pens	Cardinal			$98.95	
00002-7511-01	HUMALOG MIX SUS 75/25	LILLY	1	1	vial	Cardinal			$265.57	
00002-8715-01	HUMULIN INJ 70/30	LILLY	1	1	vial	Cardinal			$138.71	
00002-8824-27	HUMULIN R INJ U-500	LILLY	2	2	pens	Cardinal			$267.81	
00078-0874-63	KISQALI TAB 600DOSE	NOVARTIS	43	43	tablets	McKesson	Yes		$12,912.30	
00088-2220-33	LANTUS INJ 100/ML	SANOFI	1	1	vial	Cardinal			$264.50	
00088-2219-05	LANTUS SOLOS INJ 100/ML	SANOFI	5	5	pens	Cardinal			$79.35	
00186-0917-06	PULMICORT INH 90MCG	ASTRAZENECA LP	1	1	inhaler	Cardinal			$178.95	
00186-0370-20	SYMBICORT AER 160-4.5	ASTRAZENECA LP	1	1	inhaler	Cardinal			$346.68	
00186-0372-20	SYMBICORT AER 80-4.5	ASTRAZENECA LP	1	1	inhaler	Cardinal			$303.30	
00024-5869-03	TOUJEO SOLO INJ 300IU/ML	SANOFI	3	3	pens	Cardinal			$120.87	
00002-1433-80	TRULICITY INJ 0.75/0.5	LILLY	4	4	pens	Cardinal			$196.91	
00002-1434-80	TRULICITY INJ 1.5/0.5	LILLY	4	4	pens	Cardinal			$196.91	
00002-4815-54	VERZENIO TAB 100MG	LILLY	14	14	tablets	McKesson	Yes		$3,016.92	
									Total Savings Loss December 2020	$70,523.57

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Purpose: This tool can be used to report the following types of issues for covered outpatient drugs, to the Health Resources and Services Administration (HRSA):

- Table 1: Unavailable at a 340B ceiling price and/or
- Table 2: Incorrect 340B ceiling price (overcharge)

Instructions: Enter data in each field describing the issue. Before completing and submitting the tool, the stakeholder should contact the wholesaler and manufacturer directly to determine the reason for unavailability and/or to document incorrect pricing. HRSA investigates allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. If HRSA determines additional information is needed from the covered entity or manufacturer, it may extend the time for follow-up. If the tool is unable to capture all details, **please attach additional documentation as necessary.** HRSA may reach out to the person submitting this notification for additional information.

This completed tool, including copies of communications with manufacturer and/or wholesaler and any responses, should be emailed to HRSA at: 340Bpricing@hrsa.gov

Entity Name: Beverly Hospital **340B ID:** DSH220033

Please list the product(s) affected (*you may list multiple drugs as long as the labeler codes are the same; the labeler code is the first five digits of an NDC. If multiple labeler codes are represented you will need to submit multiple forms*).

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
1	see attached sheet for full list of omissions				November 2020	
2.						
3.						

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug ☐ Yes ☐ No – see attached
- The issue reported is limited to a contract pharmacy purchase ☑ Yes ☐ No
- If shortage-related, is this a recurrent/intermittent availability issue? ☐ Yes ☑ No
- If shortage-related, is this due to a local/regional/national or global shortage? no shortage

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

AVAILABILITY ISSUE: If you are unable to purchase the product at a 340B price, fill out the information below.

Reason for lack of 340B access (*check all that apply*):

- ☐ Drug shortage
- ☐ Drug subject to limited distribution or specialty pharmacy plan
- ☑ Other (*please describe*): Manufacturer refusal of 340B pricing
- ☐ Unknown

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ☑ Verified the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data and signed PPA with labeler code active in 340B OPAIS, contacted manufacturer for confirmation, etc.)

  For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.
- ☑ Confirmed shortage issues by reviewing validated resources*
- ☑ Contacted wholesaler and/or manufacturer to confirm unavailability
- ☐ ***For hospitals subject to Group Purchasing Organization (GPO) Prohibition:*** purchased product on an GPO account, after exhausting all measures for obtaining drug at a non-GPO price (please list all measures taken, including which NDC was purchased instead due to unavailability)

  not applicable / WAC for Cardinal Pharmacy pricing
- ☒ Other (*please describe issue*):

  Manufacturers deliberately withholding 340B pricing

Date issue first observed: 10.1.20

Date drug last available at 340B price (enter NEVER if has never been available): September 2020

*Recommended Drug shortage resources:
FDA: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
ASHP: https://www.ashp.org/drug-shortages/current-shortages
Wholesaler catalog information

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

PRICING ISSUE: The drug can be purchased on the 340B account but price is greater than the price in the OPAIS Pricing System.

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- [x] Determined if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturersearch), and check the Medicaid Drug Rebate Program labeler code (https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data)

  Note: *For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs*

- [x] Validated the ceiling price using the 340B OPAIS pricing system on (date): 11·31·20
  - Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS
  - The OPAIS Pricing Database displays the 340B ceiling price at the unit level; the covered entity may need to multiply the ceiling price by the package size (this might be the total number of mL, tablets, capsules, grams, etc.) in the package purchased
  - For Prime Vendor participants, verify the selling price by visiting the password-protected Prime Vendor Program Catalog or 340B & PVP Product Selling Price Lookup tool. Package size information is available.
  - Adjust the purchase price for your wholesaler distribution charge/markdown
- [x] Attempted to work with the entity's wholesaler and directly with the manufacturer to resolve the pricing issue
- [x] Other (*please describe issue*):

Manufacturer(s) deliberately refusing 340B Pricing

Price paid by the covered entity (including package size): see attached

Date issue first observed: 10·1·20

Date product last available at correct price (enter NEVER if has never been available): September 2020

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

HRSA may reach out to the following contact person from the covered entity to help resolve the issue in question. By signing below the submitter consents/acknowledges that this information may be used in correspondence with Manufacturers and other Federal Agencies.

Contact Name (printed): Laura E. Murphy **Phone:** (978) 816-3625

Email Address: Laura.E.Murphy@lahey.org

Contact Role/Organization: 340B and Purchasing Manager

Contact Signature: [signature] **Date:** 11.30.20

Beverly Hospital - DSH220033
Manufacturer 340B Pricing Refusals in the Contract Pharmacy Setting
November 2020

11 digit NDC	Drug Name and Strength	Manufacturer	Package Size	Case Package Size	Unit of Measure	CE Wholesaler	Is This a Specialty Drug?	340B Price/unit	WAC Price/unit	Savings Lost
00024-5925-05	ADMELOG SOLO INJ 100U/ML	SANOFI	5	5	pens	Cardinal	No	[redacted]	$235.50	[redacted]
00002-7715-59	BASAGLAR INJ 100UNIT	LILLY	5	5	pens	Cardinal	No		$60.89	
00186-0777-60	BRILINTA TAB 90MG	ASTRAZENECA LP	60	60	tablets	Cardinal	No		$377.62	
00310-0095-30	DALIRESP TAB 500MCG	ASTRAZENECA	30	30	tablets	Cardinal	No		$369.62	
00024-5914-01	DUPIXENT INJ 300/2ML	SANOFI	2	2	pens	Cardinal	Yes		$1,516.17	
00310-6210-30	FARXIGA TAB 10MG	ASTRAZENECA	30	30	tablets	Cardinal	No		$497.03	
00002-8400-01	FORTEO SOL 600/2.4	LILLY	1	1	pen	Cardinal	Yes		$3,683.28	
00002-8031-01	GLUCAGON KIT 1MG	LILLY	1	1	kit	Cardinal	No		$261.93	
00002-7510-01	HUMALOG INJ 100/ML 10 ML VIAL	LILLY	1	1	vial	Cardinal	No		$256.24	
00002-7516-59	HUMALOG INJ 100/ML 3 ML CARTRIDGE	LILLY	5	5	cartridges	Cardinal	No		$95.23	
00002-8799-59	HUMALOG KWIK INJ 100/ML	LILLY	5	5	pens	Cardinal	No		$98.95	
00002-7511-01	HUMALOG MIX SUS 75/25 10 ML VIAL	LILLY	1	1	vial	Cardinal	No		$265.57	
00002-8147-01	HUMATROPE INJ 6MG	LILLY	1	1	cartridge	Cardinal	Yes		$822.98	
00002-8715-01	HUMULIN INJ 70/30 10 ML VIAL	LILLY	1	1	vial	Cardinal	No		$138.71	
00002-8805-59	HUMULIN N INJ U-100KWP	LILLY	5	5	pens	Cardinal	No		$87.93	
00002-8501-01	HUMULIN R INJ U-500 20 ML VIAL	LILLY	1	1	vial	Cardinal	No		$1,387.07	

00002-8824-27	HUMULIN R INJ U-500 3 ML PEN	LILLY	2	2	pens	Cardinal	No	[redacted]	$267.81	[redacted]
00002-7737-01	INSULIN LISP INJ 100/ML 10 ML VIAL	LILLY	1	1	vial	Cardinal	No		$128.12	
00088-2220-33	LANTUS INJ 100/ML 10 ML VIAL	SANOFI	1	1	vial	Cardinal	No		$264.50	
00088-2219-05	LANTUS SOLOS INJ 100/ML PEN	SANOFI	5	5	pens	Cardinal	No		$79.35	
00186-0917-06	PULMICORT INH 90MCG INHALER	ASTRAZENECA LP	1	1	inhaler	Cardinal	No		$178.95	
00186-0370-20	SYMBICORT AER 160-4.5	ASTRAZENECA LP	1	1	inhaler	Cardinal	No		$346.68	
00186-0372-20	SYMBICORT AER 80-4.5	ASTRAZENECA LP	1	1	inhaler	Cardinal	No		$303.30	
00078-0592-87	TASIGNA CAP 150MG	NOVARTIS	112	112	capsules	Cardinal	Yes		$14,716.02	
00024-5871-02	TOUJEO MAX INJ 300IU/ML	SANOFI	2	2	pens	Cardinal	No		$241.74	
00024-5869-03	TOUJEO SOLO INJ 300IU/ML	SANOFI	3	3	pens	Cardinal	No		$120.87	
00002-1433-80	TRULICITY INJ 0.75/0.5	LILLY	4	4	pens	Cardinal	No		$196.91	
00002-1434-80	TRULICITY INJ 1.5/0.5	LILLY	4	4	pens	Cardinal	No		$196.91	
00002-4815-54	VERZENIO TAB 100MG	LILLY	14	14	tablets	Cardinal	Yes		$3,016.92	
								Total Savings Loss November 2020		$86,040.15

Gerald Champion
Regional Medical Center
Our Family Caring For Yours

2669 Scenic Drive
Alamogordo, NM 88310
575-439-6100
www.gcrmc.org

March 31, 2021

Via 340Bpricing@hrsa.gov

Krista Pedley, RADM, USPHS
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, 08W05A
Rockville, MD 20857

RE: Unavailability of 340B Pricing and Request for Enforcement Action

Dear Rear Admiral Pedley:

We participate in the 340B drug pricing program as Gerald Champion Regional Medical Center (GCRM; 340B ID DSH320004). We are writing to report instances of overcharging by drug manufacturers that participate in the 340B program in violation of the 340B statute and to request that the Health Resources and Services Administration (HRSA) use its statutory authority to take enforcement action against drug manufacturers that have caused 340B overcharges.

We are no longer able to access 340B pricing for a number of products when we attempt to place orders to be shipped to our contract pharmacy locations.

Manufacturer	Date
Sanofi	Effective October 1, 2020
Astra-Zeneca	Effective October 1, 2020
Novartis Pharmaceuticals	New policy effective Nov. 16, 2020 (40 mile range)
Eli Lilly (including subsidiaries and affiliates)	Effective September 1, 2020
Novo Nordisk	Effective January 1, 2021

Attached is a list of some products for which 340B pricing is no longer available.

As you know, drug manufacturers must offer 340B pricing to covered entities, including for drugs dispensed through contract pharmacies. The 340B statute obligates drug manufacturers to offer 340B pricing to covered entities for covered outpatient drugs and does not permit a manufacturer to pick and choose when to make 340B pricing available.[1] Denying 340B pricing

[1] 42 U.S.C. § 256b(a)(1).

to a covered entity on the basis of a drug being dispensed through a contract pharmacy is a violation of the 340B statute's obligation to offer 340B pricing.

In addition, HRSA regulations call for the imposition of civil monetary penalties (CMPs) in cases where a manufacturer knowingly and intentionally overcharges a 340B covered entity.[2] Our inability to access 340B pricing for the products listed in the attachment constitute overcharges. Statements made by the manufacturers of the listed products indicate that the decisions to deny 340B pricing are knowing and intentional. Therefore, we request that HRSA exercise its authority under the 340B statute and the agency's regulations to penalize manufacturers that are committing overcharges.

We appreciate your assistance with this matter. For questions, we can be reached at (575) 443-7848.

Sincerely,

Bashar Naser
Chief Financial Officer/Authorized Official

Enclosure

[2] 42. C.F.R. § 10.11.

From: Olivia Little
To: HRSA HSB 340B Pricing
Subject: HRSA Notification Manufacturer Overcharge Submission Paperwork-CAH281350
Date: Tuesday, January 12, 2021 3:01:22 PM
Attachments: HRSA Notification Aventis Pharm (LC 00088) Overcharge Submission1.12.2021.pdf
HRSA Notification Eli Lilly (LC 00002)Overcharge Submission1.12.2021.pdf
HRSA Notification Novartis (LC 00078)Overcharge Submission1.12.2021.pdf
HRSA Notification Sanofi-Aventis (LC00024)Overcharge Submission1.12.2021.pdf
HRSA Notification AstraZeneca (LC 00186)Overcharge Submission1.12.2021.pdf
HRSA Notification AstraZeneca (LC 00310)Overcharge Submission1.12.2021.pdf

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To Whom it May Concern,
I have attached our HRSA notification paperwork for overcharging by manufacturers by labeler code for CAH281350. Please let me know if you have any questions.
Thank you,

Olivia Little, MHA, MLS (ASCP)^{CM}, CPhT, 340B ACE
340B Director, DME Supervisor
Johnson County Hospital
202 High St
Tecumseh, NE 68450
olittle@jchosp.com
Phone 402-335-6391
Fax 402-335-6343

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Purpose: This tool can be used to report the following types of issues for covered outpatient drugs, to the Health Resources and Services Administration (HRSA):

- Table 1: Unavailable at a 340B ceiling price and/or
- Table 2: Incorrect 340B ceiling price (overcharge)

Instructions: Enter data in each field describing the issue. Before completing and submitting the tool, the stakeholder should contact the wholesaler and manufacturer directly to determine the reason for unavailability and/or to document incorrect pricing. HRSA investigates allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. If HRSA determines additional information is needed from the covered entity or manufacturer, it may extend the time for follow-up. If the tool is unable to capture all details, **please attach additional documentation as necessary.** HRSA may reach out to the person submitting this notification for additional information.

This completed tool, including copies of communications with manufacturer and/or wholesaler and any responses, should be emailed to HRSA at: 340Bpricing@hrsa.gov

Background Information

Entity Name: Johnson County Hospital **340B ID:** CAH281350

Please list the product(s) affected (*you may list multiple drugs as long as the labeler codes are the same; the labeler code is the first five digits of an NDC. If multiple labeler codes are represented you will need to submit multiple forms*).

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
Spreadsheet attached						

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug ☐ Yes ☒ No
- The issue reported is limited to a contract pharmacy purchase ☒ Yes ☐ No
- If shortage-related, is this a recurrent/intermittent availability issue? ~~☐ Yes ☐ No~~ N/A
- If shortage-related, is this due to a local/regional/national or global shortage? N/A

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Table 2: Incorrect 340B Price

PRICING ISSUE: The drug can be purchased on the 340B account but price is greater than the price in the OPAIS Pricing System.

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

☒ Determined if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturersearch), and check the Medicaid Drug Rebate Program labeler code (https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data)

Note: *For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs*

☒ Validated the ceiling price using the 340B OPAIS pricing system on (date): 1-11-2021

- Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS
- The OPAIS Pricing Database displays the 340B ceiling price at the unit level; the covered entity may need to multiply the ceiling price by the package size (this might be the total number of mL, tablets, capsules, grams, etc.) in the package purchased
- For Prime Vendor participants, verify the selling price by visiting the password-protected Prime Vendor Program Catalog or 340B & PVP Product Selling Price Lookup tool. Package size information is available.
- Adjust the purchase price for your wholesaler distribution charge/markdown

☒ Attempted to work with the entity's wholesaler and directly with the manufacturer to resolve the pricing issue
→ See below

☒ Other (*please describe issue*): _Manufacturer is publically refusing to give 340B pricing to the covered entities' contract pharmacies. _____

Price paid by the covered entity (including package size):_____ Spreadsheet Attached

Date issue first observed: _____

Date product last available at correct price (enter NEVER if has never been available): _____

Invoice Date	NDC	NDC Description	Manufacturer_Name	Package Size	Case Package Size	Unit of Measure	CE Wholesaler	Price paid by CE	Date Issue First Observed	Date Product Last Available at Correct Price
10/7/2020	00078065920	ENTRESTO 24 MG-26 MG TABLET	NOVARTIS	60	1	Each	McKesson	264.68	10/7/2020-Current	I see they have been consistantly charging about $10 over ceiling price back to Dec 2019
10/7/2020	00078065920	ENTRESTO 24 MG-26 MG TABLET	NOVARTIS	60	1	Each	McKesson	264.68	10/7/2020-Current	I see they have been consistantly charging about $10 over ceiling price back to Dec 2019
10/16/2020	00078069620	ENTRESTO 97 MG-103 MG TABLET	NOVARTIS	60	1	Each	McKesson	290.16	10/16/2020-Current	Started Purchasing in October 2020 and have never seen correct price
11/9/2020	00078065920	ENTRESTO 24 MG-26 MG TABLET	NOVARTIS	60	1	Each	McKesson	264.68	10/7/2020-Current	I see they have been consistantly charging about $10 over ceiling price back to Dec 2019
11/11/2020	00078069620	ENTRESTO 97 MG-103 MG TABLET	NOVARTIS	60	1	Each	McKesson	290.16	10/16/2020-Current	Started Purchasing in October 2020 and have never seen correct price
12/11/2020	00078065920	ENTRESTO 24 MG-26 MG TABLET	NOVARTIS	60	1	Each	McKesson	264.68	10/7/2020-Current	I see they have been consistantly charging about $10 over ceiling price back to Dec 2019
12/14/2020	00078069620	ENTRESTO 97 MG-103 MG TABLET	NOVARTIS	60	1	Each	McKesson	290.16	10/16/2020-Current	Started Purchasing in October 2020 and have never seen correct price
12/14/2020	00078069620	ENTRESTO 97 MG-103 MG TABLET	NOVARTIS	60	1	Each	McKesson	290.16	10/16/2020-Current	Started Purchasing in October 2020 and have never seen correct price
12/14/2020	00078069620	ENTRESTO 97 MG-103 MG TABLET	NOVARTIS	60	1	Each	McKesson	290.16	10/16/2020-Current	Started Purchasing in October 2020 and have never seen correct price

Dear 340B Covered Entity,

I am writing in response to your recent letter regarding 340B overcharges for Sanofi products. As we indicated in our mailing, dated July 30th, and subsequent email communications, Sanofi has instituted a new 340B policy related to contract pharmacies, effective October 1, 2020. In the event you were not informed of these communications, I am outlining the new policy below. Should you have an overcharge related to an in-house 340B purchase (and the ship to pharmacy is registered as a covered entity pharmacy with the Health Resources and Services Administration), please contact Sanofi at Sanofi340BOperations@Sanofi.com.

Sanofi supports the 340B Program's core objective of increasing access to outpatient drugs among uninsured and vulnerable patients and is committed to maintaining and strengthening its mission. However, we are concerned about the rate of duplicate discounting on Medicaid prescriptions filled with 340B-purchased drugs. Similarly, manufacturers pay ineligible rebates on Medicare Part D and commercial utilization due to the lack of transparency in the 340B program.

To resolve these issues, Sanofi requires 340B covered entities to submit claims data for 340B prescriptions of Sanofi products filled through their contract pharmacies. Sanofi uses this data to match against rebate claims it receives to ensure it is not paying ineligible discounts. This initiative is enabled through 340B ESP™, a Second Sight Solutions technology. Sanofi is requiring entities new to this policy to register at www.340BESP.com. In the absence of submitting the data requested, covered entities will remain eligible to purchase Sanofi's drugs at 340B prices for shipment to their own facilities.

Sanofi has maintained a strong commitment to the 340B program since its inception. We also recognize that for the 340B program to continue in its mission, serious program integrity and transparency challenges must be addressed. That is why we adopted the 340B ESP™ platform and we look forward to working with 340B covered entities to further strengthen the 340B program.

Government reports and our own experience show that our duplicate discount concerns are well-founded. Despite the legal ban on forcing pharmaceutical manufacturers to double pay Medicaid rebates and 340B discounts on the same drug,[1] duplicate discounting on Medicaid claims has continued to occur. Over 30% of Health Resources and Services Administration (HRSA) audits of covered entities in 2018 and 2019 found Medicaid duplicate discounting, and government reports have repeatedly documented this ongoing concern.[2] Likewise, in a limited scope test that analyzed three years of

[1] 42 U.S.C. § 256b(a)(5)(A)(i).

[2] *See, e.g.*, GAO, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, GAO-18-480 (June 2018), https://www.gao.gov/assets/700/692697.pdf (hereinafter, "Oversight of Contract Pharmacies Needs Improvement"); GAO, 340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement, GAO-20-212 (January 2020), https://www.gao.gov/assets/710/703966.pdf (hereinafter, "Oversight of MDRP Intersection Needs

Medicaid rebates from five states for three Sanofi products, we identified over $16M in 340B duplicate discounts. Further, government reports have found that contract pharmacies have unfortunately hindered efforts to prevent duplicate discounts.[3] Between 2010 and 2019, the number of 340B contract pharmacies has grown 1,700 percent to about 23,000.[4] This rapid growth in contract pharmacy arrangements has only reinforced the need for our initiative.

Our initiative complies with the 340B statute and our agreement with the Department of Health and Human Services, which require that Sanofi "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."[5] Sanofi continues to offer all of its drugs to all 340B covered entities. Covered entities may purchase Sanofi's drugs at 340B prices for shipment to their own facilities. Additionally, Sanofi will offer 340B pricing on a non-discriminatory basis through contract pharmacy arrangements if a covered entity provides the modest data Sanofi requests, which are identical to data already submitted by contact pharmacies to other third parties and by insurers to manufacturers for rebate purposes, to prevent duplicate discounts. If a covered entity refuses to provide the requested data, then no 340B overcharge could occur on its requested contract pharmacy transactions because Sanofi would be under no obligation to offer the 340B price in this circumstance.

Please understand that we have designed our initiative so as not to burden covered entities. Our data submission portal is user-friendly, and as noted above, the required information is no different than what manufacturers require of insurance companies when paying rebates. The required information is the NCPDP standard for prescription claims. These data are generated by the pharmacy and submitted to insurance companies and, in the case of 340B contract pharmacies, to the third-party administrators that identify 340B eligible claims. Moreover, we do not request data on physician-administered drugs or drugs dispensed by covered entities' own facilities. Our approach also avoids burdensome and ineffective manual data exchanges.

Even more importantly, patients will not be affected by our initiative. Government Accountability Office reports have found that contract pharmacies often do not give discounts to patients and that in-house pharmacies (to which we in all circumstances will continue to sell 340B drugs) are significantly more likely to pass along drug cost savings to patients.[6] Given these findings and the ubiquity of duplicate discounts, we are hopeful that all stakeholders invested in the success and purpose of the 340B Program will work together on what we believe is a shared goal of improving 340B Program integrity. Eliminating duplicate discounts ultimately will free resources to be focused where they belong: on reducing patients' out-of-pocket costs.

We appreciate your cooperation in this initiative and value our relationship with you very much.

Improvement"); OIG, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431 (February 4, 2014), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.

[3] *Id*.

[4] GAO, Oversight of MDRP Intersection Needs Improvement, at 2.

[5] 42 U.S.C. § 256b(a)(1).

[6] GAO, Oversight of Contract Pharmacies Needs Improvement, at 30 and n. 46.

Sincerely,

Gerry Gleeson
Vice President and Head, U.S. Market Access Shared Services
Sanofi U.S.

NEXT STEPS AND FREQUENTLY ASKED QUESTIONS

To get started with Second Sight Solutions' 340B ESP™ platform, follow these three simple steps:

1. Go to www.340BESP.com to register your account. You will receive a two-factor verification code that is sent directly to your cell phone. As part of your initial registration, you will also receive a one-time authentication code via email.
2. Once your account is activated, you will be able to securely upload data to 340B ESP™. You will receive periodic notifications of pending data submissions and new contract pharmacy set up activities.
3. Login to 340B ESP and submit your 340B contract pharmacy claims data on a bi-weekly basis. Once your account is set up, the claims upload process takes ~ 5 minutes.

In addition to the frequently asked questions below, you can visit www.340BESP.com/FAQs to learn more about 340B ESP™. For further help with the registration, account setup, and data submission process please call Second Sight Solutions at 888-398-5520. To learn more about how Sanofi is working to improve program integrity through 340B ESP™, please contact Sanofi directly at Sanofi340BOperations@sanofi.com.

Q: How will Sanofi use the 340B claims data that we provide through 340B ESP™?

A: Data uploaded by 340B covered entities will be used to identify and resolve duplicate Medicaid and commercial rebates.

Q. My covered entity excludes Medicaid patients from our contract pharmacy utilization and/or my state has a Medicaid carve out that excludes these patients from 340B. Do I still need to submit data to Sanofi through 340B ESP?

A: Yes. This initiative is to address duplicate Medicaid rebates as well as ineligible rebates paid to commercial and Medicare Part D payers. Sanofi utilizes the claims data provided by 340B covered entities to address these duplicate discounts. All forms of duplicate discounts impair the sustainability of the 340B Program, so all must be addressed. The 340B statute permits this approach because Sanofi will continue to offer 340B pricing to covered entities outside contract pharmacy arrangements, regardless of whether data is provided.

Q: How does 340B ESP™ protect the privacy of my patients?

A: Data uploaded to 340B ESP™ is de-identified and meets the definition of a De-identified Data Set under HIPAA. This means no actual protected health information (PHI) is collected and the data cannot be combined with other data sets to reveal the identity of a patient. Additional security controls are embedded throughout the platform.

Q: The required claims data elements include prescription number, prescribed date and date of service (fill date). Aren't those data elements considered PHI?

The prescription number, prescribed date and date of service (or fill date) are de-identified through a HIPAA compliant hashing process known as SHA-3 hashing. An additional layer of security called a "salt" is applied prior to any data being uploaded to 340B ESP™. This process was granted an Expert Determination by Dr. Brad Malin, a professor at Vanderbilt University Medical Center, indicating that it meets the definition of a De-Identified Data Set

under HIPAA and does not contain PHI. Additional information on this expert determination may be requested by contacting Second Sight Solutions at 888-398-5520.

Q. My covered entity requires that we enter into a Business Associate Agreement (BAA) with Second Sight Solutions prior to submitting data. How do I initiate that process?

Second Sight Solutions does make a standard BAA available to 340B covered entities that require a BAA to be in place prior to submitting data. To request a BAA, you can email support@340besp.com or complete the BAA request form at www.340Besp.com/BAA.

Q: Is Sanofi requesting data for all Sanofi products?

A: No. Sanofi is only requesting data for Sanofi drugs commonly dispensed through retail, specialty and outpatient pharmacies registered on the HRSA database as a contract pharmacy. Physician-administered drugs are not part of this program. 340B ESP™ automatically limits the data in your upload file to the applicable NDCs.

Q: How do I know which NDCs to submit into the 340B ESP™ platform?

A: At a minimum, covered entities must upload data for all Sanofi NDCs that are not physician-administered drugs. Sanofi NDCs have the following NDC "labeler code" values at the beginning of their NDC numbers: 00024, 00039, 00068, 00075, 00088, 00955, 58468 and 72733. Alternatively, a covered entity could upload a broader set of data, and the system will share with Sanofi only data on Sanofi's NDCs..

Q: What happens if my organization does not provide 340B contract pharmacy claims data?

A: Sanofi is requiring 340B covered entities to register with 340B ESP™ and begin providing 340B claims data by October 1, 2020. 340B covered entities that elect not to provide 340B claims data will no longer be eligible to place 340B Bill To / Ship To replenishment orders for Sanofi products dispensed through a contract pharmacy. All 340B covered entities will continue to be able to purchase Sanofi products at the 340B price when shipped to an address registered on the 340B covered entity database as a parent or child site.

Q: Is Sanofi requesting data for pharmacies that are registered with HRSA as a covered entity?

A: No. Sanofi is only requesting data for 340B claims that originates from contract pharmacies. Covered entities do not need to provide 340B claims for prescriptions filled in their own outpatient pharmacies.

Q: What benefit does the 340B covered entity realize by using 340B ESP™?

A: By providing 340B claims data that originate from contract pharmacies, you will enable Sanofi to definitively identify duplicate Medicaid rebates. Covered entities will then be informed which pharmacies are dispensing 340B purchased drugs to Medicaid patients. This information can be used to further strengthen the audit processes and compliance controls of the covered entity.

Q: Does HRSA and/or Apexus support this initiative?

A: HRSA encourages 340B covered entities to work with pharmaceutical manufacturers in good faith to resolve issues of non-compliance in the 340B program. Although neither HRSA nor Apexus has commented publicly on this specific initiative, Sanofi believes 340B ESP™ provides a simple platform for Sanofi and 340B covered entities to engage collaboratively and in good faith to address duplicate discounts.

Q: How often will I need to upload 340B contract pharmacy claims data to 340B ESP™?

A: The 340B ESP™ platform requires claims uploads every two weeks. The actual upload process takes ~5 minutes and should not place significant burden on 340B covered entity operations. Email reminders are automatically generated from 340B ESP™ and covered entities can monitor claims submission status when logged in to the platform.

Q: What technology requirements exist to successfully upload data to 340B ESP™?

A: 340B ESP™ is compatible with most internet browsers including Microsoft Edge, Google Chrome, Safari, FireFox and others. However, we strongly recommend using Google Chrome for the best user experience. Users will need an internet connection and access to a supported browser to successfully upload data.

MaineHealth

Dear HRSA agent,

I am writing to you on behalf of MaineHealth 340B hospitals to notify you of our lack of ability to access 340B pricing for all Eli Lilly, AstraZeneca, Sanofi and Novartis NDCs to replenish eligible 340B claims for all of our active contract pharmacies.

Please do not hesitate to reach out to me if you have any questions or need additional information.

Sincerely,

Minh Hoang

Director of 340B and Drug Supply Management

MaineHealth

MaineHealth

Background Information

340B HOSPITALS	340B ID
MAINE MEDICAL CENTER	DSH200009
PENOBSCOT BAY MEDICAL CENTER	DSH200063
LINCOLNHEALTH DBA MAINEHEALTH	CAH201302-00
WALDO COUNTY GENERAL HOSPITAL	CAH201312-00
THE MEMORIAL HOSPITAL	CAH301307-00
FRANKLIN MEMORIAL HOSPITAL	SCH200037-00
STEPHENS MEMORIAL HOSPITAL	CAH201315-00

Wholesalers: McKesson, Cardinal

Products affected:

00002327004	CYMBALTA CAP 60MG	
00002144509	TALTZ AUTO INJECTOR 80MG	3
00002144527	TALTZ AUTO INJECTOR 80MG	2
00002840001	FORTEO PEN 250MCG ML	2.4ML
00002814901	HUMATROPE CARTR KIT	24MG
00002772411	TALTZ PF SYRINGE 80MG	1
00002144511	TALTZ AUTO INJECTOR 80MG	1
00002446330	CIALIS TAB 10MG	30
00002446430	CIALIS TAB 20MG	30
00024540131	AMBIEN TAB 5MG	100
00024550131	AMBIEN CR TAB 6.25MG	100
00002762301	ALIMTA SDV 500MG	20ML
00024542131	AMBIEN TAB 10MG	100
00024552131	AMBIEN CR TAB 12.5MG	100
00777310502	PROZAC PULVULE 20MG	100
00777310402	PROZAC PULVULE 10MG	100
00002850101	HUMULIN R REG INSULN U500	20ML
00310610090	ONGLYZA TAB 2.5MG	90
00088216030	ARAVA TAB 10MG	30
00088216130	ARAVA TAB 20MG	30
00002814801	HUMATROPE CARTR KIT	12MG
00310610590	ONGLYZA TAB 5MG	90
00075291501	LOVENOX SAF SYR 150MG 1ML	10
00310027910	SEROQUEL TAB 400MG	100
00310028460	SEROQUEL XR TAB 400MG	60
00024590801	KEVZARA PFS 150MG 1.14 ML	2
00024591001	KEVZARA PFS 200MG 1.14 ML	2
00024592001	KEVZARA INJ PFP150MG 1.14ML	2

MaineHealth

00024592201	KEVZARA INJ PFP200MG 1.14ML 2
00955104818	SEVELAMER HCL TB 800MG WIN 180
00310662702	SYMLIN PEN 120 2.7ML 2
00002512377	EFFIENT TAB 10MG BP INST 90
00002445685	ZYPREXA ZYDIS TAB 20MG UD 30
00075291201	LOVENOX SAF SYR 120MG 0.8ML 10
00310028360	SEROQUEL XR TAB 300MG 60
00955105027	SEVELAM CARB TB 800MG WIN 270
00310072010	FASLODEX PFS 250MG 5ML 2X5.0ML
00024414210	MULTAQ TAB 400MG UD 10X10
00310027210	SEROQUEL TAB 200MG 100
00777310730	PROZAC PULVULE 40MG 30
00002442030	ZYPREXA TAB 20MG 30
00310661502	SYMLIN PEN 60 1.5ML 2
00002621654	VERZENIO TAB 200MG BP 14
00002533754	VERZENIO TAB 150MG BP 14
00002448354	VERZENIO TAB 50MG BP 14
00002481554	VERZENIO TAB 100MG BP 14
00002445585	ZYPREXA ZYDIS TAB 15MG UD 30
00310009590	DALIRESP 500MCG TAB 90
00024583701	FLOMAX CAP 0.4MG SAN 100
00024591401	DUPIXENT PFS300MG 2ML 2
00310028260	SEROQUEL XR TAB 200MG 60
00024591801	DUPIXENT PFS200MG 1.14 2ML 2
00075062300	LOVENOX SAF SYR 100MG 1ML 10
00310651201	BYETTA SINJ 250MCG ML
00310652401	BYETTA PEN 10MCG
00310075290	CRESTOR TAB 20MG 90
00310075590	CRESTOR TAB 5MG 90
00310075190	CRESTOR TAB 10MG 90
00310028160	SEROQUEL XR TAB 150MG 60
00002441530	ZYPREXA TAB 15MG 30
00024591502	DUPIXENT INJ 300MG 2ML 2
00310027460	SEROQUEL TAB 300MG 60
00310653004	BYDUREON PEN 2MG CT4
00002418230	OLUMIANT TAB 2MG 30
00186074282	PRILOSEC CAP 20MG 1000
00310652004	BYDUREON 2MG CT4
00002445485	ZYPREXA ZYDIS TAB 10MG UD 30
00075062280	LOVENOX SAF SYR 80MG 0.8ML 10
00002814701	HUMATROPE CARTR KIT 6MG
00024585090	AVAPRO TAB 75MG 90

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00002324090	CYMBALTA CAP 30MG	90
00186502054	NEXIUM CAP 20MG	90
00186504054	NEXIUM CAP 40MG	90
00002882427	HUMULIN R KWIK PEN U500 3ML	2
00310625030	XIGDUO XR TAB 5 500MG	30
00310627030	XIGDUO XR TAB 10 500MG	30
00024414260	MULTAQ TAB 400MG	60
00002418402	EVISTA TAB 60MG	100
00088250205	APIDRA SOLOSTAR PEN 3ML	5
00002143480	TRULICITY 1.5MG 0.5ML PEN	4
00002143380	TRULICITY 0.75MG 0.5ML PEN	4
00310027110	SEROQUEL TAB 100MG	100
00002473230	OLUMIANT TAB 1MG	30
00002771459	HUMALOG JUNIOR KWIKPEN 3ML	5
00002879759	HUMALOG KWIK PEN 75 25	5
00002879859	HUMALOG MIX KWIKPEN 50 50	5
00002879959	HUMALOG KWIK PEN 3ML	5
00310620530	FARXIGA TAB 5MG	30
00310621030	FARXIGA TAB 10MG	30
00310628030	XIGDUO XR TAB 10 1000MG	30
00310626060	XIGDUO XR TAB 5 1000MG	60
00075062160	LOVENOX SAF SYR 60MG 0.6ML	10
00002751659	HUMALOG CART 3-ML	5
00002411730	ZYPREXA TAB 10MG	30
00777310530	PROZAC PULVULE 20MG	30
00002411630	ZYPREXA TAB 7.5MG	30
00310027810	SEROQUEL TAB 50MG	100
00310654004	BYDUREON BCISE AUTOINJ 2MG CT4	
00186077739	BRILINTA TAB 90MG UD	100
00024576105	SOLIQUA 100 33 PEN	5
00955105490	SEVELAMER CARB PWD 2.4GWINT90@	
00955172150	DOXERCALCIF CAP 1MCG WIN 50@	
00024587102	TOUJEO MAX SOLOSTAR 3ML	2
00039022310	AMARYL TAB 4MG	100
00310610030	ONGLYZA TAB 2.5MG	30
00310610530	ONGLYZA TAB 5MG	30
00310613530	KOMBIGLYZ XR TB 5MG 500MG	30
00310614530	KOMBIGLYZ XR TB 5MG 1000MG	30
00310612560	KOMBIGLYZ XR TB 2.5 1000MG	60
00002733511	HUMATROP 5MG COMB PACK	KIT
66733095823	ERBITUX VL 2MG ML	100ML

MaineHealth

00002445385	ZYPREXA ZYDIS TAB 5MG UD 30
00088221905	LANTUS SOLOSTAR PEN 3ML 5
00002322930	STRATTERA CAP 40MG 30
00002323930	STRATTERA CAP 60MG 30
00955105290	SEVELAMER CARB PWD 0.8GWINT90@
00002325130	STRATTERA CAP 100MG 30
00002325030	STRATTERA CAP 80MG 30
00310622560	XIGDUO XR TAB 2.5 1000MG 60
00002237711	EMGALITY INJ PFS 120MG 1
00002143611	EMGALITY INJ PEN 120MG ML 1
00002311509	EMGALITY INJ PFS 100MG ML 3
00310028060	SEROQUEL XR TAB 50MG 60
00002880559	HUMULIN N KWIKPEN 5
00310020130	ARIMIDEX TAB 1MG 30
00002323560	CYMBALTA CAP 20MG 60
00002323430	SYMBYAX CAP 12 50MG 30
00186032254	ATACAND HCT TAB 32 12.5MG 90
00310678030	QTERN 10MG 5MG TAB 30
00186003254	ATACAND TAB 32MG 90
00186016254	ATACAND HCT TAB 16 12.5MG 90
00955172250	DOXERCALCIF CAP 2.5MCG WIN 50@
00002323830	STRATTERA CAP 18MG 30
00002322730	STRATTERA CAP 10MG 30
00002322830	STRATTERA CAP 25MG 30
00310677030	QTERN 5MG 5MG TAB 30
00002512330	EFFIENT TAB 10MG 30
00002512130	EFFIENT TAB 5MG 30
00186604001	NEXIUM IV 40MG 5ML 10
00186037020	SYMBICORT MDI 160 4.5MCG 120DO
00186032454	ATACAND HCT TAB 32 25MG 90
00024586903	TOUJEO SOLOSTAR PEN 1.5ML 3
00002764001	ALIMTA SDV 100MG 4ML
00310461612	BREZTRI AEROSPHERE 120INH 1
00002771227	HUMALOG KWIK PEN U200 3ML 2
00002512152	EFFIENT TAB 5MG BP INST 24
00002880359	HUMULIN 70 30 KWIKPEN 5
00186199004	PULMICORT RESPULE 1MG 2ML 30
00002411530	ZYPREXA TAB 5MG 30
00310027510	SEROQUEL TAB 25MG 100
00186037220	SYMBICORT MDI 80 4.5MCG 120DO

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00955101510	ENOXAP SOD SYR 150 1ML WINT10@
00186001654	ATACAND TAB 16MG 90
00075062040	LOVENOX SAF SYR 40MG 0.4ML 10
00186401001	NEXIUM DR OS PWD 10MG PKT 30
00002411230	ZYPREXA TAB 2.5MG 30
00002446534	CIALIS TAB 2.5MG BP 30
00955101210	ENOXAP SOD SYR120 0.8MLWINT10@
00310070530	CASODEX TAB 30
00186402001	NEXIUM DR OS PWD 20MG PKT 30
00186404001	NEXIUM DR OS PWD 40MG PKT 30
00024585630	AVALIDE TAB 300 12.5MG 30
00002751101	HUMALOG VIAL 75 25 10ML
00002751201	HUMALOG VIAL 50 50 10ML
00088250033	APIDRA INSULIN VIAL 10ML
00088222033	LANTUS INSULIN VIAL 10ML
00186077760	BRILINTA TAB 90MG 60
00310460012	BEVESPI AEROSPHERE 1
00002751001	HUMALOG VIAL 100U 10ML
00186402501	NEXIUM DR OS PWD 2.5MG PKT 30
00186405001	NEXIUM DR OS PWD 5MG PKT 30
00310009530	DALIRESP TAB 500MCG 30
00002323330	SYMBYAX CAP 6 50MG 30
00002323130	SYMBYAX CAP 6 25MG 30
00002775205	INSULIN LISPRO INJ100U ML 5
00002822259	INSULIN LISPRO KWIKPEN 3MLX5
00002823305	INSULIN LISP PRO INJ100U ML 5
00002823305	INSULIN LISP PROT INJ100U ML 5
00024585530	AVALIDE TAB 150 12.5MG 30
00002803101	GLUCAGON EMERG KIT 1MG SYR 1ML
00024585230	AVAPRO TAB 300MG 30
00075062430	LOVENOX SAF SYR 30MG 0.3ML 10
00075062603	LOVENOX MDV 300MG 3ML
00186077660	BRILINTA TAB 60MG 60
00310075430	CRESTOR TAB 40MG 30
00186091612	PULMICORT FLEXHLR 180MCG 120DS
00186037028	SYMBICORT MDI 160 4.5MCG HUD60
00039022210	AMARYL TAB 2MG 100
00024060545	ELIGARD KIT 45MG 6-MONTH 1

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00955101010	ENOXAP SOD SYR 100MG MLWINT10@
00024585130	AVAPRO TAB 150MG 30
00186037228	SYMBICORT MDI 80 4.5MCG HUD60
00186070210	ENTOCORT EC CAP 3MG 100
00186198904	PULMICORT RESPULE 0.5MG 2ML 30
00310111030	LOKELMA O S 10G 30
00310110530	LOKELMA O S 5G 30
00002324030	CYMBALTA CAP 30MG 30
00002327030	CYMBALTA CAP 60MG 30
66733094823	ERBITUX VL 2MG ML 50ML
00186502031	NEXIUM CAP 20MG 30
00186504031	NEXIUM CAP 40MG 30
00310009539	DALIRESP TAB 500MCG UD 20
00310461639	BREZTRI AEROSPHERE 28INH HUD 1
00186091706	PULMICORT FLEXHLR 90MCG 60DS
00002223680	TRULICITY SDV 3MG .5ML 4
00002318280	TRULICITY SDV 4.5MG .5ML 4
00955173730	LEFLUNOMIDE TAB 20MG WIN30@
00955100810	ENOXAP SOD SYR 80 0.8MLWINT10@
00955173530	LEFLUNOMIDE TAB 10MG WIN30@
00002418430	EVISTA TAB 60MG 30
00002323030	SYMBYAX CAP 3 25 30
00955170210	ZOLPIDEM TB 6.25MG ER WINT100@
00955170310	ZOLPIDEM TB ER 12.5MG WINT100@
00024581230	APLENZIN ER TAB 522MG 30
00310460039	BEVESPI AEROSPHERE HUD 1
00186198804	PULMICORT RESPULE .25MG 2ML 30
00024159601	PRIMAQUINE TAB 26.3MG 100
00002431208	REYVOW TB 50MG 8
00002449108	REYVOW TB 100MG 8
00039022110	AMARYL TAB 1MG 100
00024117190	PLAVIX TAB 75MG 90
00002773701	INSULIN LISPRO INJ100U ML 10ML
00310028139	SEROQUEL XR TAB 150MG HUD 100
00955100610	ENOXAP SOD SYR 60 0.6MLWINT10@
00002614527	BAQSIMI PWD DEVICE 3MG 2
00186003231	ATACAND TAB 32MG 30
00024059010	ELOXATIN VIAL AQ 50MG 1
00002820705	LYUMJEV KWIKPEN INJ 100U ML 5
00002831501	HUMULIN N NPH INSUL U100 10ML

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00002821501	HUMULIN R REG INSUL U100 10ML
00310197039	MOVANTIK TAB 25MG BLSTR UD 100
00186000431	ATACAND TAB 4MG 30
00186000831	ATACAND TAB 8MG 30
00186001631	ATACAND TAB 16MG 30
00002446230	CIALIS TAB 5MG 30
00002446234	CIALIS TAB 5MG BP 30
00310008828	DALIRESP TAB 250MCG UD 28
00002822827	LYUMJEV KWIKPEN INJ 200U ML 2
00075002600	DDAVP TAB 0.2MG 100
00088222541	KETEK TAB 400MG 60
00955100410	ENOXAP SOD SYR 40 0.4MLWINT10@
00955172050	DOXERCALCIF CAP 0.5MCG WIN 50@
00002751017	HUMALOG VIAL 100U 3ML
00024581130	APLENZIN ER TAB 348MG 30
00002771559	BASAGLAR KWIKPEN 3ML 5
00310111039	LOKELMA O S 10G HUD 11
00310110539	LOKELMA O S 5G HUD 11
00310008839	DALIRESP TAB 250MCG UD 20
00024586001	CLOLAR VIAL 20ML SINGLE
00024585690	AVALIDE TAB 300 12.5MG 90
00024592505	ADMELOG SOLOSTAR PEN 3ML 5
00002614511	BAQSIMI PWD DEVICE 3MG 1
00002772801	LYUMJEV INJ 10ML 1
00075001600	DDAVP TAB 0.1MG 100
00075245153	DDAVP VIAL 4MCG ML 10ML
00024581030	APLENZIN ER TAB 174MG 30
00955100310	ENOXAP SOD SYR 30 0.3MLWINT10@
00024585590	AVALIDE TAB 150 12.5MG 90
00955101601	ENOXAP SOD MDV 300MG WIN 3ML@
00024585290	AVAPRO TAB 300MG 90
00002323230	SYMBYAX CAP 12 25MG 30
00310095036	ZOLADEX SAF SYR 3.6MG SINGLE
00310010110	TENORMIN TAB 100MG 100
00310013411	ZESTRIL TAB 40MG 100
00068002001	NORPRAMIN TAB 100MG 100
00310010510	TENORMIN TAB 50MG 100
00310013311	ZESTRIL TAB 30MG 100
00002442030	VNGD ZYPREXA TAB 20MG 30

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00310010710	TENORMIN TAB 25MG 100
00310013211	ZESTRIL TAB 20MG 100
00310014511	ZESTORETIC TAB 20 25MG 100
00088120305	ANZEMET TAB 100MG BOTTLE 5
00310011510	TENORETIC TAB 50 25 100
00310013011	ZESTRIL TAB 5MG 100
00310013111	ZESTRIL TAB 10MG 100
00310013511	ZESTRIL TAB 2.5MG 100
00310014111	ZESTORETIC TAB 10 12.5MG 100
00310014211	ZESTORETIC TAB 20 12.5MG 100
00024039102	DRISDOL LIQ D DRP 8MIU 60 ML
00002759701	ZYPREXA IM SDV 10MG SINGLE
00955103710	METHENAM HIPPUR TB 1GM WINT100
00075245201	DDAVP NASAL SPR BOTTLE 5ML
00955104690	IRBESART HCTZ 300 12.5 WINT 90
00002831517	HUMULIN N NPH INSUL U100 3ML
00024592410	ADMELOG MDV 100U ML 10ML
00002441530	VNGD ZYPREXA TAB 15MG 30
00088210224	PRIFTIN TAB 150MG BP 3X8
00088120205	ANZEMET TAB 50MG BOTTLE 5
00002821517	HUMULIN R REG INSUL U100 3ML
00310196930	MOVANTIK TAB 12.5MG 30
00002871501	HUMULIN 70 30 MDV 10ML
00068001501	NORPRAMIN TAB 50MG 100
00955104590	IRBESART HCTZ 150 12.5 WINT90@
00310032520	MERREM VL 500MG 20ML 10
00186074331	PRILOSEC CAP 40MG 30
00068050960	RIFAMATE CAP 60
00068027761	HIPREX TAB 100
00024592605	ADMELOG VIAL 100U ML 3ML
00186109405	TOPROL-XL TAB 200MG 100
00024588236	AFREZZA PWD KT 30X4UN 60X8UN
00310028460	VNGD SEROQUEL XR TAB 400MG 60
00024588463	AFREZZA PWD KT 60X4UN 30X8UN
00066000708	OPSITE DRS 2.5X2GOV CMPL CS100
00002411730	VNGD ZYPREXA TAB 10MG 30
00310028360	VNGD SEROQUEL XR TAB 300MG 60
00024587490	AFREZZA PWD KIT 90X4UN
00955171016	TRIAM ACE NAS SPR WINT 16.5G
00075245001	DDAVP RHINAL TUBE 2.5ML
00186074231	PRILOSEC CAP 20MG UU 30
00068003701	CANTIL TAB 25MG 100

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00186060631	PRILOSEC CAP 10MG	30
00186061001	PRILOSEC PWD 10MG PACKET	30
00186062501	PRILOSEC PWD 2.5MG PACKET	30
00068001101	NORPRAMIN TAB 25MG	100
00186109205	TOPROL-XL TAB 100MG	100
00186109239	TOPROL-XL TAB 100MG UD	100
00039005210	DIABETA TAB 5MG	100
00002411530	VNGD ZYPREXA TAB 5MG	30
00186107008	RHINOCORT AQUA 120DS SPR 32MCG	
00002300475	PROZAC WEEKLY CAP 90MG	4
00088120806	ANZEMET VL 12.5MG	6
00002411630	VNGD ZYPREXA TAB 7.5MG	30
00002411230	VNGD ZYPREXA TAB 2.5MG	30
00088210032	PRIFTIN TAB 150MG UD 4X8	
00186108805	TOPROL-XL TAB 25MG	100
00186109039	TOPROL-XL TAB 50MG UD	100
00310040160	ACCOLATE TAB 10MG	60
00310040260	ACCOLATE TAB 20MG	60
00002871517	HUMULIN 70 30 VIAL	3ML
00066000709	OPSITE DRS3.8X3.4GOV CMPL CS20	
00039006013	LASIX TAB 40MG	100
00955104090	IRBESART TAB 75MG WINT	90
00955104290	IRBESART TAB 300MG WINT	90
00955104190	IRBESART TAB 150MG WINT	90
00039006605	LASIX TAB 80MG	50
00039001710	CLAFORAN VIAL 500MG	10
00039006710	LASIX TAB 20MG	100
00088120632	ANZEMET SDV 100MG	5ML
00002967301	LUXURA HD SINGLE PEN	1
00039001910	CLAFORAN VIAL 2GM	10
00777310507	PROZAC PULVULE 20MG	2000
00078018425	SANDOSTATIN 1 MG/ML VIAL 5 ML X 1	
00078053815	TYZEKA 600 MG TABLET 30 EACH X 1	
00078044605	VOLTAREN-XR 100 MG TABLET 100 EACH X 1	
00078050059	LAMISIL 187.5 MG GRANULES PACK 1 EACH X 42	
00078017915	LAMISIL 250 MG TABLET 30 EACH X 1	
00078038405	LOTREL 5-40 MG CAPSULE 100 EACH X 1	
00078036815	FAMVIR 500 MG TABLET 30 EACH X 1	
00078049959	LAMISIL 125 MG GRANULES PACKET 1 EACH X 42	
00078012605	CLOZARIL 25 MG TABLET 100 EACH X 1	
00078017605	LESCOL 20 MG CAPSULE 100 EACH X 1	
00078023405	LESCOL 40 MG CAPSULE 100 EACH X 1	
00078036715	FAMVIR 250 MG TABLET 30 EACH X 1	

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00078032344	EXELON 1.5 MG CAPSULE 60 EACH X 1
00078032444	EXELON 3 MG CAPSULE 60 EACH X 1
00078032544	EXELON 4.5 MG CAPSULE 60 EACH X 1
00078032644	EXELON 6 MG CAPSULE 60 EACH X 1
00078036615	FAMVIR 125 MG TABLET 30 EACH X 1
00078056130	EXFORGE HCT 10-160-12.5 MG TAB 30 EACH X 1
00078056230	EXFORGE HCT 10-160-25 MG TAB 30 EACH X 1
00078047215	DIOVAN HCT 320-25 MG TABLET 30 EACH X 1 UD
00078047115	DIOVAN HCT 320-12.5 MG TAB 30 EACH X 1 UD
00078061915	ARCAPTA NEOHALER 75 MCG CAP 30 EACH X 1
00078056030	EXFORGE HCT 5-160-25 MG TAB 30 EACH X 1
00078055930	EXFORGE HCT 5-160-12.5 MG TAB 30 EACH X 1
00078038315	DIOVAN HCT 160-25 MG TABLET 30 EACH X 1 UD
00078040001	LOPRESSOR 5 MG/5 ML AMPUL 5 ML X 10
00078052115	TEKTURNA HCT 150-12.5 MG TAB 30 EACH X 1
00067211802	KERI MOIST SEN THR PROF 2Z 144
00078060515	TEKAMLO 300 MG-5 MG TABLET 30 EACH X 1
00078060615	TEKAMLO 300 MG-10 MG TABLET 30 EACH X 1
00078052215	TEKTURNA HCT 150-25 MG TABLET 30 EACH X 1
00078017615	LESCOL 20 MG CAPSULE 30 EACH X 1
00078023415	LESCOL 40 MG CAPSULE 30 EACH X 1
00067512514	NICOTINE 14 MG/24HR PATCH 14 EACH X 1
00067512414	NICOTINE 7 MG/24HR PATCH 14 EACH X 1
00067628628	PREVACID 24HR DR 15 MG CAPSULE 28 EACH X 1
00067512407	NICOTINE 7 MG/24HR PATCH 7 EACH X 1
00067013472	GAS-X EXTRA STRENGTH SOFTGEL 72 EACH X 1
00067211016	ALPHA KERI SHOWER & BATH OIL 473.2 ML X 1
00067209103	VAGISTAT-3 COMBO PACK 1 EACH X 1
00067399942	LAMISIL AT 1% CREAM 12 GRAM X 1
00078042957	GENTEAL SEVERE 0.3% EYE GEL 10 GRAM X 2
00067210520	KERI ORIG MOIST THERAPY LOT 567 GRAM X 1
00078042524	GENTEAL GEL DROPS 15 ML X 1
00067210015	KERI NOURSHNG SHEA BUTTER LOTN 425 GRAM X 1
00067210585	KERI ORIG MOIST THERAPY LOT 241 GRAM X 1
00067203002	ACETAMIN/ASA/CAFF
00067203702	ACETAMIN/ASA/CAFF
00067813901	EXCEDRIN TENSION HEAD CAPLT 24

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug ☐ Yes ☒ No
- The issue reported is limited to a contract pharmacy purchase? ☒ Yes ☐ No
- If shortage-related, is this a recurrent/intermittent availability issue? ☐ Yes ☐ No
- If shortage-related, is this due to a local/regional/national or global shortage? _____

From: Minh N. Hoang
To: HRSA HSB 340B Pricing
Subject: RE: 340B Pricing Unavailable
Date: Tuesday, December 15, 2020 9:04:01 AM
Attachments: image010.png
image011.jpg
image012.jpg
image013.jpg
image014.jpg
image015.jpg
image016.jpg
image002.jpg
image003.jpg
image006.jpg
image007.jpg
image017.jpg
HRSA notification_MaineHealth 121520.docx

Good morning,
We would like to continue to notify HRSA of the same manufacturers, Eli Lilly, AstraZeneca, Sanofi and Novartis, continuing to withhold 340B pricing for 340B eligible dispenses at contract pharmacies. In just a few short weeks, Novo Nordisk will be joining in this unfortunate effort to withhold 340B pricing as well. This is a hard hit to our financial wellness, which is already significant impacted by the pandemic. Today, MaineHealth will administer the first doses of the COVID-19 vaccines and it is unfair for us to risk lives to take care of our vulnerable population and employees during this hard time while manufacturers selfishly try to protect their bottom line.
We need help and we hope HRSA will take actions to protect health systems, some of the true heroes during this pandemic.
Sincerely,
Minh

Minh Hoang, PharmD, MPH, BCACP, 340B ACE
Director of 340B and Drug Supply Management
MaineHealth | Pharmacy Enterprise | 131 Chadwick St, Portland ME 04102
Office: 207-662-8074 | mhoang@mainehealth.org

From: Minh N. Hoang
Sent: Monday, November 30, 2020 3:03 PM
To: 'HRSA HSB 340B Pricing' <340BPricing@hrsa.gov>
Subject: 340B Pricing Unavailable
Good afternoon,
Here is our continued effort to let HRSA know that the following manufacturers continue to withhold 340B price for their medications for eligible 340B dispenses at contract pharmacy. Besides Eli Lilly, AstraZeneca and Sanofi, Novartis has also started to block their 340B price starting 11/16. Please also note that their exception for contract pharmacies within 40-mile radius of covered entity is purely a marketing strategy. They are well aware that their medications are mostly dispensed at national specialty pharmacy chains, which utilize central fill locations that are often not anywhere near a health care facility.
We continue to urge HRSA to take action as our hospitals are hurting from these illegal activities, in a time where we are in extra dire need for resources to take care of our patients.

