No. 25-2237

United States Court of Appeals
for the First Circuit

AMERICAN HOSPITAL ASSOCIATION; ST. MARY'S REGIONAL MEDICAL CENTER; MAINE HOSPITAL ASSOCIATION; NATHAN LITTAUER HOSPITAL AND NURSING HOME; UNITY MEDICAL CENTER; DALLAS COUNTY MEDICAL CENTER,

Plaintiffs-Appellees,

v.

ROBERT F. KENNEDY, JR., Secretary of the US Department of Health and Human Services; THOMAS J. ENGELS, Administrator Health Resources and Services Administration; HEALTH RESOURCES & SERVICES ADMINISTRATION; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES,

Defendants,

ABBVIE INC.; ASTRAZENECA PHARMACEUTICALS LP; PHARMACYCLICS LLC; BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; NOVO NORDISK INC.; PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Interested Parties-Appellants.

On Appeal from the United States District Court for the District of Maine, No. 2:25-cv-00600-LEW, Judge Lance E. Walker

JOINT APPENDIX

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Certificate of Service

APPEAL,CLOSED,SECURED BOND,STANDARD

U.S. District Court
District of Maine (Portland)
CIVIL DOCKET FOR CASE #: 2:25-cv-00600-LEW

AMERICAN HOSPITAL ASSOCIATION et al v. KENNEDY et al
Assigned to: JUDGE LANCE E. WALKER
Referred to: MAGISTRATE JUDGE KAREN FRINK WOLF
Case in other court: First Circuit Court of Appeals, 25-02236
First Circuit Court of Appeals, 25-02237
Cause: 05:702 Administrative Procedure Act

Date Filed: 12/01/2025
Date Terminated: 02/10/2026
Jury Demand: None
Nature of Suit: 899 Other Statutes: Administrative Procedures Act/Review or Appeal of Agency Decision
Jurisdiction: U.S. Government Defendant

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Date Filed	#	Docket Text
12/01/2025	1	COMPLAINT against All Defendants **PAYMENT OF FILING FEE DUE WITHIN 48 HOURS. IF FILING FEE IS BEING PAID WITH A CREDIT CARD COUNSEL ARE INSTRUCTED TO LOGIN TO CMECF AND DOCKET *Case Opening Filing Fee Paid* FOUND IN THE *Complaints and Other Initiating Documents* CATEGORY. CHECK PAYMENTS DUE WITHIN 48 HOURS.**, filed by DALLAS COUNTY MEDICAL CENTER, MAINE HOSPITAL ASSOCIATION, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, AMERICAN HOSPITAL ASSOCIATION, ST MARY'S REGIONAL MEDICAL CENTER. (Service of Process Deadline 3/2/2026) Fee due by 12/3/2025.(mtm) (Entered: 12/01/2025)
12/01/2025	2	CIVIL COVER SHEET. (mtm) (Entered: 12/01/2025)
12/01/2025	3	MOTION for Temporary Restraining Order by AMERICAN HOSPITAL ASSOCIATION, DALLAS COUNTY MEDICAL CENTER, MAINE HOSPITAL ASSOCIATION, NATHAN LITTAUER HOSPITAL & NURSING HOME, ST MARY'S REGIONAL MEDICAL CENTER, UNITY MEDICAL CENTER (mtm) (Entered: 12/01/2025)
12/01/2025	4	DECLARATION of Jeffrey Austin re 3 MOTION for Temporary Restraining Order filed by AMERICAN HOSPITAL ASSOCIATION, DALLAS COUNTY MEDICAL CENTER, MAINE HOSPITAL ASSOCIATION, NATHAN LITTAUER HOSPITAL &

		NURSING HOME, ST MARY'S REGIONAL MEDICAL CENTER, UNITY MEDICAL CENTER. (mtm) (Entered: 12/01/2025)
12/01/2025	5	DECLARATION of Winfield S. Brown re 3 MOTION for Temporary Restraining Order filed by AMERICAN HOSPITAL ASSOCIATION, DALLAS COUNTY MEDICAL CENTER, MAINE HOSPITAL ASSOCIATION, NATHAN LITTAUER HOSPITAL & NURSING HOME, ST MARY'S REGIONAL MEDICAL CENTER, UNITY MEDICAL CENTER. (mtm) (Entered: 12/01/2025)
12/01/2025	6	DECLARATION of Sean M. Fadale re 3 MOTION for Temporary Restraining Order filed by AMERICAN HOSPITAL ASSOCIATION, DALLAS COUNTY MEDICAL CENTER, MAINE HOSPITAL ASSOCIATION, NATHAN LITTAUER HOSPITAL & NURSING HOME, ST MARY'S REGIONAL MEDICAL CENTER, UNITY MEDICAL CENTER. (mtm) (Entered: 12/01/2025)
12/01/2025	7	DECLARATION of Chad Golder re 3 MOTION for Temporary Restraining Order filed by AMERICAN HOSPITAL ASSOCIATION, DALLAS COUNTY MEDICAL CENTER, MAINE HOSPITAL ASSOCIATION, NATHAN LITTAUER HOSPITAL & NURSING HOME, ST MARY'S REGIONAL MEDICAL CENTER, UNITY MEDICAL CENTER. (mtm) (Entered: 12/01/2025)
12/01/2025	8	DECLARATION of H. David Mantz re 3 MOTION for Temporary Restraining Order filed by AMERICAN HOSPITAL ASSOCIATION, DALLAS COUNTY MEDICAL CENTER, MAINE HOSPITAL ASSOCIATION, NATHAN LITTAUER HOSPITAL & NURSING HOME, ST MARY'S REGIONAL MEDICAL CENTER, UNITY MEDICAL CENTER. (mtm) (Entered: 12/01/2025)
12/01/2025	9	DECLARATION of Alan W. O'Neil re 3 MOTION for Temporary Restraining Order filed by AMERICAN HOSPITAL ASSOCIATION, DALLAS COUNTY MEDICAL CENTER, MAINE HOSPITAL ASSOCIATION, NATHAN LITTAUER HOSPITAL & NURSING HOME, ST MARY'S REGIONAL MEDICAL CENTER, UNITY MEDICAL CENTER. (mtm) (Entered: 12/01/2025)
12/01/2025	10	DECLARATION of L. Rush Atkinson re 3 MOTION for Temporary Restraining Order filed by AMERICAN HOSPITAL ASSOCIATION, DALLAS COUNTY MEDICAL CENTER, MAINE HOSPITAL ASSOCIATION, NATHAN LITTAUER HOSPITAL & NURSING HOME, ST MARY'S REGIONAL MEDICAL CENTER, UNITY MEDICAL CENTER. (Attachments: # 1 Ex. 01 - Letter from Chantelle Britton Director OPA HRSA to JJ (Aug. 14 2024), # 2 Ex. 02 - Letter from Carole Johnson Administrator HRSA to JJ (Sept. 17 2024), # 3 Ex. 03 - Letter from Carole Johnson Administrator HRSA to JJ (Sept. 27 2024), # 4 Ex. 04 - Letter from Chantelle Britton Director OPA HRSA to Lilly (Sept. 18 2024), # 5 Ex. 05 - Letter from Chantelle Britton Director OPA HRSA to BMS (Nov. 4 2024), # 6 Ex. 06 - Letter from Chantelle Britton Director OPA HRSA to Sanofi (Nov. 12 2024), # 7 Ex. 07 - Letter from Chantelle Britton Director OPA HRSA to Novartis (Jan. 14 2025), # 8 Ex. 08 - HRSA-2025-0001-0052, # 9 Ex. 09 - HRSA-2025-0001-0076, # 10 Ex. 10 - HRSA-2025-0001-0110, # 11 Ex. 11 - HRSA-2025-0001-0378, # 12 Ex. 12 - HRSA-2025-0001-0401, # 13 Ex. 13 - HRSA-2025-0001-0621, # 14 Ex. 14 - HRSA-2025-0001-0802, # 15 Ex. 15 - HRSA-2025-0001-0870, # 16 Ex. 16 - HRSA-2025-0001-0974, # 17 Ex. 17 - HRSA-2025-0001-1074, # 18 Ex. 18 - HRSA-2025-0001-1111, # 19 Ex. 19 - HRSA-2025-0001-0106, # 20 Ex. 20 - HRSA-2025-0001-0495, # 21 Ex. 21 - HRSA-2025-0001-0099, # 22 Ex. 22 - HRSA-2025-0001-0005, # 23 Ex. 23 - HRSA-2025-0001-0215, # 24 Ex. 24 - HRSA-2025-0001-0842, # 25 Ex. 25 - HRSA-2025-0001-0549, # 26 Ex. 26 - HRSA-2025-0001-0465, # 27 Ex. 27 - HRSA-2025-0001-0748, # 28 Ex. 28 - HRSA-2025-0001-0951, # 29 Ex. 29 - Engels Ltr to OIR, # 30 Ex. 30 - Supporting Statement to OMB)(mtm) (Entered: 12/01/2025)

12/01/2025	11	Summons Issued as to THOMAS J ENGELS, HEALTH RESOURCES AND SERVICES ADMINISTRATION, ROBERT F KENNEDY, JR, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES OF AMERICA. **Counsel shall print the embossed summons and effect service in the manner in accordance with Fed.R.Civ.P.4.** **Note-If you are using Version 6 of Adobe Acrobat, be sure the PRINT WHAT field is set to DOCUMENTS AND COMMENTS (Click File, then Print to check this setting).** (Attachments: # 1 Summons as to The United States c/o Pamela Bondi, US Attorney General, # 2 Summons as to United States Department of Health and Human Services, # 3 Summons as to Robert F. Kennedy Jr., # 4 Summons as to Thomas J. Engels, # 5 Summons as to Health Resources and Services Administration)(mtm) (Entered: 12/01/2025)
12/01/2025		Set Deadlines : Per Civil Rule 7.1 as Amended December 1, 2022 Disclosure Statement due by 12/8/2025 as to all Plaintiffs. (mtm) (Entered: 12/01/2025)
12/02/2025		Filing Fee Paid via Credit Card (Filing fee $ 405 receipt number AMEDC-3212877.), filed by DALLAS COUNTY MEDICAL CENTER, MAINE HOSPITAL ASSOCIATION, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, AMERICAN HOSPITAL ASSOCIATION, ST MARY'S REGIONAL MEDICAL CENTER.(HEWEY, MELISSA) (Entered: 12/02/2025)
12/02/2025	12	RULE 7.1 DISCLOSURE STATEMENT by AMERICAN HOSPITAL ASSOCIATION. (HEWEY, MELISSA) (Entered: 12/02/2025)
12/02/2025	13	RULE 7.1 DISCLOSURE STATEMENT by DALLAS COUNTY MEDICAL CENTER. (HEWEY, MELISSA) (Entered: 12/02/2025)
12/02/2025	14	RULE 7.1 DISCLOSURE STATEMENT by MAINE HOSPITAL ASSOCIATION. (HEWEY, MELISSA) (Entered: 12/02/2025)
12/02/2025	15	RULE 7.1 DISCLOSURE STATEMENT by NATHAN LITTAUER HOSPITAL & NURSING HOME. (HEWEY, MELISSA) (Entered: 12/02/2025)
12/02/2025	16	RULE 7.1 DISCLOSURE STATEMENT by ST MARY'S REGIONAL MEDICAL CENTER. (HEWEY, MELISSA) (Entered: 12/02/2025)
12/02/2025	17	RULE 7.1 DISCLOSURE STATEMENT by UNITY MEDICAL CENTER. (HEWEY, MELISSA) (Entered: 12/02/2025)
12/02/2025	18	CERTIFICATION for Admission Pro Hac Vice of Karen L. Dunn, Rush Atkinson, Lyle Gruby filed by MELISSA A. HEWEY on behalf of All Plaintiffs (Total admission fee $ 600 receipt number AMEDC-3213290.) The District of Maine is a CM/ECF NextGen Court. If PHV counsel has not previously been granted electronic filing rights with the District of Maine, PHV counsel will now need to submit a PRO HAC VICE request in this District via PACER at www.pacer.uscourts.gov (Attachments: # 1 Rush Atkinson, # 2 Lyle Gruby)(HEWEY, MELISSA) (Entered: 12/02/2025)
12/02/2025	19	CERTIFICATION for Admission Pro Hac Vice of Jenifer Hartley, Tyler Thomas Mikulis filed by MELISSA A. HEWEY on behalf of All Plaintiffs (Total admission fee $ 400 receipt number AMEDC-3213318.) The District of Maine is a CM/ECF NextGen Court. If PHV counsel has not previously been granted electronic filing rights with the District of Maine, PHV counsel will now need to submit a PRO HAC VICE request in this

		District via PACER at www.pacer.uscourts.gov (Attachments: # 1 Tyler Thomas Mikulis) (HEWEY, MELISSA) (Entered: 12/02/2025)
12/02/2025	20	NOTICE of APPROVAL by Clerk's Office re 18 Certification for Admission Pro Hac Vice and 19 Certification for Admission Pro Hac Vice. Attorneys KAREN L. DUNN, RUSH ATKINSON, LYLE GRUBY, JENIFER HARTLEY, and TYLER THOMAS MIKULIS for AMERICAN HOSPITAL ASSOCIATION, DALLAS COUNTY MEDICAL CENTER, MAINE HOSPITAL ASSOCIATION, NATHAN LITTAUER HOSPITAL & NURSING HOME, ST MARY'S REGIONAL MEDICAL CENTER and UNITY MEDICAL CENTER added to this specific case only. Maine has transitioned to the NextGen ECF filing system; therefore, to complete the admissions process, Attorneys Karen L. Dunn, Rush Atkinson, Lyle Gruby, Jenifer Hartley, and Tyler Thomas Mikulis must register for a PACER account and/or request the appropriate e-filing rights in the District of Maine via PACER at www.pacer.uscourts.gov by 12/9/2025. NOTE: Counsel appearing Pro Hac Vice MUST click on the PRO HAC VICE link when requesting e-filing rights via PACER. For more details on NextGen/PACER go to our website at www.med.uscourts.gov. (jgd) (Entered: 12/02/2025)
12/04/2025	21	NOTICE of Appearance by ELISABETH NEYLAN on behalf of All Defendants (NEYLAN, ELISABETH) (Entered: 12/04/2025)
12/05/2025	22	NOTICE of Hearing: Telephone Conference set for 12/8/2025 11:00 AM before JUDGE JOHN A. WOODCOCK JR. The parties have been provided the Court's call-in information. (jam) (Entered: 12/05/2025)
12/05/2025	23	NOTICE of Appearance by JENNIFER RIGGLE on behalf of AMERICAN HOSPITAL ASSOCIATION, DALLAS COUNTY MEDICAL CENTER, MAINE HOSPITAL ASSOCIATION, NATHAN LITTAUER HOSPITAL & NURSING HOME, ST MARY'S REGIONAL MEDICAL CENTER, UNITY MEDICAL CENTER (RIGGLE, JENNIFER) (Entered: 12/05/2025)
12/05/2025	24	NOTICE of Appearance by JAY S. GELLER on behalf of AbbVie Inc., PHARMACYCLICS LLC (GELLER, JAY) (Entered: 12/05/2025)
12/05/2025	25	NOTICE/CORRESPONDENCE Re: Intent To Intervene by AbbVie Inc., PHARMACYCLICS LLC (GELLER, JAY) (Entered: 12/05/2025)
12/05/2025	26	RULE 7.1 DISCLOSURE STATEMENT by AbbVie Inc., PHARMACYCLICS LLC. (GELLER, JAY) (Entered: 12/05/2025)
12/05/2025	27	CERTIFICATION for Admission Pro Hac Vice of Matthew S. Owen filed by MATTHEW SCOTT OWEN on behalf of AbbVie Inc., PHARMACYCLICS LLC (Total admission fee $ 200 receipt number AMEDC-3215533.) The District of Maine is a CM/ECF NextGen Court. If PHV counsel has not previously been granted electronic filing rights with the District of Maine, PHV counsel will now need to submit a PRO HAC VICE request in this District via PACER at www.pacer.uscourts.gov (OWEN, MATTHEW) (Entered: 12/05/2025)
12/05/2025	28	CERTIFICATION for Admission Pro Hac Vice of Meredith Pohl filed by MEREDITH M. POHL on behalf of AbbVie Inc., PHARMACYCLICS LLC (Total admission fee $ 200 receipt number AMEDC-3215546.) The District of Maine is a CM/ECF NextGen Court. If PHV counsel has not previously been granted electronic filing rights with the District of Maine, PHV counsel will now need to submit a PRO HAC VICE request in this District via PACER at www.pacer.uscourts.gov (POHL, MEREDITH) (Entered: 12/05/2025)

12/07/2025	29	NOTICE/CORRESPONDENCE Re: AbbVie Notice (Dkt. No. 25) by AMERICAN HOSPITAL ASSOCIATION, DALLAS COUNTY MEDICAL CENTER, MAINE HOSPITAL ASSOCIATION, NATHAN LITTAUER HOSPITAL & NURSING HOME, ST MARY'S REGIONAL MEDICAL CENTER, UNITY MEDICAL CENTER (ATKINSON, LAWRENCE) (Entered: 12/07/2025)
12/08/2025	30	NOTICE of APPROVAL by Clerk's Office re 27 Certification for Admission Pro Hac Vice and 28 Certification for Admission Pro Hac Vice. Attorneys MEREDITH M. POHL and MATTHEW SCOTT OWEN for ABBVIE INC and PHARMACYCLICS LLC added to this specific case only. (jgd) (Entered: 12/08/2025)
12/08/2025	31	Minute Entry for proceedings held before JUDGE JOHN A. WOODCOCK, JR: Telephone Conference held, Set Deadlines as to Motion for TRO (Responses due by 12/15/2025, Reply due by 12/18/2025.). (Court Reporter: Michelle Feliccitti) (jam) (Entered: 12/08/2025)
12/08/2025		Set Deadlines per directive of U.S. District Judge John A. Woodcock, Jr.: Motion to Intervene due by 12/10/2025, Responses due 12/15/2025. (jam) (Entered: 12/08/2025)
12/08/2025	32	NOTICE of Hearing on Motion 3 MOTION for Temporary Restraining Order : Oral Argument set for 12/19/2025 11:00 AM in Portland Courtroom 2 before JUDGE JOHN A. WOODCOCK JR. (jam) (Entered: 12/08/2025)
12/10/2025	33	CERTIFICATION for Admission Pro Hac Vice of Alyssa Howard filed by EDWARD S. MACCOLL on behalf of 340B HEALTH, America's Essential Hospitals (Total admission fee $ 200 receipt number AMEDC-3217208.) The District of Maine is a CM/ECF NextGen Court. If PHV counsel has not previously been granted electronic filing rights with the District of Maine, PHV counsel will now need to submit a PRO HAC VICE request in this District via PACER at www.pacer.uscourts.gov (MACCOLL, EDWARD) (Entered: 12/10/2025)
12/10/2025	34	***FILED IN ERROR***CERTIFICATION for Admission Pro Hac Vice of William B. Schultz filed by EDWARD S. MACCOLL on behalf of 340B HEALTH, America's Essential Hospitals (Total admission fee $ 200 receipt number AMEDC-3217219.) The District of Maine is a CM/ECF NextGen Court. If PHV counsel has not previously been granted electronic filing rights with the District of Maine, PHV counsel will now need to submit a PRO HAC VICE request in this District via PACER at www.pacer.uscourts.gov (Attachments: # 1 Attachment)(MACCOLL, EDWARD) Modified on 12/10/2025 to mark as filed in error. Counsel to re-file (slg). (Entered: 12/10/2025)
12/10/2025	35	NOTICE of Appearance by JEFFREY D. TALBERT on behalf of ASTRAZENECA PHARMACEUTICALS LP (TALBERT, JEFFREY) (Entered: 12/10/2025)
12/10/2025	36	MOTION to Intervene by ABBVIE INC, PHARMACYCLICS LLC Responses due by 12/31/2025. (Attachments: # 1 Exhibit Ex. 1 - 2025.12.10 Pilot Program Aynilian Decl, # 2 Exhibit Ex. 2 - 2025.12.10 Pilot Progr. Scheidler Decl.)(OWEN, MATTHEW) (Entered: 12/10/2025)
12/10/2025	37	NOTICE of Docket Entry Modification regarding 34 Certification for Admission Pro Hac Vice. Marked as filed in error by the Clerk's Office. Counsel to re-file. (slg) (Entered: 12/10/2025)
12/10/2025	38	NOTICE of APPROVAL by Clerk's Office re 33 Certification for Admission Pro Hac Vice. Attorney ALYSSA HOWARD for 340B HEALTH and AMERICA'S ESSENTIAL HOSPITALS added to this specific case only. (slg) (Entered: 12/10/2025)
12/10/2025	39	MOTION to Intervene by ASTRAZENECA PHARMACEUTICALS LP Responses due by 12/31/2025. (Attachments: # 1 Exhibit 1 - Declaration In Support of Motion to

		Intervene)(TALBERT, JEFFREY) (Entered: 12/10/2025)
12/10/2025	40	RULE 7.1 DISCLOSURE STATEMENT by ASTRAZENECA PHARMACEUTICALS LP. (TALBERT, JEFFREY) (Entered: 12/10/2025)
12/10/2025		Reset Deadlines as to 36 MOTION to Intervene , 39 MOTION to Intervene per directive of U.S. District Judge John A. Woodcock, Jr. on December 8, 2025: Responses due by 12/15/2025. (jam) (Entered: 12/10/2025)
12/10/2025	41	CERTIFICATION for Admission Pro Hac Vice of Allon Kedem, Jeffrey L. Handwerker filed by JEFFREY D. TALBERT on behalf of ASTRAZENECA PHARMACEUTICALS LP (Total admission fee $ 400 receipt number AMEDC-3217340.) The District of Maine is a CM/ECF NextGen Court. If PHV counsel has not previously been granted electronic filing rights with the District of Maine, PHV counsel will now need to submit a PRO HAC VICE request in this District via PACER at www.pacer.uscourts.gov (Attachments: # 1 Supplement Certification for Admission PHV Jeffrey L. Handwerker)(TALBERT, JEFFREY) (Entered: 12/10/2025)
12/10/2025	42	NOTICE of APPROVAL by Clerk's Office re 41 Certification for Admission Pro Hac Vice. Attorney ALLON KEDEM for ASTRAZENECA PHARMACEUTICALS LP added to this specific case only. (slg) (Entered: 12/10/2025)
12/10/2025	43	NOTICE of APPROVAL by Clerk's Office re 41 Certification for Admission Pro Hac Vice. Attorney JEFFREY L. HANDWERKER for ASTRAZENECA PHARMACEUTICALS LP added to this specific case only. (slg) (Entered: 12/10/2025)
12/10/2025	44	NOTICE of Appearance by CORIN R. SWIFT on behalf of PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (SWIFT, CORIN) (Entered: 12/10/2025)
12/10/2025	45	MOTION to Intervene by PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA Responses due by 12/31/2025. (Attachments: # 1 Exhibit 1 Declaration of James C. Stansel, # 2 Exhibit 2 Declaration of Lauren Paluzzi) (SWIFT, CORIN) (Entered: 12/10/2025)
12/10/2025	46	RULE 7.1 DISCLOSURE STATEMENT by PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA. (SWIFT, CORIN) (Entered: 12/10/2025)
12/10/2025	47	CERTIFICATION for Admission Pro Hac Vice of Kwaku A. Akowuah filed by CORIN R. SWIFT on behalf of PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (Total admission fee $ 200 receipt number AMEDC-3217699.) The District of Maine is a CM/ECF NextGen Court. If PHV counsel has not previously been granted electronic filing rights with the District of Maine, PHV counsel will now need to submit a PRO HAC VICE request in this District via PACER at www.pacer.uscourts.gov (SWIFT, CORIN) (Entered: 12/10/2025)
12/10/2025	48	CERTIFICATION for Admission Pro Hac Vice of Madeleine Joseph filed by CORIN R. SWIFT on behalf of PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (Total admission fee $ 200 receipt number AMEDC-3217700.) The District of Maine is a CM/ECF NextGen Court. If PHV counsel has not previously been granted electronic filing rights with the District of Maine, PHV counsel will now need to submit a PRO HAC VICE request in this District via PACER at www.pacer.uscourts.gov (SWIFT, CORIN) (Entered: 12/10/2025)
12/10/2025	49	CERTIFICATION for Admission Pro Hac Vice of Meenakshi Datta filed by CORIN R. SWIFT on behalf of PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (Total admission fee $ 200 receipt number AMEDC-3217701.) The District of Maine is a CM/ECF NextGen Court. If PHV counsel has not previously been granted

