

Nos. 21-3128, 21-3405

IN THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

ELI LILLY AND COMPANY and LILLY USA, LLC,

Plaintiffs-appellants–cross-appellees,

v.

XAVIER BECERRA, et al.,

Defendants-appellees–cross-
appellants.

On Appeal from the United States District Court
for the Southern District of Indiana,
No. 21-81 (Barker, J.).

SUPPLEMENTAL APPENDIX

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**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA**

ELI LILLY AND COMPANY *et al.*

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity as
Secretary of Health & Human Services, *et al.*

Defendants.

Case No. 1:21-cv-81-SEB-MJD

CERTIFICATION OF ADMINISTRATIVE RECORD

I, Krista M. Pedley, Director of the Office of Pharmacy Affairs, Health Resources and Services Administration (“HRSA”), United States Department of Health and Human Services, certify, based on information obtained during the performance of my official duties as the Director of the Office of Pharmacy Affairs, that the attached documents constitute a true and accurate copy of all non-privileged documents that were directly or indirectly considered in connection with the issuance of HRSA’s May 17, 2021 letter to Eli Lilly and Company.

Executed this 11th day of June 2021, in Frederick, MD.

Krista M. Pedley, PharmD, MS
RADM, USPHS
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
United States Department of Health and Human Services

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- CHI Franciscan
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Community Care TX
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Truman Medical Center
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U Mass Memorial

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 UCLA
 UCSD
 UCSF
 Umpqua Community Health
 Unity Point Health
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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: AIDS Response Effort **340B ID:** RWI22601

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
00002446330	CIALIS TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002446430	CIALIS TAB 20MG 30	Eli Lilly and Company	30		EA	McKesson
00002446534	CIALIS TAB 2.5MG BP 30	Eli Lilly and Company	30		EA	McKesson
00002767801	MPB CYRAMZA 500MG 50ML SDV	Eli Lilly and Company	1		EA	McKesson
00002766901	MPB CYRAMZA 100MG 10ML SDV	Eli Lilly and Company	1		EA	McKesson
00002771601	MPB PORTRAZZA 800MG 50ML SDV	Eli Lilly and Company	1		EA	McKesson
00002397760	MPB RETEVMO 40MG CAP 60	Eli Lilly and Company	60		EA	McKesson
00002298060	MPB RETEVMO 80MG CAP 60	Eli Lilly and Company	60		EA	McKesson

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 Incorrect 340B Ceiling Price Notification for HRSA



00002298026	MPB RETEVMO 80MG CAP 120	Eli Lilly and Company	120		EA	McKesson
00002840001	FORTEO PEN 250MCG ML 2.4ML	Eli Lilly and Company	1		EA	McKesson
00002882427	HUMULIN R KWIK PEN U500 3ML 2	Eli Lilly and Company	2		CT	McKesson
00002850101	HUMULIN R REG INSULN U500 20ML	Eli Lilly and Company	1		EA	McKesson
00002879959	HUMALOG KWIK PEN 3ML 5	Eli Lilly and Company	5		CT	McKesson
00002879759	HUMALOG KWIK PEN 75 25 5	Eli Lilly and Company	5		CT	McKesson
00002879859	HUMALOG MIX KWIKPEN 50 50 5	Eli Lilly and Company	5		CT	McKesson
00002771459	HUMALOG JUNIOR KWIKPEN 3ML 5	Eli Lilly and Company	100		CT	McKesson
00002751659	HUMALOG CART 3-ML 5	Eli Lilly and Company	5		CT	McKesson
00002751201	HUMALOG VIAL 50 50 10ML	Eli Lilly and Company	1		EA	McKesson
00002751101	HUMALOG VIAL 75 25 10ML	Eli Lilly and Company	1		EA	McKesson
00002751001	HUMALOG VIAL 100U 10ML	Eli Lilly and Company	1		EA	McKesson
00002751017	HUMALOG VIAL 100U 3ML	Eli Lilly and Company	1		EA	McKesson
00002823305	INSULIN LISP 75 25 INJ100U ML5	Eli Lilly and Company	5		CT	McKesson
00002775205	INSULIN LISPRO JR INJ100U ML 5	Eli Lilly and Company	5		CT	McKesson
00002822259	INSULIN LISPRO KWIKPEN 3MLX5	Eli Lilly and Company	5		CT	McKesson
00002773701	INSULIN LISPRO INJ100U ML 10ML	Eli Lilly and Company	1		EA	McKesson
00002322930	STRATTERA CAP 40MG 30	Eli Lilly and Company	30		EA	McKesson
00002323930	STRATTERA CAP 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002323830	STRATTERA CAP 18MG 30	Eli Lilly and Company	30		EA	McKesson

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00002322830	STRATTERA CAP 25MG 30	Eli Lilly and Company	30		EA	McKesson
00002322730	STRATTERA CAP 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002803101	GLUCAGON EMERG KIT 1MG SYR 1ML	Eli Lilly and Company	1		EA	McKesson
00002325130	STRATTERA CAP 100MG 30	Eli Lilly and Company	30		EA	McKesson
00002325030	STRATTERA CAP 80MG 30	Eli Lilly and Company	30		EA	McKesson
00002880559	HUMULIN N KWIKPEN 5	Eli Lilly and Company	5		CT	McKesson
00002418402	EVISTA TAB 60MG 100	Eli Lilly and Company	100		EA	McKesson
00002418430	EVISTA TAB 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002814901	HUMATROPE CARTR KIT 24MG	Eli Lilly and Company	1		EA	McKesson
00002445385	ZYPREXA ZYDIS TAB 5MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002445585	ZYPREXA ZYDIS TAB 15MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002411630	ZYPREXA TAB 7.5MG 30	Eli Lilly and Company	30		EA	McKesson
00002445485	ZYPREXA ZYDIS TAB 10MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002445685	ZYPREXA ZYDIS TAB 20MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002512330	EFFIENT TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002512377	EFFIENT TAB 10MG BP INST 90	Eli Lilly and Company	90		EA	McKesson
00002512130	EFFIENT TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002814801	HUMATROPE CARTR KIT 12MG	Eli Lilly and Company	1		EA	McKesson
00002323560	CYMBALTA CAP 20MG 60	Eli Lilly and Company	60		EA	McKesson
00002327004	CYMBALTA CAP 60MG 1000=	Eli Lilly and Company	1000		EA	McKesson

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 Incorrect 340B Ceiling Price Notification for HRSA



00002324090	CYMBALTA CAP 30MG 90	Eli Lilly and Company	90		EA	McKesson
00002324030	CYMBALTA CAP 30MG 30	Eli Lilly and Company	30		EA	McKesson
00002327030	CYMBALTA CAP 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002771227	HUMALOG KWIK PEN U200 3ML 2	Eli Lilly and Company	2		CT	McKesson
00002411230	ZYPREXA TAB 2.5MG 30	Eli Lilly and Company	30		EA	McKesson
00002411730	ZYPREXA TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002814701	HUMATROPE CARTR KIT 6MG	Eli Lilly and Company	1		EA	McKesson
00002821501	HUMULIN R REG INSUL U100 10ML	Eli Lilly and Company	1		EA	McKesson
00002821517	HUMULIN R REG INSUL U100 3ML	Eli Lilly and Company	1		EA	McKesson
00002411530	ZYPREXA TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002441530	ZYPREXA TAB 15MG 30	Eli Lilly and Company	30		EA	McKesson
00002442030	ZYPREXA TAB 20MG 30	Eli Lilly and Company	30		EA	McKesson
00002759701	ZYPREXA IM SDV 10MG SINGLE	Eli Lilly and Company	1		EA	McKesson
00002831501	HUMULIN N NPH INSUL U100 10ML	Eli Lilly and Company	0.33		EA	McKesson
00002831517	HUMULIN N NPH INSUL U100 3ML	Eli Lilly and Company	1		EA	McKesson
00002880359	HUMULIN 70 30 KWIKPEN 5	Eli Lilly and Company	5		CT	McKesson
00002143380	TRULICITY 0.75MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	McKesson
00002143480	TRULICITY 1.5MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	McKesson
00002733511	HUMATROP 5MG COMB PACK KIT	Eli Lilly and Company	1		EA	McKesson
00002237711	EMGALITY INJ PFS 120MG 1	Eli Lilly and Company	1		EA	McKesson

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00002750201	GEMZAR LYO PWD 1GM IN 50ML VL1	Eli Lilly and Company	1		EA	McKesson
00002143611	EMGALITY INJ PEN 120MG ML 1	Eli Lilly and Company	1		EA	McKesson
00002323330	SYMBYAX CAP 6 50MG 30	Eli Lilly and Company	30		EA	McKesson
00002323130	SYMBYAX CAP 6 25MG 30	Eli Lilly and Company	30		EA	McKesson
00002323430	SYMBYAX CAP 12 50MG 30	Eli Lilly and Company	30		EA	McKesson
00002762301	ALIMTA SDV 500MG 20ML	Eli Lilly and Company	1		EA	McKesson
00002764001	ALIMTA SDV 100MG 4ML	Eli Lilly and Company	1		EA	McKesson
00002323030	SYMBYAX CAP 3 25 30	Eli Lilly and Company	30		EA	McKesson
00002144511	TALTZ AUTO INJECTOR 80MG 1	Eli Lilly and Company	1		EA	McKesson
00002144509	TALTZ AUTO INJECTOR 80MG 3	Eli Lilly and Company	3		EA	McKesson
00002144527	TALTZ AUTO INJECTOR 80MG 2	Eli Lilly and Company	2		EA	McKesson
00002772411	TALTZ PF SYRINGE 80MG 1	Eli Lilly and Company	1		EA	McKesson
00002533754	VERZENIO TAB 150MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002448354	VERZENIO TAB 50MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002621654	VERZENIO TAB 200MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002481554	VERZENIO TAB 100MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002418230	OLUMIANT TAB 2MG 30	Eli Lilly and Company	30		EA	McKesson
00002446230	CIALIS TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002446234	CIALIS TAB 5MG BP 30	Eli Lilly and Company	30		EA	McKesson
00002311509	EMGALITY INJ PFS 100MG ML 3	Eli Lilly and Company	3		CT	McKesson

340B Ceiling Price Unavailable/
 Incorrect 340B Ceiling Price Notification for HRSA



00002449108	REYVOW TB 100MG 8	Eli Lilly and Company	8		CT	McKesson
00002431208	REYVOW TB 50MG 8	Eli Lilly and Company	8		CT	McKesson
00002473230	OLUMIANT TAB 1MG 30	Eli Lilly and Company	30		EA	McKesson
00002763511	ZYPREXA RELPREV VL 210MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002614527	BAQSIMI PWD DEVICE 3MG 2	Eli Lilly and Company	2		CT	McKesson
00002771559	BASAGLAR KWIKPEN 3ML 5	Eli Lilly and Company	5		CT	McKesson
00002822827	LYUMJEV KWIKPEN INJ 200U ML 2	Eli Lilly and Company	2		CT	McKesson
00002763711	ZYPREXA RELPREV VL 405MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002763611	ZYPREXA RELPREV VL 300MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002772801	LYUMJEV INJ 10ML VIAL 1	Eli Lilly and Company	1		EA	McKesson
00002820705	LYUMJEV KWIKPEN INJ 100U ML 5	Eli Lilly and Company	5		CT	McKesson
00002614511	BAQSIMI PWD DEVICE 3MG 1	Eli Lilly and Company	1		EA	McKesson
00002871501	HUMULIN 70 30 MDV 10ML	Eli Lilly and Company	0.33		EA	McKesson
00002871517	HUMULIN 70 30 VIAL 3ML	Eli Lilly and Company	1		EA	McKesson

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? _____

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.

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA



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 340B Price Violation
- 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):
 - _____
 - _____
 - _____
 - _____

Date issue first observed: 9/1/2020
 Date drug last available at 340B price (enter NEVER if has never been available): 8/31/2020

*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/manufacturerssearch>), 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	
<p>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.</p>	
Contact Name (printed):	<u>Katie Vance</u> Phone: <u>540-536-5291</u>
Email Address:	<u>kvance3@valleyhealthlink.com</u>
Contact Role/Organization:	<u>Executive Director, AIDS Response Effort</u>
Contact Signature:	<u>Katie Vance</u> Date: <u>11/30/2020</u>

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.

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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: AIDS Support Group of Cape Cod **340B ID:** RWII02657

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
00002446330	CIALIS TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002446430	CIALIS TAB 20MG 30	Eli Lilly and Company	30		EA	McKesson
00002446534	CIALIS TAB 2.5MG BP 30	Eli Lilly and Company	30		EA	McKesson
00002767801	MPB CYRAMZA 500MG 50ML SDV	Eli Lilly and Company	1		EA	McKesson
00002766901	MPB CYRAMZA 100MG 10ML SDV	Eli Lilly and Company	1		EA	McKesson
00002771601	MPB PORTRAZZA 800MG 50ML SDV	Eli Lilly and Company	1		EA	McKesson
00002397760	MPB RETEVMO 40MG CAP 60	Eli Lilly and Company	60		EA	McKesson
00002298060	MPB RETEVMO 80MG CAP 60	Eli Lilly and Company	60		EA	McKesson

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA



00002298026	MPB RETEVMO 80MG CAP 120	Eli Lilly and Company	120		EA	McKesson
00002840001	FORTEO PEN 250MCG ML 2.4ML	Eli Lilly and Company	1		EA	McKesson
00002882427	HUMULIN R KWIK PEN U500 3ML 2	Eli Lilly and Company	2		CT	McKesson
00002850101	HUMULIN R REG INSULN U500 20ML	Eli Lilly and Company	1		EA	McKesson
00002879959	HUMALOG KWIK PEN 3ML 5	Eli Lilly and Company	5		CT	McKesson
00002879759	HUMALOG KWIK PEN 75 25 5	Eli Lilly and Company	5		CT	McKesson
00002879859	HUMALOG MIX KWIKPEN 50 50 5	Eli Lilly and Company	5		CT	McKesson
00002771459	HUMALOG JUNIOR KWIKPEN 3ML 5	Eli Lilly and Company	100		CT	McKesson
00002751659	HUMALOG CART 3-ML 5	Eli Lilly and Company	5		CT	McKesson
00002751201	HUMALOG VIAL 50 50 10ML	Eli Lilly and Company	1		EA	McKesson
00002751101	HUMALOG VIAL 75 25 10ML	Eli Lilly and Company	1		EA	McKesson
00002751001	HUMALOG VIAL 100U 10ML	Eli Lilly and Company	1		EA	McKesson
00002751017	HUMALOG VIAL 100U 3ML	Eli Lilly and Company	1		EA	McKesson
00002823305	INSULIN LISPRO 75 25 INJ100U ML5	Eli Lilly and Company	5		CT	McKesson
00002775205	INSULIN LISPRO JR INJ100U ML 5	Eli Lilly and Company	5		CT	McKesson
00002822259	INSULIN LISPRO KWIKPEN 3MLX5	Eli Lilly and Company	5		CT	McKesson
00002773701	INSULIN LISPRO INJ100U ML 10ML	Eli Lilly and Company	1		EA	McKesson
00002322930	STRATTERA CAP 40MG 30	Eli Lilly and Company	30		EA	McKesson
00002323930	STRATTERA CAP 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002323830	STRATTERA CAP 18MG 30	Eli Lilly and Company	30		EA	McKesson

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00002322830	STRATTERA CAP 25MG 30	Eli Lilly and Company	30		EA	McKesson
00002322730	STRATTERA CAP 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002803101	GLUCAGON EMERG KIT 1MG SYR 1ML	Eli Lilly and Company	1		EA	McKesson
00002325130	STRATTERA CAP 100MG 30	Eli Lilly and Company	30		EA	McKesson
00002325030	STRATTERA CAP 80MG 30	Eli Lilly and Company	30		EA	McKesson
00002880559	HUMULIN N KWIKPEN 5	Eli Lilly and Company	5		CT	McKesson
00002418402	EVISTA TAB 60MG 100	Eli Lilly and Company	100		EA	McKesson
00002418430	EVISTA TAB 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002814901	HUMATROPE CARTR KIT 24MG	Eli Lilly and Company	1		EA	McKesson
00002445385	ZYPREXA ZYDIS TAB 5MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002445585	ZYPREXA ZYDIS TAB 15MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002411630	ZYPREXA TAB 7.5MG 30	Eli Lilly and Company	30		EA	McKesson
00002445485	ZYPREXA ZYDIS TAB 10MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002445685	ZYPREXA ZYDIS TAB 20MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002512330	EFFIENT TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002512377	EFFIENT TAB 10MG BP INST 90	Eli Lilly and Company	90		EA	McKesson
00002512130	EFFIENT TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002814801	HUMATROPE CARTR KIT 12MG	Eli Lilly and Company	1		EA	McKesson
00002323560	CYMBALTA CAP 20MG 60	Eli Lilly and Company	60		EA	McKesson
00002327004	CYMBALTA CAP 60MG 1000=	Eli Lilly and Company	1000		EA	McKesson

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00002324090	CYMBALTA CAP 30MG 90	Eli Lilly and Company	90		EA	McKesson
00002324030	CYMBALTA CAP 30MG 30	Eli Lilly and Company	30		EA	McKesson
00002327030	CYMBALTA CAP 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002771227	HUMALOG KWIK PEN U200 3ML 2	Eli Lilly and Company	2		CT	McKesson
00002411230	ZYPREXA TAB 2.5MG 30	Eli Lilly and Company	30		EA	McKesson
00002411730	ZYPREXA TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002814701	HUMATROPE CARTR KIT 6MG	Eli Lilly and Company	1		EA	McKesson
00002821501	HUMULIN R REG INSUL U100 10ML	Eli Lilly and Company	1		EA	McKesson
00002821517	HUMULIN R REG INSUL U100 3ML	Eli Lilly and Company	1		EA	McKesson
00002411530	ZYPREXA TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002441530	ZYPREXA TAB 15MG 30	Eli Lilly and Company	30		EA	McKesson
00002442030	ZYPREXA TAB 20MG 30	Eli Lilly and Company	30		EA	McKesson
00002759701	ZYPREXA IM SDV 10MG SINGLE	Eli Lilly and Company	1		EA	McKesson
00002831501	HUMULIN N NPH INSUL U100 10ML	Eli Lilly and Company	0.33		EA	McKesson
00002831517	HUMULIN N NPH INSUL U100 3ML	Eli Lilly and Company	1		EA	McKesson
00002880359	HUMULIN 70 30 KWIKPEN 5	Eli Lilly and Company	5		CT	McKesson
00002143380	TRULICITY 0.75MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	McKesson
00002143480	TRULICITY 1.5MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	McKesson
00002733511	HUMATROP 5MG COMB PACK KIT	Eli Lilly and Company	1		EA	McKesson
00002237711	EMGALITY INJ PFS 120MG 1	Eli Lilly and Company	1		EA	McKesson

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00002750201	GEMZAR LYO PWD 1GM IN 50ML VL1	Eli Lilly and Company	1		EA	McKesson
00002143611	EMGALITY INJ PEN 120MG ML 1	Eli Lilly and Company	1		EA	McKesson
00002323330	SYMBYAX CAP 6 50MG 30	Eli Lilly and Company	30		EA	McKesson
00002323130	SYMBYAX CAP 6 25MG 30	Eli Lilly and Company	30		EA	McKesson
00002323430	SYMBYAX CAP 12 50MG 30	Eli Lilly and Company	30		EA	McKesson
00002762301	ALIMTA SDV 500MG 20ML	Eli Lilly and Company	1		EA	McKesson
00002764001	ALIMTA SDV 100MG 4ML	Eli Lilly and Company	1		EA	McKesson
00002323030	SYMBYAX CAP 3 25 30	Eli Lilly and Company	30		EA	McKesson
00002144511	TALTZ AUTO INJECTOR 80MG 1	Eli Lilly and Company	1		EA	McKesson
00002144509	TALTZ AUTO INJECTOR 80MG 3	Eli Lilly and Company	3		EA	McKesson
00002144527	TALTZ AUTO INJECTOR 80MG 2	Eli Lilly and Company	2		EA	McKesson
00002772411	TALTZ PF SYRINGE 80MG 1	Eli Lilly and Company	1		EA	McKesson
00002533754	VERZENIO TAB 150MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002448354	VERZENIO TAB 50MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002621654	VERZENIO TAB 200MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002481554	VERZENIO TAB 100MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002418230	OLUMIANT TAB 2MG 30	Eli Lilly and Company	30		EA	McKesson
00002446230	CIALIS TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002446234	CIALIS TAB 5MG BP 30	Eli Lilly and Company	30		EA	McKesson
00002311509	EMGALITY INJ PFS 100MG ML 3	Eli Lilly and Company	3		CT	McKesson

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA



00002449108	REYVOW TB 100MG 8	Eli Lilly and Company	8		CT	McKesson
00002431208	REYVOW TB 50MG 8	Eli Lilly and Company	8		CT	McKesson
00002473230	OLUMIANT TAB 1MG 30	Eli Lilly and Company	30		EA	McKesson
00002763511	ZYPREXA RELPREV VL 210MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002614527	BAQSIMI PWD DEVICE 3MG 2	Eli Lilly and Company	2		CT	McKesson
00002771559	BASAGLAR KWIKPEN 3ML 5	Eli Lilly and Company	5		CT	McKesson
00002822827	LYUMJEV KWIKPEN INJ 200U ML 2	Eli Lilly and Company	2		CT	McKesson
00002763711	ZYPREXA RELPREV VL 405MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002763611	ZYPREXA RELPREV VL 300MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002772801	LYUMJEV INJ 10ML VIAL 1	Eli Lilly and Company	1		EA	McKesson
00002820705	LYUMJEV KWIKPEN INJ 100U ML 5	Eli Lilly and Company	5		CT	McKesson
00002614511	BAQSIMI PWD DEVICE 3MG 1	Eli Lilly and Company	1		EA	McKesson
00002871501	HUMULIN 70 30 MDV 10ML	Eli Lilly and Company	0.33		EA	McKesson
00002871517	HUMULIN 70 30 VIAL 3ML	Eli Lilly and Company	1		EA	McKesson

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? _____

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.