From: Wolf, Tiffany E
To: HRSA HSB 340B Pricing
Cc: Moore, Randall A
Subject: 340B Ceiling Price Unavailable
Date: Wednesday, November 25, 2020 1:49:58 PM
Attachments: image001.jpg
List of Novartis Drugs + NDCS for HRSA.xlsx
Novartis Letter to HRSA.pdf

Hello,

Please see attachments for documentation notifying you of Novartis products no longer offered at the 340B ceiling price through contract pharmacies.

Thank you,

Tiffany Wolf, B.S., CPhT
340B Compliance Sr Analyst
Contract Pharmacy 340B Program
402-836-9136
tiwolf@nebraskamed.com

Nebraska Medicine
988444 Nebraska Medical Center - Omaha, NE 68198
Nebraska Medicine | Facebook | Twitter | YouTube | Instagram

Drug Name	NDC
KISQALI FEMARA 600 DOSE	00078-923-61
PROMACTA 75 MG	00078-687-15
PROMACTA 12.5MG 30UD SPD	00078-972-61
PROMACTA 25MG 30UD SPD	00078-697-61
TAFINLAR 75 MG	00078-681-66
VOTRIENT 200 MG	00078-670-66
MEKINIST 2 MG	00078-668-15
JADENU 180 MG	00078-655-15
COSENTYX SENSOREADY PEN 150 MG/ML	00078-639-41
COSENTYX 150 MG/ML	00078-639-98
TOBI PODHALER 28 MG	00078-630-35
AFINITOR 7.5 MG	00078-620-51
GILENYA .5 MG	00078-607-15
EXTAVIA .3 MG	00078-569-12
ZORTRESS .75 MG	00078-415-20
GLEEVEC 100 MG	00078-401-34
SANDIMMUNE 100MG 30UD SFG	00078-0241-15
SANDIMMUNE 25MG 30UD SFG	00078-0240-15
NEORAL 100MG 30UD SFG	00078-0248-15
NEORAL 25 MG	00078-246-15
GLEEVEC 400MG 30UD	00078-0649-30

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

9Purpose: This tool can be used to report the following types of issues for covered outpatient drugs, to the Health Resources and Services Administration (HRSA):

- Table 1: Unavailable at a 340B ceiling price and/or
- Table 2: Incorrect 340B ceiling price (overcharge)

Instructions: Enter data in each field describing the issue. Before completing and submitting the tool, the stakeholder should contact the wholesaler and manufacturer directly to determine the reason for unavailability and/or to document incorrect pricing. HRSA investigates allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. If HRSA determines additional information is needed from the covered entity or manufacturer, it may extend the time for follow-up. If the tool is unable to capture all details, **please attach additional documentation as necessary.** HRSA may reach out to the person submitting this notification for additional information.

This completed tool, including copies of communications with manufacturer and/or wholesaler and any responses, should be emailed to HRSA at: 340Bpricing@hrsa.gov

Background Information

Entity Name: The Nebraska Medical Center **340B ID:** DSH280013

Please list the product(s) affected (*you may list multiple drugs as long as the labeler codes are the same; the labeler code is the first five digits of an NDC. If multiple labeler codes are represented you will need to submit multiple forms*).

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
1 00078	See attachment for full list of NDC's	Novartis				Cardinal & McKesson
2.						
3.						

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug ✔ Yes ☐ No
- The issue reported is limited to a contract pharmacy purchase? ✔ Yes ☐ No
- If shortage-related, is this a recurrent/intermittent availability issue? ☐ Yes ☑ No
- If shortage-related, is this due to a local/regional/national or global shortage? _____

✓

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Table 1: Unavailable at 340B Price
AVAILABILITY ISSUE: If you are unable to purchase the product at a 340B price, fill out the information below.

Reason for lack of 340B access (*check all that apply*):

- ☐ Drug shortage
- ☐ Drug subject to limited distribution or specialty pharmacy plan
- ☑ Other (*please describe*): Manufacturer removed NDC's from 340B program at contract pharmacies outside 40 mile radius
- ☐ Unknown

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ☑ Verified the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data and signed PPA with labeler code active in 340B OPAIS, contacted manufacturer for confirmation, etc.)

  For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.

- ☐ Confirmed shortage issues by reviewing validated resources*
  - ☑ Contacted wholesaler and/or manufacturer to confirm unavailability
- ☐ ***For hospitals subject to Group Purchasing Organization (GPO) Prohibition:*** purchased product on an GPO account, after exhausting all measures for obtaining drug at a non-GPO price (please list all measures taken, including which NDC was purchased instead due to unavailability)

  _____

  _____
- ☐ Other (*please describe*): _____

Date issue first observed: 11/16/2020

Date drug last available at 340B price (enter NEVER if has never been available): 11/15/2020

*Recommended Drug shortage resources:
FDA: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
ASHP: https://www.ashp.org/drug-shortages/current-shortages
Wholesaler catalog information

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Table 2: Incorrect 340B Price
PRICING ISSUE: The drug can be purchased on the 340B account but price is greater than the price in the OPAIS Pricing System.

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

- ☐ Determined if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturersearch), and check the Medicaid Drug Rebate Program labeler code (https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data)

  Note: *For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs*

- ☐ Validated the ceiling price using the 340B OPAIS pricing system on (date): _____
  - Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS
  - The OPAIS Pricing Database displays the 340B ceiling price at the unit level; the covered entity may need to multiply the ceiling price by the package size (this might be the total number of mL, tablets, capsules, grams, etc.) in the package purchased
  - For Prime Vendor participants, verify the selling price by visiting the password-protected Prime Vendor Program Catalog or 340B & PVP Product Selling Price Lookup tool. Package size information is available.
  - Adjust the purchase price for your wholesaler distribution charge/markdown

- ☐ Attempted to work with the entity's wholesaler and directly with the manufacturer to resolve the pricing issue

- ☐ Other (*please describe*):

  _____

Price paid by the covered entity (including package size):_____

Date issue first observed: _____

Date product last available at correct price (enter NEVER if has never been available): _____

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Signature

HRSA may reach out to the following contact person from the covered entity to help resolve the issue in question. By signing below the submitter consents/acknowledges that this information may be used in correspondence with Manufacturers and other Federal Agencies.

Contact Name (printed): Randall Moore **Phone**: 402-559-1238

Email Address: Rmoore@nebraskamed.com

Contact Role/Organization: Pharmacy Manager

Contact Signature: Randy Moore **Date**: 11/25/2020

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.

From: Linda Higginson
To: HRSA HSB 340B Pricing
Subject: 340B Ceiling Price Unavailable
Date: Monday, November 16, 2020 3:24:45 PM
Attachments: HRSA_Notification_340B_Price_Unavailable_Novartis.docx

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I urge HRSA to weigh in on the manufacturers who are self-interpreting the 340B statute and pulling their drugs out of the program for contract pharmacy relationships.
This is impacting our ability to provide expanded care services for our underserved and uninsured patients. It is also impacting our small independently owned contract pharmacy located in rural Oregon which supports their ability to provide screening programs, diabetes education and other community outreach services.
Sincerely,
Linda Higginson
340B Program Manager
St. Charles Health System
Tele:541-706-6978
lkhigginson@stcharleshealthcare.org

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Purpose: This tool can be used to report the following types of issues for covered outpatient drugs, to the Health Resources and Services Administration (HRSA):

- Table 1: Unavailable at a 340B ceiling price and/or
- Table 2: Incorrect 340B ceiling price (overcharge)

Instructions: Enter data in each field describing the issue. Before completing and submitting the tool, the stakeholder should contact the wholesaler and manufacturer directly to determine the reason for unavailability and/or to document incorrect pricing. HRSA investigates allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. If HRSA determines additional information is needed from the covered entity or manufacturer, it may extend the time for follow-up. If the tool is unable to capture all details, **please attach additional documentation as necessary.** HRSA may reach out to the person submitting this notification for additional information.

This completed tool, including copies of communications with manufacturer and/or wholesaler and any responses, should be emailed to HRSA at: 340Bpricing@hrsa.gov

Background Information

Entity Name: St. Charles Health System, Inc.,d/b/a St. Charles Bend_____ **340B ID:** DSH380047

Please list the product(s) affected (*you may list multiple drugs as long as the labeler codes are the same; the labeler code is the first five digits of an NDC. If multiple labeler codes are represented you will need to submit multiple forms*).

11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
1. 00078069761	Promacta 250mg suspension	Novartis	30	1	Mg	McKesson
2. 00078068655	Promacta 50mg tab	Novartis	14	1	Mg	McKesson
3. 00078068715	Promacta 75mg tab	Novartis	30	1	Mg	McKesson
4. 00078068615	Promacta 50mg tab	Novartis	30	1	Mg	McKesson
5. 00078068515	Promacta 25mg tab	Novartis	30	1	Mg	McKesson
6. 00078068415	Promacta 12.5mg tab	Novartis	30	1	Mg	McKesson
7. 00078097261	Promacta 12.5mg Suspension	Novartis	30	1	Mg	McKesson
8.00078070184	Piqray 200mg	Novartis	28	1	Mg	McKesson
9. 00078071502	Piqray 250mg	Novartis	28	1	Mg	McKesson
10. 00078070802	Piqray 300mg	Novartis	28	1	Mg	McKesson

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug ✔ Yes ☐ No
- The issue reported is limited to a contract pharmacy purchase ✔ Yes ☐ No
- If shortage-related, is this a recurrent/intermittent availability issue? ☐ Yes ✔ No
- If shortage-related, is this due to a local/regional/national or global shortage? NO _____

Table 1: Unavailable at 340B Price

AVAILABILITY ISSUE: If you are unable to purchase the product at a 340B price, fill out the information below.

Reason for lack of 340B access (*check all that apply*):

☐ Drug shortage

☐ Drug subject to limited distribution or specialty pharmacy plan

X Other (*please describe*): Manufacturer is interpreting the 340B statute and will not honor 340B pricing to our contract pharmacies

☐ Unknown

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

X Verified the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data and signed PPA with labeler code active in 340B OPAIS, contacted manufacturer for confirmation, etc.)

For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.

☐ Confirmed shortage issues by reviewing validated resources*

☐ Contacted wholesaler and/or manufacturer to confirm unavailability

☐ ***For hospitals subject to Group Purchasing Organization (GPO) Prohibition:*** purchased product on an GPO account, after exhausting all measures for obtaining drug at a non-GPO price (please list all measures taken, including which NDC was purchased instead due to unavailability)

_____

_____

☐ Other (*please describe issue*):

_____

_____

_____

_____

_____

_____

Date issue first observed: 11/16/2020

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Date drug last available at 340B price (enter NEVER if has never been available): _11/10/2020

*Recommended Drug shortage resources:
FDA: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
ASHP: https://www.ashp.org/drug-shortages/current-shortages
Wholesaler catalog information

Table 2: Incorrect 340B Price

PRICING ISSUE: The drug can be purchased on the 340B account but price is greater than the price in the OPAIS Pricing System.

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

X Determined if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturersearch), and check the Medicaid Drug Rebate Program labeler code (https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data)

Note: *For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs*

X Validated the ceiling price using the 340B OPAIS pricing system on (date): 11/16/2020

- Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS
- The OPAIS Pricing Database displays the 340B ceiling price at the unit level; the covered entity may need to multiply the ceiling price by the package size (this might be the total number of mL, tablets, capsules, grams, etc.) in the package purchased
- For Prime Vendor participants, verify the selling price by visiting the password-protected Prime Vendor Program Catalog or 340B & PVP Product Selling Price Lookup tool. Package size information is available.
- Adjust the purchase price for your wholesaler distribution charge/markdown

X Attempted to work with the entity's wholesaler and directly with the manufacturer to resolve the pricing issue

☐ Other (*please describe issue*):
_____
_____
_____

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

_____
_____
_____

Price paid by the covered entity (including package size):_____

Date issue first observed: _11/16/2020

Date product last available at correct price (enter NEVER if has never been available): _____

Signature

HRSA may reach out to the following contact person from the covered entity to help resolve the issue in question. By signing below the submitter consents/acknowledges that this information may be used in correspondence with Manufacturers and other Federal Agencies.

Contact Name (printed): __Linda Higginson___ **Phone**: ___541-706-6978_____

Email Address: _lkhigginson@stcharleshealthcare.org_____

Contact Role/Organization:_ 340B Program Managert_____

Contact Signature: Linda Higginson (unable to sign working remotely due to COVID 19 **Date**: 11/16/2020

From: Chitra Rao
To: HRSA HSB 340B Pricing
Cc: HS-340B; Tammy Trovatten; Dorothy J Nelson
Subject: RE: UC Davis Medical Center (DSH050599)
Date: Wednesday, December 30, 2020 6:23:38 PM
Attachments: Novartis labeler code 00078 -340B-ceiling-price-unavailable-incorrect-340b-ceiling-price-notification-for-hrsa.pdf
Novartis_20201030.pdf
Novartis_20200817.pdf

Hello,
UC Davis Medical Center (UCDMC) is a DSH facility (DSH050599) and we serve both adult and pediatric patients in Northern California covering 65,000 square miles, 33 counties and more than 6 million residents. We have a level 1 trauma center and provide specialty services in cardiology, diabetes, endocrinology, pulmonology, cancer treatment, transplant and more. Our patients who live across Northern California rely on pharmacies closer to their homes. UC Davis Medical Center has many contract pharmacies and it helps our patients to have access to medication.
In the last few months, we have started receiving notices from manufacturers limiting access to their products and this has a great impact on our patients. We would like to report 340B price unavailability from the manufacturers (notice included) for the labeler codes listed on the attached HRSA form. Appreciate a response confirming receipt of this email. Thank you.

Chitra Rao, 340B ACE
340B Auditor
Department of Pharmacy Services, UCDH
3561 Business Drive, Suite 100,
Sacramento, CA 95820
Phone: 916-736-6528
Fax: 916-456-4639
Email: cgrao@ucdavis.edu

StrengthsFinder Top 5: Arranger, Belief, Responsibility, Includer, Maximizer

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Purpose: This tool can be used to report the following types of issues for covered outpatient drugs to the Health Resources and Services Administration (HRSA):

- Table 1: Unavailable at a 340B ceiling price
- Table 2: Incorrect 340B ceiling price (overcharge)

Instructions: Enter data in each field describing the issue. Before completing and submitting the tool, the stakeholder should contact the wholesaler and manufacturer directly to determine the reason for unavailability and/or to document incorrect pricing. HRSA investigates allegations of noncompliance brought to its attention and will follow up with all parties once the issue is reviewed. If HRSA determines that additional information is needed from the covered entity or manufacturer, it may extend the time for follow-up. If the tool is unable to capture all details, **please attach additional documentation as necessary.** HRSA may reach out to the person submitting this notification for additional information.

This completed tool, including copies of communications with manufacturer and/or wholesaler and any responses, should be emailed to HRSA at 340Bpricing@hrsa.gov

Background Information

Entity Name: _____ **340B ID:** _____

Please list the product(s) affected (*you may list multiple drugs as long as the labeler codes are the same; the labeler code is the first five digits of an NDC. If multiple labeler codes are represented you will need to submit multiple forms*).

11-digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (etc. mL, cap)	CE Wholesaler

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug Yes ☐ No
- The issue reported is limited to a contract pharmacy purchase Yes ☐ No
- If shortage related, is this a recurrent/intermittent availability issue? Yes ☐ No

If shortage related, is this due to (please specify) local regional national global

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Table 1: Unavailable at 340B Price
AVAILABILITY ISSUE: If you are unable to purchase the product at a 340B price, fill out the information below.

Reason for lack of 340B access (*check all that apply*):

- ☐ Drug shortage
- ☐ Drug subject to limited distribution or specialty pharmacy plan
- ☐ Other (*please describe*): _____
- ☐ Unknown

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

Verified that the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data and signed PPA with labeler code active in 340B OPAIS, contacted manufacturer for confirmation)

For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.

- ☐ Confirmed shortage issues by reviewing validated resources*
- ☐ Contacted wholesaler and/or manufacturer to confirm unavailability
- ☐ ***For hospitals subject to Group Purchasing Organization (GPO) Prohibition:*** purchased product on a GPO account, after exhausting all measures for obtaining drug at a non-GPO price (please list all measures taken, including which NDC was purchased instead due to unavailability)

_____

_____

Other (*please describe issue*):

_____

_____

_____

_____

_____

_____

Date issue first observed:

Date drug last available at 340B price (enter NEVER if it has never been available):

*Recommended drug shortage resources:
FDA: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
ASHP: https://www.ashp.org/drug-shortages/current-shortages
Wholesaler catalog information

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Apexus 340B Prime Vendor PROGRAM

Table 2: Incorrect 340B Price
PRICING ISSUE: The drug can be purchased on the 340B account but price is greater than the price in the OPAIS Pricing System.

Check all steps taken to verify and/or resolve the issue prior to submitting issue to HRSA:

☐ Determined if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturersearch), and check the Medicaid Drug Rebate Program labeler code (https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data)

Note: *For rural referral centers, sole community hospitals, critical access hospitals, and free-standing cancer hospitals, the term "covered outpatient drug" does not include orphan drugs.*

☐ Validated the ceiling price using the 340B OPAIS pricing system on (date): _____
- Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS.
- The OPAIS Pricing Database displays the 340B ceiling price at the unit level; the covered entity may need to multiply the ceiling price by the package size (this might be the total number of mL, tablets, capsules, grams, etc.) in the package purchased.
- For Prime Vendor participants, verify the selling price by visiting the password-protected Prime Vendor Program Catalog or 340B & PVP Product Selling Price Lookup tool. Package size information is available.
- Adjust the purchase price for your wholesaler distribution charge/markdown.

☐ Attempted to work with the entity's wholesaler and directly with the manufacturer to resolve the pricing issue

☐ Other (*please describe issue*):

_____
_____
_____
_____
_____
_____

Price paid by the covered entity (including package size): _____

Date issue first observed: _____

Date product last available at correct price (enter NEVER if has never been available): _____

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA

Signature

HRSA may reach out to the following contact person from the covered entity to help resolve the issue in question. By signing below, the submitter consents/acknowledges that this information may be used in correspondence with manufacturers and other federal agencies.

Contact Name (printed): _____ **Phone**: _____

Email Address: _____

Contact Role/Organization: _____

Contact Signature: _____ **Date**: _____

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.

NOVARTIS

Novartis Pharmaceuticals Corporation
Managed Markets Finance
One Health Plaza
East Hanover, NJ 07936-1080

October 30, 2020

Mark Riggle
U CA Davis Med Cntr
2315 STOCKTON BLVD
SACRAMENTO, CA 95817

Dear Mark Riggle:

In follow-up to our previous communications on August 17th, we wanted to update you on additional steps we are taking regarding our 340B program integrity initiative. Upon careful consideration, we have decided to implement a more focused, criteria-based approach that we believe will reaffirm the program's intent to serve the uninsured and vulnerable, while preserving the sustainability of this vital program.

For hospital covered entities, beginning November 16, 2020, we will continue to honor contract pharmacy (CP) arrangements as long as they are within a 40-mile radius of its parent facility for all Novartis Pharmaceuticals Corporation products. There will *not* be a limit to the number of contract pharmacies within that radius. This geographic restriction seeks to take a common-sense approach to ensure the program benefits the intended communities and is consistent with other federal guidelines around hospitals and off-site affiliates.

This change will not affect patient access to prescribed medicines, nor will it affect a CE's ability to continue to benefit from the 340B discount on CP transactions as long as the CP is located within a 40-mile radius of the parent facility. Our revised approach simply ensures that the discount will continue to serve vulnerable patients within CEs' local communities. Federal grantees are exempt from this policy.

Novartis continues to support the core mission of the 340B program to increase access to outpatient drugs among uninsured and vulnerable patients. We will continue to work alongside all stakeholders to advocate for the transparency, oversight and accountability reforms necessary for the 340B program to continue its mission as intended. As such, we continue to encourage all covered entities to voluntarily upload their claims data to the ESP™ platform, in an effort to increase transparency, mitigate instances of duplicative discounts and maintain the integrity and sustainability of this vital program.

For information on eligible pharmacies, 340B covered entities can log in to www.340BESP.com to see which 340B contract pharmacies comply with Novartis' new policy and are eligible to receive Bill To / Ship To replenishment orders. Simply navigate to the 'Entity Profile' tab to see which 340B contract pharmacies remain eligible.

We look forward to working collaboratively with you to further strengthen the 340B program. If you have any questions, please contact us at Novartis.340B@novartis.com.

Sincerely,

Daniel Lopuch
VP Novartis Managed Markets Finance

Frequently Asked Questions

Q: How does Novartis determine contract pharmacy eligibility for my hospital?
A: Utilizing address information provided in the HRSA 340B OPAIS database, Novartis measures the distance between each registered parent entity and any of its associated contract pharmacies. Any contract pharmacies that fall within a 40-mile radius of the parent entity will be considered eligible for the purposes of Bill To / Ship To replenishment orders at the 340B-discounted price.

Q: How do I know which of my contract pharmacies are deemed eligible by Novartis?
A: For information on eligible pharmacies, 340B covered entities can log in to www.340BESP.com to see which 340B contract pharmacies comply with Novartis' new policy and are eligible to receive Bill To / Ship To replenishment orders at the 340B-discounted price. Simply navigate to the 'Entity Profile' tab to see which 340B contract pharmacies remain eligible for Bill To / Ship To replenishment orders.

Q: How do I register with 340B ESP™?
A: To get started with Second Sight Solutions' 340B ESP™ platform, go to www.340BESP.com to register your account. Upon initial registration you will be prompted with an onboarding tutorial that will walk you through the account set up process step by step. This process takes ~15 minutes.

Q: How do I upload data to the ESP platform?
A: To voluntarily upload claims data first, register on the platform (see above). Then follow these steps:

1. Once your account is activated, you will be able to securely upload data to 340B ESP™. You will receive periodic notifications of pending data submissions and new contract pharmacy set up activities.

2. Login to 340B ESP and submit your 340B contract pharmacy claims data on a bi-weekly basis. Once your account is set up, the claims upload process takes ~ 5 minutes.

You can visit www.340BESP.com/FAQs to learn more about 340B ESP™. For further help with the registration, account setup, and data submission process please call Second Sight Solutions at 888-398-5520.

Q: What happens if my organization does not provide 340B contract pharmacy claims data?
A: Novartis continues to encourage all covered entities to voluntarily upload their claims data in an effort to increase transparency, mitigate instances of duplicative discounts and maintain the integrity and sustainability of this vital program. However, the provision of claims data to the ESP™ platform will not have any impact on contract pharmacy eligibility for covered entities.

Q: What products are impacted by this policy?
A: This policy will be in effect for all Novartis Pharmaceuticals Corporation products. Products belonging to Sandoz, Novartis Gene Therapies and all other Novartis subsidiaries will not be impacted by this policy.

NOVARTIS

Novartis Pharmaceuticals
One Health Plaza
East Hanover, NJ 07936

August 17, 2020

Mark Riggle
University of California Davis Med Cntr
2315 Stockton Blvd
Sacramento, CA 95817

Dear Mark Riggle:

I am writing to inform you that Novartis is implementing a new 340B program integrity initiative to address duplicate discounts. Beginning on October 1, 2020, all covered entities (CEs) will be required to register and upload all 340B claim data originating from contract pharmacies (CPs) onto a new, web-based platform called 340B ESP™. Covered entities may register at no cost at www.340BESP.com.

While Novartis continues to support the core goal of the 340B program to increase access to outpatient drugs among uninsured and vulnerable patients, there is currently no standardized solution to identify 340B claims on Medicaid, Commercial, and Medicare Part D rebate invoices. This has increasingly caused manufacturers to pay duplicate claims due to time lags and discrepancies in data reported by CEs and CPs. We believe these program integrity and transparency challenges need to be addressed for the 340B program to continue its mission as intended.

A migration to 340B ESP™ will enable Novartis to identify all Medicaid, Commercial, and Medicare Part D rebate claims for reimbursement of a drug purchased at 340B pricing from uploaded claims. This change will support the program's sustainability by bridging the information gap between CEs and manufacturers and helping Novartis to more efficiently identify duplicate discounts and ineligible rebates. This change will not affect patient access to prescribed medicines, nor will it affect a CE's ability to continue to benefit from the 340B discount on CP transactions as long as the requested claims data is provided.

We look forward to working collaboratively with you to further strengthen the 340B program.

Sincerely,

Daniel Lopuch

VP Novartis Managed Markets Finance

NOVARTIS

NEXT STEPS AND FREQUENTLY ASKED QUESTIONS

To get started with Second Sight Solutions' 340B ESP™ platform, follow these three simple steps:

1. Go to www.340BESP.com to register your account. Upon initial registration you will be prompted with an onboarding tutorial that will walk you through the account set up process step by step. This process takes ~15 minutes.

2. Once your account is activated, you will be able to securely upload data to 340B ESP™. You will receive periodic notifications of pending data submissions and new contract pharmacy set up activities.

3. Login to 340B ESP and submit your 340B contract pharmacy claims data on a bi-weekly basis. Once your account is set up, the claims upload process takes ~ 5 minutes.

In addition to the frequently asked questions below, you can visit www.340BESP.com/FAQs to learn more about 340B ESP™. For further help with the registration, account setup, and data submission process please call Second Sight Solutions at 888-398-5520.

To learn more about how Novartis is working to improve program integrity through 340B ESP™, please contact Novartis directly at Novartis.340B@novartis.com.

Q: How will Novartis use the 340B claims data that we provide through 340B ESP™?

A: Data uploaded by 340B covered entities will be used to identify and resolve duplicate Medicaid, Medicare Part D and Commercial rebates.

Q: How does 340B ESP™ protect the privacy of my patients?

A: Data uploaded to 340B ESP™ is de-identified and meets the definition of a De-identified Data Set under HIPAA. This means that protected health information (PHI) is not collected and the data provided cannot be combined with other data sets to reveal the identity of a patient. Additional security controls are embedded throughout the platform.

Q: Is Novartis requesting data for all Novartis products?

A: No. Novartis is only requesting data for Novartis drugs commonly dispensed through retail, specialty, and outpatient pharmacies registered on the HRSA database as a contract pharmacy. 340B ESP™ automatically limits the data in your upload file to the applicable NDCs.

Q: What happens if my organization does not provide 340B contract pharmacy claims data?

A: Novartis is making this service available to 340B covered entities at no cost with the goal of working collaboratively to address ongoing issues with duplicate discounts. Beginning on October 1, 2020, all 340B covered entities will be required to register at www.340BESP.com and provide 340B claims data originating from CP utilization in order to receive 340B reimbursements from Novartis.

Q: What if my organization has a unique circumstance as it relates to contract pharmacies?

A: If your organization purchases 340B drugs solely through contract pharmacies, or you have a similar unique circumstance, please reach out to Novartis.340B@novartis.com.

Q: Is Novartis requesting data for pharmacies that are registered with HRSA as a covered entity?

A: No. Novartis is only requesting data for 340B claims that originates from contract pharmacies. Covered entities do not need to provide 340B claims for prescriptions filled in their own outpatient pharmacies.

Q: My covered entity excludes Medicaid patients from our contract pharmacy utilization and/or my state has a Medicaid carve out that excludes these patients from 340B. Do I still need to submit data to Novartis through 340B ESP?

A: Yes. This initiative is to address duplicate Medicaid rebates as well as ineligible rebates paid to commercial and Medicare Part D payers. Novartis utilizes the claims data provided by 340B covered entities to address these duplicate discounts. Furthermore, as HRSA audits have demonstrated, duplicate Medicaid rebates remain a significant issue in the 340B program, in many instances without the 340B covered entity ever being aware of the issue. By comparing 340B claims with Medicaid rebates, Novartis will be able to identify duplicate Medicaid rebates

Q: What benefit does the 340B covered entity realize by using 340B ESP™?

A: By providing 340B claims data that originate from contract pharmacies, Novartis will be able to definitively identify duplicate Medicaid rebates. Covered entities will then be informed which pharmacies are dispensing 340B purchased drugs to Medicaid patients. This information can be used to further strengthen the audit processes and compliance controls of the covered entity.

Q: Will this change result in additional auditing requirements for contract pharmacies and/or covered entities?

A: No. We do not anticipate any additional auditing requirements as a result of this change. This additional data transparency will reduce the need for manufacturer outreach, making correspondence more efficient than in the past.

Q: Will Novartis use the submitted claims data to perform audits on 340B covered entities?

A: Novartis does not intend to use the data to perform audits. The intent of the request for 340B contract pharmacy claims data is to use it to identify and resolve duplicate Medicaid, Medicare Part D, and commercial rebates. This request is intended, in part, to help covered entities with contract pharmacy relationships stay compliant with the 340B prohibition on duplicate discounts when treating Medicaid patients, not to audit them.

Q: Does HRSA and/or Apexus support this initiative?

A: HRSA and Apexus are aware of this initiative and we are working with them to ensure any concerns are addressed. Novartis believes 340B ESP™ provides a simple platform for Novartis and 340B covered entities to engage collaboratively and in good faith to address duplicate discounts.

Q: How often will I need to upload 340B contract pharmacy claims data to 340B ESP™?

A: The 340B ESP™ platform requires claims to be uploaded every two weeks. The upload process takes ~5 minutes and should not place significant burden on 340B covered entity operations. Email reminders are automatically generated from 340B ESP™ and covered entities can monitor claims submission status when logged in to the platform.

Q: What technology is required to successfully upload data to 340B ESP™?

A: 340B ESP™ is compatible with most internet browsers including Microsoft Edge, Google Chrome, Safari, FireFox, and others. However, we strongly recommend using Google Chrome for the best user experience. Users will need an internet connection and access to a supported browser to successfully upload data.

NOVARTIS

Novartis Pharmaceuticals
One Health Plaza
East Hanover, NJ 07936

August 17, 2020

Mark Riggle
University of California Davis Med Cntr
2315 Stockton Blvd
Sacramento, CA 95817

Dear Mark Riggle:

I am writing to inform you that Novartis is implementing a new 340B program integrity initiative to address duplicate discounts. Beginning on October 1, 2020, all covered entities (CEs) will be required to register and upload all 340B claim data originating from contract pharmacies (CPs) onto a new, web-based platform called 340B ESP™. Covered entities may register at no cost at www.340BESP.com.

While Novartis continues to support the core goal of the 340B program to increase access to outpatient drugs among uninsured and vulnerable patients, there is currently no standardized solution to identify 340B claims on Medicaid, Commercial, and Medicare Part D rebate invoices. This has increasingly caused manufacturers to pay duplicate claims due to time lags and discrepancies in data reported by CEs and CPs. We believe these program integrity and transparency challenges need to be addressed for the 340B program to continue its mission as intended.

A migration to 340B ESP™ will enable Novartis to identify all Medicaid, Commercial, and Medicare Part D rebate claims for reimbursement of a drug purchased at 340B pricing from uploaded claims. This change will support the program's sustainability by bridging the information gap between CEs and manufacturers and helping Novartis to more efficiently identify duplicate discounts and ineligible rebates. This change will not affect patient access to prescribed medicines, nor will it affect a CE's ability to continue to benefit from the 340B discount on CP transactions as long as the requested claims data is provided.

We look forward to working collaboratively with you to further strengthen the 340B program.

Sincerely,

Daniel Lopuch

VP Novartis Managed Markets Finance

NOVARTIS

NEXT STEPS AND FREQUENTLY ASKED QUESTIONS

To get started with Second Sight Solutions' 340B ESP™ platform, follow these three simple steps:

1. Go to www.340BESP.com to register your account. Upon initial registration you will be prompted with an onboarding tutorial that will walk you through the account set up process step by step. This process takes ~15 minutes.

2. Once your account is activated, you will be able to securely upload data to 340B ESP™. You will receive periodic notifications of pending data submissions and new contract pharmacy set up activities.

3. Login to 340B ESP and submit your 340B contract pharmacy claims data on a bi-weekly basis. Once your account is set up, the claims upload process takes ~ 5 minutes.

In addition to the frequently asked questions below, you can visit www.340BESP.com/FAQs to learn more about 340B ESP™. For further help with the registration, account setup, and data submission process please call Second Sight Solutions at 888-398-5520.

To learn more about how Novartis is working to improve program integrity through 340B ESP™, please contact Novartis directly at Novartis.340B@novartis.com.

Q: How will Novartis use the 340B claims data that we provide through 340B ESP™?

A: Data uploaded by 340B covered entities will be used to identify and resolve duplicate Medicaid, Medicare Part D and Commercial rebates.

Q: How does 340B ESP™ protect the privacy of my patients?

A: Data uploaded to 340B ESP™ is de-identified and meets the definition of a De-identified Data Set under HIPAA. This means that protected health information (PHI) is not collected and the data provided cannot be combined with other data sets to reveal the identity of a patient. Additional security controls are embedded throughout the platform.

Q: Is Novartis requesting data for all Novartis products?

A: No. Novartis is only requesting data for Novartis drugs commonly dispensed through retail, specialty, and outpatient pharmacies registered on the HRSA database as a contract pharmacy. 340B ESP™ automatically limits the data in your upload file to the applicable NDCs.

Q: What happens if my organization does not provide 340B contract pharmacy claims data?

A: Novartis is making this service available to 340B covered entities at no cost with the goal of working collaboratively to address ongoing issues with duplicate discounts. Beginning on October 1, 2020, all 340B covered entities will be required to register at www.340BESP.com and provide 340B claims data originating from CP utilization in order to receive 340B reimbursements from Novartis.

Q: What if my organization has a unique circumstance as it relates to contract pharmacies?

A: If your organization purchases 340B drugs solely through contract pharmacies, or you have a similar unique circumstance, please reach out to Novartis.340B@novartis.com.

Q: Is Novartis requesting data for pharmacies that are registered with HRSA as a covered entity?

A: No. Novartis is only requesting data for 340B claims that originates from contract pharmacies. Covered entities do not need to provide 340B claims for prescriptions filled in their own outpatient pharmacies.

Q: My covered entity excludes Medicaid patients from our contract pharmacy utilization and/or my state has a Medicaid carve out that excludes these patients from 340B. Do I still need to submit data to Novartis through 340B ESP?

A: Yes. This initiative is to address duplicate Medicaid rebates as well as ineligible rebates paid to commercial and Medicare Part D payers. Novartis utilizes the claims data provided by 340B covered entities to address these duplicate discounts. Furthermore, as HRSA audits have demonstrated, duplicate Medicaid rebates remain a significant issue in the 340B program, in many instances without the 340B covered entity ever being aware of the issue. By comparing 340B claims with Medicaid rebates, Novartis will be able to identify duplicate Medicaid rebates

Q: What benefit does the 340B covered entity realize by using 340B ESP™?

A: By providing 340B claims data that originate from contract pharmacies, Novartis will be able to definitively identify duplicate Medicaid rebates. Covered entities will then be informed which pharmacies are dispensing 340B purchased drugs to Medicaid patients. This information can be used to further strengthen the audit processes and compliance controls of the covered entity.

Q: Will this change result in additional auditing requirements for contract pharmacies and/or covered entities?

A: No. We do not anticipate any additional auditing requirements as a result of this change. This additional data transparency will reduce the need for manufacturer outreach, making correspondence more efficient than in the past.

Q: Will Novartis use the submitted claims data to perform audits on 340B covered entities?

A: Novartis does not intend to use the data to perform audits. The intent of the request for 340B contract pharmacy claims data is to use it to identify and resolve duplicate Medicaid, Medicare Part D, and commercial rebates. This request is intended, in part, to help covered entities with contract pharmacy relationships stay compliant with the 340B prohibition on duplicate discounts when treating Medicaid patients, not to audit them.

Q: Does HRSA and/or Apexus support this initiative?

A: HRSA and Apexus are aware of this initiative and we are working with them to ensure any concerns are addressed. Novartis believes 340B ESP™ provides a simple platform for Novartis and 340B covered entities to engage collaboratively and in good faith to address duplicate discounts.

Q: How often will I need to upload 340B contract pharmacy claims data to 340B ESP™?

A: The 340B ESP™ platform requires claims to be uploaded every two weeks. The upload process takes ~5 minutes and should not place significant burden on 340B covered entity operations. Email reminders are automatically generated from 340B ESP™ and covered entities can monitor claims submission status when logged in to the platform.

Q: What technology is required to successfully upload data to 340B ESP™?

A: 340B ESP™ is compatible with most internet browsers including Microsoft Edge, Google Chrome, Safari, FireFox, and others. However, we strongly recommend using Google Chrome for the best user experience. Users will need an internet connection and access to a supported browser to successfully upload data.

340B Price Unavailable Notification Template For HRSA

Purpose: This document provides information on what to report to the Health Resources and Services Administration (HRSA) when a 340B price is unavailable for a covered outpatient drug.

Instructions: Enter data in each field that describe the entity's experience with the unavailable 340B price(s). Before completing and submitting the form, covered entities are encouraged to contact the wholesaler and manufacturer directly to determine the reason for the unavailability to better equip HRSA in understanding the circumstance. HRSA follows up on all allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. OPA might reach out for additional clarifying information. If additional information is needed from manufacturers, it may extend the time for follow-up with the entity. If the form is unable to capture all details, **please attach additional documentation as necessary. The completed form should be emailed to HRSA at: 340Bpricing@hrsa.gov**

Disclosure options:

1. **My signature below serves as consent for HRSA to disclose contact information to the manufacturer(s) in question, if necessary, so the covered entity can be contacted to help resolve the issue in question.**

Contact's Name:	Kerry MenMuir
Phone Number:	310-267-8503
Email Address:	kmenmuir@mednet.ucla.edu
Printed Name of Submitter:	Lana Balderrama
Date:	12/8/2020
Submitter's Signature:	

2. ☐ **Check this box if the covered entity does not want to be disclosed to the manufacturer(s).**

Field	Description	Enter Data Here		
Entity Information	Enter covered entity information	Entity Name:	Ronald Reagan UCLA Medical Center	
		340B ID:	DSH050262	
		Address:	757 Westwood Plaza, Los Angeles, CA 90095	
		Contact Name:	Kerry MenMuir	
		Contact Phone #:	310-267-8503	
		Contact Email:	kmenmuir@mednet.ucla.edu	
		Date of Submission:	12/8/2020	
Product Information	Enter information about the unavailable drug product	NDC (Labeler Code)	Drug Name & Strength	Manufacturer
		00028,00043,00058,00067, 00078, 00083,53905,58768		Novartis
Manufacturer/ Wholesaler Communications	**Attach a copy of communications with manufacturer and/or wholesaler and the response/reason for lack of price availability**	Name of wholesaler or distributor:	AmerisourceBergen, McKesson, Cardinal	
		Reason given for lack of 340B availability and communication to the entity:	Reason for lack of 340B availability (circle response) A. Drug shortage B. Limited distribution plan C. Other	
			Describe lack of 340B availability: Manufacturer refusal to offer 340B pricing for the covered entity's contract pharmacies. Please see attached letter.	

340B Price Unavailable Notification Template For HRSA

Field	Description	Enter Data Here	
340B Price Unavailable	Enter the calendar date (MM/DD/YYYY) or approximate date when the lack of a 340B price was first observed. Enter NEVER if the 340B price has never been available.	11/16/2020	
Last 340B Purchase Date	Enter the calendar data (MM/DD/YYYY) or approximate date when the product was last available for purchase or purchased by your entity. Enter NEVER if the 340B price has never been available.	11/15/2020	
Non-340B Account Availability	Identify which non-340B accounts have current drug availability (put "N/A" if your entity does not have access to the listed account)	Available on **non-GPO/WAC** account? A. Yes B. No C. N/A	Available on **GPO** account? A. Yes B. No C. N/A
Non-340B Account Purchases	Identify which non-340B accounts were used to purchase drug in place of 340B account due to unavailability (put "N/A if your entity does not have access to the listed account)	Purchased on **non-GPO/WAC** account? A. Yes B. No C. N/A Timeframe of purchases (MM/DD/YY)	Purchased on **GPO** account? A. Yes B. No C. N/A Timeframe of purchases
	DSH/CAN/PED Hospitals only If a GPO account was used to purchase drug, explain process to exhaust all measures for obtaining drug at a non-GPO price	Describe: N/A	
Other/Special Limitations	Describe any other scenarios impacting your ability to purchase the drug at 340B price due to a special limitation Example: the product is available only via a specialty pharmacy	Describe:	

Additional comments:

This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.

340B Price Unavailable Notification Template For HRSA

Purpose: This document provides information on what to report to the Health Resources and Services Administration (HRSA) when a 340B price is unavailable for a covered outpatient drug.

Instructions: Enter data in each field that describe the entity's experience with the unavailable 340B price(s). Before completing and submitting the form, covered entities are encouraged to contact the wholesaler and manufacturer directly to determine the reason for the unavailability to better equip HRSA in understanding the circumstance. HRSA follows up on all allegations of non-compliance brought to its attention and will follow-up with all parties once the issue is reviewed. OPA might reach out for additional clarifying information. If additional information is needed from manufacturers, it may extend the time for follow-up with the entity. If the form is unable to capture all details, **please attach additional documentation as necessary. The completed form should be emailed to HRSA at: 340Bpricing@hrsa.gov**

Disclosure options:

1. **My signature below serves as consent for HRSA to disclose contact information to the manufacturer(s) in question, if necessary, so the covered entity can be contacted to help resolve the issue in question.**

Contact's Name:	Kerry MenMuir
Phone Number:	310-267-8503
Email Address:	kmenmuir@mednet.ucla.edu
Printed Name of Submitter:	Lana Balderrama
Date:	12/8/2020
Submitter's Signature:	

2. ☐ **Check this box if the covered entity does not want to be disclosed to the manufacturer(s).**

Field	Description	Enter Data Here		
Entity Information	Enter covered entity information	Entity Name:	Santa Monica UCLAMC and Orthopaedic Hospital	
		340B ID:	DSH050112	
		Address:	1245 16th Street Santa Monica, CA 90404	
		Contact Name:	Kerry MenMuir	
		Contact Phone #:	310-267-8503	
		Contact Email:	kmenmuir@mednet.ucla.edu	
		Date of Submission:	12/8/2020	
Product Information	Enter information about the unavailable drug product	NDC (Labeler Code)	Drug Name & Strength	Manufacturer
		00028,00043,00058,00067, 00078, 00083,53905,58768		Novartis
Manufacturer/ Wholesaler Communications	**Attach a copy of communications with manufacturer and/or wholesaler and the response/reason for lack of price availability**	Name of wholesaler or distributor:	AmerisourceBergen, McKesson, Cardinal	
		Reason given for lack of 340B availability and communication to the entity:	Reason for lack of 340B availability (circle response) A. Drug shortage B. Limited distribution plan C. Other	
			Describe lack of 340B availability: Manufacturer refusal to offer 340B pricing for the covered entity's contract pharmacies. Please see attached letter.	

340B Price Unavailable Notification Template For HRSA

Field	Description	Enter Data Here	
340B Price Unavailable	Enter the calendar date (MM/DD/YYYY) or approximate date when the lack of a 340B price was first observed. Enter NEVER if the 340B price has never been available.	11/16/2020	
Last 340B Purchase Date	Enter the calendar data (MM/DD/YYYY) or approximate date when the product was last available for purchase or purchased by your entity. Enter NEVER if the 340B price has never been available.	11/15/2020	
Non-340B Account Availability	Identify which non-340B accounts have current drug availability (put "N/A" if your entity does not have access to the listed account)	Available on **non-GPO/WAC** account? A. Yes B. No C. N/A	Available on **GPO** account? A. Yes B. No C. N/A
Non-340B Account Purchases	Identify which non-340B accounts were used to purchase drug in place of 340B account due to unavailability (put "N/A if your entity does not have access to the listed account)	Purchased on **non-GPO/WAC** account? A. Yes B. No C. N/A Timeframe of purchases (MM/DD/YY)	Purchased on **GPO** account? A. Yes B. No C. N/A Timeframe of purchases
	DSH/CAN/PED Hospitals only If a GPO account was used to purchase drug, explain process to exhaust all measures for obtaining drug at a non-GPO price	Describe: N/A	
Other/Special Limitations	Describe any other scenarios impacting your ability to purchase the drug at 340B price due to a special limitation Example: the product is available only via a specialty pharmacy	Describe:	

Additional comments:

From: Lees, Katy F
To: HRSA HSB 340B Pricing
Cc: Dworsky, Mark; Dilmore, Nicole
Subject: RE: 340B Ceiling Price Unavailable: Arnot Ogden Medical Center [DSH330090]
Date: Monday, April 26, 2021 3:15:15 PM
Attachments: image002.png
image004.wmz
image007.png
image001.png
image003.png
image005.png
image011.png
HRSA_Notification_340B_Price_Unavailable_McKesson_Sanofi_DSH330090_12.15.20 to 4.26.21.xlsx
HRSA_Notification_340B_Price_Unavailable_Cardinal_NovoNordisk_DSH330090.pdf
HRSA_Notification_340B_Price_Unavailable_McKesson_Astra Zeneca_DSH330090_12.15.20 to 4.26.21.xlsx
HRSA_Notification_340B_Price_Unavailable_McKesson_Eli Lilly_DSH330090_12.15.20 to 4.26.21.xlsx
HRSA_Notification_340B_Price_Unavailable_McKesson_Novartis_DSH330090_12.15.20 to 4.26.21.xlsx
HRSA_Notification_340B_Price_Unavailable_McKesson_NovoNordisk_DSH330090.pdf
HRSA_Notification_340B_Price_Unavailable_McKesson_NovoNordisk_DSH330090_12.15.20 to 4.26.21.xlsx

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Good Afternoon:

I am following up on my December 16, 2020 email below. Arnot Ogden Medical Center continues to face 340B ceiling price restrictions and overcharges from Eli Lilly, Astra Zeneca, Sanofi, and Novartis. We are now unable to access the 340B ceiling price for NovoNordisk products via contract pharmacy ship-to accounts. I have attached Apexus' notification form regarding NovoNordisk products not being available at the 340B ceiling price via McKesson and Cardinal Health. I have previously submitted similar forms for Eli Lilly, Sanofi, Astra Zeneca, and Novartis. I am also attaching documentation illustrating all of the overcharges that we have incurred since my last email on December 16th, 2020.

As you can see by the overcharges provided, these restrictions have a significant financial impact on Arnot Ogden Medical Center. As I mentioned in my last email, in most cases, once a 340B price has been removed from the wholesaler drug catalog, previously eligible prescriptions will no longer be qualified. In other cases a prescription may be qualified, but due to the inability to purchase at the 340B ceiling price, purchasing is suppressed. It is for these reasons that the overcharges being provided only illustrate a small portion of the lost opportunity and financial impact to the hospital. We are estimating that the total financial impact to the hospital, year to date, exceeds $2.5 million. As a safety net provider in Elmira, New York, Arnot Ogden Medical Center is providing care in a region with a poverty rate around 30%. The hospital has operated for years in the red, with the 340B program and largely the benefit from contract pharmacy relationships being attributed to helping keep the doors open.

Combining today's submission of overcharges with the overcharges submitted in October and December, Arnot Ogden Medical Center has been charged ~$360k over the 340B ceiling price on covered outpatient drugs purchased from Eli Lilly, Astra Zeneca, Sanofi, Novartis, and NovoNordisk. As I mentioned above we are estimating that this is just a fraction of the total financial impact to the organization.

Please let me know if any other information would be helpful in the effort to resolve this issue.

Thank you,

Katy

Katy Felice Lees
Director of 340B Policy and Business Strategy | **UR Medicine**
Phone (585) 703-5169 | Fax (585)272-1062
120 Corporate Woods Suite 100 Rochester, NY 14623 | Internal Box # 278983

From: Lees, Katy F
Sent: Wednesday, December 16, 2020 3:14 PM
To: 'HRSA HSB 340B Pricing' <340BPricing@hrsa.gov>
Cc: 'Dworsky, Mark' <mark.dworsky@arnothealth.org>; 'Bacon, Bill' <bill.bacon@arnothealth.org>
Subject: RE: 340B Ceiling Price Unavailable: Arnot Ogden Medical Center [DSH330090]

Good Afternoon:

I am following up on my October 16, 2020 email below. Arnot Ogden Medical Center continues to face 340B ceiling price restrictions and overcharges from Eli Lilly, Astra Zeneca, and Sanofi. We are now unable to access the 340B ceiling price for Novartis products at contract pharmacies that are located greater than 40 miles from the covered entity. While the new restrictions are not as wide-spread as the first companies to emerge with these rogue actions, it is still financially damaging. It appears that Novartis is aiming to limit 340B pricing access through specialty contract pharmacy arrangements, a model that is often managed via mail order operations. The patients that utilize these pharmacies are often receiving medications for complex and specialized disease states, patients that, as a safety net provider, Arnot Ogden Medical Center is required to follow closely.

I have attached Apexus' notification form regarding Novartis products not being available at the 340B ceiling price via McKesson and Cardinal Health. I have previously submitted similar forms for Eli Lilly, Sanofi, and Astra Zeneca.

I am also attaching documentation illustrating all of the overcharges that we have incurred since my last email on October 16th, 2020. Myself and my leadership team feel strongly that Eli Lilly, Astra Zeneca, Sanofi, and Novartis have violated the Pharmaceutical Pricing Agreement in place with HHS by refusing to offer covered entities the ability to purchase covered outpatient drugs at the 340B ceiling price. It seems appropriate that this violation would result in termination of the agreement and/or civil monetary penalties. I hope that the attached data is helpful in achieving this outcome.

As you can see by the overcharges provided, these restrictions have a significant financial impact on Arnot Ogden Medical Center. As I mentioned in my last email, in most cases, once a 340B price has been removed from the wholesaler drug catalog, previously eligible prescriptions will no longer be qualified. In other cases a prescription may be qualified, but due to the inability to purchase at the 340B ceiling price, purchasing is suppressed. It is for these reasons that the overcharges being provided only illustrate a small portion of the lost opportunity and financial impact to the hospital.

As a safety net provider in Elmira, New York, Arnot Ogden Medical Center is providing care in a

region with a poverty rate around 30%. The hospital has operated for years in the red, with the 340B program and largely the benefit from contract pharmacy relationships being attributed to helping keep the doors open.
Combining today's submission of overcharges with the overcharges submitted in mid-October, Arnot Ogden Medical Center has been charged ~$230k over the 340B ceiling price on covered outpatient drugs purchased from Eli Lilly, Astra Zeneca, Sanofi, and Novartis. We are estimating that this is just a fraction of the total financial impact to the organization.
Please let me know if any other information would be helpful in the effort to resolve this issue.
Thank you,
Katy

Katy Felice Lees
Director of 340B Policy and Business Strategy | UR Medicine
Phone (585) 703-5169 | Fax (585)272-1062
120 Corporate Woods Suite 100 Rochester, NY 14623 | Internal Box # 278983

"Nothing is impossible, the word itself says 'I'm Possible'!"

- Audrey Hepburn

From: Lees, Katy F
Sent: Friday, October 16, 2020 4:58 PM
To: 'HRSA HSB 340B Pricing' <340BPricing@hrsa.gov>
Cc: Dworsky, Mark <mark.dworsky@arnothealth.org>; 'Bacon, Bill' <bill.bacon@arnothealth.org>
Subject: 340B Ceiling Price Unavailable: Arnot Ogden Medical Center [DSH330090]
Good Afternoon:
I am reaching out today regarding the restrictions that have been put in place by Eli Lilly, Astra Zeneca, and Sanofi. As you are aware, these three companies have taken steps to restrict purchases at the 340B ceiling price on all ship-to accounts established to replenish drugs to pharmacies contracted with 340B covered entities. These limitations are already having significant financial implications on safety net providers.
This email pertains to the overcharges and restricted pricing that has been experienced by Arnot Ogden Medical Center [DSH330090]. In just a very short period of time since these limitations were put in place, the hospital has incurred roughly $120k in overcharges and this does not include the large volume of purchases that should have occurred, but were suppressed due to the changes imposed.
As I believe you are aware, in most cases, once a 340B price has been removed from the wholesaler drug catalog, previously eligible prescriptions will no longer be qualified. In other cases a prescription may be qualified, but due to the inability to purchase at the 340B ceiling price, purchasing is suppressed. It is for these reasons that the overcharges being provided only illustrate a small portion of the lost opportunity and financial impact to the hospital.
I have provided a number of attachments with this email.

1) Notification of Astra Zeneca not offering the products at 340B ceiling price via McKesson.
2) Spreadsheet of Astra Zeneca overcharges via McKesson (totaling $8.956.70)

3) Notification of Astra Zeneca not offering the products at 340B ceiling price via Cardinal
4) Notification of Eli Lilly not offering the products at 340B ceiling price via McKesson.
5) Spreadsheet of Eli Lilly overcharges via McKesson (totaling $102,108.56)
6) Notification of Eli Lilly not offering the products at 340B ceiling price via Cardinal
7) Notification of Sanofi not offering the products at 340B ceiling price via McKesson.
8) Spreadsheet of Sanofi overcharges via McKesson (totaling $8,785.87)
9) Notification of Sanofi not offering the products at 340B ceiling price via Cardinal
10) Listing of all Eli Lilly, Astra Zeneca, and Sanofi products currently not being offered at 340B ceiling price on ship-to accounts established for replenishment of product to pharmacies contracted with covered entities.

Please let me know if you have any questions or need any other information. We would like to assist HRSA in any way possible on this matter.

Thank you,

Katy

Katy Felice Lees
Director of 340B Policy and Business Strategy | UR Medicine
Phone (585) 703-5169 | Fax (585)272-1062
120 Corporate Woods Suite 100 Rochester, NY 14623 | Internal Box # 278983

"Nothing is impossible, the word itself says 'I'm Possible'!"

- Audrey Hepburn

Manufacturer	NDC/UPC	Item Description	Invc/CrDate
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/7/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	1/11/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	2/4/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	1/28/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	3/2/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	2/8/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/16/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/2/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/5/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/8/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/12/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/2/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/5/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/8/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/7/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/7/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/14/2021
Novartis	00078069620	ENTRESTO TAB 97/103MG 60	4/14/2021
Novartis	00078069620	ENTRESTO TAB 97/103MG 60	1/20/2021
Novartis	00078069620	ENTRESTO TAB 97/103MG 60	2/10/2021
Novartis	00078069620	ENTRESTO TAB 97/103MG 60	3/3/2021
Novartis	00078069620	ENTRESTO TAB 97/103MG 60	3/17/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	12/31/2020
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	12/28/2020
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	12/28/2020
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	12/23/2020
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	3/25/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	1/6/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	2/8/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	1/29/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	1/26/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	1/6/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	2/3/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	3/3/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	1/20/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	1/27/2021

Units Purchased	UOM	Unit Price	Ext.Price	340B Price		Estimated Overcharge An
2	EA	$284.79	$569.58			
3	EA	$264.08	$792.24			
3	EA	$264.08	$792.24			
2	EA	$264.08	$528.16			
2	EA	$264.08	$528.16			
2	EA	$264.08	$528.16			
1	EA	$284.79	$284.79			
1	EA	$284.79	$284.79			
1	EA	$284.79	$284.79			
1	EA	$284.79	$284.79			
1	EA	$284.79	$284.79			
1	EA	$284.79	$284.79			
1	EA	$284.79	$284.79			
1	EA	$284.79	$284.79			
1	EA	$284.79	$284.79			
1	EA	$284.79	$284.79			
1	EA	$284.79	$284.79			
1	EA	$284.79	$284.79			
1	EA	$293.12	$293.12			
1	EA	$289.64	$289.64			
1	EA	$289.64	$289.64			
1	EA	$289.64	$289.64			
1	EA	$289.64	$289.64			
1	EA	$264.68	$264.68			
1	EA	$264.68	$264.68			
1	EA	$264.68	$264.68			
1	EA	$264.68	$264.68			
1	EA	$264.08	$264.08			
1	EA	$264.08	$264.08			
1	EA	$264.08	$264.08			
1	EA	$264.08	$264.08			
1	EA	$264.08	$264.08			
1	EA	$264.08	$264.08			
1	EA	$264.08	$264.08			
1	EA	$264.08	$264.08			
1	EA	$264.08	$264.08			
1	EA	$264.08	$264.08			

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From: Lees, Katy F
To: HRSA HSB 340B Pricing
Subject: RE: 340B Ceiling Price Unavailable: Highland Hospital [RRC330164-00]
Date: Monday, April 26, 2021 3:15:07 PM
Attachments: image003.png
image005.wmz
image007.png
image001.png
image002.png
image004.png
image011.png
HRSA_Notification_340B_Price_Unavailable_Cardinal_NovoNordisk_RRC330164-00.pdf
HRSA_Notification_340B_Price_Unavailable_McKesson_Eli Lilly_RRC330164-00_12.15.20 to 4.26.21.xlsx
HRSA_Notification_340B_Price_Unavailable_McKesson_Novartis_RRC330164-00_12.15.20 to 4.26.21.xlsx
HRSA_Notification_340B_Price_Unavailable_McKesson_NovoNordisk_RRC330164-00.pdf
HRSA_Notification_340B_Price_Unavailable_McKesson_NovoNordisk_RRC330164-00_12.15.20 to 4.26.21.xlsx
HRSA_Notification_340B_Price_Unavailable_McKesson_Sanofi_RRC330164-00_12.15.20 to 4.26.21.xlsx

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Good Afternoon:

I am following up on my December 16, 2020 email below. Highland Hospital continues to face 340B ceiling price restrictions and overcharges from Eli Lilly, Astra Zeneca, Sanofi, and Novartis. We are now unable to access the 340B ceiling price for NovoNordisk products for replenishment to contract pharmacy partners. I have attached Apexus' notification form regarding NovoNordisk products not being available at the 340B ceiling price via McKesson and Cardinal Health. I have previously submitted similar forms for Eli Lilly, Sanofi, Astra Zeneca, and Novartis.