		electronic filing rights with the District of Maine, PHV counsel will now need to submit a PRO HAC VICE request in this District via PACER at www.pacer.uscourts.gov (SWIFT, CORIN) (Entered: 12/10/2025)
12/10/2025	50	MOTION to Intervene by Boehringer Ingelheim Pharmaceuticals, Inc., Novo Nordisk Inc. Responses due by 12/31/2025. (Attachments: # 1 Decl. of Alfred C. Frawley, # 2 Exhibit A to Frawley Decl., # 3 Exhibit B to Frawley Decl., # 4 C. Marsh Decl., # 5 F. Jafery Decl.)(FRAWLEY, ALFRED) (Entered: 12/10/2025)
12/10/2025	51	RULE 7.1 DISCLOSURE STATEMENT by Boehringer Ingelheim Pharmaceuticals, Inc.. (FRAWLEY, ALFRED) (Entered: 12/10/2025)
12/10/2025	52	RULE 7.1 DISCLOSURE STATEMENT by Novo Nordisk Inc.. (FRAWLEY, ALFRED) (Entered: 12/10/2025)
12/10/2025	53	CERTIFICATION for Admission Pro Hac Vice of Thomas R. Brugato filed by ALFRED CECIL FRAWLEY, IV on behalf of Boehringer Ingelheim Pharmaceuticals, Inc., Novo Nordisk Inc. (Total admission fee $ 200 receipt number AMEDC-3217711.) The District of Maine is a CM/ECF NextGen Court. If PHV counsel has not previously been granted electronic filing rights with the District of Maine, PHV counsel will now need to submit a PRO HAC VICE request in this District via PACER at www.pacer.uscourts.gov (FRAWLEY, ALFRED) (Entered: 12/10/2025)
12/10/2025	54	CERTIFICATION for Admission Pro Hac Vice of Kevin King filed by ALFRED CECIL FRAWLEY, IV on behalf of Boehringer Ingelheim Pharmaceuticals, Inc., Novo Nordisk Inc. (Total admission fee $ 200 receipt number AMEDC-3217713.) The District of Maine is a CM/ECF NextGen Court. If PHV counsel has not previously been granted electronic filing rights with the District of Maine, PHV counsel will now need to submit a PRO HAC VICE request in this District via PACER at www.pacer.uscourts.gov (FRAWLEY, ALFRED) (Entered: 12/10/2025)
12/10/2025	55	CERTIFICATION for Admission Pro Hac Vice of Daniel G. Randolph filed by ALFRED CECIL FRAWLEY, IV on behalf of Boehringer Ingelheim Pharmaceuticals, Inc., Novo Nordisk Inc. (Total admission fee $ 200 receipt number AMEDC-3217715.) The District of Maine is a CM/ECF NextGen Court. If PHV counsel has not previously been granted electronic filing rights with the District of Maine, PHV counsel will now need to submit a PRO HAC VICE request in this District via PACER at www.pacer.uscourts.gov (FRAWLEY, ALFRED) (Entered: 12/10/2025)
12/11/2025		Reset Deadlines as to 45 MOTION to Intervene , 50 MOTION to Intervene per directive of U.S. District Judge John A. Woodcock, Jr. on December 8, 2025: Responses due by 12/15/2025. (jam) (Entered: 12/11/2025)
12/11/2025	56	NOTICE of APPROVAL by Clerk's Office re 48 Certification for Admission Pro Hac Vice 53 Certification for Admission Pro Hac Vice 49 Certification for Admission Pro Hac Vice 55 Certification for Admission Pro Hac Vice 54 Certification for Admission Pro Hac Vice 47 Certification for Admission Pro Hac Vice. Attorney KEVIN F KING, DANIEL G RANDOLPH for BOEHRINGER INGELHEIM PHARMACEUTICALS INC and NOVO NORDISK INC. KWAKU A AKOWUAH, MADELEINE A JOSEPH, MEENAKSHI A DATTA, THOMAS R BRUGATO for PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA added to this specific case only. Maine has transitioned to the NextGen ECF filing system; therefore, to complete the admissions process, Attorney Kwaku A. Akowuah, Madeleine Joseph, Meenakshi Datta, Thomas R. Brugato, Kevin F. King, Daniel G. Randolph must register for a PACER account and/or request the appropriate e-filing rights in the District of Maine via PACER at www.pacer.uscourts.gov by 12/17/2025. NOTE: Counsel appearing Pro Hac Vice

		MUST click on the PRO HAC VICE link when requesting e-filing rights via PACER. For more details on NextGen/PACER go to our website at www.med.uscourts.gov. (slg) (Entered: 12/11/2025)
12/11/2025	57	CERTIFICATION for Admission Pro Hac Vice of William B. Schultz filed by EDWARD S. MACCOLL on behalf of 340B HEALTH, AMERICA'S ESSENTIAL HOSPITALS The District of Maine is a CM/ECF NextGen Court. If PHV counsel has not previously been granted electronic filing rights with the District of Maine, PHV counsel will now need to submit a PRO HAC VICE request in this District via PACER at www.pacer.uscourts.gov (Attachments: # 1 Exhibit A - List of Atty Schultz Admissions) (MACCOLL, EDWARD) (Entered: 12/11/2025)
12/11/2025	58	NOTICE of APPROVAL by Clerk's Office re 57 Certification for Admission Pro Hac Vice. Attorney WILLIAM B. SCHULTZ for 340B HEALTH,WILLIAM B. SCHULTZ for AMERICA'S ESSENTIAL HOSPITALS added to this specific case only. (slg) (Entered: 12/11/2025)
12/11/2025	59	*FILED IN ERROR* Consent MOTION for Leave to File *Brief of Amici Curiae* by 340B HEALTH, AMERICA'S ESSENTIAL HOSPITALS Responses due by 1/2/2026. (MACCOLL, EDWARD) Modified on 12/12/2025 Counsel re-filed at ECF 60 (jam). (Entered: 12/11/2025)
12/11/2025	60	Consent MOTION for Leave to File *Brief of Amici Curiae* by 340B HEALTH, AMERICA'S ESSENTIAL HOSPITALS Responses due by 1/2/2026. (Attachments: # 1 Exhibit A - Brief of Amici)(MACCOLL, EDWARD) (Entered: 12/11/2025)
12/12/2025	61	ORDER granting 60 Motion for Leave to File Brief of Amici Curiae By JUDGE JOHN A. WOODCOCK, JR. (jam) (Entered: 12/12/2025)
12/12/2025	62	BRIEF re 3 MOTION for Temporary Restraining Order *submitted in support of plaintiff's motion by amici curiae* by 340B HEALTH, AMERICA'S ESSENTIAL HOSPITALS. (MACCOLL, EDWARD) (Entered: 12/12/2025)
12/12/2025	63	*FILED IN ERROR* SERVICE Returned EXECUTED filed by DALLAS COUNTY MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, AMERICAN HOSPITAL ASSOCIATION, MAINE HOSPITAL ASSOCIATION, UNITY MEDICAL CENTER, ST MARY'S REGIONAL MEDICAL CENTER as to ROBERT F KENNEDY, JR. (HEWEY, MELISSA) Modified on 12/15/2025 to mark as filed in error, counsel to refile (jam). (Entered: 12/12/2025)
12/12/2025	64	*FILED IN ERROR* SERVICE Returned EXECUTED filed by DALLAS COUNTY MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, AMERICAN HOSPITAL ASSOCIATION, MAINE HOSPITAL ASSOCIATION, UNITY MEDICAL CENTER, ST MARY'S REGIONAL MEDICAL CENTER as to THOMAS J ENGELS. (HEWEY, MELISSA) Modified on 12/15/2025 to mark as filed in error, counsel to refile (jam). (Entered: 12/12/2025)
12/12/2025	65	*FILED IN ERROR* SERVICE Returned EXECUTED filed by DALLAS COUNTY MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, AMERICAN HOSPITAL ASSOCIATION, MAINE HOSPITAL ASSOCIATION, UNITY MEDICAL CENTER, ST MARY'S REGIONAL MEDICAL CENTER as to HEALTH RESOURCES AND SERVICES ADMINISTRATION. (HEWEY, MELISSA) Modified on 12/15/2025 to mark as filed in error, counsel to refile (jam). (Entered: 12/12/2025)
12/12/2025	66	*FILED IN ERROR* SERVICE Returned EXECUTED filed by DALLAS COUNTY MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, AMERICAN HOSPITAL ASSOCIATION, MAINE HOSPITAL ASSOCIATION,

		UNITY MEDICAL CENTER, ST MARY'S REGIONAL MEDICAL CENTER as to UNITED STATES OF AMERICA. (HEWEY, MELISSA) Modified on 12/15/2025 to mark as filed in error, counsel to refile (jam). (Entered: 12/12/2025)
12/15/2025	67	NOTICE of Appearance by DANIEL L. ROSENTHAL on behalf of PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (ROSENTHAL, DANIEL) (Entered: 12/15/2025)
12/15/2025	68	SERVICE Returned EXECUTED filed by DALLAS COUNTY MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, AMERICAN HOSPITAL ASSOCIATION, MAINE HOSPITAL ASSOCIATION, UNITY MEDICAL CENTER, ST MARY'S REGIONAL MEDICAL CENTER as to HEALTH RESOURCES AND SERVICES ADMINISTRATION. (HEWEY, MELISSA) (Entered: 12/15/2025)
12/15/2025	69	SERVICE Returned EXECUTED filed by DALLAS COUNTY MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, AMERICAN HOSPITAL ASSOCIATION, MAINE HOSPITAL ASSOCIATION, UNITY MEDICAL CENTER, ST MARY'S REGIONAL MEDICAL CENTER as to THOMAS J ENGELS. (HEWEY, MELISSA) (Entered: 12/15/2025)
12/15/2025	70	SERVICE Returned EXECUTED filed by DALLAS COUNTY MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, AMERICAN HOSPITAL ASSOCIATION, MAINE HOSPITAL ASSOCIATION, UNITY MEDICAL CENTER, ST MARY'S REGIONAL MEDICAL CENTER as to ROBERT F KENNEDY, JR. (HEWEY, MELISSA) (Entered: 12/15/2025)
12/15/2025	71	SERVICE Returned EXECUTED filed by DALLAS COUNTY MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, AMERICAN HOSPITAL ASSOCIATION, MAINE HOSPITAL ASSOCIATION, UNITY MEDICAL CENTER, ST MARY'S REGIONAL MEDICAL CENTER as to UNITED STATES OF AMERICA. (HEWEY, MELISSA) (Entered: 12/15/2025)
12/15/2025	72	RESPONSE in Opposition re 3 MOTION for Temporary Restraining Order filed by ABBVIE INC. Reply due by 12/29/2025. (Attachments: # 1 Exhibit 1 - Vandervelde Declaration, # 2 Exhibit 2 - Banks Declaration)(OWEN, MATTHEW) (Entered: 12/15/2025)
12/15/2025	73	RESPONSE in Opposition re 3 MOTION for Temporary Restraining Order filed by PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA. Reply due by 12/29/2025. (Attachments: # 1 Exhibit 1, # 2 Exhibit 2, # 3 Exhibit 3) (ROSENTHAL, DANIEL) (Entered: 12/15/2025)
12/15/2025	74	RESPONSE to Motion re 39 MOTION to Intervene , 50 MOTION to Intervene , 45 MOTION to Intervene , 36 MOTION to Intervene filed by THOMAS J ENGELS, HEALTH RESOURCES AND SERVICES ADMINISTRATION, ROBERT F KENNEDY, JR, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES OF AMERICA. Reply due by 12/29/2025. (NEYLAN, ELISABETH) (Entered: 12/15/2025)
12/15/2025	75	RESPONSE in Opposition re 3 MOTION for Temporary Restraining Order filed by THOMAS J ENGELS, HEALTH RESOURCES AND SERVICES ADMINISTRATION, ROBERT F KENNEDY, JR, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES OF AMERICA. Reply due by 12/29/2025. (Attachments: # 1 Declaration of Chantelle Britton)(NEYLAN, ELISABETH) (Entered: 12/15/2025)
12/15/2025	76	RESPONSE in Opposition re 39 MOTION to Intervene , 50 MOTION to Intervene , 45 MOTION to Intervene , 36 MOTION to Intervene filed by AMERICAN HOSPITAL

		ASSOCIATION, DALLAS COUNTY MEDICAL CENTER, MAINE HOSPITAL ASSOCIATION, NATHAN LITTAUER HOSPITAL & NURSING HOME, ST MARY'S REGIONAL MEDICAL CENTER, UNITY MEDICAL CENTER. Reply due by 12/29/2025. (ATKINSON, LAWRENCE) (Entered: 12/15/2025)
12/16/2025		Set Answer Deadline for HEALTH RESOURCES AND SERVICES ADMINISTRATION, THOMAS J ENGELS, ROBERT F KENNEDY, JR, UNITED STATES OF AMERICA per executed summons No. 68, 69, 70, 71: Answer due by 12/26/2025. (jam) (Entered: 12/16/2025)
12/16/2025		Set Deadlines as to 3 MOTION for Temporary Restraining Order per directive of U.S. District Judge John A. Woodcock, Jr. at the telephone conference on December 8, 2025: Reply due by 12/18/2025. (jam) (Entered: 12/16/2025)
12/16/2025	77	CERTIFICATION for Admission Pro Hac Vice of Nick Bell filed by NICK BELL on behalf of ABBVIE INC, PHARMACYCLICS LLC (Total admission fee $ 200 receipt number AMEDC-3220887.) The District of Maine is a CM/ECF NextGen Court. If PHV counsel has not previously been granted electronic filing rights with the District of Maine, PHV counsel will now need to submit a PRO HAC VICE request in this District via PACER at www.pacer.uscourts.gov (BELL, NICK) (Entered: 12/16/2025)
12/17/2025	78	NOTICE of APPROVAL by Clerk's Office re 77 Certification for Admission Pro Hac Vice. Attorney NICK BELL for ABBVIE INC and PHARMACYCLICS LLC added to this specific case only. (jgd) (Entered: 12/17/2025)
12/17/2025	79	ORDER OF RECUSAL. I hereby recuse myself from presiding over this case. Although it is typical for a judge to recuse without explanation, given the circumstances, the parties and counsel are informed that I have concluded that my recusal is mandatory pursuant to 28 U.S.C. § 455(b)(4). SO ORDERED. JUDGE JOHN A. WOODCOCK, JR recused. Case reassigned to JUDGE STACEY D. NEUMANN for all further proceedings By JUDGE JOHN A. WOODCOCK, JR. (jam) (Entered: 12/17/2025)
12/17/2025		Case Reassigned to JUDGE LANCE E. WALKER. JUDGE STACEY D. NEUMANN no longer assigned to the case. (jam) (Entered: 12/17/2025)
12/17/2025	80	REPLY to Response to Motion re 39 MOTION to Intervene , 50 MOTION to Intervene , 45 MOTION to Intervene , 36 MOTION to Intervene filed by ABBVIE INC, PHARMACYCLICS LLC. (OWEN, MATTHEW) (Entered: 12/17/2025)
12/18/2025	81	NOTICE of UPDATED Hearing on Motion (JUDGE AND LOCATION CHANGE ONLY) re: 3 MOTION for Temporary Restraining Order. Oral Argument set for 12/19/2025 11:00 AM Portland Courtroom 1 before JUDGE LANCE E. WALKER. (slg) (Entered: 12/18/2025)
12/18/2025	82	REPLY to Response to Motion re 3 MOTION for Temporary Restraining Order filed by AMERICAN HOSPITAL ASSOCIATION. (Attachments: # 1 Declaration of Chad Golder in Further Support of Plaintiffs' Motion for a Temporary Restraining Order) (DUNN, KAREN) (Entered: 12/18/2025)
12/18/2025	83	ORDER on Motions to Intervene denying 36 Motion to Intervene; denying 39 Motion to Intervene; denying 45 Motion to Intervene; denying 50 Motion to Intervene. By JUDGE LANCE E. WALKER. (slg) (Entered: 12/18/2025)
12/19/2025	84	Minute Entry for proceedings held before JUDGE LANCE E. WALKER: Oral Argument held re 3 MOTION for Temporary Restraining Order filed by NATHAN LITTAUER HOSPITAL & NURSING HOME, AMERICAN HOSPITAL ASSOCIATION, ST MARY'S REGIONAL MEDICAL CENTER, DALLAS COUNTY MEDICAL CENTER,

		UNITY MEDICAL CENTER, MAINE HOSPITAL ASSOCIATION. Motion taken under advisement. (Court Reporter: Tammy Martell) (slg) (Entered: 12/19/2025)
12/22/2025		Reset Answer Deadline for UNITED STATES OF AMERICA as Court closed on 12/26/2025: Answer due by 12/29/2025. (slg) Modified on 12/22/2025 to reflect deadline was set for USA only (slg). (Entered: 12/22/2025)
12/22/2025		Reset Answer Deadline for HEALTH RESOURCES AND SERVICES ADMINISTRATION, THOMAS J ENGELS, ROBERT F KENNEDY, JR Court closed on 12/26/2025: Answer due by 12/29/2025. (slg) (Entered: 12/22/2025)
12/22/2025		Reset Deadlines: Maine has transitioned to the NextGen ECF filing system; therefore, to complete the admissions process, **Attorney Meenakshi Datta** must register for a PACER account and/or request the appropriate e-filing rights in the District of Maine via PACER at www.pacer.uscourts.gov by 12/29/2025. NOTE: Counsel appearing Pro Hac Vice MUST click on the PRO HAC VICE link when requesting e-filing rights via PACER. For more details on NextGen/PACER go to our website at www.med.uscourts.gov. (slg) (Entered: 12/22/2025)
12/22/2025		Reset Deadlines: Maine has transitioned to the NextGen ECF filing system; therefore, to complete the admissions process, Attorney **LYLE GRUBY** must register for a PACER account and/or request the appropriate e-filing rights in the District of Maine via PACER at www.pacer.uscourts.gov by 12/29/2025. NOTE: Counsel appearing Pro Hac Vice MUST click on the PRO HAC VICE link when requesting e-filing rights via PACER. For more details on NextGen/PACER go to our website at www.med.uscourts.gov. (slg) (Entered: 12/22/2025)
12/22/2025	85	NOTICE/CORRESPONDENCE Re: Portions of the Administrative Record by All Defendants (Attachments: # 1 Declaration of Chantelle Britton, # 2 Exhibit 1 - Documents Related to HRSA's Approval of Abbvie's Plan, # 3 Exhibit 2 - Documents Related to HRSA's Approval of J&J's Plan)(NEYLAN, ELISABETH) (Entered: 12/22/2025)
12/22/2025	86	NOTICE OF FILING OF OFFICIAL TRANSCRIPT of Proceedings Oral Argument held on December 19, 2025 before Judge Lance E. Walker. Court Reporter/Transcriber: Tammy Martell, Telephone Number: 207.272.5566. **NOTICE RE REDACTION OF TRANSCRIPTS: The parties have seven (7) calendar days to file with the Court a Notice of Intent to Request Redaction of this transcript. If no such Notice is filed, the transcript will be made remotely electronically available to the public without redaction after 90 calendar days. The policy is located on our website at www.med.uscourts.gov.** Transcript may be viewed at the court public terminal or purchased through the Court Reporter/Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER. Release of Transcript Restriction set for 3/23/2026. (MARTELL, TAMMY) (Entered: 12/22/2025)
12/22/2025	87	NOTICE/CORRESPONDENCE Re: Defendants' Notice (ECF Doc. 85) by AMERICAN HOSPITAL ASSOCIATION, DALLAS COUNTY MEDICAL CENTER, MAINE HOSPITAL ASSOCIATION, NATHAN LITTAUER HOSPITAL & NURSING HOME, ST MARY'S REGIONAL MEDICAL CENTER, UNITY MEDICAL CENTER (ATKINSON, LAWRENCE) (Entered: 12/22/2025)
12/23/2025	88	NOTICE/CORRESPONDENCE Re: Supplemental Filing of Records Reflecting Agency Approval of Pilot Program Proposal by ASTRAZENECA PHARMACEUTICALS LP (Attachments: # 1 Supplement Declaration of Sky Adams with Exhibits)(TALBERT, JEFFREY) (Entered: 12/23/2025)
12/23/2025	89	NOTICE/CORRESPONDENCE Re: AstraZeneca's Supplemental Filing (ECF Doc. 88) by AMERICAN HOSPITAL ASSOCIATION, DALLAS COUNTY MEDICAL

		CENTER, MAINE HOSPITAL ASSOCIATION, NATHAN LITTAUER HOSPITAL & NURSING HOME, ST MARY'S REGIONAL MEDICAL CENTER, UNITY MEDICAL CENTER (ATKINSON, LAWRENCE) (Entered: 12/23/2025)
12/29/2025	90	ORDER on Motion for Preliminary Injunction granting 3 Motion for TRO. By JUDGE LANCE E. WALKER. (slg) (Entered: 12/29/2025)
12/29/2025		Set Deadlines: Per Order #90 security in the amount of $1,000 due by 1/5/2026. (slg) (Entered: 12/29/2025)
12/29/2025	91	NOTICE OF APPEAL as to 90 Order on Motion for TRO by THOMAS J ENGELS, HEALTH RESOURCES AND SERVICES ADMINISTRATION, ROBERT F KENNEDY, JR, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES OF AMERICA . **NOTICE TO FILER:** A transcript Report/Order form MUST be completed and submitted to the First Circuit Court of Appeals. The form can be found under the Forms & Fees section on their website at https://www.ca1.uscourts.gov. **NOTICE TO COUNSEL:** Counsel should register for a First Circuit CM/ECF Appellate Filer Account at https://pacer.psc.uscourts.gov. Counsel should also review the First Circuit requirements for electronic filing by visiting the CM/ECF Information section at https://www.ca1.uscourts.gov/cmecf (NEYLAN, ELISABETH) (Entered: 12/29/2025)
12/29/2025	92	MOTION to Stay *Preliminary Injunction Pending Appeal, or in the Alternative, for an Administrative Stay* by THOMAS J ENGELS, HEALTH RESOURCES AND SERVICES ADMINISTRATION, ROBERT F KENNEDY, JR, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES OF AMERICA Responses due by 1/20/2026. (Attachments: # 1 Memorandum of Law in Support of Motion) (NEYLAN, ELISABETH) (Entered: 12/29/2025)
12/30/2025	93	APPEAL COVER SHEET Re: 91 Notice of Appeal (slg) (Entered: 12/30/2025)
12/30/2025	94	CLERK'S CERTIFICATE Re: 91 Notice of Appeal. Documents sent to the U.S. Court of Appeals. (slg) (Entered: 12/30/2025)
12/30/2025		Abbreviated Appeal Record Transmitted Electronically to U.S. Court of Appeals re 91 Notice of Appeal (slg) (Entered: 12/30/2025)
12/30/2025	95	USCA Case Number 25-2236 for 91 Notice of Appeal filed by UNITED STATES OF AMERICA, ROBERT F KENNEDY, JR, THOMAS J ENGELS, HEALTH RESOURCES AND SERVICES ADMINISTRATION, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES. (slg) (Entered: 12/30/2025)
12/30/2025	96	ORDER on Motion for Stay Pending Appeal denying 92 Motion to Stay. By JUDGE LANCE E. WALKER. (slg) (Entered: 12/30/2025)
12/30/2025	97	Joint NOTICE OF APPEAL as to 83 Order on Motion to Intervene,,, by ABBVIE INC, ASTRAZENECA PHARMACEUTICALS LP, BOEHRINGER INGELHEIM PHARMACEUTICALS INC, NOVO NORDISK INC, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, PHARMACYCLICS LLC . (Filing fee $ 605 receipt number AMEDC-3225786.) **NOTICE TO FILER:** A transcript Report/Order form MUST be completed and submitted to the First Circuit Court of Appeals. The form can be found under the Forms & Fees section on their website at https://www.ca1.uscourts.gov.