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA



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 340B Price Violation
- 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*):

Date issue first observed: 9/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 8/31/2020

*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/manufacturerssearch>), 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): Paul E Goddu **Phone:** 508-487-9445

Email Address: pgoddu@asgcc.org

Contact Role/Organization: CFO, AIDS Support Group of Cape Cod, Inc

Contact Signature: *Paul E Goddu* **Date:** 02/09/2021

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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: Alice Hyde Medical Center

340B ID: DSH330084

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
00002-1433-80	Trulicity .75 mg/0.5ml	Eli Lilly	0.5	4	mg/ml	Cardinal Health, McKesson
00002-1434-80	Trulicity 1.5 mg/0.5ml	Eli Lilly	0.5	4	mg/ml	Cardinal Health, McKesson
00002-1436-11	Emgality 120 mg/ml	Eli Lilly	1	1	mg/ml	Cardinal Health, McKesson
00002-1445-11	Taltz 80 mg/ml	Eli Lilly	1	1	mg/ml	Cardinal Health, McKesson
00002-6145-11	Baqsimi one pack 3mg/dose	Eli Lilly	1	1	mg	Cardinal Health, McKesson
00002-6145-27	Baqsimi two pack 3mg/dose	Eli Lilly	1	2	mg	Cardinal Health, McKesson
00002-7510-01	Humalog 100 unit/ml	Eli Lilly	10	1	ml	Cardinal Health, McKesson
00002-7712-27	Humalog Kwikpen 200 unit/ml	Eli Lilly	3	2	ml	Cardinal Health, McKesson

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00002-7714-59	Humalog Junior Kwikpen 100 unit/ml	Eli Lilly	3	5	ml	Cardinal Health, McKesson
00002-7715-59	Basaglar Kwikpen 100 unit/ml	Eli Lilly	3	5	ml	Cardinal Health, McKesson
00002-7724-11	Taltz 80 mg/ml	Eli Lilly	1	1	mg/ml	Cardinal Health, McKesson
00002-8031-01	Glucagon Emergency Kit 1 mg	Eli Lilly	1	1	mg	Cardinal Health, McKesson
00002-8315-01	Humulin N 100 unit/ml	Eli Lilly	10	1	ml	Cardinal Health, McKesson
00002-8799-59	Humalog Kwikpen 100 unit/ml	Eli Lilly	3	5	ml	Cardinal Health, McKesson
00002-8824-27	Humulin R U-500 Kwikpen 500 unit/ml	Eli Lilly	3	2	ml	Cardinal Health, McKesson

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug X Yes No
- The issue reported is limited to a contract pharmacy purchase? X 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? _____

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 has blocked 340B pricing at 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

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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: 9/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 8/31/2020

*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:

- 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/manufacturerearch>), 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): _____

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- 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): _____

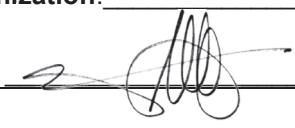
Signature

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): Michael Dufort **Phone:** (518) 481-2404

Email Address: mdufort@alicehyde.com

Contact Role/Organization: Director of Pharmacy, Alice Hyde Medical Center

Contact Signature:  **Date:** 10/14/2020

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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: Alliance for Living **340B ID:** RWII06320

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
00002446330	CIALIS TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002446430	CIALIS TAB 20MG 30	Eli Lilly and Company	30		EA	McKesson
00002446534	CIALIS TAB 2.5MG BP 30	Eli Lilly and Company	30		EA	McKesson
00002767801	MPB CYRAMZA 500MG 50ML SDV	Eli Lilly and Company	1		EA	McKesson
00002766901	MPB CYRAMZA 100MG 10ML SDV	Eli Lilly and Company	1		EA	McKesson
00002771601	MPB PORTRAZZA 800MG 50ML SDV	Eli Lilly and Company	1		EA	McKesson
00002397760	MPB RETEVMO 40MG CAP 60	Eli Lilly and Company	60		EA	McKesson
00002298060	MPB RETEVMO 80MG CAP 60	Eli Lilly and Company	60		EA	McKesson

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00002298026	MPB RETEVMO 80MG CAP 120	Eli Lilly and Company	120		EA	McKesson
00002840001	FORTEO PEN 250MCG ML 2.4ML	Eli Lilly and Company	1		EA	McKesson
00002882427	HUMULIN R KWIK PEN U500 3ML 2	Eli Lilly and Company	2		CT	McKesson
00002850101	HUMULIN R REG INSULN U500 20ML	Eli Lilly and Company	1		EA	McKesson
00002879959	HUMALOG KWIK PEN 3ML 5	Eli Lilly and Company	5		CT	McKesson
00002879759	HUMALOG KWIK PEN 75 25 5	Eli Lilly and Company	5		CT	McKesson
00002879859	HUMALOG MIX KWIKPEN 50 50 5	Eli Lilly and Company	5		CT	McKesson
00002771459	HUMALOG JUNIOR KWIKPEN 3ML 5	Eli Lilly and Company	100		CT	McKesson
00002751659	HUMALOG CART 3-ML 5	Eli Lilly and Company	5		CT	McKesson
00002751201	HUMALOG VIAL 50 50 10ML	Eli Lilly and Company	1		EA	McKesson
00002751101	HUMALOG VIAL 75 25 10ML	Eli Lilly and Company	1		EA	McKesson
00002751001	HUMALOG VIAL 100U 10ML	Eli Lilly and Company	1		EA	McKesson
00002751017	HUMALOG VIAL 100U 3ML	Eli Lilly and Company	1		EA	McKesson
00002823305	INSULIN LISP 75 25 INJ100U ML5	Eli Lilly and Company	5		CT	McKesson
00002775205	INSULIN LISPRO JR INJ100U ML 5	Eli Lilly and Company	5		CT	McKesson
00002822259	INSULIN LISPRO KWIKPEN 3MLX5	Eli Lilly and Company	5		CT	McKesson
00002773701	INSULIN LISPRO INJ100U ML 10ML	Eli Lilly and Company	1		EA	McKesson
00002322930	STRATTERA CAP 40MG 30	Eli Lilly and Company	30		EA	McKesson
00002323930	STRATTERA CAP 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002323830	STRATTERA CAP 18MG 30	Eli Lilly and Company	30		EA	McKesson

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00002322830	STRATTERA CAP 25MG 30	Eli Lilly and Company	30		EA	McKesson
00002322730	STRATTERA CAP 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002803101	GLUCAGON EMERG KIT 1MG SYR 1ML	Eli Lilly and Company	1		EA	McKesson
00002325130	STRATTERA CAP 100MG 30	Eli Lilly and Company	30		EA	McKesson
00002325030	STRATTERA CAP 80MG 30	Eli Lilly and Company	30		EA	McKesson
00002880559	HUMULIN N KWIKPEN 5	Eli Lilly and Company	5		CT	McKesson
00002418402	EVISTA TAB 60MG 100	Eli Lilly and Company	100		EA	McKesson
00002418430	EVISTA TAB 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002814901	HUMATROPE CARTR KIT 24MG	Eli Lilly and Company	1		EA	McKesson
00002445385	ZYPREXA ZYDIS TAB 5MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002445585	ZYPREXA ZYDIS TAB 15MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002411630	ZYPREXA TAB 7.5MG 30	Eli Lilly and Company	30		EA	McKesson
00002445485	ZYPREXA ZYDIS TAB 10MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002445685	ZYPREXA ZYDIS TAB 20MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002512330	EFFIENT TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002512377	EFFIENT TAB 10MG BP INST 90	Eli Lilly and Company	90		EA	McKesson
00002512130	EFFIENT TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002814801	HUMATROPE CARTR KIT 12MG	Eli Lilly and Company	1		EA	McKesson
00002323560	CYMBALTA CAP 20MG 60	Eli Lilly and Company	60		EA	McKesson
00002327004	CYMBALTA CAP 60MG 1000=	Eli Lilly and Company	1000		EA	McKesson

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00002324090	CYMBALTA CAP 30MG 90	Eli Lilly and Company	90		EA	McKesson
00002324030	CYMBALTA CAP 30MG 30	Eli Lilly and Company	30		EA	McKesson
00002327030	CYMBALTA CAP 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002771227	HUMALOG KWIK PEN U200 3ML 2	Eli Lilly and Company	2		CT	McKesson
00002411230	ZYPREXA TAB 2.5MG 30	Eli Lilly and Company	30		EA	McKesson
00002411730	ZYPREXA TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002814701	HUMATROPE CARTR KIT 6MG	Eli Lilly and Company	1		EA	McKesson
00002821501	HUMULIN R REG INSUL U100 10ML	Eli Lilly and Company	1		EA	McKesson
00002821517	HUMULIN R REG INSUL U100 3ML	Eli Lilly and Company	1		EA	McKesson
00002411530	ZYPREXA TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002441530	ZYPREXA TAB 15MG 30	Eli Lilly and Company	30		EA	McKesson
00002442030	ZYPREXA TAB 20MG 30	Eli Lilly and Company	30		EA	McKesson
00002759701	ZYPREXA IM SDV 10MG SINGLE	Eli Lilly and Company	1		EA	McKesson
00002831501	HUMULIN N NPH INSUL U100 10ML	Eli Lilly and Company	0.33		EA	McKesson
00002831517	HUMULIN N NPH INSUL U100 3ML	Eli Lilly and Company	1		EA	McKesson
00002880359	HUMULIN 70 30 KWIKPEN 5	Eli Lilly and Company	5		CT	McKesson
00002143380	TRULICITY 0.75MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	McKesson
00002143480	TRULICITY 1.5MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	McKesson
00002733511	HUMATROP 5MG COMB PACK KIT	Eli Lilly and Company	1		EA	McKesson
00002237711	EMGALITY INJ PFS 120MG 1	Eli Lilly and Company	1		EA	McKesson

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00002750201	GEMZAR LYO PWD 1GM IN 50ML VL1	Eli Lilly and Company	1		EA	McKesson
00002143611	EMGALITY INJ PEN 120MG ML 1	Eli Lilly and Company	1		EA	McKesson
00002323330	SYMBYAX CAP 6 50MG 30	Eli Lilly and Company	30		EA	McKesson
00002323130	SYMBYAX CAP 6 25MG 30	Eli Lilly and Company	30		EA	McKesson
00002323430	SYMBYAX CAP 12 50MG 30	Eli Lilly and Company	30		EA	McKesson
00002762301	ALIMTA SDV 500MG 20ML	Eli Lilly and Company	1		EA	McKesson
00002764001	ALIMTA SDV 100MG 4ML	Eli Lilly and Company	1		EA	McKesson
00002323030	SYMBYAX CAP 3 25 30	Eli Lilly and Company	30		EA	McKesson
00002144511	TALTZ AUTO INJECTOR 80MG 1	Eli Lilly and Company	1		EA	McKesson
00002144509	TALTZ AUTO INJECTOR 80MG 3	Eli Lilly and Company	3		EA	McKesson
00002144527	TALTZ AUTO INJECTOR 80MG 2	Eli Lilly and Company	2		EA	McKesson
00002772411	TALTZ PF SYRINGE 80MG 1	Eli Lilly and Company	1		EA	McKesson
00002533754	VERZENIO TAB 150MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002448354	VERZENIO TAB 50MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002621654	VERZENIO TAB 200MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002481554	VERZENIO TAB 100MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002418230	OLUMIANT TAB 2MG 30	Eli Lilly and Company	30		EA	McKesson
00002446230	CIALIS TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002446234	CIALIS TAB 5MG BP 30	Eli Lilly and Company	30		EA	McKesson
00002311509	EMGALITY INJ PFS 100MG ML 3	Eli Lilly and Company	3		CT	McKesson

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00002449108	REYVOW TB 100MG 8	Eli Lilly and Company	8		CT	McKesson
00002431208	REYVOW TB 50MG 8	Eli Lilly and Company	8		CT	McKesson
00002473230	OLUMIANT TAB 1MG 30	Eli Lilly and Company	30		EA	McKesson
00002763511	ZYPREXA RELPREV VL 210MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002614527	BAQSIMI PWD DEVICE 3MG 2	Eli Lilly and Company	2		CT	McKesson
00002771559	BASAGLAR KWIKPEN 3ML 5	Eli Lilly and Company	5		CT	McKesson
00002822827	LYUMJEV KWIKPEN INJ 200U ML 2	Eli Lilly and Company	2		CT	McKesson
00002763711	ZYPREXA RELPREV VL 405MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002763611	ZYPREXA RELPREV VL 300MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002772801	LYUMJEV INJ 10ML VIAL 1	Eli Lilly and Company	1		EA	McKesson
00002820705	LYUMJEV KWIKPEN INJ 100U ML 5	Eli Lilly and Company	5		CT	McKesson
00002614511	BAQSIMI PWD DEVICE 3MG 1	Eli Lilly and Company	1		EA	McKesson
00002871501	HUMULIN 70 30 MDV 10ML	Eli Lilly and Company	0.33		EA	McKesson
00002871517	HUMULIN 70 30 VIAL 3ML	Eli Lilly and Company	1		EA	McKesson

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? _____

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.

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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 340B Price Violation
- 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*):

Date issue first observed: 9/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 8/31/2020

*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

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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/manufacturerssearch>), 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): _____

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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): Kelly Thompson Phone: 860-447-0884

Email Address: kthompson@allianceforliving.org

Contact Role/Organization: CEO

Contact Signature: *Kelly Thompson* Date: 2/11/21

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.

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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: The Alliance of AIDS Services-Carolina 340B ID: STD27604						
Please list the product(s) affected (<i>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</i>).						
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
00002446330	CIALIS TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002446430	CIALIS TAB 20MG 30	Eli Lilly and Company	30		EA	McKesson
00002446534	CIALIS TAB 2.5MG BP 30	Eli Lilly and Company	30		EA	McKesson
00002767801	MPB CYRAMZA 500MG 50ML SDV	Eli Lilly and Company	1		EA	McKesson
00002766901	MPB CYRAMZA 100MG 10ML SDV	Eli Lilly and Company	1		EA	McKesson
00002771601	MPB PORTRAZZA 800MG 50ML SDV	Eli Lilly and Company	1		EA	McKesson
00002397760	MPB RETEVMO 40MG CAP 60	Eli Lilly and Company	60		EA	McKesson
00002298060	MPB RETEVMO 80MG CAP 60	Eli Lilly and Company	60		EA	McKesson

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 Incorrect 340B Ceiling Price Notification for HRSA



00002298026	MPB RETEVMO 80MG CAP 120	Eli Lilly and Company	120		EA	McKesson
00002840001	FORTEO PEN 250MCG ML 2.4ML	Eli Lilly and Company	1		EA	McKesson
00002882427	HUMULIN R KWIK PEN U500 3ML 2	Eli Lilly and Company	2		CT	McKesson
00002850101	HUMULIN R REG INSULN U500 20ML	Eli Lilly and Company	1		EA	McKesson
00002879959	HUMALOG KWIK PEN 3ML 5	Eli Lilly and Company	5		CT	McKesson
00002879759	HUMALOG KWIK PEN 75 25 5	Eli Lilly and Company	5		CT	McKesson
00002879859	HUMALOG MIX KWIKPEN 50 50 5	Eli Lilly and Company	5		CT	McKesson
00002771459	HUMALOG JUNIOR KWIKPEN 3ML 5	Eli Lilly and Company	100		CT	McKesson
00002751659	HUMALOG CART 3-ML 5	Eli Lilly and Company	5		CT	McKesson
00002751201	HUMALOG VIAL 50 50 10ML	Eli Lilly and Company	1		EA	McKesson
00002751101	HUMALOG VIAL 75 25 10ML	Eli Lilly and Company	1		EA	McKesson
00002751001	HUMALOG VIAL 100U 10ML	Eli Lilly and Company	1		EA	McKesson
00002751017	HUMALOG VIAL 100U 3ML	Eli Lilly and Company	1		EA	McKesson
00002823305	INSULIN LISPRO 75 25 INJ100U ML5	Eli Lilly and Company	5		CT	McKesson
00002775205	INSULIN LISPRO JR INJ100U ML 5	Eli Lilly and Company	5		CT	McKesson
00002822259	INSULIN LISPRO KWIKPEN 3MLX5	Eli Lilly and Company	5		CT	McKesson
00002773701	INSULIN LISPRO INJ100U ML 10ML	Eli Lilly and Company	1		EA	McKesson
00002322930	STRATTERA CAP 40MG 30	Eli Lilly and Company	30		EA	McKesson
00002323930	STRATTERA CAP 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002323830	STRATTERA CAP 18MG 30	Eli Lilly and Company	30		EA	McKesson

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00002322830	STRATTERA CAP 25MG 30	Eli Lilly and Company	30		EA	McKesson
00002322730	STRATTERA CAP 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002803101	GLUCAGON EMERG KIT 1MG SYR 1ML	Eli Lilly and Company	1		EA	McKesson
00002325130	STRATTERA CAP 100MG 30	Eli Lilly and Company	30		EA	McKesson
00002325030	STRATTERA CAP 80MG 30	Eli Lilly and Company	30		EA	McKesson
00002880559	HUMULIN N KWIKPEN 5	Eli Lilly and Company	5		CT	McKesson
00002418402	EVISTA TAB 60MG 100	Eli Lilly and Company	100		EA	McKesson
00002418430	EVISTA TAB 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002814901	HUMATROPE CARTR KIT 24MG	Eli Lilly and Company	1		EA	McKesson
00002445385	ZYPREXA ZYDIS TAB 5MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002445585	ZYPREXA ZYDIS TAB 15MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002411630	ZYPREXA TAB 7.5MG 30	Eli Lilly and Company	30		EA	McKesson
00002445485	ZYPREXA ZYDIS TAB 10MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002445685	ZYPREXA ZYDIS TAB 20MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002512330	EFFIENT TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002512377	EFFIENT TAB 10MG BP INST 90	Eli Lilly and Company	90		EA	McKesson
00002512130	EFFIENT TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002814801	HUMATROPE CARTR KIT 12MG	Eli Lilly and Company	1		EA	McKesson
00002323560	CYMBALTA CAP 20MG 60	Eli Lilly and Company	60		EA	McKesson
00002327004	CYMBALTA CAP 60MG 1000=	Eli Lilly and Company	1000		EA	McKesson

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00002324090	CYMBALTA CAP 30MG 90	Eli Lilly and Company	90		EA	McKesson
00002324030	CYMBALTA CAP 30MG 30	Eli Lilly and Company	30		EA	McKesson
00002327030	CYMBALTA CAP 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002771227	HUMALOG KWIK PEN U200 3ML 2	Eli Lilly and Company	2		CT	McKesson
00002411230	ZYPREXA TAB 2.5MG 30	Eli Lilly and Company	30		EA	McKesson
00002411730	ZYPREXA TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002814701	HUMATROPE CARTR KIT 6MG	Eli Lilly and Company	1		EA	McKesson
00002821501	HUMULIN R REG INSUL U100 10ML	Eli Lilly and Company	1		EA	McKesson
00002821517	HUMULIN R REG INSUL U100 3ML	Eli Lilly and Company	1		EA	McKesson
00002411530	ZYPREXA TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002441530	ZYPREXA TAB 15MG 30	Eli Lilly and Company	30		EA	McKesson
00002442030	ZYPREXA TAB 20MG 30	Eli Lilly and Company	30		EA	McKesson
00002759701	ZYPREXA IM SDV 10MG SINGLE	Eli Lilly and Company	1		EA	McKesson
00002831501	HUMULIN N NPH INSUL U100 10ML	Eli Lilly and Company	0.33		EA	McKesson
00002831517	HUMULIN N NPH INSUL U100 3ML	Eli Lilly and Company	1		EA	McKesson
00002880359	HUMULIN 70 30 KWIKPEN 5	Eli Lilly and Company	5		CT	McKesson
00002143380	TRULICITY 0.75MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	McKesson
00002143480	TRULICITY 1.5MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	McKesson
00002733511	HUMATROP 5MG COMB PACK KIT	Eli Lilly and Company	1		EA	McKesson
00002237711	EMGALITY INJ PFS 120MG 1	Eli Lilly and Company	1		EA	McKesson

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00002750201	GEMZAR LYO PWD 1GM IN 50ML VL1	Eli Lilly and Company	1		EA	McKesson
00002143611	EMGALITY INJ PEN 120MG ML 1	Eli Lilly and Company	1		EA	McKesson
00002323330	SYMBYAX CAP 6 50MG 30	Eli Lilly and Company	30		EA	McKesson
00002323130	SYMBYAX CAP 6 25MG 30	Eli Lilly and Company	30		EA	McKesson
00002323430	SYMBYAX CAP 12 50MG 30	Eli Lilly and Company	30		EA	McKesson
00002762301	ALIMTA SDV 500MG 20ML	Eli Lilly and Company	1		EA	McKesson
00002764001	ALIMTA SDV 100MG 4ML	Eli Lilly and Company	1		EA	McKesson
00002323030	SYMBYAX CAP 3 25 30	Eli Lilly and Company	30		EA	McKesson
00002144511	TALTZ AUTO INJECTOR 80MG 1	Eli Lilly and Company	1		EA	McKesson
00002144509	TALTZ AUTO INJECTOR 80MG 3	Eli Lilly and Company	3		EA	McKesson
00002144527	TALTZ AUTO INJECTOR 80MG 2	Eli Lilly and Company	2		EA	McKesson
00002772411	TALTZ PF SYRINGE 80MG 1	Eli Lilly and Company	1		EA	McKesson
00002533754	VERZENIO TAB 150MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002448354	VERZENIO TAB 50MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002621654	VERZENIO TAB 200MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002481554	VERZENIO TAB 100MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002418230	OLUMIANT TAB 2MG 30	Eli Lilly and Company	30		EA	McKesson
00002446230	CIALIS TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002446234	CIALIS TAB 5MG BP 30	Eli Lilly and Company	30		EA	McKesson
00002311509	EMGALITY INJ PFS 100MG ML 3	Eli Lilly and Company	3		CT	McKesson

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00002449108	REYVOW TB 100MG 8	Eli Lilly and Company	8		CT	McKesson
00002431208	REYVOW TB 50MG 8	Eli Lilly and Company	8		CT	McKesson
00002473230	OLUMIANT TAB 1MG 30	Eli Lilly and Company	30		EA	McKesson
00002763511	ZYPREXA RELPREV VL 210MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002614527	BAQSIMI PWD DEVICE 3MG 2	Eli Lilly and Company	2		CT	McKesson
00002771559	BASAGLAR KWIKPEN 3ML 5	Eli Lilly and Company	5		CT	McKesson
00002822827	LYUMJEV KWIKPEN INJ 200U ML 2	Eli Lilly and Company	2		CT	McKesson
00002763711	ZYPREXA RELPREV VL 405MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002763611	ZYPREXA RELPREV VL 300MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002772801	LYUMJEV INJ 10ML VIAL 1	Eli Lilly and Company	1		EA	McKesson
00002820705	LYUMJEV KWIKPEN INJ 100U ML 5	Eli Lilly and Company	5		CT	McKesson
00002614511	BAQSIMI PWD DEVICE 3MG 1	Eli Lilly and Company	1		EA	McKesson
00002871501	HUMULIN 70 30 MDV 10ML	Eli Lilly and Company	0.33		EA	McKesson
00002871517	HUMULIN 70 30 VIAL 3ML	Eli Lilly and Company	1		EA	McKesson

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? _____

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.