I am also attaching documentation illustrating all of the overcharges that we have incurred since my last email on December 16th, 2020. As I stated in my previous emails, my organization feels strongly that Eli Lilly, Astra Zeneca, Sanofi, Novartis, and NovoNordisk have violated the Pharmaceutical Pricing Agreement in place with HHS by refusing to offer covered entities the ability to purchase covered outpatient drugs at the 340B ceiling price. It seems appropriate that this violation would result in termination of the agreement and/or civil monetary penalties. I hope that the attached data is helpful in achieving this outcome.

As you can see by the overcharges provided, these restrictions have a significant financial impact on Highland Hospital. As I mentioned in my last email, in most cases, once a 340B price has been removed from the wholesaler drug catalog, previously eligible prescriptions will no longer be qualified. In other cases a prescription may be qualified, but due to the inability to purchase at the 340B ceiling price, purchasing is suppressed. It is for these reasons that the overcharges being provided only illustrate a small portion of the lost opportunity and financial impact to the hospital. We are estimating that the total financial impact to the hospital, year to date, exceeds $1.5 million.

As a safety net provider in Rochester, New York, Highland Hospital's service area has the third highest concentration of poverty in the U.S., with more than 50% of the city's children living in poverty. The losses incurred due to manufacturer restrictions will put at risk Highland's ability to maintain a robust charity care program and community services that we are able to provide, often operating at a loss, such as comprehensive mental health and wellness care for adults, adolescents, and pediatrics, substance abuse treatment programs, and Naloxone training.

Combining today's submission of overcharges with the overcharges submitted in October and December, Highland Hospital has paid more than $600k over the 340B ceiling price on covered outpatient drugs purchased from Eli Lilly, Astra Zeneca, Sanofi, Novartis, and NovoNordisk. As I shared above, we are estimating that this is just a fraction of the total financial impact to our organization.

Please let me know if any other information would be helpful in effort to resolve this issue.

Thank you,
Katy

Katy Felice Lees
Director of 340B Policy and Business Strategy | **UR Medicine**
Phone (585) 703-5169 | Fax (585)272-1062
120 Corporate Woods Suite 100 Rochester, NY 14623 | Internal Box # 278983

From: Lees, Katy F
Sent: Wednesday, December 16, 2020 2:25 PM
To: 'HRSA HSB 340B Pricing' <340BPricing@hrsa.gov>
Subject: RE: 340B Ceiling Price Unavailable: Highland Hospital [RRC330164-00]

Good Afternoon:

I am following up on my October 16, 2020 email below. Highland Hospital continues to face 340B ceiling price restrictions and overcharges from Eli Lilly, Astra Zeneca, and Sanofi. We are now unable to access the 340B ceiling price for Novartis products at contract pharmacies that are located greater than 40 miles from the covered entity.

I have attached Apexus' notification form regarding Novartis products not being available at the 340B ceiling price via McKesson and Cardinal Health. I have previously submitted similar forms for Eli Lilly, Sanofi, and Astra Zeneca.

I am also attaching documentation illustrating all of the overcharges that we have incurred since my last email on October 16th, 2020. Myself and my leadership team feel strongly that Eli Lilly, Astra Zeneca, Sanofi, and Novartis have violated the Pharmaceutical Pricing Agreement in place with HHS by refusing to offer covered entities the ability to purchase covered outpatient drugs at the 340B ceiling price. It seems appropriate that this violation would result in termination of the agreement and/or civil monetary penalties. I hope that the attached data is helpful in achieving this outcome.

As you can see by the overcharges provided, these restrictions have a significant financial impact on Highland Hospital. As I mentioned in my last email, in most cases, once a 340B price has been removed from the wholesaler drug catalog, previously eligible prescriptions will no longer be qualified. In other cases a prescription may be qualified, but due to the inability to purchase at the 340B ceiling price, purchasing is suppressed. It is for these reasons that the overcharges being provided only illustrate a small portion of the lost opportunity and financial impact to the hospital.

As a safety net provider in Rochester, New York, Highland Hospital's service area has the third highest concentration of poverty in the U.S., with more than 50% of the city's children living in poverty. The losses incurred due to manufacturer restrictions will have an impact on Highland's ability to maintain a robust charity care program and community services that we are able to provide, often operating at a loss, such as comprehensive mental health and wellness care for

adults, adolescents, and pediatrics, substance abuse treatment programs, and Naloxone training. Combining today's submission of overcharges with the overcharges submitted in mid-October, Highland Hospital has paid more than $360k over the 340B ceiling price on covered outpatient drugs purchased from Eli Lilly, Astra Zeneca, Sanofi, and Novartis. We are estimating that this is just a fraction of the total financial impact to our organization.
Please let me know if any other information would be helpful in effort to resolve this issue.
Thank you,
Katy

Katy Felice Lees
Director of 340B Policy and Business Strategy | UR Medicine
Phone (585) 703-5169 | Fax (585)272-1062
120 Corporate Woods Suite 100 Rochester, NY 14623 | Internal Box # 278983

"Nothing is impossible, the word itself says 'I'm Possible'!"

- Audrey Hepburn

From: Lees, Katy F
Sent: Friday, October 16, 2020 4:44 PM
To: 'HRSA HSB 340B Pricing' <340BPricing@hrsa.gov>
Subject: 340B Ceiling Price Unavailable: Highland Hospital [RRC330164-00]
Good Afternoon:
I am reaching out today regarding the restrictions that have been put in place by Eli Lilly, Astra Zeneca, and Sanofi. As you are aware, these three companies have taken steps to restrict purchases at the 340B ceiling price on all ship-to accounts established to replenish drugs to pharmacies contracted with 340B covered entities. These limitations are already having significant financial implications on safety net providers.
This email pertains to the overcharges and restricted pricing that has been experienced by Highland Hospital [RRC330164-00]. In just a very short period of time since these limitations were put in place, the hospital has incurred roughly $140k in overcharges and this does not include the large volume of purchases that should have occurred, but were suppressed due to the changes imposed.
As I believe you are aware, in most cases, once a 340B price has been removed from the wholesaler drug catalog, previously eligible prescriptions will no longer be qualified. In other cases a prescription may be qualified, but due to the inability to purchase at the 340B ceiling price, purchasing is suppressed. It is for these reasons that the overcharges being provided only illustrate a small portion of the lost opportunity and financial impact to the hospital.
I have provided a number of attachments with this email.

1) Notification of Astra Zeneca not offering the products at 340B ceiling price via McKesson.
2) Spreadsheet of Astra Zeneca overcharges via McKesson (totaling $7,942.28)
3) Notification of Astra Zeneca not offering the products at 340B ceiling price via Cardinal
4) Notification of Eli Lilly not offering the products at 340B ceiling price via McKesson.
5) Spreadsheet of Eli Lilly overcharges via McKesson (totaling $98,274.15)
6) Notification of Eli Lilly not offering the products at 340B ceiling price via Cardinal

7) Notification of Sanofi not offering the products at 340B ceiling price via McKesson.
8) Spreadsheet of Sanofi overcharges via McKesson (totaling $32,064.21)
9) Notification of Sanofi not offering the products at 340B ceiling price via Cardinal
10) Listing of all Eli Lilly, Astra Zeneca, and Sanofi products currently not being offered at 340B ceiling price on ship-to accounts established for replenishment of product to pharmacies contracted with covered entities.

Please let me know if you have any questions or need any other information. We would like to assist HRSA in any way possible on this matter.

Thank you,

Katy

Katy Felice Lees
Director of 340B Policy and Business Strategy | UR Medicine
Phone (585) 703-5169 | Fax (585)272-1062
120 Corporate Woods Suite 100 Rochester, NY 14623 | Internal Box # 278983

"Nothing is impossible, the word itself says 'I'm Possible'!"

- Audrey Hepburn

Manufacturer	NDC/UPC	Item Description		Invc/CrDate
Novartis	00078065920	ENTRESTO TAB 24/26MG 60		12/21/2020
Novartis	00078051005	TEGRETOL-XR ER TB 100MG	100	3/12/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60		4/16/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60		4/1/2021
Novartis	00078077720	ENTRESTO TAB 49/51MG 60		4/7/2021
Novartis	00078077720	ENTRESTO TAB 49/51MG 60		4/19/2021
Novartis	00078077720	ENTRESTO TAB 49/51MG 60		4/21/2021
Novartis	00078077720	ENTRESTO TAB 49/51MG 60		4/8/2021
Novartis	00078077720	ENTRESTO TAB 49/51MG 60		4/8/2021
Novartis	00078077720	ENTRESTO TAB 49/51MG 60		4/21/2021
Novartis	00078077720	ENTRESTO TAB 49/51MG 60		4/21/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60		4/21/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60		4/15/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60		4/21/2021

Units Purchased	UOM	Unit Price	Ext.Price	340B Ceiling Price	Overcharge Amount
1	EA	$521.88	$521.88	[redacted]	[redacted]
1	EA	$129.93	$129.93		
3	EA	$262.34	$787.02		
3	EA	$262.34	$787.02		
2	EA	$260.92	$521.84		
2	EA	$260.92	$521.84		
1	EA	$260.92	$260.92		
1	EA	$260.92	$260.92		
1	EA	$260.92	$260.92		
1	EA	$260.92	$260.92		
1	EA	$260.92	$260.92		
1	EA	$262.34	$262.34		
1	EA	$262.34	$262.34		
1	EA	$262.34	$262.34		

From: Lees, Katy F
To: HRSA HSB 340B Pricing
Subject: RE: 340B Ceiling Price Unavailable: Jones Memorial Hospital [DSH330196]
Date: Monday, April 26, 2021 3:14:46 PM
Attachments: image003.png
image005.wmz
image007.png
image006.png
image008.png
image009.png
image010.png
HRSA_Notification_340B_Price_Unavailable_Cardinal_NovoNordisk_DSH330096.pdf
HRSA_Notification_340B_Price_Unavailable_McKesson_Novartis_DSH330096_1.1.21 - 4.26.21.xlsx
HRSA_Notification_340B_Price_Unavailable_McKesson_NovoNordisk_DSH330096.pdf

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Good Afternoon:

I am following up on my December 16, 2020 email below. Jones Memorial Hospital continues to face 340B ceiling price restrictions and overcharges from Eli Lilly, Astra Zeneca, Sanofi, and Novartis. We are now unable to access the 340B ceiling price for NovoNordisk products purchased for replenishment to contract pharmacy partners. I have attached Apexus' notification form regarding NovoNordisk products not being available at the 340B ceiling price via McKesson and Cardinal Health. I have previously submitted similar forms for Eli Lilly, Sanofi, Astra Zeneca, and NovoNordisk. I am also attaching documentation illustrating all of the overcharges that we have incurred since my last email on December 16th, 2020. As I shared in my previous emails, my organization feels strongly that Eli Lilly, Astra Zeneca, Sanofi, Novartis, and NovoNordisk have violated the Pharmaceutical Pricing Agreement in place with HHS by refusing to offer covered entities the ability to purchase covered outpatient drugs at the 340B ceiling price. It seems appropriate that this violation would result in termination of the agreement and/or civil monetary penalties. I hope that the attached data is helpful in achieving this outcome.

While the overcharges provided for Jones Memorial appear to be minimal, these restrictions have had a significant financial impact on Jones Memorial Hospital. As I mentioned in my last email, in most cases, once a 340B price has been removed from the wholesaler drug catalog, previously eligible prescriptions will no longer be qualified. In other cases a prescription may be qualified, but due to the inability to purchase at the 340B ceiling price, purchasing is suppressed. It is for these reasons that the overcharges being provided only illustrate a small portion of the lost opportunity and financial impact to the hospital. We are estimating that the total financial impact to the hospital, year to date, exceeds $500k.

As a safety net provider in Wellsville, New York, Jones Memorial Hospital is located in a rural area among the poorest in New York, with large indigent populations. These patients often present sicker, require more costly care, and need financial assistance to afford critical services and medications. The 340B program and largely the benefit from contract pharmacy relationships are keeping the hospital's doors open.

Combining today's submission of overcharges with the overcharges submitted in October and December, Jones Memorial Hospital has been charged ~$14,000 over the 340B ceiling price on covered outpatient drugs purchased from Eli Lilly, Astra Zeneca, Sanofi, Novartis, and NovoNordisk. As I shared above, we are estimating that this is just a fraction of the total financial impact to our organization.

Please let me know if any other information would be helpful in the effort to resolve this issue.

Thank you,

Katy

Katy Felice Lees
Director of 340B Policy and Business Strategy | **UR Medicine**
Phone (585) 703-5169 | Fax (585)272-1062
120 Corporate Woods Suite 100 Rochester, NY 14623 | Internal Box # 278983

From: Lees, Katy F
Sent: Wednesday, December 16, 2020 2:39 PM
To: 'HRSA HSB 340B Pricing' <340BPricing@hrsa.gov>
Subject: RE: 340B Ceiling Price Unavailable: Jones Memorial Hospital [DSH330196]

Good Afternoon:

I am following up on my October 16, 2020 email below. Jones Memorial Hospital continues to face 340B ceiling price restrictions and overcharges from Eli Lilly, Astra Zeneca, and Sanofi. We are now unable to access the 340B ceiling price for Novartis products at contract pharmacies that are located greater than 40 miles from the covered entity.

I have attached Apexus' notification form regarding Novartis products not being available at the 340B ceiling price via McKesson and Cardinal Health. I have previously submitted similar forms for Eli Lilly, Sanofi, and Astra Zeneca.

I am also attaching documentation illustrating all of the overcharges that we have incurred since my last email on October 16th, 2020. Myself and my leadership team feel strongly that Eli Lilly, Astra Zeneca, Sanofi, and Novartis have violated the Pharmaceutical Pricing Agreement in place with HHS by refusing to offer covered entities the ability to purchase covered outpatient drugs at the 340B ceiling price. It seems appropriate that this violation would result in termination of the agreement and/or civil monetary penalties. I hope that the attached data is helpful in achieving this outcome.

As you can see by the overcharges provided, these restrictions have a significant financial impact on Jones Memorial Hospital. As I mentioned in my last email, in most cases, once a 340B price has been removed from the wholesaler drug catalog, previously eligible prescriptions will no longer be qualified. In other cases a prescription may be qualified, but due to the inability to purchase at the 340B ceiling price, purchasing is suppressed. It is for these reasons that the overcharges being provided only illustrate a small portion of the lost opportunity and financial impact to the hospital.

As a safety net provider in Wellsville, New York, Jones Memorial Hospital is located in a rural area among the poorest in New York, with large indigent populations. These patients often present sicker, require more costly care, and need financial assistance to afford critical services and medications. The 340B program and largely the benefit from contract pharmacy relationships are keeping the hospital's doors open.

Combining today's submission of overcharges with the overcharges submitted in mid-October, Jones Memorial Hospital has been charged ~$6,000 over the 340B ceiling price on covered outpatient

drugs purchased from Eli Lilly, Astra Zeneca, Sanofi, and Novartis. We are estimating that the annualized impact of the current restrictions will exceed $500k.
Please let me know if any other information would be helpful in the effort to resolve this issue.
Thank you,
Katy

Katy Felice Lees
Director of 340B Policy and Business Strategy | UR Medicine
Phone (585) 703-5169 | Fax (585)272-1062
120 Corporate Woods Suite 100 Rochester, NY 14623 | Internal Box # 278983

"Nothing is impossible, the word itself says 'I'm Possible'!"

- Audrey Hepburn

From: Lees, Katy F
Sent: Friday, October 16, 2020 4:50 PM
To: 'HRSA HSB 340B Pricing' <340BPricing@hrsa.gov>
Subject: 340B Ceiling Price Unavailable: Jones Memorial Hospital [DSH330196]
Good Afternoon:
I am reaching out today regarding the restrictions that have been put in place by Eli Lilly, Astra Zeneca, and Sanofi. As you are aware, these three companies have taken steps to restrict purchases at the 340B ceiling price on all ship-to accounts established to replenish drugs to pharmacies contracted with 340B covered entities. These limitations are already having significant financial implications on safety net providers.
This email pertains to the overcharges and restricted pricing that has been experienced by Jones Memorial Hospital [DSH330196]. In just a very short period of time since these limitations were put in place, the hospital has incurred roughly $1,500 in overcharges and this does not include the large volume of purchases that should have occurred, but were suppressed due to the changes imposed. As I believe you are aware, in most cases, once a 340B price has been removed from the wholesaler drug catalog, previously eligible prescriptions will no longer be qualified. In other cases a prescription may be qualified, but due to the inability to purchase at the 340B ceiling price, purchasing is suppressed. It is for these reasons that the overcharges being provided only illustrate a small portion of the lost opportunity and financial impact to the hospital.
I have provided a number of attachments with this email.

1) Notification of Astra Zeneca not offering the products at 340B ceiling price via McKesson.
2) Notification of Astra Zeneca not offering the products at 340B ceiling price via Cardinal
3) Notification of Eli Lilly not offering the products at 340B ceiling price via McKesson.
4) Notification of Eli Lilly not offering the products at 340B ceiling price via Cardinal
5) Notification of Sanofi not offering the products at 340B ceiling price via McKesson.
6) Spreadsheet of Sanofi overcharges via McKesson (totaling $1,474.50)
7) Notification of Sanofi not offering the products at 340B ceiling price via Cardinal
8) Listing of all Eli Lilly, Astra Zeneca, and Sanofi products currently not being offered at 340B ceiling price on ship-to accounts established for replenishment of product to pharmacies

contracted with covered entities.

Please let me know if you have any questions or need any other information. We would like to assist HRSA in any way possible on this matter.

Thank you,

Katy

Katy Felice Lees
Director of 340B Policy and Business Strategy | UR Medicine
Phone (585) 703-5169 | Fax (585)272-1062
120 Corporate Woods Suite 100 Rochester, NY 14623 | Internal Box # 278983

"Nothing is impossible, the word itself says 'I'm Possible'!"

- Audrey Hepburn

From: Lees, Katy F
To: HRSA HSB 340B Pricing
Subject: RE: 340B Ceiling Price Unavailable: Noyes Memorial Hospital [DSH330238]
Date: Monday, April 26, 2021 3:15:00 PM
Attachments: image003.png
image005.wmz
image007.png
image001.png
image002.png
image004.png
image011.png
HRSA_Notification_340B_Price_Unavailable_Cardinal_NovoNordisk_DSH330238.pdf
HRSA_Notification_340B_Price_Unavailable_McKesson_Novartis_DSH330238.xlsx
HRSA_Notification_340B_Price_Unavailable_McKesson_NovoNordisk_DSH330238.pdf
HRSA_Notification_340B_Price_Unavailable_McKesson_NovoNordisk_DSH330238.xlsx
HRSA_Notification_340B_Price_Unavailable_McKesson_Sanofi_DSH330238.xlsx

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Good Afternoon:

I am following up on my December 16, 2020 email below. Noyes Memorial Hospital continues to face 340B ceiling price restrictions and overcharges from Eli Lilly, Astra Zeneca, Sanofi, and Novartis. We are now unable to access the 340B ceiling price for NovoNordisk products via contract pharmacy ship-to accounts. I have attached Apexus' notification form regarding NovoNordisk products not being available at the 340B ceiling price via McKesson and Cardinal Health. I have previously submitted similar forms for Eli Lilly, Sanofi, Astra Zeneca, and Novartis.

I am also attaching documentation illustrating all of the overcharges that we have incurred since my last email on December 16th, 2020. As I have previously shared, my organization feels strongly that Eli Lilly, Astra Zeneca, Sanofi, Novartis and NovoNordisk have violated the Pharmaceutical Pricing Agreement in place with HHS by refusing to offer covered entities the ability to purchase covered outpatient drugs at the 340B ceiling price. It seems appropriate that this violation would result in termination of the agreement and/or civil monetary penalties. I hope that the attached data is helpful in achieving this outcome.

These restrictions have had a significant financial impact on Noyes Memorial Hospital. As I mentioned in my last email, in most cases, once a 340B price has been removed from the wholesaler drug catalog, previously eligible prescriptions will no longer be qualified. In other cases a prescription may be qualified, but due to the inability to purchase at the 340B ceiling price, purchasing is suppressed. It is for these reasons that the overcharges being provided only illustrate a small portion of the lost opportunity and financial impact to the hospital. We are estimating that the total financial impact to the hospital, year to date, exceeds $25k.

As a safety net provider in Dansville, New York, Noyes Memorial Hospital is located in a rural area among the poorest in New York, with large indigent populations. These patients often present sicker, require more costly care, and need financial assistance to afford critical services and medications. Combining today's submission of overcharges with the overcharges submitted in October and December, Noyes Memorial Hospital has been charged ~$10,000 over the 340B ceiling price on covered outpatient drugs purchased from Eli Lilly, Astra Zeneca, Sanofi, Novartis, and NovoNordisk.

Please let me know if any other information would be helpful in the effort to resolve this issue.

Thank you,

Katy

Katy Felice Lees
Director of 340B Policy and Business Strategy | **UR Medicine**
Phone (585) 703-5169 | Fax (585)272-1062
120 Corporate Woods Suite 100 Rochester, NY 14623 | Internal Box # 278983

From: Lees, Katy F
Sent: Wednesday, December 16, 2020 2:47 PM
To: 'HRSA HSB 340B Pricing' <340BPricing@hrsa.gov>
Subject: RE: 340B Ceiling Price Unavailable: Noyes Memorial Hospital [DSH330238]

Good Afternoon:

I am following up on my October 16, 2020 email below. Noyes Memorial Hospital continues to face 340B ceiling price restrictions and overcharges from Eli Lilly, Astra Zeneca, and Sanofi. We are now unable to access the 340B ceiling price for Novartis products at contract pharmacies that are located greater than 40 miles from the covered entity.

I have attached Apexus' notification form regarding Novartis products not being available at the 340B ceiling price via McKesson and Cardinal Health. I have previously submitted similar forms for Eli Lilly, Sanofi, and Astra Zeneca.

I am also attaching documentation illustrating all of the overcharges that we have incurred since my last email on October 16th, 2020. Myself and my leadership team feel strongly that Eli Lilly, Astra Zeneca, Sanofi, and Novartis have violated the Pharmaceutical Pricing Agreement in place with HHS by refusing to offer covered entities the ability to purchase covered outpatient drugs at the 340B ceiling price. It seems appropriate that this violation would result in termination of the agreement and/or civil monetary penalties. I hope that the attached data is helpful in achieving this outcome.

These restrictions have a significant financial impact on Noyes Memorial Hospital. As I mentioned in my last email, in most cases, once a 340B price has been removed from the wholesaler drug catalog, previously eligible prescriptions will no longer be qualified. In other cases a prescription may be qualified, but due to the inability to purchase at the 340B ceiling price, purchasing is suppressed. It is for these reasons that the overcharges being provided only illustrate a small portion of the lost opportunity and financial impact to the hospital.

As a safety net provider in Dansville, New York, Noyes Memorial Hospital is located in a rural area among the poorest in New York, with large indigent populations. These patients often present sicker, require more costly care, and need financial assistance to afford critical services and medications.

Combining today's submission of overcharges with the overcharges submitted in mid-October, Noyes Memorial Hospital has been charged ~$4,100 over the 340B ceiling price on covered outpatient drugs purchased from Eli Lilly, Astra Zeneca, Sanofi, and Novartis. We are estimating that the annualized impact of the current restrictions will exceed $100k.

Please let me know if any other information would be helpful in the effort to resolve this issue.
Thank you,
Katy

Katy Felice Lees
Director of 340B Policy and Business Strategy | UR Medicine
Phone (585) 703-5169 | Fax (585)272-1062
120 Corporate Woods Suite 100 Rochester, NY 14623 | Internal Box # 278983

"Nothing is impossible, the word itself says 'I'm Possible'!"

- Audrey Hepburn

From: Lees, Katy F
Sent: Friday, October 16, 2020 4:55 PM
To: 'HRSA HSB 340B Pricing' <340BPricing@hrsa.gov>
Subject: 340B Ceiling Price Unavailable: Noyes Memorial Hospital [DSH330238]

Good Afternoon:

I am reaching out today regarding the restrictions that have been put in place by Eli Lilly, Astra Zeneca, and Sanofi. As you are aware, these three companies have taken steps to restrict purchases at the 340B ceiling price on all ship-to accounts established to replenish drugs to pharmacies contracted with 340B covered entities. These limitations are already having significant financial implications on safety net providers.

This email pertains to the overcharges and restricted pricing that has been experienced by Noyes Memorial Hospital [DSH330238]. In just a very short period of time since these limitations were put in place, the hospital has incurred roughly $500 in overcharges and this does not include the large volume of purchases that should have occurred, but were suppressed due to the changes imposed. As I believe you are aware, in most cases, once a 340B price has been removed from the wholesaler drug catalog, previously eligible prescriptions will no longer be qualified. In other cases a prescription may be qualified, but due to the inability to purchase at the 340B ceiling price, purchasing is suppressed. It is for these reasons that the overcharges being provided only illustrate a small portion of the lost opportunity and financial impact to the hospital.

I have provided a number of attachments with this email.

1) Notification of Astra Zeneca not offering the products at 340B ceiling price via McKesson.
2) Notification of Astra Zeneca not offering the products at 340B ceiling price via Cardinal
3) Notification of Eli Lilly not offering the products at 340B ceiling price via McKesson.
4) Notification of Eli Lilly not offering the products at 340B ceiling price via Cardinal
5) Notification of Sanofi not offering the products at 340B ceiling price via McKesson.
6) Spreadsheet of Sanofi overcharges via McKesson (totaling $497.30)
7) Notification of Sanofi not offering the products at 340B ceiling price via Cardinal
8) Listing of all Eli Lilly, Astra Zeneca, and Sanofi products currently not being offered at 340B ceiling price on ship-to accounts established for replenishment of product to pharmacies contracted with covered entities.

Please let me know if you have any questions or need any other information. We would like to assist

HRSA in any way possible on this matter.
Thank you,
Katy

Katy Felice Lees
Director of 340B Policy and Business Strategy | UR Medicine
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- Audrey Hepburn

Manufacturer	NDC/UPC	Item Description	Invc/CrDate
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/15/2021

Units Purchased	UOM	Unit Price	Ext.Price	340B Price		Estimated Overcharge An	
1	EA	**$285.07**	$285.07		[redacted]		[redacted]

From: Lees, Katy F
To: HRSA HSB 340B Pricing
Subject: RE: 340B Ceiling Price Unavailable: Strong Memorial Hospital [DSH330285]
Date: Monday, April 26, 2021 3:14:51 PM
Attachments: image003.png
image004.wmz
image007.png
image006.png
image008.png
image009.png
image010.png
HRSA_Notification_340B_Price_Unavailable_Cardinal_NovoNordisk_DSH330285.pdf
HRSA_Notification_340B_Price_Unavailable_McKesson_Astra Zeneca_DSH330285_12.15.20 to 4.26.21.xlsx
HRSA_Notification_340B_Price_Unavailable_McKesson_Eli Lilly_DSH330285_12.15.20 to 4.26.21.xlsx
HRSA_Notification_340B_Price_Unavailable_McKesson_Novartis_DSH330285_12.15.20 to 4.26.21.xlsx
HRSA_Notification_340B_Price_Unavailable_McKesson_NovoNordisk_DSH330285.pdf
HRSA_Notification_340B_Price_Unavailable_McKesson_NovoNordisk_DSH330285_12.14.20 to 4.26.21.xlsx
HRSA_Notification_340B_Price_Unavailable_McKesson_Sanofi_DSH330285_12.14.20 to 4.26.21.xlsx

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Good Afternoon:

I am following up on my December 16, 2020 email below. Strong Memorial Hospital continues to face 340B ceiling price restrictions and overcharges from Eli Lilly, Astra Zeneca, Sanofi, and Novartis. We are now unable to access the 340B ceiling price for NovoNordisk products via contract pharmacy ship-to accounts. I have attached Apexus' notification form regarding NovoNordisk products not being available at the 340B ceiling price via McKesson and Cardinal Health. I have previously submitted similar forms for Eli Lilly, Sanofi, Astra Zeneca, and Novartis.

I am also attaching documentation illustrating all of the overcharges that we have incurred since my last email on December 16th, 2020. As I mentioned in my past emails, myself and my leadership team feel strongly that Eli Lilly, Astra Zeneca, Sanofi, Novartis, and NovoNordisk have violated the Pharmaceutical Pricing Agreement in place with HHS by refusing to offer covered entities the ability to purchase covered outpatient drugs at the 340B ceiling price. It seems appropriate that this violation would result in termination of the agreement and/or civil monetary penalties. I hope that the attached data is helpful in achieving this outcome.

As you can see by the overcharges provided, these restrictions have a significant financial impact on Strong Memorial Hospital. As I mentioned in my previous emails, in most cases, once a 340B price has been removed from the wholesaler drug catalog, previously eligible prescriptions will no longer be qualified. In other cases a prescription may be qualified, but due to the inability to purchase at the 340B ceiling price, purchasing is suppressed. It is for these reasons that the overcharges being provided only illustrate a small portion of the lost opportunity and financial impact to the hospital. We are estimating that the total financial impact to the hospital, year to date, exceeds $10 million.

As a safety net provider in Rochester, New York, Strong Memorial Hospital's service area has the third highest concentration of poverty in the U.S., with more than 50% of the city's children living in poverty. Nearly 40% of the patients receiving care from Strong Memorial Hospital are on Medicaid or low-income Medicare. The losses incurred due to manufacturer restrictions puts at risk Strong's ability to maintain a robust charity care program and community services that we are able to provide, often operating at a loss, such as comprehensive mental health and wellness care for adults, adolescents, and pediatrics, substance abuse treatment programs, and Naloxone training.

Combining today's submission of overcharges with the overcharges submitted in October and December, Strong Memorial Hospital has paid more than $2 million over the 340B ceiling price on covered outpatient drugs purchased from Eli Lilly, Astra Zeneca, Sanofi, Novartis, and NovoNordisk.

As I mentioned above, we are estimating that this is just a fraction of the total financial impact to our

organization.
Please let me know if any other information would be helpful in effort to resolve this issue.
Thank you,
Katy

Katy Felice Lees
Director of 340B Policy and Business Strategy | **UR Medicine**
Phone (585) 703-5169 | Fax (585)272-1062
120 Corporate Woods Suite 100 Rochester, NY 14623 | Internal Box # 278983

From: Lees, Katy F
Sent: Wednesday, December 16, 2020 2:04 PM
To: 'HRSA HSB 340B Pricing' <340BPricing@hrsa.gov>
Subject: RE: 340B Ceiling Price Unavailable: Strong Memorial Hospital [DSH330285]

Good Afternoon:
I am following up on my October 16, 2020 email below. Strong Memorial Hospital continues to face 340B ceiling price restrictions and overcharges from Eli Lilly, Astra Zeneca, and Sanofi. We are now unable to access the 340B ceiling price for Novartis products at contract pharmacies that are located greater than 40 miles from the covered entity. While the new restrictions are not as wide-spread as the first companies to emerge with these rogue actions, it is still financially damaging. It appears that Novartis is aiming to limit 340B pricing access through specialty contract pharmacy arrangements, a model that is often managed via mail order operations. The patients that utilize these pharmacies are often receiving medications for complex and specialized disease states, patients that, as a safety net provider, Strong Memorial Hospital is required to follow closely.
I have attached Apexus' notification form regarding Novartis products not being available at the 340B ceiling price via McKesson and Cardinal Health. I have previously submitted similar forms for Eli Lilly, Sanofi, and Astra Zeneca.
I am also attaching documentation illustrating all of the overcharges that we have incurred since my last email on October 16th, 2020. Myself and my leadership team feel strongly that Eli Lilly, Astra Zeneca, Sanofi, and Novartis have violated the Pharmaceutical Pricing Agreement in place with HHS by refusing to offer covered entities the ability to purchase covered outpatient drugs at the 340B ceiling price. It seems appropriate that this violation would result in termination of the agreement and/or civil monetary penalties. I hope that the attached data is helpful in achieving this outcome.
As you can see by the overcharges provided, these restrictions have a significant financial impact on Strong Memorial Hospital. As I mentioned in my last email, in most cases, once a 340B price has been removed from the wholesaler drug catalog, previously eligible prescriptions will no longer be qualified. In other cases a prescription may be qualified, but due to the inability to purchase at the

340B ceiling price, purchasing is suppressed. It is for these reasons that the overcharges being provided only illustrate a small portion of the lost opportunity and financial impact to the hospital.
As a safety net provider in Rochester, New York, Strong Memorial Hospital's service area has the third highest concentration of poverty in the U.S., with more than 50% of the city's children living in poverty. Nearly 40% of the patients receiving care from Strong Memorial Hospital are on Medicaid or low-income Medicare. The losses incurred due to manufacturer restrictions will have an impact on Strong's ability to maintain a robust charity care program and community services that we are able to provide, often operating at a loss, such as comprehensive mental health and wellness care for adults, adolescents, and pediatrics, substance abuse treatment programs, and Naloxone training.
Combining today's submission of overcharges with the overcharges submitted in mid-October, Strong Memorial Hospital has paid ~$1.6 million over the 340B ceiling price on covered outpatient drugs purchased from Eli Lilly, Astra Zeneca, Sanofi, and Novartis. We are estimating that this is just a fraction of the total financial impact to our organization.
Please let me know if any other information would be helpful in effort to resolve this issue.
Thank you,
Katy

Katy Felice Lees
Director of 340B Policy and Business Strategy | UR Medicine
Phone (585) 703-5169 | Fax (585)272-1062
120 Corporate Woods Suite 100 Rochester, NY 14623 | Internal Box # 278983

"Nothing is impossible, the word itself says 'I'm Possible'!"

- Audrey Hepburn

From: Lees, Katy F
Sent: Friday, October 16, 2020 11:55 AM
To: 'HRSA HSB 340B Pricing' <340BPricing@hrsa.gov>
Subject: 340B Ceiling Price Unavailable: Strong Memorial Hospital [DSH330285]
Good Morning:
I am reaching out today regarding the restrictions that have been put in place by Eli Lilly, Astra Zeneca, and Sanofi. As you are aware, these three companies have taken steps to restrict purchases at the 340B ceiling price on all ship-to accounts established to replenish drugs to pharmacies contracted with 340B covered entities. These limitations are already having significant financial implications on safety net providers.
This email pertains to the overcharges and restricted pricing that has been experienced by Strong Memorial Hospital [DSH330285]. In just a very short period of time since these limitations were put in place, the hospital has incurred more than $560k in overcharges and this does not include the large volume of purchases that should have occurred, but were suppressed due to the changes imposed.
As I believe you are aware, in most cases, once a 340B price has been removed from the wholesaler drug catalog, previously eligible prescriptions will no longer be qualified. In other cases a prescription may be qualified, but due to the inability to purchase at the 340B ceiling price,

purchasing is suppressed. It is for these reasons that the overcharges being provided only illustrate a small portion of the lost opportunity and financial impact to the hospital.

I have provided a number of attachments with this email.

1) Notification of Astra Zeneca not offering the products at 340B ceiling price via McKesson.
2) Spreadsheet of Astra Zeneca overcharges via McKesson (totaling $43,032.60)
3) Notification of Astra Zeneca not offering the products at 340B ceiling price via Cardinal
4) Notification of Eli Lilly not offering the products at 340B ceiling price via McKesson.
5) Spreadsheet of Eli Lilly overcharges via McKesson (totaling $435,017.55)
6) Notification of Eli Lilly not offering the products at 340B ceiling price via Cardinal
7) Spreadsheet of Eli Lilly overcharges via Cardinal (totaling $1,531.82)
8) Notification of Sanofi not offering the products at 340B ceiling price via McKesson.
9) Spreadsheet of Sanofi overcharges via McKesson (totaling $81,012.88)
10) Notification of Sanofi not offering the products at 340B ceiling price via Cardinal
11) Listing of all Eli Lilly, Astra Zeneca, and Sanofi products currently not being offered at 340B ceiling price on ship-to accounts established for replenishment of product to pharmacies contracted with covered entities.

Please let me know if you have any questions or need any other information. We would like to assist HRSA in any way possible on this matter.

Thank you,

Katy

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Manufacturer	NDC/UPC	Item Description	Invc/CrDate
Novartis	00078063941	COSENTYX SENSOR PEN 150MG/ML 2	2/24/2021
Novartis	00078036034	DIOVAN TAB 320MG 90	12/21/2020
Novartis	00078091112	XIIDRA SOL 5% 50MG/ML 60	1/26/2021
Novartis	00078091112	XIIDRA SOL 5% 50MG/ML 60	2/24/2021
Novartis	00078077720	ENTRESTO TAB 49/51MG 60	12/15/2020
Novartis	00078063941	COSENTYX SENSOR PEN 150MG/ML 2	2/1/2021
Novartis	00078060715	GILENYA CAP 0.5MG 30	12/16/2020
Novartis	00065924007	DUREZOL OPH EMUL 0.05% 5ML	12/31/2020
Novartis	00078063941	COSENTYX SENSOR PEN 150MG/ML 2	3/17/2021
Novartis	00078063941	COSENTYX SENSOR PEN 150MG/ML 2	2/24/2021
Novartis	00078077720	ENTRESTO TAB 49/51MG 60	4/21/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/19/2021
Novartis	00078063998	COSENTYX PFS 150MG/ML 2	1/18/2021
Novartis	00078063941	COSENTYX SENSOR PEN 150MG/ML 2	3/17/2021
Novartis	00078077720	ENTRESTO TAB 49/51MG 60	4/8/2021
Novartis	00078077720	ENTRESTO TAB 49/51MG 60	4/1/2021
Novartis	00078077720	ENTRESTO TAB 49/51MG 60	4/21/2021
Novartis	00078077720	ENTRESTO TAB 49/51MG 60	4/8/2021
Novartis	00078077720	ENTRESTO TAB 49/51MG 60	4/1/2021
Novartis	00078077720	ENTRESTO TAB 49/51MG 60	4/1/2021
Novartis	00078077720	ENTRESTO TAB 49/51MG 60	4/9/2021
Novartis	00078077720	ENTRESTO TAB 49/51MG 60	4/8/2021
Novartis	00078077720	ENTRESTO TAB 49/51MG 60	4/19/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/1/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/19/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/19/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/21/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/16/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/21/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/21/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/15/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/15/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/15/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/15/2021
Novartis	00078065920	ENTRESTO TAB 24/26MG 60	4/21/2021

Units Purchased	UOM	Unit Price	Ext.Price	340B Price	
1	CT	$5,677.93	$5,677.93		[redacted]
1	EA	$920.82	$920.82		
1	EA	$567.18	$567.18		
1	EA	$567.18	$567.18		
1	EA	$544.76	$544.76		
3	CT	$1,793.81	$5,381.43		
1	EA	$2,554.64	$2,554.64		
1	EA	$188.46	$188.46		
2	CT	$1,793.81	$3,587.62		
2	CT	$1,793.81	$3,587.62		
3	EA	$260.81	$782.43		
3	EA	$262.23	$786.69		
1	CT	$1,793.81	$1,793.81		
1	CT	$1,793.81	$1,793.81		
2	EA	$260.81	$521.62		
1	EA	$260.81	$260.81		
1	EA	$260.81	$260.81		
1	EA	$260.81	$260.81		
1	EA	$260.81	$260.81		
1	EA	$260.81	$260.81		
1	EA	$260.81	$260.81		
1	EA	$260.81	$260.81		
1	EA	$260.81	$260.81		
1	EA	$260.81	$260.81		
1	EA	$260.81	$260.81		
1	EA	$262.23	$262.23		
1	EA	$262.23	$262.23		
1	EA	$262.23	$262.23		
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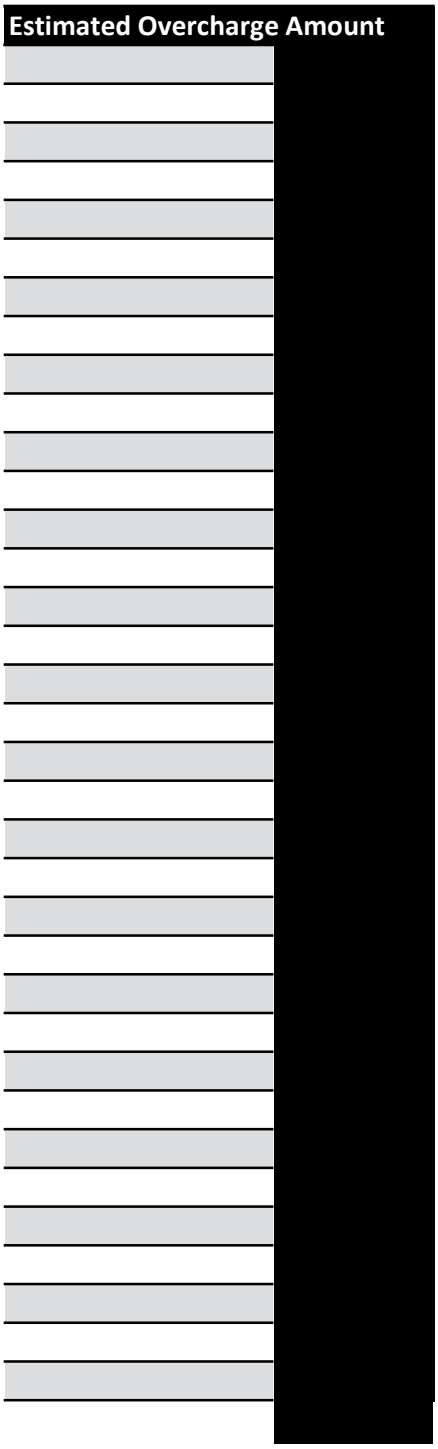
1	EA	$262.23	$262.23		
1	EA	$262.23	$262.23		
1	EA	$262.23	$262.23		
1	EA	$262.23	$262.23		
1	EA	$262.23	$262.23		


Estimated Overcharge Amount

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

The General Counsel
Washington, D.C. 20201

ADVISORY OPINION 20-06 ON CONTRACT PHARMACIES UNDER THE 340B PROGRAM
DECEMBER 30, 2020

The 340B Program, established by section 340B of the Public Health Service Act ("PHSA"), 42 U.S.C. § 256b, imposes limitations on the prices manufacturers may charge for medications sold to specified health care facilities, referred to as "covered entities." Those facilities include public hospitals and community health centers, many of which provide safety-net services to the poor. The 340B Program requires drug manufacturers, as a condition of coverage of their products under Medicaid (*see* Social Security Act ("SSA") § 1902(a)(54)) and Medicare Part B (*see, e.g.*, SSA §§ 1842(o)(1), 1847A), to agree to sell their covered outpatient drugs to covered entities at no more than the statutorily-set "ceiling price." *See* SSA § 1927(a)(1).

Many covered entities enter into written agreements with pharmacies ("contract pharmacies") to distribute their covered outpatient drugs to the entities' patients. Under those agreements, the covered entity orders and pays for the 340B drugs, which are then shipped from the manufacturer to the contract pharmacy. Although the contact pharmacy has physical possession of the drug, it has been purchased by the covered entity.

Recently, certain drug manufacturers participating in the 340B Program are declining to distribute covered outpatient drugs through contract pharmacies at the ceiling price.

The Office of the General Counsel ("OGC") has received numerous requests from both manufacturers and covered entities to address whether it is proper for a drug manufacturer participating in the 340B Program to refuse to provide covered outpatient drugs at the 340B ceiling price to a covered entity for drugs distributed at the entity's contract pharmacies. For the reasons set forth below, we conclude that to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs.

I. Analysis

A. The Plain Meaning of Section 340B Requires Manufacturers to Sell Covered Drugs to Covered Entities at or Below the Ceiling Price, Independent of Whether the Entity Opts to Use Contract Pharmacies to Dispense the Drugs

"[O]ur inquiry begins with the statutory text, and ends there as well if the text is unambiguous." *BedRoc Ltd., LLC v. United States*, 541 U.S. 176, 183 (2004). Section 340B of the PHSA, entitled "Limitation on prices of drugs purchased by covered entities," states, in relevant part, that "[t]he Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . purchased by a covered entity . . . does not exceed [the ceiling price]." 42 U.S.C. § 256b(a)(1) (emphasis supplied). Furthermore, "[e]ach such agreement . . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.* As a result, the obligations placed on manufacturers by 340B are set out in a Pharmaceutical Pricing Agreement ("PPA") between the Secretary and the respective manufacturer. *See generally Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110 (2011) (describing role of PPAs in 340B Program). The exemplar PPA provides, in pertinent part, as follows:

> Pursuant to requirements under section 340B of the Act, the Manufacturer agrees to the following: (a) for single source and innovator multiple source drugs, to charge covered entities a price for each unit of the drug that does not exceed an amount equal to [the ceiling price].

PPA § II(a). The exemplar PPA Addendum provides that a "[m]anufacturer shall offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price, if such drug is made available to any other purchaser at any price." PPA Addendum ¶ 2.

Thus, the core requirement of the 340B statute, as also reflected in the PPA and Addendum, is that manufacturers must "offer" covered outpatient drugs at or below the ceiling price for "purchase by" covered entities. This fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. All that is required is that the discounted drug be "purchased by" a covered entity. In this setting, neither the agency nor a private actor is authorized by section 340B to add requirements to the statute. *See Radovich v. Nat'l Football League*, 352 U.S. 445, 454 (1957) ("Congress itself has placed the private antitrust litigant in a most favorable position . . . . In the face of such a policy this Court should not add requirements to burden the private litigant beyond what is specifically set forth by Congress in those laws."); *Financial Planning Ass'n v. SEC,* 482 F.3d 481 (D.C. Cir. 2007); *Baker v. Bell Textron, Inc*., 2020 WL 5513431, at *4 (N.D. Tex. 2020) ("The Court will not add requirements to the law that Congress could have included but did not.").

It is against this backdrop that we examine the 340B phrase "purchased by." It is difficult to envision a less ambiguous phrase and no amount of linguistic gymnastics can ordain otherwise. The Court recently cautioned against seeing ambiguity where none exists. For

example, a regulation must be "genuinely ambiguous" before resorting to deference. *Kisor v. Wilkie*, ___U.S.___, 139 S.Ct. 2400, 2415 (2019). Here, as we understand it, the medications at issue are sold by the manufacturer to the covered entity; the covered entity takes title and the covered entity pays the manufacturer either directly or through the manufacturer's distributor. In either event, the arrangement between the manufacturer and covered entity is a straightforward "sale" which "consists of the passing of title from the seller [drug manufacturer] to the buyer [covered entity] for a price." Uniform Commercial Code (U.C.C.) § 2-106.[1] A "buyer" is, by definition, a "purchaser." BLACK'S LAW DICTIONARY (11th ed. 2019) (defining "buyer" as "[s]omeone who makes a purchase"). The situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant. *See* U.C.C. § 2-401(2) ("Unless otherwise explicitly agreed title passes to the buyer at the time and place at which the seller completes his performance with reference to the physical delivery of the goods . . . ").

Given the lack of ambiguity in the plain text of the statute, the above analysis is dispositive. *Bostock v. Clayton Cty.*, ___U.S.___, 140 S. Ct. 1731, 1739 (2020) ("[W]hen the meaning of the statute's terms is plain, our job is at an end."). This straightforward textual interpretation, aside from dutifully reflecting the plain meaning of the statute, has the added benefit of comporting with the statute's purpose and history.

B. The Purpose and History of the 340B Program Reflect the Provision's Plain Meaning

1. Contract Pharmacies Have Been an Integral Part of the 340B Program Since Its Outset

The 340B Program was created to allow covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rept. No. 102–384(II), at 12 (1992). As the Health Resources and Services Administration ("HRSA")—the agency primarily responsible for administering the 340B Program—has explained in prior guidance, a substantial number of covered entities are practically constrained to rely on contract pharmacies to access the 340B Program; if manufacturers can simply shut off this means of access, the Program's effectiveness will be greatly diminished. *See Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services*, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996); *see also Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*, 84 Fed. Reg. 2340 (proposed Feb. 6, 2019) (OIG proposed rule discussing distribution of pharmaceuticals).[2]

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[1] The U.C.C. can be used for statutory construction, even if it does not directly apply. *See Comm'r of Internal Revenue v. Brown*, 380 U.S. 563, 571 (1965) (interpreting provision of the Internal Revenue Code by pointing to U.C.C. as support for the "ordinary sense" of the word "sale").

[2] The argument that the statute also evinces a purpose to prevent drug diversion or duplicate discounting, and therefore prohibits contract-pharmacy arrangements, is not persuasive. That is like arguing that the main purpose of federal healthcare programs are their antifraud provisions. In the absence of the core 340B discount mechanism, there would be no need for the duplicate-discount or diversion provisions.

This is particularly pertinent given that at the outset of the 340B Program only approximately 500 out of 11,500 covered entities (less than 5 percent) used in-house pharmacies. *See* 61 Fed. Reg. at 43,550. This is not surprising: the Program is aimed at benefiting providers that are small, remote, resource-limited, receiving federal assistance, or serving disadvantaged populations. *See, e.g.*, 42 U.S.C. § 256b(a)(4) (defining covered entities); *Astra USA*, 563 U.S. at 113. These are the poster children of providers that one would expect to lack an in-house pharmacy. To champion a policy, ungrounded in the language of the statute, that would foreclose 340B discounts to 95 percent of covered entities and foreclose discounts to the neediest of this cohort is inconsistent with purpose of the Program and common sense. Had Congress intended to reach such a bizarre result, it would have used language affirmatively precluding the use of contract pharmacies as arms in the distribution channel, but it did not. *Doe v. Hesketh*, 828 F.3d 159, 167 (3d Cir. 2016) (the result is "so bizarre that Congress could not have intended it").

2. The Department's Longstanding Interpretation of Section 340B Reflects the Plain Language of the Section by Recognizing the Use of Contract Pharmacies

The Department's longstanding interpretation of the statute, as expressed through guidance, is that manufacturers are required to offer ceiling prices even where contract pharmacies are used. In 1996, HRSA issued the aforementioned guidance and stated, "[i]t has been the Department's position that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price." 61 Fed. Reg. at 43,549. HRSA's assertion cannot be attacked as impermissible legislative rulemaking,[3] because the guidance only sought to "explain the statutory language by clarifying the meaning given by the Department to particular words or phrases"—it "create[d] no new law and create[d] no new rights or duties" not otherwise present in the statute. *See id.* at 43,550. HRSA reaffirmed its interpretation of the statute in guidance issued in 2010. *See* HRSA, *Notice Regarding 340B Drug Pricing Program–Contract Pharmacy Services*, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

The Department's consistent position over the past 24-plus years would factor into a court's interpretation of the statute. Courts defer to agency expertise in the interpretation of statutes, especially where they govern complex administrative regimes. *See, e.g.*, *United States v. Mead Corp.*, 533 U.S. 218, 227–28 (2001). Conversely, a court would be skeptical of an abrupt about-face. *See, e.g.*, *Wyeth v. Levine*, 555 U.S. 555, 577–81 (2009). Courts may also look to agency implementation and the actions of regulated parties to determine the meaning of a statute. *See, e.g.*, *S.D. Warren Co. v. Me. Bd. of Env't Prot.*, 547 U.S. 370, 377–78 (2006) (even though relevant agencies had not "formally settled the definition, or even set out agency reasoning," the "administrative usage of [the disputed term] in this way confirm[ed the Court's]

[3] *See, generally*, *Pharm. Rsch. and Mfrs. of Am. v. U.S. Dep't of Health and Human Servs.*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014) ("Within section 340B, Congress specifically authorized rulemaking in three places: (1) the establishment of an administrative dispute resolution process, (2) the 'regulatory issuance' of precisely defined standards of methodology for calculation of ceiling prices, and (3) the imposition of monetary civil sanctions."); *Pharm. Rsch. and Mfrs. of Am. v. U.S. Dep't of Health and Human Servs.*, 138 F. Supp. 3d 31, 39 (D.D.C. 2015) (even if "HHS lacks the authority to promulgate the rule as a binding statement of law, HHS is not forbidden altogether from proffering its interpretation of the statute").

understanding"); *Bd. of the Trs. of Leland Stanford Jr. Univ. v. Roche Molecular Sys.*, 563 U.S. 776, 792–93 (2011) ("[I]t is worth noting that our construction of the [statute in question] is reflected in the common practice among parties operating under the Act."). Here, contract-pharmacy arrangements have been utilized, and honored by manufacturers, since 1996 and earlier.[4]

C. Manufacturers' Rationale for Precluding the Use of Contract Pharmacies Is Not Supported by the Language of the Statute and Leads to Absurd Results

The primary rationale offered for cutting off contract pharmacies—that such arrangements lead to a heightened risk of diversion and duplicate discounts—makes clear that manufacturers are attempting to circumvent section 340B's procedures for resolving disputes between manufacturers and covered entities. *See, e.g.*, *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1984) ("In ascertaining the plain meaning of the statute, the court must look to the particular statutory language at issue, as well as the language and design of the statute as a whole.") (emphasis supplied). Not surprisingly, the manufacturers have been unable to point to any language in the statute that would support this hobbling interpretation. If a manufacturer is concerned that a covered entity has engaged in duplicate discounting or diversion, *see* 42 U.S.C. § 256b(a)(5)(A), (B), it must (1) conduct an audit, and (2) submit the claim to the administrative dispute resolution ("ADR") process, *see* §256b(d)(3)(A). The PPA even provides that a covered entity's failure to comply with the audit requirement does not "relieve the Manufacturer from its obligation to conform to the pricing requirements as provided in section 340B(a) of the Act and the Agreement." PPA § IV(d). Moreover, the Department specifically rejected this reasoning when issuing regulations regarding the calculation of the 340B ceiling price. In responding to a comment regarding perceived 340B violations, HRSA stated "[m]anufacturers cannot condition sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity." *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation*, 82 Fed. Reg. 1210, 1223 (Jan. 5, 2017). In addition, "[m]anufacturers that suspect diversion are encouraged to work in good faith with the covered entity, conduct an audit per the current audit guidelines, or contact HHS directly." *Id.* Certain manufacturers' newfound and unilateral refusal to sell drugs through contract pharmacies is at odds with the structure and intended operation of the statute.[5]

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[4] The fact that Congress has not amended the 340B statute to expressly exclude contract-pharmacy arrangements from coverage can be read as supporting the agency's longstanding construction. *See* Valerie C. Brannon, Cong. Rsch. Serv., R45153, *Statutory Interpretation: Theories, Tools, and Trends* 63 (2018) (discussing "presumption of legislative acquiescence").

[5] For 24-plus years, manufacturers have offered the ceiling price to covered entities using contract-pharmacy distribution. To the extent manufacturers now have sincere concerns about diversion or duplicate discounting, the 340B statute speaks directly to how they should proceed. *See also 340B Drug Pricing Program; Administrative Dispute Resolution Regulation*, 85 Fed. Reg. 80,632, 80,633 (Dec. 14, 2020) ("The purpose of the ADR process is to resolve . . . claims by manufacturers, after a manufacturer has conducted an audit as authorized by section 340B(a)(5)(C) of the PHSA, that a covered entity has violated the prohibition on diversion or duplicate discounts."). Manufacturers who shut off contract-pharmacy access may have also skipped over any effort to resolve disputes with covered entities in "good faith." PPA § IV(a)(1) ("If the Manufacturer believes that a covered entity has violated the prohibition against resale or transfer of covered outpatient drugs, section 340B(a)(5)(B), or the prohibition against duplicate discounts or rebates, section 340B(a)(5)(A) . . . [t]he Manufacturer shall attempt in good faith to resolve the matter with the covered entity."); 85 Fed. Reg. at 80,633 ("Historically, HHS has

Relatedly, it has also been argued that the use of contract pharmacies is inconsistent with the 340B statute's prohibition on diversion of discount drugs. We start with the basic proposition that subsection (a)(5)(B) was intended to prohibit the diversion of 340B drugs. *See* 42 U.S.C. § 256b(a)(5)(B) ("With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity."). According to one court, the 340B Program places a "ban on 'diversion,' *i.e.*, a requirement that covered entities refrain from reselling or otherwise transferring covered drugs to non–340B entities[.]" *Cty. of Santa Clara v. Astra USA, Inc*., 257 F.R.D. 207, 211–12 (N.D. Cal. 2009), *vacated on other grounds*, *Astra USA,* 563 U.S. 110; *see also* 85 Fed. Reg. at 80,636 (subsection (a)(5)(B) prohibits diversion).