		NOTICE TO COUNSEL: Counsel should register for a First Circuit CM/ECF Appellate Filer Account at https://pacer.psc.uscourts.gov. Counsel should also review the First Circuit requirements for electronic filing by visiting the CM/ECF Information section at https://www.ca1.uscourts.gov/cmecf (AKOWUAH, KWAKU) (Entered: 12/30/2025)
12/30/2025	98	CLERK'S FIRST SUPPLEMENTAL CERTIFICATE Re: 91 Notice of Appeal. Documents Sent to U.S. Court of Appeals (slg) (Entered: 12/30/2025)
12/30/2025	99	***FILED IN ERROR***CLERK'S FIRST SUPPLEMENTAL CERTIFICATE Re: 91 Notice of Appeal. Documents Sent to U.S. Court of Appeals (slg) Modified on 12/30/2025 to mark as filed in error by the Clerk's Office (slg). (Entered: 12/30/2025)
12/30/2025		Supplemental Record on Appeal transmitted to US Court of Appeals re 91 Notice of Appeal (slg) (Entered: 12/30/2025)
12/30/2025	100	APPEAL COVER SHEET Re: 97 Notice of Appeal (slg) (Entered: 12/30/2025)
12/30/2025	101	CLERK'S CERTIFICATE Re: 97 Notice of Appeal. Documents sent to the U.S. Court of Appeals. (slg) (Entered: 12/30/2025)
12/30/2025		Abbreviated Appeal Record Transmitted Electronically to U.S. Court of Appeals re 97 Notice of Appeal (slg) (Entered: 12/30/2025)
12/30/2025	102	USCA Case Number 25-2237 for 97 Notice of Appeal filed by NOVO NORDISK INC, BOEHRINGER INGELHEIM PHARMACEUTICALS INC, ABBVIE INC, PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, PHARMACYCLICS LLC, ASTRAZENECA PHARMACEUTICALS LP. (slg) (Entered: 12/30/2025)
12/30/2025		Reset Answer Deadline for UNITED STATES OF AMERICA, THOMAS J ENGELS, HEALTH RESOURCES AND SERVICES ADMINISTRATION, ROBERT F KENNEDY, JR, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES as previous deadline set in error: Answer due by 2/3/2026. (slg) (Entered: 12/30/2025)
01/05/2026	103	Secured BOND in the amount of $ 1,000.00 posted by MAINE HOSPITAL ASSOCIATION (slg) (Entered: 01/05/2026)
01/06/2026	104	SERVICE Returned EXECUTED filed by DALLAS COUNTY MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, AMERICAN HOSPITAL ASSOCIATION, MAINE HOSPITAL ASSOCIATION, UNITY MEDICAL CENTER, ST MARY'S REGIONAL MEDICAL CENTER as to UNITED STATES OF AMERICA. (HEWEY, MELISSA) (Entered: 01/06/2026)
01/15/2026	105	MOTION by Attorney Jay S. Geller to Withdraw as Attorney by ABBVIE INC, PHARMACYCLICS LLC Responses due by 2/5/2026. (GELLER, JAY) (Entered: 01/15/2026)
01/15/2026	106	NOTICE of Appearance by PAUL MCDONALD on behalf of ABBVIE INC, PHARMACYCLICS LLC (MCDONALD, PAUL) (Entered: 01/15/2026)
01/15/2026	107	NOTICE of Appearance by LUCAS LEVITE FORTIER on behalf of ABBVIE INC, PHARMACYCLICS LLC (FORTIER, LUCAS) (Entered: 01/15/2026)
01/16/2026	108	ORDER granting 105 Motion of Attorney Geller to Withdraw as Counsel. By MAGISTRATE JUDGE KAREN FRINK WOLF. (WOLF, KAREN) (Entered: 01/16/2026)
01/20/2026	109	JUDGMENT of USCA re 91 Notice of Appeal (mjlt) (Entered: 01/21/2026)

01/20/2026	110	MANDATE of USCA as to 91 Notice of Appeal,,, filed by UNITED STATES OF AMERICA, ROBERT F KENNEDY, JR, THOMAS J ENGELS, HEALTH RESOURCES AND SERVICES ADMINISTRATION, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES (mjlt) (Entered: 01/21/2026)
01/30/2026	111	NOTICE of Appearance by JASON ALTABET on behalf of All Defendants (ALTABET, JASON) (Entered: 01/30/2026)
01/30/2026	112	Unopposed MOTION to Extend Time to File Answer re 1 Complaint,, Set/Reset Answer Deadline, by THOMAS J ENGELS, HEALTH RESOURCES AND SERVICES ADMINISTRATION, ROBERT F KENNEDY, JR, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES OF AMERICA Responses due by 2/20/2026. (ALTABET, JASON) (Entered: 01/30/2026)
02/02/2026	113	ORDER granting 112 Motion for Extension of Time. Defendants' answer or other response to Complaint due by March 5, 2026. By MAGISTRATE JUDGE KAREN FRINK WOLF. (WOLF, KAREN) (Entered: 02/02/2026)
02/03/2026		Reset Answer Deadline for UNITED STATES OF AMERICA, THOMAS J ENGELS, HEALTH RESOURCES AND SERVICES ADMINISTRATION, ROBERT F KENNEDY, JR, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES: Answer due by 3/5/2026. (slg) (Entered: 02/03/2026)
02/05/2026	114	Joint MOTION to Vacate , Joint MOTION to Remand to Health Resources and Services Administration (Responses due by 2/26/2026.) by THOMAS J ENGELS, HEALTH RESOURCES AND SERVICES ADMINISTRATION, ROBERT F KENNEDY, JR, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, UNITED STATES OF AMERICA (ALTABET, JASON) (Entered: 02/05/2026)
02/10/2026	115	ORDER granting 114 Joint Motion to Vacate, Joint Motion to Remand to Health Resources and Services Administration. By JUDGE LANCE E. WALKER. (slg) (Entered: 02/10/2026)

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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER, Plaintiffs, v. ROBERT F. KENNEDY, JR. Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA, Defendants.	Case No. **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF** **REQUEST FOR IMMEDIATE RELIEF**

Introduction

1. More than thirty years ago, Congress created a drug pricing program that is essential to safety-net healthcare providers. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967–71 (1992), codified at § 340B, Public Health Service Act, 42 U.S.C. § 256b (1992). Now commonly known as the "340B Program," this law allows these healthcare providers to purchase certain outpatient medications at reduced cost and use the savings to expand access to care, improve patient services, and reach America's most vulnerable populations. *See* H.R. Rep. No. 102–384, pt. 2, at 12 (1992). As a unanimous Supreme Court explained a few years ago: "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 738 (2022).

2. Since the inception of the 340B Program, the Health Resources and Services Administration ("HRSA")—the agency of the U.S. Department of Health and Human Services ("HHS") tasked with administering the 340B Program—has required drug manufacturers to offer discounted medications at the time of the sale rather than as a delayed rebate. This is known as an "upfront discount." Many covered entities that participate in the 340B Program operate on razor-thin (or negative) margins and cannot afford the costs of paying market prices for drugs (which are multiples of the 340B price) without sacrificing the care they provide to patients. Implementing the 340B Program via "upfront discounts" honors the purpose of the statute by enabling healthcare providers to stretch scarce federal resources as far as possible to provide greater access to care for the patients and communities they serve.

3. For years, drug companies have sought to move from an "upfront discount" model to what they call a "rebate" model. Under this approach, safety-net providers would be forced to

initially pay drug companies full market price and then seek reimbursement for the discounted difference after administering the drugs to patients and providing detailed claims data to drug companies. Such a change would inflict hundreds of millions of dollars' worth of annual costs on hospitals and other covered entities. *First*, a rebate system would impose vast administrative costs to submit, track, recover, and potentially dispute the rebates. *Second*, it would drain 340B hospitals of huge sums of money through payments to drug companies that the hospitals then must wait to have refunded by those drug companies. *Third*, a rebate system would invite mischief from drug companies that have every incentive to slow and stymie the issuance of rebates, figuring that some number of rebates can be withheld from safety-net hospitals by throwing the proverbial "sand in the gears."

4. For these reasons, the 340B Program has operated under the "upfront discount" model for more than 30 years. They are why HRSA has refused drug companies' repeated efforts to switch to a "rebate" program. They are why HRSA has, for decades, pointed to the benefits of the "upfront discount" model and the shortcomings of a "rebate" program. And they are why HRSA reiterated those very costs and benefits in repeated federal court filings *this year*.

5. But, without any warning to 340B hospitals or other covered entities, HRSA has suddenly reversed course. This summer, the agency announced that it was commencing a "340B Rebate Model Pilot Program" (hereinafter "Rebate Program") that would institute a rebate model for a swath of popular drugs. HRSA acknowledged that "rebate models could fundamentally shift how the 340B Program has operated for over 30 years[.]" 90 Fed. Reg. 36163, 36164. Yet it proceeded to ignore the reasons behind its historic skepticism of the rebate model; it failed to explain its change in position or clarify its rationale for the new program; and it failed to account for thirty-plus years of reliance interests on the part of covered entities.

6. HRSA announced this mandatory Rebate Program with manifest disregard for the tremendous costs it will impose upon the most vulnerable covered entities—costs that HRSA recognizes in internal government documents will total hundreds of millions of dollars per year. Astonishingly, when explaining its new Rebate Program, HRSA has not even acknowledged its own longstanding concerns about the massive costs of forcing a rebate model on safety-net providers. Its public discussion, including a notice published in the Federal Register and details posted to a government website, are entirely silent on the subject of costs. HRSA has given no public explanation of what it believes the costs are, what the benefits of the Rebate Program are, or why it is necessary to place those costs on the intended beneficiaries of the 340B Program—safety net healthcare providers that serve America's most vulnerable patients.

7. The newly announced Rebate Program is a "pilot" in name only. Rather than starting in a more circumscribed fashion, as is customary for any true pilot program, it applies to *every* 340B hospital and covered entity in America—approximately 14,600 entities by HRSA's own estimate. Participation is *compulsory* for those covered entities; they are *required* to participate or lose their statutorily-owed discounts. By contrast, drug companies have the *option* of applying to participate. Likewise, the drugs covered by HRSA's new Rebate Program are among the most commonly prescribed in the country, meaning that the costs of including these drugs in the Rebate Program will be especially high.

8. HRSA's surprise announcement garnered more than 1,100 comments from stakeholders raising concerns about the Rebate Program. Commenters identified a slew of important issues, including: (a) the costs that HRSA failed to address or balance against any purported benefits of the program; (b) less burdensome alternatives that would achieve HRSA's stated goals; (c) serious concerns about HRSA's chosen software platform, "Beacon," that have

since proven to be prescient; (d) problems with an underdeveloped mechanism for resolving disputes between drug companies and covered entities; and (e) the difficulties that struggling safety-net hospitals will face in standing up this program by the January 1, 2026 effective date.

9. HRSA ignored those comments. It did not, as the law requires, address "important problem[s] the public could and did raise during the comment period." *Ohio v. EPA*, 603 U.S. 279, 298 (2024). And having offered no response at all, HRSA necessarily did not, as the law requires, offer a "*reasoned* response." *Id.* at 293 (emphasis added).

10. Instead, on October 15, 2025, HRSA confirmed that the new program would commence on January 1, 2026—giving hospitals only two months to comply or risk losing millions of dollars in discounts they are entitled to under the 340B statute. Since then, HRSA has been largely absent as covered entities await further guidance on how the program will work in practice. Indeed, on information and belief, HRSA has not even bothered to test the software platform on which this program is supposed to run—just one more example of the lack of careful consideration that has gone into this transformative decision.

11. HRSA's "340B Rebate Model Pilot Program" is a textbook disregard of administrative law. HRSA has failed to grapple with the key problems of a rebate model that the *agency itself* flagged for years—again, as recently as this year. HRSA has ignored the thousand-plus comments from 340B hospitals and other stakeholders, including comments that identified "important aspect[s] of the problem" like the massive costs of standing up and administering the rebate model. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.,* 463 U.S. 29, 43, 52 (1983). HRSA has never balanced those costs against the limited benefits of its Rebate Program "pilot." HRSA has never addressed 340B providers' strong reliance interests, including that they have built entire internal operations around the upfront discount model and rely on the

benefits of that model to provide more comprehensive care to patients. HRSA has not explained why a nationwide mandate on all covered entities is necessary for its so-called "pilot" program, rather than narrower and less costly alternatives. And HRSA ignored comments explaining that a delayed effective date would allow covered entities to better prepare for what HRSA itself recognized is a "fundamental[] shift" in how the 340B Program will operate.

12. Thousands of 340B hospitals and other 340B providers will face crushing costs and consequences should the Rebate Program go into effect as intended on January 1, 2026. That, in turn, will jeopardize their ability to provide care to their communities. Many of these safety-net hospitals provide the only healthcare services in their areas. For covered entities to continue providing their current levels of healthcare to their patients, this Court must quickly enjoin this unlawful, unnecessary, unexplained, and substantively unreasonable program that jeopardizes one of the key pillars of U.S. healthcare—the 340B Program.

Parties

13. Plaintiff American Hospital Association ("AHA") is a nonprofit trade association representing hospitals, healthcare systems, networks, and other providers of care. Its principal place of business is in Chicago, Illinois. AHA represents its members, including St. Mary's Regional Medical Center, Nathan Littauer Hospital & Nursing Home, Unity Medical Center, and Dallas County Medical Center, in this action. More than 2,000 of the AHA's member-hospitals participate in the 340B Program. Those members will have no choice but to participate in the Rebate Program and are therefore aggrieved by Defendants' decision to implement that Program, including the decision to implement it by the January 1, 2026 effective date. Protecting those members' interests is germane to AHA's organizational purpose of advancing the health of all

individuals and communities, and the individual members' participation is not required to adjudicate the claims for relief.

14. Plaintiff Maine Hospital Association (MHA) is a nonprofit association that represents 32 community-governed hospitals in Maine. Its principal place of business is Augusta, Maine. MHA represents its members, including St. Mary's Health System, in this action. Twenty-six of MHA's 32 member-hospitals participate in the 340B Program. Those members will have no choice but to participate in the Rebate Program and are therefore aggrieved by Defendants' decision to implement that program, including the decision to implement it by the January 1, 2026 effective date. Protecting those members' interests is germane to MHA's organizational purpose of supporting its members in improving the health of their patients and the communities they serve, and the individual members' participation is not required to adjudicate the claims for relief.

15. Plaintiff St. Mary's Regional Medical Center is a 501(c)(3) nonprofit health system comprised of an acute care community hospital, a professional provider network of specialists and primary care providers, urgent care, an emergency department, and a broad spectrum of behavioral health services. It strives to provide patients with convenient access to high quality, compassionate care throughout Androscoggin County, Maine. St. Mary's principal place of business is in Lewiston, Maine. St. Mary's participates in the 340B Program, prescribes one or more drugs included in the Rebate Program, and therefore will be required to participate in the Rebate Program.

16. Plaintiff Nathan Littauer Hospital & Nursing Home is a nonprofit health system, whose mission is to provide excellent medical care in the communities it serves. It is a New York nonprofit corporation with its principal place of business in Gloversville, New York. Nathan

Littauer participates in the 340B Program, prescribes one or more drugs included in the Rebate Program, and therefore will be required to participate in the Rebate Program.

17. Plaintiff Unity Medical Center is a nonprofit health system, whose mission is to provide excellent medical care in the communities it serves. It is a North Dakota nonprofit corporation with its principal place of business in Grafton, North Dakota. Unity Medical Center participates in the 340B Program, prescribes one or more drugs included in the Rebate Program, and therefore will be required to participate in that Rebate Program.

18. Plaintiff Dallas County Medical Center is a nonprofit health system, whose mission is to provide excellent medical care in the communities it serves. It is an Arkansas county-owned entity with its principal place of business in Fordyce, Arkansas. Dallas County Medical Center participates in the 340B Program, prescribes one or more drugs included in the Rebate Program, and therefore will be required to participate in that Rebate Program.

Defendants

19. Defendant Robert F. Kennedy, Jr. is the Secretary of the U.S. Department of Health and Human Services ("HHS"). He is sued in his official capacity.

20. Defendant Thomas J. Engels is the Administrator, Health Resources and Services Administration ("HRSA"), an office within HHS. He is sued in his official capacity.

21. Defendant HHS is a department of the United States government.

22. Defendant HRSA is an HHS agency that administers the 340B Program.

23. The United States of America is named in accordance with 5 U.S.C. § 702. This is an action in a court of the United States seeking relief other than money damages and stating a claim that an agency or an officer thereof acted or failed to act in an official capacity.

Jurisdiction and Venue

24. This action arises under, and asserts violations of, the Administrative Procedure Act ("APA"), 5 U.S.C. § 551, *et seq*., and Section 340B of the Public Health Service Act, 42 U.S.C. § 256b. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1346. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief, injunctive relief, and other appropriate relief pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, and the APA, 5 U.S.C. §§ 705–706.

25. Venue lies in this District pursuant to 28 U.S.C. § 1391(e)(1) because Plaintiffs MHA and St. Mary's reside in the District, Plaintiffs seek relief against federal agencies and federal officials acting in their official capacities, and no real property is involved.

26. This Court may grant relief pursuant to 5 U.S.C. §§ 701–706.

27. Plaintiffs challenge a "final agency action" within the meaning of 5 U.S.C. § 704. To constitute final agency action, a decision "must [1] mark the 'consummation' of the agency's decision-making process—it must not be of a merely tentative or interlocutory nature" and "[2] be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (internal citations omitted).

28. The Rebate Program reflects the consummation of the agency's decision-making process. HRSA has approved drug company rebate plans for a total of ten drugs, all but one of which will take effect on January 1, 2026. That creates real-world consequences for Plaintiffs, their members, and other covered entities. They must either proceed to expend immense amounts of capital to comply with the Rebate Program or forgo their ability to purchase certain drugs through the 340B Program and thereby reduce access to care for their patients and communities.

29. HRSA's establishment and implementation of the 340B Rebate Model Pilot Program, as well as its approval of drug company applications, are final agency actions that are subject to judicial review under the APA. *See* 5 U.S.C. §§ 704, 706.

The 340B Program

30. Congress created the 340B Drug Pricing Program in 1992 to give safety-net healthcare providers a financial lifeline by allowing them to purchase drugs at discounted prices. When it was enacted, Congress stated that the program's purpose was to "enable these entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12 (1992); *e.g., Am. Hosp. Ass'n v. Hargan*, 289 F.Supp.3d 45, 47 (D.D.C. 2017); *see also Novartis Pharms. Corp. v. Frey*, 1:25-cv-00407, 2025 WL 2813787, at *9 (D. Me. Sep. 23, 2025) ("The program is designed to use two other large federal spending programs to incentivize manufacturers to provide a subsidy to healthcare entities caring for underserved patients."). Examples of qualifying covered entities include federally qualified health centers, family planning clinics, entities providing outpatient early intervention services for HIV, state-operated AIDS drug assistance programs, black lung clinics, hemophilia diagnostic treatment centers, Native Hawaiian health centers, and disproportionate share hospitals, *i.e.*, hospitals that serve a disproportionate share of Medicare, Medicaid, and other low income and uninsured patients. 42 U.S.C. § 256b(a)(4).

31. Congress incentivized drug manufacturers to participate in the 340B Program by conditioning federal health-insurance coverage of their products on those manufacturers' participation. 42 U.S.C. §§ 1396r-8(a)(1), 256b(a). Specifically, if drug companies decline to provide discounted drugs to safety-net providers through the 340B Program, Medicaid and Medicare Part B will not cover the companies' drugs. *Id.* § 1396r-8(a)(1).

32. The 340B Program plays a critical role in the continued viability of safety-net hospitals and other covered entities. Covered entities generally pay only a fraction of the retail costs of drugs and use those savings to fund their broader caregiving operations. As of 2023, more than 2,600 hospitals participated in the 340B Program.

33. For Plaintiffs like St. Mary's, Nathan Littauer Hospital, Unity Medical Center, and Dallas County Medical Center, the 340B Program is necessary to their mission and survival. For example, in 2025, the 340B Program will provide approximately $3.3 million in savings to St. Mary's, which has not had a positive operating margin since before the COVID-19 pandemic and is projecting a substantial operating loss this year. The 340B Program provides approximately $1.1 million to Dallas County Medical Center each year. Without that money, Dallas County Medical Center could not maintain its hospital, equipment, and staffing levels, leaving the approximately 3,400 residents of Fordyce, Arkansas, and the surrounding area, without access to critical services. Plaintiffs are not outliers; the savings provided by the 340B Program are critical to the operations of safety net hospitals across the country. Hospitals and healthcare providers like these Plaintiffs are the intended beneficiaries of the 340B Program, and Plaintiffs' experiences are perfect examples of the program functioning precisely the way Congress intended.

HRSA and the Upfront Discount Model

34. HRSA is responsible for administering the 340B Program. HRSA's Administrator is charged with numerous responsibilities under the statute, including the certification of specific categories of covered entities and auditing functions to ensure covered entities have not received duplicate discounts or diverted prescriptions to non-340B patients. 42 U.S.C. § 256b(a)(4)(J)–(K), (a)(5), (7), (9).

35. To effectuate the 340B Program, HRSA's Administrator also enters into an agreement, known as a Pharmaceutical Pricing Agreement ("PPA"), "with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for [such] drugs . . . purchased by a covered entity . . . does not exceed [the ceiling price]." *Id.* § 256b(a)(1). The ceiling price is calculated using a formula that takes into account each drug's "average" and "best" price in the Medicaid Drug Rebate Program. *Id.* § 256b(a)(1)–(2). Each PPA "require[s] that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." *Id.*; *see also* 58 Fed. Reg. 27289, 27291 (May 7, 1993). Manufacturers that do not comply with the PPA can be subject to monetary sanctions and even termination from the 340B Program. 42 U.S.C. § 256b(d)(1)(B)(vi).

36. Since the beginning of the 340B Program, HRSA has required drug companies to offer upfront discounts—not rebates—to covered entities. *See* 42 U.S.C. § 256b(a)(1); 58 Fed. Reg. at 27291–92. Upfront discounts work as follows: a covered entity makes an initial purchase of drugs at wholesale cost. The covered entity then dispenses drugs from that initial purchase to both 340B eligible and non-eligible patients. A third-party evaluates the claims data to determine how many units were dispensed to a 340B eligible patient. After the covered entity has dispensed enough 340B eligible units of a particular drug to equal the number of units in the drug's package, the covered entity may purchase subsequent packages of those drugs from the manufacturer at a 340B-discounted price. As a result, other than a first-time purchase at full price, 340B providers almost always pay only the discounted price.

37. The single narrow exception to the upfront discount model is for drugs sold to a certain category of covered entities to which none of Plaintiffs belong: AIDS Drug Assistance

Programs ("ADAPs"). HRSA determined that rebates were an appropriate mechanism to effectuate price reductions for ADAPs because ADAPs had drug purchasing systems that largely prevented their participation in the section 340B discount program. Specifically, before 1998, covered entities could only work with one pharmacy to make drug purchases, regardless of whether that pharmacy was in-house or contracted. As a result, a significant number of ADAPs did not participate in the 340B Program, which led to HRSA "recogniz[ing] rebates obtained by the State ADAPs that equal or exceed the discount provided by the statutory ceiling price as a method of accessing the 340B Program." 62 Fed. Reg. 45823, 45824. But even when HRSA approved rebates as a permissible mechanism for ADAPs, the agency declined to authorize manufacturers to pay rebates to all other covered entities. HRSA specifically found that "the [upfront] discount system is *functioning successfully for most covered entities*[.]" 62 Fed. Reg. at 45824 (emphasis added). In any event, rebate purchases from ADAPs made up less than *$43 thousand* of all *$66.3 billion* in 340B Program purchases in 2023, the most recent year for which HRSA has published data, so there has never been a significant rebate model imposed in the 340B context. *See* HRSA, *2023 340B Covered Entity Purchases,* https://www.hrsa.gov/opa/updates/2023-340b-covered-entity-purchases.

38. Covered entities often implement upfront pricing through what is known as the "product-replenishment model." Under this longstanding model, covered entities purchase an initial package of drugs at the market price. After confirming a certain quantity of a drug has been sold to 340B-eligible patients, the provider then purchases replacement quantities at the 340B prices. *See generally Novartis Pharms. Corp.*, 2025 WL 2813787, at *3 (explaining replenishment model). As Defendants described in an August 1, 2025 brief to the D.C. Circuit, "[u]nder this approach, providers obtain an upfront discount for purchases allowing them to get the immediate

benefit that the 340B Program is meant to provide." Doc. 2128443 at 2, *Novartis Pharms. Corp. v. Kennedy*, No. 25-5177 (D.C. Cir. Aug. 1, 2025).

39. This "upfront discount" model makes perfect sense given Congress's intent for the 340B Program. Rural hospitals and other 340B providers operate on thin (or negative margins) and serve vulnerable patient populations. Forcing those entities to float hundreds of millions of dollars to the drug industry each year until the drug companies decide whether and when to issue a rebate puts covered entities at existential risk and endangers the health of their patients and communities.

HRSA Repeatedly Rejected Drug Companies' Efforts to Move to Rebate Models

40. For years, drug companies have tried to undermine the value and efficacy of the 340B Program through proposals that would, in effect, transfer hundreds of millions of dollars from covered entities to drug companies—many of which are among the most profitable companies in the world. One such technique has been to try to deploy a rebate model for some or all drugs covered under the 340B Program, not because the administration of these drugs requires a rebate mechanism, but because this would make the drug companies more money.