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA



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 340B Price Violation
- 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*):

Date issue first observed: 9/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 8/31/2020

*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/manufacturerearch>), 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): Melissa Haithcox-Dennis Phone: 919 934 2437

Email Address: M.haithcoxdennis@aas-c.org

Contact Role/Organization: Executive Director, Alliance of AIDS services-Carolina

Contact Signature: Melissa Haithcox-Dennis Date: 11/10/2020

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.

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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: Presence St. Francis Hospital

340B ID: DSH140080

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*).

NDC	Drug Name	Manufacturer	Package Size	Case Package Size	Unit of Measure	CE Wholesaler
	List Attached	Eli Lilly & Co				McKesson

Regarding the purchase and distribution processes, please answer yes or no to the following:

- This drug is commonly referred to as a specialty drug No
- The issue reported is limited to a contract pharmacy purchase? Yes
- If shortage-related, is this a recurrent/intermittent availability issue? No
- If shortage-related, is this due to a local/regional/national or global shortage?

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 the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation <https://data.medicare.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicare-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:

Date drug last available at 340B price (enter NEVER if has never been available):

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/manufacturerearch>), and check the Medicaid Drug Rebate Program labeler code (<https://data.medicare.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): Manufacturer no longer offering 340B price.

Price paid by the covered entity (including package size):

Date issue first observed: 10/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 9/30/2020

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): Rick Fischer **Phone:** 630-914-2872

Email Address: Rick.Fischer@amitahealth.org

Contact Role/Organization: 340B Program Director

Contact Signature: *Rick Fischer* **Date:** 2/1/2021

Supplier	NDC	Product Number	Label Name	Generic Name	Brand Description
Eli Lilly & Co	00002764001	00002764001	ALIMTA 100 MG VIAL	pemetrexed disodium	ALIMTA
Eli Lilly & Co	00002762301	0002-7623-01	ALIMTA 500 MG VIAL	pemetrexed disodium	ALIMTA
Eli Lilly & Co	00002120001	00002120001	AMYVID VIAL	florbetapir F-18	AMYVID
Eli Lilly & Co	00002197590	00002197590	AXIRON 30 MG/ACTUATION SOLN	testosterone	AXIRON
Eli Lilly & Co	00002614511	00002614511	BAQSIMI 3 MG SPRAY ONE PACK	glucagon	BAQSIMI
Eli Lilly & Co	00002614527	00002614527	BAQSIMI 3 MG SPRAY TWO PACK	glucagon	BAQSIMI
Eli Lilly & Co	00002771559	00002771559	BASAGLAR 100 UNIT/ML KWIKPEN	insulin glargine,hum.rec.anlog	BASAGLAR KWIKPEN U-100
Eli Lilly & Co	00002446330	00002446330	CIALIS 10 MG TABLET	tadalafil	CIALIS
Eli Lilly & Co	00002446534	00002446534	CIALIS 2.5 MG TABLET	tadalafil	CIALIS
Eli Lilly & Co	00002446430	00002446430	CIALIS 20 MG TABLET	tadalafil	CIALIS
Eli Lilly & Co	00002446234	00002446234	CIALIS 5 MG TABLET	tadalafil	CIALIS
Eli Lilly & Co	00002446230	00002446230	CIALIS 5 MG TABLET	tadalafil	CIALIS
Eli Lilly & Co	00002323560	00002323560	CYMBALTA 20 MG CAPSULE	duloxetine HCl	CYMBALTA
Eli Lilly & Co	00002324090	00002324090	CYMBALTA 30 MG CAPSULE	duloxetine HCl	CYMBALTA
Eli Lilly & Co	00002324030	00002324030	CYMBALTA 30 MG CAPSULE	duloxetine HCl	CYMBALTA
Eli Lilly & Co	00002327030	00002327030	CYMBALTA 60 MG CAPSULE	duloxetine HCl	CYMBALTA
Eli Lilly & Co	00002327004	00002327004	CYMBALTA 60 MG CAPSULE	duloxetine HCl	CYMBALTA
Eli Lilly & Co	00002766901	00002-7669-01	CYRAMZA 100 MG/10 ML VIAL	ramucirumab	CYRAMZA
Eli Lilly & Co	00002767801	00002-7678-01	CYRAMZA 500 MG/50 ML VIAL	ramucirumab	CYRAMZA
Eli Lilly & Co	00002512377	00002512377	EFFIENT 10 MG TABLET	prasugrel HCl	EFFIENT
Eli Lilly & Co	00002512330	00002512330	EFFIENT 10 MG TABLET	prasugrel HCl	EFFIENT
Eli Lilly & Co	00002512130	00002512130	EFFIENT 5 MG TABLET	prasugrel HCl	EFFIENT
Eli Lilly & Co	00002512152	00002512152	EFFIENT 5 MG TABLET	prasugrel HCl	EFFIENT
Eli Lilly & Co	00002143611	00002143611	EMGALITY 120 MG/ML PEN	galcanezumab-gnlm	EMGALITY PEN
Eli Lilly & Co	00002237711	00002237711	EMGALITY 120 MG/ML SYRINGE	galcanezumab-gnlm	EMGALITY SYRINGE
Eli Lilly & Co	00002311509	00002311509	EMGALITY 300 MG (100 MG X3SYR)	galcanezumab-gnlm	EMGALITY SYRINGE
Eli Lilly & Co	66733094823	66733094823	ERBITUX 100 MG/50 ML VIAL	cetuximab	ERBITUX
Eli Lilly & Co	66733095823	66733095823	ERBITUX 200 MG/100 ML VIAL	cetuximab	ERBITUX
Eli Lilly & Co	00002418407	00002418407	EVISTA 60 MG TABLET	raloxifene HCl	EVISTA
Eli Lilly & Co	00002418430	00002418430	EVISTA 60 MG TABLET	raloxifene HCl	EVISTA
Eli Lilly & Co	00002418402	00002418402	EVISTA 60 MG TABLET	raloxifene HCl	EVISTA
Eli Lilly & Co	00002840001	00002840001	FORTEO 600 MCG/2.4 ML PEN INJ	teriparatide	FORTEO
Eli Lilly & Co	00002750201	00002750201	GEMZAR 1 GRAM VIAL	gemcitabine HCl	GEMZAR
Eli Lilly & Co	00002750101	00002750101	GEMZAR 200 MG VIAL	gemcitabine HCl	GEMZAR
Eli Lilly & Co	00002803101	0002-8031-01	GLUCAGON 1 MG EMERGENCY KIT	glucagon,human recombinant	GLUCAGON EMERGENCY KIT

VLTR_000393

Eli Lilly & Co	00002751001	00002751001 HUMALOG 100 UNIT/ML VIAL	insulin lispro	HUMALOG
Eli Lilly & Co	00002751017	00002751017 HUMALOG 100 UNIT/ML VIAL	insulin lispro	HUMALOG
Eli Lilly & Co	00002751659	00002751659 HUMALOG 100 UNITS/ML CARTRIDGE	insulin lispro	HUMALOG
Eli Lilly & Co	00002879959	00002879959 HUMALOG 100 UNITS/ML KWIKPEN	insulin lispro	HUMALOG KWIKPEN U-100
Eli Lilly & Co	00002771227	00002771227 HUMALOG 200 UNITS/ML KWIKPEN	insulin lispro	HUMALOG KWIKPEN U-200
Eli Lilly & Co	00002771459	00002771459 HUMALOG JR 100 UNIT/ML KWIKPEN	insulin lispro	HUMALOG JUNIOR KWIKPEN
Eli Lilly & Co	00002879859	00002879859 HUMALOG MIX 50-50 KWIKPEN	insulin lispro protamin/lispro	HUMALOG MIX 50-50 KWIKPEN
Eli Lilly & Co	00002751201	00002751201 HUMALOG MIX 50-50 VIAL	insulin lispro protamin/lispro	HUMALOG MIX 50-50
Eli Lilly & Co	00002879759	00002879759 HUMALOG MIX 75-25 KWIKPEN	insulin lispro protamin/lispro	HUMALOG MIX 75-25 KWIKPEN
Eli Lilly & Co	00002751101	00002751101 HUMALOG MIX 75-25 VIAL	insulin lispro protamin/lispro	HUMALOG MIX 75-25
Eli Lilly & Co	00002814801	00002814801 HUMATROPE 12 MG CARTRIDGE	somatropin	HUMATROPE
Eli Lilly & Co	00002814901	00002814901 HUMATROPE 24 MG CARTRIDGE	somatropin	HUMATROPE
Eli Lilly & Co	00002733511	00002733511 HUMATROPE 5 MG VIAL	somatropin	HUMATROPE
Eli Lilly & Co	00002814701	00002814701 HUMATROPE 6 MG CARTRIDGE	somatropin	HUMATROPE
Eli Lilly & Co	00002871501	00002871501 HUMULIN 70-30 VIAL	insulin NPH hum/reg insulin hm	HUMULIN 70-30
Eli Lilly & Co	00002871517	00002871517 HUMULIN 70-30 VIAL	insulin NPH hum/reg insulin hm	HUMULIN 70-30
Eli Lilly & Co	00002880359	00002880359 HUMULIN 70/30 KWIKPEN	insulin NPH hum/reg insulin hm	HUMULIN 70/30 KWIKPEN
Eli Lilly & Co	00002831501	00002831501 HUMULIN N 100 UNIT/ML VIAL	insulin NPH human isophane	HUMULIN N
Eli Lilly & Co	00002831517	00002831517 HUMULIN N 100 UNIT/ML VIAL	insulin NPH human isophane	HUMULIN N
Eli Lilly & Co	00002880559	00002880559 HUMULIN N 100 UNITS/ML KWIKPEN	insulin NPH human isophane	HUMULIN N KWIKPEN
Eli Lilly & Co	00002821501	00002821501 HUMULIN R 100 UNIT/ML VIAL	insulin regular, human	HUMULIN R
Eli Lilly & Co	00002821517	00002821517 HUMULIN R 100 UNIT/ML VIAL	insulin regular, human	HUMULIN R
Eli Lilly & Co	00002882427	00002882427 HUMULIN R 500 UNITS/ML KWIKPEN	insulin regular, human	HUMULIN R U-500 KWIKPEN
Eli Lilly & Co	00002850101	00002850101 HUMULIN R 500 UNITS/ML VIAL	insulin regular, human	HUMULIN R U-500
Eli Lilly & Co	66733082259	66733082259 INSULIN LISPRO 100 UNIT/ML PEN	insulin lispro	INSULIN LISPRO KWIKPEN U-100
Eli Lilly & Co	00002822259	00002822259 INSULIN LISPRO 100 UNIT/ML PEN	insulin lispro	INSULIN LISPRO KWIKPEN U-100
Eli Lilly & Co	00002773701	00002773701 INSULIN LISPRO 100 UNIT/ML VL	insulin lispro	INSULIN LISPRO
Eli Lilly & Co	66733077301	66733077301 INSULIN LISPRO 100 UNIT/ML VL	insulin lispro	INSULIN LISPRO
Eli Lilly & Co	00002775205	00002775205 INSULIN LISPRO JR 100 UNIT/ML	insulin lispro	INSULIN LISPRO JUNIOR KWIKPEN
Eli Lilly & Co	00002823305	00002823305 INSULIN LISPRO MIX 75-25 KWKPEN	insulin lispro protamin/lispro	INSULIN LISPRO PROTAMINE MIX
Eli Lilly & Co	00002719001	0002-7190-01 LARTRUVO 190 MG/19 ML VIAL	olaratumab	LARTRUVO
Eli Lilly & Co	00002892601	00002892601 LARTRUVO 500 MG/50 ML VIAL	olaratumab	LARTRUVO
Eli Lilly & Co	00002473230	00002473230 OLUMIANT 1 MG TABLET	baricitinib	OLUMIANT
Eli Lilly & Co	00002418230	00002418230 OLUMIANT 2 MG TABLET	baricitinib	OLUMIANT
Eli Lilly & Co	00002771601	0002-7716-01 PORTRAZZA 800 MG/50 ML VIAL	necitumumab	PORTRAZZA
Eli Lilly & Co	00777310402	00777310402 PROZAC 10 MG PULVULE	fluoxetine HCl	PROZAC
Eli Lilly & Co	00777310530	00777310530 PROZAC 20 MG PULVULE	fluoxetine HCl	PROZAC
Eli Lilly & Co	00777310507	00777310507 PROZAC 20 MG PULVULE	fluoxetine HCl	PROZAC

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Eli Lilly & Co	00777310502	00777310502	PROZAC 20 MG PULVULE	fluoxetine HCl	PROZAC
Eli Lilly & Co	00777310730	00777310730	PROZAC 40 MG PULVULE	fluoxetine HCl	PROZAC
Eli Lilly & Co	00002140701	0002-1407-01	QUINIDINE GLUC 80 MG/ML VIAL	quinidine gluconate	QUINIDINE GLUCONATE
Eli Lilly & Co	00002714001	00002714001	REOPRO 10 MG/5 ML VIAL	abciximab	REOPRO
Eli Lilly & Co	00002397760	00002397760	RETEVMO 40 MG CAPSULE	selpercatinib	RETEVMO
Eli Lilly & Co	00002298026	00002298026	RETEVMO 80 MG CAPSULE	selpercatinib	RETEVMO
Eli Lilly & Co	00002298060	00002298060	RETEVMO 80 MG CAPSULE	selpercatinib	RETEVMO
Eli Lilly & Co	00002449108	00002449108	REYVOW 100 MG TABLET	lasmiditan succinate	REYVOW
Eli Lilly & Co	00002431208	00002431208	REYVOW 50 MG TABLET	lasmiditan succinate	REYVOW
Eli Lilly & Co	00002322730	00002322730	STRATTERA 10 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002325130	00002325130	STRATTERA 100 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002323830	00002323830	STRATTERA 18 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002322830	00002322830	STRATTERA 25 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002322930	00002322930	STRATTERA 40 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002323930	00002323930	STRATTERA 60 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002325030	00002325030	STRATTERA 80 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002323230	00002323230	SYMBYAX 12-25 MG CAPSULE	olanzapine/fluoxetine HCl	SYMBYAX
Eli Lilly & Co	00002323430	00002323430	SYMBYAX 12-50 MG CAPSULE	olanzapine/fluoxetine HCl	SYMBYAX
Eli Lilly & Co	00002323030	00002323030	SYMBYAX 3-25 MG CAPSULE	olanzapine/fluoxetine HCl	SYMBYAX
Eli Lilly & Co	00002323130	00002323130	SYMBYAX 6-25 MG CAPSULE	olanzapine/fluoxetine HCl	SYMBYAX
Eli Lilly & Co	00002323330	00002323330	SYMBYAX 6-50 MG CAPSULE	olanzapine/fluoxetine HCl	SYMBYAX
Eli Lilly & Co	00002144527	00002144527	TALTZ 80 MG/ML AUTOINJ (2-PK)	ixekizumab	TALTZ AUTOINJECTOR (2 PACK)
Eli Lilly & Co	00002144509	00002144509	TALTZ 80 MG/ML AUTOINJ (3-PK)	ixekizumab	TALTZ AUTOINJECTOR (3 PACK)
Eli Lilly & Co	00002144511	00002144511	TALTZ 80 MG/ML AUTOINJECTOR	ixekizumab	TALTZ AUTOINJECTOR
Eli Lilly & Co	00002772411	00002772411	TALTZ 80 MG/ML SYRINGE	ixekizumab	TALTZ SYRINGE
Eli Lilly & Co	00002143380	00002143380	TRULICITY 0.75 MG/0.5 ML PEN	dulaglutide	TRULICITY
Eli Lilly & Co	00002143480	00002143480	TRULICITY 1.5 MG/0.5 ML PEN	dulaglutide	TRULICITY
Eli Lilly & Co	00002481554	00002481554	VERZENIO 100 MG TABLET	abemaciclib	VERZENIO
Eli Lilly & Co	00002533754	00002533754	VERZENIO 150 MG TABLET	abemaciclib	VERZENIO
Eli Lilly & Co	00002621654	00002621654	VERZENIO 200 MG TABLET	abemaciclib	VERZENIO
Eli Lilly & Co	00002448354	00002448354	VERZENIO 50 MG TABLET	abemaciclib	VERZENIO
Eli Lilly & Co	00002411730	00002411730	ZYPREXA 10 MG TABLET	olanzapine	ZYPREXA
Eli Lilly & Co	00002759701	00002-7597-01	ZYPREXA 10 MG VIAL	olanzapine	ZYPREXA
Eli Lilly & Co	00002441530	00002441530	ZYPREXA 15 MG TABLET	olanzapine	ZYPREXA
Eli Lilly & Co	00002411230	00002411230	ZYPREXA 2.5 MG TABLET	olanzapine	ZYPREXA
Eli Lilly & Co	00002442030	00002442030	ZYPREXA 20 MG TABLET	olanzapine	ZYPREXA
Eli Lilly & Co	00002411530	00002411530	ZYPREXA 5 MG TABLET	olanzapine	ZYPREXA
Eli Lilly & Co	00002411630	00002411630	ZYPREXA 7.5 MG TABLET	olanzapine	ZYPREXA

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Eli Lilly & Co	00002763511	00002763511 ZYPREXA RELPREVV 210 MG VL KIT	olanzapine pamoate	ZYPREXA RELPREVV
Eli Lilly & Co	00002763611	00002763611 ZYPREXA RELPREVV 300 MG VL KIT	olanzapine pamoate	ZYPREXA RELPREVV
Eli Lilly & Co	00002763711	00002763711 ZYPREXA RELPREVV 405 MG VL KIT	olanzapine pamoate	ZYPREXA RELPREVV
Eli Lilly & Co	00002445485	00002445485 ZYPREXA ZYDIS 10 MG TABLET	olanzapine	ZYPREXA ZYDIS
Eli Lilly & Co	00002445585	00002445585 ZYPREXA ZYDIS 15 MG TABLET	olanzapine	ZYPREXA ZYDIS
Eli Lilly & Co	00002445685	00002445685 ZYPREXA ZYDIS 20 MG TABLET	olanzapine	ZYPREXA ZYDIS
Eli Lilly & Co	00002445385	00002445385 ZYPREXA ZYDIS 5 MG TABLET	olanzapine	ZYPREXA ZYDIS

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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. Vincent Indianapolis - Hospital & Health

340B ID: DSH150084

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*).