Diversion means that, on net, covered outpatient drugs end up in the hands of persons who are not patients of the covered entity. The movement of drugs purchased by the covered entity and ultimately dispensed to the patient by a contract pharmacy can involve complex inventory models. Whether diversion occurs, however, should be independent of the inventory-accounting model contemplated by the agreement between the contract pharmacy and the covered entity. *See Toyota Motor Sales, U.S.A., Inc. v. United States,* 35 Ct. Int'l Trade 1205 (2011) (noting that inventory-accounting methods are authorized to determine tariffs and drawbacks); *Sears, Roebuck & Co. v. King County*, 487 P.2d 221, 223, 5 Wash. App. 273, 276 (1971) (for tax purposes "identification by any reasonable and reliable [inventory-accounting] method [is proper], rather than by a strict tracing method.").

The notion that the legitimate transfer of drugs to contract pharmacies so that they can be dispensed to patients of the covered entity constitutes diversion not only ignores the realities of accounting, but also that the covered entity and contract pharmacy are not distinct, but function as principal-agent. As explained, the covered entity remains the purchaser whether it chooses to have discount drugs distributed through an in-house pharmacy or a contract pharmacy. *See also* 61 Fed. Reg. at 43,550 ("The mechanism does not in any way extend this pricing to entities which do not meet program eligibility."); *id.* (agreeing that "[a]s a general rule, a person or entity privileged to perform an act may appoint an agent to perform the act unless contrary to public policy or an agreement requiring personal performance") (citing Restatement (Second) of Agency § 17 (Am. L. Inst. 1995)); *id.* ("The contract pharmacy would act as an agent of the covered entity, in that it would not resell a prescription drug but rather distribute the drug on behalf of the covered entity. This situation is akin to a covered entity having its own pharmacy."); *id.* at 43,552 (under "bill to/ship to" arrangement contemplated in guidance, "[t]he contract pharmacy does not purchase the drug. Title to the drugs passes to the covered entity" and "the manufacturer is still selling to the covered entities"); *cf. Abramski v. United States*, 573 U.S. 169, 186 (2014) ("[t]he individual who sends a straw [purchaser] to a gun store to buy a firearm is transacting with the dealer, in every way but the most formal" such that "straw arrangements are not a part of the secondary market, separate and apart from the dealer's sale") (emphasis in original).[6]

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encouraged manufacturers and covered entities to work with each other to attempt to resolve disputes in good faith.").

[6] Similar reasoning still applies under the so-called "replenishment" model, where the contract pharmacy dispenses medications from a general inventory to the covered entity's patient and "replenishes" its general

In addition, the argument that use of contract pharmacies constitutes an illicit "transfer" leads to absurd results. For instance, if a covered entity uses a courier service to send discount drugs to its patient, this, too, would be appear to be an illegal "transfer" to the shipper. Any arrangement that did not involve a physical hand-off from the employee of a covered entity to the patient him or herself could be an unauthorized "transfer" under the 340B statute. To avoid such absurdities, and under the canon of *noscitur a sociis*,[7] the phrase "otherwise transfer" must be interpreted in conjunction with the word "resell" and the title of that specific provision ("Prohibiting resale of drugs") (emphasis supplied).[8]

This conclusion is reinforced by an understanding of the practical realities of drug distribution. Such distribution often functions through intermediaries. For example, covered entities often purchase 340B discounted drugs from wholesalers, not directly from manufacturers. And yet, the obligations of § 256b(a) are placed on manufacturers. If it were correct that distribution to any entity other than a covered entity freed the manufacturer from the obligation to charge no more than the ceiling price, then there would be no firm basis for the wholesalers to charge-back discounts to the manufacturer. Large portions of the current 340B Program would seem to turn on solely manufacturers' voluntary choice to offer the ceiling price,

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inventory with discount medications purchased by the covered entity. The inventory commingling (drugs purchased by covered entity(ies) under the auspices of 340B, commingled with what the contract pharmacy might otherwise have) does not change the analysis. *Cf. Martin Marietta Corp. v. N.J. Nat'l Bank*, 612 F.2d 745, 749 (3d Cir. 1979) ("identification" of goods for purposes of U.C.C. § 2-501 not broken even if "seller removes some of the fungibles and later replaces them . . . because such conduct is quite natural with fungibles and cannot be taken as an intent to negate the buyer's interest in the goods"); *Apex Oil Co. v. Belcher Co. of N.Y., Inc.*, 855 F.2d 997, 1,003–05 (2d Cir. 1988) ("[W]here fungible goods are concerned, identification is not always an irrevocable act and does not foreclose the possibility of substitution."); *Matter of Bevill, Bresler & Schulman Asset Mgmt. Corp.*, 67 B.R. 557, 588 (D.N.J. 1986) (under U.C.C. § 9-207, "a secured party is allowed to commingle fungible collateral, including certain types of securities, and may sell the collateral and replace it with instruments which are equivalent in kind and value without breaching his duty to exercise reasonable care in the custody and preservation of the pledged collateral"). Nor does the ordering of events. If the contract pharmacy's dispensing of the drugs is event "A" and the contract pharmacy's receipt of the drugs is event "B," the ordering of events does not matter if repeated over time. Whether the series looks like ...BABABA... or ...ABABAB... is simply a function of the reference timeframe. In sum, where the contract pharmacy is replenished by the covered entity and dispenses to the covered entity's patients on a rolling basis, it is still true that the covered entity's patients are receiving the covered entity's drugs—they are not re-sold or "otherwise transfer[red]" to the contract pharmacy.

It also bears mention that the replenishment inventory model is currently an integral part of many patient assistance programs operated by drug manufacturers. *See, e.g.*, *Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees*, 70 Fed. Reg. 70,623, 70,624 (Nov. 22, 2005); Merck & Co., Inc. *For Health Care Professionals*, MERCK HELPS, https://www.merckhelps.com/HCPs.aspx (last visited Dec. 21, 2020); Pfizer, Inc., *The Pfizer Institutional Patient Assistance Program (IPAP) At-a-Glance* (April 2019), https://www.pfizerrxpathways.com/sites/default/files/attachment/PP-PAT-USA1032%20RxPathways_IPAP_Factsheet%202019.pdf (last visited Dec. 21, 2020).

[7] "[W]e rely on the principle of *noscitur a sociis*—a word is known by the company it keeps—to avoid ascribing to one word a meaning so broad that it is inconsistent with its accompanying words, thus giving unintended breadth to the Acts of Congress." *Yates v. United States*, 574 U.S. 528, 543 (2015) (plurality op.) (quotes omitted).

[8] An exact delineation of the scope of the phrase "otherwise transfer" is beyond the scope of the Advisory Opinion. The point here is simply that the phrase must have some limiting principle to avoid sweeping in innocuous conduct that is inevitable in the functioning of the 340B Program.

not a statutory mandate. Thus, manufacturers may not refuse to offer the ceiling price to covered entities, even where the latter use distribution systems involving contract pharmacies.

II. Conclusion and Limitations

For these reasons, the Office of the General Counsel concludes that covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients.[9]

This Advisory Opinion may be supplemented or modified by the Office of the General Counsel. It is intended to minimize the need for individual advisory opinions. This Advisory Opinion sets forth the current views of the Office of the General Counsel.[10] It is not a final agency action or a final order, and it does not have the force or effect of law.

Robert Charrow

Robert P. Charrow
General Counsel
December 30, 2020

[9] This Advisory Opinion is limited to interpretation of the 340B statutory requirements in general and does not opine on the legality of any specific contract-pharmacy model, under either the 340B statute or other laws that may apply (such as the anti-kickback statute, 42 U.S.C. § 1320a-7b).

[10] *See Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 647–48 (6th Cir. 2004) (holding that the Chief Counsel of the National Highway Traffic Safety Administration had delegated authority to issue advisory opinions to regulated entities in fulfillment of a congressional directive to promote regulatory compliance); 5 U.S.C. § 301 ("The head of an executive department . . . may prescribe regulations for the government of his department, the conduct of its employees, [and] the distribution and performance of its business[.]"); *Statement of Organization, Functions, and Delegations of Authority*, 85 Fed. Reg. 54,581, 54,583 (Sept. 2, 2020).

July 24, 2020

BY FEDERAL EXPRESS & EMAIL

Rear Admiral Krista Pedley, PharmD, MS
Office of Pharmacy Affairs
Health Resources and Services Administration
Office of Pharmacy Affairs
5600 Fishers Lane, 08W10
Rockville, MD 20857

Re: AstraZeneca: 340B Contract Pharmacies

Dear Rear Admiral Pedley:

I am writing on behalf of AstraZeneca Pharmaceuticals, LP ("AstraZeneca" or the "Company") to address upcoming changes to the Company's approach to "contract pharmacy" arrangements in the 340B Program. AstraZeneca to date has honored chargebacks associated with contract pharmacy arrangements consistent with the Health Resources and Services Administration's ("HRSA") 2010 guidance. Beginning on October 1, 2020, AstraZeneca plans to adjust this approach for the products listed in the Attachment to this letter and any future products, such that AstraZeneca will recognize one contract pharmacy per covered entity for those covered entities that do not maintain an on-site dispensing pharmacy.

AstraZeneca is deeply committed to the 340B Program and to ensuring that any patient prescribed an AstraZeneca product has access to that medicine. Our new approach to recognizing contract pharmacies will be fully consistent with HRSA's original 1996 guidance regarding the use of contract pharmacies and will continue to ensure that eligible covered entities are offered the 340B ceiling pricing consistent with the 340B statute. At the same time, we hope this new approach will help to mitigate the significant compliance issues that exist -- and that AstraZeneca has experienced -- with covered entity contract pharmacy arrangements. We explain the basis for our revised approach below and we would be pleased to discuss with HRSA at the agency's convenience.

Contract Pharmacy Background and HRSA Guidance

The 340B statute requires manufacturers that have signed a Pharmaceutical Pricing Agreement to make the statutory ceiling pricing available for covered outpatient drugs that are

"***purchased by*** a covered entity[.]"[1] The statute thus focuses exclusively on purchases by covered entities. It does not mention "contract pharmacies." The 340B statute requires manufacturers to provide discounted drug purchases for dispensing to eligible outpatients ***at a provider site*** -- not through contracted pharmacies.

HRSA first published guidelines regarding contract pharmacy arrangements in 1996. Shortly after the inception of the 340B Program, HRSA recognized that some covered entities lacked on-site pharmacies and therefore had no vehicle for dispensing outpatient drugs to their patients. To remedy this concern, HRSA allowed those covered entities who lacked their own in-house pharmacy to retain a contract pharmacy "to facilitate program participation for those eligible covered entities that do not have access to appropriate 'in house' pharmacy services."[2] HRSA limited covered entities to ***one contract pharmacy***: "The limitation of one pharmacy contractor per entity does not preclude the selection of a pharmacy contractor with multiple sites, ***as long as only one site is used for the contracted services***."[3]

But, in 2010, HRSA replaced its 1996 guidelines with new guidance that enabled covered entities to use multiple contract pharmacies per covered entity site without regard to geographic considerations or whether the covered entity itself maintained an in-house pharmacy.[4] This guidance has spurred dramatic growth in the use of contract pharmacies and has caused many implementation challenges. While many covered entities, including hospitals, maintain their own dispensing capabilities, they also have entered myriad contract pharmacy arrangements. In fact, a recent independent analysis identified over 25,000 contract pharmacy locations.[5] This number contrasts starkly with the fewer than 3,000 contract pharmacies that existed in 2010.[6] AstraZeneca also has determined that, as of the first quarter of 2018, 415 covered entities within California alone maintained 1,245 contract pharmacy arrangements, several of those contract pharmacies are located in states not contiguous with California. AstraZeneca does not believe that this overly-expansive use of contract pharmacies supports the mission and the central goals of the 340B Program.

When HRSA issued the 2010 contract pharmacy guidelines, it asserted that the Program had "appropriate safeguards in place" to combat covered entity statutory violations that could arise in connection with contract pharmacy arrangements.[7] But, since that time, the 340B Program has

[1] 42 U.S.C. § 256b(a)(1) (emphasis added).
[2] 61 Fed. Reg. 43549, 43555 (Aug. 23, 1996).
[3] 61 Fed. Reg. at 43555.
[4] *See* Final Notice Regarding 340B Drug Pricing Program - Contract Pharmacy Services, 75 Fed. Reg. 10272 (Mar. 5, 2010).
[5] *See* https://www.drugchannels.net/2019/07/walgreens-cvs-and-walmart-lead-25000.html.
[6] *See* https://www.drugchannels.net/2017/07/the-booming-340b-contract-pharmacy.html.
[7] 75 Fed. Reg. at 10274.

seen significant increases in covered entity violations of the statutory prohibitions against product diversion and duplicate discounting.

HRSA's audits of covered entities have identified considerable concerns with contract pharmacies. For example, based on information on the HRSA website, over 25% of covered entities audited since 2017 have had at least one finding related to contract pharmacy noncompliance. AstraZeneca itself has received numerous covered entity refund disclosures associated with contract pharmacy violations. Additionally, HRSA itself has raised concerns that contract pharmacy arrangements are correlated with product diversion. HRSA has reported, for example, that it is "aware of a resolution practice" utilized by contract pharmacies for instances of product diversion.[8] Where product dispensed at 340B pricing later is identified not to meet program criteria, contract pharmacies may issue "repayment to the manufacturer(s) for transactions the contract pharmacy/TPA no longer considers 340B-eligible." HRSA observed that covered entities may have no "prior knowledge or engagement" as to this practice. In HRSA's view, these arrangements do not comply with 340B Program rules and each "covered entity [must] retain responsibility for ensuring full compliance and integrity of its use of the 340B Program."

AstraZeneca's Contract Pharmacy Approach Beginning October 1, 2020

AstraZeneca fully supports the mission of the 340B Program to provide a healthcare safety net for the most vulnerable patients in our country. But the Company does not believe that today's contract pharmacy framework is necessary to further that mission. We also are cognizant of the statutory "must offer" provision, and we are committed to ensuring that our products remain available to patients of covered entities consistent with that provision. Accordingly, and balancing these considerations, AstraZeneca will change its approach to working with contract pharmacies going forward. For those products listed in the Attachment to this letter, beginning October 1, 2020, AstraZeneca will recognize one contract pharmacy arrangement per covered entity site in the event that the covered entity does not maintain its own, on-site pharmacy. This change is fully consistent with the guidelines that HRSA put in place in 1996 and that remained through 2010. This approach also complies with operative 340B statutory provisions because AstraZeneca will make its products available to all covered entities at or below the applicable ceiling price.

AstraZeneca plans to communicate this change in operations to its supply chain partners and customers by August 10, 2020. AstraZeneca also will ensure that Company personnel are well versed in this change in operations so that they will be able to field inquiries from any customers.

[8] *See* "Best Practices for Covered Entities: Resolving Contract Pharmacy Related Non-Compliance" *available at* https://www.hrsa.gov/opa/updates/2018/june.html.

AstraZeneca

* * *

AstraZeneca thanks HRSA for its attention to this important matter, and the Company looks forward to its continued participation in the 340B Program. As noted above, AstraZeneca will plan to communicate this change in approach to wholesalers and other stakeholders by August 10, 2020 and to implement this change effective October 1, 2020. We would be happy to discuss this change with the agency in more detail if helpful. Please note that the information contained in this letter is confidential and not subject to disclosure under Exemption 4 to the Freedom of Information Act, 5 U.S.C. § 552(b)(4), the Trade Secrets Act, 18 U.S.C. § 1905, and the Medicaid Drug Rebate Act, 42 U.S.C. §1396r-8(b)(3)(D).

Sincerely,

Christie Bloomquist

Vice President Corporate Affairs, North America

participate in and receive reimbursements pursuant to Medicare Part B and Medicaid—Lilly responded to HRSA the next day (August 27, 2020). *See* Exh. I. In its August 27 letter, Lilly reiterated its position that its distribution program was entirely lawful under the plain text and original understanding of the 340B Statute. *See id.* at 1. Lilly also highlighted the imminent harm resulting from HRSA's "threats of sanctions," which were transparently designed to force Lilly to acquiesce to HRSA's position. *Id.* Lilly accordingly requested that HRSA "confirm by August 31st that nothing in the 340B Statute prohibits the Cialis Limited Distribution Plan or an expansion of that plan," and that if HRSA believed there was a "violation of the statute, [to] please identify with specificity the agency's grounds for that position." *Id.*

103. HRSA neither responded nor posted Lilly's updated notice on its website. Instead, on September 2, 2020, it released a new public statement to the *340B Report* reiterating its threat. HRSA stated to the *340B Report* that it was "considering whether manufacturer policies, ***including Lilly's***, violate the 340B statute and whether sanctions may apply." Bronwyn Mixter, *HRSA is Investigating Whether Manufacturer Policies to Restrict 340B Pricing at Contract Pharmacies Violates Statute*, 340B Report (Sept. 2, 2020) (emphasis added), https://bit.ly/3aWgZPT.

104. In light of these threats, Lilly reached out to HHS on September 8, 2020, seeking "confirmation that HHS is not considering, and will not consider, sanctions against Lilly in response to Lilly's stated plan to discontinue providing 340B discounts to contract pharmacies." Exh. J at 1; *see also id.* at 1-5.

105. HHS responded nearly two weeks later on September 21, 2020. *See* Exh. K. HHS did not state that Lilly's distribution plan was unlawful. *See id.* Nor did it identify a single statutory provision that the plan violates. *See id.* Nevertheless, HHS declined to state that neither HRSA nor HHS was considering sanctions against Lilly. *See id.* And rather than defusing HRSA's

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS	)	
PLAINTIFF,	)	
	)	Civil Action No. 1:20-cv-03032
V.	)	
ALEX M. AZAR II, ET. AL	)	

Declaration of J.R. Richards

I, J.R. Richards, declare as follows:

1. I am the CEO at Neighborhood Improvement Project, Inc., d/b/a Medical Associates Plus ("MAP") and have held this role since in or around January 2015. As CEO, I am responsible for overall operations and implementation of the policies of the Board of Directors. I supervise a senior leadership team consisting of the Chief Operations Officer, the Chief Financial and Business Development Officer, the Chief Medical Officer, the Chief Information Officer, the Chief Compliance Officer, and the Satellite Operations Administrator. I am also responsible for oversight of all departments within the organization, including the Pharmacy Department, whose members have regular access as part of their job duties to all information related to pharmacy operations. To prepare this declaration, I consulted with all members of the senior management team, as well as our Director of Pharmacy Operations, and reviewed relevant data and information.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. MAP is a Federally Qualified Health Center (FQHC) that receives federal grant funds under Section 330 of the Public Health Service Act to provide health care and related services to a medically underserved population in Augusta, Georgia and surrounding areas, including in Richmond, Burke, and Jefferson counties. MAP has served this patient population regardless of patient insurance status or ability to pay since in or around 1997.

4. MAP estimates it will serve over 25,000 patients in 2020, over 5,000 of whom are uninsured and below 200% of the federal poverty level. MAP currently provides primary care, woman's health, dental, pediatrics, behavioral health, diabetes management, pharmacy, endocrinology, pulmonary, dermatology, infusion therapy, and infectious disease services for our patients and community.

5. In 2019 alone, MAP provided over $8,000,000 in uncompensated care to patients who could not, either through insurance or independently, cover some or all the costs for their care.

6. MAP is a "covered entity" for purposes of the 340B Drug Pricing Program ("340B Program") and first received Health Resources and Services Administration (HRSA) approval to participate in the 340B Program in or around 2008. MAP recertifies its status annually with HRSA to maintain that approval.

7. The 340B Program allows MAP to purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount. MAP purchases these discounted medications for dispensing at its in-house pharmacies, clinics, and contract pharmacies from several wholesalers, including Cardinal, McKesson, Henry Schein, and other independent companies. MAP currently spends an estimated $410,000 per month—close to $5 million per year—in 340B drugs for its patients.

8. MAP uses a combination of in-house pharmacy and contract pharmacy arrangements to provide all-inclusive access to its patients for their prescription needs. Due to several patient-related factors, MAP is only able to serve about 40% of its patients through in-house pharmacies. Most of MAP's patients thus rely on our contract pharmacy network to fulfill their prescription needs. All contract pharmacy arrangements are memorialized in written agreements between MAP and the pharmacy. Dispensing is available through contract pharmacies only after an agreement is finalized and approved by HRSA's Office of Pharmacy Affairs (OPA).

9. Our contract pharmacy network expands our ability to offer 340B savings and reach more of our vulnerable patients to fulfill their pharmacy needs. Because of 340B, MAP is able to provide its qualified patients medications such as insulin and epinephrine for as little as $4 to $7 a dose, or even at no cost at all.

10. Six of our eleven sites do not have an in-house pharmacy and MAP's patients who rely on these sites for care strictly rely on contract pharmacies to meet their prescription needs at affordable prices. Additionally, because our in-house pharmacies are only open during clinic hours—weekdays from 8AM to 5PM—our contract pharmacy network allows our patients to access 340B discounted drugs outside of these hours. A lack of available time during the traditional workday is a significant barrier for our patient population.

11. An optimized network of contract pharmacies also allows MAP to generate additional revenue by increasing its "capture rate," which in turn enables MAP to retain more 340B savings and therefore support more services for its patients. As required, we reinvest all 340B savings and revenue in services that expand access for its medically underserved patient population.

12. Our participation in the 340B Program further allows us to provide services to vulnerable populations such as the homeless, migrant workers, people living in public housing, and low-income individuals and families.

13. MAP does not—and legally cannot—refuse to see an individual based on his or her inability to pay for services. We offer all our services on a sliding fee scale for those that are 200% below the poverty level, and many patients receive services for free. This means that a patient can see a provider for a primary care medical visit valued at $175 including lab work, for as little as $25, or for free depending on their family's income and size.

14. MAP also uses 340B Program savings and revenue to provide patient services that could not be offered without these funds. These services include behavioral health, dental, mobile van services, a patient assistance program, and free prescription delivery services, which annually entail an estimated 6,000 free prescription deliveries to our underserved community to overcome major transportation barriers to care.

15. Across all pharmacies, MAP currently fills an average of approximately 7,500 prescriptions per month, and approximately 90,000 prescriptions per year.

16. All our contract pharmacies operate on a virtual inventory model, which means pharmacies dispense medications from their retail stock, identify qualified 340B claims, and replenish their stock with 340B medications. The claim matching process is handled by Third-party Administrators (TPAs) and goes through several filters before a claim is deemed eligible for 340B pricing. MAP pays a fee to the contract pharmacies (for providing dispensing services) and TPAs (for qualifying claims and ordering medications).

17. As required by HRSA, MAP does not and will never enter into an agreement with contract pharmacies where it does not retain the majority of the savings from the 340B discount. MAP views compliance of contract pharmacies very seriously and has hired a pharmacist who is a 340B Apexus Certified Expert (340BACE) to audit and reconcile inventories on all contract pharmacy claims. In or around July 2020, MAP underwent a 340B HRSA Audit where there were no findings.

18. Beginning on or about July 22, 2020, I became aware that certain drug manufacturers including Eli Lilly, Sanofi, and AstraZeneca had unilaterally decided to cease providing outpatient prescription drugs at 340B prices to MAP's contract pharmacies.

19. Because of this action, many of MAP's patients can no longer fill their prescriptions for life-saving and life-sustaining medications through MAP's contract pharmacy network.

20. MAP currently has no access to Eli Lilly or Sanofi medications at 340B pricing to be dispensed through its contract pharmacies.

21. MAP likewise has no access to AstraZeneca drugs at 340B pricing at most of its contract pharmacies. After its initial announcement, AstraZeneca indicated it would ship drugs purchased at 340B prices to certain contract pharmacies. On or about October 14, 2020, MAP requested that AstraZeneca approve six of its contract pharmacies for this exception. MAP received notice on or about November 30, 2020, that AstraZeneca would continue to ship drugs at 340B pricing to three of the six requested pharmacies. MAP is currently working with its TPA to implement 340B purchases and dispensing for these pharmacies.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS PLAINTIFF, V. ALEX M. AZAR II, ET. AL	)	Civil Action No. 1:20-cv-03032

Declaration of Donald A. Simila

I, Donald A. Simila, declare as follows:

1. I am Chief Executive Officer at Upper Great Lakes Family Health Center, Inc. ("Upper Great Lakes"), and I have held this role since on or about October 1, 2009. As Chief Executive Officer, I am responsible for oversight of all services, including pharmacy services. To fulfill my job duties, I have access to all pharmacy-related transactions generated by prescriptions written by our physicians. Additionally, Upper Great Lakes has a dedicated analyst and 340B/pharmacy committee that reviews program activity, and educates me, as well as the board, staff, and patients, on the program. To prepare this declaration, I reviewed wholesaler invoices, pharmacy contracts, and pharmacy invoices.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. Upper Great Lakes is a Federally-Qualified Health Center ("FQHC") that receives federal grant funds under Section 330 of the Public Health Service Act to provide primary health care and related services across a 10,000 square mile service area at 11 distinct and dispersed clinic sites, 20 congregate care facilities, and various school-based clinics.

4. Upper Great Lakes has been in business as an FQHC since approximately May 2010, and is a member of the National Association of Community Health Centers.

5. On an annual basis, Upper Great Lakes provides approximately 25,000 unique patients with 80,000 clinical visits for comprehensive primary care, OB/GYN, Behavioral Health including Medication Assisted Treatment for Opioid Use Disorder, and preventative and restorative dental services. As a rural community, Upper Great Lakes' target population is significantly underserved, aging, and impoverished. Sixty percent of Upper Great Lakes patients are either on Michigan Medicaid or on Medicare. Seventy percent of our patients

are at or below 200% of the federal poverty level ("FPL"), and 25% are at or below 100% of the FPL.

6. Upper Great Lakes is a "covered entity" for purposes of the 340B Drug Program ("340B Program). As a covered entity, Upper Great Lakes can purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount.

7. Upper Great Lakes has been a covered entity since in or around 2010 and, as required, annually recertifies its locations as 340B eligible sites with the Health Resources and Services Administration ("HRSA").

8. As a covered entity, Upper Great Lakes is permitted to choose how it will deliver pharmacy services to its patients. Upper Great Lakes—across its 10,000-mile service area—maintains contractual arrangements with local retail pharmacies to support its patients by ensuring local access to reduced price medications for those who meet federal poverty guidelines.

9. Upper Great Lakes requests HRSA approval for each of its contracted pharmacy partners. Once approved, Upper Great Lakes enters into a contractual relationship with the individual pharmacy's wholesaler under which Upper Great Lakes purchases 340B-priced drugs from the wholesaler and directs those drugs to be shipped to the contract pharmacy. The health center maintains title to the 340B drugs, but the contract pharmacies store the drugs and provide dispensing services to eligible Upper Great Lakes patients.

10. When an Upper Great Lakes provider writes a prescription, it is electronically transmitted to a local pharmacy where the prescription is filled by the retail pharmacist; a third-party application identifies patients who qualify to purchase medications at 340B pricing, as well as claims that are submitted to insurance plans.

11. The "virtual inventory" owned by Upper Great Lakes is tracked by an Upper Great Lakes 340B analyst through real-time data reporting from third-party administrator software. Reconciliations occur each month.

12. Upper Great Lakes carves in a select few pharmacies that bill a single managed Medicaid plan for most claims; as required, Medicaid is not billed for outpatient medications. The retail pharmacy directly submits claims to Medicaid for medications purchased at retail pricing from non-340B inventory.

13. Upper Great Lakes passes its 340B savings directly to eligible patients who meet federal poverty guidelines.

14. Savings generated through claims made to commercial insurance and other third-party payers ensure that Upper Great Lakes can continue to provide essential health care services to its underserved rural community.

15. With its 340B savings, Upper Great Lakes is able to provide its vulnerable patient population access to a board-certified addiction medicine physician for treatment of Opioid

Use Disorder—the only Addiction Medicine Specialist in the entire Upper Peninsula of Michigan, which encompasses 15 counties and approximately 17,000 square miles—and is able to support the training of an additional 4 physicians to meet DEA licensing requirements for Medication Assisted Treatment. The approximate annual cost to support the addiction services above and beyond reimbursement is $200,000.

16. Additionally, as the only dental provider that accepts Medicaid in large volumes in the service area, Upper Great Lakes is able, due in part to 340B savings, to maintain a dental service at two locations with combined annual operating losses of approximately $450,000.

17. 340B savings also support OB/GYN services in a 4-county area with a population of approximately 45,000. The approximate annual operating loss of this service for the community exceeds $225,000 annually. Without this service, women in our service area and target population would be required to travel more than 100 miles one-way for access to OB/GYN care.

18. Clinic locations in rural counties such as Ontonagon, Iron, and Menominee all carry annual operating losses as the cost of employing physicians and operating a clinic exceed reimbursement from Medicaid, Medicare, and private insurance. In total, clinic services for these counties add up to an annual operating loss of more than $600,000.

19. Federal grant money falls far short of covering the operating losses outlined in the preceding paragraphs. 340B savings help to fill these gaps.

20. Finally, as an organization, Upper Great Lakes has completed over 10,000 COVID-19 tests in local communities through mobile services and walk-up or drive-up testing. Funds from 340B savings have supported the costs associated with standing up testing teams, purchasing test kits, and underwriting coordination of this service. Our health center has been the only source of community testing in most communities we serve. In addition, Upper Great Lakes has been instrumental at two local Universities commencing face-to-face instruction; at those institutions, we conduct random COVID-19 surveillance testing for students and employees daily, providing approximately 600 tests per week. This service enabled the Universities to bring 6,700 students back to campus. Without the safe integration of students into these communities, the economic impact to the greater community would be dire.

21. Upper Great Lakes follows HRSA requirements and the 340B statute to ensure all contract pharmacies are engaged in a binding contractual agreement with the Health Center. Each pharmacy has executed a contract with Upper Great Lakes prior to registering and obtaining approval for including the pharmacy in Upper Great Lakes' approved network.

22. Upper Great Lakes designed its contract pharmacy network to ensure that all patients across the 10,000-mile, 11-county rural service area have access to discount medications. In addition to being located in the communities we serve, most contract pharmacies have expansive hours of operation that many of our patients need.

23. Our annual operating margin is approximately 1-2% on a budget of $22 million. The average salary for a primary care physician in this region is approximately $240,000 plus benefits of about $50,000. Without 340B savings, all our primary care practices lose money. On an annual basis, across all 11 locations, Upper Great Lakes' drug sales through the 340B Program at all contract pharmacies amounts to approximately $6 million dollars. After administrative fees, ingredients costs, and dispensing fees, the health center nets approximately $250,000 to $300,000 per month (or approximately $3 million to $3.6 million annually).

24. Beginning on or about September 1, 2020, I became aware that certain drug manufacturers, including Eli Lilly, Sanofi, and AstraZeneca would cease providing outpatient prescription drugs at 340B prices to Upper Great Lakes' contract pharmacies.

25. Because of these actions by the drug manufacturers, health center patients, staff, and the community Upper Great Lakes serves will be significantly and irreparably harmed both clinically and economically.

26. Although Eli Lilly at least appeared to offer us the option of selecting one single contract pharmacy through which 340B-priced medications could be dispensed to eligible patients, a single pharmacy for all our patients would severely limit our patients' access to life saving medications.

27. The travel distance between our northern most and southern most clinical delivery sites is 200 miles. The Upper Peninsula of Michigan is a roughly 17,000 square mile region that is sparsely populated with approximately 300,000 individuals. Only one 90-mile stretch of interstate highway exists in the region, running north and south on the Peninsula's extreme eastern edge. Most of the population is served by two-lane state and county highways. As a region, the Peninsula will receive annual snowfalls in excess of 200 inches. Some areas receive more than 300 inches annually. Given the geographic and weather realities here, travel is hampered nine months of any given year.

28. The drug manufacturers' decisions were seemingly made without regard for the narrow margins on which safety net providers like Upper Great Lakes operate, or for the immediate and unplanned-for financial losses that result from these actions. Since September 1, 2020, and on a monthly basis, Upper Great Lakes has lost and will lose anticipated revenues in excess of approximately $50,000 from Eli Lilly's actions alone. Annualized, this amounts to approximately $600,000 from Eli Lilly alone.

29. As a result of this loss, we are currently planning major reductions in services, which will include closure of access points/service delivery sites, termination of employees, reductions in health center providers, and likely closure of OB/GYN (for which we have already reduced staffing), dental, and mental health services.

30. The ultimate result of the manufacturers' actions will be a significant reduction in access to comprehensive care for an elderly, impoverished, and underserved rural community with chronic health conditions that require ongoing care.

31. Additionally, as a major employer in the region with a monthly payroll in excess of approximately $1.2 million, a likely necessary staff reduction of about 50% will have a direct economic impact on our communities of approximately $7.2 million annually.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on 12/03/2020 By_____

Donald A. Simila
Chief Executive Officer, Upper
Great Lakes Health Center, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS	)	
PLAINTIFF,	)	
V.	)	Civil Action No. 1:20-cv-03032
ALEX M. AZAR II, ET. AL	)	

Declaration of Heather Rickertsen

I, Heather Rickertsen, PharmD, declare as follows:

1. I am Director of Clinical Pharmacy Services at Crescent Community Health Center (Crescent) in Dubuque, Iowa. I began working with Crescent in or around the spring of 2006, just prior to the clinic's official opening. I have served as Crescent's Director of Clinical Pharmacy Services since in or around August 2016. As director I have developed our pharmacy services to better serve our patients' health through improved medication access and compliance.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. Crescent is a Federally-qualified health center (FQHC) that receives federal grant funds under Section 330 of the Public Health Service Act. Crescent opened in or around the fall of 2006. Our health center serves approximately 6,500 patients annually; a third of the patients identify as racial or ethnic minority, 92% are 200% below poverty level, and 50% are uninsured. Compared to other health centers, we have slightly higher rate of hypertension at 29% of patients and diabetes at 17%, whereas within Iowa the average rates for hypertension is 26% and diabetes is 15%.

4. The cornerstone of Crescent's pharmacy services is patient access to necessary medications. In addition to providing our patients discounted medications, we cover the entire cost of medications for patients who cannot afford even discounted drugs. We also cover the cost of medication compliance packaging to assist those individuals with complex medication regimens.

5. Further refining pharmacy services, we provide pharmacists embedded within Crescent's medical and behavioral health clinic. These pharmacists provide a variety of services from medication reviews, anticoagulation, diabetes, and hypertension management, as well as support to providers for prior authorizations and pharmaceutical education.

6. Crescent is a "covered entity" for purposes of the 340B Drug Pricing Program (the "340B Program"). We have been eligible for 340B since in or around January 2008 and added a second contract pharmacy in or around January 2020. We maintain a physical inventory at each pharmacy and review reports, inventory, and eligibility on a monthly basis.

7. The 340B Program allows Crescent to purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount.

8. As a covered entity, Crescent is permitted to choose how it will deliver pharmacy services to its patients. We use Cardinal Health as our wholesaler. Reorder points are set at the pharmacy, once prescriptions are dispensed and the inventory falls below order point, the pharmacy will generate replenishment to maintain physical inventory to allow a three-month supply of medication to be dispensed.

9. We contract with two pharmacies, both within walking distance of Crescent. The first contract is with Mercy Family Pharmacy (Mercy One Elm) at 1920 Elm Street. This was approved by the Office of Pharmacy Affairs (OPA) on January 1, 2008. The second contract pharmacy is Infocus Pharmacy Services, at 1690 Elm Street Suite 200. This was approved by the OPA on January 1, 2020. Our pharmacy model is 'physical on hand inventory' where prescriptions are dispensed to the patient at 340B acquisition cost of the drug plus a $9.50 dispensing fee. When patients are unable to afford the cost of drugs, Crescent covers the total cost for them.

10. Crescent retains all savings from each contract pharmacy model and does not utilize a third-party administrator ("TPA"). Crescent reimburses each pharmacy approximately $20 per prescription for dispensing fee, which we believe is in alignment with national and regional averages.

11. Both contract pharmacies offer a variety of services for patients including same day or next day delivery services within the city and free mail out services for our rural patients. Both pharmacies provide medication compliance packaging. Mercy One Elm offers additional transitions of care services for patients being discharged from their health systems and Infocus provides transitions of care services through their connection with Midwest Medical Center in Galena, Illinois. Both pharmacies offer flexibility to meet patients' needs, providing additional care coordination and leveraging referral-based prescriptions; the leveraging of additional funds allows medications to be affordable and guidance on regimens to meet patients' needs.

12. Both of our pharmacies maintain a physical inventory, reorder points are routinely set to allow for a three-month supply of a prescription to be dispensed, however as a result of the COVID-19 pandemic, and ongoing threats to the 340B Program, we have increased inventory to a 6 to 12 month supply. The pharmacies report when inventory falls below that threshold, and orders are directly uploaded to inventory. Additionally, for those items that are above acquisition cost of $100, the pharmacy has an inventory on demand and can order the medication for next day, rather than having physical inventory. Each contract pharmacy then provides a monthly report to the health center on prescription medications dispensed,

and a variety of detail on transaction and community benefit services offered, as well as specific therapeutic class and demographic information. These reports are reviewed and collated monthly for compliance to 340B policy, patient eligibility, and referral data. Additionally, report out on financial and volume data is reviewed and compiled for monthly reports to quality improvement, financial and board.

13. Annual prescription purchases in the 2020 fiscal year include over 2,300 unique National Drug Codes (NDCs) and current 340B purchase prices of approximately $350,000, 50% of which is directly tied to treatment of diabetes, hypertension, and mental health.

14. In the past 5 years, we have seen our annual prescription volume grow from about 10,000 to about 20,000, with approximately half of prescriptions for uninsured patients. Of the medications dispensed, the largest percentage of therapeutic classes include 17% to treat diabetes, 15% for hypertension, and 14% for mental health, these three categories represent nearly 50% of overall prescriptions dispensed.

15. Approximately 20% of our patients access prescriptions through the community health center. If out-of-pocket expense becomes a barrier for a patient, Crescent pays for the entire cost of the medication.

16. Our 340B Program participation also helps us to provide pharmacy services at no cost to patients, including medication management, anticoagulation management, diabetes education and management, and hypertension management.

17. Crescent's participation in the 340B Program helps it to stretch scarce resources and meet the needs of its medically underserved patients, including uninsured and underinsured patients. Federal law and regulations, as well as Crescent's mission, require that every penny of 340B savings be invested in services that expand access for its medically underserved patient population.

18. In addition to various prescription medications—including insulin—Crescent also currently provides the following at no cost to any patient who is unable to afford a copay: blood pressure cuffs, diabetic testing supplies, and wound care supplies. This service is available to all patients who report being unable to afford medication, all patients on medication compliance services, and all Pacific Islander patients. We are able to do this for our most vulnerable patients because of the savings and revenue we generate through the 340B Program.

19. Furthermore, with 340B savings, we cover the cost of medication compliance packaging for patients with complex medication regimens that can make compliance a challenge.

20. 340B savings and revenue support our non-revenue generating Pacific Islander programs, which serve the unique needs of pocket populations of individuals from Marshall Islands and Federated State of Micronesia located in Dubuque and surrounding counties. These individual's may legally live and work in the area but may not rely on Medicaid or Medicare. Many of these patients are uninsured, food insecure, and in poor health.

Additionally, many were exposed to radiation during routine nuclear testing on these islands and suffer direct and ancillary health consequences. These unique patients are frequently found to have poorly controlled diabetes, higher rates of cancer, and heart disease.

21. The COVID-19 pandemic has exacerbated the situation for these patients, many of whom work in meat packing plants and reside in overcrowded living arrangements, both of which are ideal environments for rapid virus spread. To help meet the needs of this population, Crescent has implemented our Pacific Islander Health Project, which provides dedicated community health workers, as well as language interpreters and translators, social workers, and nursing staff. Participation in this program provides monthly group classes, free access to all medication, and frequent outreach.

22. Crescent's other non-revenue generating activities aimed at its general population include social services, community health workers, offsets to wellness center costs, and care coordination.

23. In early April 2020, we became aware of Bausch Health reducing distribution to one limited wholesaler in "direct distribution model" for 340B medication via a phone call by the new wholesaler appointed by Bausch Health. We did not receive direct notice of this change. This contact came on the heels of the COVID-19 outbreak, particularly devastating to a subset of Pacific Islander population, as well as having little prescription volume for our program. As seen as a limited threat, I choose not to register with a new wholesaler due to timing, limited use, and uncertainty surrounding COVID-19.

24. Additionally, on June 29, 2020, Merck notified us that it would only continue shipment of drugs we purchase to contract pharmacies, if we registered with 340B ESP to report data on prescriptions. We did initially register and attempted to submit data for July, but we were hampered by technical issues; we were able to upload and report data for August and September, but changes in terms and conditions on part of 340B ESP effective October 1, 2020 have made it impossible for us to upload data.

25. On or about August 17, 2020, we received notices from drug manufacturers Sanofi and Novartis, also requiring us to report data via 340B ESP.

26. Additionally, Astra Zeneca has informed health centers that they will only ship drugs to in-house pharmacies or, if a health center lacks that capacity, to a single contract pharmacy. Limiting shipment to a single contract pharmacy choice would severely limit patients' access as well as create inconsistent pharmacy services for patients.

27. Finally, on or about September 2, Eli Lilly indicated to the media that while it had ceased shipping covered entity-purchased drugs to contract pharmacies, it might be willing to ship insulin products to a single contract pharmacy per health center if the health center and pharmacy agreed to (1) dispense insulin at 340B purchase price and (2) to not leverage reimbursement from patients' private insurers.

28. Because of the actions by Bausch Health, Merck, Eli Lilly, AstraZeneca and Novartis, we face the possibility of losing 340B savings and revenue. Without these funds, we would no longer be able to cover patient copays, Pacific Islander programing, or our wellness center. We will also need to consider limiting patient access to dentures due to our loss of savings and the increasing cost of goods sold.

29. Beginning in or around July 2020, as changes began to develop with the 340B Program, we not only looked closely at revenue and expense specifically supporting the 340B Program, but also prepared a drug utilization review of distribution of medications based on manufactures and therapeutic classes.

30. We have determined that based on the manufacturers' actions, many patients will lose access to medications to treat diabetes, hypertension, asthma/COPD, and heart disease. Approximately thirty-two uninsured patients will no longer be able to afford their Asthma/COPD medications including rescue inhaler albuterol, 76 diabetic patients will lose access to critical oral medications to treat diabetes, an additional 51 patients will lose access to their insulin, an additional 40 patients will no longer have access to the medication to treat both acute and chronic health conditions. We would anticipate in response that patients will start to ration medications, and we will see an accompanying chronic decline in diabetes control over a period of 3 to 6 months; specifically for diabetic patients this will cause an uninsured hospital expense due to untreated diabetes including diabetic ketoacidosis, infections, heart disease, and renal disease.

31. For many patients on maintenance medication regimens, there are alternative drugs on the market; however, the appropriateness of a medication change is complicated by differing medication potencies, renal dosing, insurance formularies, and challenges in medication adherence posed by a new routine.

32. I have approximately nine patients who currently take Humulin U-500 from Eli Lilly, this medication has no alternative and patients who require this medication take insulin dosing well outside of dosing ranges in typical insulin products on market. Due to these patients' high insulin dosing requirements, we would expect a more rapid decline in diabetes control and rapid increase in negative patient outcomes.

33. The cost of medication for our patients is expected to rise from an average of approximately $180 annually, to approximately $5,000 for patients with large chronic disease burden.

34. Starting our new budget year in November 2020, our health center anticipates an annual reduction of $1,000,000 in lost revenue, and $500,000 in increased costs of goods sold. However, some cost projections are upwards of $2,000,000 cost increase of goods sold just in the top 100 drugs dispensed.

35. We are also now having to consider costs associated with opening an in-house pharmacy, which are estimated to be an additional $250,000 annually.

36. As we shift expenses, we would no longer be able to cover patient copays. We will also need to decrease our clinical pharmacy programs, enabling services, care coordination, and Pacific Islander health project.

37. We have increased inventory levels to attempt to weather the storm, increasing monthly cost of goods sold from $30,000 to approximately $50,000. Unfortunately, our inventory will only last 3 to 6 months, and if this destruction of 340B structure continues, in a year we would no longer be able to provide access to medications or clinical pharmacy services.

38. Our number one goal in navigating these unfortunate circumstances will be to continue to provide our patients access to life-saving and life-sustaining medications. If needed will move to patient assistance programs and samples; however, this is known to increase patient burden and decrease patient compliance and is not a sustainable long-term solution.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on 12/9/2020 (Date) Signature Mariella Reek

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS	)	
PLAINTIFF,	)	
	)	Civil Action No. 1:20-cv-03032
V.	)	
ALEX M. AZAR II, ET. AL	)	

Declaration of Lee Francis, MD, MPH

I, Lee Francis, MD, MPH, declare as follows:

1. I am the President and CEO of Erie Family Health Center, Inc. ("Erie"), located in and around Chicago, Illinois. I joined Erie in 1991 and have held the role of President and CEO since 2007. As President and CEO, I am charged with enacting Erie's strategic vision of serving as a national leader in the provision of community-based health care. I am responsible for the overall health of the organization, including financial stability, operational success, and clinical quality.

2. Regarding the 340B Drug Pricing Program ("340B Program"), as President and CEO, I have regular access to 340B financial and operational updates. I also receive regular updates on the 340B Program from Erie's Chief Financial Officer, who serves as the federal OPAIS Authorizing Official. As part of my regular duties, I am also made aware of provider and staff feedback related to 340B successes and barriers. Additionally, in my role as an Internal Medicine physician at Erie, I am keenly aware of the benefit the 340B Program offers for my own patients. To prepare this declaration, I have reviewed 340B Program metrics and feedback from providers and staff.

3. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

4. Erie is a Federally-qualified health center, and a member of the National Association of Community Health Centers. The health center receives federal funding under Section 330 of the Public Health Service Act to provide health care and related services to a medically underserved patient population residing across over 185 zip codes in the Chicagoland region.

5. Erie is an approximately 63-year-old primary healthcare provider that delivers integrated and affordable medical, dental, and behavioral health care for patients of all ages. We also encourage good health in our underserved patient population through ongoing health education, case/care management, strong hospital partnerships, and community outreach.

6. Motivated by our belief that high-quality health care is a human right, Erie serves more than 80,000 patients per year at 12 locations throughout Chicago and the surrounding suburbs, regardless of patient insurance status, immigration status, or ability to pay for Erie's services. Almost all of Erie's patients are low income, and approximately 27% of Erie's patients are uninsured. Approximately 71% of patients are Hispanic and about 44% are best served in a language other than English.

7. Erie is a "covered entity" for purposes of the 340B Program. Erie has been registered with the Health Resources and Services Administration ("HRSA") as a 340B covered entity since on or about January 1, 1997. As required, we maintain accurate management of our clinic registrations within HRSA's OPAIS database. We recertify our 340B covered entity status annually, and most recently recertified for all twelve of our participating 340B locations on or about February 18, 2020. A list of our covered entity locations, downloaded from HRSA's 340B OPAIS database on October 7, 2020, is attached as Exhibit A.

8. The 340B Program allows Erie to purchase significantly discounted outpatient prescription drugs for pharmacy dispensing and as clinic-administered drugs. We acquire 340B discounted drugs for pharmacy dispensing through wholesaler AmerisourceBergen; we are also in the process of adding Cardinal Health as another 340B wholesaler account. For clinic-administered medications, we have 340B drug purchasing accounts with Allergan, Henry Schein, Paragard Direct, Theracom, and R&S Northeast, LLC.

9. Erie's participation in the 340B Program allows us to help our low-income uninsured and underinsured patients afford their medications. Without 340B discounts, critical medications—including, among many others, insulin, asthma inhalers, blood pressure medications, Pre-Exposure Prophylaxis (PrEP) for HIV, Suboxone and Narcan to treat opioid use disorder—would be unaffordable and inaccessible for these patients. 340B contract pharmacies enable our patients to access, and many other medications.

10. As required by federal law and regulations, and in keeping with our mission, we reinvest 100% of 340B savings and revenue from third-party reimbursement into expanding access for our underserved patients. For example, this money is used to cover costs associated with comprehensive care, a Medication-Assisted Treatment Program for opioid use disorder, and telemedicine and electronic population health tools, which enable Erie to serve patients at greatest risk for missing health screenings or services.

11. Many Erie patients have chronic conditions exacerbated by social challenges. Improving health outcomes depends on Erie providing: 1:1 Care Management, Maternal and Child Case Management, HIV/AIDS Case Management, Health Coaching, Referrals support,

Care Coordination and Outreach, Public Benefits navigation, Resource navigation, and PrEP navigation services. Because robust comprehensive care and case management are not usually reimbursed by third-party payers, Erie would not be able to offer these services without 340B savings.

12. As a covered entity, Erie is permitted to choose how it will deliver pharmacy services to its patients. While we use drugs purchased at 340B pricing for a select portion of our in-clinic medication supply, Erie contracts with local pharmacies to dispense all other 340B medications to its patients. We do not own or operate our own pharmacies. We currently contract with many local Walgreens pharmacy stores and one independent community pharmacy, Allcare Discount Pharmacy, which is co-located within one of our clinic sites.

13. Erie has a written agreement with Walgreens to dispense the 340B drugs we purchase to eligible Erie patients. We first contracted with Walgreens in or around 2011 and received HRSA approval for our first Walgreens contract pharmacy location on or about August 22, 2011. In the intervening years—following guidance from HRSA and Apexus—we have registered additional Walgreens locations. Our current Pharmacy Services Agreement with Walgreens—which applies to of all our active Walgreens pharmacy locations and all of our active covered entity locations, as registered in HRSA's 340B OPAIS database—was executed on or about April 4, 2017.

14. Erie likewise has a written agreement with Allcare Discount Pharmacy to dispense 340B drugs to eligible patients. We first contracted with Allcare Discount Pharmacy in or around September 2010; HRSA approved the pharmacy arrangement on or about May 23, 2011. Our current Pharmacy Services Agreement with Allcare Discount Pharmacy was executed on or about August 7, 2019.

15. As described in our Pharmacy Services Agreements, Erie purchases 340B drugs from wholesalers and directs those drugs to be shipped to the contract pharmacy as part of a "bill-to, ship-to" arrangement. Under this arrangement, Erie maintains the title to the 340B drugs, and the contract pharmacies, in exchange for a fee, store the drugs and provide dispensing services to our eligible patients. Some of our contract pharmacies use a precise accumulation software to dispense a retail pharmacy product to patients and perform a careful 340B eligibility assessment; if the dispense meets all eligibility criteria, the accumulator will be replenished with an Erie-purchased 340B drug for that dispense.

16. Understanding that 340B compliance falls squarely on Erie, we have multiple compliance safeguards in place and perform extensive auditing, including an audit of all contract pharmacy 340B dispenses for patient and provider eligibility and audits to verify that Medicaid Fee-For-Service was not billed for any contract pharmacy 340B claim (to avoid prohibited duplicate discounts). All audits are completed on a monthly basis and reported out quarterly to our 340B Compliance Committee. We also commission an annual external 340B audit. Our most recent external audit, in January 2020, yielded positive feedback on Erie meeting HRSA 340B compliance standards.

17. Our contract pharmacies dispense over 115,000 340B discounted prescriptions annually to our eligible patients. On average, Erie spends approximately $470,000 on 340B drug products monthly for dispensing through our contract pharmacies.

18. The critical benefit the 340B drug discount to patient outcomes is illustrated in an email from an Erie pediatrician attached as Exhibit B. In the email, the pediatrician explains how one of her patients benefited from access to affordable insulin through the 340B Program. The patient turned 18 this year, moved out to live independently, started working, and lost his Medicaid coverage. Previously, the patient's Type 1 diabetes had been managed by providers at the local children's hospital. During this transition to adulthood, he was unable to stay with his care team and could no longer afford the insulin he was prescribed. The Erie pediatrician was able to work collaboratively with the patient's previous provider to assume care for his diabetic condition and prescribed an affordable Lantus pen (a Sanofi product) through the 340B Program. Aligning the patient with access to the affordable 340B drug helped to keep his sugars under control, keep him out of diabetic ketoacidosis, and keep him out of the hospital until he was able to get his insurance reinstated. The 340B Program helped this young adult access life-saving medicine and avoid hospitalization.

19. Erie's ability to offer our patients—who are dispersed across more than 185 zip codes—access to affordable life-saving and life-sustaining medications is entirely dependent on our contract pharmacy partnerships.

20. Our contracts with local pharmacies to dispense 340B medications allow our patients to receive their critical 340B medication at a pharmacy close to their home. Erie patients generally experience multiple barriers to accessing care, including significant transportation barriers. Even though Erie has twelve clinic locations, some Erie patients still have significant travel times to attend their visit at the health center. The trip for some patients requires multiple segments on public transportation, as well as walking. Providing medication access near a patient's home supports that patient's ability to take their medication regularly, without potentially dangerous gaps around refills.

21. Many of our patients are hourly wage-earners, essential workers, work long hours, hold multiple jobs, or have care-giving responsibilities during the business day, and most will not get paid to take time away from work to obtain medications. Our contract pharmacy partners include 24-hour pharmacies and those with home delivery capabilities, providing crucial access to our patients, both day-to-day and in times of crisis.

22. Beginning on or about July 7, 2020, I became aware that certain drug manufacturers—starting first with Eli Lilly and its Cialis products and now including Eli Lilly, Sanofi, and AstraZeneca, Merck, and Novartis—had unilaterally decided, without government approval, to cease providing outpatient prescription drugs at 340B prices to most or all of Erie's contract pharmacies.

23. Eli Lilly's notification affecting all products made or distributed by the company was implemented without advance notice on September 1, 2020, which did not allow Erie adequate time to respond to protect our patients' access to Lilly medication. Sanofi, Merck, and Novartis, for their parts, have requested that covered entities enroll in an unsanctioned and burdensome data collection platform called 340B ESP. Erie will not be participating in this data collection; our patients have thus lost access to Sanofi products. To date, Novartis has not yet followed through on threats to block 340B price access at contract pharmacies.

24. Because of these actions, our ability to provide patients with affordable medications has been dramatically reduced—Erie patients who were regularly receiving a 340B drug made by Eli Lilly, Sanofi, or AstraZeneca no longer have access to that medication at the discounted 340B price. Without the 340B discount, these medications are inaccessible for an Erie patient paying out-of-pocket. The following table provides Erie's average annual 340B prescription volumes prior to the manufacturers' actions:

Medication Impacted	**Medication Type**	**Average number of Erie 340B prescription fills annually at contract pharmacies, prior to recent manufacturer limitations**
Eli Lilly		
Basaglar	Insulin (diabetes)	840
Humalog	Insulin (diabetes)	1080
Humulin	Insulin (diabetes)	240
Trulicity	GLP-1 Agonist (diabetes)	120
Sanofi		
Admelog	Insulin (diabetes)	300
Lantus	Insulin (diabetes)	2400
AstraZeneca		
Brilinta	Antiplatelet (heart, circulation)	120
Bydureon	GLP-1 Agonist (diabetes)	240
Byetta	GLP-1 Agonist (diabetes)	480
Farxiga	SGLT2 Inhibitor (diabetes)	180
Symbicort	Inhaler (LABA+ICS) (asthma)	840

25. Erie is in communication with AstraZeneca regarding designating one exception contract pharmacy. This process is not finalized, and at present, our contract pharmacies are unable to purchase 340B priced AstraZeneca drugs. Even if the AstraZeneca exception process comes to fruition, it would only allow 340B access at one of our contract

pharmacies. To provide just one example of how unworkable this will be for our patients, patients of our Erie HealthReach Waukegan clinic would need to travel nearly three hours one-way on public transportation to arrive at our one remaining contract pharmacy in the Humboldt Park neighborhood of Chicago.

26. Erie is actively assessing opportunities to switch patients to affordable alternative medications. But I know as a medical provider that it is neither easy nor seamless to switch patients from one product to another. Many medication alternatives require a medical provider to review the patient chart, consider comorbidities, and assess appropriate dosing for the substitute medication. Several of the impacted diabetic treatments have very different dosing—for example daily versus weekly dosing—which requires extensive patient education and provider troubleshooting.

27. Language barriers add another layer of difficulty for patients who proceed to the pharmacy to pick-up their 340B refill and are told the price will potentially be hundreds of dollars more than it was last month. Forty-four percent of Erie patients are best served in a language other than English, and in 2019 Erie, through our interpretation service, provided care in 77 unique languages.

28. Erie has teams of Diabetes Educators who help teach patients how to use their insulin, diabetes medications, and glucose monitoring systems. As an Erie clinician, I directly see how important it is for my patients to thoroughly understand how to use their medication as directed. Frequent and/or rushed switching between medication formulations increases the opportunity for medication errors.