41. HRSA has long taken the position that it has the authority to approve how drug companies must provide 340B discounts, including whether through an upfront discount or a rebate model. This is consistent with the 340B statute's legislative history, which states:

> The Committee bill does not specify whether "covered entities" would receive these favorable prices through a point-of-purchase discount, through a manufacturer rebate, or through some other mechanism. A mechanism that is appropriate to one type of "covered entity," such as community health centers, may not be appropriate to another type, such as State AIDS drug purchasing programs. The Committee expects that the Secretary of HHS, in developing these agreements, will use the mechanism that is the *most effective and most efficient from the standpoint of each type of "covered entity."*

H.R. Rep. 102-384, pt. 2, at 16 (1992) (emphasis added) (quoted in *Johnson & Johnson Health Care Sys. Inc. v. Kennedy*, 2025 WL 1783901, at *10 (D.D.C. June 27, 2025)). For years, HRSA rejected drug company efforts to impose rebate models, recognizing that they are decidedly *not* the "most effective and most efficient" mechanisms for providing discounts "from the standpoint of" 340B hospitals. *Johnson & Johnson Health Care Sys. Inc.*, 2025 WL 1783901, at *10.

42. In 2024, certain drug companies tried again to undermine the 340B Program's upfront discount model. Specifically, in mid-to-late 2024, drug companies Johnson & Johnson ("J&J"), Eli Lilly, Bristol Myers Squibb, Novartis, and Sanofi announced plans to require at least some 340B covered entities to purchase certain drugs at market prices, known as the full Wholesale Acquisition Cost ("WAC"), and then apply for a rebate after dispensing to a 340B-eligible patient. WAC is the highest cost for which a pharmaceutical company sells a drug. Despite some differences in their proposed rebate models—J&J's initial proposal was limited to two drugs, while Eli Lilly's proposed model would have applied to all of its drugs—the end result would have been the same: drug companies would have unilaterally imposed a rebate system.

43. Recognizing that the abandonment of the upfront discount model would jeopardize the goals of the 340B Program and grievously harm covered entities, HRSA promptly took action to prevent the drug companies from switching to a rebate model. For example, on August 14, 2024, HRSA sent a letter to J&J stating that "[t]his shift [to a rebate model] would disrupt how the 340B Program has operated for over thirty years. As a result of this shift, covered entities, including those which primarily serve rural and underserved populations, would need to pay significantly higher prices on prescription drugs at the time of purchase." 340B_REBATES_000064 at -66, filed in *Eli Lilly & Co. v. Kennedy*, No. 1:24-cv-03220 (D.D.C. 2024) (the "*Eli Lilly* Case"), Dkt. 60-1.

44. HRSA also warned J&J that it did not have the authority to unilaterally impose a rebate program and asked J&J a series of questions about its proposed rebate model. Notably, several of these are questions that, as discussed below, HRSA *itself* has not answered about its own pilot program. Among other things, HRSA asked:

a. Whether "J&J conducted an evaluation of the impact of this proposal on the scope and breadth of health care access for patients served by affected covered entities";

b. Whether "J&J conducted an analysis of the extent of the additional burden and/or costs to the affected covered entities, particularly those that are the sole or primary source of health care in a rural or underserved community";

c. How J&J planned to protect the claims information it collected, with whom it would share that information, and how it would "ensure such information would solely be used in support of the 340B Program";

d. On what specific grounds would J&J deny a rebate claim;

e. How J&J would adjudicate actual and potential rebate claim denials, and what appeal process would J&J put in place for denials; and

f. How J&J planned to issue refunds.

Id. at -66–68.

45. On September 17, 2024, HRSA followed up with a second letter to J&J, stating that the company risked violating the law if it implemented its rebate program. In this letter, HRSA again noted that J&J's model would impose enormous costs on hospitals and covered entities: "[U]nder the J&J proposal, covered entities would be forced to pay a higher price point up front for every purchase. This would create significantly higher up-front costs for covered entities." 340B_REBATES_000201 at -03, filed in the *Eli Lilly* Case, Dkt. 60-1. HRSA went on to note

other flaws in J&J's proposal, namely that J&J "does not commit to an enforceable timeframe for issuing the 'rebate payment,'" and that the proposal subjected rebate payments to so many conditions that "issuance of the 'rebate payment' is conditioned on J&J's prior approval at J&J's sole discretion." *Id.*

46. In its September 17, 2024 letter, HRSA went so far as to argue that any rebate program that forces a covered entity to pay more than the ceiling price, as calculated under the 340B statute, is *illegal* under federal law: "J&J intends to unilaterally charge disproportionate share hospitals 'commercial price[s], such as [WAC]' for covered outpatient drugs . . . . J&J's rebate proposal would require disproportionate share hospitals to purchase [J&J's drugs] at prices that exceed 'the maximum price[s] that covered entities may permissibly be required to pay' for those drugs. This, too, violates Section 340B(a)(1) of the [Public Health Service] Act." *Id.*

47. On September 27, 2024, HRSA sent a third letter to J&J warning that if it did not cease its proposed rebate program, HRSA would terminate J&J's participation in the 340B Program (thereby making it ineligible for Medicare and Medicaid participation) and refer J&J to the HHS Office of Inspector General. 340B_REBATES_000212 at -14, filed in the *Eli Lilly* Case, Dkt. 60-1.

48. Eli Lilly, Bristol Myers Squibb Co., Novartis Pharmaceuticals Corp., and Sanofi-Aventis U.S. LLC ("Sanofi"), all received similar letters from HRSA about their proposed rebate programs. In a September 18, 2024 letter to Eli Lilly, for example, HRSA informed Eli Lilly that its unilateral imposition of a rebate program was illegal and stated that it "would disrupt how the 340B Program has operated for over thirty years. As a result of this shift, covered entities, including those which primarily serve rural and underserved populations, would need to pay

significantly higher prices on prescription drugs at the time of purchase." 340B_REBATES_000292, filed in the *Eli Lilly* Case, Dkt. 60-1.

49. On November 12, 2024, J&J responded to HRSA's defense of the upfront discount model by filing a federal lawsuit against the same Defendants as in this case—HHS, HRSA, and the HHS Secretary and HRSA Administrator in their official capacities. *J&J Health Care Sys. Inc. v. Kennedy*, No. 24-cv-3188 (D.D.C. Nov. 12, 2024). The other drug companies followed suit soon thereafter. *Eli Lilly & Co., et al. v. Becerra*, No. 24-cv-3220 (D.D.C. Nov. 14, 2024); *Bristol Myers Squibb Co. v. Johnson*, No. 24-cv-03337 (D.D.C. Nov. 26, 2024); *Sanofi-Aventis U.S. LLC v. U.S. Dep't of Health and Human Servs.*, No. 24-cv-03496 (D.D.C. Dec. 16, 2024); *Novartis Pharms. Corp. v. Becerra*, No. 25-cv-00117 (D.D.C. Jan. 15, 2025). Collectively, the companies asked the courts to vacate HRSA's letters and declare that their rebate models were lawful under the 340B statute.

50. While defending themselves against the drug companies' lawsuits, HRSA and HHS—Defendants in the instant action—repeatedly defended the upfront discount model.

a. In their March 17, 2025 motion for summary judgment in the *Eli Lilly* litigation, Defendants noted that "widespread adoption of rebate models would cause unprecedented disruption to the program." Dkt. 35-1 at 20, the *Eli Lilly* Case, No. 24-cv-3220.

b. In their April 2, 2025 motion for summary judgment in the *J&J* litigation, HRSA and HHS noted that HRSA "has long envisioned upfront discounts as the preferred price reduction mechanism, noting that '[c]overed entities generally preferred a discount system, because they could negotiate lower prices and needed less initial outlay of drug purchasing money.'" Dkt. 41-1 at 18, *J&J*, No. 24-cv-03188. HRSA

and HHS noted that HRSA "was concerned that the arrangement that [J&J] proposed would 'create significantly higher up-front costs for covered entities.'" *Id.* at 19.

c. In that same motion, HHS and HRSA further emphasized that "[t]he Agency [HRSA] would neglect its duty if it did not consider all aspects of the problem, including not only the manufacturers' preferences, but also how the changes would affect the operations of covered entities and the wellbeing of patients who rely on 340B drugs, before allowing manufactures to redesign the operation of the program." *Id.* at 20.

d. In an August 1, 2025 brief filed with the D.C. Circuit, HHS and HRSA further defended the upfront discounts and flagged concerns with rebates in the 340B Program. "Unlike discounts, rebates require covered entities to spend more money upfront and put greater financial pressure on those safety-net programs." Doc. 2128443 at 2, *Novartis Pharms. Corp. v. Kennedy*, No. 25-5177.

51. The presiding federal district courts concluded that HRSA could prohibit drug companies from unilaterally imposing rebate models, explaining that covered entities would "'be forced to incur higher carrying costs for these drugs, essentially floating revenue to drug manufacturers'" and "'reduc[ing] the hospitals' resources available for other patient care.'" *Johnson & Johnson Health Care Sys. Inc.*, 2025 WL 1783901 at *12 (quoting AR 568); *see also Eli Lilly & Co. v. Kennedy*, 2025 WL 1423630, at *12 (D.D.C. May 15, 2025) ("Most critically, a cash rebate model shifts the initial outlay for drug costs from manufacturers to covered entities. . . . Thus, the impact of a rebate float was a relevant factor the agency was entitled to take into

consideration.").[1] This litigation is currently on appeal and remained pending when HRSA suddenly and without explanation abandoned three decades of practice.

HRSA's Abrupt and Unexplained Announcement of a Rebate Program

52. At the same time the government attorneys representing Defendants were highlighting the risks of rebate programs in federal courts, and after thirty-three years of implementing the 340B Program through upfront discounts, HRSA abruptly announced that it was launching a 340B rebate program that would have a devastating financial impact on covered entities across the country, especially rural and other safety-net hospitals.

53. On July 31, 2025, HRSA announced a new "340B Rebate Model Pilot Program" via press release, followed by an initial notice in the Federal Register on August 1, 2025. *See* 90 Fed. Reg. at 36163. On August 7, 2025, HRSA reposted a largely identical announcement with corrections (the "Notice"). *See* 90 Fed. Reg. 38165.

54. The Notice, in summary, announced that HRSA would allow the manufactures of certain drugs to apply for the Rebate Program and submit their own proposed 340B rebate models to HRSA for review, with the intention for these models to go into effect on January 1, 2026. Under the Rebate Program, covered entities would be required to initially purchase these drugs at the WAC, and then wait for a rebate to be issued by drug companies.

55. Despite having argued only months before that the change from an "upfront discount" model to a "rebate" model would have a seismic effect on the 340B Program, the Notice

[1] The court overseeing the *Sanofi* litigation found that HRSA had acted arbitrarily and capriciously as to Sanofi. *Sanofi-Aventis U.S. LLC v. Kennedy*, No. 24-cv-03496, 2025 WL 1423630, at *13–14 (D.D.C. May 15, 2025). According to the court, HRSA had made a "determinative legal finding and final rejection" of Sanofi's proposed rebate model and therefore needed to consider all important aspects of the problem before making that determination. *Id.* at *13. HRSA conceded that "the administrative record [did] not address [numerous] concerns that Sanofi and the other plaintiffs raised[,]" which was "dispositive." *Id.* at *14.

contained little justification or explanation for the Rebate Program. The Notice principally stated that HRSA had "received inquiries" from drug companies about the upcoming implementation of the Centers for Medicare and Medicaid Services ("CMS") Medicare Drug Price Negotiation Selected List, which imposed new "Maximum Fair Prices" for certain drugs in the Medicare context and foreclosed duplicate discounts under the 340B Program.[2] *Id.* The Notice nowhere acknowledged that stakeholders had previously explained that there were alternative methods for achieving such deduplication or that the purported benefits of Inflation Reduction Act ("IRA")/340B deduplication did not come close to outweighing the tremendous costs of a rebate model. Indeed, the Notice did not elaborate on why such a convoluted Rebate Program involving the transfers of hundreds of millions of dollars was necessary if the goal is really a data-checking deduplication exercise. Put another way, there is nothing in the Notice that rationally connects the Rebate Program to Defendants' purported goals.

56. The Notice described the proposed rebate system as a "voluntary 340B Rebate Model Pilot Program." *Id.* But the Rebate Program is neither voluntary nor a "pilot" in any traditional sense of the word. Pilot programs are ordinarily limited in scope, whereas the "340B Rebate Model Pilot Program" is unquestionably not. While HRSA offered a few drug companies the option to participate in the pilot, *every single* 340B participating safety-net hospital and other

[2] The CMS Medicare Drug Price Negotiation Selected List is a new pricing regime for certain Medicare drugs established through the IRA. Pursuant to the IRA, CMS negotiated a "Maximum Fair Price" for drugs with the highest Medicare Parts B and D expenditures and no generic or biosimilar competitors and that have been marketable for at least seven years (for drugs) and 11 years (for biologics) (*i.e.*, products that have had little market competition). *See* 42 U.S.C. §§ 1320f *et seq*. CMS was required to negotiate the price of up to ten drugs for price applicability year 2026, up to fifteen for initial price applicability years 2027 and 2028, and up to twenty for initial price applicability year 2029 and subsequent years. *Id.* § 1320f-1(a)–(b). Drug manufacturers must offer 340B covered entities the lesser of the Maximum Fair Price or the 340B ceiling price, and these discounts may not be duplicated. 42 U.S.C. § 1320f-2(d).

covered entity in America is required to participate to obtain the 340B savings for the pilot drugs. HRSA did not seek a smaller pool of 340B providers to volunteer for a pilot program. It did not incentivize certain 340B hospitals to participate. Nor did HRSA consider using a regional model to experiment with the concept of rebates, excluding particular hospitals from the administrative burden of a pilot program, or any other of the many obvious narrower and less burdensome alternatives.

57. Likewise, the Notice did not address any of the concerns about the rebate model's financial impact on safety-net hospitals and other covered entities that HRSA itself had raised in the past, including in its 2024 letters to drug companies and the ensuing litigation. The Notice itself provided no estimate of the costs associated with complying with the pilot program; no explanation about why HRSA believed those costs (or any costs of compliance) to be reasonable; and no explanation about why imposing costs upon all covered entities was necessary in light of the purportedly limited purpose of the "pilot program."

58. Moreover, HRSA did not publish any clear or binding rules for drug manufacturers to follow in implementing their rebate programs. Instead, HRSA published vague, non-binding "criteria" for the rebate programs.[3] *Id.* at 38166–67. For example:

a. The Notice indicates that "all costs for data submission through an Information Technology (IT) platform be borne by the manufacturer and no additional administrative costs of running the rebate model shall be passed onto the covered entities." *Id.* at 38166 (Criterion #1). But the Notice provides no definition of "administrative costs" or explanation for how it expects covered entities are to

[3] Although HRSA included a series of "criteria" in the Notice, drug companies had the option of deviating from the criteria so long as they provided justification. *Id.* at 38166. HRSA has not indicated whether it approved any drug company applications that deviated from these criteria.

avoid such costs. Indeed, as discussed below, HRSA itself subsequently concluded that hundreds of millions of dollars in administrative costs would *not* be borne by drug companies and instead passed onto covered entities.

b. The Notice indicates that a "[p]lan should ensure that all rebates are paid to the covered entity (or denied, with documentation in support) within 10 calendar days of data submission." *Id.* (Criterion #12). But the Notice provides no criteria for a method of resolving disputes, the evidentiary burden or bases that drug companies are to use when evaluating claims, or any other key details. This is particularly troubling because HRSA had previously stated that the lack of a clear dispute mechanism was one of the major concerns it had with drug companies' rebate proposals, but HRSA repeated the same mistake in the Rebate Program.

c. The Notice notes at one point that the Rebate Program would "facilitate other aims such as the prevention of 340B Medicaid duplicate discounts and diversion." *Id.* at 38165. But later in the Notice, HRSA made clear that each company's "[p]lan should ensure that 340B rebates are not denied based on compliance concerns with diversion or Medicaid duplicate discounts." *Id.* at 38166 (Criterion #13). HRSA never reconciled this inconsistency. Critically, if drug companies cannot deny rebates based on program integrity concerns, the *only* conceivable purpose the Rebate Program can serve is the limited one of effectuating 340B/IRA deduplication.

59. HRSA wrongly claimed that the rebate model was informed by "the significant amount of feedback received from (or on behalf of) . . . covered entities regarding the

implementation of rebate models." *Id.* at 38165. Upon information and belief, this program was developed in meetings between drug companies and HRSA.

60. Subsequent to publishing the Notice, in August 2025 HRSA launched a website for the new Rebate Program that included a section entitled Frequently Asked Questions (FAQs). *See* HRSA, *340B Rebate Model Pilot Program*, (Nov. 2025), https://www.hrsa.gov/opa/340b-model-pilot-program (hereinafter the "FAQs"). The FAQs provided no meaningful details about the agency's reason for abandoning the upfront discount model it had championed for the previous three decades.

a. The FAQs did not address the massive costs that covered entities will bear under the Rebate Program, or why HRSA had suddenly decided that it was appropriate for covered entities to bear these costs, particularly after HRSA had previously objected to the imposition of such costs. *See id.*

b. The FAQs did not acknowledge or address any of the concerns HRSA itself had identified regarding rebate models, including those that HRSA raised in its 2024 letters to drug companies and the follow-on litigation. *See id.*

c. The FAQs were silent about why HRSA had not chosen narrower alternatives for the "pilot" program, such as voluntary participation for 340B providers, a regional pilot program, or a program that excludes financially fragile 340B providers. *See id.*

d. The FAQs underscored the lack of any enforceable deadline for drug companies to pay rebates. They suggested only that "[i]f a claim takes longer than 10 days for a rebate to be paid, covered entities and manufacturers should work to resolve the issue." *Id.* So, while HRSA had criticized the J&J proposal in September 2024

because it did "not commit to an enforceable timeframe for issuing the 'rebate payment,'" 340B_REBATES_000203, less than a year later, HRSA greenlit (with no explanation) a rebate pilot with no functionally enforceable timeline for paying rebates.

e. The FAQs did not identify a true process for adjudicating disputes between covered entities and drug companies if they could not "resolve the issue" themselves. The FAQs stated only that "[i]f after attempting to work with the manufacturer a covered entity cannot resolve the issue with the manufacturer, the covered entity should email 340BPricing@hrsa.gov with the details of its concern. A manufacturer that is consistently unable to timely resolve rebate reimbursement issues may have its participation in the pilot program revoked." The FAQs. The FAQs did not specify who would be reviewing complaints sent to this generic inbox; what it meant by "consistently unable"; what it meant by "timely"; how HRSA would gather facts or arguments about the dispute; or whether there was any way to ensure payment of the statutorily-owed discounts short of kicking a drug company out of the Rebate Program. *See id.*

f. The FAQs did not address concerns and complaints about the drug companies' chosen software platform, "Beacon." *See id.*

61. To implement the Rebate Program, HRSA directed manufacturers of the ten drugs in question to submit plans for their rebate programs by September 15, 2025. The drug companies were told to submit plans directly to HRSA without subjecting them to public scrutiny. Despite the massive implications for the U.S. healthcare system, HRSA did not request or require that the proposed plans contain any empirical data about the potential impact on the 340B Program's

implementation or the affected covered entities. Alarmingly, HRSA demanded that proposals "not exceed 1,000 words," 90 Fed. Reg. at 38166—a grossly inadequate number for a program that threatened the delivery of healthcare to millions of Americans.

62. Importantly, the drugs selected for HRSA's 340B "pilot" program are not the types of limited-purpose drugs that one would rationally select if the goal was to measure a new model without disrupting a massively critical program like the 340B Program. All ten drugs are high-volume, high-cost brand-name drugs with a substantial impact on the healthcare system, which is why they were also selected for initial Medicare price negotiation. If the supply of these drugs to rural hospitals and other 340B providers is disrupted under the Rebate Program—for example, if safety-net providers cannot pay the new massive upfront costs—then patients' health and lives will be at risk. For example, Imbruvica is an enzyme inhibitor used to treat chronic lymphocytic leukemia, Waldenström's macroglobulinemia, and chronic graft-versus-host disease. Clinical trials have shown that Imbruvica can improve the survival rate of leukemia patients by up to 56%, and Imbruvica is a last line of defense for patients rejecting their skin grafts after other therapies have failed. Losing access to Imbruvica jeopardizes patients' lives.

HRSA Concedes That the Rebate Program Will Cost Hospitals and Other Covered Entities Hundreds of Millions of Dollars

63. HRSA's Notice was entirely silent about the costs that would accompany the Rebate Program. Weeks after publishing the Notice, however, HRSA acknowledged elsewhere the exorbitant administrative costs its Rebate Program would impose on covered entities. But HRSA, again, never evaluated the necessity of these costs, whether these costs outweighed the benefits of a rebate program, or why its own implicit cost-benefit analysis had changed in the matter of months.

64. Under the Paperwork Reduction Act of 1995, 44 U.S.C. § 3501, *et seq.*, ("PRA"), HRSA was required to calculate the Rebate Program's burden on affected entities, including the time they would spend to generate, maintain, retain, disclose, or provide the data requested. HRSA did so in an Information Collection Request ("ICR") submitted to the Office of Information and Regulatory Affairs ("OIRA"). In August 2025, HRSA completed its ICR, in which it estimated that the proposed Rebate Program would require covered entities to expend over **1.5 million hours** in 2026 to comply with the data collection requirements. HRSA's monetary quantification of these hours was $200,428,800.

65. Viewed another way, HRSA calculated that the burden imposed on covered entities was *more than 4,000 times* the burden that would be imposed upon drug companies, which HRSA calculated would only amount to 360 hours per year to comply with the Rebate Program's data collection requirements.

66. HRSA submitted the following chart of administrative costs associated with the Rebate Program, with the rows "Lawyer" and "Accountant" reflecting the drug companies' costs, and the "Pharmacist" row reflecting the 340B providers' costs:

Type of Respondent	Total Estimated Burden Hours	Hourly Wage Rate	Total Respondent Costs
Lawyer	72	$176.00/ hour[4]	$12,672
Accountant	288	$90.00/ hour	$25,920
Pharmacist	1,518,400	$132.00/hour	$200,428,800
Estimated Total	**1,518,760**	-	**$200,467,392**

67. HRSA's calculations about the burden on 340B providers are staggering on their own. But those numbers grossly undercount the actual burden that the Rebate Program will place on covered entities. HRSA's estimate of 1.5 million hours is based on the notion that 14,600

covered entities will each spend *only 2 hours per week* complying with the requirements of the Rebate Program. But many providers will need to hire full-time staff just to comply with the administrative burden of the new 340B Rebate Program. Full-time means *full*-time—far more than two hours a week. In reality, the collection and submission of the requisite data will take many hospitals dozens of hours per week. *See infra*, ¶¶ 73–80. Tellingly, HRSA has provided no explanation for the basis of its two-hour calculation, and HRSA has offered no evidence that this estimate was empirically tested or validated.

68. The Rebate Program's actual administrative burden on 340B providers will be far higher than the 1.5 million hours and $200,428,800 that HRSA estimated.

69. While HRSA included these estimated administrative costs in its ICR submitted to OIRA, HRSA never updated its Notice or its FAQs to reflect this. Nor did HRSA provide any other public explanation about the value or necessity of imposing hundreds of millions of dollars in costs upon covered entities, whether there was an alternative means of avoiding or reducing those costs, or what benefits outweighed these extraordinary costs.

70. Likewise, while this calculation addresses the administrative costs of compliance, it does not calculate or address the upfront-payment costs that providers will be forced to bear in paying the far-higher WAC under the Rebate Program, rather than receiving the upfront discount. While HRSA had repeatedly expressed concern about those upfront-payment costs in prior positions and litigations, HRSA never discussed the size or impact of upfront-payment costs in connection with its Rebate Program.

71. Nor did HRSA identify or evaluate the *non-monetary* costs that its Rebate Program would impose on patients and communities as a result of the Rebate Program, including reduced access to comprehensive healthcare.

HRSA Receives Over 1,100 Comments About the Flaws in the 340B Rebate Program

72. In its Notice, HRSA solicited comments to be submitted within 31 days, although the agency took the position that it "will consider comments received but is under no obligation to respond to or act on the comments." 90 Fed. Reg. at 38165. Despite this short deadline for responses,[4] HRSA received more than 1,100 comments. Commenters flagged concerns about the scope of the Rebate Program, the administrative and operational challenges of the Program, and the costs that the Rebate Program would impose on covered entities, particularly rural and other safety-net hospitals. The comments also proposed multiple obvious and less-burdensome ways to address the IRA/340B deduplication concerns that HRSA described as the motivating purpose for its proposed Rebate Program. And many covered entity commenters raised concerns about their ability to meet a January 1, 2026 effective date.