NDC	Drug Name	Manufacturer	Package Size	Case Package Size	Unit of Measure	CE Wholesaler
	List Attached	Eli Lilly & Co				McKesson

Regarding the purchase and distribution processes, please answer yes or no to the following:

- | | |
|---|-----|
| This drug is commonly referred to as a specialty drug | No |
| The issue reported is limited to a contract pharmacy purchase? | Yes |
| If shortage-related, is this a recurrent/intermittent availability issue? | No |
| If shortage-related, is this due to a local/regional/national or global shortage? | |

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 the product is a covered outpatient drug and requires manufacturer participation in the 340B Program (confirmed MDRP participation <https://data.medicare.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicare-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:

Date drug last available at 340B price (enter NEVER if has never been available):

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/manufacturerearch>), and check the Medicaid Drug Rebate Program labeler code (<https://data.medicare.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): Manufacturer no longer offering 340B price.

Price paid by the covered entity (including package size):

Date issue first observed: 10/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 9/30/2020

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): Jason Ashby

Phone: 812-454-3218

Email Address: jashby@ascension.org

Contact Role/Organization: 340B Program Director

Contact Signature:

Date: 2/1/2021

Supplier	NDC	Product Number	Label Name	Generic Name	Brand Description
Eli Lilly & Co	00002764001	00002764001	ALIMTA 100 MG VIAL	pemetrexed disodium	ALIMTA
Eli Lilly & Co	00002762301	0002-7623-01	ALIMTA 500 MG VIAL	pemetrexed disodium	ALIMTA
Eli Lilly & Co	00002120001	00002120001	AMYVID VIAL	florbetapir F-18	AMYVID
Eli Lilly & Co	00002197590	00002197590	AXIRON 30 MG/ACTUATION SOLN	testosterone	AXIRON
Eli Lilly & Co	00002614511	00002614511	BAQSIMI 3 MG SPRAY ONE PACK	glucagon	BAQSIMI
Eli Lilly & Co	00002614527	00002614527	BAQSIMI 3 MG SPRAY TWO PACK	glucagon	BAQSIMI
Eli Lilly & Co	00002771559	00002771559	BASAGLAR 100 UNIT/ML KWIKPEN	insulin glargine,hum.rec.anlog	BASAGLAR KWIKPEN U-100
Eli Lilly & Co	00002446330	00002446330	CIALIS 10 MG TABLET	tadalafil	CIALIS
Eli Lilly & Co	00002446534	00002446534	CIALIS 2.5 MG TABLET	tadalafil	CIALIS
Eli Lilly & Co	00002446430	00002446430	CIALIS 20 MG TABLET	tadalafil	CIALIS
Eli Lilly & Co	00002446234	00002446234	CIALIS 5 MG TABLET	tadalafil	CIALIS
Eli Lilly & Co	00002446230	00002446230	CIALIS 5 MG TABLET	tadalafil	CIALIS
Eli Lilly & Co	00002323560	00002323560	CYMBALTA 20 MG CAPSULE	duloxetine HCl	CYMBALTA
Eli Lilly & Co	00002324090	00002324090	CYMBALTA 30 MG CAPSULE	duloxetine HCl	CYMBALTA
Eli Lilly & Co	00002324030	00002324030	CYMBALTA 30 MG CAPSULE	duloxetine HCl	CYMBALTA
Eli Lilly & Co	00002327030	00002327030	CYMBALTA 60 MG CAPSULE	duloxetine HCl	CYMBALTA
Eli Lilly & Co	00002327004	00002327004	CYMBALTA 60 MG CAPSULE	duloxetine HCl	CYMBALTA
Eli Lilly & Co	00002766901	00002-7669-01	CYRAMZA 100 MG/10 ML VIAL	ramucirumab	CYRAMZA
Eli Lilly & Co	00002767801	00002-7678-01	CYRAMZA 500 MG/50 ML VIAL	ramucirumab	CYRAMZA
Eli Lilly & Co	00002512377	00002512377	EFFIENT 10 MG TABLET	prasugrel HCl	EFFIENT
Eli Lilly & Co	00002512330	00002512330	EFFIENT 10 MG TABLET	prasugrel HCl	EFFIENT
Eli Lilly & Co	00002512130	00002512130	EFFIENT 5 MG TABLET	prasugrel HCl	EFFIENT
Eli Lilly & Co	00002512152	00002512152	EFFIENT 5 MG TABLET	prasugrel HCl	EFFIENT
Eli Lilly & Co	00002143611	00002143611	EMGALITY 120 MG/ML PEN	galcanezumab-gnlm	EMGALITY PEN
Eli Lilly & Co	00002237711	00002237711	EMGALITY 120 MG/ML SYRINGE	galcanezumab-gnlm	EMGALITY SYRINGE
Eli Lilly & Co	00002311509	00002311509	EMGALITY 300 MG (100 MG X3SYR)	galcanezumab-gnlm	EMGALITY SYRINGE
Eli Lilly & Co	66733094823	66733094823	ERBITUX 100 MG/50 ML VIAL	cetuximab	ERBITUX
Eli Lilly & Co	66733095823	66733095823	ERBITUX 200 MG/100 ML VIAL	cetuximab	ERBITUX
Eli Lilly & Co	00002418407	00002418407	EVISTA 60 MG TABLET	raloxifene HCl	EVISTA
Eli Lilly & Co	00002418430	00002418430	EVISTA 60 MG TABLET	raloxifene HCl	EVISTA
Eli Lilly & Co	00002418402	00002418402	EVISTA 60 MG TABLET	raloxifene HCl	EVISTA
Eli Lilly & Co	00002840001	00002840001	FORTEO 600 MCG/2.4 ML PEN INJ	teriparatide	FORTEO
Eli Lilly & Co	00002750201	00002750201	GEMZAR 1 GRAM VIAL	gemcitabine HCl	GEMZAR
Eli Lilly & Co	00002750101	00002750101	GEMZAR 200 MG VIAL	gemcitabine HCl	GEMZAR
Eli Lilly & Co	00002803101	0002-8031-01	GLUCAGON 1 MG EMERGENCY KIT	glucagon,human recombinant	GLUCAGON EMERGENCY KIT

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Eli Lilly & Co	00002751001	00002751001 HUMALOG 100 UNIT/ML VIAL	insulin lispro	HUMALOG
Eli Lilly & Co	00002751017	00002751017 HUMALOG 100 UNIT/ML VIAL	insulin lispro	HUMALOG
Eli Lilly & Co	00002751659	00002751659 HUMALOG 100 UNITS/ML CARTRIDGE	insulin lispro	HUMALOG
Eli Lilly & Co	00002879959	00002879959 HUMALOG 100 UNITS/ML KWIKPEN	insulin lispro	HUMALOG KWIKPEN U-100
Eli Lilly & Co	00002771227	00002771227 HUMALOG 200 UNITS/ML KWIKPEN	insulin lispro	HUMALOG KWIKPEN U-200
Eli Lilly & Co	00002771459	00002771459 HUMALOG JR 100 UNIT/ML KWIKPEN	insulin lispro	HUMALOG JUNIOR KWIKPEN
Eli Lilly & Co	00002879859	00002879859 HUMALOG MIX 50-50 KWIKPEN	insulin lispro protamin/lispro	HUMALOG MIX 50-50 KWIKPEN
Eli Lilly & Co	00002751201	00002751201 HUMALOG MIX 50-50 VIAL	insulin lispro protamin/lispro	HUMALOG MIX 50-50
Eli Lilly & Co	00002879759	00002879759 HUMALOG MIX 75-25 KWIKPEN	insulin lispro protamin/lispro	HUMALOG MIX 75-25 KWIKPEN
Eli Lilly & Co	00002751101	00002751101 HUMALOG MIX 75-25 VIAL	insulin lispro protamin/lispro	HUMALOG MIX 75-25
Eli Lilly & Co	00002814801	00002814801 HUMATROPE 12 MG CARTRIDGE	somatropin	HUMATROPE
Eli Lilly & Co	00002814901	00002814901 HUMATROPE 24 MG CARTRIDGE	somatropin	HUMATROPE
Eli Lilly & Co	00002733511	00002733511 HUMATROPE 5 MG VIAL	somatropin	HUMATROPE
Eli Lilly & Co	00002814701	00002814701 HUMATROPE 6 MG CARTRIDGE	somatropin	HUMATROPE
Eli Lilly & Co	00002871501	00002871501 HUMULIN 70-30 VIAL	insulin NPH hum/reg insulin hm	HUMULIN 70-30
Eli Lilly & Co	00002871517	00002871517 HUMULIN 70-30 VIAL	insulin NPH hum/reg insulin hm	HUMULIN 70-30
Eli Lilly & Co	00002880359	00002880359 HUMULIN 70/30 KWIKPEN	insulin NPH hum/reg insulin hm	HUMULIN 70/30 KWIKPEN
Eli Lilly & Co	00002831501	00002831501 HUMULIN N 100 UNIT/ML VIAL	insulin NPH human isophane	HUMULIN N
Eli Lilly & Co	00002831517	00002831517 HUMULIN N 100 UNIT/ML VIAL	insulin NPH human isophane	HUMULIN N
Eli Lilly & Co	00002880559	00002880559 HUMULIN N 100 UNITS/ML KWIKPEN	insulin NPH human isophane	HUMULIN N KWIKPEN
Eli Lilly & Co	00002821501	00002821501 HUMULIN R 100 UNIT/ML VIAL	insulin regular, human	HUMULIN R
Eli Lilly & Co	00002821517	00002821517 HUMULIN R 100 UNIT/ML VIAL	insulin regular, human	HUMULIN R
Eli Lilly & Co	00002882427	00002882427 HUMULIN R 500 UNITS/ML KWIKPEN	insulin regular, human	HUMULIN R U-500 KWIKPEN
Eli Lilly & Co	00002850101	00002850101 HUMULIN R 500 UNITS/ML VIAL	insulin regular, human	HUMULIN R U-500
Eli Lilly & Co	66733082259	66733082259 INSULIN LISPRO 100 UNIT/ML PEN	insulin lispro	INSULIN LISPRO KWIKPEN U-100
Eli Lilly & Co	00002822259	00002822259 INSULIN LISPRO 100 UNIT/ML PEN	insulin lispro	INSULIN LISPRO KWIKPEN U-100
Eli Lilly & Co	00002773701	00002773701 INSULIN LISPRO 100 UNIT/ML VL	insulin lispro	INSULIN LISPRO
Eli Lilly & Co	66733077301	66733077301 INSULIN LISPRO 100 UNIT/ML VL	insulin lispro	INSULIN LISPRO
Eli Lilly & Co	00002775205	00002775205 INSULIN LISPRO JR 100 UNIT/ML	insulin lispro	INSULIN LISPRO JUNIOR KWIKPEN
Eli Lilly & Co	00002823305	00002823305 INSULIN LISPRO MIX 75-25 KWKPEN	insulin lispro protamin/lispro	INSULIN LISPRO PROTAMINE MIX
Eli Lilly & Co	00002719001	0002-7190-01 LARTRUVO 190 MG/19 ML VIAL	olaratumab	LARTRUVO
Eli Lilly & Co	00002892601	00002892601 LARTRUVO 500 MG/50 ML VIAL	olaratumab	LARTRUVO
Eli Lilly & Co	00002473230	00002473230 OLUMIANT 1 MG TABLET	baricitinib	OLUMIANT
Eli Lilly & Co	00002418230	00002418230 OLUMIANT 2 MG TABLET	baricitinib	OLUMIANT
Eli Lilly & Co	00002771601	0002-7716-01 PORTRAZZA 800 MG/50 ML VIAL	necitumumab	PORTRAZZA
Eli Lilly & Co	00777310402	00777310402 PROZAC 10 MG PULVULE	fluoxetine HCl	PROZAC
Eli Lilly & Co	00777310530	00777310530 PROZAC 20 MG PULVULE	fluoxetine HCl	PROZAC
Eli Lilly & Co	00777310507	00777310507 PROZAC 20 MG PULVULE	fluoxetine HCl	PROZAC

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Eli Lilly & Co	00777310502	00777310502	PROZAC 20 MG PULVULE	fluoxetine HCl	PROZAC
Eli Lilly & Co	00777310730	00777310730	PROZAC 40 MG PULVULE	fluoxetine HCl	PROZAC
Eli Lilly & Co	00002140701	0002-1407-01	QUINIDINE GLUC 80 MG/ML VIAL	quinidine gluconate	QUINIDINE GLUCONATE
Eli Lilly & Co	00002714001	00002714001	REOPRO 10 MG/5 ML VIAL	abciximab	REOPRO
Eli Lilly & Co	00002397760	00002397760	RETEVMO 40 MG CAPSULE	selpercatinib	RETEVMO
Eli Lilly & Co	00002298026	00002298026	RETEVMO 80 MG CAPSULE	selpercatinib	RETEVMO
Eli Lilly & Co	00002298060	00002298060	RETEVMO 80 MG CAPSULE	selpercatinib	RETEVMO
Eli Lilly & Co	00002449108	00002449108	REYVOW 100 MG TABLET	lasmiditan succinate	REYVOW
Eli Lilly & Co	00002431208	00002431208	REYVOW 50 MG TABLET	lasmiditan succinate	REYVOW
Eli Lilly & Co	00002322730	00002322730	STRATTERA 10 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002325130	00002325130	STRATTERA 100 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002323830	00002323830	STRATTERA 18 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002322830	00002322830	STRATTERA 25 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002322930	00002322930	STRATTERA 40 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002323930	00002323930	STRATTERA 60 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002325030	00002325030	STRATTERA 80 MG CAPSULE	atomoxetine HCl	STRATTERA
Eli Lilly & Co	00002323230	00002323230	SYMBYAX 12-25 MG CAPSULE	olanzapine/fluoxetine HCl	SYMBYAX
Eli Lilly & Co	00002323430	00002323430	SYMBYAX 12-50 MG CAPSULE	olanzapine/fluoxetine HCl	SYMBYAX
Eli Lilly & Co	00002323030	00002323030	SYMBYAX 3-25 MG CAPSULE	olanzapine/fluoxetine HCl	SYMBYAX
Eli Lilly & Co	00002323130	00002323130	SYMBYAX 6-25 MG CAPSULE	olanzapine/fluoxetine HCl	SYMBYAX
Eli Lilly & Co	00002323330	00002323330	SYMBYAX 6-50 MG CAPSULE	olanzapine/fluoxetine HCl	SYMBYAX
Eli Lilly & Co	00002144527	00002144527	TALTZ 80 MG/ML AUTOINJ (2-PK)	ixekizumab	TALTZ AUTOINJECTOR (2 PACK)
Eli Lilly & Co	00002144509	00002144509	TALTZ 80 MG/ML AUTOINJ (3-PK)	ixekizumab	TALTZ AUTOINJECTOR (3 PACK)
Eli Lilly & Co	00002144511	00002144511	TALTZ 80 MG/ML AUTOINJECTOR	ixekizumab	TALTZ AUTOINJECTOR
Eli Lilly & Co	00002772411	00002772411	TALTZ 80 MG/ML SYRINGE	ixekizumab	TALTZ SYRINGE
Eli Lilly & Co	00002143380	00002143380	TRULICITY 0.75 MG/0.5 ML PEN	dulaglutide	TRULICITY
Eli Lilly & Co	00002143480	00002143480	TRULICITY 1.5 MG/0.5 ML PEN	dulaglutide	TRULICITY
Eli Lilly & Co	00002481554	00002481554	VERZENIO 100 MG TABLET	abemaciclib	VERZENIO
Eli Lilly & Co	00002533754	00002533754	VERZENIO 150 MG TABLET	abemaciclib	VERZENIO
Eli Lilly & Co	00002621654	00002621654	VERZENIO 200 MG TABLET	abemaciclib	VERZENIO
Eli Lilly & Co	00002448354	00002448354	VERZENIO 50 MG TABLET	abemaciclib	VERZENIO
Eli Lilly & Co	00002411730	00002411730	ZYPREXA 10 MG TABLET	olanzapine	ZYPREXA
Eli Lilly & Co	00002759701	00002-7597-01	ZYPREXA 10 MG VIAL	olanzapine	ZYPREXA
Eli Lilly & Co	00002441530	00002441530	ZYPREXA 15 MG TABLET	olanzapine	ZYPREXA
Eli Lilly & Co	00002411230	00002411230	ZYPREXA 2.5 MG TABLET	olanzapine	ZYPREXA
Eli Lilly & Co	00002442030	00002442030	ZYPREXA 20 MG TABLET	olanzapine	ZYPREXA
Eli Lilly & Co	00002411530	00002411530	ZYPREXA 5 MG TABLET	olanzapine	ZYPREXA
Eli Lilly & Co	00002411630	00002411630	ZYPREXA 7.5 MG TABLET	olanzapine	ZYPREXA

VLTR_000687

Eli Lilly & Co	00002763511	00002763511 ZYPREXA RELPREVV 210 MG VL KIT	olanzapine pamoate	ZYPREXA RELPREVV
Eli Lilly & Co	00002763611	00002763611 ZYPREXA RELPREVV 300 MG VL KIT	olanzapine pamoate	ZYPREXA RELPREVV
Eli Lilly & Co	00002763711	00002763711 ZYPREXA RELPREVV 405 MG VL KIT	olanzapine pamoate	ZYPREXA RELPREVV
Eli Lilly & Co	00002445485	00002445485 ZYPREXA ZYDIS 10 MG TABLET	olanzapine	ZYPREXA ZYDIS
Eli Lilly & Co	00002445585	00002445585 ZYPREXA ZYDIS 15 MG TABLET	olanzapine	ZYPREXA ZYDIS
Eli Lilly & Co	00002445685	00002445685 ZYPREXA ZYDIS 20 MG TABLET	olanzapine	ZYPREXA ZYDIS
Eli Lilly & Co	00002445385	00002445385 ZYPREXA ZYDIS 5 MG TABLET	olanzapine	ZYPREXA ZYDIS

VLTR_000688

From: Ernesty, Gwen
To: HRSA HSB 340B Pricing
Subject: 340B Pricing Notices
Date: Monday, October 19, 2020 5:04:26 PM

Attachments:
image001.jpg
Astrazeneca 340B Pricing Notice.pdf
Cardinal ineligible purchases.docx
Lilly 340B Pricing Notice.pdf
McKesson 340b pricing screenshots.docx
Sanofi 340B Pricing Notice.pdf

Hello,

I am submitting the attachments for review of 340B pricing issues related to three manufacturers at our contract pharmacy locations.

Thank you,

GWEN ERNESTY, R.Ph., MBA

Director of Pharmacy



2579 Chimney Rock Road
Hendersonville, NC 28792
828.692.4289 Ext. 3451

gernesty@brchs.com

www.brchs.com

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Background Information

Entity Name: ___Blue Ridge Community Health Service, Inc. _____ **340B ID:** __CH040940__

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. 00186-0370-20	Symbicort Aer 160-4.5	AstraZeneca	10.2		Gram	Cardinal, McKesson
2. 00310-6205-30	Farxiga 5mg	AstraZeneca	30		Tab	Cardinal, McKesson
3. 00186-0372-20	Symbicort Aer 80-4.5	AstraZeneca	10.2		Gram	Cardinal, McKesson
4. 00310-6524-01	Byetta Inj. 10mcg	AstraZeneca	2.4		mL	Cardinal, McKesson
5. 00310-0095-30	Daliresp 500mcg	AstraZeneca	30		Tab	Cardinal, McKesson

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? _____

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 is refusing to ship to my contract pharmacies___
- 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.)

Confirmed shortage issues by reviewing validated resources*

Contacted wholesaler and/or manufacturer to confirm unavailability

Other (please describe issue): ___ AstraZeneca is refusing to ship to my contract pharmacies at 340B prices. Our covered entity is forced to pay WAC for these products if purchased for the contract pharmacy.

Date issue first observed: October 1, 2020

Date drug last available at 340B price (enter NEVER if has never been available): 9.30.2020

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>)

- 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): _____

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): __Gwendolen Ernesty_____ **Phone:** ____828-692-4289 ext. 3451____

Email Address: __gernesty@brchs.com_____

Contact Role/Organization: Primary Contact and Director of Pharmacy/ Blue Ridge Community Health Services, Inc.

Contact Signature: Gwendolen Esf **Date:** 10/19/2020

CardinalHealth Order Express

Home | Lists | Order History | Returns | Reports | Services | Admin

Account: 394132 CVS Pharmacy 03582 3 | Auto-Submit: Off | Cart Total \$0.00 (0) | Welcome:ernesty

Product Name, Num or Mfr Go

Search Results
You searched for **lantus**
Total results 10

Custom Field Search
 Eligible On Contract
[View All Filters](#)
Previously Purchased

This product(s) is ineligible to order. Review potential alternatives below by expanding or clicking VIEW.