29. The loss of 340B savings and revenue—100% of which is reinvested into expanding access for our underserved patients—threatens Erie's ability to (1) provide comprehensive care to existing patients and (2) expand services to reach more individuals in its underserved target population. During the COVID-19 pandemic especially, 340B savings have been critical to our ability to continue serving patients and to maintain capacity to provide future services.

30. We already know that critical patient programs will need to be reduced or eliminated because of the decline in 340B savings and revenue. Erie is proud of the work of our care managers, case managers, health educators, and patient navigators, who provide personalized services that address social determinants of health and help Erie patients navigate their chronic health conditions. Without 340B savings, we would not have the capacity to fund these unreimbursed comprehensive care programs.

31. Erie is exploring all available options, but there is no action we can take to promptly remedy the drug manufacturers' refusal to provide 340B discount pricing. Erie has always used contract pharmacy partnerships to provide 340B medication access to patients. We do not have the pharmacy infrastructure to participate in the 340B program as an in-house pharmacy, and creating that infrastructure would involve a lengthy and expensive endeavor. Our patients cannot wait, they need access to affordable medications now.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: _____

By: _____ *December 2, 2020*
Lee Francis, MD, MPH, President and CEO
Erie Family Health Center, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS	)	
PLAINTIFF,	)	
	)	Civil Action No. _____
V.	)	
ALEX M. AZAR II, ET. AL	)	

Declaration of Kiame Jackson Mahaniah

I, Kiame Jackson Mahaniah, declare as follows:

1. I am CEO at Lynn Community Health Center ("LCHC") in Lynn, Massachusetts and have held this role since October 2017. As CEO, I am responsible for overall compliance and adherence to all HRSA requirements, including requirements related to our participation in the 340B Program. To prepare this declaration, I reviewed relevant internal patient and prescribing data with Kim Macleod, our CFO, and discussed the current situation and its challenges in depth with my executive team, the Board of Directors, and most of our external stakeholders.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. LCHC is a nonprofit community health center that receives federal grant funds under Section 330 of the Public Health Service Act to provide healthcare and related services to a medically underserved population in the city of Lynn, Massachusetts regardless of patient insurance status or ability pay. We have been designated as a federally qualified health center (FQHC) since 1993.

4. Since 1971, LCHC that has served as the primary source of healthcare services in Lynn, Massachusetts, a dense, urban community with high rates of poverty. In 2019, LCHC provided approximately 286,980 medical, behavioral health, vision, and dental visits to approximately 41,115 patients.

5. Over 94% of our patients live at or below 200% of the federal poverty level, over 83% are racial/ethnic minorities, and about 59% are best served in a language other than English. Close to 60% of LCHC patients are on Medicaid, 9% are on Medicare, and 12% are uninsured.

6. The COVID-19 emergency is having a severe impact on Lynn and our patients. As of November 30, 2020, Lynn had 7,537 cases and 134 deaths in a city with 94,655 residents.

7. Lynn Community Health Center is a "covered entity" for purposes of the 340B Program. Our participation in the 340B Program, which provides us discount pricing on outpatient prescription drugs, began in or around 1999. We certify our covered entity status annually with the Health Resources and Services Administration (HRSA).

8. LCHC has contracted with pharmacies—principally Walgreens and CVS—to provide dispensing services to our eligible patients. We purchase drugs at 340B pricing from wholesalers McKesson, Cardinal, and AmeriSource Bergen and direct those drugs to be shipped to our contract pharmacies on a replenishment basis. LCHC maintains title to the drugs, but storage, distribution, and patient-related information is done by the contract pharmacies. LCHC's contract pharmacies undergo an annual certification process with HRSA's Office of Pharmacy Affairs.

9. One of the consistent barriers our patients face to accessing healthcare, including filling prescriptions, is transportation. In addition, we have a growing number of elderly patients for whom ambulation is also difficult. Contracting with pharmacies close to where our patients resides ensures convenient access, increases medication adherence, and provides opportunities for education within established patient-pharmacist relationships. Although always difficult to measure, this type of preventative and community-oriented care ultimately benefits total cost of care.

10. LCHC's average number of monthly 340B prescriptions is 14,000. Although that number is astounding, LCHC has one of the lowest ER use rates of any outpatient institution in Massachusetts.

11. Our annual purchases of pharmaceuticals at 340B pricing is approximately $4 million.

12. We ensure 340B Program compliance—including compliance with prohibitions on diversion and duplicate discounts—through a monthly reviews and independent third-party compliance testing.

13. LCHC's participation in the 340B Program helps it to stretch scarce resources and meet the needs of its medically underserved patients, including uninsured and underinsured patients.

14. We are a national leader in integration of behavioral health (BH), Substance Use Disorder (SUD) treatment, and primary care. BH in particular does not have payment parity: providing psychopharmacologic services for children would simply be impossible without the margin provided by 340B discount pricing.

15. Support services, though vital to our patients, are generally not reimbursed. We use 340B savings and revenue to fund:
    - foreign language interpretation/translation services, which are currently provided in 30+ languages, with the top five languages accounting for 85% of our patients;

- social services, including assiduous screening for social determinants of health and a referral system through which we coordinate access to various services in the area (such as housing services coordinated through our relationship with the Massachusetts Coalition for the Homeless);
- recovery coaches and case management for our highest risk tier of patients, which includes patients suffering from homelessness, serious mental illness, and social isolation.

16. We respond to the needs of our most vulnerable constituents. Although we maximize our efficiency through lean management practices, we have limited flexibility given that we cannot choose our market, but instead simply answer identified community needs.

17. Without 340B discount pricing, we could not cover the cost of the programming listed above. With our care and services, there is a way forward for the most vulnerable in our underserved patient population. Our patients' needs will not disappear in the absence of such services, they will instead be pushed onto law enforcement, the schools, and/or the courts.

18. In September 2020, I became aware that certain drug manufacturers, including Eli Lilly and Sanofi, had unilaterally decided, without government approval, to cease providing outpatient prescription drugs at 340B prices to most or all of LCHC's contract pharmacies.

19. Because of this action, we estimate an approximate loss of $6 million from our roughly $8 million budget.

20. As a result of this loss, we are preparing for the permanent layoff of about 5% of our employees, or about 35 people. This includes all data management capabilities (3 FTE) that allow us to use our funding in the most efficient way possible; a dramatic scaling back of our mental health team, particularly in the psychopharmacology realm, to include our recovery coaches and most of our case managers.

21. We will also have to cut services, most of which are exactly those that heighten our efficiency and our ability to deliver targeted services: case management for vulnerable patients, programs targeting mentally ill folks suffering from homelessness, and therapy provided in our patients' native languages.

22. As a health center, we are used to operating very close to bare bone. Two years ago, for the first time in decades, we were ecstatic to realize a margin above 2%. A good month is one in which we clear $200,000. We normally have 4 good months a year.

23. LCHC would simply cease to exist as we now know it without our ability to purchase prescription drugs for our patients at 340B discount pricing. We would retrench to very basic care.

24. Crucially, our most vulnerable and marginalized patients would suffer the most. These patients will suffer untreated mental illness, lack of access to substance use disorder/addiction treatment, and lack of support services. I fear that the gains we have made in tackling some of the most profound problems in our community will be lost.

25. There are no good strategies we could employ to mitigate the drug manufacturers' actions. We could certainly develop a mail-in pharmacy program, yet we already have a 20% mail rejection rate. Trusting life-sustaining medication to this process seems unwise. Could we act as a wholesaler? Perhaps, but we currently don't have our own pharmacy and to expand in that way would require the development of a complex process that clearly lies outside our current services. It would take precious funds and bandwidth away from areas that cannot afford to spare either money, time, or expertise. There is no reasonable alternative to the 340B Program in its current iteration.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on: 12/3/2020

By: 
Dr. Kiame Jackson Mahaniah
CEO
Lynn Community Health Center

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS Plaintiff, v. ALEX M. AZAR II, et. al	)	Civil Action No. 1:20-cv-03032

Declaration of Kimberly Christine Chen

I, Kimberly Christine Chen, declare as follows:

1. I am the Director of Pharmacy at North Country HealthCare, Inc. ("NCHC") in Flagstaff, Arizona and have held this role since July 2012. As the Director of Pharmacy, I am responsible for oversight of our 340B compliance program, our in-house pharmacy programs, our contract pharmacy partnerships, and our clinical pharmacy services. I am also part of our management team, and to fulfill my job duties have access to financial and strategic planning information, including information related to the application of pharmacy revenue to other areas of the organization. My role reports directly to the Chief Financial Officer (CFO), who in turn reports to the Chief Executive Officer (CEO).

2. To prepare this declaration, I met with my pharmacy management team—which includes the pharmacy manager, pharmacy business manager, and clinical pharmacist representative—met with our CEO and CFO, and reviewed relevant internal data and reporting. I also met with my clinical pharmacists to discuss general patient impact and specific patient cases in which recent changes to our access to 340B discount pricing have impacted patient care.

3. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

4. NCHC, a member of the National Association of Community Health Centers, is a Federally-Qualified Health Center ("FQHC") that receives federal grant funds under Section 330 of the Public Health Service Act to provide health care and related services to a medically underserved patient population regardless of patient insurance status or ability to pay. NCHC has its historical roots in a free health clinic model that transitioned to FQHC status upon community health center funding in 1996. The center has approximately 500 employees, approximately 85 of whom are medical providers.

5. Our primary clinic site and administrative hub is located in Flagstaff, Arizona, a population center with Medically Underserved Population (MUP) designation.

6. We also provide primary care services at behavioral health centers and homeless shelters, and operate satellite clinics targeting uninsured patients in Seligman, Winslow, Holbrook, Round Valley, Show Low, Williams, Grand Canyon, Dolan Springs/Kingman, Bullhead City, Lake Havasu City, and Payson communities. All, excluding Lake Havasu City, are designated Medically Underserved Areas (MUA's) and Health Professional Shortage Areas (HPSA's). These communities vary in distance from Flagstaff, primarily across the Interstate 40 corridor of Northern Arizona. The table below indicates the approximate distance and direction of these communities from our Flagstaff location.

Site (PCA)	Distance from Flagstaff (miles)	Direction from Flagstaff
Seligman	70	W
Winslow	60	E
Holbrook	90	E
Round Valley	180	SE
Show Low	140	E
Williams-Grand Canyon	35	NE
Dolan Springs/Kingman	143	W
Bullhead City	184	W
Lake Havasu City	208	W
Payson	115	SE

7. NCHC's services include diagnosis, treatment and referral for all illnesses, chronic disease management, prenatal/perinatal and delivery care, well woman checks, well child services/immunizations, pharmacy, laboratory and radiology services, preventive care/health education, oral health services, and integrated behavioral health. We also provide significant health promotion/disease prevention and enabling programs.

8. The Center has grown rapidly over the past twenty-five years, providing approximately 164,000 patient visits in calendar year ending December 31, 2019 to approximately 52,000 unduplicated users who call NCHC their "medical home."

9. The current payer mix from our most recent financials show that approximately: 7.2% of our patients are uninsured; 38% are Medicaid; 19.1% are Medicare; and 32.8% are commercially insured. The Medicare user population is expected to continue growing as few local providers accept new Medicare assignment.

10. According to the three Medicaid Managed Care plans in our service areas, diabetes, hypertension, and cardiovascular issues are the top three medical issues among that population. NCHC sees these issues similarly reflected in their patient population regardless of payer type.

11. NCHC has three in-house pharmacies situated within our Flagstaff, Grand Canyon, and Kingman locations. Our Grand Canyon and Kingman pharmacies are tele-pharmacies, staffed by pharmacy technicians (with Flagstaff-based pharmacists performing all

pharmacist's duties, oversight, and counseling). These tele-pharmacies were the first in Arizona—approved by special waiver from the Arizona Board of Pharmacy in 2010—and represent two of only a handful across the state. Tele-pharmacies help address the critical and unique needs in rural health care.

12. NCHC is a "covered entity" for purposes of the 340B Drug Program ("340B Program") and has been registered as such with the Health Resources and Services Administration (HRSA) since July 1, 1998. As required, NCHC recertifies all its eligible locations annually with HRSA. A current covered entity listing pulled from HRSA's Office of Pharmacy Affairs Information System (OPAIS) 340B database is attached as Exhibit A.

13. The 340B Program allows NCHC to purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount.

14. NCHC uses a combination of both in-house and contract pharmacies to meet our patients' pharmaceutical needs. In addition to NCHC's three in-house pharmacies, NCHC utilizes 52 contract pharmacies in 12 different communities. Specific contract pharmacies, contract dates, HRSA OPA registration dates, and active dates are included as Exhibit B.

15. NCHC works with both McKesson and Cardinal distributors in a "bill-to/ship-to" replenishment model for providing 340B medications to eligible patients. The 340B medications are purchased after the prescription has been filled at a contract pharmacy and it has been confirmed that the prescription is (1) eligible for the 340B Program and (2) is not a Medicaid claim.

16. Our claims are managed by a third-party administrator (TPA) and audited by NCHC compliance staff. The TPA matches the prescriptions to patient, provider and encounter files to "carve in" those claims as 340B eligible. Depending on the TPA, there are also additional mechanisms to ensure accuracy, such as embedded coding in electronic prescriptions from our electronic medical record and bar coding on printed prescriptions. Once the TPA has "carved in" a prescription, a record of that eleven-digit national drug code (NDC) is recorded. When the TPA identifies that a full package of a medication (11-digit NDC match required) has been dispensed to eligible patients, an order is generated for that medication. The drug is purchased by NCHC (aka "bill-to") and provided to the contract pharmacy where the medication was originally filled (aka "ship-to"). At no point in this process can the contract pharmacy order 340B medications directly or see the 340B drug pricing.

17. All claims the TPA "carves in" are communicated to NCHC and audited to ensure compliance. No such claims are billed to Medicaid—the TPA is provided with all Bank Identification Numbers (BIN) and Processor Controller Number (PCN) listed on Arizona's Medicaid Exclusion File and NCHC audits all carved in claims to additionally ensure that all prescriptions were eligible and that none were billed to Medicaid.

18. NCHC also achieves compliance through (1) ongoing internal and external audits of both in-house pharmacy and contract pharmacy claims; and (2) extensive staff training.

19. NCHC providers prescribe roughly 280,000 prescriptions annually. Of those prescriptions, only about 13.97% were filled by NCHC's in-house pharmacy; approximately 65.33% were filled by NCHC contract pharmacies. However, of the prescriptions sent to the contract pharmacies, only about 26% were ultimately applied to the 340B Program. The other 74% were either Medicaid or otherwise not eligible for the 340B Program.

20. Contract pharmacy agreements are critical to provide our most vulnerable patients access to affordable medications for several reasons.

21. First, NCHC's service area spans approximately 576 miles across all of Northern Arizona. Without contract pharmacies, patients would have to travel (one-way trip), to reach the closest of NCHC's in-house pharmacies:

Service Areas	Pharmacy Locations		
	Flagstaff Pharmacy	Kingman Pharmacy	Grand Canyon Pharmacy
Seligman	70	74	
Lake Havasu		60	
Bullhead City		37	
Williams	35		59
Winslow	50		
Payson	115		
Holbrook	90		
Show Low	140		
Round Valley	180		

22. Traveling such tremendous distances to access affordable medications is not feasible for our patients, especially in northern Arizona where inclement weather is a significant factor during the winter months.

23. Our contract pharmacy agreements provide our patients access to affordable medications within their communities.

24. Second, our contract pharmacies, unlike our in-house pharmacies, are open on nights, weekends, and holidays. Even in the communities where we have an in-house pharmacy, contract pharmacies are critical to provide medication access outside regular business hours.

25. Finally, our homeless populations are best served by community pharmacies near where they are located to increase their adherence and reduce their significant barriers to care.

26. NCHC's participation in the 340B Program allows us to provide our uninsured and underinsured patients—including low-income workers and homeless individuals—access to affordable or no-cost medications. All our contract pharmacies provide a modified sliding fee scale pricing to our patients who are 200% or more below the federal poverty level.

27. Additionally, revenue from prescriptions filled for our insured patients is used in furtherance of our mission and federal grant project.

28. For example, 340B Program proceeds support our clinical pharmacy program, in which pharmacists work in the clinics as members of interdisciplinary care teams to optimize medication regimens, promote adherence, generate medication alternatives and provide both group and individual patient education. Clinical pharmacists are critical on teams that provide chronic disease management, anticoagulation services, and pain management. Clinical pharmacy services expand patient access to care, improve patient outcomes, decrease medical providers' workloads, and improve provider satisfaction. This service is not reimbursable by CMS or commercial insurance, and would not be possible without the 340B Program.

29. Revenue generated from the 340B contract pharmacy environment is also used to support our most rural clinics. Without this subsidy, these clinics, which have lower patient volumes, would not be sustainable. Without this funding source, NCHC may be forced to close as many as six of our locations and lay off approximately 100 staff and providers.

30. Beginning in or around June 2020, I became aware that certain drug manufacturers, including Merck (notified June 29, 2020), Sanofi (notified July 31, 2020), AstraZeneca (notified August 20, 2020; position since modified to permit limited use of contract pharmacies) and Eli Lilly (notified September 1, 2020) had unilaterally decided, without government approval, to cease providing most or all outpatient prescription drugs at 340B prices to most or all of NCHC's contract pharmacies.

31. These actions significantly and negatively impact our patients.

32. Without contract pharmacies, only three of the twelve communities NCHC serves would have access to pharmacy.

33. Without contract pharmacies, patients will not be able to afford their medications at commercial pricing and most will not be able to travel the great distances required to procure their medication from our in-house pharmacies.

34. For example, Symbicort, made by AstraZeneca, is the only approved first line medication in the treatment of asthma according to the 2020 guidelines by Global Initiative for Asthma (GINA). NCHC has multiple patients who are homeless who were tried and failed on other alternative treatments. The clinical pharmacist was able to switch them to Symbicort and the patients experienced marked improvement in their asthma, decrease in their exacerbations, and quality of life due the medication change. Many of these patients can no longer use a contract pharmacy for Symbicort and instead must find a way to access the medication through an NCHC in-house pharmacy. Although NCHC identified and implemented workarounds for these patients, there is a limit to what we can do, and inevitably patients' health outcomes will be negatively impacted by limits on medication access.

35. An uninsured, Type 1 diabetic patient of our Show Low clinic, which is located approximately 280 miles from our closest in-house pharmacy, was taking Novartis-produced Novolin N, an insulin medication, but was experiencing frequent hypoglycemia (low blood sugar). Our clinical pharmacy staff worked with this patient to switch him to Sanofi-produced Lantus, on which he was able to keep his blood sugars stable. On or about October 1, his Lantus was no longer available through the contract pharmacy. Additionally, even if he could tolerate being switched back to Novolin N, the product and its comparable product made by Eli Lilly (Humulin N) are also not available at 340B pricing.

36. This patient's body is unable to make insulin. Without it he will die. Insulin is not a choice. Type 1 diabetes is not a choice.

37. I would also add that with the loss of contract pharmacy revenue, the clinical pharmacist who was able to get this patient on a stable, healthy insulin regimen targeted to his particular needs is potentially in jeopardy of losing their job, leaving this patient and all the others like him struggling to manage chronic diseases and navigate access to affordable mediations.

38. While this is just one patient story, all our diabetic patients face similar terrible outcomes. In the short term, switching insulins on stable patients can increase weight gain, reduce adherence due to formulations that require more frequent dosing throughout the day, and increase the risk of hypoglycemia, which can lead to seizures, coma, and even death. Insulin changes are difficult to titrate and require frequent contact with a clinical pharmacist, whose jobs are hanging in the balance. In the long term, these patients face higher risk for renal damage, retinopathy and blindness, and cardiovascular events.

39. Our patients are being denied access to evidence-based, guideline-driven, best practice quality care because of their inability to access affordable medications. Our providers are being forced to deviate from the standards of care based on a patient's payer type.

40. These changes have caused immediate harm and will cause additional harm the longer this is allowed to continue. Due to our geographical barriers, NCHC has had to scramble to get couriers in place at our various clinics and establish other workarounds for access to affordable care. We have also placed additional staffing burdens on our pharmacy team to identify those patients most impacted by these manufacturer's actions and to determine what treatment options may be available that the patient can both afford and access. Our pharmacy team has also had to create and support new processes for these deliveries and solutions for managing the influx of changed prescriptions. Our clinic staff has scrambled to navigate processes to allow patients to pick up medications in our clinics, a process that many front office clinic staff have never had to do before.

41. These additional burdens come at a time when health care across the nation is trying to adapt to the global pandemic.

42. If these actions continue, NCHC will have to make crucial decisions on what will need to be cut to compensate for the reduction in program income derived from our participation in the

340B Program. We will likely have eliminate our clinical pharmacists and determine which rural clinic location would need to be the first of possibly multiple clinic closures.

43. Last fiscal year, NCHC's in-house pharmacy wrote off more than $3.2 million in direct patient medication costs. As an FQHC, NCHC does not have the capacity to continue to provide the scope and depth of our services to patients if these attacks on the 340B Program continue.

44. NCHC has done its best to protect our patients during this crisis, but our solutions fall short.

45. For example, the courier deliveries we have established occur weekly and cannot address acute patient needs. If a patient realizes that they will run out of their insulin after the courier has left the clinic, they will not be able to access their medications for another week, putting the patient in danger of significant medical emergency that may require hospitalization or even result in death. Additionally, in northern Arizona, where severe snowstorms can occur on short notice during the winter months, it is common for couriers to have to cancel deliveries. The resulting delays in therapy are detrimental for patients and pose significant costs and burdens to the healthcare system.

46. Mailing prescriptions to patients poses challenges as well. Many of our patients do not have consistent addresses, our homeless patients have no addresses at which they can receive mail, our insurance contracts prohibit mailing beyond individual patient exceptions, and even if we were to secure mail-order status, all mail in our region is routed through Phoenix, where summer heat exceeds manufacturer recommendations for safe medication storage. Safely and legally mailing medications would involve significant expense and would still fail to help many of our most vulnerable patients.

47. A longer-term solution to consider is expanding our tele-pharmacy program. These pharmacies are very expensive to maintain, and the Arizona Board of Pharmacy requirements state that the pharmacy technician that staffs these locations must have a minimum of 1,000 hours of technician experience prior to working in tele-pharmacy. This is a huge barrier due to the rural nature of these locations. Staffing in these locations by skilled, credentialed team members is an ongoing issue and this would also be the problem for tele-pharmacy. Additionally, due to the parameters of operation, these pharmacies do not demonstrate a high capture rate of prescriptions for those patients who have insurance, making the model not financially sustainable without outside funding.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on: December 3, 2020

By: _____
Kimberly Christine Chen
Director of Pharmacy
North Country HealthCare, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS	)	
PLAINTIFF,	)	
V.	)	Civil Action No. 1:20-cv-03032
ALEX M. AZAR II, ET. AL	)	

Declaration of Ludwig M. Spinelli

I, Ludwig M. Spinelli declare as follows:

1. I am the Chief Executive Officer at Optimus Health Care Inc ("Optimus"), which serves approximately 50,000 patients in the Bridgeport and Stamford regions of Connecticut. In this position, which I have held since in or around September 1983, I am ultimately responsible to the Board of Directors for health center performance and patient care.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. Optimus is a Federally-qualified health center ("FQHC") that receives federal grant funds under Section 330 of the Public Health Service Act to provide health care and related services to a medically underserved patient population regardless of patient insurance status or ability to pay. Optimus is a member of the National Association of Community Health Centers.

4. Optimus has been in operation since approximately December 1976, and presently offers some 210,000 annual visits to approximately 50,000 unduplicated patients at our 35 service locations. Our target population is low-income residents in our southwestern Connecticut service area that ranges from western New Haven county to the New York border.

5. Approximately 22% of our patients have no insurance and are thus placed on a sliding fee scale based on their income. Some 60% of our patients qualify for Medicaid and approximately 8% for Medicare.

6. We have around 7,000 patients with diabetes, hypertension, and asthma, and we provide comprehensive support to approximately 500 HIV positive patients.

7. Optimus is a covered entity for purposes of the 340B Drug Pricing Program ("340 Program") and has been for some 10 years. Optimus recertifies its covered entity status

annually with the Health Resources and Services Administration (HRSA) in keeping with HRSA's Office of Pharmacy Affairs guidelines and directives.

8. The 340B Program allows Optimus to purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount. Optimus purchases drugs at 340B pricing from two main wholesalers: Cardinal Health and McKesson. We purchase approximately $1.4 million in prescription medications from our 340B wholesalers every year.

9. Optimus dispenses the drugs it purchases at 340B pricing to eligible patients via contracted pharmacy partners. These contracted pharmacies include Walgreens, CVS, Walmart, Rite Aid, and three local pharmacies in our service area: Slavins, Cornerstone, and Bridgeport Pharmacy.

10. From a patient perspective, these pharmacies are accessible and conveniently located. Many also have home delivery options, which help out patients to obtain their medications and remain compliant with medication regimens.

11. Optimus has written agreements with each contract pharmacy that detail how the program works. In compliance with 340B rules, each of these pharmacies was registered with and approved by HRSA, before any 340B medications were dispensed to any of our patients. The approximate date of approval for each pharmacy is as follows:

    - Walgreens Pharmacies executed on 8/24/2011
    - Rite Aid Pharmacies executed on 7/1/2014
    - Slavins-Hancock Pharmacy executed on 1/1/2013
    - Cornerstone Pharmacy executed on 9/18/2013
    - Bridgeport Pharmacy executed on 4/4/2019
    - Wal-Mart Pharmacy (Stratford CT) executed on 4/1/2019
    - CVS Pharmacies executed on 7/22/2019

12. With the exception of Walgreens, our 340B operations are managed by our Third-Party Administrators ("TPAs") CaptureRx and Wellpartner. Through the services provided by the TPAs, we ensure 340B Program compliance including:

    - Patient, prescriber and covered entity eligibility
    - Exclusion of Medicaid prescriptions to prevent duplicate discounts
    - Purchasing and tracking inventory
    - Reports for auditing

13. Although the TPAs assist us in fulfilling these responsibilities, we know that Optimus is ultimately accountable for adherence with 340B Program requirements. Our Finance Department tracks the activity overseen by our in-house pharmacist, who helps to manage the program and is a resource to the contract pharmacies and the patients. Our 340B Committee and our Compliance Department are actively involved in ensuring that we meet all relevant HRSA and program requirements.

14. At the pharmacy level, each prescription is verified for eligibility in accordance with 340B rules. Patient eligibility, covered entity and prescriber eligibility, and all other 340B criteria must be met. We achieve this through our TPA's, CaptureRx, WellPartner, and Walgreens. If a prescription does not meet any of the qualifying criteria, it is excluded from our 340B Program. This applies to both insured and uninsured patients.

15. Optimus' participation in the 340B Program helps it to stretch scarce resources and meet the needs of its medically underserved patients, including uninsured and underinsured patients. Uninsured patients get 100% of the savings at our partner (contract) pharmacies, as explicitly spelled out in our agreements with these pharmacies, and pharmacists do not mark-up our 340B medications. In addition to the 340B cost of the medication, a reasonable, pre-negotiated dispensing fee is charged to patients who can afford it. For our patients who cannot afford the dispensing fee, we cover the entire cost of their prescription.

16. Any net revenue we derive from the 340B Program also goes directly to our patients. Our Dental, Podiatry, and Clinical Nutrition departments are excellent examples of how we provide enhanced patient care with 340B dollars. In our geographical area, we are one of the only sites to offer dentures and other procedures at deep discounts.

17. Similar to dentistry, our Podiatry and Clinical Nutrition Departments are supported by 340B dollars. These departments reach some of our most needy patients, including those with diabetes, for whom podiatry and clinical nutrition services can be crucial to overall wellbeing.

18. Optimus has a robust 340B Program with approximately 3,200 unique patients participating. Of these, about 1,500 patients have no prescription insurance. The remaining 1,700 some odd patients have prescription insurance; however, they may still need additional assistance affording their medications. Through our partnerships with contract pharmacies, our patients receive approximately 17,000 prescriptions every year.

19. At Optimus, pharmacy services are an integral part of comprehensive health care. In addition to 340B dispensing services, our community pharmacy partners provide pharmacy-based health care to our patients and support to our clinical staff. Some of these services include chronic disease state monitoring, medication adherence programs, medication therapy management services, and timely feedback to our clinicians. The strong communication link between our providers and pharmacists allows for easy communication and delivery of patient care.

20. Convenient locations and service hours, coupled with culturally competent staff, make our 340B partner pharmacies the best choice for our patients. To accommodate patient care priorities, we do not require patients to change pharmacies for 340B pricing. Instead, we expand 340B access to the patients' pharmacies of choice.

21. Beginning on or about July 23, I became aware that certain drug manufacturers, including Eli Lilly, AstraZeneca, and Sanofi had unilaterally decided, without government approval,

to cease providing outpatient prescription drugs at 340B prices to most or all of Optimus' contract pharmacies. These restrictions have impacted our uninsured patients' ability to acquire life-saving and life-improving medications. We have determined the impact from these three manufacturers alone to be as follows:

- Uninsured patients will lose access to approximately 773 affordable prescription medications for their chronic health conditions. Our records show that before COVID-19, annually 1,610 unique (unduplicated) patients received one or more medications made by one of these three manufacturers. The need for affordable medications in underserved communities has been amplified by the pandemic and the economic fall-out that resulted. Access to insulin, asthma controllers, and other essential medications are cut off when people need them the most. Patients that were paying about $12 to $15 for three months' supply of these medications will now have to pay about $300 to $600 per month to continue their treatment.

- Our health center will lose over $560,000 a year in 340B revenue, this does not include the impact from Merck and other manufacturers who have also announced plans to restrict access to 340B pricing but have not implemented their plans to date. If the current trend is allowed to continue, we believe this figure will be much higher. 340B is a vital revenue stream that allows us to expand primary care to patients who need it the most. As a result, vital programs like Dental, Podiatry, Clinical Nutrition, and others will be at risk of losing their funding. Without 340B revenue, our expanded dental services would become an expense we could not afford to cover.

- To limit the loss to our patients, we are actively searching for suitable alternatives for medications made by Eli Lilly, AstraZeneca, and Sanofi. Please see the attached list of recommendations developed by our Clinical Pharmacist to help support our providers and patients.

22. There is significant harm done to our patients due to the sudden discontinuation of 340B pricing of maintenance medications. As pharmaceutical companies continue to exclude more medications from the 340B Program, we are quickly running out of options for our patients.

- The sudden discontinuation of 340B pricing did not allow time to notify patients and work out an effective strategy.

- Providers are forced to change medication therapies without adequate time to evaluate the health outcome of new therapies to their patients.

- In the case of the "one contract pharmacy only" requirement imposed by certain manufacturers, providers are put in the uncomfortable (and sometimes inappropriate) position of telling patients which pharmacy they can go to for their medications.

23. Patients who rely on our 340B Program for their medications have been harmed directly. Mrs. P. is an uninsured patient. Since 2017 her diabetes has been controlled on insulin

made by Eli Lilly, for which she paid $15 a month. On September 4, 2020, she went to the pharmacy and she was asked to pay $270. Without any prior notice or a reasonable alternative, she was left without her medication. To complicate matters more, Mrs. P. is a visually impaired patient who does not speak English. She depended on the 340B Program to access her medication at a local pharmacy that accommodates her needs. She has been let down.

24. Mrs. A. has a similar story. She is followed in our ob-gyn practice in Stamford for gestational diabetes. While her pregnancy is high risk, she has been managed well on an insulin product made by Eli Lilly. However, 27 weeks into her pregnancy, she was asked to pay full price for her insulin, $320 which she could not afford. Like many of our patients, Mrs. A. is not eligible for discount programs sponsored by pharmaceutical companies due to her undocumented immigrant status.

25. Many of our asthmatic patients are also affected by Astrazeneca's restriction on 340B priced medications. Mr. O. can be cited as an example. He suffers from severe asthma. While his illness has been difficult to control, he and his doctor have worked closely together to manage his condition and stabilize him on the right medication. Mr. O. paid $15 a month and visited the local pharmacy frequently since 2014. In October 2020, his medication therapy was interrupted due to Astrazeneca's policy change. Mr. O. could not afford to pay $315 a month for his inhaler. He is now starting treatment on a new medication, uncertain how well it will control his asthma. Even more uncertain of what might happen to him if more pharmaceutical companies block access to the 340B Program.

26. These patient experiences demonstrate the challenges uninsured individuals face to pay for their medications. The pandemic has worsened the problem with additional health problems and a lack of jobs to pay for these medications. At a time of dire need, access to 340B priced medications is being restricted by some pharmaceutical companies.

27. The harms listed above are in addition to the financial burden levied on Optimus to continue to provide comprehensive health services, without the vital dollars to reach more patients. To fill the gap created by the 340B loss, Optimus anticipates a $1.5 million budget reduction. At risk are our patients who receive free and reduced-cost care, many of the same patients who lost their 340B savings at the pharmacy.

28. Optimus is coming out of the last fiscal year with an overall loss caused by COVID-19. We did participate in the Payroll Protection Program, but our revenue remains below that of the pre-COVID period. Our visits are down approximately 20%, and many patients are reluctant to visit Optimus for routine care due to recent COVID-19 positive spikes in the population.

29. We are working with some drug manufacturers that will ship our drug purchases to one contract pharmacy, but our service area is approximately 25 miles wide. It is impossible to expect all of our patients to travel to one single pharmacy given the significant practical barriers that stand in the way such as time and transportation availability.

30. Additionally, many patients are hesitant to use mail order pharmacies, and those pharmacies are not part of our 340B Program. Thus, this option does not improve access to needed medications.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on: 12/8/20

By: Ludwig M Spinelli

Ludwig M. Spinelli
Chief Executive Officer
Optimus Health Care Inc

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS	)	
PLAINTIFF,	)	
	)	Civil Action No. _____
V.	)	
ALEX M. AZAR II, ET. AL	)	

Declaration of Daniel Fulwiler, President and CEO of Esperanza Health Centers

I, Daniel Fulwiler, declare as follows:

1. I am the President and CEO at Esperanza Health Centers (Esperanza) and have held this role since April 2008. As President and CEO, I am responsible for the overall leadership and management of Esperanza programs and services. To prepare this declaration, I reviewed Esperanza's 340B Program and financial data including, but not limited to, financial statements, contracts, and government filings. I have access to this information to perform my job duties.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. Esperanza is a Federally Qualified Health Center (FQHC) that receives federal grant funds under Section 330 of the Public Health Service Act to serve a medically underserved population within our designated service area regardless of patient ability to pay. Founded in 2004, we serve over 30,000 patients annually in Chicago, Illinois. Over 90% of our patients identify as Hispanic/Latino, and over 95% live near or below the federal poverty level. Roughly, 50% of our adult patients is uninsured.

4. Esperanza is a "covered entity" for purposes of the 340B Drug Program, and has been for approximately seven years, since in or around April 2013. As required, we recertify this status annually with the Health Resources and Services Administration's Office of Pharmacy Affairs (HRSA OPA) OPAIS system.

5. The 340B Drug Program allows Esperanza to purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount. We pass this discount on to our uninsured patients, who can purchase life-saving medications at 340B cost, plus minor administrative and dispensing fees.

6. Esperanza's participation in the 340B Drug Program helps it to stretch scarce resources and meet the needs of its medically underserved patients in other ways as well. As an FQHC, we must serve any patient who comes in with a medical need, regardless of that individual's ability to pay or insurance status. Because a large portion of our adult medicine patients are uninsured, on average we lose money on each patient visit. The 340B program is critical in keeping our adult medicine program financially sustainable.

7. Esperanza's participation in the 340B Drug Program allows us to serve approximately 30,000 patients a year who fill, on average, approximately 59,000 prescriptions a year.

8. As a covered entity, Esperanza is permitted to choose how it will deliver pharmacy services to its patients. We utilize contract pharmacies to provide 340B benefits to our patients. For all our contract pharmacies, there are written agreements between Esperanza and the contract pharmacy:

    a. We have a Pharmacy Service Agreement with Surecare Pharmacy Inc. (Surecare) dated July 29, 2011. This Contract Pharmacy Agreement was approved by HRSA in OPAIS on August 9, 2011.

    b. We have a Pharmacy Service Agreement with Walgreen Co. (Walgreens) dated October 11, 2011. This Contract Pharmacy Agreement was approved by HRSA in OPAIS on October 11, 2011.

9. Esperanza's contract pharmacies operate on a "virtual inventory" system. Each contract pharmacy dispenses covered prescriptions to our patients, and when enough medication is dispensed to our eligible patients, Esperanza places an order via our 340B wholesaler to replenish the contract pharmacies' stock.

10. Contract pharmacies have expanded our patients' ability to access affordable drugs by offering both (1) more convenient geographic locations for drug refills and (2) service on evenings and weekends. Contract pharmacies also allow us to focus on providing excellent care to our patients without having to bear administrative work that comes with operating an onsite pharmacy. The communities in which we operate have always been underserved by pharmacies, and this has been exacerbated by current events including the COVID-19 pandemic and civil unrest.

11. Esperanza maintains responsibility for compliance with all 340B rules for drugs dispensed at contract pharmacies and undertakes the following efforts:

    a. For Surecare, we utilize a live information feed from our Electronic Medical Records (EMR) system that allows us to verify that only eligible Esperanza patients are included in our 340B Program.

    b. For Walgreens, we include a barcode in our electronic prescriptions that allows Walgreens to verify that the prescriptions came from Esperanza and should, where applicable, be processed under our program.

c. We annually engage an outside entity to complete an audit of our 340B program, to ensure its integrity and compliance with all regulations.

12. In the 12 months ended September 30, 2020, Esperanza purchased approximately $910,000 of drugs at 340B pricing. These include medications to treat and prevent diabetes, HIV, and Hepatitis C.

13. During the period from July to September 2020, I became aware that certain drug manufacturers, including Eli Lilly, Merck Sharpe & Dohme Corp., Sanofi, Astra-Zeneca and Novartis Pharmaceuticals (Manufacturers) had unilaterally decided, without government approval, to cease providing outpatient prescription drugs at 340B prices to most or all of Esperanza's contract pharmacies.

14. These actions will likely cause irreparable harm to our patients and affect clinical outcomes:

a. Limiting our contract pharmacy network will cause uninsured patients to lose access to certain drugs because they would be too expensive without the discount 340B pricing we pass on to these patients. For example, the average 340B price for a 30-day supply Humalog, a fast-acting insulin made by Eli Lilly, including dispensing fee, is less than $17.00. Without 340B discount pricing, the price for a 30-day supply of Humalog is around $700. The difference in price can result in up to $8,200 of extra costs every year for each of our uninsured patients taking this life saving drug. These drugs would be unaffordable to our uninsured patients at these prices.

b. Certain Manufacturers, such as Eli Lilly, now allow only one contract pharmacy for all our patients. This change means that around 12,000 of our patients will have to travel 4 miles or more in an urban area just to get access to Eli Lilly drugs. Several of our patients depend on public transportation, which puts an added burden on them in accessing drugs, and, during the ongoing pandemic, increases the likelihood that they may contract COVID-19.

c. The 340B Program allows providers to prescribe drugs that are in our patients' clinical best interests. Changing medications for financial—rather than clinical efficacy— reasons creates the potential for harmful and/or unpleasant side effects and contraindications with these new medications.

d. Switching patients' medications also inevitably creates the potential for confusion and medication errors. Many of our patients primarily speak Spanish, rather than English, and some have low literacy levels even in their primary language. It can take months or years for our patients to get used to a particular medication regimen. Rapid, forced changes can cause significant patient harm.

e. Our patients, who are historically and systematically disenfranchised, have not always brought medication cost concerns to our attention. There have been instances in which patients who could not afford their medication simply stopped refilling their

prescriptions. This has happened with diabetic patients, who did not voice cost concerns initially and only came to our attention months later when their blood sugar levels were uncontrolled.

15. The Manufacturers' actions have caused and will cause irreparable harm to Esperanza:

    a. Undercutting the 340B program will severely impact our ability to provide healthcare to our patients without regard to their ability to pay. Of the approximately $2,900,000 in net 340B Program revenue generated in fiscal year ended June 30, 2020, every penny, as required by law, has been invested in medical care and services that expand access for our medically underserved patient population. During the same period, we provided approximately 34,555 uninsured visits at a total cost to Esperanza of around $6,700,000. Our net surplus for the year—which we are also required to use in furtherance of our mission—is only around $550,000, a small amount considering our $25,000,000 budget. Taking away or limiting our ability to participate meaningfully in the 340B program would put us in a deficit of roughly $2,400,000. Such a deficit would be catastrophic to Esperanza and our patients.

    b. The changes have also increased work for our care teams, which have had to scramble to switch patients from one prescription drug to another, and to monitor these patients for potential adverse reactions and medication compliance. If the changes continue we will have to consider adding clinical staff such as nurses merely to deal with an administrative burden unfairly placed upon us by the manufacturers. This will divert critical resources from devoting meaningful clinical care to our underserved patients.

    c. In the case of Eli Lilly, we were notified of the change 3 days after it took effect, which left Esperanza no time to prepare either our care teams or our patients for significant shifts in both prescribed medications and cost.

16. Esperanza has explored alternatives to mitigate the harms described here, but all either fall short of an adequate remedy or are administratively unfeasible:

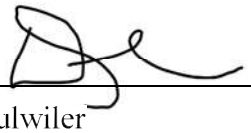
    d. We could theoretically mail drugs to our patients, but there is no way with current staff and resources for Esperanza to process and mail out approximately 59,000 prescriptions a year.

    e. It would take years and significant capital investment to build out our own onsite pharmacies. Our patients cannot wait months, let alone years, to get access to life-saving and life-sustaining medications.

    f. Esperanza could purchase and accept all drugs for our patients and, acting as a wholesaler, distribute the drugs to our contract pharmacies. But such a massive, costly, and logistically complex effort would create no real value for Esperanza, the manufacturers, or our patients.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: November 30, 2020

By: 

Dan Fulwiler
President and CEO, Esperanza Health Centers

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS	)	
PLAINTIFF,	)	
	)	Civil Action No. _____
V.	)	
ALEX M. AZAR II, ET. AL	)	

Declaration of Ronald E. Castle

I, Ronald E. Castle, declare as follows:

1. I am the Chief Executive Officer (CEO) at Community Health Centers of the Central Coast, Inc. (CHCCC) and have held this role since in or around September 1978. As CEO, I am responsible for overseeing 30 health centers and seven mobile dental and medical units. I also oversee our participation in the 340B Drug Pricing Program and, to prepare this declaration, I reviewed CHCCC data relevant to that program and consulted with knowledgeable staff.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. CHCCC is a Federally-qualified health center ("FQHC") operating in California's San Luis Obispo and Northern Santa Barbara counties and funded in part through federal grants made under Section 330 of the Public Health Service Act. CHCCC has been in business since 1978 and is a member of the National Association of Community Health Centers.

4. In 2019, according to our Uniform Data System (UDS) reporting, CHCCC provided primary care services to approximately 111,735 unduplicated patients in approximately 549,173 patient encounters.

5. Also, according to that report, approximately:
   - 52,952 CHCCC patients were at or below 100% of the Federal Poverty Level (FPL)
   - 19,031 were 101–150% below FPL
   - 7,375 were 151–200% below FPL
   - 9,516 were more than 200% below FPL

6. CHCCC special populations include approximately:
   - 32,245 migrant/seasonal patients

- 31,272 patients living in public housing
- 8,877 homeless patients
- 6,797 school-based health center patients
- 2,157 veterans

7. Per that same data, our patients suffer high rates of diabetes mellitus, obesity, hypertension, heart disease and mental health conditions including anxiety disorders, PTSD, depression and mood disorders, and substance use disorders.

8. CHCCC is a "covered entity" for purposes of the 340B Program and has held that status since on or about April 1, 1996. As required, CHCCC recertifies its covered entity status annually with the Health Resources and Services Administration (HRSA). CHCCC's HRSA Office of Pharmacy Affairs has the following information related to CHCCC's covered entity status:

   Grant Number: H80CS00621
   Site ID Number: BPS-H80-002350
   Employer ID Number: 953253302 340BID: CH090710
   Participating: True
   Date: 4/1/1996
   Last Recertification Date: 1/27/2020
   Entity Name: Community Health Centers of the Central Coast, Inc. Entity Sub-Division Name: Nipomo Community Medical Center

9. CHCCC passes on its 340B savings to its patients. Uninsured CHCCC patients making less than 200% of the FPL qualify for a sliding scale discount on all our services, including significant discounts for medications.

10. CHCCC makes drugs purchased at 340B discount pricing available to its patients in three ways: through clinic administered drugs, in-house pharmacy dispensed prescriptions (including by mail and courier delivery), and via seventy-five contracted pharmacies that dispense drugs to eligible CHCCC patients on CHCCC's behalf. A list of pharmacies with which CHCCC has contractual relationships for the dispensing of 340B drugs to eligible CHCCC patients is attached as Exhibit A.

11. Third-party administrators (TPAs) largely manage the logistics of our day-to-day participation in the 340B Program. Our contract pharmacy partners use their own inventory for 340B eligible fills, and third-party administrators tally 340B accumulations and automatically trigger drug orders from the appropriate wholesaler to replenish their inventory whenever a full package size of a particular drug has been used. The cost of the 340B purchases are billed to CHCCC and the drugs are shipped to the contract pharmacies.

12. CHCCC is responsible for and ensures program compliance in part through daily self-audits of prescription claims and drug purchasing records.

13. From in or about January 1, 2020 to in or about September 30, 2020, CHCCC's in-house Pharmacy filled approximately 53,834 prescriptions; of that number, about 28,657

prescriptions were for filled for uninsured patients. CHCCC's contract pharmacies filled over 500,000 prescriptions during that period.

14. CHCCC's relationships with its contract pharmacies significantly expand our patients' access to the medications they need.

15. CHCCC's 30 clinics and 7 mobile units span a service area of nearly 110 miles across California's Central Coast. Our in-house pharmacy is located at roughly the midway point between all clinics and mobile units, which makes it difficult for patients at each extreme of our service area to reach.

16. A large population of our patients are working, low-income individuals. Many work late and are only able to pick up their medications either after hours or on weekends. Many do not have transportation and can only fill their prescriptions at a pharmacy within walking distance. Our contract pharmacies meet these patients' needs.

17. Our contract pharmacy relationships also allow CHCCC to retain more savings and generate revenue on eligible claims billed to appropriate third-party payers.

18. CHCCC estimates 340B savings generated from contract pharmacies account for about 20% of our direct patient care staffing expenses.

19. 340B-generated savings and revenue also fund expanded patient services—including, but not limited to, patient transportation to appointments, a Navigation Center to assist with patient calls, centralized referral capabilities, and health educations programs—as well as in-house outreach staff, case managers, care coordinators, referral staff, call center staff, and pharmacy technicians. These types of services are crucial to patient health but generally non-billable/non-reimbursable.

20. Beginning in or around August 17, 2020, I became aware that certain drug manufacturers, including Eli Lilly, Sanofi, Novartis, and AstraZeneca, had unilaterally decided, without government approval, to cease providing outpatient prescription drugs at 340B prices to all of CHCCC's contract pharmacies. Sanofi conditioned continued shipment of 340B priced drugs to our contract pharmacies on our participation in burdensome reporting via a platform called 340B ESP. CHCCC decided not to enroll in 340B ESP.

21. As of this writing, CHCCC has been blocked from purchasing Eli Lilly, Sanofi, and AstraZeneca drugs at 340B pricing where those drugs would be dispensed via contract pharmacies. Novartis has not yet followed through on blocking 340B prices at contract pharmacies.

22. Although we are doing our very best, despite these changes, to meet our most vulnerable patients' pharmaceutical needs—including by mailing prescriptions and using a courier service to deliver prescriptions to our clinic sites and even to patients' homes—we cannot absorb the cost of these changes indefinitely while losing 340B-related program income.

23. Because of the drug manufacturers' actions, CHCCC patient services and programs such as our call center, referral center, case management services, pharmacy technicians, care

coordinators, in-house behavioral services, and dental services are at risk of being significantly reduced or eliminated.

24. Such reductions put our patients' access to care at risk, which can threaten patient health and potentially increase health care costs to the entire primary care medical home health care system.

25. In addition to loss of services, higher costs, poorer patient outcomes, and loss of employee positions, losing contract pharmacy 340B savings would negatively impact our strategic plans for a much needed facility expansion within the next five years aimed at increasing our ability to serve more of the uninsured and underinsured population in our service area.

26. The result of the drug manufacturers' refusal to supply drugs at required 340B pricing is a dismantling of the safety net that is so needed and which we worked so hard to build.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed On December 2, 2020

By: _____
Ronald E. Castle
Chief Executive Officer, Community Health Centers of the Central Coast, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS PLAINTIFF, V. ALEX M. AZAR II, ET. AL	)	Civil Action No. 1:20-cv-03032

Declaration of Timothy E. Starkey

I, Timothy E. Starkey, declare as follows:

1. I am Chief Executive Officer (CEO) at Great Salt Plains Health Center, Inc. (GSP Health) and have held this role since April 2008. As CEO, I oversee all patient care. In the normal course of my job I have access to financial and clinical records for our 340B Drug Pricing Program (340B Program) as well as agreements with our contract pharmacies. To prepare this declaration, I reviewed internal patient and prescribing data including information related to prescribing and billing for patients receiving 340B drugs from our contract pharmacies.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. GSP Health is a Federally-qualified health center (FQHC) that receives federal grant funds under Section 330 of the Public Health Service Act to provide health care and related services in Northwestern Oklahoma regardless of patient insurance status or ability to pay. Our records indicate that in 2019 we served 10,690 patients through 37,018 encounters.

4. GSP Health has been in operation since 2008, serves most of northwestern Oklahoma with four rural FQHC sites, and is the only FQHC in all of Northwestern Oklahoma.

5. Approximately 61% of our patients are below 200% of Federal Poverty Level and receive discounted services. About 25% of our patients are uninsured and have absolutely no way to pay for services or prescription medications.

6. GSP Health is a "covered entity" for purposes of the 340B Program. GSP Health received its "covered entity" status after registration with and approval by the Health Resources and Services Administration's Office of Pharmacy Affairs (HRSA OPA) in 2008. GSP Health is required to recertify annually with OPA and has done so every year since 2008. Attached as Exhibit A is a copy of our OPA registration records for 2020.

7. The 340B Program allows GSP Health to purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount. We use both McKesson and Amerisource Bergen for wholesalers.

8. As a covered entity, GSP Health is permitted to choose how it will deliver pharmacy services to its patients. We deliver pharmacy services to our patients through contracts with seven local retail pharmacies located throughout our service area. In every case, we have a written agreement with the local pharmacy outlining the relationship. Some of these agreements date back to 2008 when GSP Health began seeing patients. HRSA OPA approved each of these arrangements before services commenced.

9. GSP Health opted to contract with local pharmacies rather than to establish an internal pharmacy for several reasons. GSP Health clinics are located in mostly rural communities with limited infrastructure and public services. The local pharmacies with which we contract provide the best possible services to our patients in return for a minimal fee for processing our prescriptions. Additionally, GSP Health does not have to cover overhead costs associated with establishing and maintaining a pharmacy, including labor costs for highly compensated pharmacist employees. This leaves more dollars within the health center budget to provide more services to our patients.

10. GSP Health works with a third-party administrator (TPA) who carefully monitors all 340B prescription transactions utilizing data from (1) the pharmacy and (2) GSP Health's Electronic Medical Records system. The TPA identifies GSP Health patients, determines patient and prescription eligibility for 340B pricing, and informs the pharmacy how much to collect from self-pay patients based on GSP Health's sliding fee scale. The pharmacy collects a small fee per prescription dispensed and remits any remaining prescription fees to GSP Health on a regular basis. The TPA also determines when inventory needs to be replenished and places corresponding drug orders with our wholesalers, who bill associated costs to GSP Health.

11. Our TPA is responsible, in exchange for a monthly fee, for ensuring compliance with all 340B rules. Additionally, GSP Health regularly audits claims to ensure compliance.

12. With our 340B savings, we are able to provide affordable medications to all of our patients regardless of their ability to pay or insurance status. We put revenue received from insurance companies for prescriptions we purchase at 340B discount pricing toward hiring more medical providers and behavioral health providers to treat more low-income patients.

13. GSP Health providers annually write more than 42,000 prescriptions for our patients. The estimated savings and revenue generated through 340B discounts is more than $1 million annually, all of which is used in furtherance of GSP Health's mission and for the benefit of GSP Health patients.

14. During 2019, GSP Health purchased approximately 42,756 drug doses through the 340B Program for a total expenditure of approximately $293,315. In particular, we provide large

quantities of inhalers for our respiratory patients through the program. For most of these patients, inhalers keep them alive and functioning and would otherwise be very expensive, and thus unaffordable, to many of our patients.

15. I recently became aware that certain drug manufacturers, including Eli Lilly, Sanofi, and others, had unilaterally decided, without government approval, to cease providing outpatient prescription drugs at 340B prices to most or all of our contract pharmacies.

16. Because of these actions, GSP Health patients will be denied access to medications that are critical to their survival, such as rescue inhalers, blood pressure medications, and insulin. Still other patients will decide not to purchase their medications due to increased costs at a time when there are intense economic pressures on the community we serve and some patients are forced to choose between food and medications.

17. Because of this action, GSP Health will likely lose nearly $1 million annually, which will necessarily result in cuts to services for all our patients. The amount we project we will lose is roughly 10% of our total annual budget.

18. To absorb this loss, we anticipate having to make drastic cuts to dental and mental health and reductions of medical providers and their staffs. At this time it appears we will have to eliminate at least two provider positions. These providers, like all our providers, are currently treating low-income, uninsured patients who are in need of care and have no other options.

19. We have no realistic alternative to meeting our patients' prescription needs outside of our contract pharmacy network.

20. GSP Health is not currently licensed to provide in-house pharmacy services and does not employ pharmacists. Our facilities are not built to provide a secure location for storing and distributing drugs. Our budget cannot accommodate a pharmacist at each of our sites during all of the hours we are serving patients.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on 12/3/20

By _____
Timothy E. Starkey
Chief Executive Officer, Great Salt Plains Health Center, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS	)	
PLAINTIFF,	)	
V.	)	Civil Action No. 1:20-cv-03032
ALEX M. AZAR II, ET. AL	)	

Declaration of David Steven Taylor

I, David Steven Taylor, declare as follows:

1. I am the Director of Pharmacy Operations for Appalachian Mountain Community Health Centers (Appalachian Mountain) in western North Carolina, and have held this position since September 2018. As Director of Pharmacy Operations, I am responsible, among other duties, for overseeing Appalachian Mountain's 340B program participation, our Hepatitis Treatment program, and many aspects of our Outpatient Based Opioid Therapy.

2. I have personal knowledge of all facts stated in this declaration, and if called to testify, I could and would testify truthfully thereto.

3. Appalachian Mountain, a member of the National Association of Community Health Centers, is a Federally-qualified health center that receives federal grant funds under Section 330 of the Public Health Service Act to provide health care and related services to a medically underserved population in a mixed urban and rural six-county area of roughly 2,916 square miles, much of which is deep in the Appalachian Mountains. As required, we provide our care and services regardless of patient insurance status or ability to pay.

4. In 2019, we served over 12,000 unduplicated patients at our six clinic locations.

5. Our overall uninsured patient count tops 2,000, or about 20% of our patient population, depending on the month. We treat over 1,000 patients with some form of substance use disorder, and this patient population is growing rapidly. Our more urban clinics currently serve just under 1,000 homeless and completely indigent patients.

6. Appalachian Mountain is a "covered entity" for purposes of the 340B Program.

7. The 340B Program allows Appalachian Mountain to purchase outpatient prescription drugs from manufacturers or wholesalers at a significant discount.

8. As a covered entity, Appalachian Mountain is permitted to choose how it will deliver pharmacy services to its patients. We have a single in-house pharmacy located in Robbinsville, North Carolina, which, due to its size, is only able to service the patients of that particular clinic.

9. Additionally, we use a network of over 20 community partner pharmacies to provide care for Appalachian Mountain patients seen at our other five clinics. Each one of these partnerships was created with the execution of a unique contract that lays out the terms agreed upon by both parties, including the manner in which the avoidance of duplicate discounts and diversion will be accomplished (as required by statute). Each contract is also certified and enrolled via the Health Resources and Services Administration (HRSA) OPAIS web portal.

10. Our contract pharmacy relationships are absolutely necessary to our patients. It would be highly unreasonable to ask our patients in Asheville or those who are homeless to drive to our in-house pharmacy roughly two hours away to retrieve their medications. It would be equally unreasonable to force single parents working two jobs to find the time to come to a 9-to-5 pharmacy when they could use a Walgreens that is open 24 hours.

11. We currently purchase drugs to be dispensed by our contract pharmacies from three wholesalers: Amerisource Bergen, McKesson, and Smith Drug. The primary drive for determining which wholesaler to use is the established relationship of the contract pharmacy in question. By using the pharmacy's primary wholesaler, we ensure cohesiveness between all parties.