The Rebate Program Will Impose Increased Administrative Costs

[4] Plaintiff AHA and other organizations representing hospitals asked HRSA to extend the comment period. Their letter stated:

> A change of this magnitude requires careful consideration by all stakeholders. To that end, the agency is seeking comments on its pilot program by September 8 and has asked drug manufacturers to submit rebate model plans by September 15. That timeline gives the agency only one week to consider any stakeholder feedback, make any necessary changes to its program, and communicate those changes to all 340B stakeholders, including the drug company applicants. With the fundamental changes a rebate model will impose on all 340B stakeholders, it is impossible for the agency to meaningfully consider, in just seven days, all the feedback it will surely receive. Moreover, drug companies have spent years developing and preparing for a rebate model, but the agency's current timeline would give 340B hospitals far less time to prepare.

Comment ID HRSA-2025-0001-0005 at 1 (all comments available at https://www.regulations.gov/docket/HRSA-2025-0001/comments). HRSA never responded to this request and forged ahead with its abbreviated comment timeline.

73. Commenters carefully described the increased administrative costs and burdens that the Rebate Program will impose on covered entities. Many noted that under the program, they would need to hire additional staff to (a) comply with the significant data collection and submission requirements, (b) track whether their hospital actually received a rebate, and (c) handle the inevitable disagreements with drug companies and navigate HRSA's opaque dispute resolution process.

74. Commenters also identified costs resulting from having to manage two discount systems. Covered entities will have to prepare, submit, and track one set of data for the traditional upfront discount program, and then prepare, submit, request and track rebates, and reconcile payments for HRSA's new Rebate Program. Covered entities operating on thin or negative margins commented that they do not have the budget and resources to do both.

75. Commenters also responded that while the Notice suggested that "administrative costs" would not be passed to covered entities, nowhere does the final program actually provide for these costs to be borne by drug companies.

76. As noted above, HRSA itself estimated that claims submission will cost covered entities at least $200 million annually, based on the assumption that providers will incur two hours of extra administrative burden per week. A number of commenters warned that HRSA's estimates for complying with the new 340B rebate program—two hours per week—were wildly unrealistic. For example, Plaintiff AHA reported that its "member hospitals . . . may need, on average, two additional full-time equivalents (FTEs) to gather the appropriate data, submit the data in the format required under the drug company's IT platform, and track the data to ensure the appropriate rebates are paid." Comment ID HRSA-2025-0001-0052 at 13. Likewise, multiple other covered entities noted that the administrative costs of complying with the new rebate model program would require

them to hire or reassign full-time employees—drawing resources away from the provision of healthcare in the name of complying with new bureaucracy. *E.g.*, Comment IDs HRSA-2025-0001-0099 at 1, HRSA-2025-0001-0110 at 3, 5.

77. A non-profit health center in Florida likewise wrote that "health centers will need to hire or reassign existing staff to untangle the mentioned complexities related to varying data submission requirements, timelines, and systems." Comment ID HRSA-2025-0001-0215 at 3.

78. This resource commitment means that HRSA's own estimates of cost and burden were highly inaccurate. Plaintiff AHA explained the true financial and operational impact of the Rebate Program in response to HRSA's notice of its intent to submit an Information Collection Request to the Office of Management and Budget per the Paperwork Reduction Act:

> With currently over 2,700 340B hospitals, that would amount to nearly 11.2 million burden hours — a far cry from the agency's estimates. Moreover, 340B hospitals indicated to us that the operational costs associated with the rebate model could range from $150,000 to over $500,000 per hospital, with costs increasing further if there are significant delays and denials with the rebate payments. Even a conservative estimate would yield over $400 million in annual costs for 340B hospitals to comply with the rebate model. And these costs don't include the millions of dollars 340B hospitals would be providing to drug companies as interest-free loans through the rebate model.[5]

Am. Hosp. Ass'n, *AHA Letter to HRSA re: The 340B Rebate Model Pilot Program* (Sept. 30, 2025), https://www.aha.org/lettercomment/2025-09-30-aha-letter-hrsa-re-340b-rebate-model-pilot-program.

79. Commenters further stressed that the process for addressing claim denials would impose unique administrative costs. They emphasized that there would be administrative costs

[5] Importantly, these estimates apply only to the burden and costs that would borne by the 2,700 340B hospitals. They do not cover the costs of the approximately 14,600 340B covered entities that are not hospitals.

because HRSA's guidance on how covered entities should handle the denial of claims for rebates is threadbare. Multiple commenters identified the "dangerously insufficient" gaps in HRSA's dispute resolution system and the unaccounted-for costs of those gaps. *E.g.*, Comment IDs HRSA-2025-0001-0052 at 5–6, HRSA-2025-0001-0076 at 5–6, HRSA-2025-0001-1074 at 5–6. In addition to highlighting the lack of information about how the dispute resolution would operate, covered entities warned that it will allow drug companies "to weaponize the alternative dispute resolution process by leveraging it to further delay rebates and/or discourage covered entities from pursuing the accrued rebates due to the complexities and burden associated with pursuing such a claim." Comment ID HRSA-2025-0001-0378 at 3.

80. Commenters such as Plaintiff AHA made the commonsense recommendations that drug manufacturers should be required to provide (a) a clear, detailed reason for claim denials, including "a narrative description of why a rebate claim is being denied"; (b) "supporting primary source materials . . . justifying such a denial"; and (c) "a signature or attestation by a drug company employee, along with their telephone number or email address, so that covered entities can reach them to address any incorrect denials." Comment ID HRSA-2025-0001-0052 at 6. This would serve as the foundation for covered entities and drug companies to meaningfully engage when attempting to resolve the issue, as required by HRSA's meager FAQs. HRSA did not address these suggestions.

The Rebate Program Will Impose Enormous Costs Due To Delayed Payment

81. Several commenters focused on the calamitous effects of cash-strapped covered entities having to float billions of dollars to drug companies each year while waiting for their statutorily-owed discounts. The enormity of these new upfront-payment costs was described by providers large and small.

82. One community health center in Fargo, North Dakota calculated the difference for a single pilot drug, Jardiance. Comment ID HRSA-2025-0001-0842 at 2. The 340B price for a 90-day supply of Jardiance is about $25 for this provider (28 cents per dose times 90), and its patients pay $7.00. *Id.* But, under the Rebate Program, covered entities will have to float approximately $1,800 per 90-day supply until the drug manufacturer rebates the difference. *Id.* Given the exorbitant upfront costs that must be paid under the Rebate Program, as well as the risks of delays in reimbursement, this commenter had already investigated obtaining loans from drug wholesalers to enable it to acquire those drugs. The costs of loans will be difficult for covered entities to bear, however. "At least one wholesaler charges 18% annual interest, and even the Small Business Administration charges 12.5% annually." *Id.* at 4.

83. A nonprofit membership organization with more than 1,600 public and private non-profit hospitals and health systems that participate in the 340B Program estimated that each of its hospitals would need to float, on average, $8.6 million annually to drug manufacturers. Comment ID HRSA-2025-0001-1111 at 4. This multi-million-dollar annual outlay, the organization warned, would generate major liquidity challenges for safety-net providers. As a result, those healthcare providers would ultimately reduce access to care and services for low-income patients.

84. Similarly, one healthcare consulting company measured the potential financial impact of the Rebate Program by the costs that 81 covered entities would have incurred had the rebate program been operative in 2025. Comment ID HRSA-2025-0001-0076 at 1–2. This commenter calculated that the 81 covered entities would have needed to float drug companies more than $348 million under the rebate model just for these 10 drugs for only the first six months of 2025. *Id.* As the commenter concluded, "[t]he most significant hidden cost of the rebate model

for covered entities is the time value of money—the financial impact of advancing millions in drug spend while waiting for reimbursement." *Id.* at 3.

85. Several commenters noted that the need to stock drugs at facilities would mean weeks or months would elapse before covered entities were reimbursed for the millions of dollars paid initially to the drug companies. Put another way, the program's 10-day rebate requirement program would have diminished value because some drugs sit on the shelf for longer periods of time before being dispensed. For example, two regional providers noted "several months may pass between the time of purchase and the time of dispensing [a drug]. Under the rebate model, covered entities would be required to absorb the higher upfront cost for an indefinite period[,]" compounding the difficulties covered entities will face covering the enormous upfront costs. Comment ID HRSA-2025-0001-0378 at 3; *see also* Comment ID HRSA-2025-0001-0401.

86. Commenters, including Plaintiff AHA, noted that these upfront-payment costs and attendant loss of liquidity would have real-world implications for the provision of healthcare. Plaintiff AHA explained that these costs would undermine the ability of covered entities to expand coverage to underserved geographies, refresh medical equipment, and invest in other capital-intensive projects that benefit the communities these hospitals serve. Comment ID HRSA-2025-0001-0052 at 12–14. Plaintiff AHA also warned that requiring such a substantial outlay could have devastating collateral consequences on hospitals' finances, such as violating bond covenants that require hospitals to maintain a certain amount of cash on hand, which could lead to a spiral of downgrades in credit ratings, increased borrowing costs, and even closure. *Id.*

Obvious and Less Burdensome Alternatives to a Rebate Program

87. Commenters submitted several alternatives to the Rebate Program that would address the underlying concerns flagged by HRSA in its Notice. They noted that HRSA's only

stated justification for the Rebate Program was to address the risk of duplicated discounts—that is discounts under both the 340B Program and Medicare's maximum fair price under the IRA. But, these commenters explained, IRA/340B duplication could have been addressed by less costly and less disruptive mechanisms.

88. Many of these proposed alternatives involved a neutral, third-party entity that would facilitate the collection and adjudication of claims data to facilitate deduplication. For instance, one commenter suggested that HHS rely on a government-backed "clearinghouse" to exchange information between covered entities and drug companies. Comment ID HRSA-2025-0001-0974 at 6–7. HHS has already established a clearinghouse in two contexts related to IRA implementation—one of which was *specifically designed* to collect 340B claims data.

a. The first, called the Medicare Transaction Facilitator, was established to facilitate access to Medicare's maximum fair price by serving as a data and payment exchange between dispensing entities and manufacturers.[6] Plaintiff AHA explained in a comment letter that a rebate program was unnecessary to avoid duplication because HRSA could rely on the preexisting Medicare Transaction Facilitator as an alternative. AHA noted, "drug companies [could] make access to the [maximum fair price] for Medicare negotiated drugs available *prospectively* as is currently done for drugs purchased under the 340B Program." Comment ID HRSA-2025-0001-0052 at 11. This alternative:

> would allow dispensing entities, like hospitals and pharmacies, to purchase Medicare negotiated drugs at either the drug's maximum fair price or 340B price, whichever price is lower for that particular drug. Dispensing entities would then submit certain data to CMS'

[6] *See* Centers for Medicare & Medicaid Services, *Medicare Transaction Facilitator (MTF) Overview for Dispensing Entities* (Apr. 2025), available at https://www.cms.gov/files/document/pharmacy-and-dispensing-entity-mtf-fact-sheet.pdf.

> Medicare Transaction Facilitator (MTF), which would verify that the dispensing entity purchased the drug at the correct price. If the purchase was made at the incorrect price, the MTF could facilitate a transfer of funds between the drug company and the dispensing entity to rectify the error.

Id. This proposal makes intuitive sense, because HHS itself has acknowledged that drug companies are not required to make access to Medicare's maximum fair prices retrospectively and may choose to make access to maximum fair prices *prospectively*, which is exactly what AHA recommended in place of the Rebate Program.

b. The second existing clearinghouse, called the Part D claims repository, was established to collect 340B claims data to identify and exclude Part D drug units purchased under 340B for the purpose of calculating Medicare inflation rebates as required under the IRA. Commenters, including Plaintiff AHA, identified this new "clearinghouse" as a viable alternative to address IRA/340B deduplication, since CMS proposed to use this data repository to identify 340B units for the calculation of Medicare inflation rebates required under the IRA.[7] *Id.* at 5. Defendant HRSA was completely silent on the Part D claims repository "clearinghouse" alternative in connection with its approval of the Rebate Program.

Obvious and Less Burdensome Versions of a Rebate "Pilot"

[7] Notably, HHS released its final 2026 Physician Fee Schedule rule on October 31, 2025—only one day after it approved drug companies' applications to participate in the Rebate Program. That final rule adopted the Part D claims repository "clearinghouse" alternative in that context. But despite receiving multiple comments suggesting that this same "clearinghouse" could be used in place of the costly and complex Rebate Program, Defendants never explained why they chose a clearinghouse in one IRA/340B deduplication context but not the other.

89. Commenters also highlighted less costly alternatives to the structure of HRSA's mandatory-for-covered-entities Rebate Program. For example, if this were truly a pilot to test the efficacy and practicalities of a rebate program, commenters noted that HRSA should have begun with a more limited scope of covered entities and drugs, consistent with the past practice of federal healthcare agencies.

90. One commenter stated: "HHS has a long history of testing new policies through limited demonstration programs, such as state-driven Section 1115 waivers for the Medicaid program and experimental Medicare models from the Centers for Medicare and Medicaid Innovation. The Notice fails to consider whether the 340B Rebate Program's goals could be achieved through a more limited model, such as one open to covered entity volunteers." Comment ID HRSA-2025-0001-0974 at 8.

91. Commenters separately noted that the proposed pilot was "overbroad with regard to in-scope drugs. The 340B Rebate Pilot is open only to manufacturers of drugs that are on the CMS Medicare Drug Price Negotiation Selected Drug List ('MDPNP List'). By design, the drugs on the MDPNP List are among the most-prescribed drugs for Medicare beneficiaries. From June 2022 through May 2023, these drugs made up about 20% of total Part D gross covered prescription drug costs. The Notice fails to consider whether a pilot open to fewer drugs could achieve the Deduplication goals stated in the Notice." *Id*.; *see also* Comment ID HRSA-2025-0001-1074 at 3–4.

Problems with the "Beacon" Software Platform

92. Commenters raised concerns about HRSA allowing the drug companies to select their own preferred technological platform to run the rebate program. The drug companies chose to hire a platform named Beacon Channel Management ("Beacon") as the exclusive conduit

through which covered entities must submit rebate claims. Beacon is run by Second Sight Solutions, LLC, which is itself owned by Berkeley Research Group ("BRG").[8]

93. One commenter explained: "When manufacturers proposed to use BRG's Beacon platform to impose a rebate model in 2024, covered entities were shocked at the non-negotiable terms and conditions ('Terms') required to access the platform. These Terms are designed to benefit BRG/Second Sight and its manufacturer clients and shift effectively all risk associated with data sharing to covered entities." Comment ID HRSA-2025-0001-0974 at 11.

94. Given these objectionable Terms, this commenter stated: "[A]t a minimum[,] self-serving and prejudicial terms such as those contemplated for rebate models such as the BRG/Second Sight Beacon platform noted above should be prohibited. Instead, standard terms and conditions developed and approved by HHS should be implemented to avoid the inappropriate utilization/monetization of data and application of unrelated terms benefiting manufacturers and their third party for-profit partners." *Id.* at 12.

95. This commenter identified a second important aspect of the problem: giving such broad authority to the creator of the Beacon software platform. It explained that "this approach serves to delegate HHS' 340B Program enforcement authority to a for-profit company as well as drug manufacturers with clear conflicts of interest." *Id.*

[8] In addition to owning Second Sight, BRG regularly publishes adversarial reports on the 340B Program, often with funding from drug companies. *See, e.g.*, Eleanor Blalock & Carlee Launsbach, *The Financial Impact to Medicaid from the 340B Drug Pricing Program,* BRG (July 2025), https://www.thinkbrg.com/insights/publications/the-financial-impact-to-medicaid-from-the-340b-drug-pricing-program/ (describing study funded by Pharmaceutical Research and Manufacturers of America).

96. Another commenter specifically attached Beacon's Terms to its comment letter, explaining that Beacon's contract included terms that the covered entity "would not be able to agree to." Comment ID HRSA-2025-0001-0951 at 5. Complaining that Beacon's terms and conditions would be forced on it, this commenter asked HRSA to "[a]llow for covered entity negotiation power on Terms and Conditions." *Id.*

97. Commenters additionally raised "significant data privacy and cybersecurity concerns associated with" Beacon and urged that "[a]ny platform utilized must provide verifiable assurances regarding the confidentiality, integrity, and availability of protected health information (PHI) and personally identifiable information (PII)." Comment ID HRSA-2025-0001-0495 at 1; *see also* Comment ID HRSA-2025-0001-0106 at 2.

Problems With the January 1, 2026 Effective Date

98. Numerous commenters identified problems with the proposed January 1, 2026 start date and asked HRSA to delay implementation. For example, Plaintiff AHA wrote: "A delay will allow HRSA to address the many operational and administrative problems that the AHA and others identified" in the many comment letters the agency received on its pilot program notice. The Am. Hosp. Ass'n, *AHA Letter to HRSA re: The 340B Rebate Model Pilot Program* (Sept. 30, 2025), https://www.aha.org/lettercomment/2025-09-30-aha-letter-hrsa-re-340b-rebate-model-pilot-program.

99. Another commenter explained: "It is difficult to comprehend how HRSA will be able to review comments on this demonstration, make corrections to potential design flaws, and ensure that this demonstration is conducted fairly for covered entities, drug makers, and even HRSA within this compressed timeframe. We would suggest that HRSA at least delay the start of

the demonstration to address these concerns." Comment ID HRSA-2025-0001-0549 at 2 (emphasis omitted).

100. Other commenters noted the January 1, 2026, deadline placed unnecessary costs and burdens on 340B providers, and some simply would not be ready. One explained, "Implementing rebate programs beginning January 1st will put an immense burden on rural covered entities." Comment ID HRSA-2025-0001-0748 at 3. Another stated: "Giving notice of less than three months before implementation of such significant operational changes is not sufficient for covered entities to implement the infrastructure and staff needed to support the data submissions required to run these models and report the requested data.… [S]hould the Agency continue to pursue this pilot program the Agency must push back the application deadline and effective date to give covered entities and manufacturers ample time to implement." Comment ID HRSA-2025-0001-0465 at 5.

HRSA Ignores the Comments and Launches a Broad 340B Rebate Program with No Explanation

101. Despite soliciting and receiving over 1,100 comments during a month-long period, HRSA *has not responded to a single one*. Instead, HRSA's Notice stated that it "will consider comments received but is under no obligation to respond to or act on the comments." 90 Fed. Reg. at 38165. That is emphatically an incorrect statement of law. *See W. Coal Traffic League v. Surface Transp. Bd.*, 998 F.3d 945, 954 (D.C. Cir. 2021) ("[T]he failure to respond to significant comments . . . violates a substantive guarantee of the APA."). Among other things, HRSA must consider important aspects of the problem, supply a satisfactory explanation for its actions, demonstrate consideration of reliance interests when changing policy, and offer explanations consistent with the evidence before it. *See e.g.*, *Ohio*, 603 U.S. at 293–94; *State Farm,* 463 U.S. at 52.

102. HRSA's refusal to respond to comments also is in stark contrast with HRSA's past practice. HRSA has a long history of soliciting *and responding* to feedback, considering viable alternatives, and providing a reasoned explanation for its actions. For example, in December 1993, HRSA requested and, in May 1994, responded to comments on its proposal for covered entity use of discounted drugs. In August 1997, HRSA requested public comments on the potential of switching from a discount model to rebate model for State AIDS Drug Assistance Programs ("ADAPs"). And in June 1998, HRSA responded to "all major comments"—and made "several modifications based upon the comments"—in publishing the guidelines for the ADAP rebate program. HRSA has engaged in numerous other policymaking exercises where it solicited, substantively responded to, and incorporated comments.[9]

103. As of the date of filing this Complaint, HRSA has yet to address concerns regarding, among others: (a) the underlying rationale for the program, and an explanation of its about-face on the costs and other downsides of a 340B rebate model; (b) the obvious value of running a more limited pilot program rather than imposing it on all of the 14,600 340B covered entities; (c) the staggering costs of the proposed rebate program, particularly as compared to its

[9] *See, e.g.*, Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Contracted Pharmacy Services, 60 Fed. Reg. 55586 (Nov. 1, 1995) and Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43549 (Aug. 23, 1996) (requesting comments and noting that "all comments were considered" in propagating final guidelines on guidelines for contract pharmacies); Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 60 Fed. Reg. 39762 (Aug. 3, 1995) and Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (Oct. 24, 1996) (same for guidelines regarding definition of covered entity "patient"); Notice Regarding the 340B Drug Pricing Program; Children's Hospitals, 72 Fed. Reg. 37250 (July 9, 2007) and Notice Regarding 340B Drug Pricing Program—Children's Hospitals, 74 Fed. Reg. 45206 (Sept. 1, 2009) (same for adding children's hospitals to 340B Program); Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 72 Fed. Reg. 1540 (Jan. 12, 2007) and Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (Mar. 5, 2010) (same for contract pharmacies).

narrow purpose and limited benefits; (d) the absence of any meaningful dispute resolution process; (e) the obvious, less-intrusive alternatives to address deduplication; (f) concerns about the Beacon platform; and (g) the challenges of implementing this Rebate Program in just a few months and the manifest need for delayed implementation.

104. Instead of responding to public comments, HRSA has barreled on with the program, reviewing and approving the rebate plan applications that were privately submitted by eligible drug companies without any input from the 14,600 covered entities. These applications were due on September 15, 2025.

105. On October 30, 2025, HRSA announced via its website that it had approved nine drug companies' applications for a total of nine drugs with a January 1, 2026, effective date. HRSA did not provide any further explanation of what criteria the agency used or what, if any, modifications it required from the drug companies.

106. On November 14, 2025, HRSA announced that it had approved a plan from Novartis Pharmaceuticals Corporation to include a tenth drug, Entresto, in the Rebate Program, with the effective date of April 1, 2026. [10]

107. To date, HRSA has not made any of the applications available for public review.

108. Importantly, the drugs selected for HRSA's 340B "pilot" program are not the types of limited-purpose drugs that one would rationally select if the goal was to measure a new model without disrupting a massively critical program like the 340B Program. All ten drugs are high-

[10] The approved applications are for the following drugs and drug manufacturers: Eliquis (Bristol Myers Squibb); Enbrel (Immunex Corporation); Farxiga (Astra Zeneca AB); Imbruvica (Pharmacyclics); Januvia (Merck Sharp Dohme); Jardiance (Boehringer Ingelheim); Novolog, Novolog Flexpen, Novolog Penfill, Fiasp, Fiasp Flextouch, and Fiasp Penfill (Novo Nordisk Inc.); Stelara (Janssen Biotech, Inc.); Xarelto (Janssen Pharmaceuticals, Inc.); and Entresto (Novartis Pharmaceuticals Corporation).

volume, high-cost brand-name drugs with a substantial impact on the healthcare system, which is why they were also selected for initial Medicare price negotiation. If the supply of these drugs to rural hospitals and other 340B providers is disrupted under the rebate model—for example, if safety-net providers cannot pay the new massive upfront costs—then patients' health and lives will be at risk.

109. Since receiving over 1,100 comments, HRSA has not filed any new notice or equivalent statement in the Federal Register, has not addressed the comments as required under the APA, and has not given further explanation or published any other indication that it considered the comments it received or evaluated the proposed program in light of public feedback.

110. In particular, HRSA has never analyzed the vast costs of its pilot program, the necessity of those costs, and how those costs compare to any benefits that could flow from the program. Put differently, HRSA has never addressed *the very same cost concerns* that it previously flagged for Eli Lilly, J&J, and other drug companies in 2024 that a rebate model inherently generates "significantly higher up-front costs for covered entities" or that "widespread adoption of rebate models would cause unprecedented disruption to the [340B] program." 340B_REBATES_000292, 340B_REBATES_000064 (both filed in the *Eli Lilly* Case, Dkt. 60-1).

111. Tellingly, HRSA's disregard for costs was so obvious that it announced its final decision about the drugs for the Rebate Program *weeks before* the comment period under the Paperwork Reduction Act had even closed. That period, provided for under federal law, allows the public to comment on the necessity of the proposed information collection, the accuracy of the estimated burden (time and cost), ways to enhance the quality and utility of the information, and ways to minimize the burden on respondents. HRSA did not even wait to see whether its estimate of cost and burden was accurate.

112. Furthermore, HRSA showed a blatant disregard for the public's comments by submitting a "Request for Emergency Approval" to Jeffrey Clark, the Acting Administrator of the Office of Information and Regulatory Affairs ("OIRA") on August 25, 2025. This request was submitted pursuant to the Paperwork Reduction Act, which requires OIRA to approve of any agency solicitation of information from the public.

113. This August 25, 2025 submission to Mr. Clark was legally concerning for two reasons. *First*, the Paperwork Reduction Act request for public input on cost and burden was *not* included with the original Rebate Program announcement. Usually, such requests are included when new rules or programs are proposed or announced. The nearly one-month delay of this request is strong evidence that Defendants did not care at all about the costs their new program would impose. At the very least, it is further evidence of the Defendants' slipshod approach to this Rebate Program.