Display: **Table** | Images | Full Screen | Results Per Page: 20 | 1 of 1

Columns | Print | Export .xls | Buy Now | Add to Cart

ALT	QTY	STOCK STATUS	CIN	NDC/UPC	STRENGTH	FORM	SIZE	NET COST	TRADE NAME	UOI COST	MFR	TYPE
<input checked="" type="checkbox"/>	<input type="text" value="0"/>	INELIG	3636743	00088-2220-52	100U/ML	CART	5X3 ML	\$0.00	LANTUS	\$0.0000	SANOFI	Rx
<input checked="" type="checkbox"/>	<input type="text" value="0"/>	INELIG	4182804	00088-2220-52	100U/ML	CART	5X3 ML	\$0.00	LANTUS	\$0.0000	SANOPI	Rx
<input checked="" type="checkbox"/>	<input type="text" value="0"/>	INELIG	4182861	00088-2220-60	100U/ML	SYRN	5X3 ML	\$0.00	LANTUS SOLOSTAR	\$0.0000	SANOPI	Rx
<input checked="" type="checkbox"/>	<input type="text" value="0"/>	INELIG	3995552	00088-2220-60	100U/ML	SYRN	5X3 ML	\$0.00	LANTUS SOLOSTAR	\$0.0000	SANOPI	Rx
<input checked="" type="checkbox"/>	<input type="text" value="0"/>	INELIG	3238193	00088-2220-33	100U/ML	MDV	1X10 ML	\$0.00	LANTUS	\$0.0000	SANOPI	Rx
<input checked="" type="checkbox"/>	<input type="text" value="0"/>	INELIG	4182614	00088-2220-33	100U/ML	MDV	1X10 ML	\$0.00	LANTUS	\$0.0000	SANOPI	Rx
<input checked="" type="checkbox"/>	<input type="text" value="0"/>	INELIG	4341327	00088-2219-05	100U/ML	SYRN	5X3 ML	\$0.00	LANTUS SOLOSTAR	\$0.0000	SANOPI	Rx
<input checked="" type="checkbox"/>	<input type="text" value="0"/>	INELIG	4354171	00088-2219-05	100U/ML	SYRN	5X3 ML	\$0.00	LANTUS SOLOSTAR	\$0.0000	SANOPI	Rx
<input checked="" type="checkbox"/>	<input type="text" value="0"/>	INELIG	5373378	00088-5021-01	100U/ML	MDV	1X10 ML	\$0.00	LANTUS NVP	\$0.0000	SANOPI	Rx
<input checked="" type="checkbox"/>	<input type="text" value="0"/>	INELIG	5373386	00088-5020-05	100U/ML	SYRN	5X3 ML	\$0.00	LANTUS SOLOSTAR NVP	\$0.0000	SANOPI	Rx

Buy Now | Add to Cart

The products from **Sanofi** are marked as "Ineligible" for purchase on the contract pharmacy 340B account due to the removal of the 340B pricing by the manufacturer.

VLTR_001589

Product Name, Num or Mfr

Custom Field Search

Eligible On Contract

View All Filters

Previously Purchased

Home > Search Results

Search Results

You searched for **humalog**

Total results 46

This product(s) is ineligible to order. Review potential alternatives below by expanding or clicking VIEW.

Display: **Table** | Images | Full Screen

Results Per Page: 20 1 of 3

Columns | Print | Export .xls

Buy Now | Add to: Cart

ALT	QTY	STOCK STATUS	CIN	NDC/UPC	STRENGTH	FORM	SIZE	NET COST	TRADE NAME	UOI COST	MFR	TYPE
	<input type="text" value="0"/>	INELIG	3709771	00002-8793-59	50-50U/ML	SYRN	5X3 ML	\$0.00	HUMALOG MIX 50/50	\$0.0000	ELILIL	Rx
	<input type="text" value="0"/>	INELIG	2530871	00002-7515-59	100U/ML	CART	5X1.5 ML	\$0.00	HUMALOG	\$0.0000	ELILIL	Rx
	<input type="text" value="0"/>	INELIG	2532307	00002-7515-59	100U/ML	CART	1X8 ML	\$0.00	HUMALOG	\$0.0000	ELILIL	Rx
	<input type="text" value="0"/>	INELIG	2824530	00002-8725-59	100U/ML	SYRN	5X3 ML	\$0.00	HUMALOG	\$0.0000	ELILIL	Rx
	<input type="text" value="0"/>	INELIG	4177440	00002-8725-59	100U/ML	SYRN	5X3 ML	\$0.00	HUMALOG	\$0.0000	ELILIL	Rx
	<input type="text" value="0"/>	INELIG	4177481	00002-8794-59	75-25U/ML	SYRN	5X3 ML	\$0.00	HUMALOG MIX 75/25	\$0.0000	ELILIL	Rx
	<input type="text" value="0"/>	INELIG	4177739	00002-8793-59	50-50U/ML	SYRN	5X3 ML	\$0.00	HUMALOG MIX 50/50	\$0.0000	ELILIL	Rx
	<input type="text" value="0"/>	INELIG	2934578	00002-8794-59	75-25U/ML	SYRN	5X3 ML	\$0.00	HUMALOG MIX 75/25	\$0.0000	ELILIL	Rx
	<input type="text" value="0"/>	INELIG	2487866	00002-7510-01	100U/ML	MDV	1X10 ML	\$0.00	HUMALOG	\$0.0000	ELILIL	Rx
	<input type="text" value="0"/>	INELIG	4177408	00002-7510-01	100U/ML	MDV	1X10 ML	\$0.00	HUMALOG	\$0.0000	ELILIL	Rx

The products from Lilly are marked as "Ineligible" for purchase on the contract pharmacy 340B account due to the removal of the 340B pricing by the manufacturer.

VLTR_001590



Order Express

Welcome:ern

- Home
- Lists
- Order History
- Returns
- Reports
- Services
- Admin

Product Name, Num or Mfr

Custom Field Search

Eligible On Contract

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Previously Purchased

Home >> Search Results

Search Results

You searched for **sybiccort**

Total results 8

Available on SOURCE™ **Generic Sybiccort®**

budesonide - formoterol fumarate dihydrate

This product(s) is ineligible to order. Review potential alternatives below by expanding or clicking VIEW.

Display: Table | Images | Full Screen Results Per Page: 1 of 1

Add to:

ALT	QTY	STOCK STATUS	CIN	NDC/UPC	STRENGTH	FORM	SIZE	NET COST	TRADE NAME	UOI COST	MFR	TYPE
<input type="checkbox"/>	<input type="text" value="0"/>	INELIG	3976750	00186-0372-20	80-4.5MCG	ARIN	1X10.2 GM	\$0.00	SYMBICORT	\$0.0000	ASTRAZ	Rx
<input type="checkbox"/>	<input type="text" value="0"/>	INELIG	3976768	00186-0370-20	160-4.5MCG	ARIN	1X10.2 GM	\$0.00	SYMBICORT	\$0.0000	ASTRAZ	Rx
<input type="checkbox"/>	<input type="text" value="0"/>	INELIG	4014833	00186-0370-28	160-4.5MCG	ARIN	1X6 GM	\$0.00	SYMBICORT INP	\$0.0000	ASTRAZ	Rx
<input type="checkbox"/>	<input type="text" value="0"/>	INELIG	4014841	00186-0372-28	80-4.5MCG	ARIN	1X6.9 GM	\$0.00	SYMBICORT INP	\$0.0000	ASTRAZ	Rx
<input type="checkbox"/>	<input type="text" value="0"/>	INELIG	4214946	00186-0370-20	160-4.5MCG	ARIN	1X10.2 GM	\$0.00	SYMBICORT	\$0.0000	ASTRPR	Rx
<input type="checkbox"/>	<input type="text" value="0"/>	INELIG	4214979	00186-0372-20	80-4.5MCG	ARIN	1X10.2 GM	\$0.00	SYMBICORT	\$0.0000	ASTRPR	Rx
<input type="checkbox"/>	<input type="text" value="0"/>	INELIG	4215125	00186-0372-28	80-4.5MCG	ARIN	1X6.9 GM	\$0.00	SYMBICORT	\$0.0000	ASTRPR	Rx
<input type="checkbox"/>	<input type="text" value="0"/>	INELIG	4215091	00186-0370-28	160-4.5MCG	ARIN	1X6 GM	\$0.00	SYMBICORT	\$0.0000	ASTRPR	Rx

The products from **AstraZeneca** are marked as "Ineligible" for purchase on the contract pharmacy 340B account due to the removal of the 340B pricing by the manufacturer.

VLTR_001591



Background Information

Entity Name: ___Blue Ridge community Health Services, Inc. _____ **340B ID:** ___CH040940___

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. 00002-7510-01	Humalog Inj. 100mg/mL	Lilly	10		mL	Cardinal, McKesson
2. 00002-8215-01	Humulin R Inj. U-100	Lilly	10		mL	Cardinal, McKesson
3. 00002-7510-17	Humalog Inj. 100/mL	Lilly	3		mL	Cardinal, McKesson
4. 00002-1434-80	Trulicity Inj. 1.5/0.5	Lilly	4		ct	Cardinal, McKesson
5. 00002-8031-01	Glucagon Kit 1mg	Lilly	1		Each	Cardinal, McKesson
6. 00002-7715-59	Basaglar Inj.	Lilly	15		mL	Cardinal, McKesson

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? _____

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 is refusing to ship to my contract pharmacies
- 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.)
- Confirmed shortage issues by reviewing validated resources*
- Contacted wholesaler and/or manufacturer to confirm unavailability
- Other (please describe issue): Lilly is refusing to ship to my contract pharmacies at 340B prices. My covered entity is forced to pay WAC for these products if purchased for a contract pharmacy.

Date issue first observed: 9/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 8/31/2020

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>)
 - Validated the ceiling price using the 340B OPAIS pricing system on (date): _____
 - o Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS
 - o 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
 - o 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.
 - o 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): _____

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): Gwendolen Ernesty **Phone:** 828-692-4289 ext. 3451

Email Address: gernesty@brchs.com

Contact Role/Organization: Primary Contact and Director of Pharmacy / Blue Ridge Community Health Services, Inc.

Contact Signature: Gwendolen Ernesty **Date:** 10/19/2020

MCKESSON

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TELXON
REPORTS
ADMINISTRATION
HELP
TUTORIAL

CATALOG SEARCH
QUICK ORDER RESULTS

Account: 870821-INGLES MRKTS77/BLURDG PHS
 By: Keyword Search (Recommended)
 For: lantus
 Non-Mck?
 Show Images?
Tips

CATALOG : SEARCH RESULTS

Mck Item #	Pref Ind	Hist	Description	NDC	AWP	Est. Net Price	Purchase Price	Unit Price	Price Ind
1565415			SEMGLEE PF PEN 100U/ML 3ML 5	49502019675	\$177.58	\$108.11	\$108.11	\$21.6220	PHS1
1565431			SEMGLEE MDV 100U/ML 10ML	49502019580	\$118.38	\$72.07	\$72.07	\$72.0700	PHS1
3605177			BASAGLAR KWIKPEN 3ML 5	00002771559	\$391.63	\$310.04	\$310.04	\$62.0080	
1626688			LANTUS SOLOSTAR PEN 3ML 5	00088221905	\$510.37	\$404.04	\$404.04	\$80.8080	
2722601			LANTUS INSULIN VIAL 10ML	00088222033	\$340.27	\$269.38	\$269.38	\$269.3800	

Screenshot reflects pricing currently loaded to PHS account for one of our contract pharmacy sites for Sanofi.

340B ceiling price for Lantus (NDC 00088-2219-05) per OPAIS as of 10/19/2020: ██████████

MCKESSON

Home Ordering / Inventory Pharmacy Management / Programs Generics Industry Info / Events Community

CATALOG ▾ ORDERS ▾ BACKORDERS RETURNS ▾ PHY INV ▾ TELXON ▾ REPORTS ▾ ADMINISTRATION ▾ HELP TUTORIAL

CATALOG SEARCH QUICK ORDER RESULTS

Account: 870821-INGLES MRKTS77/BLURDG PHS ▾ By: Keyword Search (Recommended) ▾ For: symbicort Non-Mck? Show Images? Tips

CATALOG : SEARCH RESULTS

Mck Item #	Pref Ind	Hist	Description	NDC	AWP	Est. Net Price	Purchase Price	Unit Price	Price Ind
3946563			BUDE FORMO FUMDIH80/4.5PRA120@	00310737220	\$352.52	\$92.04	\$92.04	\$92.0400	PHS1
3946555			BUDE FORM FUMDIH160/4.5PRA120@	00310737020	\$402.96	\$122.53	\$122.53	\$122.5300	PHS1
1474154			SYMBICORT MDI 80/4.5MCG HUD60	00186037228	\$258.29	\$204.48	\$204.48	\$204.4800	
1480797			SYMBICORT MDI 160/4.5MCG HUD60	00186037028	\$297.12	\$235.22	\$235.22	\$235.2200	
1757400			SYMBICORT MDI 80/4.5MCG 120DO	00186037220	\$382.54	\$302.84	\$302.84	\$302.8400	
1773100			SYMBICORT MDI 160/4.5MCG 120DO	00186037020	\$437.26	\$346.16	\$346.16	\$346.1600	

Screenshot reflects pricing currently loaded to PHS account for one of our contract pharmacy sites for AstraZeneca.

340B ceiling price for Symbicort (00186-0370-20) per OPAIS as of 10/19/2020: ██████████

McKESSON

Home Ordering / Inventory Pharmacy Management / Programs Generics Industry Info / Events Community

CATALOG ORDERS BACKORDERS RETURNS PHY INV TELXON REPORTS ADMINISTRATION HELP TUTORIAL

CATALOG SEARCH QUICK ORDER RESULTS

Account: 870821-INGLES MRKTS77/BLURDG PHS By: Keyword Search (Recommended) For: humalog Non-Mck? Show Images? Tips

CATALOG : SEARCH RESULTS

Mck Item #	Pref Ind	Hist	Description	NDC	AWP	Est. Net Price	Purchase Price	Unit Price	Price Ind
3704699			HUMALOG JUNIOR KWIKPEN 3ML 5	00002771459	\$636.48	\$503.88	\$503.88	\$5.0388	
3739307			ADMELOG VIAL 100U/ML 3ML	00024592605	\$47.08	\$37.27	\$37.27	\$37.2700	
1529874			INSULIN LISPRO 75/25 INJ100U/ML5	00002823305	\$318.24	\$251.94	\$251.94	\$50.3880	
1529882			INSULIN LISPRO JR INJ100U/ML 5	00002775205	\$318.24	\$251.94	\$251.94	\$50.3880	
1545037			INSULIN LISPRO KWIKPEN 3MLX5	00002822259	\$318.24	\$251.94	\$251.94	\$50.3880	
1499250			HUMALOG VIAL 100U 3ML	00002751017	\$98.89	\$78.29	\$78.29	\$78.2900	
1379528			HUMALOG CART 3-ML 5	00002751659	\$612.54	\$484.93	\$484.93	\$96.9860	
1800531			HUMALOG KWIK PEN 3ML 5	00002879959	\$636.48	\$503.88	\$503.88	\$100.7760	
1801703			HUMALOG KWIK PEN 75/25 5	00002879759	\$636.48	\$503.88	\$503.88	\$100.7760	
1803329			HUMALOG MIX KWIKPEN 50/50 5	00002879859	\$636.48	\$503.88	\$503.88	\$100.7760	
3760469			ADMELOG MDV 100U/ML 10ML	00024592410	\$156.91	\$124.22	\$124.22	\$124.2200	
1545029			INSULIN LISPRO INJ100U/ML 10ML	00002773701	\$164.82	\$130.48	\$130.48	\$130.4800	
3459286			HUMALOG KWIK PEN U200 3ML 2	00002771227	\$509.18	\$403.10	\$403.10	\$201.5500	
3760477			ADMELOG SOLOSTAR PEN 3ML 5	00024592505	\$302.96	\$239.85	\$239.85	\$239.8500	
1622513			HUMALOG VIAL 100U 10ML	00002751001	\$329.64	\$260.97	\$260.97	\$260.9700	
1818624			HUMALOG VIAL 50/50 10ML	00002751201	\$341.64	\$270.47	\$270.47	\$270.4700	
1683473			HUMALOG VIAL 75/25 10ML	00002751101	\$341.64	\$270.47	\$270.47	\$270.4700	
3782265			INPEN LILYGREY PEN INJ W/CALC	62088000032	\$1,005.00	\$763.80	\$763.80	\$763.8000	
3782281			INPEN LILYPINK PEN INJ W/ CALC	62088000033	\$1,005.00	\$763.80	\$763.80	\$763.8000	
3782257			INPEN LILYBLU PEN INJ W/ CALC	62088000031	\$1,005.00	\$763.80	\$763.80	\$763.8000	

Screenshot reflects pricing currently loaded to PHS account for one of our contract pharmacy sites for Lilly.

340B ceiling price for Humalog (NDC 00002-7510-01) per OPAIS as of 10/19/2020: [REDACTED]

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: East Valley **340B ID:** CH099000

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
00002446330	CIALIS TAB 10MG 30	Eli Lilly and Company	30		EA	ABC
00002446430	CIALIS TAB 20MG 30	Eli Lilly and Company	30		EA	ABC
00002446534	CIALIS TAB 2.5MG BP 30	Eli Lilly and Company	30		EA	ABC
00002767801	MPB CYRAMZA 500MG 50ML SDV	Eli Lilly and Company	1		EA	ABC
00002766901	MPB CYRAMZA 100MG 10ML SDV	Eli Lilly and Company	1		EA	ABC
00002771601	MPB PORTRAZZA 800MG 50ML SDV	Eli Lilly and Company	1		EA	ABC
00002397760	MPB RETEVMO 40MG CAP 60	Eli Lilly and Company	60		EA	ABC
00002298060	MPB RETEVMO 80MG CAP 60	Eli Lilly and Company	60		EA	ABC

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA



00002298026	MPB RETEVMO 80MG CAP 120	Eli Lilly and Company	120		EA	ABC
00002840001	FORTEO PEN 250MCG ML 2.4ML	Eli Lilly and Company	1		EA	ABC
00002882427	HUMULIN R KWIK PEN U500 3ML 2	Eli Lilly and Company	2		CT	ABC
00002850101	HUMULIN R REG INSULN U500 20ML	Eli Lilly and Company	1		EA	ABC
00002879959	HUMALOG KWIK PEN 3ML 5	Eli Lilly and Company	5		CT	ABC
00002879759	HUMALOG KWIK PEN 75 25 5	Eli Lilly and Company	5		CT	ABC
00002879859	HUMALOG MIX KWIKPEN 50 50 5	Eli Lilly and Company	5		CT	ABC
00002771459	HUMALOG JUNIOR KWIKPEN 3ML 5	Eli Lilly and Company	100		CT	ABC
00002751659	HUMALOG CART 3-ML 5	Eli Lilly and Company	5		CT	ABC
00002751201	HUMALOG VIAL 50 50 10ML	Eli Lilly and Company	1		EA	ABC
00002751101	HUMALOG VIAL 75 25 10ML	Eli Lilly and Company	1		EA	ABC
00002751001	HUMALOG VIAL 100U 10ML	Eli Lilly and Company	1		EA	ABC
00002751017	HUMALOG VIAL 100U 3ML	Eli Lilly and Company	1		EA	ABC
00002823305	INSULIN LISPRO 75 25 INJ100U ML5	Eli Lilly and Company	5		CT	ABC
00002775205	INSULIN LISPRO JR INJ100U ML 5	Eli Lilly and Company	5		CT	ABC
00002822259	INSULIN LISPRO KWIKPEN 3MLX5	Eli Lilly and Company	5		CT	ABC
00002773701	INSULIN LISPRO INJ100U ML 10ML	Eli Lilly and Company	1		EA	ABC
00002322930	STRATTERA CAP 40MG 30	Eli Lilly and Company	30		EA	ABC
00002323930	STRATTERA CAP 60MG 30	Eli Lilly and Company	30		EA	ABC
00002323830	STRATTERA CAP 18MG 30	Eli Lilly and Company	30		EA	ABC

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00002322830	STRATTERA CAP 25MG 30	Eli Lilly and Company	30		EA	ABC
00002322730	STRATTERA CAP 10MG 30	Eli Lilly and Company	30		EA	ABC
00002803101	GLUCAGON EMERG KIT 1MG SYR 1ML	Eli Lilly and Company	1		EA	ABC
00002325130	STRATTERA CAP 100MG 30	Eli Lilly and Company	30		EA	ABC
00002325030	STRATTERA CAP 80MG 30	Eli Lilly and Company	30		EA	ABC
00002880559	HUMULIN N KWIKPEN 5	Eli Lilly and Company	5		CT	ABC
00002418402	EVISTA TAB 60MG 100	Eli Lilly and Company	100		EA	ABC
00002418430	EVISTA TAB 60MG 30	Eli Lilly and Company	30		EA	ABC
00002814901	HUMATROPE CARTR KIT 24MG	Eli Lilly and Company	1		EA	ABC
00002445385	ZYPREXA ZYDIS TAB 5MG UD 30	Eli Lilly and Company	30		EA	ABC
00002445585	ZYPREXA ZYDIS TAB 15MG UD 30	Eli Lilly and Company	30		EA	ABC
00002411630	ZYPREXA TAB 7.5MG 30	Eli Lilly and Company	30		EA	ABC
00002445485	ZYPREXA ZYDIS TAB 10MG UD 30	Eli Lilly and Company	30		EA	ABC
00002445685	ZYPREXA ZYDIS TAB 20MG UD 30	Eli Lilly and Company	30		EA	ABC
00002512330	EFFIENT TAB 10MG 30	Eli Lilly and Company	30		EA	ABC
00002512377	EFFIENT TAB 10MG BP INST 90	Eli Lilly and Company	90		EA	ABC
00002512130	EFFIENT TAB 5MG 30	Eli Lilly and Company	30		EA	ABC
00002814801	HUMATROPE CARTR KIT 12MG	Eli Lilly and Company	1		EA	ABC
00002323560	CYMBALTA CAP 20MG 60	Eli Lilly and Company	60		EA	ABC
00002327004	CYMBALTA CAP 60MG 1000=	Eli Lilly and Company	1000		EA	ABC