12. These relationships are managed with the utmost attention to detail and always keeping in mind the intended goal of expanding care. Our wholesalers create separate 340B accounts for each pharmacy and establish individual "ship-to, bill-to" arrangements under which medications sent to each pharmacy are owned by Appalachian Mountain and are audited every two weeks to ensure that 340B medications have only been used for eligible patients and prescriptions, and that the medications have been dispensed in a way that avoids duplicate Medicaid discounts. The contracted pharmacy provides these medications to our patients often at a highly discounted rate—sometimes at only 1–2% of the medication's wholesale value—while only charging a nominal dispensing fee.

13. Appalachian Mountain's participation in the 340B Program helps it to stretch scarce resources and meet the needs of its medically underserved patients, including uninsured and underinsured patients. Through participation in the 340B program, we have established avenues through which our patients can get ultra-low cost and even free medications.

14. We have also used our 340B savings to expand numerous services within our community: we have hired staff for community outreach who build bridges to access for care; provided a fleet to take homeless patients to and from appointments and to pick up their medications; hired behavioral health staff and embedded them in each of our clinics; expanded access to Outpatient Based Opioid Treatment to each of our clinics; and overall created a place where those less fortunate in our community can come to get care that is equal to or better than the care provided by anyone else.

15. Appalachian Mountain processes over 38,000 out-patient medications a year under the 340B Program, many of which would not be affordable to our patients were it not for the discount pricing that is extended to us under the statute. These include, but are not limited to, medications necessary to treat hepatitis, diabetes, behavioral health diagnoses, and cardiac conditions, as well as addiction treatment medicines.

16. Appalachian Mountain currently purchases over $100,000 a month in 340B medications, which results in over $250,000 in net 340B savings at a margin of between 64% and 70%. Just under half of these purchases are dispensed to patients through our contract pharmacy relationships. We do our best to utilize our in-house services when possible, but we should not be required to do so at the expense of our patient's care.

17. Beginning on or about August 15, 2020, I became aware that certain drug manufacturers, including AstraZeneca, Eli Lilly, and Sanofi, would no longer provide outpatient prescription drugs at 340B prices to most or all of Appalachian Mountain's contract pharmacies.

18. After only a few short weeks, I saw first-hand the extent to which the actions taken by these drug manufacturers caused irreparable harm to our patient population. For example:

- Numerous patients who live miles away from our offices have already gone without insulin because when they arrived at the pharmacy, instead of a $20 out of pocket cost they were met with a $285 cost.
- Individuals who were on Farxiga, an AstraZeneca drug used in the treatment of diabetes, cannot always be switched to Invokana (a similar medication produced by Janssen Pharmaceuticals, Inc.) due to certain comorbidities, so they are forced to take an inferior class of medication altogether.
- Patients who were taking Lantus, a Sanofi insulin medication used in the treatment of diabetes, are having to be switched to the only remaining affordable, long-acting insulin, Levemir, which is an inferior molecule and requires 2 shots a day versus just one with Lantus. With such a switch, not only is the patient inconvenienced with twice as many shots per day, he or she now also must purchase twice as many lancets for use.
- Having to travel long distances for medications that are needed acutely puts an unneeded strain on a population that already struggles to simply afford medication, let alone transportation costs.

19. Our attempts to switch patients to alternate medications create an ethical (as well as practical/logistical) dilemma. Our providers want our patients to be on the drug that is best-suited to treat their current disease state, not on whatever medication is left over after multibillion-dollar companies disassemble the 340B statute.

20. Since its initial announcement, AstraZeneca has walked back its position, allowing some health centers to designate one contract pharmacy location for each health center site that does not already have an in-house pharmacy. Appalachian Mountain applied for this exception on or about November 11, 2020, using an AstraZeneca form. This process was not straightforward—AstraZeneca was not clear about which covered entities or sites would qualify—but Appalachian Mountain received notice on or about November 17, 2020 that AstraZeneca had approved its application retroactive to October 1, 2020. On or about

November 24, 2020 pricing for the contract pharmacies selected was updated within our wholesaler ordering platform. Although this is an improvement, it does not restore access to all of our contract pharmacies.

21. The actions taken by these drug manufacturers have caused and will continue to cause irreparable harm to our health center, which in turn harms our patients. Between September 1, 2020 and October 1, 2020, we lost just under 4% of our 340B savings due to Eli Lilly's actions alone. After reviewing September and October data, we project that because of the drug manufacturers' actions, we will lose approximately 7–8% of 340B revenue, or approximately $250,000 over the next year. That figure assumes that no additional manufacturers limit our access to 340B pricing.

22. The money we have lost and will lose has been used to fill gaps in programs for our most vulnerable patients. As described above, among other patient-focused uses, this money is used to provide transportation to individuals without vehicles and to pay for medications for those without sufficient income.

23. Additionally, finding a way to fit scores of patients into a full schedule for additional visits to consult on medication alterations without being able to bill for those visits is a near impossibility.

24. If the actions taken by drug manufacturers are not reversed, our ability to be the safety net provider in our community—our very mission and the reason we receive federal grant funds—will be diminished. I am concerned we will be reduced to nothing more than an Urgent Care facility, and that we will lose our ability to provide affordable medications to patient who need them.

25. Our efforts to mitigate the harm done by these manufacturers unfortunately have fallen, and will continue to fall, short of the mark. We could establish a mail order pharmacy, but this would take almost a year to set up and we would still be left with no solution for highly indigent Appalachian Mountain patients and those experiencing homelessness.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on: 12-3-2020

By: _____
David Steven Taylor
Director of Pharmacy Operations,
Appalachian Mountain Community Health Centers

Office of Pharmacy Affairs Health Resources and Services Administration
Attn: Deputy Director Herzog
5600 Fishers Lane
Rockville, MD 20857

Dear Deputy Director Herzog,

I am writing to inform you that Sanofi is launching a 340B program integrity initiative effective October 1, 2020 to address duplicate Medicaid and commercial rebates on Sanofi products. As you know, pharmaceutical manufacturers are statutorily prohibited from paying Medicaid rebates on drugs purchased at the 340B price. While manufacturers may adopt contract language that disallows commercial rebate payments for drugs that have already received a discount through a federal program such as Medicaid, Tricare, the Federal Supply Schedule or the 340B program, Sanofi requires claims level detail in order to more effectively address duplicate discounts.

Sanofi supports the 340B Program's core objective of increasing access to outpatient drugs among uninsured and vulnerable patients and is committed to maintaining and strengthening its mission. Part of this commitment means ensuring 340B program integrity remains a shared objective of pharmaceutical manufacturers, covered entities and Health Resources and Services Administration (HRSA). Sanofi is very concerned with the continued high rate of duplicate Medicaid rebates in HRSA audits. Despite HRSA not auditing for duplicate Medicaid rebates attributable to managed Medicaid utilization, over 30% of audits still identified duplicate Medicaid rebates in 2018 and 2019. This rate of non-compliance by 340B covered entities is not sustainable and threatens to undermine the mission of the 340B program.

To address the issue of duplicate discounts on 340B purchased drugs, Sanofi is implementing 340B ESP™, a Second Sight Solutions technology. Prior to October 1, 2020, covered entities will need to register with 340B ESP™ and submit claims level detail on all 340B contract pharmacy utilization in order to be able to be eligible for 340B Bill To / Ship To replenishment orders for Sanofi products dispensed through a contract pharmacy. Sanofi is only requesting data for Sanofi drugs commonly dispensed through retail, specialty and outpatient pharmacies registered on the HRSA database as a contract pharmacy. Physician-administered drugs are not part of this program. Sanofi will continue to offer 340B pricing on all of its products to all 340B covered entities when making purchases for parent and child site locations that are properly registered with HRSA and listed on the covered entity database. Further, Sanofi will exercise flexibility for covered entities who purchase 340B price drugs solely through contract pharmacies, such as grantees. This 340B program integrity initiative is currently focused on contract pharmacy utilization because our research indicates this is where the highest rates of non-compliance exist.

Sanofi welcomes the opportunity to discuss this 340B program integrity initiative further with HRSA. We support the 340B program and believe this initiative will further strengthen the program and support its mission. Therefore, we would appreciate HRSA posting this letter to its website.

Sincerely,

Gerald Gleeson
VP & Head, Sanofi US Market Access Shared Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

August 26, 2020

Mr. Derek L. Asay
Senior Director, Government Strategy
Lilly USA, LLC
Lilly Corporate Center
893 Delaware St
Indianapolis, Indiana 46285

Dear Mr. Asay:

This is in response to your letters of May 18, 2020, and August 19, 2020. In your May 18 letter, you indicated the Lilly USA ("Lilly") would cease selling the drug Cialis at the section 340B ceiling price to pharmacies operating under contract with a covered entity unless the covered entity lacked an in-house pharmacy, in which case Lilly would offer the ceiling price to one contract pharmacy. In your August 19 letter, you indicated that Lilly was planning to extend this policy to all of its drugs.

HRSA is considering whether your new proposed policy constitutes a violation of section 340B and whether sanctions apply. Those sanctions could include, but are not limited to, civil monetary penalties pursuant to 42 U.S.C. § 256b(d)(1)(B)(vi).

Lilly claims that HRSA concluded that Lilly's plan "did not give rise to any enforceable violation of the 340B statute." That is not correct. In fact, in HRSA's response letter dated June 11, 2020, HRSA expressed its concern that the plan would undermine the entire 340B Program and the Congressional intent behind enactment of the 340B statute. HRSA encouraged Lilly to reconsider its decision to restrict access to 340B drugs and HRSA warned Lilly of the plan's impact on underserved and vulnerable populations.

Under 42 U.S.C. § 256b(a)(1), manufacturers must offer covered entities outpatient drugs at specified prices. HRSA continues to examine whether Lilly's actions amount to attempts to circumvent that statutory requirement by inappropriately restricting access to 340B drugs for at least some covered entities.

We understand that Lilly's rationale is its concern that distribution to contract pharmacies can lead to duplicate discounts and diversion. To the extent that Lilly has evidence of specific duplicate-discount and diversion violations, please share that evidence, including the alleged covered entities and drugs involved.

HRSA will respond to your other requests as quickly as possible. However, given the urgent demands of the COVID-19 pandemic and other demands, HRSA may not be in a position to respond by your requested date.

Sincerely,

Krista M. Pedley, PharmD, MS
RADM, USPHS
Assistant Surgeon General
Director, Office of Pharmacy Affairs
Health Resources and Services Administration

August 26, 2020

The Honorable Alex M. Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

On behalf of the nation's 340B hospitals, we urge you to protect vulnerable communities from actions taken by five of the nation's largest pharmaceutical manufacturers that undermine access to critical drugs and other health care services. We ask the Department of Health and Human Services (HHS) to use its authority to require that these and other pharmaceutical manufacturers comply with the law. This is particularly critical now as these hospitals need every resource available to care for their patients in vulnerable communities during the COVID-19 public health crisis.

So far, a number of companies are complicit with these unlawful tactics:

Eli Lilly

Last month, Eli Lilly announced that effective July 1, 2020, the company will no longer provide 340B pricing on three of its products when purchased by 340B hospitals to be dispensed by 340B contract pharmacies.[1] This refusal to sell a drug at a 340B price is a violation of the statute's requirement that manufacturers offer 340B prices to eligible covered entities. Eli Lilly has left open the possibility that it will extend this policy to other drugs, which include several high-priced drugs to treat diabetes.

AstraZeneca

The drug manufacturer AstraZeneca recently announced that, starting October 1, 2020, it will no longer offer 340B pricing to covered entities for any drugs that will be dispensed through contract pharmacies. AstraZeneca sells a wide range of products eligible for 340B pricing, including many costly cancer and diabetes drugs that do not have lower-priced generic alternatives. Cutting off access to 340B pricing for these expensive products would significantly reduce hospital access to program savings, affecting their ability to provide services to patients.

[1] Limited Distribution Plan Notice for Cialis® (tadalafil) Erectile Dysfunction NDCs, https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-plan-notice-cialis.pdf.

Section 340B(a)(1) of the Public Health Services Act requires manufacturers to sell covered outpatient drugs to covered entities at or below the 340B ceiling price if such drug is made available to any other purchaser at any price.[2] There is no provision under the statute that allows these companies to deny 340B pricing to a covered entity for any drug. Therefore, these policies are a clear violation of the law, and HHS is compelled to take action to stop it from being carried out.

Merck

On June 29, Merck sent letters to 340B covered entities asking them to submit contract pharmacy claims data for "commonly dispensed" Merck drugs to allow the company to prevent duplicate discounts related to contract pharmacies. Without "significant cooperation" from covered entities, Merck says it "may take further action to address 340B Program integrity." While Merck did not state that such action would include no longer offering 340B pricing to covered entities for drugs dispensed by contract pharmacies, we are concerned the company appears poised to do so.

Sanofi

The drug manufacturer Sanofi sent letters last month similar to those sent by Merck threatening to deprive 340B covered entities' access to discounted drugs for dispensing through contract pharmacies if the claims data demanded are not supplied to the company by October 1.

Novartis

In a similar manner, Novartis recently sent letters to 340B covered entities requiring them to submit all 340B claims data originating from contract pharmacies beginning October 1, stating that 340B discounts will be unavailable to entities that fail to do so.

As you are aware, Congress created the 340B drug pricing program to allow hospitals and other covered entities serving vulnerable populations "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[3] Covered entities use the savings from the high prices of prescription drugs enabled under the 340B drug program to support care for vulnerable communities in a variety of ways, including supporting clinic and medical services that would otherwise be unavailable.

If left unaddressed, these actions will open the way for other drug manufacturers to deny discounts for other products. This is clearly contrary to the intent of the 340B program

[2] 42 U.S.C. § 256b(a)(1).
[3] H.R. Rep. 102-384(II) at 12 (1992).

and will result in significant harm to the millions of patients and communities who rely on providers that participate in the program for their care.

At a time when our nation and our hospitals are focused on confronting the global pandemic of COVID-19 and dealing with the continuing increase in prescription drug costs, we urge the Department to use its authority to address these troubling actions and assure that the pharmaceutical industry does not prioritize excess profits over care for vulnerable communities. We thank you for your continued leadership.

Sincerely,

340B Health
America's Essential Hospitals
American Hospital Association
American Society of Health-System Pharmacists
Association of American Medical Colleges
Catholic Health Association
Children's Hospital Association

cc: Eric D. Hargan, Deputy Secretary, Department of Health and Human Services
Thomas J. Engels, Administrator, Health Resources and Services Administration
Krista Pedley, Director, Office of Pharmacy Affairs, Health Resources and Services Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration
Office of Pharmacy Affairs

Rockville, MD 20857

September 2, 2020

Christie Bloomquist
Vice President Corporate Affairs, North America
AstraZeneca Pharmaceuticals, LP
701 Pennsylvania Avenue NW #500
Washington, DC 20004

Dear Ms. Bloomquist:

This in response to your July 24, 2020 correspondence regarding contract pharmacies in the 340B Drug Pricing Program (340B Program). Your letter states that beginning October 1, 2020, AstraZeneca Pharmaceuticals, LP (AstraZeneca) will recognize only one contract pharmacy arrangement per covered entity site for covered entities that do not maintain an on-site pharmacy for certain drug products.

Under 42 U.S.C. §256b(a)(1), manufacturers must offer covered entities outpatient drugs at specified prices. HRSA is considering whether AstraZeneca's proposed policy constitutes a violation of the 340B statute and whether sanctions would apply. Those sanctions could include, but are not limited to, civil monetary penalties pursuant to section 340B(d)(1)(B)(vi) of the Public Health Service Act.

We understand that AstraZeneca's rationale is its concern that distribution to contract pharmacies can lead to duplicate discounts and diversion. To the extent that AstraZeneca has any evidence of specific duplicate discount and diversion violations, please share that evidence, including the alleged covered entities and drugs involved.

Contract pharmacies, which are only a mode for dispensing 340B drugs and not independent covered entities, serve a vital function in covered entities' ability to serve underserved and vulnerable populations. Many health centers, and other safety net organizations receiving HRSA grants are able to participate in the 340B Program only through a contract pharmacy, and having multiple contract pharmacy arrangements allows them to reach to the patients they serve. In addition, certain covered entities serve communities where patients must travel great distances for health care services. In order to encourage medication adherence, these covered entities often contract with pharmacies that are closer to where their patients reside. AstraZeneca's policy could have the effect of severely limiting access for underserved and vulnerable populations served by these covered entities' access to 340B discounted drugs. This result would undermine

the 340B Program and the Congressional intent behind enactment of the 340B statute.[1] Even for those covered entities with in-house pharmacies, AstraZeneca's position to limit contract pharmacy orders would have the effect of significantly limiting access to 340B discounted drugs for many underserved and vulnerable populations who may reside in geographically isolated areas and rely on a contract pharmacy to obtain their prescriptions.

AstraZeneca's limitation of the number of contract pharmacies a covered entity can use to obtain 340B discounts would significantly harm the nation's safety net, especially at a time when the health care community is under great pressure to address the current COVID-19 pandemic and maintain general public health, often in limited in-person settings.

AstraZeneca indicated in its letter that it considers its letter to be "confidential and proprietary not subject to release or disclosure under FOIA or otherwise." HRSA fails to see any confidential or proprietary information in the letter. If AstraZeneca believes that portions of its correspondence are confidential or proprietary, please respond by September 30 with an explanation and reference to the specific portions of the letter that AstraZeneca believes are confidential and proprietary.

As HRSA continues to evaluate this issue, it will not be posting AstraZeneca's "Notice to Covered Entities Regarding 340B Pricing" until this matter is resolved. If you have any further questions, please feel free to contact me. Thank you for your interest in the 340B Program.

Sincerely,

Krista M. Pedley

Krista M. Pedley, PharmD, MS
RADM, USPHS
Assistant Surgeon General
Director, Office of Pharmacy Affairs

[1] The intent of the 340B Program is to permit covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. (See: H.R. REP No. 102-384(II), at 12 (1992) (Conf. Report)).

From: Pedley, Krista (HRSA)
To: Burgess, William (HHS/OGC); Kurland, Pamela (HHS/OGC); Hargrove, Sherine (HHS/OGC)
Cc: Britton, Chantelle (HRSA); Zadecky, Julie (HRSA); Hardin, Josh (HRSA); Herzog, Michelle (HRSA)
Subject: FW: Novartis Pharmaceuticals Corporation's Revised Contract Pharmacy Policy
Date: Friday, November 13, 2020 12:45:42 PM
Attachments: image001.png
image002.png
image003.png
image004.png
image005.png
image006.png
image007.png
Novartis - HRSA Letter - Execution.pdf

FYI – Please share with your chain. Thanks.

Krista M. Pedley, PharmD, MS
RADM, USPHS
Assistant Surgeon General
Director, Office of Pharmacy Affairs
301-443-5294

HRSA Logo

Sign up for email updates!

From: Lopuch, Daniel <daniel.lopuch@novartis.com>
Sent: Friday, November 13, 2020 12:38 PM
To: Pedley, Krista (HRSA) <KPedley@hrsa.gov>
Cc: Herzog, Michelle (HRSA) <MHerzog@hrsa.gov>
Subject: RE: Novartis Pharmaceuticals Corporation's Revised Contract Pharmacy Policy

Dear Rear Admiral Pedley:

As mentioned in our note to you on October 30, I am sending the attached letter which more fully sets forth the legal background for our policy change with regard to contract pharmacies.

Sincerely,

Dan Lopuch

Dan Lopuch
Managed Markets Finance
Novartis Pharmaceuticals Corp.
One Health Plaza – 135/4110F
East Hanover, NJ 07936

Daniel.Lopuch@Novartis.com
Work – (862)778-1590

From: Pedley, Krista (HRSA) <KPedley@hrsa.gov>
Sent: Monday, November 2, 2020 11:18 AM
To: Lopuch, Daniel <daniel.lopuch@novartis.com>
Cc: Herzog, Michelle (HRSA) <MHerzog@hrsa.gov>
Subject: RE: Novartis Pharmaceuticals Corporation's Revised Contract Pharmacy Policy

Thank you. We are in process of reviewing the information provided.

Krista M. Pedley, PharmD, MS
RADM, USPHS
Assistant Surgeon General
Director, Office of Pharmacy Affairs
ph: 301-443-5294
kpedley@hrsa.gov

HRSA Logo

Sign up for email updates!

From: Lopuch, Daniel <daniel.lopuch@novartis.com>
Sent: Friday, October 30, 2020 12:03 PM
To: Pedley, Krista (HRSA) <KPedley@hrsa.gov>
Subject: Novartis Pharmaceuticals Corporation's Revised Contract Pharmacy Policy

Dear Rear Admiral Pedley:

Novartis Pharmaceuticals Corporation (Novartis) takes seriously its obligations under the 340B Drug Pricing Program (340B program), and fully supports the mission of the program to serve uninsured and other vulnerable patients. Novartis believes, however, that the exponential

growth of hospital covered entity contract pharmacy arrangements over the last decade threatens that mission by exacerbating systemic program compliance concerns. This is a particularly pressing issue when contract pharmacies are located great distances from the covered entity, sometimes hundreds or thousands of miles away, and therefore are not serving the vulnerable patients in the covered entity hospital's community.

Therefore, Novartis is announcing today a focused approach that uses common-sense criteria to address concerns under the current contract pharmacy model:

- Hospital Covered Entities—Beginning November 16, 2020, Novartis will continue to honor hospital contract pharmacy arrangements with respect to all Novartis Pharmaceuticals Corporation products so long as the contract pharmacy is located within a 40-mile radius of the hospital. This policy will not restrict the number of contract pharmacies that a hospital may establish within its own community (as defined by the 40-mile radius).
    - Novartis will decline contract pharmacy orders at the 340B price where the contract pharmacy is located outside the 40-mile radius and have not been provided an exemption; Novartis will not convert such orders to commercial orders.
    - If any special circumstances arise with respect to a hospital covered entity and its contract pharmacies, such as if it is determined that this policy has an undue impact on a rural hospital due to geographical limitations, Novartis will work with the affected institution to ensure that its patients have continued access to Novartis drugs.
- Federal Grantee Covered Entities— All federal grantee covered entities are exempt from the new policy, and these covered entities may continue to acquire 340B product through contract pharmacy arrangements exactly as before.

Importantly, this new policy will not harm patients' ability to access their medicines; it will help to ensure that 340B program benefits flow to patients in the community the hospital covered entity serves. In support of the program's mission—and our commitment to strengthen the health care system more broadly—this focused approach aims to align 340B utilization with its intended purpose, by encouraging more appropriate 340B utilization by hospital covered entities.

Novartis believes this approach is fully consistent with the 340B statute, the implementing regulation, and Novartis's obligations under the Pharmaceutical Pricing Agreement. Novartis intends to promptly provide a letter to HRSA that will more fully set forth the legal background.

Novartis had previously announced that it would require covered entities to submit contract pharmacy claims data via the Berkeley Research Group 340B ESP™ platform (BRG platform). Novartis continues to encourage all covered entities to voluntarily upload their claims data in an effort to increase transparency, mitigate instances of duplicative discounts, and maintain the integrity and sustainability of this vital program. However, for now, the provision of claims data to the BRG platform will not have any impact on contract pharmacy eligibility.

Please contact me if you have any questions or concerns regarding the foregoing in advance of receiving our more detailed letter.

Sincerely,

Dan Lopuch

Dan Lopuch
Managed Markets Finance
Novartis Pharmaceuticals Corp.
One Health Plaza – 135/4110F
East Hanover, NJ 07936

Novartis Pharmaceuticals
One Health Plaza
East Hanover, NJ 07936

November 13, 2020

BY ELECTRONIC MAIL (Krista.Pedley@hrsa.hhs.gov) AND FEDERAL EXPRESS

Rear Admiral Krista M. Pedley, PharmD, MS, USPHS
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, Mail Stop 08W05A
Rockville, MD 20857

Re: Novartis Pharmaceuticals Corporation 340B Contract Pharmacy Policy

Dear Rear Admiral Pedley:

I am writing on behalf of Novartis Pharmaceuticals Corporation ("Novartis") in follow-up to our communication on August 17, 2020. We wish to disclose to the Health Resources and Services Administration ("HRSA") new steps that Novartis is taking as part of its 340B Drug Pricing Program ("340B program") integrity initiative. After careful consideration, we have decided to implement a more focused, criteria-based approach to contract pharmacy arrangements that will start to shift the 340B program back to its intended focus on the patients of covered entities, and thereby put the program on a pathway toward long-term sustainability.

As we had indicated by e-mail to you dated October 30, 2020, and as more fully described below, beginning on November 16, 2020, Novartis will continue to honor hospital contract pharmacy arrangements so long as the contract pharmacy is located within a 40-mile radius of the parent hospital. This policy will not restrict the number of contract pharmacies that a hospital may establish within its own community (as defined by the 40-mile radius). All federal grantee covered entities are exempt from the new policy, and these covered entities may continue to acquire 340B product through contract pharmacy arrangements exactly as before.

I. The Novartis Policy Is Necessary Because the Explosive Growth of Contract Pharmacy Arrangements Has Greatly Exacerbated Ongoing Systemic Program Integrity Concerns

Despite contract pharmacy arrangements having no basis in law, as detailed below, the number of contract pharmacy arrangements by hospitals has grown exponentially, with little evidence that patients are benefiting as a result. These contract pharmacies are often located hundreds or

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even thousands of miles from their associated hospital covered entity and the community that it serves. As explained in a recent study by Berkeley Research Group ("BRG"), "contract pharmacy participation grew 4,228 percent between April 2010 and April 2020," with "more than 27,000 individual pharmacies (almost one out of every three pharmacies)" now participating, and the number of contract pharmacy arrangements by hospitals increasing from 193 to more than 43,000 during this period.[1] Underscoring the profit-driven nature of this growth, the BRG study found that "340B covered entities and their contract pharmacies realized an average 72 percent profit margin on 340B purchased brand medicines," which is "more than three times greater than the average margin realized by independent pharmacies."[2] In a subversion of program intent, the 340B savings generated by this profit margin "are now distributed across a vertically integrated supply chain that includes not just the covered entities but also pharmacies, contract pharmacy administrators, [pharmacy benefit managers], health plans, and employer groups."[3] And, as a result of the complete absence of transparency, it is unclear how much of the 340B program savings is absorbed by these commercial actors.[4]

This explosive growth of contract pharmacy arrangements has greatly exacerbated longstanding systemic 340B program integrity concerns. Indeed, federal agencies have documented this program integrity risk. For example, in 2015, the Department of Health and Human Services Office of Inspector General ("OIG") concluded that "[c]ontract pharmacy arrangements . . . create complications in preventing duplicate discounts."[5] OIG also found that "most covered entities in [the] study do not conduct all of the oversight activities recommended by HRSA . . . . Few covered entities reported retaining independent auditors for their contract pharmacy arrangements as recommended in HRSA guidance. Without adequate oversight, the complications created by the contract pharmacy arrangements may introduce vulnerabilities to the 340B Program."[6] And, in 2018, GAO found that "weaknesses in HRSA's oversight impede its ability to ensure compliance with 340B Program requirements at contract pharmacies," and that "HRSA's audit process does not adequately identify compliance issues, nor does it ensure that identified issues are corrected."[7]

In particular, the explosive growth of contract pharmacy arrangements has significantly increased the inherent risk of non-compliance with the diversion prohibition. By their nature,

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[1] BRG, For-Profit Pharmacy Participation in the 340B Program, at 4 (Oct. 2020), *available at* https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf.

[2] *Id.* at 7.

[3] *Id.*

[4] A recent review by the Government Accountability Office ("GAO") of a comparatively small sample of only thirty contract pharmacy agreements found that, in some cases, the contract pharmacy was entitled to a flat fee of $15 for each prescription, plus twenty percent of the reimbursement for the drug, by both the patient and her payer. GAO, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, No. GAO-18-480, at 51 (Jun. 2018), *available at* https://www.gao.gov/assets/700/692697.pdf.

[5] OIG, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, No. OEI-05-13-00431 at 16 (Feb. 2014) (available at https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf).

[6] *Id.*

[7] GAO, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement, No. GAO-18-480, at 45 (Jun. 2018) (available at https://www.gao.gov/assets/700/692697.pdf).

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contract pharmacy arrangements pose such risk, as it is unknown at the time of the dispensing whether an individual is a patient of the covered entity. This necessitates a retrospective determination, and there is no transparency into whether or how this determination is made. Where a covered entity makes arrangements with pharmacies well outside of its community, this risk of diversion is amplified by orders of magnitude. Simply put, because there is no reasonable proximity between such pharmacies and the covered entity (i.e., where patients of the covered entity obtain services), such pharmacies are highly unlikely to dispense drugs to patients of the covered entity in fact. Thus, such arrangements cannot be squared with the statutory prohibition on diversion – one of the Congressionally established cornerstones of the 340B program that mark its outer boundary.[8]

II. The Novartis Policy's Modest Steps Will Start to Redress the Significant Concerns Posed by the Contract Pharmacy Program

Novartis takes seriously its obligations under the 340B program and remains committed to supporting its core mission – to serve uninsured, low-income, and other vulnerable patients. As set forth below, our intended actions are entirely consistent with this mission, even as they start to redress the well-documented, long-standing, and significant program integrity risks occasioned by the contract pharmacy program in its current form.

Under the Novartis approach, we will continue to honor all contract pharmacy arrangements of all federal grantee covered entities, i.e., there will be no restriction on such arrangements. Federal grantee covered entities are subject to independent requirements that encourage them to share the benefits of the 340B program with their patients.[9] Thus, the unintended financial incentives to maximize 340B utilization in order to maximize profit, potentially at the expense of program integrity, are less pronounced where federal grantee covered entities are concerned.

For hospital covered entities, beginning November 16, 2020, with respect to all Novartis covered outpatient drugs, we will continue to honor contract pharmacy arrangements to the extent that the contract pharmacy is within a 40-mile radius of the hospital. There will not be a limit on the number of contract pharmacies within that radius with which the hospital may have an arrangement. This geographic restriction represents a common-sense approach toward ensuring that the 340B program benefits the hospital's patients, as intended. In adopting the 40-mile radius as a proxy for the community of patients served by the hospital, we were informed by Medicare provider-based policy governing hospitals and affiliated facilities, which generally utilizes a 35-mile radius.[10]

Additionally, if a hospital covered entity were to bring a special circumstance to our attention, e.g., if the hospital were to have no in-house pharmacy and our approach would leave it with no contract pharmacy, we intend to work in good faith with the hospital to ensure appropriate access to a contract pharmacy.

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[8] Public Health Service Act (PHSA) § 340B(a)(5)(B).

[9] *See, e.g.*, PHSA § 330(k)(3)(G)(iii).

[10] *See* 42 C.F.R. § 413.65(e)(3)(i).

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Notably, when Novartis does not recognize a contract pharmacy under its approach, Novartis will not convert a 340B order to a commercial order. Rather, Novartis will simply decline to fill the 340B order, and the hospital will not be charged. In addition, under the Novartis approach, covered entities will not be disadvantaged relative to non-covered entities. That is because Novartis does not have commercial arrangements that are equivalent to 340B contract pharmacy arrangements.

Most importantly, the Novartis policy will not harm patient access to medicines, because the Novartis policy applies to arrangements between covered entities and contract pharmacies, and not to patients. Patients of a covered entity will still be able to obtain 340B-purchased drugs from a contract pharmacy in the community.

Additionally, in the interest of improving transparency and program integrity (by mitigating the risk of duplicate discounts), we are encouraging covered entities to upload all contract pharmacy claims data to the Second Sight Solutions' 340B ESP™ web-based platform. This action is not required, however, and declining to take this action will not have an effect on 340B purchasing through contract pharmacies or otherwise.

Novartis believes that these steps, taken together, are necessary to help ensure the integrity of the 340B program, and therefore protect the sustainability of this critical program.

III. The Novartis Contract Pharmacy Approach Is Fully Consistent With the Law

A. Legal Background

HRSA has issued guidance providing that a covered entity may contract with one or more pharmacies for the purpose of dispensing 340B-purchased drugs to its patients on its behalf.[11] HRSA first issued contract pharmacy guidance in the mid-1990s.[12] After soliciting comment on a proposed notice,[13] HRSA issued a final notice implementing its original contract pharmacy policy.[14] In that 1996 final notice, HRSA stated that it was implementing its policy because, in its view, it would defeat the purpose of the 340B program if a covered entity without an in-house pharmacy could not use an outside pharmacy to dispense 340B-purchased drugs to its patients on its behalf.[15] Accordingly, HRSA provided that a covered entity could use either an in-house

[11] HRSA, *Contract Pharmacy: Important Tips* (Aug. 2016) (available at https://www.hrsa.gov/opa/updates/2016/august.html) ("Covered entities participating in the 340B Program are permitted to use contract pharmacies for the dispensing of 340B drugs, in addition to or in lieu of an in-house pharmacy.").

[12] *See* 75 Fed. Reg. 10,272, 10,272-73 (Mar. 5, 2010) (setting forth the history of HRSA's contract pharmacy guidance).

[13] 60 Fed. Reg. 55,586 (Nov. 1, 1995).

[14] 61 Fed. Reg. 43,549 (Aug. 23, 1996).

[15] *Id.* at 43,550.

pharmacy or, if the covered entity did not have an in-house pharmacy, a single contracted outside pharmacy site.[16]

In issuing the 1996 final notice, HRSA did not expressly state that manufacturers were obligated to honor contract pharmacy arrangements. Nor did HRSA identify any statutory basis for its policy. Rather, the agency stated only that "[t]he statute is silent as to permissible drug distribution systems. There is no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself."[17] It then stated that the 340B statute does not preclude a "[covered] entity direct[ing] the drug shipment to its contract pharmacy."[18] HRSA also stated that, "[a]s a matter of State law, entities possess the right to hire retail pharmacies to act as their agents in providing pharmaceutical care to their patients."[19]

In 2010, HRSA issued a revised notice that significantly expanded its contract pharmacy policy.[20] Under that revised notice, which remains in effect today, covered entities are permitted to use a contracted outside pharmacy, even if they have an in-house pharmacy.[21] In addition, covered entities are permitted to use an unlimited number of contracted outside pharmacy sites, so long as there is a written contract between the covered entity and the pharmacy, and the contract pharmacy meets certain limited compliance and certification requirements.[22]

The 2010 revised notice, like its 1996 predecessor, does not expressly state that manufacturers are obligated to honor contract pharmacy arrangements or identify any statutory basis for the contract pharmacy policy. To the contrary, in responding to a commenter that had argued that a notice-and-comment rulemaking was required to adopt the policy, HRSA explained that it was not required to proceed via such rulemaking because its contract pharmacy policy does not "impose additional burdens upon manufacturers []or create[] any new rights for covered entities under the law."[23]

As discussed above, HRSA's revised contract pharmacy policy has resulted in the rapid growth of contract pharmacy arrangements, with an attendant increase in the risk of program non-compliance.

B. Legal Analysis

Manufacturers are not legally bound to abide by HRSA's contract pharmacy policy, which merely constitutes agency guidance, and not a binding legal standard. The policy appears

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16 *Id.* at 43,551.
17 *Id.* at 43,549.
18 *Id.* at 43,549-50.
19 *Id.* at 43,550.
20 75 Fed. Reg. at 10,277 (HRSA solicited comment on a proposed notice before issuing this revised notice).
21 *Id.* at 10,275 (stating that covered entities "with an in-house pharmacy could use any acceptable contract pharmacy arrangement to supplement the in-house pharmacy").
22 *Id.* at 10,277-78.
23 *Id.* at 10,273. HRSA also failed to provide a convincing rationale for its departure from the 1996 contract pharmacy guidance.

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nowhere in the 340B statute.[24] Moreover, it appears nowhere in any regulation implementing the 340B statute.[25] Rather, the policy is set forth only in guidance which, by its nature, is not legally binding.[26] This is a black letter principle of administrative law, and it is a universally accepted proposition. HRSA itself has correctly acknowledged it – publicly, repeatedly, and recently.[27] Covered entities have recognized it as well.[28]

Notably, HRSA has not only embraced the general notion that guidance is not legally binding, but has specifically acknowledged that this is the case with respect to its contract pharmacy policy.

First, HRSA denominated its contract pharmacy policy issuance as a mere "notice."[29] In addition, HRSA characterized its contract pharmacy policy as a mere "interpretive rule [or] statement of policy."[30] This is significant because an agency's own characterizations are a factor that courts consider in determining whether its policies are legally binding.[31]

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[24] The same holds true with respect to the Pharmaceutical Pricing Agreement (and its addendum) implementing the 340B statute.

[25] Indeed, there could be no such regulation: The 340B statute does not grant HRSA general rulemaking authority, and instead grants HRSA rulemaking authority only with respect to "(1) the establishment of an administrative dispute resolution process, (2) the 'regulatory issuance' of precisely defined standards of methodology for calculation of ceiling prices, and (3) the imposition of monetary civil sanctions." *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 42 (D.D.C. 2014).

[26] *United States v. Mead Corp.*, 533 U.S. 218, 227 (2001) (informal interpretations do not "carry the force of law" and therefore are not entitled to "judicial deference"); *Chrysler Corp. v. Brown*, 441 U.S. 281, 296 & n.31 (1979) (informal interpretations have no power to bind regulated parties because they do not carry the force and effect of law); *Am. Tort Reform Ass'n v. Occupational Health & Safety Admin.*, 738 F.3d 387, 393 (D.C. Cir. 2013) ("When an agency issues an interpretative rule or statement, an interpretative guideline, or a policy statement with respect to a matter that it is not empowered to decide, the interpretative rule, statement, guideline, or policy statement merely informs the public of the agency's views on the subject. It does not, however, create 'adverse effects of a strictly legal kind' because it cannot 'command anyone to do anything or to refrain from doing anything.'") (citing and quoting *Nat'l Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 809 (2003)).

[27] *See also* Executive Order on Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication (Oct. 19, 2019) (available at https://www.whitehouse.gov/presidential-actions/executive-order-promoting-rule-law-transparency-fairness-civil-administrative-enforcement-adjudication/) ("When an agency takes an administrative enforcement action, engages in adjudication, or otherwise makes a determination that has legal consequence for a person, it must establish a violation of law by applying statutes or regulations. The agency may not treat noncompliance with a standard of conduct announced solely in a guidance document as itself a violation of applicable statutes or regulations."); Executive Order on Promoting the Rule of Law Through Improved Agency Guidance Documents (Oct. 9, 2019) (available at https://www.whitehouse.gov/presidential-actions/executive-order-promoting-rule-law-improved-agency-guidance-documents/) ("[G]uidance documents lack the force and effect of law, except as authorized by law or as incorporated into a contract.").

[28] *See Genesis Health Care, Inc. v. Azar*, No. 4:19-cv-1531-RBH (D.S.C.).

[29] 75 Fed. Reg. at 10,272.

[30] *Id.* at 10,273.

[31] *See Molycorp, Inc. v. EPA*, 197 F.3d 543, 545 (D.C. Cir. 1999) ("To determine whether a regulatory action constitutes promulgation of a regulation, we look to three factors: (1) the Agency's own characterization of the action; (2) whether the action was published in the Federal Register or the Code of Federal Regulations; and (3) whether the action has binding effects on private parties or on the agency.").

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Second, HRSA's contract pharmacy policy nowhere expressly states that manufacturers are obligated to honor contract pharmacy arrangements. To the contrary, in issuing the 2010 revised notice, HRSA stated that its contract pharmacy policy does not "impose additional burdens upon manufacturers []or create[] any new rights for covered entities under the law."[32] This is significant because legally binding rules create new obligations or rights.[33] By conceding that its contract pharmacy policy does not do so, HRSA conceded that the policy is not legally binding.

Finally, HRSA has expressly stated that it does not have authority to enforce the policy.[34]

HRSA's acknowledgement that its contract pharmacy policy is not legally binding reflects the fact that the 340B statute nowhere can be read to require a manufacturer to ship a covered outpatient drug purchased by a covered entity to the covered entity's contract pharmacy for dispensing to the covered entity's patient on the covered entity's behalf. There is simply no statutory text supporting the contract pharmacy policy. The statute entitles a covered entity only to purchase a covered outpatient drug from the manufacturer at the 340B price. It in no way suggests that the covered entity is also entitled to dictate to the manufacturer the destination of shipment, particularly if a third party. Rather, so long as the manufacturer ships to a reasonable destination, such as the covered entity itself, the manufacturer cannot be held out of compliance with the statute.

While Novartis is not legally bound to honor contract pharmacy arrangements at all, Novartis currently does not propose to cease to honor contract pharmacy arrangements altogether, notwithstanding the patent abuse engendered by the contract pharmacy expansion. Rather, we are willing to recognize such arrangements within reasonable limits. Thus, we have adopted the revised policy to impose a set of limits that seek to strike a reasonable balance. In short, we will honor contract pharmacy arrangements on the reasonable terms of our approach set forth above.

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[32] 75 Fed. Reg. at 10,273.

[33] *See Chrysler Corp.*, 441 U.S. at 296 & n.31; *Nat'l Min. Ass'n v. McCarthy*, 758 F.3d 243, 252 (D.C. Cir. 2014) (informal interpretations cannot "impose new obligations or prohibitions or requirements on regulated parties"); *Batterton v. Marshall*, 648 F.2d 694, 702 (D.C. Cir. 1980) (unlike a legally binding rule, "[n]on-binding . . . actions or statements are not determinative of issues or rights addressed. They express the agency's intended course of action . . . [or] its tentative view of the meaning of a particular statutory term . . . . They do not, however, foreclose alternate courses of action or conclusively affect rights of private parties.").

[34] Tom Mirga, HRSA Says Its 340B Contract Pharmacy Guidance Is Not Legally Enforceable, 340B Report (Jul. 9, 2020) (available at https://340breport.substack.com/p/hrsa-says-its-340b-contract-pharmacy) (quoting HRSA as stating, "The 2010 [contract pharmacy] guidance is still in effect. However, guidance is not legally enforceable. Regarding the 340B Program's guidance documents, HRSA's current authority to enforce certain 340B policies contained in guidance is limited unless there is a clear violation of the 340B statute. Without comprehensive regulatory authority, HRSA is unable to develop enforceable policy that ensures clarity in program requirements across all the interdependent aspects of the 340B Program.").

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We ask that, if you have any legal concern with the Novartis approach to contract pharmacy arrangements, you communicate such concern to us in writing as soon as possible. If you have any questions about our approach, please contact me at (862) 778-1590 or Daniel.Lopuch@Novartis.com. We would be happy to make time to discuss any questions at your convenience. We look forward to continuing to work together to further strengthen this important program.

Sincerely,

Dan Lopuch
VP, Managed Markets Finance
Novartis Pharmaceuticals Corporation

Notice Regarding Limitation on Hospital Contract Pharmacy Distribution

December 1, 2020

Beginning on January 1, 2021, Novo Nordisk Inc. (labeler codes 00169 and 71090) and Novo Nordisk Pharma, Inc. (labeler code 73070)) (Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. are collectively referred to herein as "Novo Nordisk") will no longer facilitate "bill-to/ship-to" distribution of 340B product to a contract pharmacy of any of the six "hospital" covered entity types.

If a "hospital" covered entity does not have an in-house pharmacy capable of dispensing product to outpatients, that covered entity may designate one contract pharmacy location to which product purchased by that covered entity may be shipped.

A hospital covered entity that does not maintain an on-site pharmacy at either a parent or child location may contact Novo Nordisk at 340BInfo@novonordisk.com to designate a single contract pharmacy location to accept bill-to/ship-to orders.

Novo Nordisk's new policy will not deny access to 340B-priced covered outpatient drugs to any "hospital" covered entity. Each may purchase as much Novo Nordisk product at the discounted 340B price that it wishes. At no time will Novo Nordisk fail to offer 340B prices to each and every 340B covered entity. It is merely the Novo Nordisk-facilitated shipment of that product to contract pharmacies (which are not themselves covered entities) that will be curtailed as of January 1, 2021.

None of the "grantee" covered entity types are impacted by this change in policy. Novo Nordisk will continue to facilitate contract pharmacy "bill-to/ship-to" arrangements for these covered entities. All "grantees," including Community Health Centers, Ryan White HIV Clinics, Hemophilia Treatment Centers, Indian Health Centers, and all other grantee covered entity types, may continue to place orders for Novo Nordisk product and have them shipped to their registered contract pharmacies, without limitation.

Questions about this policy change should be directed to 340BInfo@novonordisk.com .

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Novo Nordisk Inc.
PCOR

800 Scudders Mill Road
Plainsboro, NJ 08536
USA

Telephone:
+1 609-987-5800

E-mail:
340BInfo@novonordisk.com
Internet:
www.novonordisk-us.com

HRSA Meeting with National Association of Chain Drug Stores

October 2, 2020

1:00 pm

Participants
Tom O'Donnell, Senior Vice President, Government Affairs & Public Policy
Don Bell, Senior Vice President, Health Policy and Legal Affairs/General Counsel
Kala Shankle, Director, Legal Affairs/Assistant General Counsel
Tom Engels – Administrator, Health Resources and Services Administration
RADM Krista Pedley – Director, HRSA Office of Pharmacy Affairs
Michelle Herzog – Deputy Director, HRSA Office of Pharmacy Affairs

Notes

- Tom started the meeting stating we would be listening only to their concerns and encouraged them to ask questions that we could document, but would be unable to answer today.
- NACDS thanked us for taking the time and understand the ground rules.
- NACDS and their members agree that the 340B Program is super important for both the NACDS members and the patients.
- They are concerned with the moves of major manufacturers both preventing sales to contract pharmacies and requiring claims level data to access 340B pricing.
- Manufacturers like AztraZeneca and Sanofi are already not offering the prices. It has gone from theoretical to real time. They believe these moves are part of a broader strategy by manufacturers to undermine the 340B program and companies are not understanding the dramatic consequences including higher drug costs, decreased contract pharmacy participation which decreases patient access, which is especially bad during a pandemic
- NACDS members play a critical role for the covered entities beyond dispensing including access to lower costs for patients, assistance to ensure medication adherence, medication counseling and administrative services to the covered entities. These services and more could be eliminated based on these practices.
- One WV member of NACDS has already had 14 patients denied insulin based on these practices – which is a cost to their health, and to Medicaid/Medicare

- Believes manufacturer PPA requires these companies to provide pricing. The statute does not require the submission of claims data for access to prices nor does it allow a manufacturer to deny pricing.
- NACDS believes these practices are a direct violation of the PPA and both the 1996 and 2010 guidance is a clear interpretation that allows contract pharmacies.
- NACDS had a call with the CEOs and the members are asking HRSA to enforce and make the manufacturers offer 340B pricing to entities utilizing contract pharmacies.
- Next steps:
    - Ask HRSA to enforce and make the manufacturers offer 340B pricing to covered entities regardless of their contract pharmacy usage or submission of claims level data.
    - What can NACDS do to help the viability of the program?
- Tom and Krista thanked them for their time, stressed that we are actively investigating the issue, and encouraged them to continue to inform HRSA with specific data regarding the impact on the entities.

HRSA Meeting with Avita Pharmacy and Ballard Partners

October 1, 2020

2:00 pm

Participants
Lorrie Carr – President of Avita Pharmacy
Justin Sayfie – Partner Ballard Partners
Morgan – Ballard Partners
Tom Engels – Administrator, Health Resources and Services Administration
RADM Krista Pedley – Director, HRSA Office of Pharmacy Affairs
Michelle Herzog – Deputy Director, HRSA Office of Pharmacy Affairs

Notes

- Tom started the meeting stating we would be listening only to their concerns and encouraged them to ask questions that we could document, but would be unable to answer today. RADM Pedley also stated there was an active FOIA request from Avita.
- Avita is a national pharmacy that contracts almost exclusively with HRSA grantees – CHCs, RW.
    - 270 covered entity clients, all grantees, can't access pricing at this time
    - 98% of Avita clients do not have their own pharmacies
    - Largest client – $800,000 impact annually on Lilly insulin alone
    - Multiple million in lost revenue overall to their clients
    - Public health crisis will lead to imminent harm to patients and possible site closures
    - Health centers were charging $0-$40 for insulin, now charging $300
    - Some are switching from Lilly's insulin to other products which is not good for patients
- Believes manufacturer PPA requires these companies to provide pricing, and not shipping is a direct violation of that agreement. They were not able to sit down with manufacturers and have discussions prior to the change and requests are now falling on deaf ears.
- Avita is trying to understand why there is now uncertainty regarding the 1996 contract pharmacy guidelines:
    - See guidelines as clear authority and rule of law for 24 years

  - Questioned what switched and why are the companies now not honoring contract pharmacies
  - Believes guidance is a foundation for HRSA to stand on and take action
- Concerned that Lilly was able to publish their plan on the OPA website which they believed was limited to shortages. See this as a policy interpretation of the program and they are now running the program.
- Biggest fear is that other manufacturers will pile on if nothing happens and then there will be no 340B Program.
- Grantees are being hit the hardest because many don't have pharmacies. Entities will have to close their doors in 6 months if this continues.
- Wondering if there will be any follow up action from the Charrow letter.
- There is a recognition that duplicate discounts are a problem and they are not opposed to working out a collaborative approach.
- Next steps:
  - Awaiting a response from HRSA regarding these company practices
  - Litigation is coming whether from covered entities and/or manufacturers
  - Short term goal – save the 340B Program
  - Long term goal – work out kinks with the practices to ensure long-term success
  - What can Avita do to help solve the problem
- Tom and Krista thanked them for their time, stressed that we are actively investigating the issue, and encouraged them to continue to inform HRSA with specific data regarding the impact on the entities.

HEALTH RESOURSES AND SERVICES ADMINISTRATION
Rapid Listening Session for Tribal Leaders on the 340B Program
October 7, 2020
Take Away Notes

AGENDA ITEM	*NOTES*	*B/O of Interest*	*STATUS/UPDATES/ACTION*
Michelle Allender, MS, BSN, RN, Director, Office of Health Equity, HRSA **Opening Remarks**	Ms. Allender provided welcome remarks and the importance of this Rapid Listening Session.		
RADM Krista Pedley, PharmD, MS Office of Pharmacy Affairs **340B Discount Drug Program Update**	RADM Pedley said this listening session will provide tribes and tribal leaders an opportunity to express their concerns regarding the issues impacting covered entities that participate in the 340B Drug Pricing Program. It is important to note that this will be a listening session only, as HRSA continues to actively evaluate this issue and any potential actions. RADM Pedley recognizes the importance of these 340B issues in Indian County. She indicated the issues are complicated and many people are working on these issues.		
Tribal Response	Mr. Ashworth, Port Gamble S'Klallam Tribe in Washington. Mr. Ashworth said that Eli Lilly and AstraZeneca are no longer honoring the 340B Pharmacy Program contracts. The Port Gamble S'Klallam Tribe is not financially able to operate their own pharmacy. Their pharmacy bill more than doubled without the 340B Program, paying $3,432.80 for 114 pills and $3,689.60 or $41 a pill. These are not sustainable costs. What is HRSA's emergency plan to back up the 340B Program?	OA OPA	
	W. Ron Allen, Chairman, Jamestown S'Klallam Tribe, Washington. Chairman Allen reports his is a small tribe. Mr. Allen urges and challenges HRSA to resolve this unacceptable practice by pharmaceutical companies that are resulting in gauging patients and clinics. He expects the Federal Government to address these inappropriate and unacceptable issues, as there are trust responsibilities. Mr. Allen said both Rite Aide and Walmart have alerted his tribe that they will cease to recognize their contracts to	OA OPA	

AGENDA ITEM	*NOTES*	*B/O of Interest*	*STATUS/UPDATES/ACTION*
	provide 340B drugs. He asked OIG to take immediate action to address these wrong and unacceptable actions of pharmaceutical companies.		
	Dean Garcia, Pharm.D., RPh, Pharmacist with the Southern Indian Health Council, Inc. Campo Health Center in Campo, CA. They represent seven Federally recognized Tribes in southern California. Mr. Garcia indicated that Sonofi sent them a threatening letter regarding using contract pharmacy by their Medi-Cal patients. Mr. Garcia indicated that there are no other pharmacies for 35-40 miles and that there is a mandatory pharmacy carve out for remote patients. He also indicated that Governor Gavin Newson enable the carve-out to change poor health outcomes for disadvantages rural Medi-Cal patients.	OA OPA	
	Anna Baten, Valdez Native Tribe is located in Valdez, Alaska. Ms. Baten stated their contract was cancelled from their only pharmacy. She indicates this is unfair and implores sister and brother tribes to help them.	OA OPA	
	Joni Buffalohead, PhD., Chair Indian Health Board of Minneapolis. Ms. Buffalohead indicated that the pharmaceutical company's actions regarding the 340B Program are inhumane. She says 80% of medical costs are pharmaceuticals. She indicated that 60% of tribal members go back and forth to their tribes. These actions of pharmaceutical companies are attacking low income families. Ms. Buffalohead said we need HRSA as an ally.	OA OPA	
	Aqula Kenison (sp. ?) Selbual West Village Tribe in Alaska. Ms. Kenison indicated that drug companies hike prices. She said there is nothing in federal law that prohibits contracting. There is a burdensome reporting mechanism that pharmaceutical companies are asking 340B providers to do to assure compliance. She indicated these 340B issues should be delegated to OIG to manage the enforcement actions.	OA OPA	

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	W. Ron Allen, Chairman, Jamestown S'Klallam Tribe, Washington. Chairman Allen asked when we would hear back from HRSA on the 340B Pharmacy issues? He asked for a timely response as the actions of pharmaceutical companies are costing his clinic $100,000 a month. They have 17,000 patients and they are having to pare back the level and quality of services to their tribe, as a consequence of the actions of pharmaceutical companies.	OA OPA	
	Rosa Rivera (?) reiterated that the actions of pharmaceutical companies are affecting her tribal people as well.	OA OPA	
	Gaga N, Pharmacy Director for the Hoopa Valley Tribe in California. Mr. Gaga N said they can't afford the price of drugs and 340B is critical part of their payment for drugs. He says patients can't pay already discounted prices and some can't afford even $5 co-pays. For underprivileged communities the 340B program is essential. Patients are having to choose between buying food and buying medications. Patients are ending up in the Emergency Room that costs a lot more money than medications cost. The 340B Program helps patients get medication, which in turn increases patient compliance.	OA OPA	
	Rosario Arreola Pro, MPH, California Rural Indian Health Board (CRIHB). Ms. Arreola Pro says CRIHB represents 59 Federally Recognized Tribes and 200,000 members. She asked HRSA about the limited distribution protocol and the refusal of pharmaceutical companies to participate in the 340B Program when medications are dispensed from contract pharmacies. This impacts elders and those that live long distances and over the mountain from pharmacies. The actions of these pharmaceutical companies are already starting to impact the Tribal Health Program. Pharmaceutical companies are demanding they completed onerous reporting requirements.	OA OPA	

HEALTH RESOURSES AND SERVICES ADMINISTRATION
Rapid Listening Session for Tribal Leaders on the 340B Program
October 7, 2020
Take Away Notes

AGENDA ITEM	*NOTES*	*B/O of Interest*	*STATUS/UPDATES/ACTION*
	Emily ?, Pharmacy Manager of the contract pharmacy for the ? Reservation in AZ. She indicated that there are skyrocketing medication prices and they are not getting reimbursed. They are receiving minimal reimbursement from the AZ Medicaid program. She asked the HRSA please look into these matters quickly as they are incurring significant cost every day.	OA OPA	

Tribal Consultation – 340B 7 Oct. 2020

Q: Example: → Lilly Sanofi, AstraZeneca = small entity. Not financially feasible for the tribe to operate its own pharmacy – $114/per pill; 90 tabs = $41/per pill > pharmacy bill has more than doubled since
→ What's HRSA's emergency plan to back this up since Manuf. → this is not a sustainable cost for the tribes.

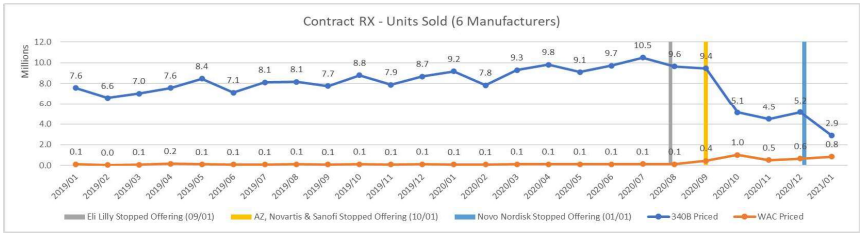
Q: Ron Allen → Small tribe w/ small operation – urge + challenge HRSA to take immediate action of pharm. industry – manuf. experiencing record-breaking profit. Unacceptable for them to gouge small entities. Huge deal for tribes w/ respect to COVID – challenge for getting reimbursement through pharmaceutical
* 340B drugs have been in effect since 1996 – / CP guidance in place since 2010. Drug companies in violation of their rebate agreement.
Rite Aid + Walmart > cease contracts? Data/Reporting Reqmt's not illegal
→ Investigate + take immediate action.

Q Indian Health Council →
Q Andrea Bateman (Alaska)
Q: Dwayne Bufflehead (SD) – MAS Indian Health Clinic
Q: Rosa Rivera
? Next steps from HRSA?