114. *Second*, Defendant Engels described the need for a shortened Paperwork Reduction Act timeline as an "emergency." In so doing, he demonstrated that he and other Defendants were unalterably committed to acceding to drug company requests to implement rebate models under 340B as a way to deduplicate 340B discounts and the IRA's Medicare Fair Price by January 1, 2026. Defendants' characterization of that January 1 date as an "emergency" indicates that Defendants did not have an open mind about whether to move forward with this so-called "pilot" program, but rather intended to press forward as quickly as possible.

115. Further demonstrating a disregard for the cost side of the equation, the "Request for Emergency Approval" was exclusively focused on what *drug companies* wanted or might do in the absence of a rebate model. For example, Engels stated: "[i]f HRSA does not receive emergency approval, then manufacturers may argue that they do not have the tools they need to effectuate

nonduplication of the MFP and the 340B discount." By contrast, nowhere in Engels' "Request for Emergency Approval" did he indicate any serious concern for the views of other regulated parties like 340B hospitals and other covered entities. Nor did he express any concern about the costs to patients, communities, and comprehensive healthcare in general.

A Lack of Deliberation and Guidance from HRSA Has Resulted in Chaos and Confusion in Advance of the Upcoming January 1 Implementation

116. Unsurprisingly, HRSA's handover of the Rebate Program to drug companies has caused chaos and uncertainty, which will, in turn, impose additional costs and administrative burden on covered entities. These costs and burdens are exacerbated by the exceedingly short time period before the program goes into effect on January 1, 2026.

117. To take one example, on November 20, 2025, Walgreens, the nation's second largest pharmacy chain, announced that it will temporarily stop processing 340B contract pharmacy claims for drugs included in the rebate program. According to public reporting, Walgreens told 340B providers with which it has contracted to distribute drugs that it is diligently working to prepare its systems to support and participate in the rebate program, but the exact timeline for implementing system enhancements is still being determined. Not only will this further prevent 340B hospitals from obtaining vital statutory discounts, but it will hamper patients' ability to obtain drugs closer to where they live—a particular concern for hospitals serving rural populations. Walgreens' decision was a direct result of Defendants' rushed timeline for implementation; even a company of Walgreens' size and resources did not have enough time to update their systems to comply with the rebate model. 340B hospitals fear that other pharmacies will follow Walgreens' example and refuse to process claims for drugs included in the Rebate Program.

118. To take another example, several problems have arisen, as predicted in multiple comment letters, with the drug companies' chosen "Beacon" platform. Following HRSA's approvals, covered entities are now mandated to use the Beacon platform and must agree to Beacon's nonnegotiable terms of use to participate in the 340B program.

119. As predicted by multiple commenters, Beacon's terms are overwhelmingly one-sided and leave covered entities with little legal recourse should the platform fail to function adequately. For example, Beacon's take-it-or-leave-it contract includes a term that limits its aggregate liability for direct damages under the Rebate Program platforms agreements to $1,000. *Beacon Rebate Model Terms of Use*, Beacon (Oct. 1, 2025), available at https://cm.beaconchannelmanagement.com/pages/terms.

120. Given that Beacon will be handling millions of patients' data, as well as the transactions of billions of dollars' worth of claims, this limitation is preposterously low and essentially immunizes Beacon from its own negligence or harm it causes. HRSA has not insisted on any terms that would appropriately hold Beacon responsible in cases of malfeasance.

121. Even more concerning, HRSA is allowing Beacon to harvest and sell the patient data that covered entities must provide as part of this rebate program. This not only allows Beacon to profit enormously from 340B hospitals' data, but it also raises serious questions about compliance with federal and state privacy laws, with downstream consequences for patients and providers.

a. Section 3(a) of Beacon's "Rebate Model Terms of Use" states that covered entities grant a "worldwide, sublicensable, non-exclusive, royalty-free, perpetual, and irrevocable license to collect, process, disclose, create derivative works of, and otherwise use the Rebate Data ('Data License')[.]"

b. Section 3(a) also provides that the "Data License will survive termination of these Terms with respect to any Rebate Data submitted prior to termination." Even if HRSA elects to abandon the "pilot" program after a year, therefore, Beacon is permitted to retain the data for decades for its own commercial purposes. It can sell that data to drug companies, insurance companies, artificial intelligence companies, or anyone else who will recognize the significant value of hospitals' information. HRSA has offered no explanation for why it will allow Beacon to retain *and profit from* this data in the event that the program ends.

122. Upon information and belief, as of the time of the filing of this Complaint, HRSA has not even tested the Beacon platform that is so integral to the Rebate Program.

123. Since the approval of Beacon as HRSA's exclusive platform for the Rebate Program, numerous entities—including 340B vendors and third-party administrators—have warned HRSA of significant technical issues with the Beacon platform due to a lack of testing and completed integration. But HRSA has largely ceded control of the technical implementation of the Rebate Program to the drug companies and their chosen contractor. On information and belief, HRSA has taken no action to address these problems.

Thousands of Hospitals Will Be Immediately and Irreparably Harmed by the 340B Rebate Program

124. HRSA's repeated violations of basic administrative law requirements will irreparably harm thousands of covered entities, especially the most vulnerable safety-net hospitals.

125. Beginning on January 1, 2026, as HRSA itself concedes, covered entities collectively will be required to spend hundreds of millions of dollars in administrative costs. Those costs are unrecoverable. Even today, weeks before the Program is set to go into effect, covered entities are expending substantial resources to comply with an agency action that is unlawful, but

they cannot seek damages from the federal government to recoup these costs. What's more, these costs were known to and ignored by HRSA as it rushed ahead with this Rebate Program to satisfy drug company "inquiries."

126. For instance, as both commenters and Plaintiffs have stated, they will be required to hire or divert staff to deal with the administrative side of the Rebate Program. Even small safety-net hospitals will have to deploy scarce headcount to comply with the new administrative burdens. Plaintiff St. Mary's anticipates needing to hire a full-time employee to handle the administrative burden of the Rebate Program. Plaintiff Nathan Littauer will be hiring one full-time employee due exclusively to the pilot program, and Plaintiff Dallas County Medical Center is hiring two, one in its pharmacy department and another in its accounting department. Covered entities operating on tiny margins (if any margin at all) simply do not have the requisite resources.

127. Any dollar spent on complying with the Rebate Program is one less dollar that hospitals can spend on patient care. As a result of the costs associated with the Rebate Program, covered entities will be required to close service lines, hire fewer clinicians, and delay replacing outdated and unrepairable medical equipment. All of those consequences will harm patients.

128. The safety-net provider Plaintiffs here are each at risk of curtailing services because of the increased costs of Defendants' Rebate Program, such as:

a. Plaintiff St. Mary's' use of its 340B savings to help reduce the price of some outpatient drugs for its patients and to offer an infusion therapy program in which eligible patients receive the drug for free.

b. Other hospitals in Maine that are members of MHA similarly use of their 340B savings to provide financial assistance to patients who cannot afford care; community-based health clinics at schools, nursing homes, and other easy-to-

access locations; and life-saving opioid intervention services (such as the provision of naloxone, suboxone, and methadone), which they will not be able to continue at their current levels if the Rebate Program becomes effective.

c. Plaintiff DCMC's recently opened cancer telehealth clinic, which spares patients the two-hour round-trip to see the nearest oncologist but is unprofitable.

d. Plaintiff Unity Medical Center's recently opened cardiac and pulmonary rehabilitation services.

e. Plaintiff Nathan Littauer Hospital's planned expansion of a new primary care clinic (for which it has already been gifted property).

129. With respect to delaying necessary improvements, for example, Plaintiffs have been unable to move forward with updates to their facilities with the Rebate Program looming. Plaintiff DCMC has been forced to delay critical maintenance on its boiler room and construction of a ramp for disabled patients at its occupational therapy clinic, among other facility improvements. Plaintiff Nathan Littauer Hospital has similarly put its pharmacy build-out on hold. These delays in Plaintiffs' ability to deploy capital for necessary projects causes irreparable harm to them and their missions.

Count I – Administrative Procedure Act

(Rebate Program Is Arbitrary, Capricious, an Abuse of Discretion, or Otherwise Not in Accordance with Law – Failure to Consider Important Aspects of the Problem; Decision Runs Counter to Evidence Before the Agency; Failure to Provide Reasonable Explanation)

130. Plaintiffs repeat, re-allege, and incorporate the allegations in the preceding paragraphs.

131. Defendants' establishment and upcoming January 1, 2026 implementation of the 340B Rebate Model Pilot Program, as well as their approval of drug company applications to participate in that program, are arbitrary and capricious under 5 U.S.C. § 706(2)(A).

132. The APA requires courts to "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), or is "in excess of statutory jurisdiction, authority, or limitations," *id.* § 706(2)(C), or is "unsupported by substantial evidence," *id.* § 706(2)(E); *see also Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 413–15 (1971); *U.S. Sugar Corp. v. EPA*, 113 F.4th 984, 997 (D.C. Cir. 2024).

133. Agency action is arbitrary and capricious if based on an unlawful interpretation of statute or regulations, or if it is "not rational and based on consideration of the relevant factors." *FCC v. Nat'l Citizens Comm. for Broad.*, 436 U.S. 775, 803 (1978). Furthermore, "agency action [must] be reasonable and reasonably explained," *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021), resulting in a "product of reasoned decisionmaking." *State Farm,* 436 U.S. at 52. Arbitrariness and capriciousness also results "if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.* at 43. "These are merely 'examples'" of arbitrary and capricious agency action. *Penobscot Air Services, Ltd. v. FAA*, 164 F.3d 713, 720 (1st Cir. 1999) (quoting *Puerto Rico Sun Oil Co. v. United States EPA*, 8 F.3d 73, 77 (1st Cir. 1993)). "'[O]thers could be recited as well.'" *Id.* (quoting *Dubois v. United States Dep't of Agric.*, 102 F.3d 1273, 1285 (1st Cir. 1996)).

134. These black letter requirements are all the more important when there is a change—or reversal—in an established agency practice because the change can have dramatic effects on relevant parties' reliance interests. When an agency is "not writing on a blank slate," it is "required to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." *DHS v. Regents of the Univ. of Cal.*, 591 U.S. 1, 33 (2020)*; see also Perez v. Mortg. Bankers Ass'n,* 575 U.S. 92, 106 (2015) ("[T]he APA requires an agency to provide more substantial justification when 'its new policy rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests that must be taken into account. It would be arbitrary and capricious to ignore such matters.'" (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)).[11]

135. Defendants have not considered or addressed the interests of the more than 14,000 safety-net hospitals and other covered entities across the country that have relied on upfront discounts for more than 30 years. As HRSA has previously acknowledged, and as was repeatedly noted in the comments HRSA received, covered entities structure key operations and financial decisions on their ability to access drugs at discounted prices through the 340B program *without* a rebate model. They have built their IT systems and designed their contracts with third-party vendors based on an upfront discount model. They have made internal hiring decisions based on this long-standing model. And the thirty-plus year use of an upfront discount model informs covered entities' budgets, allows them to honor their debt covenants with lenders, helps them

[11] Indeed, counsel for the Defendants noted during a November 17, 2025 D.C. Circuit oral argument over drug companies' unilateral efforts to impose 340B rebate models that "*Fox v. FCC* says if you change your position there's a heightened standard for explaining it."

finance the expansion of care through capital-intensive projects, and ensures liquidity with these systems.

136. HRSA knows this. In court filings just months before the announcement of the rebate program, HRSA took the position that it "has long envisioned upfront discounts as the preferred price reduction mechanism" because covered entities "generally preferred a discount system, because they could negotiate lower prices and needed less initial outlay of drug purchasing money." Dkt. 41-1 at 22, *J&J*, No. 24-cv-03188. HRSA has given no reasons for its fundamental change in position, nor has it addressed any of these important reliance interests in creating its new rebate model program.

137. Defendants disrupted thirty-three years of established practice on an unnecessarily hurried timeline, and without considering or responding to important aspects of the problems identified in the more than 1,100 HRSA-solicited comments. As the D.C. Circuit has emphasized, "the failure to respond to significant comments . . . violates a substantive guarantee of the APA.'" *Western Coal Traffic League v. Surface Transp. Bd.*, 998 F.3d 945, 954 (D.C. Cir. 2021); *Marasco & Nesselbush, LLP v. Collins*, 6 F.4th 150, 169 (1st Cir. 2021) ("Importantly, even if the rule is not subject to the notice-and-comment process, it is subject to review under the arbitrary and capricious standard."). Here, the commenters identified a host of serious problems with the rebate model. HRSA failed to consider or provide a reasoned explanation with respect to all of these problems.

138. Defendants also failed to consider comments raising problems with rushing the program into effect on January 1, 2026, despite the clear evidence that the participants will not be prepared to participate by that deadline. Many basic operational questions remain unanswered, even as of the filing of this complaint. On information and belief, for example, Defendants have

not bothered with the most basic implementation steps, such as testing the software platform on which the entire Rebate Program will rely. But, again, Defendants have not acknowledged, much less addressed, the host of operational challenges that have been raised, some of which were the basis for a request for delay. Indeed, as of the filing of this Complaint, HRSA has not provided a single response to—or even an acknowledgment of—any of the more than 1,100 comments (or problems identified therein). These omissions are fatal to the Rebate Program.

139. The APA's substantive requirements to respond to significant comments and not ignore important aspects of the problem exist for an important reason: to ensure that agencies reach the best outcomes. "[P]ublic participation assures that the agency will have before it the facts and information relevant to a particular administrative problem ... [and] increase[s] the likelihood of administrative responsiveness to the needs and concerns of those affected." *Am. Hosp. Ass'n v. Bowen,* 834 F.2d 1037, 1061 (D.C.Cir.1987) (omission in original) (alterations in original) (quoting *Guardian Fed. Sav. & Loan v. Fed. Sav. & Loan Ins. Corp.,* 589 F.2d 658, 662 (D.C.Cir.1978); *cf. Azar v. Allina Health Servs*., 587 U.S. 566, 582 (2019) (requiring agency to consider public comments "affords the agency a chance to avoid errors and make a more informed decision"); *see generally* Eugene Scalia, *The Value of Public Participation in Rulemaking*, The Regulatory Review (Sept. 25, 2017), available at https://www.theregreview.org/2017/09/25/scalia-public-participation-rulemaking/ ("We value public participation in rulemakings in part because it is an opportunity to bring valuable evidence to the agency's attention, to explain effects of a proposed rule that the agency may not have appreciated, and simply to bring a perspective that the agency itself otherwise would not have."). Defendants' abject disregard of public input here underscores Congress' wisdom in enacting these substantive APA requirements.

140. In a litigation filing earlier this year, Defendants appeared to acknowledge this. They emphasized that HRSA "would neglect its duty if it did not consider all aspects of the problem, including . . . how the changes would affect the operations of covered entities and the wellbeing of patients who rely on 340B drugs, before allowing manufactures to redesign the operation of the program." Dkt. 41-1 at 24, *J&J*, No. 24-cv-03188. And yet, months later, HRSA instituted the same changes in the 340B program that it had vociferously opposed, without any explanation. Defendants have, in their own words, neglected their duty.

141. For these reasons, the 340B Rebate Model Pilot Program is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, all in violation of the Administrative Procedure Act.

Count II – Administrative Procedure Act

(Rebate Program Is Arbitrary, Capricious, an Abuse of Discretion, or Otherwise Not in Accordance with Law – Failed to Consider Costs and Benefits, an Important Aspect of the Problem; Decision Runs Counter to Evidence of Costs and Benefits Before the Agency)

142. Plaintiffs repeat, re-allege, and incorporate the allegations in the preceding paragraphs.

143. Defendants' establishment and upcoming January 1, 2026 implementation of the 340B Rebate Model Pilot Program, as well as their approval of drug company applications to participate in that program, are arbitrary and capricious under 5 U.S.C. § 706(2)(A).

144. "Agencies have long treated cost as a centrally relevant factor when deciding whether to regulate. Consideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages and the disadvantages of agency decisions." *Michigan v. EPA*, 576 U.S. 743, 752–53 (2015); *id*. at 769 ("Cost is almost always a relevant—and usually, a highly important—factor in regulation. . . . [A]n agency must take costs into account

in some manner before imposing significant regulatory burdens.") (Kagan, J., dissenting). Thus, a regulation is arbitrary and capricious "if the agency 'failed to consider an important aspect of the problem,'" which "includes, of course, considering the costs and benefits associated with the regulation." *Mexican Gulf Fishing v. U.S. Dep't of Com.*, 60 F.4th 956, 973 (5th Cir. 2023) (quoting *State Farm*, 463 U.S. at 43). As part of that cost-benefit analysis, the agency must identify benefits that "bear a rational relationship to the . . . costs imposed." *Id.* Here, Defendants acted arbitrarily with respect to at least three types of costs: (a) administrative costs; (b) "upfront-payment costs," *i.e.*, costs associated with making full-price payments to drug companies while awaiting a rebate; and (c) non-monetary costs to patients and communities that will result from reduced access to healthcare.[12]

145. *First*, Defendants ignored the massive administrative costs involved with this program. Although Defendants referenced a $200 million estimate of administrative costs, they did not explain how they arrived at that figure. Defendants did not offer any data, surveys, or other empirical evidence to support that number. Indeed, Defendants' only written estimate of costs

[12] *See, e.g.*, *Business Roundtable v. SEC*, 647 F.3d 1144, 1148–49 (D.C. Cir. 2011) ("Here the Commission . . . failed adequately to quantify the certain costs or to explain why those costs could not be quantified; neglected to support its predictive judgments; contradicted itself; and failed to respond to substantial problems raised by commenters. For these and other reasons, its decision to apply the rule to investment companies was also arbitrary."); *id.* at 1152 ("By ducking serious evaluation of the costs that could be imposed upon companies from use of the rule by shareholders representing special interests, particularly union and government pension funds, we think the Commission acted arbitrarily."); *see also Sorenson Commc'ns Inc. v. FCC*, 765 F.3d 37, 50 (D.C. Cir. 2014) ("By adopting the new speed-of-answer metric without evidence of the cost to comply with it, the Commission acted arbitrarily and capriciously."); *Council of Parent Attorneys and Advocates, Inc. v. DeVos*, 365 F.Supp.3d 28, 53–54 (D.D.C. 2019) ("The Delay Regulation is also arbitrary and capricious because the government failed to consider all the relevant factors when considering the cost of the regulation. . . . Here, the government failed to adequately account for two relevant factors—the States' reliance cost and the cost of delay on children, parents, and society.").

seems to be based on a random, finger-in-the-air guess—not the standard that is legally required to impose a transformative regulatory action that departs from more than three decades of practice.

146. Defendants also received—but ignored—evidence that their own estimates of administrative costs were far lower than what will in fact occur. Through both the regular and Paperwork Reduction Act comment processes, Defendants received a variety of cost estimates from covered entities showing that compliance would require hiring staff or diverting significantly more resources than the two-hour-per-week estimate that was underlying Defendants' own cost estimate. As noted, for example, the AHA submitted comment letters identifying administrative costs for 340B hospitals. Likewise, Advocates for Community Health submitted a comment letter during the Paperwork Reduction Act process explaining that "47% of [community health centers] would need to hire 0.5 to 1 full-time equivalent (FTE), 36% estimate needing 1 to 2 FTEs, and 7% project needing more than two FTEs to meet the anticipated demand of reporting 340B rebate claims. Advocates for Cmty. Health, Ltr. to C. Britton (Nov. 12, 2025), available at https://advocatesforcommunityhealth.org/wp-content/uploads/2025/11/ACH-340B-Rebate-Model-Pilot-Program-Application-Implementation-and-Evaluation-OMB.pdf. Commenters also identified other administrative costs, such as additional payments to third-party vendors that would be necessary to comply with the requirements of the new program. Nevertheless, Defendants either ignored or failed to evaluate the benefits of the program against these costs.

147. *Second*, Defendants did not consider or address non-administrative monetary costs associated with a rebate program—the hundreds of millions of dollars' worth of upfront-payment costs imposed on covered entities. Again, HRSA knew these costs were critically important considerations. Even last year, HRSA repeatedly warned drug companies that under a 340B rebate model, "covered entities, including those which primarily serve rural and underserved populations,

would need to pay significantly higher prices on prescription drugs at the time of purchase." 340B_REBATES_000292, 340B_REBATES_000064 (both filed in the *Eli Lilly* Case, Dkt. 60-1). Likewise, HRSA noted concerns "that covered entities, operating with limited cash on hand would have difficulty finding sufficient funds to pay market prices for drugs at every purchase." *Id.* And yet, in announcing the present program, Defendants did not consider, balance, or explain those costs.

148. *Third*, the agency did not consider the non-monetary costs associated with the Rebate Program. For example, it nowhere calculated or considered the impact that the Rebate Program would have on patients and communities due to reduced access to care. Again, Defendants previously criticized drug companies' failure to "conduct[] an evaluation of the impact of this [rebate] proposal on the scope and breadth of health care access for patients served by affected covered entities." *Id.* Yet no such consideration or explanation of the costs to these patients took place prior to implementing the Defendants' Rebate Program.

149. On the other side of the ledger, the agency did not quantify or otherwise explain the benefits of the Rebate Program. Naturally, then, Defendants did not *balance* the (unexplained) benefits against the (undercounted) costs of the Rebate Program. That violates the APA. *E.g.*, *Chamber of Com. v. SEC*, 85 F.4th 760, 777 (5th Cir. 2023) ("[A]s part of that cost-benefit analysis, the agency must identify benefits that 'bear a rational relationship to the ... costs imposed.'" (quoting *Mexican Gulf Fishing*, 60 F.4th at 973)).

150. For these reasons, the 340B Rebate Model Pilot Program is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, all in violation of the Administrative Procedure Act.

Count III – Administrative Procedure Act

(Order Is Arbitrary, Capricious, an Abuse of Discretion, or Otherwise Not in Accordance with Law – Failure to Consider Obvious and Less Burdensome Alternatives)

151. Plaintiffs repeat, re-allege, and incorporate the allegations in the preceding paragraphs.

152. Defendants' establishment and upcoming January 1, 2026 implementation of the 340B Rebate Model Pilot Program, as well as their approval of drug company applications to participate in that program, are arbitrary and capricious under 5 U.S.C. § 706(2)(A).

153. The Rebate Program is invalid because Defendants "fail[ed] to consider 'significant and viable and obvious alternatives.'" *Dist. Hosp. Partners, LP v. Burwell*, 786 F.3d 46, 59 (D.C. Cir. 2015) (quoting *Nat'l Shooting Sports Found., Inc. v. Jones*, 716 F.3d 200, 215 (D.C. Cir. 2013)). There are obvious alternatives to Defendants' decision to impose a rebate model to address a purported interest in deduplication of IRA and 340B Program discounts. Additionally, even if Defendants genuinely wanted to launch a "pilot" program to assess the costs and benefits of a rebate model for the 340B Program, there are numerous obvious and less-burdensome ways to deploy a true pilot program that would not impose hundreds of millions of dollars in costs across approximately 14,600 covered entities, including rural and other safety-net hospitals.

154. As noted in numerous letters Defendants received during comment period, there are obvious alternatives to addressing the concerns about duplicate discounts and diversion without needing to deploy a full rebate model. To take just one example, Plaintiff AHA proposed two versions of a "clearinghouse" that Defendants could have relied on to effectuate its goal of IRA/340B deduplication. Comment ID HRSA-2025-0001-0052. Despite formally adopting one of those "clearinghouses" *the day after* it approved drug company rebate program applications, Defendants did not adopt the less costly, less burdensome, perfectly functional, *co-existing* alternative for the rebate program.

155. Likewise, to the extent that Defendants wished to conduct a "pilot" program, Defendants could have designed a program that is much more limited in scope and burden. Defendants offered no reasons why they did not elect for a more constrained approach.

156. These alternatives were presented to the Defendants throughout the 1,100 comments that it received, but Defendants have not addressed any of these proposed alternatives.

157. For these reasons, the 340B Rebate Model Pilot Program is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, all in violation of the Administrative Procedure Act.

Count IV – Administrative Procedure Act

(Rebate Program Is Substantively Unreasonable)

158. Plaintiffs repeat, re-allege, and incorporate the allegations in the preceding paragraphs.

159. Defendants' establishment and upcoming January 1, 2026 implementation of the 340B Rebate Model Pilot Program, as well as their approval of drug company applications to participate in that program, are arbitrary and capricious under 5 U.S.C. § 706(2)(A).