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA



00002324090	CYMBALTA CAP 30MG 90	Eli Lilly and Company	90		EA	ABC
00002324030	CYMBALTA CAP 30MG 30	Eli Lilly and Company	30		EA	ABC
00002327030	CYMBALTA CAP 60MG 30	Eli Lilly and Company	30		EA	ABC
00002771227	HUMALOG KWIK PEN U200 3ML 2	Eli Lilly and Company	2		CT	ABC
00002411230	ZYPREXA TAB 2.5MG 30	Eli Lilly and Company	30		EA	ABC
00002411730	ZYPREXA TAB 10MG 30	Eli Lilly and Company	30		EA	ABC
00002814701	HUMATROPE CARTR KIT 6MG	Eli Lilly and Company	1		EA	ABC
00002821501	HUMULIN R REG INSUL U100 10ML	Eli Lilly and Company	1		EA	ABC
00002821517	HUMULIN R REG INSUL U100 3ML	Eli Lilly and Company	1		EA	ABC
00002411530	ZYPREXA TAB 5MG 30	Eli Lilly and Company	30		EA	ABC
00002441530	ZYPREXA TAB 15MG 30	Eli Lilly and Company	30		EA	ABC
00002442030	ZYPREXA TAB 20MG 30	Eli Lilly and Company	30		EA	ABC
00002759701	ZYPREXA IM SDV 10MG SINGLE	Eli Lilly and Company	1		EA	ABC
00002831501	HUMULIN N NPH INSUL U100 10ML	Eli Lilly and Company	0.33		EA	ABC
00002831517	HUMULIN N NPH INSUL U100 3ML	Eli Lilly and Company	1		EA	ABC
00002880359	HUMULIN 70 30 KWIKPEN 5	Eli Lilly and Company	5		CT	ABC
00002143380	TRULICITY 0.75MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	ABC
00002143480	TRULICITY 1.5MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	ABC
00002733511	HUMATROP 5MG COMB PACK KIT	Eli Lilly and Company	1		EA	ABC
00002237711	EMGALITY INJ PFS 120MG 1	Eli Lilly and Company	1		EA	ABC

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00002750201	GEMZAR LYO PWD 1GM IN 50ML VL1	Eli Lilly and Company	1		EA	ABC
00002143611	EMGALITY INJ PEN 120MG ML 1	Eli Lilly and Company	1		EA	ABC
00002323330	SYMBYAX CAP 6 50MG 30	Eli Lilly and Company	30		EA	ABC
00002323130	SYMBYAX CAP 6 25MG 30	Eli Lilly and Company	30		EA	ABC
00002323430	SYMBYAX CAP 12 50MG 30	Eli Lilly and Company	30		EA	ABC
00002762301	ALIMTA SDV 500MG 20ML	Eli Lilly and Company	1		EA	ABC
00002764001	ALIMTA SDV 100MG 4ML	Eli Lilly and Company	1		EA	ABC
00002323030	SYMBYAX CAP 3 25 30	Eli Lilly and Company	30		EA	ABC
00002144511	TALTZ AUTO INJECTOR 80MG 1	Eli Lilly and Company	1		EA	ABC
00002144509	TALTZ AUTO INJECTOR 80MG 3	Eli Lilly and Company	3		EA	ABC
00002144527	TALTZ AUTO INJECTOR 80MG 2	Eli Lilly and Company	2		EA	ABC
00002772411	TALTZ PF SYRINGE 80MG 1	Eli Lilly and Company	1		EA	ABC
00002533754	VERZENIO TAB 150MG BP 14	Eli Lilly and Company	14		EA	ABC
00002448354	VERZENIO TAB 50MG BP 14	Eli Lilly and Company	14		EA	ABC
00002621654	VERZENIO TAB 200MG BP 14	Eli Lilly and Company	14		EA	ABC
00002481554	VERZENIO TAB 100MG BP 14	Eli Lilly and Company	14		EA	ABC
00002418230	OLUMIANT TAB 2MG 30	Eli Lilly and Company	30		EA	ABC
00002446230	CIALIS TAB 5MG 30	Eli Lilly and Company	30		EA	ABC
00002446234	CIALIS TAB 5MG BP 30	Eli Lilly and Company	30		EA	ABC
00002311509	EMGALITY INJ PFS 100MG ML 3	Eli Lilly and Company	3		CT	ABC

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00002449108	REYVOW TB 100MG 8	Eli Lilly and Company	8		CT	ABC
00002431208	REYVOW TB 50MG 8	Eli Lilly and Company	8		CT	ABC
00002473230	OLUMIANT TAB 1MG 30	Eli Lilly and Company	30		EA	ABC
00002763511	ZYPREXA RELPREV VL 210MG D S 1	Eli Lilly and Company	1		EA	ABC
00002614527	BAQSIMI PWD DEVICE 3MG 2	Eli Lilly and Company	2		CT	ABC
00002771559	BASAGLAR KWIKPEN 3ML 5	Eli Lilly and Company	5		CT	ABC
00002822827	LYUMJEV KWIKPEN INJ 200U ML 2	Eli Lilly and Company	2		CT	ABC
00002763711	ZYPREXA RELPREV VL 405MG D S 1	Eli Lilly and Company	1		EA	ABC
00002763611	ZYPREXA RELPREV VL 300MG D S 1	Eli Lilly and Company	1		EA	ABC
00002772801	LYUMJEV INJ 10ML VIAL 1	Eli Lilly and Company	1		EA	ABC
00002820705	LYUMJEV KWIKPEN INJ 100U ML 5	Eli Lilly and Company	5		CT	ABC
00002614511	BAQSIMI PWD DEVICE 3MG 1	Eli Lilly and Company	1		EA	ABC
00002871501	HUMULIN 70 30 MDV 10ML	Eli Lilly and Company	0.33		EA	ABC
00002871517	HUMULIN 70 30 VIAL 3ML	Eli Lilly and Company	1		EA	ABC

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? _____

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.

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA



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 340B Price Violation
- 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*):

Date issue first observed: 9/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 8/31/2020

*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/manufacturerssearch>), 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): 10/26/2020
 - 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
- 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): Alicia Mardini **Phone:** 626-919-4333 x 2220

Email Address: amardini@evchc.org

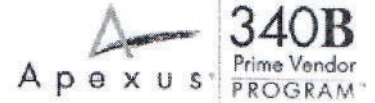
Contact Role/Organization: CEO

Contact Signature:  **Date:** 10/26/2020

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.

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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

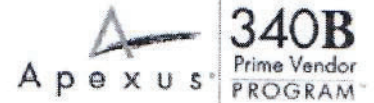
Background Information

Entity Name: Life Changers Intervention Services **340B ID:** RWII28470

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).

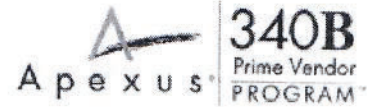
11 digit NDC	Drug Name and Strength (as shown in 340B OPAIS)	Manufacturer	Package Size	Case Package Size	Unit of Measure (e.g. mL, cap, etc.)	CE Wholesaler
00002446330	CIALIS TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002446430	CIALIS TAB 20MG 30	Eli Lilly and Company	30		EA	McKesson
00002446534	CIALIS TAB 2.5MG BP 30	Eli Lilly and Company	30		EA	McKesson
00002767801	MPB CYRAMZA 500MG 50ML SDV	Eli Lilly and Company	1		EA	McKesson
00002766901	MPB CYRAMZA 100MG 10ML SDV	Eli Lilly and Company	1		EA	McKesson
00002771601	MPB PORTRAZZA 800MG 50ML SDV	Eli Lilly and Company	1		EA	McKesson
00002397760	MPB RETEVMO 40MG CAP 60	Eli Lilly and Company	60		EA	McKesson
00002298060	MPB RETEVMO 80MG CAP 60	Eli Lilly and Company	60		EA	McKesson

340B Ceiling Price Unavailable/
Incorrect 340B Ceiling Price Notification for HRSA



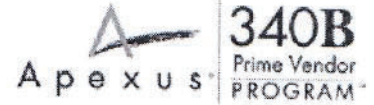
00002298026	MPB RETEVMO 80MG CAP 120	Eli Lilly and Company	120		EA	McKesson
00002840001	FORTEO PEN 250MCG ML 2.4ML	Eli Lilly and Company	1		EA	McKesson
00002882427	HUMULIN R KWIK PEN U500 3ML 2	Eli Lilly and Company	2		CT	McKesson
00002850101	HUMULIN R REG INSULN U500 20ML	Eli Lilly and Company	1		EA	McKesson
00002879959	HUMALOG KWIK PEN 3ML 5	Eli Lilly and Company	5		CT	McKesson
00002879759	HUMALOG KWIK PEN 75 25 5	Eli Lilly and Company	5		CT	McKesson
00002879859	HUMALOG MIX KWIKPEN 50 50 5	Eli Lilly and Company	5		CT	McKesson
00002771459	HUMALOG JUNIOR KWIKPEN 3ML 5	Eli Lilly and Company	100		CT	McKesson
00002751659	HUMALOG CART 3-ML 5	Eli Lilly and Company	5		CT	McKesson
00002751201	HUMALOG VIAL 50 50 10ML	Eli Lilly and Company	1		EA	McKesson
00002751101	HUMALOG VIAL 75 25 10ML	Eli Lilly and Company	1		EA	McKesson
00002751001	HUMALOG VIAL 100U 10ML	Eli Lilly and Company	1		EA	McKesson
00002751017	HUMALOG VIAL 100U 3ML	Eli Lilly and Company	1		EA	McKesson
00002823305	INSULIN LISP 75 25 INJ100U ML5	Eli Lilly and Company	5		CT	McKesson
00002775205	INSULIN LISPRO JR INJ100U ML 5	Eli Lilly and Company	5		CT	McKesson
00002822259	INSULIN LISPRO KWIKPEN 3MLX5	Eli Lilly and Company	5		CT	McKesson
00002773701	INSULIN LISPRO INJ100U ML 10ML	Eli Lilly and Company	1		EA	McKesson
00002322930	STRATTERA CAP 40MG 30	Eli Lilly and Company	30		EA	McKesson
00002323930	STRATTERA CAP 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002323830	STRATTERA CAP 18MG 30	Eli Lilly and Company	30		EA	McKesson

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Incorrect 340B Ceiling Price Notification for HRSA



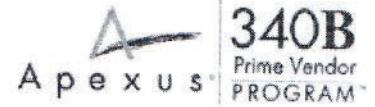
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00002322730	STRATTERA CAP 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002803101	GLUCAGON EMERG KIT 1MG SYR 1ML	Eli Lilly and Company	1		EA	McKesson
00002325130	STRATTERA CAP 100MG 30	Eli Lilly and Company	30		EA	McKesson
00002325030	STRATTERA CAP 80MG 30	Eli Lilly and Company	30		EA	McKesson
00002880559	HUMULIN N KWIKPEN 5	Eli Lilly and Company	5		CT	McKesson
00002418402	EVISTA TAB 60MG 100	Eli Lilly and Company	100		EA	McKesson
00002418430	EVISTA TAB 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002814901	HUMATROPE CARTR KIT 24MG	Eli Lilly and Company	1		EA	McKesson
00002445385	ZYPREXA ZYDIS TAB 5MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002445585	ZYPREXA ZYDIS TAB 15MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002411630	ZYPREXA TAB 7.5MG 30	Eli Lilly and Company	30		EA	McKesson
00002445485	ZYPREXA ZYDIS TAB 10MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002445685	ZYPREXA ZYDIS TAB 20MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002512330	EFFIENT TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002512377	EFFIENT TAB 10MG BP INST 90	Eli Lilly and Company	90		EA	McKesson
00002512130	EFFIENT TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002814801	HUMATROPE CARTR KIT 12MG	Eli Lilly and Company	1		EA	McKesson
00002323560	CYMBALTA CAP 20MG 60	Eli Lilly and Company	60		EA	McKesson
00002327004	CYMBALTA CAP 60MG 1000=	Eli Lilly and Company	1000		EA	McKesson

340B Ceiling Price Unavailable/
Incorrect 340B Ceiling Price Notification for HRSA



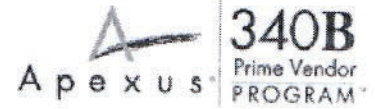
00002324090	CYMBALTA CAP 30MG 90	Eli Lilly and Company	90		EA	McKesson
00002324030	CYMBALTA CAP 30MG 30	Eli Lilly and Company	30		EA	McKesson
00002327030	CYMBALTA CAP 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002771227	HUMALOG KWIK PEN U200 3ML 2	Eli Lilly and Company	2		CT	McKesson
00002411230	ZYPREXA TAB 2.5MG 30	Eli Lilly and Company	30		EA	McKesson
00002411730	ZYPREXA TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002814701	HUMATROPE CARTR KIT 6MG	Eli Lilly and Company	1		EA	McKesson
00002821501	HUMULIN R REG INSUL U100 10ML	Eli Lilly and Company	1		EA	McKesson
00002821517	HUMULIN R REG INSUL U100 3ML	Eli Lilly and Company	1		EA	McKesson
00002411530	ZYPREXA TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002441530	ZYPREXA TAB 15MG 30	Eli Lilly and Company	30		EA	McKesson
00002442030	ZYPREXA TAB 20MG 30	Eli Lilly and Company	30		EA	McKesson
00002759701	ZYPREXA IM SDV 10MG SINGLE	Eli Lilly and Company	1		EA	McKesson
00002831501	HUMULIN N NPH INSUL U100 10ML	Eli Lilly and Company	0.33		EA	McKesson
00002831517	HUMULIN N NPH INSUL U100 3ML	Eli Lilly and Company	1		EA	McKesson
00002880359	HUMULIN 70 30 KWIKPEN 5	Eli Lilly and Company	5		CT	McKesson
00002143380	TRULICITY 0.75MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	McKesson
00002143480	TRULICITY 1.5MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	McKesson
00002733511	HUMATROP 5MG COMB PACK KIT	Eli Lilly and Company	1		EA	McKesson
00002237711	EMGALITY INJ PFS 120MG 1	Eli Lilly and Company	1		EA	McKesson

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Incorrect 340B Ceiling Price Notification for HRSA



00002750201	GEMZAR LYO PWD 1GM IN 50ML VL1	Eli Lilly and Company	1		EA	McKesson
00002143611	EMGALITY INJ PEN 120MG ML 1	Eli Lilly and Company	1		EA	McKesson
00002323330	SYMBYAX CAP 6 50MG 30	Eli Lilly and Company	30		EA	McKesson
00002323130	SYMBYAX CAP 6 25MG 30	Eli Lilly and Company	30		EA	McKesson
00002323430	SYMBYAX CAP 12 50MG 30	Eli Lilly and Company	30		EA	McKesson
00002762301	ALIMTA SDV 500MG 20ML	Eli Lilly and Company	1		EA	McKesson
00002764001	ALIMTA SDV 100MG 4ML	Eli Lilly and Company	1		EA	McKesson
00002323030	SYMBYAX CAP 3 25 30	Eli Lilly and Company	30		EA	McKesson
00002144511	TALTZ AUTO INJECTOR 80MG 1	Eli Lilly and Company	1		EA	McKesson
00002144509	TALTZ AUTO INJECTOR 80MG 3	Eli Lilly and Company	3		EA	McKesson
00002144527	TALTZ AUTO INJECTOR 80MG 2	Eli Lilly and Company	2		EA	McKesson
00002772411	TALTZ PF SYRINGE 80MG 1	Eli Lilly and Company	1		EA	McKesson
00002533754	VERZENIO TAB 150MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002448354	VERZENIO TAB 50MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002621654	VERZENIO TAB 200MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002481554	VERZENIO TAB 100MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002418230	OLUMIANT TAB 2MG 30	Eli Lilly and Company	30		EA	McKesson
00002446230	CIALIS TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002446234	CIALIS TAB 5MG BP 30	Eli Lilly and Company	30		EA	McKesson
00002311509	EMGALITY INJ PFS 100MG ML 3	Eli Lilly and Company	3		CT	McKesson

340B Ceiling Price Unavailable/
 Incorrect 340B Ceiling Price Notification for HRSA



00002449108	REYVOW TB 100MG 8	Eli Lilly and Company	8		CT	McKesson
00002431208	REYVOW TB 50MG 8	Eli Lilly and Company	8		CT	McKesson
00002473230	OLUMIANT TAB 1MG 30	Eli Lilly and Company	30		EA	McKesson
00002763511	ZYPREXA RELPREV VL 210MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002614527	BAQSIMI PWD DEVICE 3MG 2	Eli Lilly and Company	2		CT	McKesson
00002771559	BASAGLAR KWIKPEN 3ML 5	Eli Lilly and Company	5		CT	McKesson
00002822827	LYUMJEV KWIKPEN INJ 200U ML 2	Eli Lilly and Company	2		CT	McKesson
00002763711	ZYPREXA RELPREV VL 405MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002763611	ZYPREXA RELPREV VL 300MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002772801	LYUMJEV INJ 10ML VIAL 1	Eli Lilly and Company	1		EA	McKesson
00002820705	LYUMJEV KWIKPEN INJ 100U ML 5	Eli Lilly and Company	5		CT	McKesson
00002614511	BAQSIMI PWD DEVICE 3MG 1	Eli Lilly and Company	1		EA	McKesson
00002871501	HUMULIN 70 30 MDV 10ML	Eli Lilly and Company	0.33		EA	McKesson
00002871517	HUMULIN 70 30 VIAL 3ML	Eli Lilly and Company	1		EA	McKesson

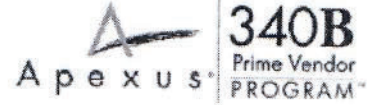
Regarding the purchase and distribution processes, please answer yes or no to the following:

- 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? _____

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.

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA



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 340B Price Violation
- 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*):

Date issue first observed: 9/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 8/31/2020

*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

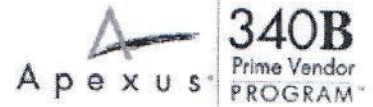


Table 2: Incorrect 340B Price

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:

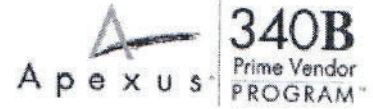
- Determined if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Check the labeler code on 340B OPAIS (<https://340bopais.hrsa.gov/manufacturerearch>), and check the Medicaid Drug Rebate Program labeler code (<https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-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): _____

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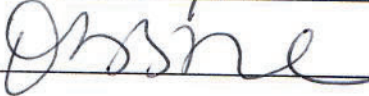
Signature

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): BEVERLY STANLEY Phone: 910-754-7988

Email Address: lifechangersllc@yahoo.com

Contact Role/Organization: CEO/EXECUTIVE DIRECTOR

Contact Signature:  Date: 10/29/20

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.