Summary and Background

There are 6 manufacturers that have stopped or added limitations to offering 340B price in contract pharmacy arrangements. This analysis attempts to quantify the loss of units sold and savings.
There is not a longterm reciprocal increase in the WAC price purchasing when 340B contract pharmacy pricing is not available. This is because the third party administrator will stop identifying the newly WAC priced products as 340B eligible. There may be a transient spike in WAC purchases initially, but once the entities/software block these products from 340B purchasing, the NDC won't be used moving forward. This analysis demonstrates a decrease in 340B priced units sold from a high of 10.5M prior to the manufacturers' actions in 2020 to 2.9M in January 2021. Annualized this equates to a reduction in 340B units sold of nearly 83M. Note that the "By Units Sold (Contract RX)" tab outlines the consolidated and individual manufactures' units sold, and has units impact on grantees and hospitals.

Figure 1 - Monthly 340B Units Sold Before and After Manufacturers' Actions



There are two tabs related to savings lost from the manufacturers' actions "Savings from WAC (Contract RX)" and "AverageLostSavings(ContractRX)". The "Savings from WAC (Contract RX)" tab outlines the monthly savings from the 6 manufacturers from January 2019 to January 2021. The highest month of savings before the changes was July 2020 and the savings was $357M with the lowest savings in January 2021, with $92M in savings. The annualized savings lost between the high and low savings months was $3.2B. Figure 2 is a roll up of all 6 manfacturers and the tab has a breakdown by each manufacturer and then by grantee and hospital savings.

Figure 2 - Monthly 340B Contract Pharmacy Savings Before and After 6 Manufacturers' Actions- Lost Annualized Savings = $3.2B

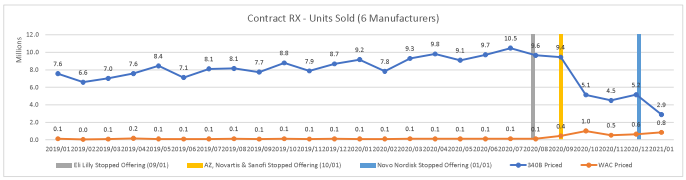
The "AverageLost Savings(ContractRX)" outlines the impact on covered entities in lost savings until January 2021, by comparing the savings from the period of 3/2020-8/2020 as a control to the actual savings in that month. Figure 3 demonstrates the loses from 9/2020 to 1/2021.

Figure 3 - Lost Savings from 9/2020 to 1/2021

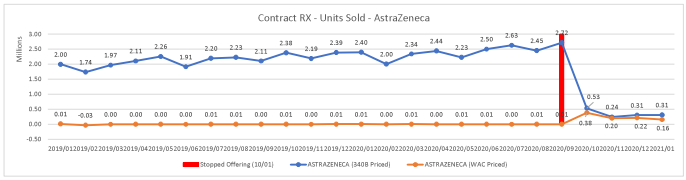
Key to Remaining Tabs

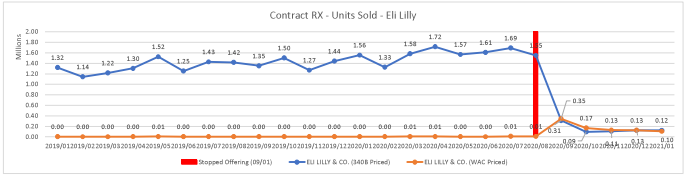
"By Sales (Contract RX)": Provides contract pharmacy sales at 340B and the WAC prices for all 6 manufacturers, for each manufacturer, and then by grantees and hospitals.
"Total Contract RX Sales": Outlines all manufacturers sales to contract pharmacy arrangements.
"By Units Sold (non-Contract RX): Outlines the monthly units sold for the 6 manufacturers rolled up, individually and by grantees and hospitals for all non-contract pharmacy sales.
"By Sales (non-Contract RX): Outlines the monthly sales for the 6 manufacturers rolled up, individually and by grantees and hospitals for all non-contract pharmacy sales.

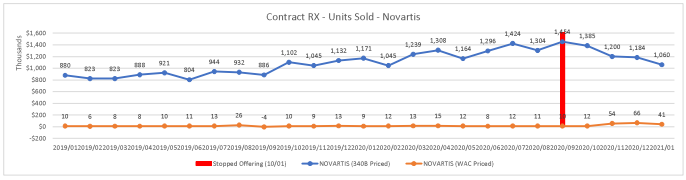
Sale_type	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
340B Price	7,552,965	6,580,202	7,015,318	7,571,563	8,448,783	7,119,865	8,111,379	8,146,720	7,740,482	8,790,498	7,859,882	8,681,258	9,158,240	7,824,473	9,295,598	9,805,474	9,088,852	9,706,344	10,482,697	9,648,675	9,446,163	5,131,307	4,494,375	5,150,687	2,882,688
WAC Price	117,257	39,222	72,466	164,015	99,981	84,535	94,210	118,600	75,454	119,954	87,441	110,382	96,657	95,354	115,964	106,877	106,038	108,063	123,102	109,945	445,096	1,015,051	521,761	647,288	845,724
Eli Lilly Stopped Offering (09/01)																				12,000,000					
AZ, Novartis & Sanofi Stopped Offering (10/01)																					12,000,000				
Novo Nordisk Stopped Offering (01/01)																								12,000,000	

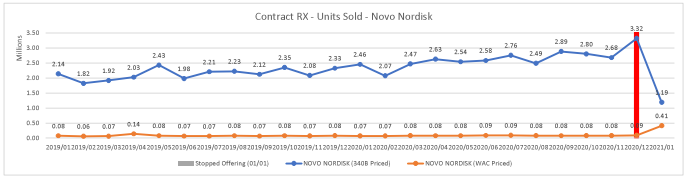


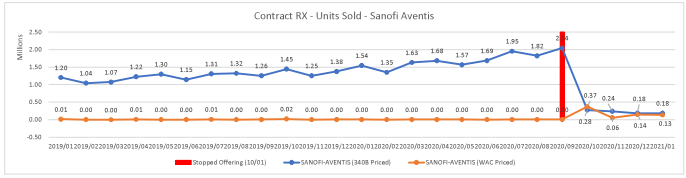
Sale_type	Manufacturer	Manufacture	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
340B	ASTRAZENEC	ASTRAZENEC	1,998,712	1,739,242	1,968,534	2,107,359	2,257,358	1,913,786	2,196,264	2,226,694	2,105,130	2,381,596	2,188,639	2,387,922	2,401,066	2,003,315	2,340,905	2,441,548	2,228,982	2,501,787	2,629,031	2,452,825	2,719,494	534,773	244,521	306,482	311,210
WAC	ASTRAZENEC	ASTRAZENEC	14,144	-28,444	403	4,553	4,822	2,290	5,273	5,922	3,621	5,241	2,340	6,235	6,195	4,926	8,128	4,028	5,020	5,399	2,401	5,199	5,102	384,787	201,627	217,649	156,204
		Stopped Offering (10/01)																					3,000,000				
340B	ELI LILLY & C	ELI LILLY & C	1,319,983	1,142,145	1,217,714	1,303,748	1,524,679	1,252,729	1,427,013	1,419,225	1,352,628	1,502,821	1,268,730	1,443,154	1,555,998	1,325,501	1,580,931	1,715,723	1,568,058	1,608,907	1,692,781	1,550,370	310,292	94,811	107,136	125,075	124,134
WAC	ELI LILLY & C	ELI LILLY & C	3,512	1,018	2,062	4,019	5,069	3,702	3,154	3,800	3,727	3,410	4,503	3,075	4,311	4,026	6,278	5,170	4,457	2,663	11,102	7,536	345,761	167,380	127,493	126,721	104,215
		Stopped Offering (09/01)																				2,000,000					
340B	NOVARTIS	NOVARTIS (3	879,808	823,276	822,953	888,065	921,269	803,538	943,648	931,998	886,287	1,101,776	1,045,489	1,132,481	1,171,197	1,045,481	1,239,245	1,308,137	1,163,811	1,295,602	1,423,690	1,304,216	1,454,065	1,385,358	1,200,306	#######	#######
WAC	NOVARTIS	NOVARTIS (V	9,518	6,428	7,785	7,884	9,811	10,791	12,547	25,875	-4,058	10,283	8,570	12,860	8,996	12,318	13,412	14,927	11,886	7,729	12,494	10,794	10,214	12,218	53,855	65,653	40,951
		Stopped Offering (10/01)																					1,600,000				
340B	NOVO NORE	NOVO NORE	2,136,916	1,820,302	1,918,451	2,025,451	2,428,105	1,982,299	2,207,817	2,225,149	2,121,566	2,351,448	2,084,486	2,327,073	2,455,256	2,073,740	2,471,838	2,626,907	2,540,323	2,584,100	2,755,221	2,490,662	2,886,577	2,802,020	2,677,460	#######	#######
WAC	NOVO NORE	NOVO NORE	76,755	59,568	65,385	139,512	79,573	67,276	65,784	80,760	68,585	80,252	70,283	84,551	73,697	71,098	84,026	79,293	80,257	89,590	92,902	82,928	80,070	81,983	83,027	92,791	411,585
		Stopped Offering (01/01)																								#######	
340B	SANOFI-AVE	SANOFI-AVE	1,202,433	1,043,040	1,072,812	1,223,742	1,299,603	1,145,878	1,307,758	1,323,118	1,255,091	1,445,102	1,250,943	1,375,718	1,544,893	1,351,079	1,632,413	1,683,305	1,568,555	1,686,781	1,954,766	1,823,862	2,044,945	275,917	237,835	181,832	182,269
WAC	SANOFI-AVE	SANOFI-AVE	13,328	652	-3,169	8,047	707	477	7,452	2,244	3,579	20,767	1,745	3,661	3,459	2,987	4,121	3,461	4,418	2,682	4,203	3,488	3,949	368,683	55,760	144,474	132,769
		Stopped Offering (10/01)																					2,500,000				
340B	UNITED THE	UNITED THE	15,113	12,197	14,856	23,199	17,769	21,634	28,879	20,536	19,781	7,755	21,596	14,911	29,831	25,359	30,268	29,856	19,124	29,168	27,209	26,740	30,790	38,428	27,118	30,102	13,722

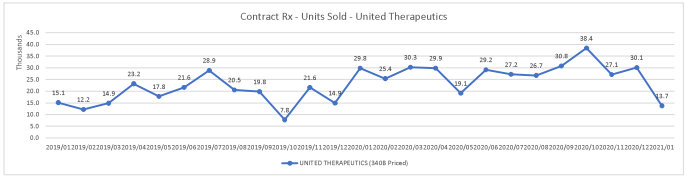




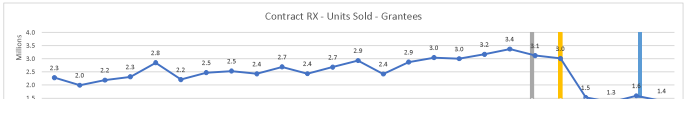


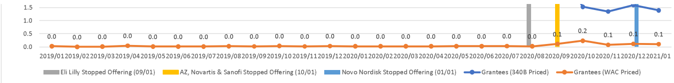






Entity Typ	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
Grantees (	2,280,420	1,992,511	2,187,386	2,315,154	2,847,660	2,208,062	2,473,405	2,534,883	2,427,625	2,689,858	2,430,162	2,684,283	2,934,068	2,421,545	2,874,069	3,046,538	3,000,116	3,168,578	3,370,808	3,123,130	3,011,456	1,524,702	1,349,553	1,589,823	1,393,951
Grantees (	26,763	2,793	9,522	42,905	14,751	15,947	15,991	26,151	17,299	35,546	16,844	31,726	21,377	21,520	23,042	23,198	26,929	24,515	30,065	20,586	111,574	235,643	77,892	114,771	105,630
Eli Lilly Stopped Offering (09/01)																				4,000,000					
AZ, Novartis & Sanofi Stopped Offering (10/01)																					4,000,000				
Novo Nordisk Stopped Offering (01/01)																								4,000,000	
Hospitals (	5,272,545	4,587,691	4,827,932	5,256,409	5,601,122	4,911,803	5,637,974	5,611,837	5,312,857	6,100,639	5,429,719	5,996,974	6,224,172	5,402,928	6,421,528	6,758,936	6,088,736	6,537,767	7,111,889	6,525,545	6,434,707	3,606,605	3,144,822	3,560,864	1,488,737
Hospitals (	90,495	36,430	62,944	121,110	85,230	68,588	78,219	92,449	58,155	84,408	70,598	78,656	75,280	73,834	92,923	83,679	79,109	83,548	93,037	89,359	333,522	779,408	443,869	532,517	740,094
Eli Lilly Stopped Offering (09/01)																				8,000,000					
AZ, Novartis & Sanofi Stopped Offering (10/01)																					8,000,000				
Novo Nordisk Stopped Offering (01/01)																								8,000,000	




1.5
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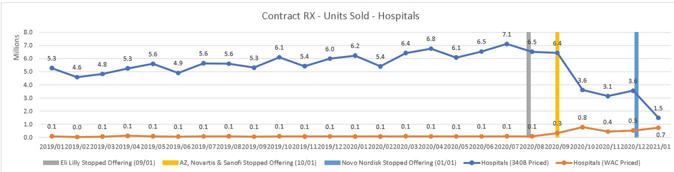
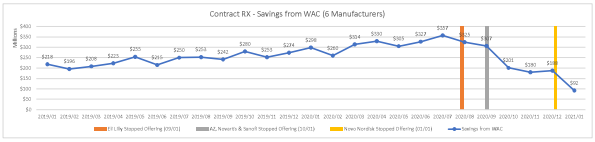
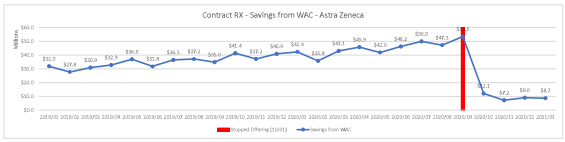
2019/01 2019/02 2019/03 2019/04 2019/05 2019/06 2019/07 2019/08 2019/09 2019/10 2019/11 2019/12 2020/01 2020/02 2020/03 2020/04 2020/05 2020/06 2020/07 2020/08 2020/09 2020/10 2020/11 2020/12 2021/01
Eli Lilly Stopped Offering (09/01)
AZ, Novartis & Sanofi Stopped Offering (10/01)
Novo Nordisk Stopped Offering (01/01)
Grantees (340B Priced)
Grantees (WAC Priced)

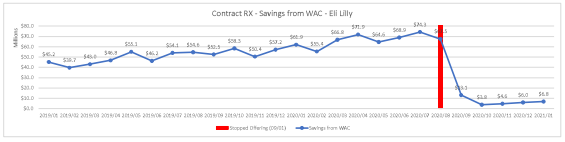

Contract RX - Units Sold - Hospitals
Millions
8.0
7.0
6.0
5.0
4.0
3.0
2.0
1.0
0.0
2019/01 2019/02 2019/03 2019/04 2019/05 2019/06 2019/07 2019/08 2019/09 2019/10 2019/11 2019/12 2020/01 2020/02 2020/03 2020/04 2020/05 2020/06 2020/07 2020/08 2020/09 2020/10 2020/11 2020/12 2021/01
Eli Lilly Stopped Offering (09/01)
AZ, Novartis & Sanofi Stopped Offering (10/01)
Novo Nordisk Stopped Offering (01/01)
Hospitals (340B Priced)
Hospitals (WAC Priced)

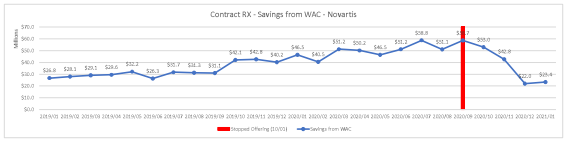
	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
Savings from WAC	$218,236,006		$195,997,254	$208,174,595	$223,400,167	$254,509,076	$214,589,045	$250,206,876	$252,895,575	$241,972,098	$280,021,994	$252,600,196	$273,677,477	$298,478,790	$259,595,764	$314,122,762	$329,683,546	$305,324,535	$327,100,755	$357,368,890	$324,970,091	$306,501,169	$200,773,880	$179,701,615	$188,132,591	$91,884,890
Eli Lilly Stopped Offering (09/01)																					$400,000,000				
AZ, Novartis & Sanofi Stopped Offering (10/01)																						$400,000,000			
Novo Nordisk Stopped Offering (01/01)																								$400,000,000	

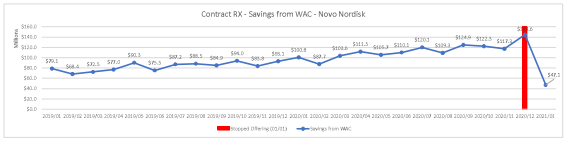


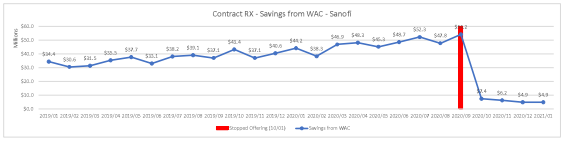
			2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
Savings from WAC	ASTRAZENECA	Savings from WAC Stopped Offering (10/01)	$31,987,191	$27,800,118	$30,878,154	$32,879,113	$36,934,324	$31,799,552	$36,471,421	$37,186,394	$34,989,723	$41,396,744	$37,237,664	$40,948,134	$42,441,421	$35,833,551	$43,121,007	$45,902,941	$41,986,004	$46,246,770	$50,028,632	$47,324,434	$53,477,151 $60,000,000	$52,127,989	$7,229,308	$9,001,091	$8,726,284
Savings from WAC	ELI LILLY & CO.	Savings from WAC Stopped Offering (09/01)	$45,172,066	$39,658,299	$43,042,392	$46,776,458	$55,143,309	$46,187,649	$54,078,947	$54,649,521	$52,556,469	$58,309,269	$50,385,315	$57,223,052	$63,944,782	$55,408,633	$66,775,351	$73,893,338	$64,617,091	$68,901,655	$74,307,111	$67,556,605 $80,000,000	$53,089,875	$3,786,056	$4,623,274	$5,972,528	$6,751,854
Savings from WAC	NOVARTIS	Savings from WAC Stopped Offering (10/01)	$26,764,299	$28,095,082	$29,085,099	$29,559,111	$32,207,877	$26,346,691	$31,723,978	$33,131,431	$33,059,207	$42,057,285	$42,723,795	$40,203,100	$46,512,416	$40,497,057	$51,247,026	$50,181,455	$46,464,295	$51,201,738	$58,801,128	$51,087,955	$38,677,825 $70,000,000	$32,996,432	$42,804,901	$23,965,723	$23,361,175
Savings from WAC	NOVO NORDISK	Savings from WAC Stopped Offering (01/01)	$79,050,248	$68,444,521	$72,106,334	$76,982,417	$90,301,190	$75,516,328	$87,164,407	$88,504,526	$84,866,379	$94,014,252	$85,780,413	$93,120,854	$100,774,255	$87,660,395	$103,611,905	$111,528,019	$105,669,572	$110,113,332	$120,128,165	$109,335,765	$124,917,354	$122,288,114	$117,251,750	$144,630,419 $160,000,000	$47,071,806
Savings from WAC	SANOFI-AVENTIS	Savings from WAC Stopped Offering (10/01)	$34,391,418	$30,581,862	$31,479,901	$35,454,878	$37,740,967	$33,122,552	$38,230,409	$39,328,648	$37,127,065	$43,570,426	$37,116,310	$40,569,552	$44,218,810	$38,292,941	$46,931,876	$48,265,295	$45,257,173	$48,654,307	$52,301,943	$47,825,773	$54,238,892 $60,000,000	$7,399,059	$6,209,633	$4,895,540	$4,910,149
Savings from WAC	UNITED THERAP	Savings from WAC	$870,784	$1,417,372	$1,382,516	$1,748,190	$2,181,330	$1,616,273	$2,537,714	$2,095,055	$1,413,254	$874,018	$1,306,800	$1,612,786	$2,585,107	$1,903,186	$2,433,597	$1,912,495	$1,330,400	$1,982,733	$1,801,912	$1,859,578	$2,099,872	$2,176,229	$1,380,747	$1,667,289	$1,063,623

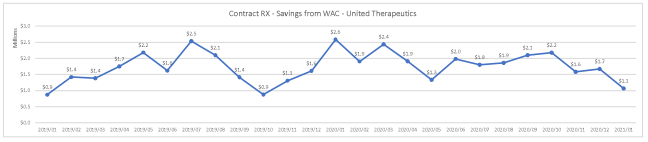




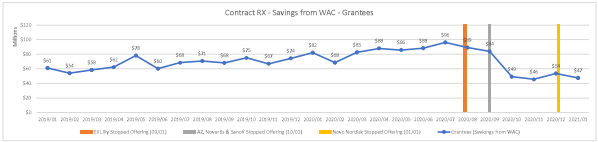


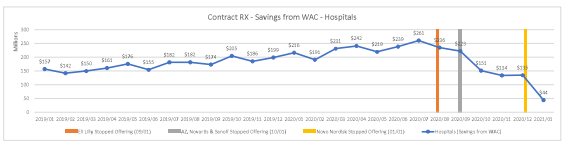




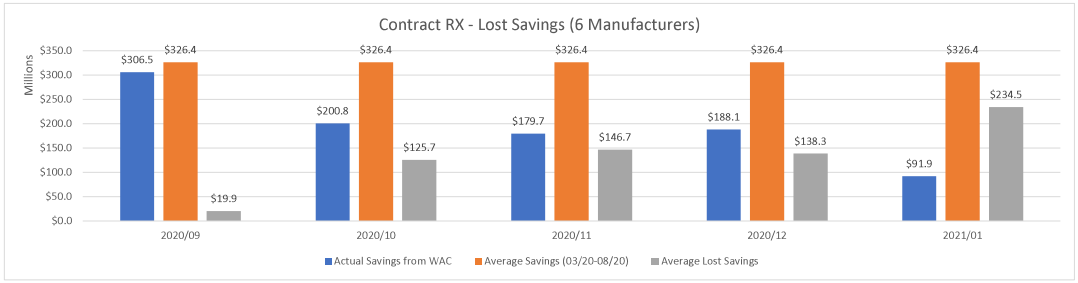


	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
Grantees (Savings from WAC)	$60,963,136		$53,894,259	$58,420,019	$62,179,463	$78,310,959	$60,084,096	$68,395,945	$70,737,015	$68,140,115	$74,891,608	$67,004,896	$74,383,384	$82,013,232	$68,497,073	$82,683,472	$88,075,893	$85,870,254	$88,360,046	$96,291,397	$89,320,923	$83,970,126	$49,294,890	$45,578,255	$53,532,159	$47,456,461
Eli Lilly Stopped Offering (09/01)																					$120,000,000					
AZ, Novartis & Sanofi Stopped Offering (10/01)																						$120,000,000			
Novo Nordisk Stopped Offering (01/01)																								$120,000,000	
Hospitals (Savings from WAC)	$157,272,630		$142,102,996	$149,954,575	$161,220,704	$176,198,117	$154,504,949	$181,810,931	$182,138,560	$173,831,984	$205,130,185	$185,595,400	$199,294,093	$216,465,559	$191,098,691	$231,439,290	$241,607,653	$219,454,281	$238,740,689	$261,077,493	$235,649,168 $300,000,000	$222,331,043	$151,478,990	$134,123,361	$134,600,431	$44,428,429
Eli Lilly Stopped Offering (09/01)																						$300,000,000			
AZ, Novartis & Sanofi Stopped Offering (10/01)																									
Novo Nordisk Stopped Offering (01/01)																								$100,000,000	

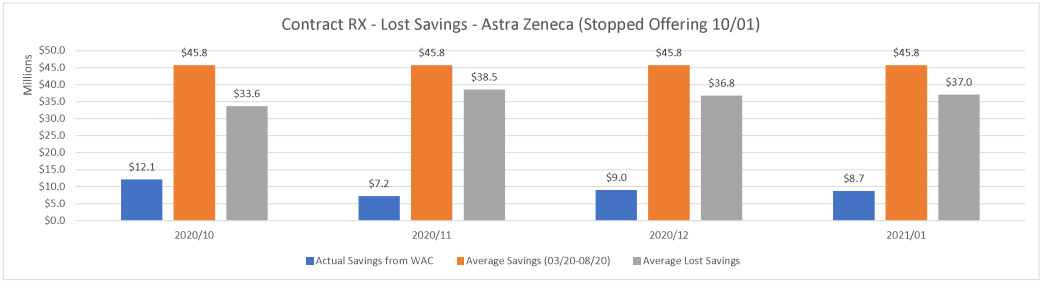


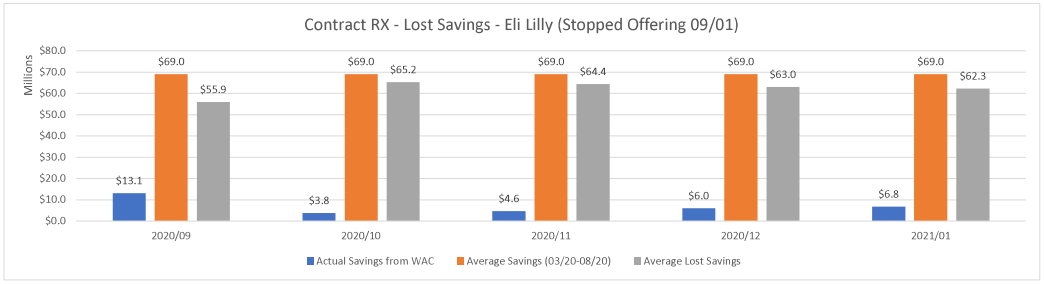


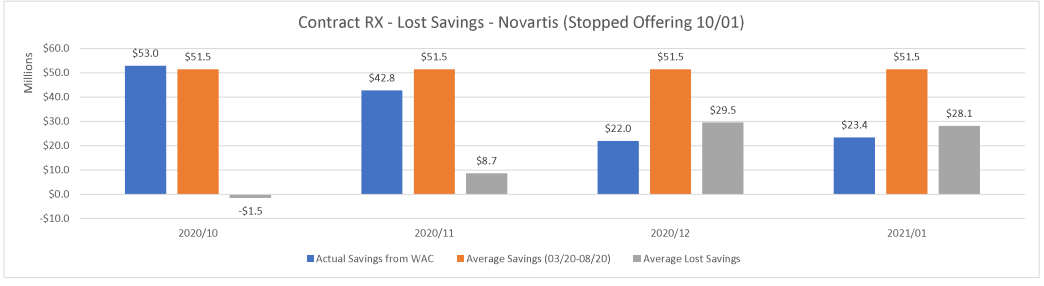
	2020/09	2020/10	2020/11	2020/12	2021/01
Actual Savings from WAC	$306,501,169	$200,773,880	$179,701,615	$188,132,591	$91,884,890
Average Savings (03/20-08/20)	$326,428,427	$326,428,427	$326,428,427	$326,428,427	$326,428,427
Average Lost Savings	$19,927,258	$125,654,547	$146,726,812	$138,295,836	$234,543,537

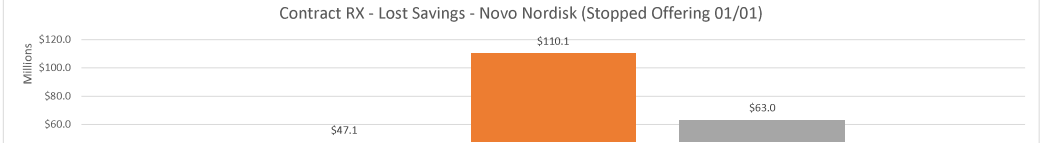


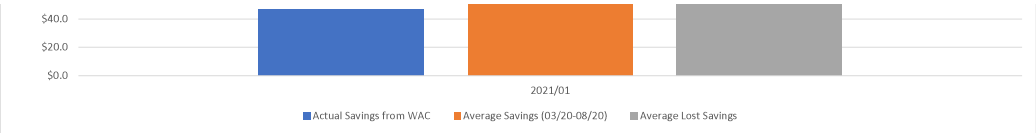
			2020/09	2020/10	2020/11	2020/12	2021/01
Savings from WAC	ASTRAZENECA	Actual Savings from WAC	$53,477,351	$12,127,989	$7,229,308	$9,001,091	$8,726,284
		Average Savings (03/20-08/20)	$45,768,298	$45,768,298	$45,768,298	$45,768,298	$45,768,298
		Average Lost Savings		$33,640,309	$38,538,990	$36,767,207	$37,042,015
Savings from WAC	ELI LILLY & CO.	Actual Savings from WAC	$13,089,875	$3,786,056	$4,625,274	$5,972,528	$6,751,854
		Average Savings (03/20-08/20)	$69,005,192	$69,005,192	$69,005,192	$69,005,192	$69,005,192
		Average Lost Savings	$55,915,317	$65,219,136	$64,379,918	$63,032,664	$62,253,338
Savings from WAC	NOVARTIS	Actual Savings from WAC	$58,677,825	$52,996,432	$42,804,901	$21,965,723	$23,361,175
		Average Savings (03/20-08/20)	$51,497,263	$51,497,263	$51,497,263	$51,497,263	$51,497,263
		Average Lost Savings		-$1,499,169	$8,692,362	$29,531,539	$28,136,087
Savings from WAC	NOVO NORDISK	Actual Savings from WAC	$124,917,354	$122,288,114	$117,251,750	$144,630,419	$47,071,806
		Average Savings (03/20-08/20)	$110,064,493	$110,064,493	$110,064,493	$110,064,493	$110,064,493
		Average Lost Savings					$62,992,687
Savings from WAC	SANOFI-AVENTIS	Actual Savings from WAC	$54,238,892	$7,399,059	$6,209,635	$4,895,540	$4,910,149
		Average Savings (03/20-08/20)	$48,206,061	$48,206,061	$48,206,061	$48,206,061	$48,206,061
		Average Lost Savings		$40,807,002	$41,996,426	$43,310,521	$43,295,913
Savings from WAC	UNITED THERAP	Actual Savings from WAC	$2,099,872	$2,176,229	$1,580,747	$1,667,289	$1,063,623

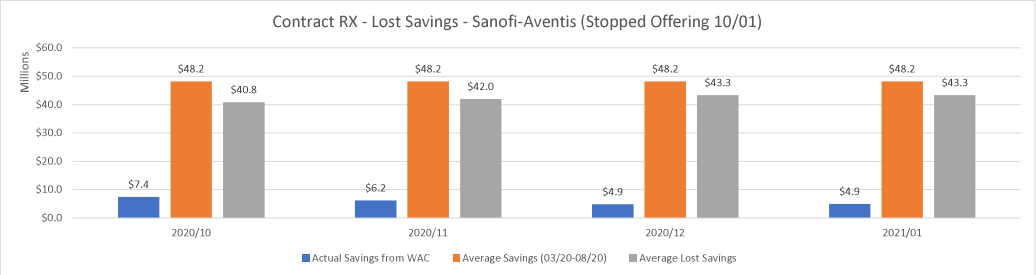




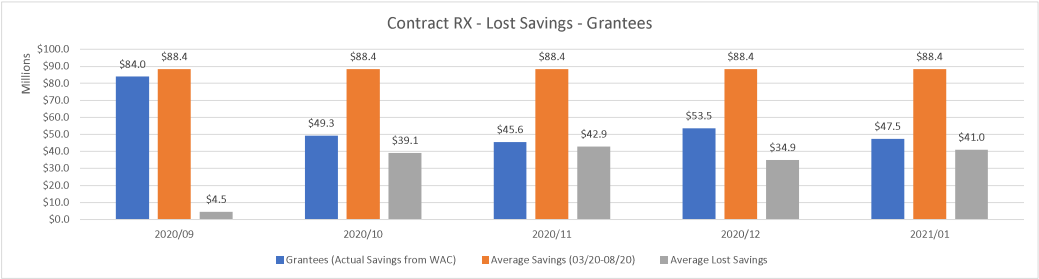


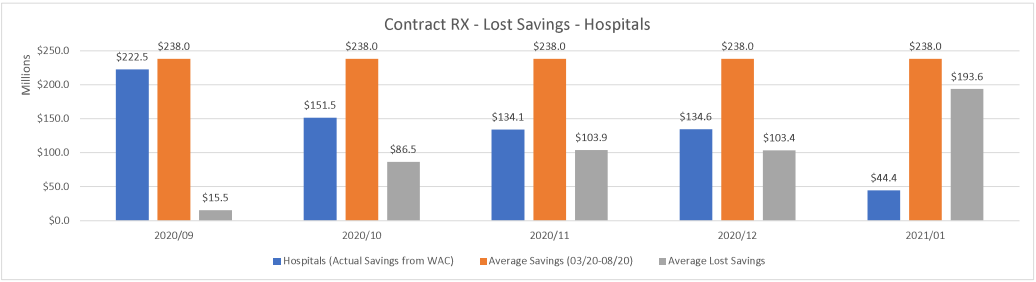




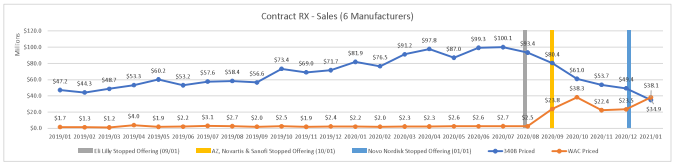


	2020/09	2020/10	2020/11	2020/12	2021/01
Grantees (Actual Savings from WAC)	$83,970,126	$49,294,890	$45,578,255	$53,532,159	$47,456,461
Average Savings (03/20-08/20)	$88,433,664	$88,433,664	$88,433,664	$88,433,664	$88,433,664
Average Lost Savings	$4,463,538	$39,138,774	$42,855,410	$34,901,505	$40,977,203
Hospitals (Actual Savings from WAC)	$222,531,043	$151,478,990	$134,123,361	$134,600,431	$44,428,429
Average Savings (03/20-08/20)	$237,994,762	$237,994,762	$237,994,762	$237,994,762	$237,994,762
Average Lost Savings	$15,463,719	$86,515,773	$103,871,402	$103,394,331	$193,566,334

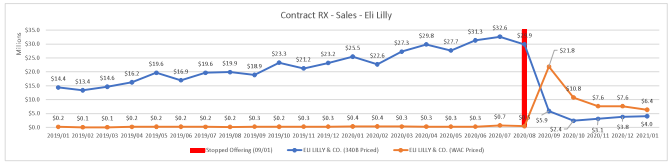


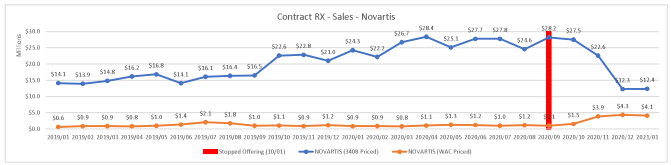


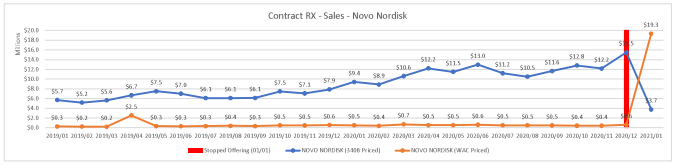
Sale_type	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
340B Prio	$47,233,754	$44,268,176	$48,717,162	$53,342,884	$60,184,419	$53,150,047	$57,648,828	$58,390,695	$56,637,970	$73,382,014	$69,044,375	$71,686,914	$81,876,125	$76,514,954	$91,218,227	$97,759,228	$86,984,799	$99,301,110	##########	$93,437,305	$80,388,069	$61,009,921	$53,694,659	$49,361,871	$34,936,559
WAC Price	$1,672,435	$1,301,437	$1,176,144	$3,985,431	$1,911,959	$2,171,506	$3,136,259	$2,722,887	$1,975,478	$2,512,029	$1,893,616	$2,357,752	$2,156,962	$2,016,086	$2,317,429	$2,316,780	$2,601,683	$2,591,927	$2,692,876	$2,540,922	$23,843,621	$38,320,383	$22,377,816	$23,507,403	$38,127,622
Eli Lilly Stopped Offering (09/01)																				##########					
AZ, Novartis & Sanofi Stopped Offering (10/01)																						##########			
Novo Nordisk Stopped Offering (01/01)																								##########	

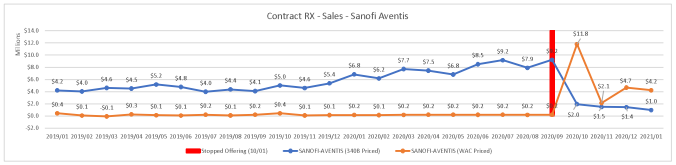


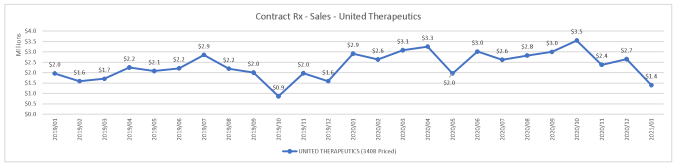
Sale_type	Manufacturer	Manufacturer	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
340B	ASTRAZENECA	ASTRAZENECA	$6,847,909	$6,160,751	$7,342,797	$7,515,468	$8,860,327	$8,116,067	$8,970,604	$9,465,034	$9,022,974	$14,128,115	$11,337,985	$12,870,924	$12,989,809	$13,999,429	$15,863,675	$16,596,233	$13,939,296	$15,770,541	$16,768,319	$17,736,939	$22,393,442	$12,751,382	$11,999,781	##########	$12,386,476
WAC	ASTRAZENECA	ASTRAZENECA	$123,358	$39,796	$66,189	$126,312	$203,716	$168,487	$305,778	$281,104	$145,842	$258,508	$187,839	$238,051	$267,295	$192,466	$298,868	$223,245	$305,023	$262,228	$219,563	$224,899	$266,778	$13,808,408	$8,336,125	$6,245,794	$4,099,236
		Stopped Offering (10/01)																					$25,000,000			
340B	ELI LILLY & CO	ELI LILLY & CO	$14,381,859	$13,366,802	$14,608,372	$16,232,631	$19,646,923	$16,948,139	$19,645,824	$19,891,968	$18,885,911	$23,291,323	$21,245,210	$23,178,397	$25,459,716	$22,649,526	$27,250,162	$29,844,153	$27,664,193	$31,287,638	$32,625,382	$29,875,200	$5,896,218	$2,425,997	$3,100,516	$3,775,024	$4,038,926
WAC	ELI LILLY & CO	ELI LILLY & CO	$205,796	$83,880	$78,747	$220,290	$231,188	$249,715	$202,870	$193,604	$274,749	$248,225	$262,887	$261,845	$363,154	$379,937	$326,915	$292,549	$272,040	$282,426	$729,139	$452,316	$21,830,860	$10,755,206	$7,619,844	$7,642,672	$6,366,458
		Stopped Offering (09/01)																				$35,000,000					
340B	NOVARTIS	NOVARTIS (34	$14,139,724	$13,946,332	$14,836,196	$16,175,991	$16,837,899	$14,105,251	$16,085,275	$16,366,225	$16,499,703	$22,613,891	$22,839,890	$20,994,713	$24,270,885	$22,180,487	$26,698,479	$28,380,005	$25,115,690	$27,749,078	$27,753,762	$24,575,399	$28,226,589	$27,518,310	$22,568,070	##########	$12,388,314
WAC	NOVARTIS	NOVARTIS (W	$647,149	$873,055	$909,575	$845,059	$1,004,827	$1,374,354	$2,080,140	$1,761,646	$1,012,988	$1,075,844	$881,110	$1,151,669	$862,086	$911,682	$813,468	$1,067,626	$1,284,746	$1,240,564	$1,031,395	$1,193,493	$1,055,162	$1,549,723	$3,886,876	$4,349,388	$4,102,164
		Stopped Offering (10/01)																					$30,000,000			
340B	NOVO NORDI	NOVO NORDI	$5,693,848	$5,164,681	$5,618,821	$6,665,797	$7,486,560	$6,999,830	$6,108,672	$6,103,533	$6,124,622	$7,468,570	$7,059,205	$7,890,643	$9,411,552	$8,875,378	$10,606,197	$12,225,522	$11,482,760	$12,963,427	$11,203,543	$10,503,343	$11,649,469	$12,804,742	$12,163,091	##########	$3,744,566
WAC	NOVO NORDI	NOVO NORDI	$257,393	$225,075	$188,757	$2,531,218	$335,069	$299,209	$335,561	$388,464	$339,036	$492,629	$470,081	$559,687	$504,509	$386,036	$701,208	$527,413	$533,581	$616,663	$510,549	$486,334	$477,065	$404,963	$401,459	$600,293	$19,333,972
		Stopped Offering (01/01)																									##########
340B	SANOFI-AVEN	SANOFI-AVEN	$4,207,821	$4,039,119	$4,602,132	$4,503,904	$5,171,014	$4,769,350	$3,983,734	$4,371,122	$4,103,828	$5,022,206	$4,589,540	$5,361,532	$6,831,723	$6,175,612	$7,716,041	$7,458,899	$6,816,411	$8,511,936	$9,169,058	$7,919,808	$9,223,676	$1,959,768	$1,482,514	$1,442,193	$979,648
WAC	SANOFI-AVEN	SANOFI-AVEN	$438,739	$79,632	-$67,124	$262,552	$137,159	$79,741	$211,910	$98,069	$202,863	$436,823	$91,699	$146,502	$159,919	$145,965	$176,972	$205,947	$206,292	$190,045	$202,231	$183,880	$213,756	$11,802,083	$2,133,513	$4,669,257	$4,225,792
		Stopped Offering (10/01)																					$14,000,000			
340B	UNITED THER	UNITED THER	$1,962,593	$1,590,492	$1,708,843	$2,249,094	$2,081,695	$2,211,411	$2,854,721	$2,192,813	$2,000,933	$857,910	$1,972,545	$1,590,705	$2,912,440	$2,634,522	$3,083,673	$3,254,414	$1,966,449	$3,018,490	$2,617,394	$2,826,517	$2,998,676	$3,549,722	$2,380,686	$2,652,317	$1,398,629



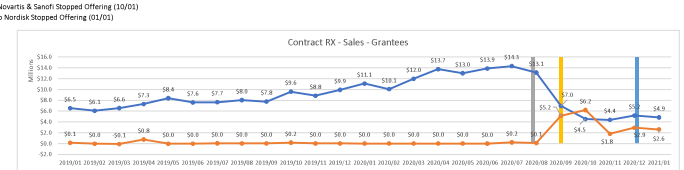


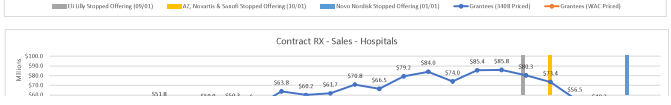


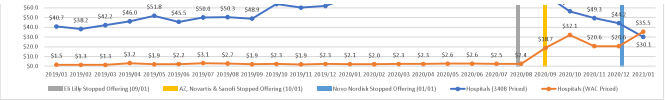




Entity Typ	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
Grantees (	$6,543,342	$6,070,358	$6,558,481	$7,315,311	$8,394,288	$7,601,253	$7,653,990	$8,048,114	$7,759,275	$9,601,237	$8,848,681	$9,937,690	$11,097,196	$10,060,387	$11,982,352	$13,745,320	$13,011,150	$13,876,865	$14,330,007	$13,122,594	$6,968,089	$4,544,230	$4,396,038	$5,183,018	$4,853,317
Grantees (	$147,494	-$12,601	-$90,794	$770,247	-$27,325	-$7,885	$45,832	$36,870	$28,979	$171,587	$33,500	$29,279	$15,767	$16,505	$10,565	$19,995	$22,620	$7,260	$240,630	$91,110	$5,163,772	$6,204,579	$1,802,904	$2,930,799	$2,626,763
Eli Lilly Stopped Offering (09/01)																				$16,000,000					
AZ, Novartis & Sanofi Stopped Offering (10/01)																					$16,000,000				
Novo Nordisk Stopped Offering (01/01)																								$16,000,000	
Hospitals	$40,690,413	$38,197,818	$42,158,681	$46,027,573	$51,790,130	$45,548,794	$49,994,838	$50,342,581	$48,878,696	$63,780,778	$60,195,694	$61,749,224	$70,778,929	$66,454,568	$79,235,876	$84,013,908	$73,973,649	$85,424,245	$85,807,451	$80,314,711	$73,419,980	$56,465,692	$49,298,621	$44,178,853	$30,083,242
Hospitals	$1,524,940	$1,314,038	$1,266,938	$3,215,184	$1,939,284	$2,179,391	$3,090,427	$2,686,017	$1,946,499	$2,340,443	$1,860,116	$2,328,473	$2,141,195	$1,999,582	$2,306,865	$2,296,785	$2,579,063	$2,584,667	$2,452,247	$2,449,812	$18,679,849	$32,115,804	$20,574,913	$20,576,604	$35,500,859
Eli Lilly Stopped Offering (09/01)																				##########					
AZ, Novartis & Sanofi Stopped Offering (10/01)																						##########			
Novo Nordisk Stopped Offering (01/01)																								##########	



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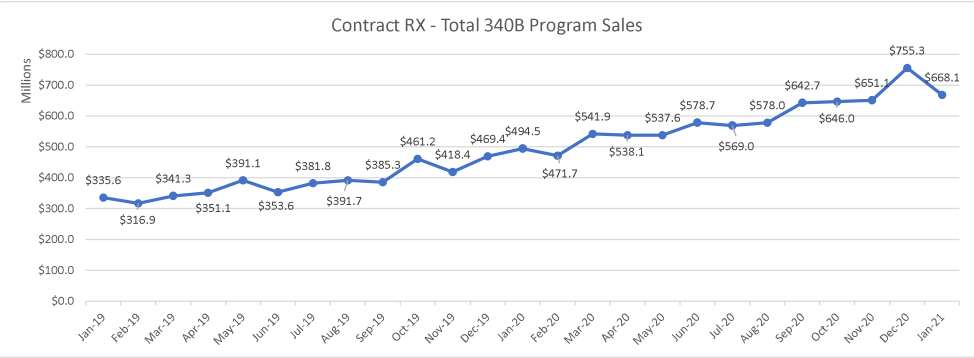
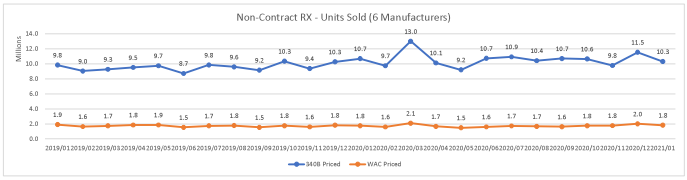
2019/01 2019/02 2019/03 2019/04 2019/05 2019/06 2019/07 2019/08 2019/09 2019/10 2019/11 2019/12 2020/01 2020/02 2020/03 2020/04 2020/05 2020/06 2020/07 2020/08 2020/09 2020/10 2020/11 2020/12 2021/01
Eli Lilly Stopped Offering (09/01)
AZ, Novartis & Sanofi Stopped Offering (10/01)
Novo Nordisk Stopped Offering (01/01)
Hospitals (340B Priced)
Hospitals (WAC Priced)

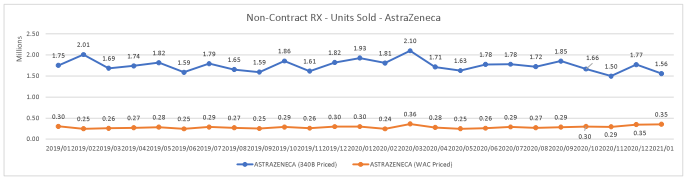
month_id		340B Program Sales
201901	Jan-19	$335,648,321
201902	Feb-19	$316,934,962
201903	Mar-19	$341,299,952
201904	Apr-19	$351,079,369
201905	May-19	$391,096,101
201906	Jun-19	$353,597,659
201907	Jul-19	$381,818,209
201908	Aug-19	$391,679,711
201909	Sep-19	$385,337,284
201910	Oct-19	$461,206,439
201911	Nov-19	$418,384,234
201912	Dec-19	$469,353,000
202001	Jan-20	$494,507,259
202002	Feb-20	$471,675,485
202003	Mar-20	$541,858,892
202004	Apr-20	$538,138,207
202005	May-20	$537,570,794
202006	Jun-20	$578,699,218
202007	Jul-20	$569,024,130
202008	Aug-20	$577,998,591
202009	Sep-20	$642,698,059
202010	Oct-20	$646,020,439
202011	Nov-20	$651,097,296
202012	Dec-20	$755,342,588
202101	Jan-21	$668,146,966
202102	Feb-21	$49,965

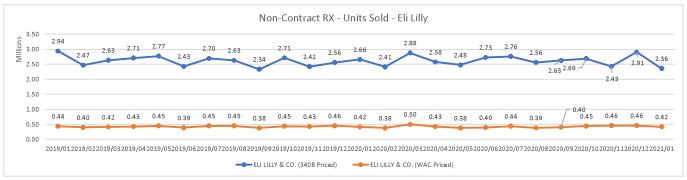


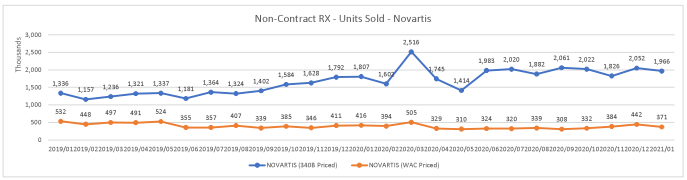
Sale_type	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
340B Price	9,829,705	9,045,070	9,267,129	9,512,558	9,738,373	8,706,660	9,848,616	9,586,697	9,153,628	10,345,448	9,374,296	10,267,586	10,686,262	9,736,714	13,003,772	10,114,669	9,196,249	10,724,490	10,923,193	10,411,793	10,704,500	10,649,424	9,773,403	11,535,451	########
WAC Price	1,898,528	1,632,847	1,743,902	1,842,632	1,851,799	1,537,554	1,738,691	1,778,358	1,529,681	1,757,526	1,600,014	1,822,791	1,750,566	1,587,024	2,085,811	1,665,593	1,487,533	1,598,279	1,727,909	1,657,593	1,617,251	1,753,227	1,759,613	2,004,193	1,830,951

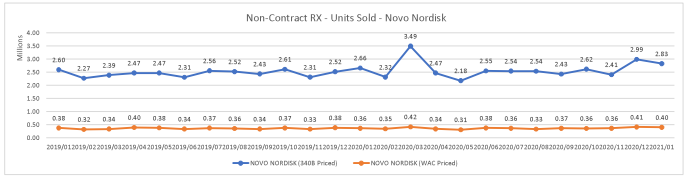


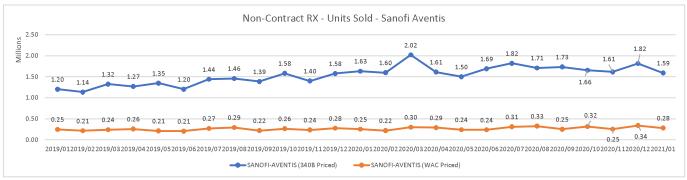
Sale_type	Manufacturer	Manufacturer	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
340B	ASTRAZENEC	ASTRAZENEC	1,752,155	2,009,957	1,685,943	1,740,990	1,816,354	1,587,303	1,793,907	1,653,237	1,594,435	1,855,965	1,614,166	1,820,854	1,927,918	1,808,007	2,099,239	1,714,191	1,628,641	1,775,529	1,779,156	1,721,356	1,853,601	1,664,717	1,495,746	########	########
WAC	ASTRAZENEC	ASTRAZENEC	302,650	247,129	257,188	271,661	283,977	245,016	286,225	270,106	251,573	287,592	259,044	296,499	298,298	244,783	362,123	278,858	245,953	258,938	288,762	271,676	285,154	301,402	293,646	347,456	354,055
340B	ELI LILLY & C	ELI LILLY & C	2,941,878	2,470,779	2,633,648	2,710,543	2,771,848	2,428,412	2,695,400	2,631,474	2,337,180	2,713,108	2,421,183	2,560,030	2,661,594	2,414,558	2,880,291	2,576,380	2,478,621	2,727,329	2,762,601	2,562,415	2,628,638	2,687,830	2,430,225	########	########
WAC	ELI LILLY & C	ELI LILLY & C	438,278	401,649	415,016	426,611	454,085	394,190	452,720	453,523	383,023	445,204	427,362	455,305	418,725	383,318	501,715	427,150	383,188	400,643	444,780	385,688	404,622	445,673	463,373	462,037	422,983
340B	NOVARTIS	NOVARTIS (3	1,336,108	1,156,533	1,235,953	1,321,264	1,336,625	1,181,452	1,363,570	1,324,090	1,401,717	1,583,849	1,628,054	1,792,147	1,806,863	1,601,959	2,515,526	1,744,875	1,413,522	1,982,521	2,019,971	1,881,569	2,061,032	2,022,040	1,825,754	########	########
WAC	NOVARTIS	NOVARTIS (V	531,384	448,272	496,790	491,120	524,224	354,677	357,443	407,313	338,854	385,319	346,035	411,112	416,275	394,154	504,859	328,590	309,801	323,848	319,535	339,242	308,243	331,959	384,482	442,468	371,198
340B	NOVO NORD	NOVO NORD	2,595,595	2,272,300	2,387,623	2,470,086	2,466,531	2,305,624	2,555,638	2,521,341	2,434,974	2,611,710	2,312,132	2,518,395	2,658,876	2,315,937	3,490,762	2,467,170	2,175,061	2,549,455	2,541,258	2,537,829	2,428,674	2,619,493	2,407,615	########	########
WAC	NOVO NORD	NOVO NORD	377,613	321,011	335,318	396,092	379,935	337,174	371,218	355,009	335,365	374,795	331,306	383,434	363,979	345,108	417,054	339,232	308,613	377,694	364,865	333,785	366,303	357,854	364,690	412,033	401,924
340B	SANOFI-AVE	SANOFI-AVE	1,203,830	1,135,250	1,323,843	1,269,631	1,346,886	1,203,805	1,440,016	1,456,464	1,385,073	1,580,568	1,398,621	1,575,785	1,630,902	1,595,998	2,017,793	1,611,889	1,500,395	1,689,343	1,820,001	1,708,585	1,732,134	1,655,032	1,613,724	########	########
WAC	SANOFI-AVE	SANOFI-AVE	247,210	214,057	239,069	256,538	209,068	205,927	270,315	291,868	220,172	263,936	235,682	275,431	252,460	218,965	299,425	290,907	239,348	236,372	309,327	325,967	251,923	315,035	252,747	339,404	280,386
340B	UNITED THE	UNITED THE	140	252	120	45	130	65	85	92	250	248	140	376	110	255	160	165	10	315	205	40	421	311	340	370	132
WAC	UNITED THE	UNITED THE	793	730	522	610	510	570	770	540	695	680	585	1010	830	695	635	855	630	785	640	1235	1005	1305	675	795	405

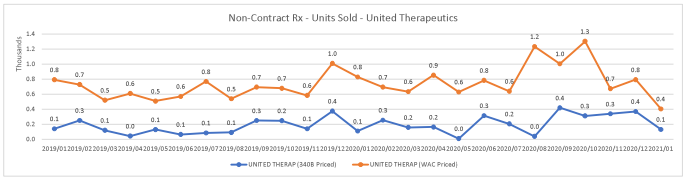




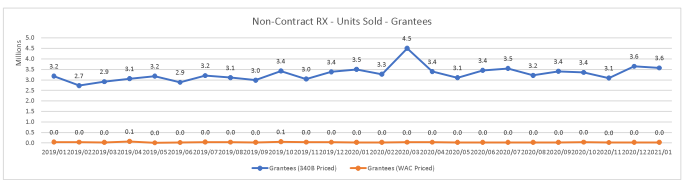


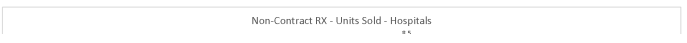


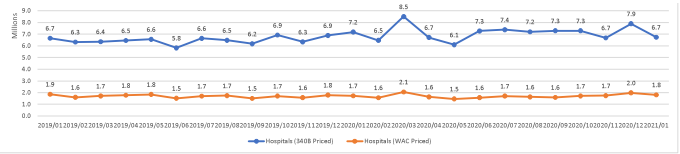




Entity Typ	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
Grantees (	3,174,423	2,724,460	2,913,122	3,058,251	3,177,089	2,884,321	3,202,627	3,108,903	2,982,386	3,424,958	3,038,159	3,381,093	3,498,737	3,269,794	4,503,726	3,395,172	3,102,174	3,449,788	3,542,723	3,215,120	3,408,486	3,355,189	3,090,279	3,645,975	3569165
Grantees (	38,921	34,751	24,125	72,956	6,634	18,919	40,112	36,240	27,814	52,539	35,231	33,890	27,350	26,624	29,821	29,631	23,756	27,733	23,380	21,808	25,244	36,336	17,923	25,768	26670.8
Hospitals (	6,655,282	6,320,610	6,354,008	6,454,307	6,561,284	5,822,340	6,645,990	6,477,794	6,171,242	6,920,490	6,336,137	6,886,493	7,187,525	6,466,921	8,500,046	6,719,497	6,094,075	7,274,703	7,380,470	7,196,673	7,296,015	7,294,235	6,683,123	7,889,476	6732305
Hospitals (	1,859,607	1,598,097	1,719,777	1,769,676	1,845,165	1,518,634	1,698,580	1,742,118	1,501,867	1,704,987	1,564,783	1,788,902	1,723,216	1,560,400	2,055,989	1,635,962	1,463,777	1,570,547	1,704,529	1,635,785	1,592,007	1,716,891	1,741,690	1,978,425	1804280