160. "In arbitrary and capricious cases, [courts] distinguish substantive unreasonableness claims from lack-of-reasoned-explanation claims. A substantive unreasonableness claim ordinarily is an argument that, given the facts, the agency exercised its discretion unreasonably. A decision that the agency's action was substantively unreasonable generally means that, on remand, the agency must exercise its discretion differently and reach a different bottom-line decision." *Multicultural Media, Telecom & Internet Council v. Fed. Commc'ns Comm'n*, 873 F.3d 932, 936 (D.C. Cir. 2017); *see also Penobscot Air Servs., Ltd. v. F.A.A.*, 164 F.3d 713, 719–20 (1st Cir. 1999) ("The reviewing court must 'look to see if the agency

decision, in the context of the record, is too unreasonable (given its statutory and factual context) for the law to permit it to stand.'" (quoting *Sierra Club v. Marsh*, 976 F.2d 763, 769 (1st Cir., 1992)).

161. The Rebate Program is substantively unreasonable because the hundreds of millions of dollars in monetary and non-monetary costs that HRSA would impose on covered entities (and their patients) could never outweigh the limited purported benefits that could come from it. The only justification HRSA has provided for the Rebate Program is that it will aid in deduplicating submissions under the IRA and the 340B Program. It was substantively unreasonable for Defendants to conclude that this narrow goal should cost $200 million or more. *E.g.*, *Thompson v. Clark*, 741 F.2d 401, 405 (D.C. Cir. 1984) ("Thus, if data in the regulatory flexibility analysis—or data anywhere else in the rulemaking record—demonstrates that the rule constitutes such an unreasonable assessment of social costs and benefits as to be arbitrary and capricious, . . . the rule cannot stand."); *see id.* ("For example, if a defective regulatory flexibility analysis caused an agency to underestimate the harm inflicted upon small business to such a degree that, when adjustment is made for the error, that harm clearly outweighs the claimed benefits of the rule, then the rule must be set aside. It is set aside, however, *not* because the regulatory flexibility analysis was defective, but because the mistaken premise reflected in the regulatory flexibility analysis deprives the rule of its required rational support, and thus causes it to violate—not any special obligations imposed by the Regulatory Flexibility Act—but the general legal requirement of reasoned, nonarbitrary decisionmaking[.]").

162. The Program is even more substantively unreasonable given that HRSA views the Rebate Program as a run-of-the-mill "pilot program" (which it is not). Even assuming that it is a typical pilot program, HRSA would force covered entities to bear at least $200 million (and, by

Plaintiffs' calculation, far more) in costs *to simply test* whether a rebate model should be used to deduplicate claims under the IRA and 340B Program. A true "pilot program" should not cost that much. That exorbitant price tag, particularly as compared to the benefits of the Rebate Program, falls outside the "zone of reasonableness." *Multicultural Media, Telecom & Internet Council*, 873 F.3d at 937.

163. The substantive unreasonableness of the Rebate Program is compounded by the fact that it contradicts the purposes of the 340B Program. Rather than allowing 340B hospitals to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services," H.R. Rep. No. 102-384, pt. 2, at 12 (1992), it requires them to spend millions of dollars on administrative costs and divert resources away from patient care. And rather than selecting a payment mechanism that is "most effective and most efficient from the standpoint of each type of "covered entity," *id.* at 16, it imposes one on 340B hospitals that is manifestly ineffective and inefficient. In these respects, HRSA "has failed to exercise its discretion in a reasoned manner" because the Rebate Program is "is unmoored from the purposes and concerns of the [340B] law[]." *Judulang v. Holder*, 565 U.S. 42, 53, 64 (2011).

164. For these reasons, the 340B Rebate Model Pilot Program is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, all in violation of the Administrative Procedure Act.

Count V – Administrative Procedure Act

(Rebate Program Is Arbitrary, Capricious, an Abuse of Discretion, or Otherwise Not in Accordance with Law – Predetermined Result)

165. Plaintiffs repeat, re-allege, and incorporate the allegations in the preceding paragraphs.

166. Defendants' establishment and upcoming January 1, 2026 implementation of the 340B Rebate Model Pilot Program, as well as their approval of drug company applications to participate in that program, are arbitrary and capricious under 5 U.S.C. § 706(2)(A).

167. An agency acts unlawfully if it acts to seek a predetermined result, such that it is "unwilling or unable to rationally consider counterarguments." *New York v. U.S. Dep't of Com.*, 351 F. Supp. 3d 502, 663 (S.D.N.Y. 2019) (citation and internal quotation marks omitted), *aff'd in part, rev'd in part on other grounds*, 588 U.S. 752 (2019); *see Kravitz v. United States Dep't of Com.*, 366 F.Supp.3d 681, 750 (D. Md. 2019) (finding agency action to be unlawful where "Administrative Record ultimately shows that the citizenship question was the Secretary's predetermined answer to a question that he and his staff solicited"); *cf. Davis v. Mineta*, 302 F.3d 1104, 1112–13 (10th Cir. 2002) (granting relief on the ground that the agency had prejudged the decision at issue and conducted "an evidently *pro forma* public opportunity to comment"), *abrogated on other grounds by Dine Citizens Against Ruining our Env't v. Jewell*, 839 F.3d 1276 (10th Cir. 2016).

168. Defendants' actions demonstrate an unlawful commitment to a predetermined result. The following facts, among others, amply support that conclusion.

169. *First*, Defendants' total failure to respond to any comments identifying problems with the rebate program is strong evidence of their closed-mindedness.

170. *Second*, Defendant Engels' August 25, 2025 "Request for Emergency Approval" to OIRA evidences that Defendants were unalterably committed to acceding to drug company demands to "implement[] rebate models under 340B." Defendants' characterization of the January 1, 2026 effective date as an "emergency" shows that Defendants did not have an open mind about whether to move forward with this so-called "pilot" program. Agencies typically do not use pilot

programs to address "emergencies." And a true pilot program designed for testing the rebate model could have started at any time.

171. In reality, there was no real "emergency." Defendants' subsequent approval of an April 1, 2026 start-date for Novartis' rebate model severely undermines that assertion. Ultimately, Defendants' stated (but false) rationale that there was an "emergency" demonstrates that they were never going to reconsider their ill-advised and underdeveloped Rebate Program.

172. It is telling, moreover, that the "Request for Emergency Approval" was exclusively focused on what *drug companies* wanted. For example, Defendant Engels noted: "[i]f HRSA does not receive emergency approval, then manufacturers may argue that they do not have the tools they need to effectuate nonduplication of the MFP and the 340B discount." By contrast, at no point in Defendant Engels' "Request for Emergency Approval" did he indicate that Defendants had any concern for the views of *other regulated entities* like hospitals and health systems. Again, this indicates that Defendants were unalterably committed to acceding to *drug company* demands for a rebate model, no matter how many problems or reasonable alternatives *covered entities* identified.

173. *Third*, Defendants approved nine drug company applications *weeks before* the Paperwork Reduction Act comment period had even closed. This, too, is powerful evidence that cost was no object. Defendants were going to proceed with their predetermined Rebate Program no matter the cost or burden on covered entities.

174. This evidence proves that Defendants conducted a *pro forma* solicitation of public comments but, in reality, were unwilling to rationally consider counterarguments to their predetermined Rebate Program.

175. For these reasons, the 340B Rebate Model Pilot Program is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, all in violation of the Administrative Procedure Act.

Prayer for Relief

Wherefore, Plaintiffs respectfully request that this Court declare that the 340B Rebate Model Pilot Program is unlawful; "set aside" the 340B Rebate Model Pilot Program under 5 U.S.C. § 706(2)(A); and award any other relief the Court deems necessary and just, including as appropriate using its equitable powers to enter orders providing:

A. The Rebate Program is permanently enjoined as unlawful and invalid;

B. Defendants are enjoined from implementing or giving effect to the Rebate Program in any way; and

C. Defendants are directed to rescind any and all statements, guidance, or direction that has already issued that relates to announcing, implementing, or enforcing the Program, including Frequently Asked Questions, as they pertain to the Rebate Program.

Dated: December 1, 2025

Respectfully submitted,

/s/ Melissa A. Hewey

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**Pro hac vice certification forthcoming.*
***Admitted in NY only; practice supervised by members of D.C. Bar. Pro hac vice application forthcoming.*

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER, Plaintiffs, v. ROBERT F. KENNEDY, JR. Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA, Defendants.	Case No. **MOTION FOR TEMPORARY RESTRAINING ORDER WITH INCORPORATED MEMORANDUM OF LAW** **REQUEST FOR IMMEDIATE RELIEF**

INTRODUCTION

More than three decades ago, Congress created a drug pricing program that is a financial lifeline for safety-net healthcare providers. This lifeline, known as the "340B Program," is now in serious jeopardy due to a hastily made, ill-considered, and unlawful decision by the U.S. Department of Health and Human Services ("HHS") and its agency, the Health Resources and Services Administration ("HRSA"). Hospitals in Maine and across America serving rural and other underserved communities now face imminent and irreparable injury, both in hundreds of millions of dollars in costs they cannot afford and inevitable disruptions to patient care. With the situation becoming increasingly dire, judicial intervention is necessary.

Defendants recently announced a program—the "340B Rebate Model Pilot Program" ("Rebate Program")—that would force safety-net hospitals to pay "significantly higher prices" to drug companies starting on January 1, 2026. *See* Ex. 1 at -66. Stunningly, Defendants just last year stopped drug companies from enacting similar programs, noting that rebates would "disrupt how the 340B program has operated for over thirty years" and citing a litany of cost- and burden-related issues. *Id.* Defendants now try to impose the same costs and burdens without addressing these concerns or explaining their about-face. Indeed, Defendants received over 1,100 public comments on their program, but as of this filing, have not responded to any. Instead, they are racing to a January 1 start date that will have calamitous effects on safety-net hospitals and their patients.

Defendants' actions violate the most basic and well-established principles of administrative law. The decisions to reverse course on a 33-year policy without explanation and leave 1,100 comments fully unconsidered are paradigmatically "arbitrary and capricious." *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983). Defendants have not offered any well-reasoned explanation. *FCC v. Prometheus Radio Project*, 592 U.S. 414,

423 (2021). They have not accounted for the reliance interests of thousands of safety-net providers in underserved communities. *DHS v. Regents of the Univ. of Cal.*, 591 U.S. 1, 33 (2020). They have not considered massive costs that threaten to close these providers. *Mexican Gulf Fishing Co. v. U.S. Dep't of Com.*, 60 F.4th 956, 973 (5th Cir. 2023). In failing to properly weigh costs and benefits, not only have Defendants ignored an "important aspect of the problem," *Ohio v. EPA*, 603 U.S. 279, 293 (2024) (citation omitted), but their program is "substantively unreasonable," *Multicultural Media, Telecom & Internet Council v. FCC*, 873 F.3d 932, 936 (D.C. Cir. 2017). And they have not considered obvious and less burdensome alternatives, *Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 59 (D.C. Cir. 2015), instead improperly resorting to predetermined results, *New York v. U.S. Dep't of Com.*, 351 F. Supp. 3d 502, 663 (S.D.N.Y. 2019), *aff'd in part, rev'd in part on other grounds*, 588 U.S. 752 (2019).

Plaintiffs are safety-net hospitals that rely on the 340B Program and membership organizations representing more than 2,000 340B providers. Compl. ¶¶ 13–18. Defendants' decision to hastily implement this unlawful Rebate Program is causing irreparable harm to the very providers the 340B Program is meant to support. Struggling hospitals will spend millions of dollars to comply with this unlawful program, none of which can be recovered. And hospital money earmarked for patient care instead will now be diverted to drug companies, inhibiting providers' ability to fulfill their missions and deliver healthcare to the neediest Americans. Plaintiffs therefore ask this Court to issue a temporary restraining order. *See* Fed. R. Civ. P. 65.

BACKGROUND

Congress created the 340B Drug Pricing Program in 1992 to give safety-net healthcare providers (known as "covered entities"[1]) access to prescription drugs at significantly discounted

[1] Covered entities include, for example, federally qualified health centers and hospitals that serve a disproportionate share of Medicare, Medicaid, and low income and uninsured patients. 42 U.S.C. § 256b(a)(4).

prices. Pub. L. No. 102-585 § 602 (1992). Under the 340B Program, HRSA calculates a "ceiling price" to set the maximum price drug companies can charge 340B providers. 42 U.S.C. § 256b(a)(1). This ceiling price is a fraction of what drug companies would otherwise charge. To encourage drug company participation in the 340B Program, Congress conditioned federal health insurance coverage of their products on participation. *Id.* § 1396r-8(a)(1); *id.* § 256b(a).

Since the 340B Program's inception, Defendants have required drug companies to provide statutory discounts at the time of the sale, a requirement known as the "upfront discount." *See* 42 U.S.C. § 256b(a)(1); 58 Fed. Reg. 27289, 27291–92 (May 7, 1993). Many 340B providers operate on thin (or negative) margins and cannot afford market prices for drugs without sacrificing patient care. Golder Decl. ¶ 36. The upfront discount honors the 340B Program's purpose by allowing 340B providers "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2, at 12 (1992).

Over the years, drug companies have repeatedly tried to institute a "rebate" model, under which safety-net providers would be forced to pay them full market price, known as the wholesale acquisition cost ("WAC"), and then seek reimbursement for the difference between the WAC and "ceiling price" only after administering the drugs and submitting detailed claims data to the drug companies. Such a change would impose millions, if not billions, of dollars of costs on covered entities. *First*, a rebate system would involve vast administrative costs to submit, track, recover, and potentially resolve disputes over rebates. *Second*, it would force 340B hospitals to essentially provide drug companies with interest-free loans while awaiting refunds due by law. *Third*, a rebate system would allow drug companies to slow and stymie rebates, thereby withholding statutorily owed discounts based on technicalities and other mischief. *See* Golder Decl. ¶¶ 22, 28, 30–38.

HRSA has historically rejected drug companies' rebate proposals and required upfront

discounts. In 2024, for example, HRSA stopped multiple drug companies from deploying rebate programs. In doing so, HRSA articulated numerous costs and drawbacks of a rebate model. *E.g.*, Compl. ¶¶ 43–46, 48; Ex. 1 at -66; Ex. 4 at -292; Ex. 5 at -342. It told companies that a "shift [to a rebate model] would disrupt how the 340B Program has operated for over thirty years. As a result of this shift, covered entities, including those which primarily serve rural and underserved populations, would need to pay significantly higher prices on prescription drugs at the time of purchase." *Id.* HRSA identified multiple concerns about abandoning the upfront discount model, including: (1) how a rebate model would affect "the scope and breadth of health care access for patients served by affected covered entities"; (2) how it would add burdens for covered entities, "particularly those that are the sole or primary source of health care in a rural or underserved community"; (3) the grounds on which a drug company would deny a rebate claim; (4) what process would govern the adjudication of disputes about rebates and appeals of denials; (5) how drug companies planned to protect claims information they collect; and (6) how the companies planned to issue refunds. Ex. 1 at -66–68; Ex. 4 at -292–94; Ex. 5 at -342–44.

Several drug companies sued Defendants.[2] While defending themselves, Defendants again repeatedly noted the risks and costs of introducing rebate models to the 340B Program. For example, in litigation against Johnson & Johnson ("J&J"), Defendants noted in April 2025 that HRSA "has long envisioned upfront discounts as the preferred price reduction mechanism" and that a rebate model "would 'create significantly higher up-front costs for covered entities.'" Dkt. 41-1 at 18–20, *J&J v. Kennedy*, No. 1:24-cv-03188 (D.D.C. Apr. 2, 2025).[3] In an August 1, 2025

[2] *See* Doc. 2128443 at i–iv, *Novartis Pharms. Corp. v. Kennedy*, No. 25-5177 (D.C. Cir. Aug. 1, 2025).

[3] The presiding courts in these cases agreed, explaining that covered entities would "be forced to incur higher carrying costs for these drugs, essentially floating revenue to drug manufacturers" and "reduc[ing] the hospitals' resources available for other patient care." *J&J Health Care Sys. Inc. v. Kennedy*, 2025 WL 1783901, at *12–13 (D.D.C. June 27, 2025) (alteration in original); *see also Eli Lilly & Co v. Kennedy*, 2025 WL 1423630, at *12 (D.D.C. May 15, 2025) ("[T]the impact of a rebate float was a relevant factor the agency was entitled to take into consideration.").

brief filed with the D.C. Circuit, Defendants further flagged concerns, noting that "[u]nlike discounts, rebates require covered entities to spend more money upfront and put greater financial pressure on those safety-net programs." Doc. 2128443 at 2, *Novartis Pharms. Corp.*, No. 25-5177.

But at the same time Defendants were highlighting the risks of a rebate model in court, HRSA abruptly launched a 340B rebate program that would have a devastating impact on 340B providers and their patients. On July 31, 2025, HRSA announced a new "340B Rebate Model Pilot Program," followed by a notice in the *Federal Register* ("Notice"). The Notice stated Defendants would allow certain drug companies to mandate 340B rebate pricing for specific drugs, effective January 1, 2026. 90 Fed. Reg. 36163 (Aug. 1, 2025). Covered entities would be required to purchase drugs at full WAC, and wait for a rebate to be issued by the drug company—the exact arrangement HRSA had objected to before. Moreover, the announced Rebate Program was a "pilot" in name only; the Notice provided the program would cover all 14,600 covered entities and involve ten critical and common drugs. *See* Compl. ¶¶ 7, 56.

Despite recognizing that a change from an upfront discount to a rebate model could have a seismic, harmful effect on 340B hospitals, HRSA's Notice contained no serious justification or explanation for the Rebate Program. The Notice stated that HRSA had "received inquiries" from drug companies about implementation of new "Maximum Fair Prices" for certain drugs under the CMS Medicare Drug Price Negotiation Selected List. *See* 90 Fed. Reg. at 38165. But the Notice did not elaborate on why such a convoluted Rebate Program involving the transfer of hundreds of millions of dollars was needed to address deduplication concerns for that program. *See* Compl. ¶¶ 55, 58. It did not consider or address 340B providers' longstanding operational reliance on upfront discounts, nor the economic costs that would result from a sudden shift to a rebate model. *Id.* ¶¶ 57, 63–71. It also did not address the impact on patient care that would result from a move to a

rebate model. *Id*. ¶¶ 62, 71, 82–83, 107. Finally, the Notice did not consider any of the obvious and less costly alternatives to the proposed Rebate Program. *Id*. ¶¶ 56, 60, 87–91.

The Notice solicited comments, and Defendants received many—over 1,100 within the 31-day period. Commenters detailed the costs and burdens that the Rebate Program will impose on covered entities and their patients—none of which were discussed in the Notice. *See, e.g*., Ex. 8 at 13–14; Ex. 17 at 2–3; Ex. 21 at 1–2. Several commenters focused on the calamitous effects of cash-strapped covered entities having to float billions to the drug industry while waiting for their 340B discounts. *See, e.g.*, Ex. 18 at 6; Ex. 10 at 3; Ex. 14 at 1–2. Commenters flagged concerns with HRSA's chosen "Beacon" software platform. *See, e.g*., Ex. 16 at 11–12. Commenters submitted alternatives to the Rebate Program that would address the underlying concerns flagged by HRSA in its Notice. *See, e.g*., Ex. 8 at 5; Ex. 13 at 2. Commenters also highlighted less costly alternatives to the structure of HRSA's Rebate Program. *See, e.g*., Ex. 16 at 8; Ex. 17 at 3–4.

Defendants ignored all 1,100 comments. HRSA did not update its Notice, respond to comments in its online FAQs,[4] or take any other steps to address the many problems the public raised. As of the date of filing this Motion, HRSA has yet to address, among others: (a) HRSA's about-face on its position regarding the downsides of a 340B rebate model; (b) the staggering costs of the proposed rebate program; (c) the obvious, less burdensome alternatives that would address Defendants' stated goals; and (d) other obvious problems, from the lack of a functional dispute resolution process (a concern HRSA itself had raised in 2024) to the outrageous conditions imposed by the drug companies' chosen software vendor to the risks of implementing this Rebate Program on such a hurried timeline. Compl. ¶¶ 72–100; Golder Decl. ¶¶ 24–25, 29–33.

[4] After publishing the Notice, HRSA made a website about the Rebate Program on which it included Frequently Asked Questions (FAQs). *See* HRSA, *340B Rebate Model Pilot Program* (Nov. 2025), https://www.hrsa.gov/opa/340b-model-pilot-program. The FAQs, however, do not address any of the issues above. Compl. ¶ 60.

Rather than answer any of the 1,100 comments they received, Defendants have barreled ahead with the program, risking significant disruption to healthcare in Maine and across the country at the beginning of the new year. Between October 30 and November 14, 2025, HRSA approved the rebate program applications that were privately submitted by nine eligible drug companies for ten drugs. All ten drugs are high-volume, high-cost brand-name drugs, and if 340B providers' supply of these drugs is disrupted under the Rebate Program—for example, if safety-net providers cannot pay the new massive upfront costs—then patients' health and lives will be at risk. Compl. ¶ 62. All ten drugs will impose, in the prior words of HRSA, "significantly higher up-front costs for covered entities," Dkt. 41-1 at 18–19, *J&J*, No. 1:24-cv-03188, and "cause unprecedented disruption to the [340B] program," Dkt. 35-1 at 20, *Eli Lilly*, No. 1:24-cv-03220.

Defendants' operational roll-out of their Rebate Program has been alarmingly deficient, and the program is at significant risk of failure come January 1. On information and belief, Defendants have not even tested the software platform on which the entire Rebate Program relies. Golder Decl. ¶ 32. Likewise, they have ignored that the software operator is claiming the right to retain and monetize all data given to it by 340B providers, posing cybersecurity and data privacy risks (an issue HRSA flagged in its 2024 letters to drug companies). Compl. ¶¶ 44, 118–20.

Even before the Rebate Program takes effect, 340B providers, like Plaintiffs, are suffering harmful costs and disruptions. The prospect of multi-million-dollar financial outlays to drug companies is forcing 340B providers to pause key service improvements and projects, from providing new patient services to refreshing lifesaving equipment. Providers also are assuming new costs, including hiring personnel and vendors to handle the massive administrative burden associated with the Rebate Program. *See infra* pp. 16–19. Without immediate intervention by this Court, patients and 340B providers will irreversibly bear the costs of the unlawful Rebate Program.

LEGAL STANDARD AND REVIEWABILITY

The purpose of preliminary relief is to "preserve the relative positions of the parties until a trial on the merits can be held." *Starbucks Corp. v. McKinney*, 602 U.S. 339, 346 (2024) (citation omitted). A district court may grant a temporary restraining order when a movant shows "(1) it is likely to succeed on the merits; (2) it is likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in its favor; and (4) an injunction is in the public interest." *Doe v. Trump*, 157 F. 4th 36, 46 (1st Cir. 2025) (cleaned up); *Monga v. Nat'l Endowment for Arts*, 323 F. Supp. 3d 75, 82 (D. Me. 2018) (temporary restraining order test same as for preliminary injunction). When the government is the opposing party, the balance-of-equities and public-interest factors merge. *See, e.g.*, *Nken v. Holder*, 556 U.S. 418, 435 (2009).

HRSA's 340B Rebate Program is reviewable under the Administrative Procedure Act ("APA") as a final agency action for which there is no other remedy. 5 U.S.C. § 704. The Rebate Program is set to take effect on January 1, and HRSA has already approved nine drug companies' rebate plans for ten drugs.[5] The hospital Plaintiffs, as well as many other 340B providers that belong to Plaintiffs AHA and MHA, are experiencing the program's "effects" in a very "concrete way," as they begin to bear costs of complying with the Rebate Program. *Nat'l Park Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 807–08 (2003) (citation omitted). The issues raised in this motion are ripe, and "the hardship" to Plaintiffs "of withholding court consideration" until later would be immense. *Saline Parents v. Garland*, 88 F.4th 298, 306 (D.C. Cir. 2023) (citation omitted).

ARGUMENT

All four factors weigh heavily in favor of Plaintiffs. *First*, Plaintiffs are likely to succeed on the merits of their APA claims because, among other things: (a) Defendants' explanation for the

[5] Novartis Pharmaceuticals Corp.'s plan for the drug Entresto has also been approved, but for an April 1, 2026 start. *See* Compl. ¶ 105. There is therefore nothing magical about Defendants' January 1, 2026 deadline.

Rebate Program lacks sufficient justification and ignores the decades-long reliance interests on the upfront discount model; (b) Defendants ignored critical, material information raised in comments, thereby ignoring important aspects of the problem, including costs and benefits; and (c) Defendants disregarded reasonable alternatives. *Second*, Plaintiffs face severe, imminent, and irreparable harm in the absence of preliminary relief. In addition to imposing unrecoverable financial losses upon Plaintiffs, the Rebate Program now impairs both their operations and their ability to fulfill their missions of providing care to rural and underserved populations. *Finally*, the balance of the equities and the public interest support preliminary relief to protect public access to healthcare and pause Defendants' unlawful agency action.