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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: MQVN Community Development Corp **340B ID:** CHC26582-00

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
00002446330	CIALIS TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002446430	CIALIS TAB 20MG 30	Eli Lilly and Company	30		EA	McKesson
00002446534	CIALIS TAB 2.5MG BP 30	Eli Lilly and Company	30		EA	McKesson
00002767801	MPB CYRAMZA 500MG 50ML SDV	Eli Lilly and Company	1		EA	McKesson
00002766901	MPB CYRAMZA 100MG 10ML SDV	Eli Lilly and Company	1		EA	McKesson
00002771601	MPB PORTRAZZA 800MG 50ML SDV	Eli Lilly and Company	1		EA	McKesson
00002397760	MPB RETEVMO 40MG CAP 60	Eli Lilly and Company	60		EA	McKesson
00002298060	MPB RETEVMO 80MG CAP 60	Eli Lilly and Company	60		EA	McKesson

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 Incorrect 340B Ceiling Price Notification for HRSA



00002298026	MPB RETEVMO 80MG CAP 120	Eli Lilly and Company	120		EA	McKesson
00002840001	FORTEO PEN 250MCG ML 2.4ML	Eli Lilly and Company	1		EA	McKesson
00002882427	HUMULIN R KWIK PEN U500 3ML 2	Eli Lilly and Company	2		CT	McKesson
00002850101	HUMULIN R REG INSULN U500 20ML	Eli Lilly and Company	1		EA	McKesson
00002879959	HUMALOG KWIK PEN 3ML 5	Eli Lilly and Company	5		CT	McKesson
00002879759	HUMALOG KWIK PEN 75 25 5	Eli Lilly and Company	5		CT	McKesson
00002879859	HUMALOG MIX KWIKPEN 50 50 5	Eli Lilly and Company	5		CT	McKesson
00002771459	HUMALOG JUNIOR KWIKPEN 3ML 5	Eli Lilly and Company	100		CT	McKesson
00002751659	HUMALOG CART 3-ML 5	Eli Lilly and Company	5		CT	McKesson
00002751201	HUMALOG VIAL 50 50 10ML	Eli Lilly and Company	1		EA	McKesson
00002751101	HUMALOG VIAL 75 25 10ML	Eli Lilly and Company	1		EA	McKesson
00002751001	HUMALOG VIAL 100U 10ML	Eli Lilly and Company	1		EA	McKesson
00002751017	HUMALOG VIAL 100U 3ML	Eli Lilly and Company	1		EA	McKesson
00002823305	INSULIN LISP 75 25 INJ100U ML5	Eli Lilly and Company	5		CT	McKesson
00002775205	INSULIN LISPRO JR INJ100U ML 5	Eli Lilly and Company	5		CT	McKesson
00002822259	INSULIN LISPRO KWIKPEN 3MLX5	Eli Lilly and Company	5		CT	McKesson
00002773701	INSULIN LISPRO INJ100U ML 10ML	Eli Lilly and Company	1		EA	McKesson
00002322930	STRATTERA CAP 40MG 30	Eli Lilly and Company	30		EA	McKesson
00002323930	STRATTERA CAP 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002323830	STRATTERA CAP 18MG 30	Eli Lilly and Company	30		EA	McKesson

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00002322830	STRATTERA CAP 25MG 30	Eli Lilly and Company	30		EA	McKesson
00002322730	STRATTERA CAP 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002803101	GLUCAGON EMERG KIT 1MG SYR 1ML	Eli Lilly and Company	1		EA	McKesson
00002325130	STRATTERA CAP 100MG 30	Eli Lilly and Company	30		EA	McKesson
00002325030	STRATTERA CAP 80MG 30	Eli Lilly and Company	30		EA	McKesson
00002880559	HUMULIN N KWIKPEN 5	Eli Lilly and Company	5		CT	McKesson
00002418402	EVISTA TAB 60MG 100	Eli Lilly and Company	100		EA	McKesson
00002418430	EVISTA TAB 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002814901	HUMATROPE CARTR KIT 24MG	Eli Lilly and Company	1		EA	McKesson
00002445385	ZYPREXA ZYDIS TAB 5MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002445585	ZYPREXA ZYDIS TAB 15MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002411630	ZYPREXA TAB 7.5MG 30	Eli Lilly and Company	30		EA	McKesson
00002445485	ZYPREXA ZYDIS TAB 10MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002445685	ZYPREXA ZYDIS TAB 20MG UD 30	Eli Lilly and Company	30		EA	McKesson
00002512330	EFFIENT TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002512377	EFFIENT TAB 10MG BP INST 90	Eli Lilly and Company	90		EA	McKesson
00002512130	EFFIENT TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002814801	HUMATROPE CARTR KIT 12MG	Eli Lilly and Company	1		EA	McKesson
00002323560	CYMBALTA CAP 20MG 60	Eli Lilly and Company	60		EA	McKesson
00002327004	CYMBALTA CAP 60MG 1000=	Eli Lilly and Company	1000		EA	McKesson

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00002324090	CYMBALTA CAP 30MG 90	Eli Lilly and Company	90		EA	McKesson
00002324030	CYMBALTA CAP 30MG 30	Eli Lilly and Company	30		EA	McKesson
00002327030	CYMBALTA CAP 60MG 30	Eli Lilly and Company	30		EA	McKesson
00002771227	HUMALOG KWIK PEN U200 3ML 2	Eli Lilly and Company	2		CT	McKesson
00002411230	ZYPREXA TAB 2.5MG 30	Eli Lilly and Company	30		EA	McKesson
00002411730	ZYPREXA TAB 10MG 30	Eli Lilly and Company	30		EA	McKesson
00002814701	HUMATROPE CARTR KIT 6MG	Eli Lilly and Company	1		EA	McKesson
00002821501	HUMULIN R REG INSUL U100 10ML	Eli Lilly and Company	1		EA	McKesson
00002821517	HUMULIN R REG INSUL U100 3ML	Eli Lilly and Company	1		EA	McKesson
00002411530	ZYPREXA TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002441530	ZYPREXA TAB 15MG 30	Eli Lilly and Company	30		EA	McKesson
00002442030	ZYPREXA TAB 20MG 30	Eli Lilly and Company	30		EA	McKesson
00002759701	ZYPREXA IM SDV 10MG SINGLE	Eli Lilly and Company	1		EA	McKesson
00002831501	HUMULIN N NPH INSUL U100 10ML	Eli Lilly and Company	0.33		EA	McKesson
00002831517	HUMULIN N NPH INSUL U100 3ML	Eli Lilly and Company	1		EA	McKesson
00002880359	HUMULIN 70 30 KWIKPEN 5	Eli Lilly and Company	5		CT	McKesson
00002143380	TRULICITY 0.75MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	McKesson
00002143480	TRULICITY 1.5MG 0.5ML PEN 4	Eli Lilly and Company	4		CT	McKesson
00002733511	HUMATROP 5MG COMB PACK KIT	Eli Lilly and Company	1		EA	McKesson
00002237711	EMGALITY INJ PFS 120MG 1	Eli Lilly and Company	1		EA	McKesson

340B Ceiling Price Unavailable/
 Incorrect 340B Ceiling Price Notification for HRSA



00002750201	GEMZAR LYO PWD 1GM IN 50ML VL1	Eli Lilly and Company	1		EA	McKesson
00002143611	EMGALITY INJ PEN 120MG ML 1	Eli Lilly and Company	1		EA	McKesson
00002323330	SYMBYAX CAP 6 50MG 30	Eli Lilly and Company	30		EA	McKesson
00002323130	SYMBYAX CAP 6 25MG 30	Eli Lilly and Company	30		EA	McKesson
00002323430	SYMBYAX CAP 12 50MG 30	Eli Lilly and Company	30		EA	McKesson
00002762301	ALIMTA SDV 500MG 20ML	Eli Lilly and Company	1		EA	McKesson
00002764001	ALIMTA SDV 100MG 4ML	Eli Lilly and Company	1		EA	McKesson
00002323030	SYMBYAX CAP 3 25 30	Eli Lilly and Company	30		EA	McKesson
00002144511	TALTZ AUTO INJECTOR 80MG 1	Eli Lilly and Company	1		EA	McKesson
00002144509	TALTZ AUTO INJECTOR 80MG 3	Eli Lilly and Company	3		EA	McKesson
00002144527	TALTZ AUTO INJECTOR 80MG 2	Eli Lilly and Company	2		EA	McKesson
00002772411	TALTZ PF SYRINGE 80MG 1	Eli Lilly and Company	1		EA	McKesson
00002533754	VERZENIO TAB 150MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002448354	VERZENIO TAB 50MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002621654	VERZENIO TAB 200MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002481554	VERZENIO TAB 100MG BP 14	Eli Lilly and Company	14		EA	McKesson
00002418230	OLUMIANT TAB 2MG 30	Eli Lilly and Company	30		EA	McKesson
00002446230	CIALIS TAB 5MG 30	Eli Lilly and Company	30		EA	McKesson
00002446234	CIALIS TAB 5MG BP 30	Eli Lilly and Company	30		EA	McKesson
00002311509	EMGALITY INJ PFS 100MG ML 3	Eli Lilly and Company	3		CT	McKesson

340B Ceiling Price Unavailable/ Incorrect 340B Ceiling Price Notification for HRSA



00002449108	REYVOW TB 100MG 8	Eli Lilly and Company	8		CT	McKesson
00002431208	REYVOW TB 50MG 8	Eli Lilly and Company	8		CT	McKesson
00002473230	OLUMIANT TAB 1MG 30	Eli Lilly and Company	30		EA	McKesson
00002763511	ZYPREXA RELPREV VL 210MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002614527	BAQSIMI PWD DEVICE 3MG 2	Eli Lilly and Company	2		CT	McKesson
00002771559	BASAGLAR KWIKPEN 3ML 5	Eli Lilly and Company	5		CT	McKesson
00002822827	LYUMJEV KWIKPEN INJ 200U ML 2	Eli Lilly and Company	2		CT	McKesson
00002763711	ZYPREXA RELPREV VL 405MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002763611	ZYPREXA RELPREV VL 300MG D S 1	Eli Lilly and Company	1		EA	McKesson
00002772801	LYUMJEV INJ 10ML VIAL 1	Eli Lilly and Company	1		EA	McKesson
00002820705	LYUMJEV KWIKPEN INJ 100U ML 5	Eli Lilly and Company	5		CT	McKesson
00002614511	BAQSIMI PWD DEVICE 3MG 1	Eli Lilly and Company	1		EA	McKesson
00002871501	HUMULIN 70 30 MDV 10ML	Eli Lilly and Company	0.33		EA	McKesson
00002871517	HUMULIN 70 30 VIAL 3ML	Eli Lilly and Company	1		EA	McKesson

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? _____

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.

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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 340B Price Violation
- 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.medicicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicicaid-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: 9/1/2020

Date drug last available at 340B price (enter NEVER if has never been available): 8/31/2020

*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

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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/manufacturerearch>), 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): Diem Nguyen Phone: 504-254-2741

Email Address: diemnnguyen.nguoncdc@gmail.com

Contact Role/Organization: CEO

Contact Signature:  Date: 11/2/2020

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.

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From: Zweerink, Scott
Sent: Thursday, November 05, 2020 1:28 PM
To: Orth, Paul <LINUS.ORTH@tmcmcd.org>; 340BPricing@hrsa.gov
Cc: Lamar, Lona M <Lona.Lamar@tmcmcd.org>; Hennenfent, Joel A <Joel.Hennenfent@tmcmcd.org>
Subject: RE: 340B Pricing Not Made Available by a Manufacturer and Overcharge by a Manufacturer
Ms. Zadecky,
I am circling back on the submission below. Is there any update?

?	University Health ?	<p>K. SCOTT ZWEERINK, PharmD Director of Outpatient Pharmacy Services and 340B Program Compliance (816) 404-4223 Kenneth.Zweerink@tmcmcd.org</p>
?		

From: Orth, Paul
Sent: Monday, October 12, 2020 4:41 PM
To: 340BPricing@hrsa.gov
Cc: Zweerink, Scott <Kenneth.Zweerink@tmcmcd.org>; Lamar, Lona M <Lona.Lamar@tmcmcd.org>; Hennenfent, Joel A <Joel.Hennenfent@tmcmcd.org>; Orth, Paul <LINUS.ORTH@tmcmcd.org>
Subject: FW: 340B Pricing Not Made Available by a Manufacturer and Overcharge by a Manufacturer
Good Afternoon Ms Zadecky,
In August 2020 Truman Medical Center Lakewood (DSH260102) received notification that Lilly will stop providing 340B pricing on all of their medication with labeler code 00002 when the 340B covered entity (CE) purchasing the drug elects to have it shipped to a 340B contract pharmacy. Since September 1, 2020, when Lilly’s policy went into effect, Truman Medical Center (TMC) – Lakewood (DSH260102) has been unable to purchase any medication with labeler code 00002 at the 340B ceiling price for delivery to its contract pharmacy. This action impacts patient care in that it prevents TMC Lakewood’s ability to perform its safety net mission by providing 340B pricing discounts directly to vulnerable patients in the communities where they live.

In addition, in August 2020 Truman Medical Center Lakewood (DSH260102) received notification that AstraZeneca will stop providing 340B pricing on all of their medication with labeler code 00186 when the 340B covered entity (CE) purchasing the drug elects to have it shipped to a 340B contract pharmacy. Since October 1, 2020, when AstraZeneca’s policy went into effect, Truman Medical Center (TMC) – Lakewood (DSH260102) has been unable to purchase any medication with labeler code 00186 at the 340B ceiling price for delivery to its contract pharmacy. This action impacts patient care in that it prevents TMC Lakewood’s ability to perform its safety net mission by providing 340B pricing discounts directly to vulnerable patients in the communities where they live.

In addition, Lilly and AstraZeneca’s failure to sell covered outpatient drugs to TMC Lakewood for delivery to TMC Lakewood’s contract pharmacies at the 340B ceiling price is contrary to the 340B statute. Under the terms of the statute and the Pharmaceutical Pricing Agreement (PPA) Lilly has entered with HRSA, Lilly and AstraZeneca must charge TMC Lakewood no more than the 340B ceiling price for any covered outpatient drug. See section 340B(a)(1). Failure to do so, to the outlet chosen by the hospital, violates the 340B statute and the PPA.

We understand that in response to a request from 340B Health for HRSA’s official position on Lilly’s notice, on July 8, 2020, HRSA stated that it cannot require Lilly and AstraZeneca to offer the drug at the 340B ceiling price because the 2010 contract pharmacy guidance (75 Fed. Reg. 10272 (March 5, 2010)) is not legally enforceable.

The 340B statute, which HRSA acknowledged in the July 8 statement controls HRSA’s decision, however, requires Lilly and AstraZeneca to sell its drugs to TMC Lakewood at the 340B ceiling price, regardless of whether the drug is furnished at the TMC Lakewood’s pharmacy or at a pharmacy that has entered into a contract with TMC Lakewood to furnish 340B drugs to TMC Lakewood’s patients. The guidance merely described the correct interpretation of the statute, and the statute plainly binds HRSA.

In light of the plain meaning of the statute, TMC Lakewood is asking HRSA to reconsider the formal response it provided to 340B Health and to direct Lilly and AstraZeneca to sell its products to TMC Lakewood through its contract pharmacies at or below the 340B ceiling price and to work in good faith to correct overcharges. Attached are appropriate forms to document the lack pricing availability and overcharge of product.

We look forward to hearing from you. Please reach out if you have any questions.

Sincerely,

Paul Orth

	University Health 	Paul Orth 340B Compliance Analyst, Pharmacy (816) 404-4177 linus.orth@tmcmed.org 
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From: HRSA HSB 340B Pricing [<mailto:340BPricing@hrsa.gov>]
Sent: Thursday, September 03, 2020 9:53 AM
To: Zweerink, Scott <Kenneth.Zweerink@tmcmed.org>
Subject: RE: 340B Pricing Not Made Available by a Manufacturer and Overcharge by a Manufacturer

Good morning Mr. Zweerink:

HRSA is aware of the communication you forwarded. HRSA is not posting a letter at this time as HRSA is considering whether manufacturer policies, including Lilly's, violate the 340B statute and whether sanctions may apply. Under section 340B(a)(1) of the Public Health Service Act (PHSA), a manufacturer participating in the 340B Program must offer its covered outpatient drugs for purchase at or below the 340B ceiling price. Those sanctions could include, but are not limited to, civil monetary penalties pursuant to section 340B(d)(1)(B)(vi) of the PHSA.

The 340B statute does not specify the mode by which 340B drugs may be dispensed. However, the Agency believes contract pharmacies serve a vital function in covered entities' ability to serve underserved and vulnerable populations, particularly as many covered entities do not operate in-house pharmacies. Without comprehensive regulatory authority, HRSA has only limited ability to issue enforceable regulations to ensure clarity in program requirements across all the interdependent aspects of the 340B Program.

We believe that manufacturers that refuse to honor contract pharmacy orders could significantly limit access to 340B-discounted drugs for many underserved and vulnerable populations who may be located in geographically isolated areas and rely on contract pharmacies as a critical point of access for obtaining their prescriptions. To this end, HRSA continues to strongly encourage all manufacturers to sell 340B priced drugs to covered entities directly and through contract pharmacy arrangements.

Julie Zadecky, Pharm D, BCNP
Office of Pharmacy Affairs
Phone: 301-945-9481

HRSA 

From: Zweerink, Scott <Kenneth.Zweerink@tmcmed.org>
Sent: Wednesday, September 2, 2020 1:25 PM
To: HRSA HSB 340B Pricing <340BPricing@hrsa.gov>
Cc: Hoelscher, Marga J <Marga.Hoelscher@tmcmed.org>; Zweerink, Scott <Kenneth.Zweerink@tmcmed.org>
Subject: RE: 340B Pricing Not Made Available by a Manufacturer and Overcharge by a Manufacturer

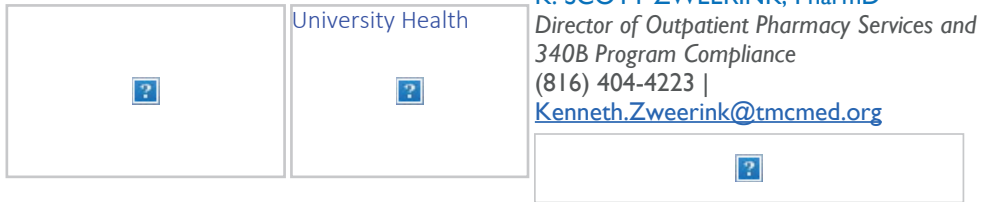
Importance: High

Ms. Zadecky,

I wanted to confirm that HRSA/OPA was aware of the communications attached. Our 340B team could not find this on the HRSA database under manufacturer communication. Is this communication and stated action approved by HRSA/OPA?

Thank you,

Scott



From: Zweerink, Scott

Sent: Friday, August 28, 2020 10:27 AM

To: '340bpricing@hrsa.gov' <340bpricing@hrsa.gov>

Subject: FW: 340B Pricing Not Made Available by a Manufacturer and Overcharge by a Manufacturer

Ms. Zadecky,

Please find TMC responses below. We appreciate HRSA/OPA investigation and look forward to your response. Please continue to reach out if further clarification is needed.

Thank you,

Scott



From: HRSA HSB 340B Pricing [<mailto:340BPricing@hrsa.gov>]

Sent: Wednesday, August 26, 2020 10:19 AM

To: Zweerink, Scott <Kenneth.Zweerink@tmcmcd.org>; HRSA HSB 340B Pricing <340BPricing@hrsa.gov>

Subject: RE: 340B Pricing Not Made Available by a Manufacturer and Overcharge by a Manufacturer

Dear Mr. Zweerink:

As HRSA continues to monitor the Cialis purchasing restrictions at contract pharmacies, HRSA requests some additional information regarding your entity's experience purchasing Cialis. To help us better understand the situations, please answer the following questions:

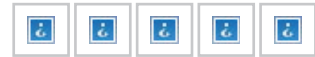
- **How were you notified that your requests for the 340B ceiling price were denied?** TMC RESPONSE: TMC was notified through Lilly public notice on HRSA database July 1, 2020 that 340B pricing would not be honored at contract pharmacies. TMC monitored purchasing accounts and confirmed 340B pricing was unavailable when replenishment product was ordered and shipped to contract pharmacy after July 1, 2020. TMC worked with wholesaler account manager to confirm pricing is unavailable.
 - **Was a 340B price unavailable in your wholesaler 340B account?** TMC RESPONSE: Yes
 - **What account (e.g. 340B account, WAC account, GPO account) was the product ultimately purchased on?** TMC RESPONSE: 340B account
- **How was the transaction executed?** TMC RESPONSE: 340B eligible patients were dispensed Cialis prior to July 1, 2020. After July 1, 2020, the 340B administrator for the contract pharmacy placed a replenishment order and TMC was charged WAC price for the purchases.
 - **Was the entity charged WAC for the purchase?** TMC RESPONSE: Yes
 - **Was the WAC price loaded into the 340B account?** TMC RESPONSE: Yes
 - **Did the contract pharmacy count the transaction as a non-340B commercial dispense?** TMC RESPONSE: No, the dispensations for purchases occurred prior to 340B price being unavailable and 340B eligible patients were dispensed 340B drugs.
- **Please provide any additional information regarding your experience.** TMC RESPONSE: TMC is a good steward of the 340B program and passes 340B savings on to 340B eligible patients. Patients benefiting from discount are most often vulnerable patient populations without prescription "coverage." Any manufacturer who denies 340B pricing to a covered entity within its contract pharmacies is in violation of the 340B statute and is certainly not working in the spirit of the 340B program to enable covered entities to stretch scarce

federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. Leveraging contract pharmacy agreements is a key element of TMC strategy to provide 340B discounts to 340B eligible patients in the communities where they live.

Thank you for your participation in the 340B Program.

Sincerely,

Julie Zadecky, Pharm D, BCNP
Office of Pharmacy Affairs
Phone: 301-945-9481



From: Zweerink, Scott <Kenneth.Zweerink@tmcmcd.org>

Sent: Tuesday, August 18, 2020 5:31 PM

To: HRSA HSB 340B Pricing <340BPricing@hrsa.gov>

Subject: Potential SPAM:340B Pricing Not Made Available by a Manufacturer

August 18, 2020

[Via Electronic Mail: 340bppricing@hrsa.gov](mailto:340bppricing@hrsa.gov)

Rear Admiral Krista Pedley

Director

Office of Pharmacy Affairs

Health Resources and Services Administration

5600 Fishers Lane

Parklawn Building, Mail Stop 10C-03

Rockville, MD 20857

RE: HRSA's Position on Eli Lilly's Policy for Cialis Products

Dear RADM Pedley:

In June 2020, HRSA posted a notice from Lilly which states that effective July 1, 2020, the company will no longer provide 340B pricing on three formulations of its drug Cialis® when the 340B covered entity (CE) purchasing the drug elects to have it shipped to a 340B contract pharmacy. Since July 1, 2020, when Lilly's policy went into effect, Truman Medical Center (TMC) – Hospital Hill (DSH260048) has been unable to purchase Cialis® at the 340B ceiling price for delivery to its contract pharmacy, and was significantly overcharged on several purchases. This action impacts patient care in that it prevents TMC Hospital Hill's ability to perform its safety net mission by providing 340B pricing discounts directly to vulnerable patients in the communities where they live.