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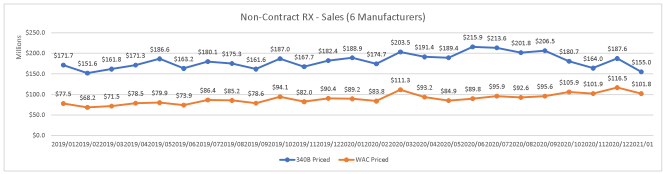
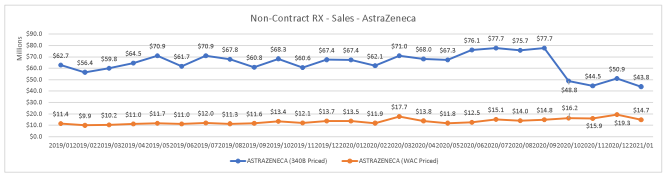
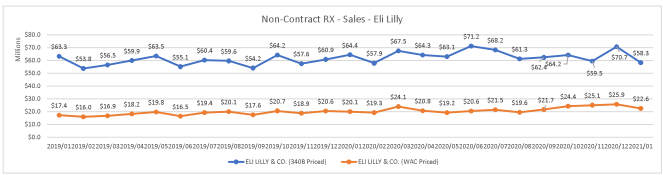
1.9 1.6 1.7 1.8 1.8 1.5 1.7 1.7 1.5 1.7 1.6 1.8 1.7 1.6 2.1 1.6 1.5 1.6 1.7 1.6 1.6 1.7 1.7 2.0 1.8
2019/01 2019/02 2019/03 2019/04 2019/05 2019/06 2019/07 2019/08 2019/09 2019/10 2019/11 2019/12 2020/01 2020/02 2020/03 2020/04 2020/05 2020/06 2020/07 2020/08 2020/09 2020/10 2020/11 2020/12 2021/01
Hospitals (340B Priced)
Hospitals (WAC Priced)

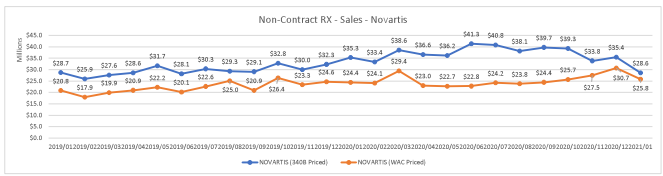
Sale type	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
340B Price	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########
WAC Price	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	$93,195,650	##########	$89,815,433	$95,850,383	$92,604,603	##########	##########	##########	##########	##########

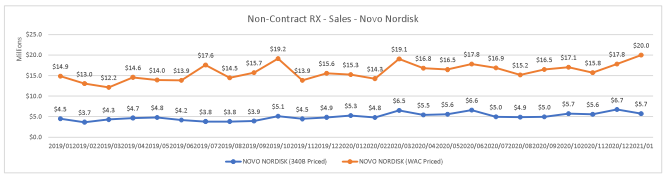


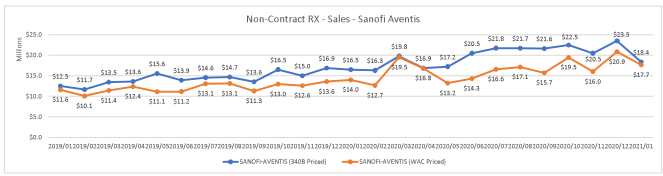
Sale type	Manufacture	Manufacture	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
340B	ASTRAZENEC	ASTRAZENEC	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	$62,135,146	##########	$68,040,633	$67,284,586	$76,095,377	##########	##########	##########	##########	$44,501,174	##########	##########
WAC	ASTRAZENEC	ASTRAZENEC	##########	$9,896,407	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	$11,869,377	##########	$13,758,999	$11,809,788	$12,509,331	##########	##########	##########	##########	$15,912,933	##########	##########
340B	ELI LILLY & C	ELI LILLY & C	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	$57,941,570	##########	$64,323,284	$63,086,763	$71,212,851	##########	##########	##########	##########	$59,464,216	##########	##########
WAC	ELI LILLY & C	ELI LILLY & C	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	$19,316,192	##########	$20,762,494	$19,241,649	$20,568,777	##########	##########	##########	##########	$25,143,179	##########	##########
340B	NOVARTIS	NOVARTIS (3	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	$33,377,676	##########	$36,594,049	$36,180,645	$41,333,342	##########	##########	##########	##########	$33,825,574	##########	##########
WAC	NOVARTIS	NOVARTIS (N	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	$24,065,806	##########	$23,028,996	$22,676,101	$22,770,661	##########	##########	##########	##########	$27,499,128	##########	##########
340B	NOVO NORC	NOVO NORC	$4,510,976	$3,680,141	$4,301,591	$4,683,337	$4,811,406	$4,206,428	$3,844,114	$3,824,175	$3,916,144	$5,117,100	$4,459,566	$4,859,514	$5,271,339	$4,816,275	$6,532,649	$5,464,951	$5,613,756	$6,614,817	$4,984,848	$4,909,618	$4,958,706	$5,737,008	$5,568,077	$6,731,314	$5,741,159
WAC	NOVO NORC	NOVO NORC	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	$14,272,415	##########	$16,837,304	$16,484,964	$17,830,450	##########	##########	##########	##########	$15,758,944	##########	##########
340B	SANOFI-AVE	SANOFI-AVE	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	$16,324,801	##########	$16,882,651	$17,249,632	$20,527,074	##########	##########	##########	##########	$20,522,262	##########	##########
WAC	SANOFI-AVE	SANOFI-AVE	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	$12,661,830	##########	$16,845,637	$13,208,365	$14,335,216	##########	##########	##########	##########	$16,029,856	##########	##########
340B	UNITED THE	UNITED THEI	$65,147	$160,386	$93,272	$51,516	$126,885	$52,473	$51,329	$31,194	$81,523	$132,789	$95,899	$99,196	$89,819	$87,794	$55,629	$74,110	$12,666	$95,530	$58,074	$22,931	$145,626	$161,275	$115,100	$222,260	$91,254
WAC	UNITED THE	UNITED THEI	$1,372,965	$1,288,315	$933,292	$1,321,606	$1,104,491	$1,235,215	$1,668,633	$1,169,853	$1,506,691	$1,473,684	$1,266,758	$2,189,579	$1,904,481	$1,593,859	$1,457,833	$1,962,220	$1,445,149	$1,800,998	$1,466,844	$2,887,025	$2,385,178	$3,100,166	$1,597,642	$1,889,041	$1,012,918

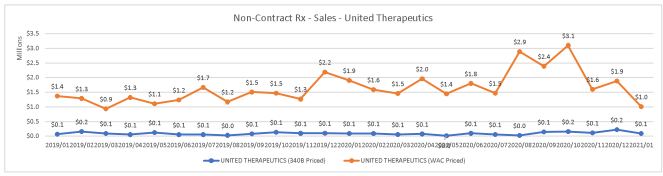




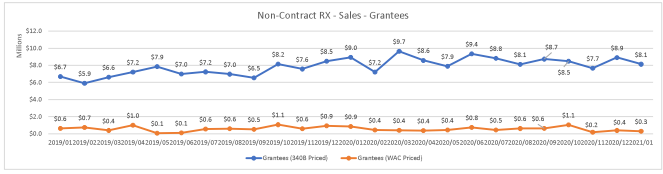








Entity Typ	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
Grantees (	$6,688,096	$5,904,276	$6,638,527	$7,217,040	$7,867,776	$6,990,614	$7,236,303	$6,979,319	$6,537,129	$8,160,162	$7,576,645	$8,490,188	$8,956,892	$7,214,426	$9,655,012	$8,592,097	$7,901,435	$5,361,045	$8,838,079	$8,131,320	$8,742,479	$8,493,050	$7,677,161	$8,922,429	$8,137,870
Grantees (	$629,481	$742,837	$387,255	$1,005,086	$67,678	$116,901	$566,726	$598,886	$525,668	$1,068,719	$589,909	$949,723	$851,115	$434,361	$398,887	$383,761	$436,070	$764,790	$450,757	$622,568	$631,938	$1,053,344	$192,877	$391,587	$303,901
Hospitals	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########
Hospitals	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	##########	$92,811,889	##########	$89,050,643	$95,399,626	$91,982,035	##########	##########	##########	##########	##########

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Hospitals (340B Priced)
Hospitals (WAC Priced)

340B HEALTH

2020 340B Health Annual Survey: 340B Hospitals Use Savings to Provide Services and Improve Outcomes for Low-Income and Rural Patients

Overview

From November 2020 through early January 2021, 340B Health conducted its annual survey to learn how 340B hospitals are using their 340B savings to support care for patients with low incomes and/or living in rural areas and other features of program operation and financing. Nearly 500 hospitals responded with disproportionate share (DSH) hospitals slightly over-represented. This issue brief presents findings from this survey including:

- All hospitals surveyed reported using their savings to benefit patients with low incomes and/or those living in rural communities.
- The most common ways savings were used were to increase access for patients with low incomes or living in rural areas, support uncompensated care, and expand service offerings.
- Three-quarters of critical access hospitals (CAHs)—defined as having 25 beds or fewer and located more than 35 miles from another hospital—rely on 340B savings to keep their doors open.
- More than half of respondents are using 340B savings to support their COVID-19 response.
- Cuts to the 340B program would force nearly all respondents to scale back key programs.
    - Oncology and diabetes services would be most affected for DSH hospitals, defined for this report to include rural referral centers (RRCs), and sole community hospitals (SCHs) that also must meet a DSH threshold.
    - For CAHs, cuts to the program would most impact their ability to maintain general patient care services and diabetes care.
- Nearly all are feeling the impact of the refusal of some large drug companies to provide discounts on drugs dispensed by community pharmacies, and cuts are likely if these actions become more widespread.

The 340B Program Has a Long History of Supporting the Safety Net

340B hospitals are a critical element of America's health care safety net. 340B DSH hospitals serve a patient population that is more likely to be low-income, disabled and/or minority[1] and are more likely to offer services that are low-margin but critical to patients.[2] Rural 340B hospitals often are the only source of care in a wide geographic area. The populations served by 340B hospitals in general face greater health challenges and barriers to accessing health care. 340B hospitals are on the front lines of the U.S. response to the global COVID-19 pandemic, treating patients with COVID-19 and administering the new vaccines approved for use by the Food & Drug Administration (FDA).

Enacted in 1992, the 340B drug pricing program requires drug companies to provide discounts on most outpatient drugs to qualifying safety-net hospitals, clinics, and health centers. While the program is small relative to total U.S. drug spending, it plays an outsized role in supporting the safety net. Savings from these discounts enable 340B providers to offer additional programs and services to low-income, rural, and/or vulnerable patients at no additional cost to taxpayers. This meets the stated congressional intent for the program "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[3] The care supported by 340B savings comes from drug companies' revenue, not from taxpayer dollars.

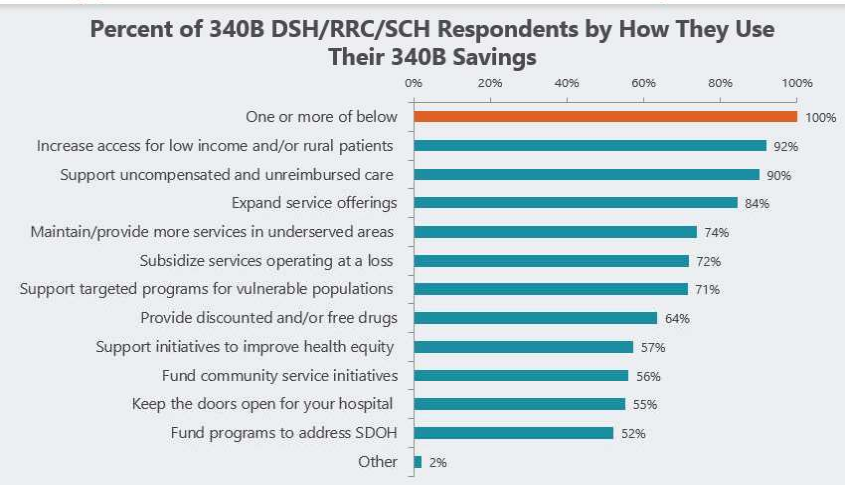
DSH Hospitals Use Their 340B Savings to Support a Wide Range of Programs and Services for Patients with Low Incomes and Those Living in Rural Communities

The purpose of the 340B program is to provide discounts on outpatient drugs to create savings that allow safety-net providers to stretch scarce resources as far as possible to reach more patients and provide more comprehensive services.[4] This year's survey documents the many ways 340B hospitals are using their savings to support services for patients with low incomes and those living in rural areas.

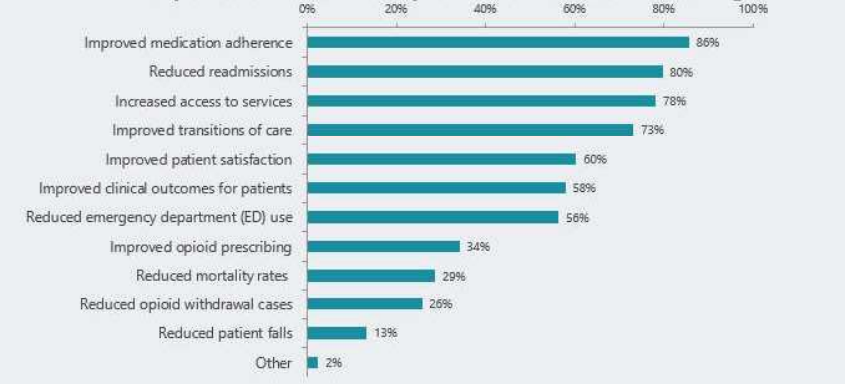
Fully 100% of DSH hospitals reported that they use their 340B savings in one or more ways to serve vulnerable patients, and most reported many. The most common uses reported were to increase access for low-income and/or rural patients (92%) and to support uncompensated and unreimbursed care (90%).

Respondents also reported areas where 340B savings have supported improved outcomes. Nearly nine of 10 reported 340B savings supported programs that improved medication adherence. Increased access and reduced readmissions were close behind. Hospitals also highlighted specific ways their organizations use their 340B savings and outcomes they have worked to improve.

All 340B DSH hospitals use their savings to support care for low-income and rural patients.



86% percent of DSH hospitals report the 340B savings has helped support medication adherence.



Specific examples of ways DSH hospitals use their 340B savings to serve patients include providing:

- Infusion services for oncology, respiratory diseases, infectious diseases, and auto-immune diseases to patients with low incomes
- Outpatient behavioral health to children and adolescents including therapy and medication management
- A pharmacy in a low-incomes area where retail chains have left
- Resources and medication to school-based clinics
- A mobile mammography service for underserved communities
- Clinical pharmacy services including medication therapy management and disease management

340B hospitals use 340B savings to improve quality outcomes, including:

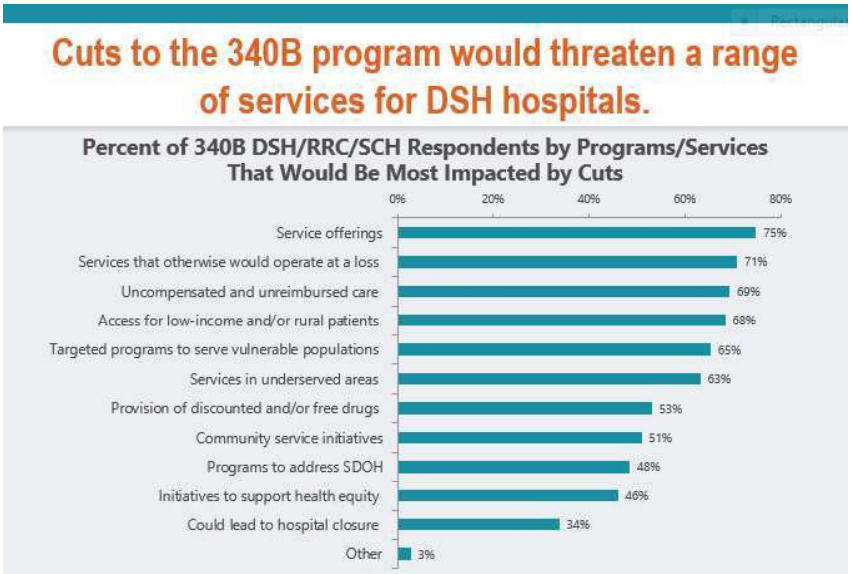
- Better glucose management
- Medication safety and antimicrobial stewardship
- Medication adherence through pharmacists working with individual patients in primary care clinics
- "Meds to beds" and pharmacy transition of care programs to reduce readmissions
- Reduced overdose deaths by providing free nalaxone to at-risk patients

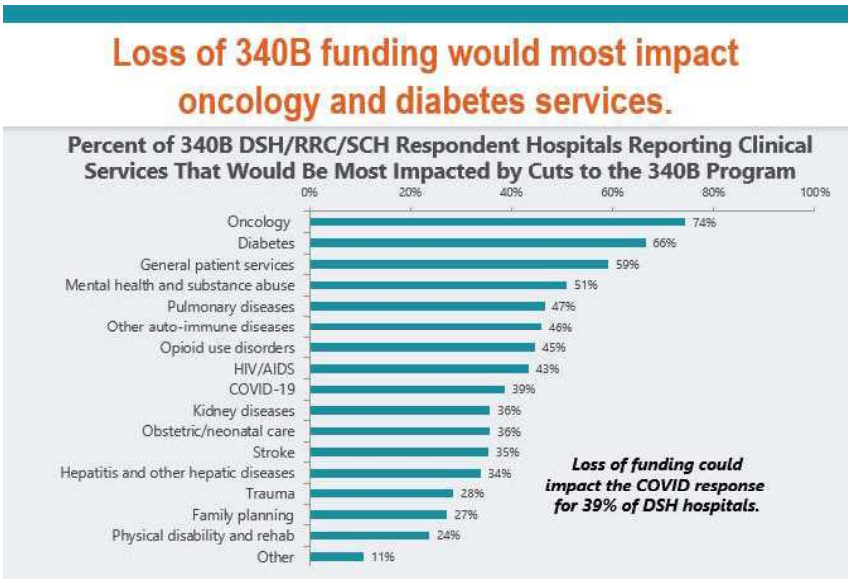
Cuts to the 340B Program Would Hurt DSH Hospitals and Patients

Actions by federal or state legislatures and regulatory agencies and/or drug companies that reduce 340B savings would take resources away from critical safety-net services provided by 340B hospitals.

340B DSH hospitals most often reported that cuts would threaten service offerings overall (75%), harm those services that would operate at a loss without 340B support (71%), and reduce the ability to provide uncompensated or unreimbursed care (69%). Programs to provide discounted or free drugs would be at risk for more than half. A third (34%) said a loss of savings could lead to hospital closure.

Clinical services that would be most affected by cuts to savings are oncology (74%) and diabetes care (66%). Other services critical to vulnerable populations such as mental health (51%), substance abuse (45%), and HIV/AIDS care (43%) are also at risk. Two in five said cuts could impact COVID-19 response.





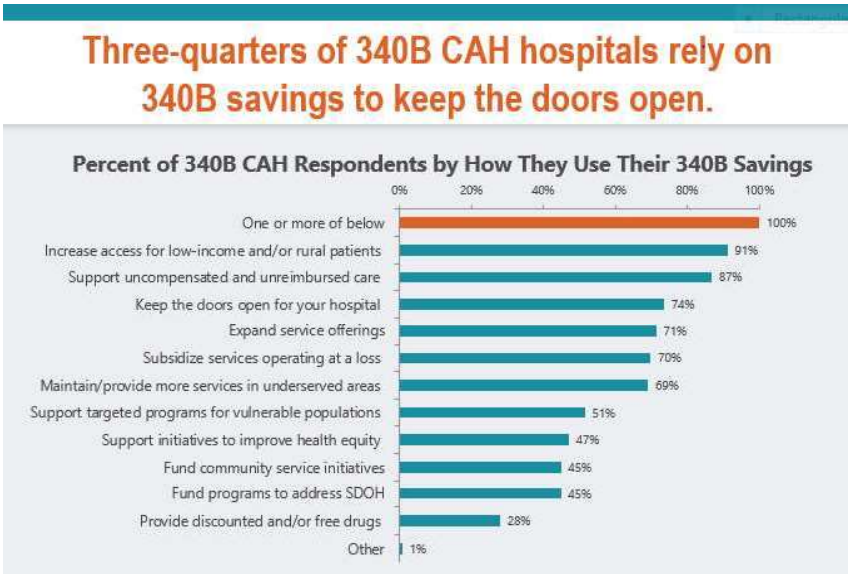
"It is difficult to imagine what our organization would look like without 340B as it would leave substantial annual losses from overall hospital operations."

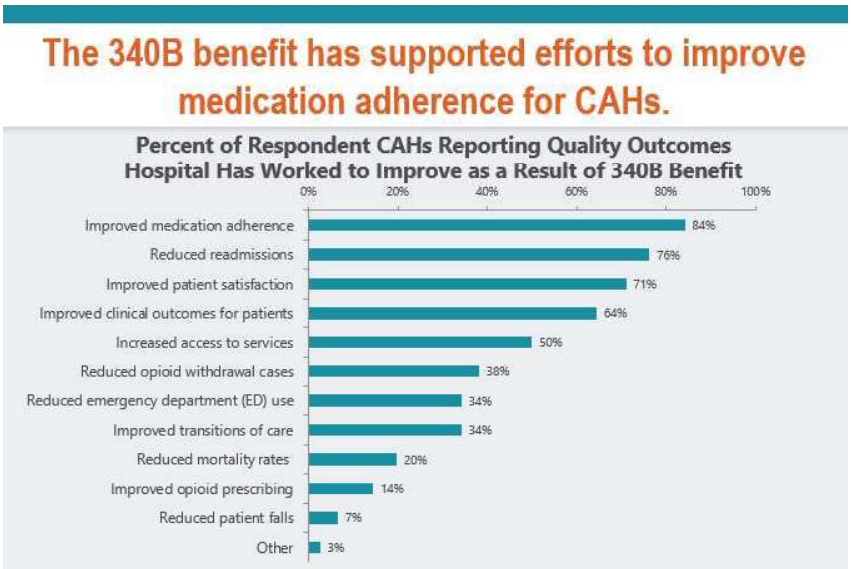
340B is a Lifeline for Small Rural Hospitals

340B is particularly critical to rural hospitals. One in five Americans live in rural areas.[5] Many of these areas are sparsely populated and far from urban areas. As such, accessing health care can be a challenge. Rural areas often don't have enough residents to support a hospital as low volumes create financial challenges. In 1997, Congress created the critical access hospital (CAH) designation, which provides special reimbursement for hospitals with 25 beds or fewer and that are at least 35 miles from another hospital. Today nearly three-quarters of rural hospitals are CAHs.[6]

"Our CAH has used our 340B benefits to open a retail pharmacy so that our residents don't have to drive 30 plus miles to obtain their prescription medications."

Despite the CAH program, rural hospitals have continued to struggle. Since 2010, more than 134 rural hospitals have closed,[7] and many remain vulnerable to closure. The financial fallout from COVID-19 is yet to be seen. The loss of a hospital in a rural community has devastating effects on the local economy.



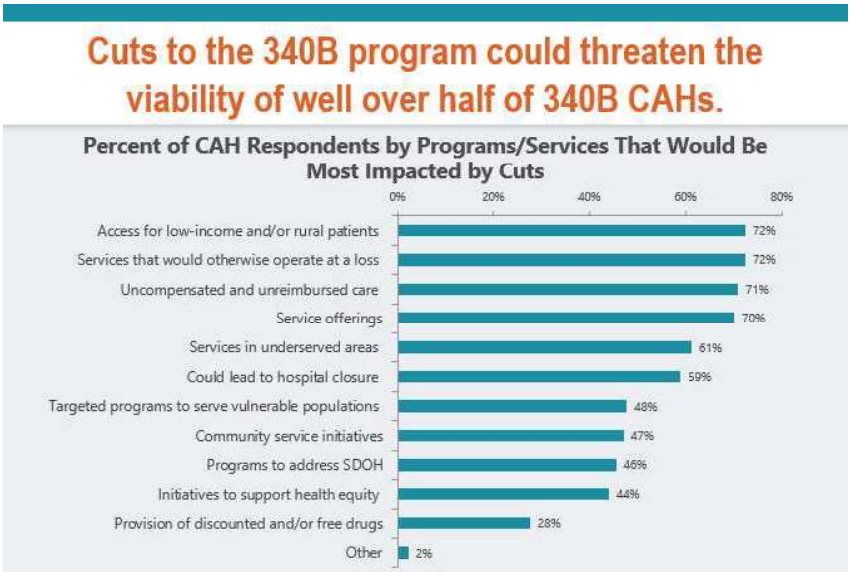


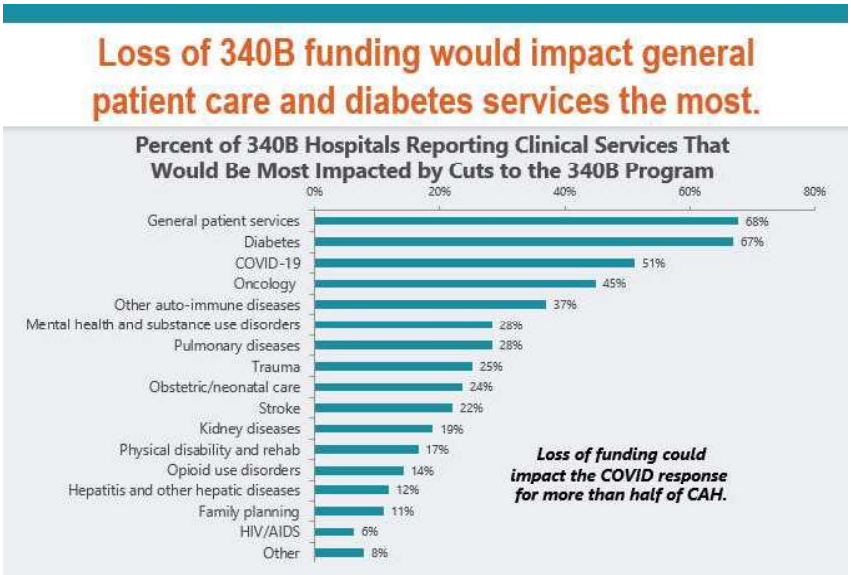
Congress expanded the 340B program to CAHs and other types of rural hospitals in 2010, offering a financial lifeline. Three-quarters of CAH survey respondents reported that 340B savings help keep their doors open. Nine in 10 rural hospitals use their savings to increase access for patients with low incomes and/or those living in rural areas and to support uncompensated and unreimbursed care (87%).

The 340B program also provides CAHs with resources they can use to improve quality. Eight of 10 CAH respondents reported that 340B savings help them improve medication adherence. Other outcomes supported by 340B savings include reduced readmissions (76%), improved patient satisfaction (71%), and increased access to services (51%).

Telemedicine programs are an important way that CAHs can provide access to specialty care in rural communities. More than half of CAHs reported using their 340B benefit to support a telemedicine program.

Cuts to the 340B Program Would Harm Small Rural Hospitals and Their Patients





"Our CAH uses our 340B benefit to help maintain clinic access in rural outlying areas. Without those, patients would need to drive 20-30 miles to access healthcare providers."

340B savings represent a critical funding source for CAHs. About 59% of CAHs report that the reduction or elimination of 340B savings would threaten their ability to stay open. Nearly three-quarters said cuts could harm access, put services otherwise operating at a loss at risk, and reduce the ability to provide uncompensated and unreimbursed care.

Any cuts could harm clinical services. For CAHs, which tend not to provide much specialty care, general patient services and diabetes care are most at risk. More than half noted COVID-19 response could be harmed. Cancer also was an area of concern. Loss of cancer services in CAHs would increase travel times and expenses for chemotherapy and other cancer treatments for rural populations.

Specific ways CAHs use their 340B savings include:

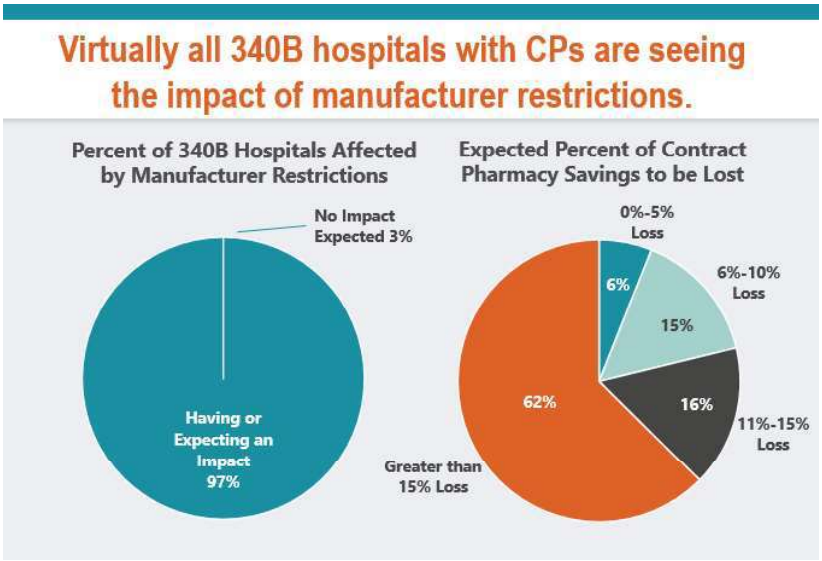
- Offer pharmacist led medication therapy management services
- Improve management of diabetes and obesity; provide insulin for $1 per month
- Hold three-night teen wellness event including dental exams, physicals, mental health, reproductive health, immunizations, and sports health
- Outreach to rural areas for diabetes, chronic obstructive pulmonary disease, and other chronic illnesses
- Bridge the gap between cost and reimbursement to keep the doors open
- Keep women's services open, the only delivery service within 45 miles
- Support services that otherwise would operate at a loss
- Offer more lenient charity care guidelines (up to 400% of federal poverty level)

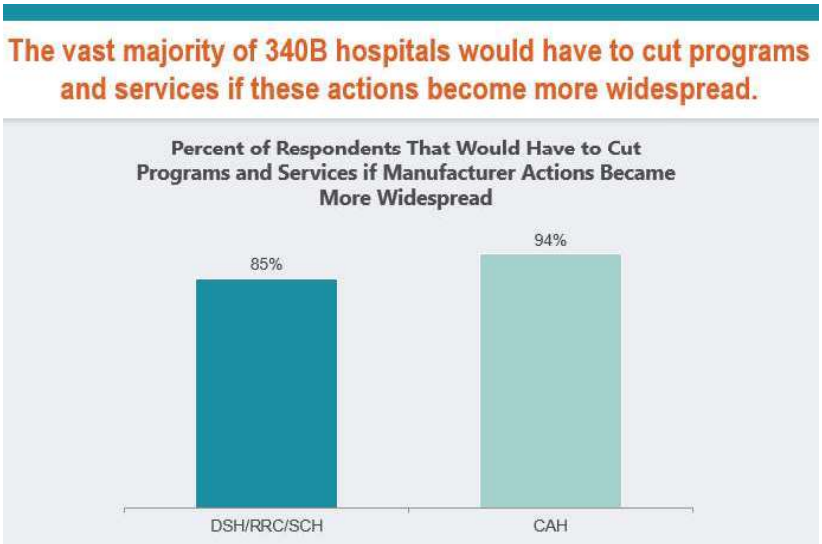
Manufacturer Restrictions on Community Pharmacy (CP) are Hurting 340B Hospitals and the Patients They Serve

The 340B program allows covered entities to receive discounts on both drugs provided by in-house outpatient and retail pharmacies as well as through contracts with community pharmacies. Prescriptions for patients of 340B hospitals filled at community pharmacies are eligible for the 340B discount.

Overall, more than a quarter of the average 340B savings comes from CP arrangements, though this varies by hospital type. CAHs reported receiving more than half (51%) of their 340B savings from arrangements with community pharmacies while DSH hospitals reported 26%.

Recently, a number of large drug-makers have cut off discounts on drugs dispensed through community pharmacies. Two-thirds of hospitals estimated these actions are reducing CP savings by 15% or more. Nearly all 340B hospitals report they will have to cut programs and services if these restrictions become more widespread.





In addition, a drug industry consulting company is marketing a new 340B payment model that would replace upfront discounts with rebates. Nearly all responding hospitals expressed concerns about the operational difficulties inherent in such a model (97%), the cash flow implications of having to front payment for drugs at the undiscounted price (95%), lack of transparency (95%), and risk of denials (93%).

"Even with 340B savings, we are budgeting for a loss this year for a second year in a row. 340B doesn't make us rich; it helps us maintain the care we provide to the community."

Survey Responses Demonstrate Value of 340B

This year's 340B Health survey documents the multiple programs and services made possible by the savings the 340B program provides to safety-net and rural hospitals. By offering care and assistance such as free and reduced-price medications, medication therapy management, and comprehensive oncology programs, 340B hospitals are using 340B savings to meet a wide variety of community needs, especially for populations with low incomes or who live in rural communities. 340B savings are helping many 340B hospitals respond to COVID-19. Without the 340B program, critical programs would need to be scaled back. In some cases, loss of 340B funding could lead to closure.

> *"We are the only hospital within 60 miles. Our system is so financially fragile that at the beginning of the pandemic when ancillary services were halted, we had to terminate services to keep our doors open. We cannot withstand another financial blow. We desperately need the savings generated through the 340B program."*

[1] L&M Policy Research. A Comparison of Characteristics of Patients Treated by 340B and Non-340B Providers. 2019 Apr 8. https://www.340bhealth.org/files/340B_Patient_Characteristics_Report_FINAL_04-10-19.pdf
[2] Dobson DaVanzo. The Role of 340B DSH Hospitals in Serving Medicaid and Low-Income Medicare Patients. 2020. https://www.340bhealth.org/files/340B_and_Medicaid_and_Low_Income_Medicare_Patients_Report_7.10.2020_FINAL_.pdf
[3] Veterans' Health Care Act of 1992. Section 602, Public Law 102-585.
[4] *Ibid.*
[5] U.S. Census Bureau. https://www.census.gov/library/stories/2017/08/rural-america.html
[6] American Hospital Association. https://www.aha.org/statistics/fast-facts-us-hospitals. Rural Health Information Hub. https://www.ruralhealthinfo.org/topics/critical-access-hospitals
[7] The Cecil G. Sheps Center for Health Services Research. https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/

340B HEALTH

340B Health is an association of more than 1,400 non-profit hospitals. We are the leading advocate and resource for hospitals that serve their communities through participation in the 340B drug pricing program. For more information about us and the 340B program, visit www.340bhealth.org.

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

The General Counsel
Washington, D.C. 20201

ADVISORY OPINION 20-06 ON CONTRACT PHARMACIES UNDER THE 340B PROGRAM
DECEMBER 30, 2020

The 340B Program, established by section 340B of the Public Health Service Act ("PHSA"), 42 U.S.C. § 256b, imposes limitations on the prices manufacturers may charge for medications sold to specified health care facilities, referred to as "covered entities." Those facilities include public hospitals and community health centers, many of which provide safety-net services to the poor. The 340B Program requires drug manufacturers, as a condition of coverage of their products under Medicaid (*see* Social Security Act ("SSA") § 1902(a)(54)) and Medicare Part B (*see, e.g.*, SSA §§ 1842(o)(1), 1847A), to agree to sell their covered outpatient drugs to covered entities at no more than the statutorily-set "ceiling price." *See* SSA § 1927(a)(1).

Many covered entities enter into written agreements with pharmacies ("contract pharmacies") to distribute their covered outpatient drugs to the entities' patients. Under those agreements, the covered entity orders and pays for the 340B drugs, which are then shipped from the manufacturer to the contract pharmacy. Although the contact pharmacy has physical possession of the drug, it has been purchased by the covered entity.

Recently, certain drug manufacturers participating in the 340B Program are declining to distribute covered outpatient drugs through contract pharmacies at the ceiling price.

The Office of the General Counsel ("OGC") has received numerous requests from both manufacturers and covered entities to address whether it is proper for a drug manufacturer participating in the 340B Program to refuse to provide covered outpatient drugs at the 340B ceiling price to a covered entity for drugs distributed at the entity's contract pharmacies. For the reasons set forth below, we conclude that to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs.

I. Analysis

A. The Plain Meaning of Section 340B Requires Manufacturers to Sell Covered Drugs to Covered Entities at or Below the Ceiling Price, Independent of Whether the Entity Opts to Use Contract Pharmacies to Dispense the Drugs

"[O]ur inquiry begins with the statutory text, and ends there as well if the text is unambiguous." *BedRoc Ltd., LLC v. United States*, 541 U.S. 176, 183 (2004). Section 340B of the PHSA, entitled "Limitation on prices of drugs purchased by covered entities," states, in relevant part, that "[t]he Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . purchased by a covered entity . . . does not exceed [the ceiling price]." 42 U.S.C. § 256b(a)(1) (emphasis supplied). Furthermore, "[e]ach such agreement . . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.* As a result, the obligations placed on manufacturers by 340B are set out in a Pharmaceutical Pricing Agreement ("PPA") between the Secretary and the respective manufacturer. *See generally Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110 (2011) (describing role of PPAs in 340B Program). The exemplar PPA provides, in pertinent part, as follows:

> Pursuant to requirements under section 340B of the Act, the Manufacturer agrees to the following: (a) for single source and innovator multiple source drugs, to charge covered entities a price for each unit of the drug that does not exceed an amount equal to [the ceiling price].

PPA § II(a). The exemplar PPA Addendum provides that a "[m]anufacturer shall offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price, if such drug is made available to any other purchaser at any price." PPA Addendum ¶ 2.

Thus, the core requirement of the 340B statute, as also reflected in the PPA and Addendum, is that manufacturers must "offer" covered outpatient drugs at or below the ceiling price for "purchase by" covered entities. This fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. All that is required is that the discounted drug be "purchased by" a covered entity. In this setting, neither the agency nor a private actor is authorized by section 340B to add requirements to the statute. *See Radovich v. Nat'l Football League*, 352 U.S. 445, 454 (1957) ("Congress itself has placed the private antitrust litigant in a most favorable position . . . . In the face of such a policy this Court should not add requirements to burden the private litigant beyond what is specifically set forth by Congress in those laws."); *Financial Planning Ass'n v. SEC,* 482 F.3d 481 (D.C. Cir. 2007); *Baker v. Bell Textron, Inc*., 2020 WL 5513431, at *4 (N.D. Tex. 2020) ("The Court will not add requirements to the law that Congress could have included but did not.").

It is against this backdrop that we examine the 340B phrase "purchased by." It is difficult to envision a less ambiguous phrase and no amount of linguistic gymnastics can ordain otherwise. The Court recently cautioned against seeing ambiguity where none exists. For

example, a regulation must be "genuinely ambiguous" before resorting to deference. *Kisor v. Wilkie*, ___U.S.___, 139 S.Ct. 2400, 2415 (2019). Here, as we understand it, the medications at issue are sold by the manufacturer to the covered entity; the covered entity takes title and the covered entity pays the manufacturer either directly or through the manufacturer's distributor. In either event, the arrangement between the manufacturer and covered entity is a straightforward "sale" which "consists of the passing of title from the seller [drug manufacturer] to the buyer [covered entity] for a price." Uniform Commercial Code (U.C.C.) § 2-106.[1] A "buyer" is, by definition, a "purchaser." BLACK'S LAW DICTIONARY (11th ed. 2019) (defining "buyer" as "[s]omeone who makes a purchase"). The situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant. *See* U.C.C. § 2-401(2) ("Unless otherwise explicitly agreed title passes to the buyer at the time and place at which the seller completes his performance with reference to the physical delivery of the goods . . . ").

Given the lack of ambiguity in the plain text of the statute, the above analysis is dispositive. *Bostock v. Clayton Cty.*, ___U.S.___, 140 S. Ct. 1731, 1739 (2020) ("[W]hen the meaning of the statute's terms is plain, our job is at an end."). This straightforward textual interpretation, aside from dutifully reflecting the plain meaning of the statute, has the added benefit of comporting with the statute's purpose and history.

B. The Purpose and History of the 340B Program Reflect the Provision's Plain Meaning

1. Contract Pharmacies Have Been an Integral Part of the 340B Program Since Its Outset

The 340B Program was created to allow covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rept. No. 102–384(II), at 12 (1992). As the Health Resources and Services Administration ("HRSA")—the agency primarily responsible for administering the 340B Program—has explained in prior guidance, a substantial number of covered entities are practically constrained to rely on contract pharmacies to access the 340B Program; if manufacturers can simply shut off this means of access, the Program's effectiveness will be greatly diminished. *See Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services*, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996); *see also Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*, 84 Fed. Reg. 2340 (proposed Feb. 6, 2019) (OIG proposed rule discussing distribution of pharmaceuticals).[2]

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[1] The U.C.C. can be used for statutory construction, even if it does not directly apply. *See Comm'r of Internal Revenue v. Brown*, 380 U.S. 563, 571 (1965) (interpreting provision of the Internal Revenue Code by pointing to U.C.C. as support for the "ordinary sense" of the word "sale").

[2] The argument that the statute also evinces a purpose to prevent drug diversion or duplicate discounting, and therefore prohibits contract-pharmacy arrangements, is not persuasive. That is like arguing that the main purpose of federal healthcare programs are their antifraud provisions. In the absence of the core 340B discount mechanism, there would be no need for the duplicate-discount or diversion provisions.

This is particularly pertinent given that at the outset of the 340B Program only approximately 500 out of 11,500 covered entities (less than 5 percent) used in-house pharmacies. *See* 61 Fed. Reg. at 43,550. This is not surprising: the Program is aimed at benefiting providers that are small, remote, resource-limited, receiving federal assistance, or serving disadvantaged populations. *See, e.g.*, 42 U.S.C. § 256b(a)(4) (defining covered entities); *Astra USA*, 563 U.S. at 113. These are the poster children of providers that one would expect to lack an in-house pharmacy. To champion a policy, ungrounded in the language of the statute, that would foreclose 340B discounts to 95 percent of covered entities and foreclose discounts to the neediest of this cohort is inconsistent with purpose of the Program and common sense. Had Congress intended to reach such a bizarre result, it would have used language affirmatively precluding the use of contract pharmacies as arms in the distribution channel, but it did not. *Doe v. Hesketh*, 828 F.3d 159, 167 (3d Cir. 2016) (the result is "so bizarre that Congress could not have intended it").

2. The Department's Longstanding Interpretation of Section 340B Reflects the Plain Language of the Section by Recognizing the Use of Contract Pharmacies

The Department's longstanding interpretation of the statute, as expressed through guidance, is that manufacturers are required to offer ceiling prices even where contract pharmacies are used. In 1996, HRSA issued the aforementioned guidance and stated, "[i]t has been the Department's position that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price." 61 Fed. Reg. at 43,549. HRSA's assertion cannot be attacked as impermissible legislative rulemaking,[3] because the guidance only sought to "explain the statutory language by clarifying the meaning given by the Department to particular words or phrases"—it "create[d] no new law and create[d] no new rights or duties" not otherwise present in the statute. *See id.* at 43,550. HRSA reaffirmed its interpretation of the statute in guidance issued in 2010. *See* HRSA, *Notice Regarding 340B Drug Pricing Program–Contract Pharmacy Services*, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

The Department's consistent position over the past 24-plus years would factor into a court's interpretation of the statute. Courts defer to agency expertise in the interpretation of statutes, especially where they govern complex administrative regimes. *See, e.g.*, *United States v. Mead Corp.*, 533 U.S. 218, 227–28 (2001). Conversely, a court would be skeptical of an abrupt about-face. *See, e.g.*, *Wyeth v. Levine*, 555 U.S. 555, 577–81 (2009). Courts may also look to agency implementation and the actions of regulated parties to determine the meaning of a statute. *See, e.g.*, *S.D. Warren Co. v. Me. Bd. of Env't Prot.*, 547 U.S. 370, 377–78 (2006) (even though relevant agencies had not "formally settled the definition, or even set out agency reasoning," the "administrative usage of [the disputed term] in this way confirm[ed the Court's]

[3] *See, generally*, *Pharm. Rsch. and Mfrs. of Am. v. U.S. Dep't of Health and Human Servs.*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014) ("Within section 340B, Congress specifically authorized rulemaking in three places: (1) the establishment of an administrative dispute resolution process, (2) the 'regulatory issuance' of precisely defined standards of methodology for calculation of ceiling prices, and (3) the imposition of monetary civil sanctions."); *Pharm. Rsch. and Mfrs. of Am. v. U.S. Dep't of Health and Human Servs.*, 138 F. Supp. 3d 31, 39 (D.D.C. 2015) (even if "HHS lacks the authority to promulgate the rule as a binding statement of law, HHS is not forbidden altogether from proffering its interpretation of the statute").

understanding"); *Bd. of the Trs. of Leland Stanford Jr. Univ. v. Roche Molecular Sys.*, 563 U.S. 776, 792–93 (2011) ("[I]t is worth noting that our construction of the [statute in question] is reflected in the common practice among parties operating under the Act."). Here, contract-pharmacy arrangements have been utilized, and honored by manufacturers, since 1996 and earlier.[4]

C. Manufacturers' Rationale for Precluding the Use of Contract Pharmacies Is Not Supported by the Language of the Statute and Leads to Absurd Results

The primary rationale offered for cutting off contract pharmacies—that such arrangements lead to a heightened risk of diversion and duplicate discounts—makes clear that manufacturers are attempting to circumvent section 340B's procedures for resolving disputes between manufacturers and covered entities. *See, e.g.*, *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1984) ("In ascertaining the plain meaning of the statute, the court must look to the particular statutory language at issue, as well as the language and design of the statute as a whole.") (emphasis supplied). Not surprisingly, the manufacturers have been unable to point to any language in the statute that would support this hobbling interpretation. If a manufacturer is concerned that a covered entity has engaged in duplicate discounting or diversion, *see* 42 U.S.C. § 256b(a)(5)(A), (B), it must (1) conduct an audit, and (2) submit the claim to the administrative dispute resolution ("ADR") process, *see* §256b(d)(3)(A). The PPA even provides that a covered entity's failure to comply with the audit requirement does not "relieve the Manufacturer from its obligation to conform to the pricing requirements as provided in section 340B(a) of the Act and the Agreement." PPA § IV(d). Moreover, the Department specifically rejected this reasoning when issuing regulations regarding the calculation of the 340B ceiling price. In responding to a comment regarding perceived 340B violations, HRSA stated "[m]anufacturers cannot condition sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity." *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation*, 82 Fed. Reg. 1210, 1223 (Jan. 5, 2017). In addition, "[m]anufacturers that suspect diversion are encouraged to work in good faith with the covered entity, conduct an audit per the current audit guidelines, or contact HHS directly." *Id.* Certain manufacturers' newfound and unilateral refusal to sell drugs through contract pharmacies is at odds with the structure and intended operation of the statute.[5]

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[4] The fact that Congress has not amended the 340B statute to expressly exclude contract-pharmacy arrangements from coverage can be read as supporting the agency's longstanding construction. *See* Valerie C. Brannon, Cong. Rsch. Serv., R45153, *Statutory Interpretation: Theories, Tools, and Trends* 63 (2018) (discussing "presumption of legislative acquiescence").

[5] For 24-plus years, manufacturers have offered the ceiling price to covered entities using contract-pharmacy distribution. To the extent manufacturers now have sincere concerns about diversion or duplicate discounting, the 340B statute speaks directly to how they should proceed. *See also 340B Drug Pricing Program; Administrative Dispute Resolution Regulation*, 85 Fed. Reg. 80,632, 80,633 (Dec. 14, 2020) ("The purpose of the ADR process is to resolve . . . claims by manufacturers, after a manufacturer has conducted an audit as authorized by section 340B(a)(5)(C) of the PHSA, that a covered entity has violated the prohibition on diversion or duplicate discounts."). Manufacturers who shut off contract-pharmacy access may have also skipped over any effort to resolve disputes with covered entities in "good faith." PPA § IV(a)(1) ("If the Manufacturer believes that a covered entity has violated the prohibition against resale or transfer of covered outpatient drugs, section 340B(a)(5)(B), or the prohibition against duplicate discounts or rebates, section 340B(a)(5)(A) . . . [t]he Manufacturer shall attempt in good faith to resolve the matter with the covered entity."); 85 Fed. Reg. at 80,633 ("Historically, HHS has

Relatedly, it has also been argued that the use of contract pharmacies is inconsistent with the 340B statute's prohibition on diversion of discount drugs. We start with the basic proposition that subsection (a)(5)(B) was intended to prohibit the diversion of 340B drugs. *See* 42 U.S.C. § 256b(a)(5)(B) ("With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity."). According to one court, the 340B Program places a "ban on 'diversion,' *i.e.*, a requirement that covered entities refrain from reselling or otherwise transferring covered drugs to non–340B entities[.]" *Cty. of Santa Clara v. Astra USA, Inc*., 257 F.R.D. 207, 211–12 (N.D. Cal. 2009), *vacated on other grounds*, *Astra USA,* 563 U.S. 110; *see also* 85 Fed. Reg. at 80,636 (subsection (a)(5)(B) prohibits diversion).

Diversion means that, on net, covered outpatient drugs end up in the hands of persons who are not patients of the covered entity. The movement of drugs purchased by the covered entity and ultimately dispensed to the patient by a contract pharmacy can involve complex inventory models. Whether diversion occurs, however, should be independent of the inventory-accounting model contemplated by the agreement between the contract pharmacy and the covered entity. *See Toyota Motor Sales, U.S.A., Inc. v. United States,* 35 Ct. Int'l Trade 1205 (2011) (noting that inventory-accounting methods are authorized to determine tariffs and drawbacks); *Sears, Roebuck & Co. v. King County*, 487 P.2d 221, 223, 5 Wash. App. 273, 276 (1971) (for tax purposes "identification by any reasonable and reliable [inventory-accounting] method [is proper], rather than by a strict tracing method.").

The notion that the legitimate transfer of drugs to contract pharmacies so that they can be dispensed to patients of the covered entity constitutes diversion not only ignores the realities of accounting, but also that the covered entity and contract pharmacy are not distinct, but function as principal-agent. As explained, the covered entity remains the purchaser whether it chooses to have discount drugs distributed through an in-house pharmacy or a contract pharmacy. *See also* 61 Fed. Reg. at 43,550 ("The mechanism does not in any way extend this pricing to entities which do not meet program eligibility."); *id.* (agreeing that "[a]s a general rule, a person or entity privileged to perform an act may appoint an agent to perform the act unless contrary to public policy or an agreement requiring personal performance") (citing Restatement (Second) of Agency § 17 (Am. L. Inst. 1995)); *id.* ("The contract pharmacy would act as an agent of the covered entity, in that it would not resell a prescription drug but rather distribute the drug on behalf of the covered entity. This situation is akin to a covered entity having its own pharmacy."); *id.* at 43,552 (under "bill to/ship to" arrangement contemplated in guidance, "[t]he contract pharmacy does not purchase the drug. Title to the drugs passes to the covered entity" and "the manufacturer is still selling to the covered entities"); *cf. Abramski v. United States*, 573 U.S. 169, 186 (2014) ("[t]he individual who sends a straw [purchaser] to a gun store to buy a firearm is transacting with the dealer, in every way but the most formal" such that "straw arrangements are not a part of the secondary market, separate and apart from the dealer's sale") (emphasis in original).[6]

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encouraged manufacturers and covered entities to work with each other to attempt to resolve disputes in good faith.").

[6] Similar reasoning still applies under the so-called "replenishment" model, where the contract pharmacy dispenses medications from a general inventory to the covered entity's patient and "replenishes" its general

In addition, the argument that use of contract pharmacies constitutes an illicit "transfer" leads to absurd results. For instance, if a covered entity uses a courier service to send discount drugs to its patient, this, too, would be appear to be an illegal "transfer" to the shipper. Any arrangement that did not involve a physical hand-off from the employee of a covered entity to the patient him or herself could be an unauthorized "transfer" under the 340B statute. To avoid such absurdities, and under the canon of *noscitur a sociis*,[7] the phrase "otherwise transfer" must be interpreted in conjunction with the word "resell" and the title of that specific provision ("Prohibiting resale of drugs") (emphasis supplied).[8]

This conclusion is reinforced by an understanding of the practical realities of drug distribution. Such distribution often functions through intermediaries. For example, covered entities often purchase 340B discounted drugs from wholesalers, not directly from manufacturers. And yet, the obligations of § 256b(a) are placed on manufacturers. If it were correct that distribution to any entity other than a covered entity freed the manufacturer from the obligation to charge no more than the ceiling price, then there would be no firm basis for the wholesalers to charge-back discounts to the manufacturer. Large portions of the current 340B Program would seem to turn on solely manufacturers' voluntary choice to offer the ceiling price,

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inventory with discount medications purchased by the covered entity. The inventory commingling (drugs purchased by covered entity(ies) under the auspices of 340B, commingled with what the contract pharmacy might otherwise have) does not change the analysis. *Cf. Martin Marietta Corp. v. N.J. Nat'l Bank*, 612 F.2d 745, 749 (3d Cir. 1979) ("identification" of goods for purposes of U.C.C. § 2-501 not broken even if "seller removes some of the fungibles and later replaces them . . . because such conduct is quite natural with fungibles and cannot be taken as an intent to negate the buyer's interest in the goods"); *Apex Oil Co. v. Belcher Co. of N.Y., Inc.*, 855 F.2d 997, 1,003–05 (2d Cir. 1988) ("[W]here fungible goods are concerned, identification is not always an irrevocable act and does not foreclose the possibility of substitution."); *Matter of Bevill, Bresler & Schulman Asset Mgmt. Corp.*, 67 B.R. 557, 588 (D.N.J. 1986) (under U.C.C. § 9-207, "a secured party is allowed to commingle fungible collateral, including certain types of securities, and may sell the collateral and replace it with instruments which are equivalent in kind and value without breaching his duty to exercise reasonable care in the custody and preservation of the pledged collateral"). Nor does the ordering of events. If the contract pharmacy's dispensing of the drugs is event "A" and the contract pharmacy's receipt of the drugs is event "B," the ordering of events does not matter if repeated over time. Whether the series looks like ...BABABA... or ...ABABAB... is simply a function of the reference timeframe. In sum, where the contract pharmacy is replenished by the covered entity and dispenses to the covered entity's patients on a rolling basis, it is still true that the covered entity's patients are receiving the covered entity's drugs—they are not re-sold or "otherwise transfer[red]" to the contract pharmacy.

It also bears mention that the replenishment inventory model is currently an integral part of many patient assistance programs operated by drug manufacturers. *See, e.g.*, *Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees*, 70 Fed. Reg. 70,623, 70,624 (Nov. 22, 2005); Merck & Co., Inc. *For Health Care Professionals*, MERCK HELPS, https://www.merckhelps.com/HCPs.aspx (last visited Dec. 21, 2020); Pfizer, Inc., *The Pfizer Institutional Patient Assistance Program (IPAP) At-a-Glance* (April 2019), https://www.pfizerrxpathways.com/sites/default/files/attachment/PP-PAT-USA1032%20RxPathways_IPAP_Factsheet%202019.pdf (last visited Dec. 21, 2020).

[7] "[W]e rely on the principle of *noscitur a sociis*—a word is known by the company it keeps—to avoid ascribing to one word a meaning so broad that it is inconsistent with its accompanying words, thus giving unintended breadth to the Acts of Congress." *Yates v. United States*, 574 U.S. 528, 543 (2015) (plurality op.) (quotes omitted).

[8] An exact delineation of the scope of the phrase "otherwise transfer" is beyond the scope of the Advisory Opinion. The point here is simply that the phrase must have some limiting principle to avoid sweeping in innocuous conduct that is inevitable in the functioning of the 340B Program.

not a statutory mandate. Thus, manufacturers may not refuse to offer the ceiling price to covered entities, even where the latter use distribution systems involving contract pharmacies.

II. Conclusion and Limitations

For these reasons, the Office of the General Counsel concludes that covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients.[9]

This Advisory Opinion may be supplemented or modified by the Office of the General Counsel. It is intended to minimize the need for individual advisory opinions. This Advisory Opinion sets forth the current views of the Office of the General Counsel.[10] It is not a final agency action or a final order, and it does not have the force or effect of law.

Robert Charrow

Robert P. Charrow
General Counsel
December 30, 2020

[9] This Advisory Opinion is limited to interpretation of the 340B statutory requirements in general and does not opine on the legality of any specific contract-pharmacy model, under either the 340B statute or other laws that may apply (such as the anti-kickback statute, 42 U.S.C. § 1320a-7b).

[10] *See Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 647–48 (6th Cir. 2004) (holding that the Chief Counsel of the National Highway Traffic Safety Administration had delegated authority to issue advisory opinions to regulated entities in fulfillment of a congressional directive to promote regulatory compliance); 5 U.S.C. § 301 ("The head of an executive department . . . may prescribe regulations for the government of his department, the conduct of its employees, [and] the distribution and performance of its business[.]"); *Statement of Organization, Functions, and Delegations of Authority*, 85 Fed. Reg. 54,581, 54,583 (Sept. 2, 2020).