In addition, Lilly's failure to sell Cialis® to TMC Hospital Hill for delivery to TMC Hospital Hill's contract pharmacies at the 340B ceiling price is contrary to the 340B statute. Under the terms of the statute and the Pharmaceutical Pricing Agreement (PPA) Lilly has entered with HRSA, Lilly must charge TMC Hospital Hill no more than the 340B ceiling price for any covered outpatient drug, including Cialis®. See section 340B(a) (1). Failure to do so, including the refusal to sell Cialis® to the outlet chosen by the hospital, violates the 340B statute and the PPA.

We understand that in response to a request from 340B Health for HRSA's official position on Lilly's notice, on July 8, 2020, HRSA stated that it cannot require Lilly to offer the drug at the 340B ceiling price because the 2010 contract pharmacy guidance (75 Fed. Reg. 10272 (March 5, 2010)) is not legally enforceable.

The 340B statute, which HRSA acknowledged in the July 8 statement controls HRSA's decision, however, requires Lilly to sell its drugs to TMC Hospital Hill at the 340B ceiling price, regardless of whether the drug is furnished at the TMC Hospital Hill's pharmacy or at a pharmacy that has entered into a contract with TMC

Hospital Hill to furnish 340B drugs to TMC Hospital Hill’s patients. The guidance merely described the correct interpretation of the statute, and the statute plainly binds HRSA.

In light of the plain meaning of the statute, TMC Hospital Hill is asking HRSA to reconsider the formal response it provided to 340B Health and to direct Lilly to sell its Cialis® products to TMC Hospital Hill through its contract pharmacies at or below the 340B ceiling price and to work in good faith to correct overcharges. Attached are appropriate forms to document the lack pricing availability and overcharge of product.

We look forward to hearing from you. Please reach out if you have any questions.

Sincerely,

K. Scott Zweerink, PharmD
Director of Outpatient Pharmacy Services and
340B Program Compliance
(816) 404-4223 | Kenneth.Zweerink@tmcmed.org
Truman Medical Center – Hospital Hill (DSH260048)

?	University Health ?	<p>K. SCOTT ZWEERINK, PharmD <i>Director of Outpatient Pharmacy Services and 340B Program Compliance</i> (816) 404-4223 Kenneth.Zweerink@tmcmed.org</p>
		?

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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 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.

22. We have been working to switch patients to alternate medications and to convince our patients, where possible, to fill their prescriptions at our own, in-house pharmacies where they will still have access to discount pricing.
23. Both efforts have challenges. Even for patients who don't face significant barriers to filling their prescriptions at one of MAP's in-house pharmacies, many are reticent to switch because of familiarity and comfort. Switching patients to alternate formulations to avoid paying full price for these medications may cause patients to become unstable and potentially cause adverse health consequences. For example, a patient whose diabetes was fully controlled by Humalog (an Eli Lilly insulin) may be forced to switch to Novolog (a Novo Nordisk insulin) since Eli Lilly has banned or restricted shipments of its products at 340B pricing to our contract pharmacies. This patient's diabetes may become uncontrolled or the patient may experience adverse effects from switching. In 2019, approximately 19% of MAP's patients were diabetics compared to the State and National averages of 12% and 9%, respectively.
24. Additionally, MAP estimates we will lose up to approximately \$350,000 in annual net revenue as a result of these manufacturer's actions. MAP receives grant dollars to help serve its patients, but these grants only cover about 28% of MAP's total expenses, and MAP depends on its 340B Program savings and revenue to help support approximately 41% of the remaining expenses, which include underfunded and unfunded programs and services such as behavioral health and dental services.
25. This significant financial loss, if not prevented or recovered, will also result in reduction in other clinical and/or patient services, increased work for clinicians, and increases in costs where MAP is covering costs for its uninsured patients and/or patients who are unable to pay.
26. MAP has actively tried to find ways to mitigate the negative financial consequences of the manufacturers' actions. We have considered eliminating or charging a fee for our current free prescription delivery program, increasing per-provider patient volume, and making reductions in some clinical services. Each of these options, however, ultimately negatively impacts patient care and still falls short of an adequate remedy.
27. These restrictions from manufacturers, and MAP's inability to access an administrative remedy through HRSA, will drastically impact our health center's operations and could severely alter our ability to provide access to low-cost services to our underserved community, which is the premise of the FQHC program.

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 9, 2020

By: 

J.R. Richards, MPA
Chief Executive Officer

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.

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 medications.
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.



Lilly USA, LLC

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www.lilly.com

By E-mail (KPedley@hrsa.gov)

August 19, 2020

Rear Admiral Krista M. Pedley
Director, Office of Pharmacy Affairs (OPA)
Health Resources and Services Administration (HRSA)
5600 Fishers Lane
Parklawn Building, Mail Stop 10C-03
Rockville, MD 20857

RE: Availability of 340B-Priced Products to Contract Pharmacies

Dear RADM Pedley:

Eli Lilly and Company (Lilly) is writing to inform the Health Resources and Services Administration (HRSA) that, effective September 1, we have instructed wholesalers to discontinue our practice of voluntarily honoring requests for 340B “contract pharmacies” for orders on all Lilly products except where Lilly has approved an exception that (1) a covered entity does not have an in-house pharmacy and/or (2) for certain insulins, if the 340B discounted price is passed on to the patient. Unless HRSA objects and states that it believes our proposed discontinuation of voluntary contract pharmacy 340B discounts is unlawful by August 31, providing us the reasons for its conclusions, Lilly will no longer honor contract pharmacy-related requests for Lilly products (labeler codes 00002, 00777, and 66173), subject to the exceptions above.

As we explained in our May 18, 2020 letter to you, we believe this action is prudent, reasonable and lawful, particularly in light of the substantial and ongoing expansion of contract pharmacy participation in the 340B program and the now overwhelming evidence demonstrating that contract pharmacy transactions result in 340B duplicate discounts and diversion. Based on these concerns, coupled with the risk that contract pharmacy transactions may be incorrectly considered a basis for Civil Money Penalties or incorrectly subject us to onerous repayment obligations, Lilly feels compelled to take this additional action at this time.

In discussing our plan with respect to the Cialis products, HRSA concluded that its Contract Pharmacy Guidances were non-binding and that our plan did not give rise to any enforceable violation of the 340B statute. Indeed, in our view, contract pharmacy transactions constitute prohibited diversion and lead to duplicate discounts in violation of the statute. We believe that the legal analyses performed previously by HRSA and Lilly apply equally here.

I. The Insulin Exception and Lilly’s Commitment to Transparency with HRSA

On July 24, the President signed Executive Order 13,937, “Access to Affordable Life-saving Medications.” That order instructs the Secretary of Health and Human Services (HHS) to condition federal grant eligibility for federally qualified health centers (FQHCs) on an FQHC’s commitment to pass on the 340B ceiling price to vulnerable patients. Lilly supports this goal. As the Executive Order states, insulin is a critical and lifesaving medication and many insulins “are subject to the

Suppl. App'x 129

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‘penny pricing’ policy when distributed to FQHCs, meaning FQHCs may purchase the drug at a price of one penny per unit of measure. These steep discounts, however, are not always passed through to low-income Americans at the point of sale. Those with low-incomes can be exposed to high insulin and injectable epinephrine prices....”

We applaud the Administration’s concern with how discounts provided by pharmaceutical manufacturers are consumed by intermediaries and are not passed on to patients. And, unlike the Administration, which is legally more constrained than a manufacturer who voluntarily seeks to extend the 340B price through a contract pharmacy, Lilly can apply this HHS policy more broadly.

To that end, and for the reasons set forth below, Lilly will grant an exception to our contract pharmacy limited distribution program for certain Lilly insulin products (NDCs attached) to any 340B contract pharmacy that agrees to the following:

- Any and all 340B eligible patients will be able to acquire their Lilly insulins through the contract pharmacy at the 340B price (typically \$.03 per 3 mL pen or \$.10 per 10 mL vial) at the point-of-sale.
 - Rationale: This is consistent with the approach set forth in the recent Executive Order. We appreciate that most contract pharmacies currently may not identify 340B eligible patients at that point-of-sale, choosing instead to identify these patients retrospectively. However, retroactive determinations are inconsistent with HRSA’s expectations in both 1996 and 2010 Contract Pharmacy Guidance documents. Both of those guidances suggested that the following “contract provisions” be included in the agreements with the contract pharmacy:

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.¹

While we agree these guidances are not legally binding, we assume that HRSA based its position, at least in part, on the fact that identification of 340B patients at the point-of-sale was, and remains, a critical safeguard to prevent duplicate discounts and diversion. It appears that covered entities and contract pharmacies have ignored this expectation from the outset. Given the growth in contract pharmacies and the well-documented non-compliance referenced in our May 18, 2020 letter, we believe that this is a reasonable condition to qualify for the insulin exception.

¹ 61 Fed. Reg. 43553 (Aug. 23, 1996) and 75 Fed. Reg. 10279 (Mar. 5, 2010); as we also noted in our May 18 letter, HRSA has elsewhere advised against covered entities retroactively reclassifying. See HRSA/OPA 340B FAQs, at <https://www.hrsa.gov/opa/faqs/index.html> (last visited August 11, 2020).

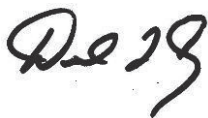
- Neither the covered entity nor the contract pharmacy marks-up or otherwise charges a dispensing or any administration fee for the Lilly insulin.
 - Rationale: Just as Lilly does not seek to recoup the cost to manufacture or distribute penny priced insulins when they are sold to 340B covered entities, covered entities and their contract pharmacies seeking to obtain this exception we would expect covered entities and contract pharmacies to be willing to dispense the product free of charge.
- No insurer or payer is billed for the Lilly insulin dispensed.
 - Rationale: To avoid overcharges by 340B entities to federal or commercial payers, as well as to facilitate the avoidance of duplicative Medicaid rebates claims, Lilly believes that no third party should be billed for insulins dispensed under this exception.
- The covered entity provides claim-level detail (CLD) for their contract pharmacy(s) to Lilly so that we can validate that the foregoing conditions have been satisfied.
 - Rationale: Several other manufacturers have recently started requesting or requiring CLD from covered entities for their contract pharmacies. As these data should be both readily available and sufficient to confirm that the terms of our voluntary exception have been met, Lilly would seek this documentation.

Lilly shares the Administration's goal of ensuring that 340B patients should directly benefit from the significant 340B discounts on Lilly insulins. Lilly will provide quarterly reports (or more frequently, if requested) regarding covered entity use of the two exceptions provided for under our policy.

Attached please find an updated Limited Distribution Notice for posting on the manufacturer notices website on September 1, 2020. Please note that this updated notice is intended to replace the Cialis Limited Distribution Notice which was effective July 1, 2020. If you have questions or comments related to this proposed notice, please do not hesitate to contact me.

Please feel free to contact me at derek.asay@lilly.com directly if you have any questions or need any additional information. Thank you for your attention to this very important matter.

Sincerely,

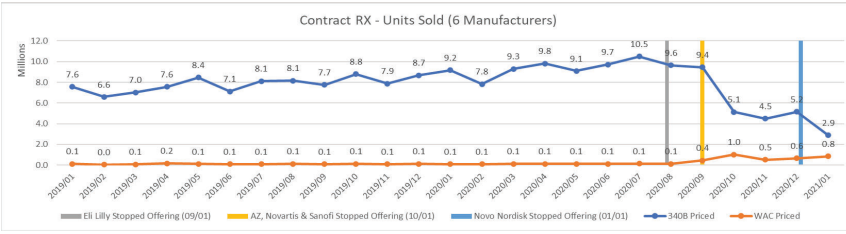


Derek L. Asay
Sr. Director, Government Strategy

Summary and Background

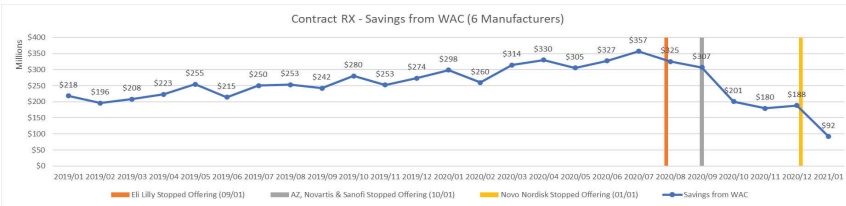
There are 6 manufacturers that have stopped or added limitations to offering 340B price in contract pharmacy arrangements. This analysis attempts to quantify the loss of units sold and savings. There is not a longterm reciprocal increase in the WAC price purchasing when 340B contract pharmacy pricing 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



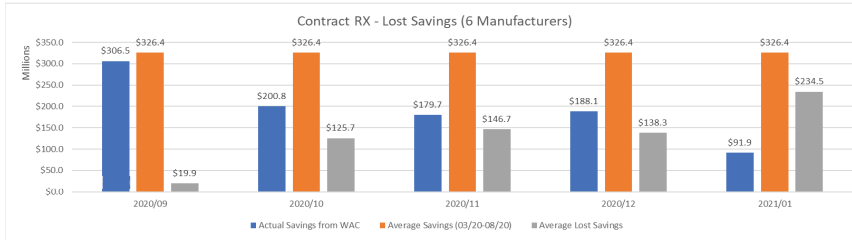
There are two tabs related to savings lost from the manufacturers' actions "Savings from WAC (Contract RX)" and "AverageLostSavings(ContractRX)". The "Savings from WAC (Contract RX)" tab outlines the monthly savings from the 6 manufacturers from January 2019 to January 2021. The highest month of savings 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 manufacturers 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 losses from 9/2020 to 1/2021.

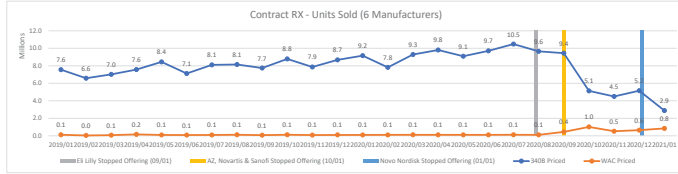
Figure 3 - Lost Savings from 9/2020 to 1/2021



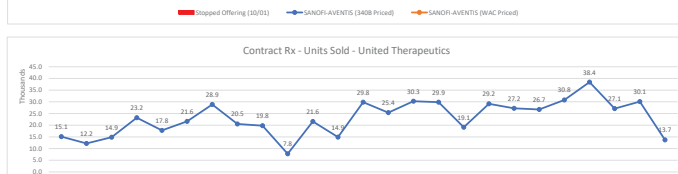
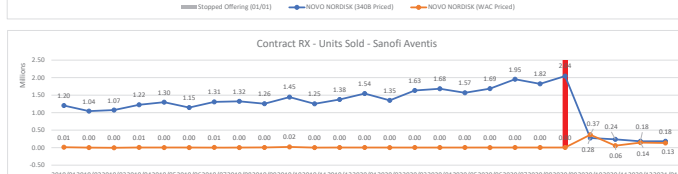
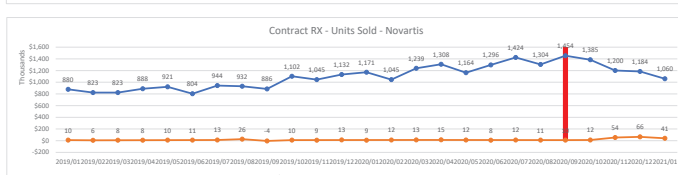
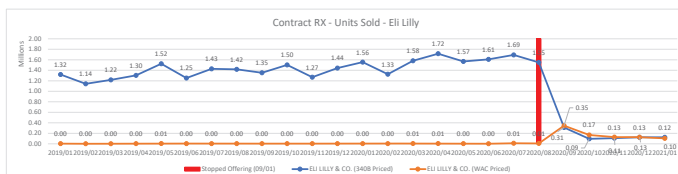
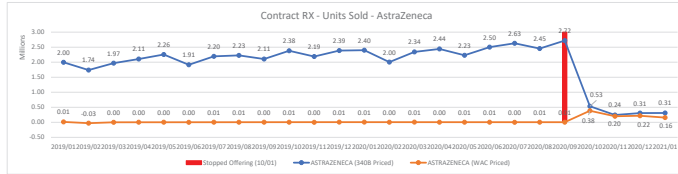
Key to Remaining Tabs

- "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.

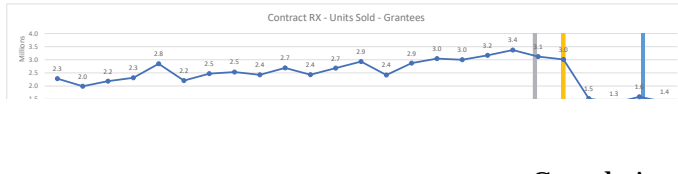
Sale type	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01
340B Price	7,252,965	6,580,202	7,015,318	7,571,563	8,448,783	7,119,865	8,111,379	8,146,720	7,740,482	8,790,498	7,859,882	8,681,258	8,158,240	7,824,473	9,295,598	8,905,474	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	39,122	72,466	164,015	99,981	84,535	94,210	118,000	75,454	119,954	67,441	110,382	96,657	95,354	115,964	106,677	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)																									
AZ, Novartis & Sanofi Stopped Offering (10/01)																									
Novo Nordisk Stopped Offering (01/01)																									

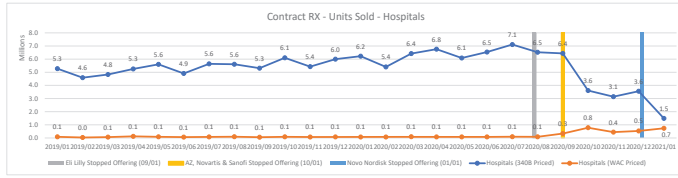
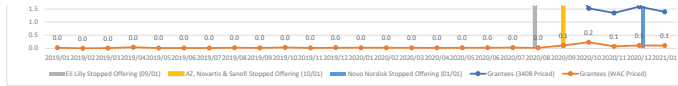


Sale type	Manufacturer	2019/01	2019/02	2019/03	2019/04	2019/05	2019/06	2019/07	2019/08	2019/09	2019/10	2019/11	2019/12	2020/01	2020/02	2020/03	2020/04	2020/05	2020/06	2020/07	2020/08	2020/09	2020/10	2020/11	2020/12	2021/01	
340B	ASTRAZENECA (ASTRAZENECA)	1,998,712	1,739,242	1,968,534	2,107,359	2,257,358	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	ASTRAZENECA (ASTRAZENECA)	14,144	28,444	403	4,553	4,822	2,290	5,273	5,922	3,154	5,241	2,340	6,235	6,195	4,926	8,128	4,028	5,020	5,999	2,401	5,199	5,102	384,787	201,627	217,649	156,204	
340B	Stopped Offering (10/01)																										
WAC	Stopped Offering (10/01)																										
340B	Eli Lilly & C (Eli Lilly & C)	1,142,145	1,217,714	1,303,748	1,524,679	1,252,729	1,427,013	1,419,235	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	1,608,000	1,550,370	3,000,000	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	
340B	Stopped Offering (09/01)																										
WAC	Stopped Offering (09/01)																										
340B	NOVARTIS (NOVARTIS)	823,276	823,823	888,055	921,209	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	1,423,680	1,304,216	1,295,602	2,000,000	1,454,065	1,305,358	1,200,306	#####	#####
WAC	NOVARTIS (NOVARTIS)	9,518	6,428	7,785	7,884	9,119	10,791	12,547	25,875	8,058	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	
340B	NOVO NORDISK (NOVO NORDISK)	2,136,916	1,820,302	1,918,451	2,025,451	2,428,105	1,982,299	2,007,817	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 NORDISK (NOVO NORDISK)	76,755	59,568	65,385	136,512	79,573	67,276	65,784	80,760	68,585	80,252	70,283	84,551	73,697	71,098	84,026	79,259	89,590	92,902	82,928	80,070	81,983	83,027	92,791	411,585		
340B	Stopped Offering (01/01)																										
WAC	Stopped Offering (01/01)																										
340B	SANOFI-AVE (SANOFI-AVE)	1,202,433	1,223,742	1,223,742	1,223,742	1,223,742	1,223,742	1,223,742	1,223,742	1,223,742	1,223,742	1,223,742	1,223,742	1,223,742	1,223,742	1,223,742	1,223,742	1,223,742	1,223,742	1,223,742	1,223,742	1,223,742	1,223,742	1,223,742	1,223,742	1,223,742	1,223,742
WAC	SANOFI-AVE (SANOFI-AVE)	11,328	652	-1,169	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	3,949	3,949	3,949	3,949	
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 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
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	1,849,553	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	20,386	111,574	235,643	77,892	114,771	105,630	
Eli Lilly Stopped Offering (09/01)																									
AZ, Novartis & Sanofi Stopped Offering (10/01)																									
Novo Nordisk Stopped Offering (01/01)																									
Hospitals	5,272,545	4,587,691	4,827,932	5,256,405	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	3,560,894	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	75,834	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)																									
AZ, Novartis & Sanofi Stopped Offering (10/01)																									
Novo Nordisk Stopped Offering (01/01)																									





CERTIFICATE OF SERVICE

I certify that on June 24, 2022, I filed a copy of this supplemental appendix with the Clerk of Court for the Seventh Circuit Court of Appeals through the Court's CM/ECF system, which will serve counsel for all parties.

/s/ Daniel Aguilar

Daniel Aguilar