I. Plaintiffs Are Likely to Prevail on the Merits of Their APA Claims.

Plaintiffs will likely succeed on their claims because Defendants failed to follow basic principles of administrative law, which require consideration of reliance interests, material comments, costs, and less burdensome alternatives. Defendants also failed to address key issues they have raised about rebate models, including in 2024 letters to drug companies and court filings *this year*. An agency acts arbitrarily and capriciously, in violation of the APA, when it "entirely fail[s] to consider an important aspect of the problem, offer[s] an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *State Farm,* 463 U.S. at 43.

A. *Defendants Offered No Justification for Abandoning the Upfront Discount Model and Ignored Decades of Reliance by Thousands of Healthcare Providers.*

Defendants have offered no reasonable explanation for instituting the Rebate Program. "[A]gency action [must] be reasonable and reasonably explained," *Prometheus Radio Project*, 592 U.S. at 423, and a "product of reasoned decisionmaking." *State Farm,* 463 U.S. at 52. Critically, when an agency reverses its prior policies, as here, the Supreme Court has held that the APA

requires "more detailed justification than what would suffice for a new policy created on a blank slate," particularly "when its prior policy has engendered serious reliance interests." *Fox Television Stations, Inc.*, 556 U.S. at 515. In explaining a policy change, the agency is "required to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." *Regents of the Univ. of Cal.*, 591 U.S. at 33.

Defendants devote, at most, a few sentences in their Notice to explaining the rationale for the Rebate Program. 90 Fed. Reg. 38165. The Notice claims Defendants are "introducing this pilot program to test the rebate model on a select group of drugs." *Id.* Though muddled in the Notice, the agency indicated a desire to address deduplication of discounts between the 340B and Medicare programs (*i.e.*, a way of ensuring two discounts are not applied to the same drug when only one is permitted).[6] Defendants never publicly supplemented their reasoning after issuing the Notice.

This barebones explanation falls far short of the reasoned decision-making demanded by the APA, because "statements of aspirational goals are not the same as reasoned explanations for why an action is chosen or how the chosen action will effectuate the stated goals." *Ass'n of Am. Univ. v. Nat'l Sci. Found.*, 788 F. Supp. 3d 106, 136 (D. Mass. 2025). Here, there is no discussion, for example, of why it is necessary to implement the program this way, what costs and benefits might be relevant, or how patients could be affected. "The reasoned explanation requirement" is "meant to ensure that agencies offer genuine justifications . . . that can be scrutinized by courts and the interested public." *Dep't of Com.*, 588 U.S. at 785. "The failure to provide any type of reasoning renders the [challenged] Notice arbitrary and capricious." *Massachusetts v. NIH*, 770 F. Supp. 3d 277, 306 (D. Mass. 2025).

[6] The Notice says that HRSA has received inquiries about proposed rebate models "primarily to address 340B and Maximum Fair Price (MFP) deduplication, but also to facilitate other aims such as the prevention of 340B Medicaid duplicate discounts and diversion." *Id.* (footnote omitted). The Notice does not, however, say the latter goals motivated the Rebate Program; in fact, Criterion #13 bars drug companies from denying rebates on those bases. *Id.*

Defendants' reasoning would be inadequate even if this were a new policy written on a blank state, but Defendants utterly failed to provide the "more substantial justification" required for a changed policy. *Mortg. Bankers Ass'n*, 575 U.S. at 106. Where, as here, an agency reverses itself, it must "show that there are good reasons for the new policy." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016). "In such cases it is not that further justification is demanded by the mere fact of policy change; but that a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy." *Id.* at 222. Defendants offered no such explanation here.

In proposing to abandon a 33-year policy, Defendants also made no examination of the reliance interests 340B hospitals have developed, how significant those interests are, and how those interests weigh against competing policy aims. *See Regents of the Univ. of Cal.*, 591 U.S. at 33. This absence is even more confounding since Defendants have acknowledged 340B providers' reliance on the upfront discount model this year. *See, e.g.*, Dkt. 35-1 at 19*, Eli Lilly,* No. 1:24-cv-3220 ("Covered entities generally preferred a discount system, because they could negotiate lower prices and needed less initial outlay of drug purchasing money."). This disregard of reliance interests further proves that Defendants violated the APA's most basic requirements.

B. *Defendants Improperly Ignored Over 1,100 Comments Identifying Significant Problems with the Rebate Program.*

Defendants received over 1,100 comments identifying a multitude of problems with the Rebate Program and the negative ramifications it could have for the 340B Program. Defendants have not responded to a single comment, which is definitionally arbitrary and capricious.

In the Notice, Defendants stated that they were "under no obligation to respond to or act on the comments." 90 Fed. Reg. 38165. That is emphatically incorrect.[7] "[T]he failure to respond

[7] Tellingly, far as Plaintiffs can tell, a disclaimer about being under no obligation to respond or act on comments has

to significant comments . . . violates a substantive guarantee of the APA." *W. Coal Traffic League v. Surface Transp. Bd.*, 998 F.3d 945, 954 (D.C. Cir. 2021); *see also Marasco & Nesselbush, LLP v. Collins*, 6 F.4th 150, 169 (1st Cir. 2021) ("[E]ven if the rule is not subject to the notice-and-comment process, it is subject to review under the arbitrary and capricious standard."); *see generally Ohio*, 603 U.S. at 293, 298 (discussing substantive APA standards and holding that "EPA failed to address an important problem the public could and did raise during the comment period").

Aside from the Notice's revealing misstatement of the law, Defendants' silence in response to 1,100 comments proves they gave no adequate consideration to "important aspect[s] of the problem," *State Farm,* 463 U.S. at 43, particularly since these comments identified a host of problems with the Rebate Program. For example, commenters explained (a) that HRSA vastly underestimated the burdens that this program will impose on 340B hospitals, particularly as compared to the purported benefits; (b) that 340B providers could not be ready for a January 1 start date; (c) that there will be serious negative consequences for healthcare access, particularly in rural areas; (d) the absence of a functional dispute resolution mechanism; (e) that the chosen "Beacon" software platform is deeply flawed; and (f) that there are obvious, less burdensome alternatives. Compl. ¶¶ 72–100; Exs. 8–28. Total silence in response to this avalanche of identified problems makes this action straightforwardly unlawful.

C. *Defendants Ignored the Scale of the Rebate Program's Costs, Including as Compared to Its Benefits.*

In promulgating the Rebate Program, Defendants ignored at least two types of significant monetary costs: (a) administrative costs and (b) costs associated with making full-price upfront payments to drug companies. Defendants also ignored critical non-monetary costs to patients and communities that will result from reduced access to healthcare. Given the magnitude of these costs,

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never appeared elsewhere in the *Federal Register*.

Defendants' failure to appropriately consider them plainly violates the APA.

As the Supreme Court has held, "[a]gencies have long treated cost as a centrally relevant factor when deciding whether to regulate. Consideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages and the disadvantages of agency decisions." *Michigan v. EPA*, 576 U.S. 743, 752–53 (2015). A regulation is arbitrary and capricious "if the agency 'failed to consider an important aspect of the problem,'" which "includes, of course, considering the costs and benefits associated with the regulation." *Mexican Gulf Fishing*, 60 F.4th at 973 (quoting *State Farm*, 463 U.S. at 43). As part of its analysis, the agency must identify benefits that "bear a rational relationship to the . . . costs imposed." *Id.* Here, no such analysis happened for *any* of the significant costs inherent to the Rebate Program.

Administrative Costs: Neither the Notice nor the FAQs discussed the administrative costs to 340B providers. Defendants' only mention of administrative costs that has become public is in a memorandum they submitted to the Office of Management and Budget (OMB).[8] In that document, Defendants estimated the administrative burden on 340B providers to be $200,428,800 per year.[9] While a staggering amount in itself, the number grossly understates the true cost.

First, Defendants based their cost estimate on an assumption that covered entities will need to spend only two hours per week complying with the Rebate Program. This assumption appears to have been a wild guess that was never empirically evaluated. Defendants never explained how they arrived at that figure. They received a multitude of data in comments showing that compliance

[8] Under the Paperwork Reduction Act of 1995, HRSA was required to calculate the burden and time that would be expended by affected entities to generate, maintain, retain, disclose, or provide the data requested. 44 U.S.C. § 3506(c). HRSA did so in a Supporting Statement to an August 2025 Information Collection Request (ICR) submitted to OMB's Office of Information and Regulatory Affairs (OIRA). Ex. 30. In the ICR Supporting Statement, HRSA estimated the proposed Rebate Program would require covered entities to expend over *1.5 million hours* in 2026 to comply with the data collection requirements, which HRSA calculated would amount to over $200 million in costs. *Id.* at 6.

[9] To arrive at the figure, Defendants multiplied the (a) current number of covered entities (14,600), (b) an estimated 2 hours per week of compliance work, (c) 52 weeks in a year, and (d) the average hourly wage rate for pharmacists (as reported by Bureau of Labor Statistics data), totaling $200,428,800. *Id.*

would require much more than two hours per week, including that many covered entities would need to hire entirely new full-time staff to facilitate compliance. *See, e.g.*, Ex. 8 at 13–14; Ex. 17 at 2–3; Ex. 21. Defendants ignored this evidence that the $200 million was low by orders of magnitude, and they never updated their assessment of the administrative costs.

Second, Defendants never identified, evaluated, or quantified benefits that "bear a rational relationship" to costs imposed by the Rebate Program. *Mexican Gulf Fishing*, 60 F.4th at 973. Put differently, Defendants privately (under-)calculated a $200 million administrative cost but never explained why that cost, if true, would be worth any (uncalculated) benefits of the Rebate Program.

Costs of Upfront Full-Price Payments: Defendants' $200 million calculation exclusively focuses on administrative costs, but a rebate program imposes other significant costs: upfront payments for drugs. As Defendants wrote last year, "[a]s a result of this shift [to a rebate model], covered entities, including those which primarily serve rural and underserved populations, would need to pay significantly higher prices on prescription drugs at the time of purchase." Ex. 1 at -66; Ex. 4 at -292; Ex. 5 at -342; *see also* Ex. 18 at 6; Ex. 10 at 3; Ex. 14. The costs to 340B providers of paying significantly higher prices to drug companies is an issue that Defendants *never* address in the Notice or FAQs. Nor did they respond to comments showing those costs would amount to hundreds of millions.[10] There was no effort to quantify these upfront payment costs that Defendants have historically conceded would be significant (and would favor the discount model).

Non-Monetary Costs: Defendants also failed to address how the Rebate Program might impact patient care, the availability of life-saving drugs, participation in the 340B Program, or the long-term viability of 340B providers—all of which are affected by the dramatic increase in costs imposed by the Rebate Program. These non-monetary costs are relevant factors and "important

[10] For example, one commenter calculated that a set of 81 covered entities would have needed to float drug companies more than $348 million under the rebate model during the first half of 2025 had the program been in effect. Ex. 9.

aspect[s] of the problem." *State Farm,* 463 U.S. 29 at 43; Compl. ¶ 51 n.1.

D. *Defendants Failed to Consider Any of the Significant, Viable, or Obvious Alternative Options and Improperly Sought a Predetermined Result.*

Several stakeholders submitted comments that identified alternatives to the Rebate Program that would address the underlying concerns flagged in the Notice. By ignoring these comments, Defendants "fail[ed] to consider 'significant and viable and obvious alternatives.'" *Dist. Hosp. Partners*, 786 F.3d at 59 (citation omitted); *see Stauffer v. Internal Revenue Serv.*, 285 F. Supp. 3d 474, 485 (D. Mass. 2017) ("the agency must explain why it rejected 'reasonably obvious' alternatives"); *Ass'n of Am. Univ. v. Dep't of Def.*, 792 F. Supp. 3d 143, 170 (D. Mass. 2025). The proposed alternatives can be divided into two categories: (1) less burdensome alternatives to a rebate model that would address the reason why Defendants claimed the Rebate Program was necessary, and (2) less burdensome "pilot programs" that would avoid tens, if not hundreds, of millions of dollars in compliance and upfront payment costs over the next year. Defendants' failure to consider these alternatives constitutes unreasonable decision-making.

Alternatives to the Rebate Model: Commenters submitted several alternatives to the Rebate Program that would address HRSA's rationale for it. Compl. ¶¶ 87–88. To take just one example, Plaintiff AHA noted that IRA/340B deduplication could be done via a government-backed "clearinghouse" to exchange information between covered entities and drug companies, which would achieve the purported goal of this program without requiring safety-net hospitals to pay millions of dollars in administrative costs and full price upfront drug payments. Ex. 8 at 5; Ex. 13 at 2. In fact, Plaintiff AHA noted that CMS recently adopted the same "340B claims data repository" to address a similar IRA/340B deduplication concern. Ex. 8 at 5; Compl. ¶ 88. In fact, Defendants formally adopted that particular "clearinghouse" *right after* they approved drug company applications for the Rebate Program. Yet Defendants ignored this and other alternatives.

Alternative Pilot Programs: Commenters also highlighted less costly alternatives to the structure of HRSA's all-encompassing so-called "pilot" program. Compl. ¶¶ 89–91. They noted that HRSA should have begun with a more limited scope of covered entities, consistent with the past practice of federal healthcare agencies. For example, commenters noted that the Notice failed to consider whether the Rebate Program's goals could be achieved through a pilot program open to covered entity *volunteers*. Ex. 16 at 8. Alternatively, commenters proposed limiting the Rebate Program to Medicare Part D patients, who were the only ones at risk of duplication. Ex. 17 at 3–4. Commenters separately noted that a pilot could be narrowed to a smaller subset of drugs that would foist fewer administrative and upfront costs on safety-net providers. Ex. 16 at 8.

Any of these alternatives would have reduced the significant costs to 340B hospitals, as well as the concomitant risks to patient care. Yet Defendants ignored every possible alternative proposed and instead stormed forward with the Rebate Program without any notable change in design. Indeed, what is clear from the agency process—or lack thereof—is that Defendants never actually intended to, and did not, engage in an open-minded decision-making process. Instead, the outcome was predetermined by Defendants, such that they were "unwilling or unable to rationally consider counterarguments." *Dep't of Com.*, 351 F. Supp. 3d at 663; *see* Compl. ¶¶ 113, 167–73.

II. Plaintiffs Will Suffer Irreparable Harm Without Immediate Injunctive Relief.

A plaintiff seeking preliminary relief must show "a cognizable threat" of "a substantial injury that is not accurately measurable or adequately compensable by money damages" and thus constitutes irreparable harm. *Ross-Simons of Warwick, Inc. v. Baccarat, Inc.*, 102 F.3d 12, 19 (1st Cir. 1996). "District courts have broad discretion to evaluate the irreparability of alleged harm and to make determinations regarding the propriety of injunctive relief." *Id.* (citation omitted).

Defendants have implicitly conceded—both in interagency memoranda and federal court

filings—that covered entities will incur massive costs both from administrative burden and increased upfront payment costs. These costs extend to all individual Plaintiffs and other members of the organization Plaintiffs and have already begun in anticipation of the January 1 start date. In total, AHA estimates the Rebate Program will cost its members more than $400 million annually in administrative costs alone. Golder Decl. ¶¶ 28, 38. Individually, Plaintiff Dallas County Medical Center (DCMC) has to hire two full-time employees, one in the pharmacy department and another in accounting, to handle the Rebate Program. Mantz Decl. ¶ 18. Plaintiff Nathan Littauer Hospital (NLH) also is hiring a full-time employee exclusively for the Rebate Program, Fadale Decl. ¶ 22, and Plaintiff St. Mary's Regional Medical Center anticipates needing to do the same, Brown Decl. ¶ 21. All will face mounting costs leading up to and after January 1, and these costs will force diversion of critical resources to simply comply with the mandatory Rebate Program.

"Complying with an agency order later held invalid almost always produces the irreparable harm of nonrecoverable compliance costs." *Wages & White Lion Invs., LLC v. FDA*, 16 F.4th 1130, 1142 (5th Cir. 2021) (cleaned up). "The costs of complying with challenged regulations have been recognized as irreparable given the obstacles faced when suing for monetary damages," particularly "in the context of the APA, which does not allow for monetary damages." *California v. Kennedy*, __ F. Supp. 3d __, 2025 WL 2807729, at *6 (D. Mass. Oct. 1, 2025). Here, Plaintiffs will be unable to recover any of the costs that result from the Rebate Program, meaning they will be irreparably harmed.

By diverting 340B providers' operating capital to drug companies for unknown periods of time—with no enforceable guarantee of repayment—the Rebate Program has put covered entities in a period of financial stasis and retrenchment. Providers cannot undertake investments and service line expansions with this level of uncertainty—especially hospitals in Maine that, on

average, have extremely limited cash on hand. Austin Decl. ¶ 9. St. Mary's has explained that "[b]y cutting into our savings from the 340B discount program, the rebate program will force us to cut back or discontinue health-promoting services." Brown Decl. ¶ 18. DCMC, moreover, has been forced to delay critical maintenance on its hospital facilities and the construction of a ramp for disabled patients at its occupational therapy clinic due to the Rebate Program. Mantz Decl. ¶¶ 15, 20. And NLH has put its pharmacy build-out, which would ensure more patients get access to their medications consistent with the goal of 340B, on hold. Fadale Decl. ¶ 24. Each of these is an irreparable harm. *See Rhode Island v. Trump*, 781 F. Supp. 3d 25, 52 (D.R.I. 2025) (halting library services and forcing an entity into a hiring freeze constituted irreparable harm).

Finally, the Rebate Program will irreparably harm Plaintiffs by preventing them from carrying out their missions. The 340B Program is intended to allow covered entities to stretch their resources to provide more comprehensive care for the patients and communities, but the Rebate Program threatens to imminently constrict services, such as:

- St. Mary's' ability to reduce the price of some outpatient drugs for its patients and to offer an infusion therapy program in which eligible patients receive the drug for free. Brown Decl. ¶ 18. So too for other hospitals in Maine. Austin Decl. ¶¶ 11, 15.
- DCMC's recently opened cancer telehealth clinic, which spares patients from driving two hours to see the nearest oncologist. Mantz Decl. ¶¶ 12, 20.
- Unity Medical Center's recently opened cardiac and pulmonary rehabilitation services and patient access services. O'Neil Decl. ¶ 12.
- NLH's plan to expand its primary care services to a new location (for which it has been gifted property). Fadale Decl. ¶¶ 18, 24.

Illegal agency actions cause irreparable harm by forcing regulated parties to divert

resources away from their core mission or abandon vital programs. *See, e.g., Somerville Pub. Schs. v. McMahon*, 139 F.4th 63, 75 (1st Cir. 2025) (irreparable harm where "the challenged actions would jeopardize [plaintiffs'] ability to proceed with their programs"); *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 9 (D.C. Cir. 2016) (similar); *Mass. Fair Hous. Ctr. v. U.S. Dep't of Hous. & Urb. Dev.*, 496 F. Supp. 3d 600, 611 (D. Mass. 2020). That is exactly what will happen here. As a unanimous Supreme Court explained, "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 738 (2022). The diversion of that funding, which is *already occurring* in advance of January 1, irreparably harms those valuable services and that mission.

III. The Balance of the Equities Strongly Favors Plaintiffs and A Preliminary Injunction Serves the Public Interest.

For the final factor, courts "must balance the competing claims of injury and must consider the effect on each party [and the public] of the granting or withholding of the requested relief." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008) (citation omitted). Plaintiffs, their patients, and their communities face imminent injury from the diversion of resources that would otherwise go to healthcare for vulnerable patients. *See supra* pp. 18–19. In addition, it contravenes the public interest to interfere with patient care by impairing access to critical medications. *Rio Grande Cmty. Health Ctr., Inc. v. Rullan*, 397 F.3d 56, 77 (1st Cir. 2005) (affirming preliminary injunction requiring government payment to health center as in the public interest because "any shut down of [the clinic] would adversely affect hundreds of Medicaid patients"); *see also Mass. Ass'n of Older Ams. v. Sharp*, 700 F.2d 749, 753–54 (1st Cir. 1983) (harm from being "financially unable to obtain necessary medical treatment" held to "far outweigh[]" claimed harm to government of having to pay benefits that may not be owed); *e.g.*, Golder Decl. ¶¶ 33–39.

On Defendants' side, there is no public interest in continuing unlawful action. *Somerville*

Pub. Schs., 139 F.4th at 76. "To the contrary, there is a substantial public interest in having governmental agencies abide by the federal laws that govern their existence and operations." *League of Women Voters*, 838 F.3d at 12 (cited in *Maine v. Dep't of Agric.*, 778 F. Supp. 3d 200, 236 (D. Me. 2025)). And Plaintiffs are seeking preliminary relief for its quintessential purpose: to maintain the status quo. *Starbucks Corp.*, 602 U.S. at 346. Defendants cannot credibly claim harm from keeping the upfront discount system they have endorsed for decades until this case resolves.

IV. Plaintiffs Should Not Be Required to Post Any Substantial Bond.

Relief will "do the defendant[s] no material damage," such that the Court should "dispense with any security requirement." *Am. First Legal Found. v. Becerra*, 2024 WL 3741402, at *16 n.11 (D.D.C. Aug. 9, 2024). If the Court requires a bond, Plaintiffs respectfully request it be nominal, consistent with Court practice. *See Maine*, 778 F. Supp. 3d at 236–38 (collecting cases).

CONCLUSION

This Court should grant Plaintiffs' motion for a temporary restraining order prohibiting the "340B Rebate Model Pilot Program" from going into effect until this Court enters a final judgment in this case and prohibiting Defendants from implementing the Rebate Program until the same. This Court should enter the order **before January 1, 2026** when the Rebate Program unlawfully forces safety-net providers to lose immense—potentially existential—amounts of unrecoverable capital that will impair health services to patients in Maine and across the country.

Dated: December 1, 2025

Respectfully submitted,

/s/ Melissa A. Hewey

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**Pro hac vice certification forthcoming.*
***Admitted in NY only; practice supervised by members of D.C. Bar. Pro hac vice application forthcoming.*

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA,

Defendants.

Case No. 2:25-cv-00600-JAW

NOTICE OF INTENT TO MOVE TO INTERVENE

Undersigned counsel for AbbVie Inc. and Pharmacyclics LLC (together, "AbbVie") hereby submit this notice of intent to move to intervene under Federal Rule of Civil Procedure 24 in the above-captioned matter. AbbVie has been accepted as a participant into the Rebate Model Pilot Program that Plaintiffs seek to enjoin in this litigation. AbbVie will file a motion to intervene and, if the motion is granted, will further oppose Plaintiffs' request for a temporary restraining order and any motion for a preliminary injunction.

In light of the accelerated timeline Plaintiffs have sought for this case, AbbVie respectfully requests that the Court permit AbbVie to participate in the telephone conference set for 11:00 a.m.

on Monday, December 8, 2025 in order to align its anticipated intervention motion with the Court's schedule in a manner efficient for the parties and the Court.

Dated: December 5, 2025

Respectfully submitted,

/s/ Jay S. Geller

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CERTIFICATE OF SERVICE

I, Jay S. Geller, hereby certify that on December 5, 2025, I caused the foregoing Notice of Intent to Move to Intervene to be filed via the Court's CM/ECF electronic filing system ("CM/ECF"), which sent notice to all parties receiving notification through CM/ECF.

/s/Jay S. Geller

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA,

Defendants.

Case No. 2:25-cv-00600-JAW

ABBVIE INC.'S AND PHARMACYCLICS LLC'S MOTION TO INTERVENE

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INTRODUCTION

AbbVie Inc. and its subsidiary, Pharmacyclics LLC (together, "AbbVie"), move to intervene as defendants so they may adequately represent their interests with respect to the Rebate Model Pilot Program ("Pilot Program"). The Health Resources & Services Administration ("HRSA") adopted the Pilot Program to allow manufacturers to comply with the requirements of the Inflation Reduction Act ("IRA"). AbbVie is entitled to intervene as of right under Federal Rule of Civil Procedure 24(a) for all purposes, including but not limited to opposing Plaintiffs' motion for a Temporary Restraining Order and any other equitable relief, because: (1) AbbVie possesses a significant protectable interest in both participating in the Pilot Program and ensuring its timely implementation on January 1, 2026 given the significant compliance burdens and the risk of duplicate price concessions that the Pilot Program aims to resolve; (2) AbbVie's interest in the Pilot Program is threatened by this proceeding; (3) the United States government cannot adequately represent AbbVie's distinct commercial interest; and (4) AbbVie's motion—noticed mere days after Plaintiffs' complaint and filed within 48 hours of the Court's telephone conference—is timely. Alternatively, AbbVie seeks permissive intervention under Rule 24(b).

BACKGROUND

Plaintiffs file a complaint and seek a Temporary Restraining Order against a federal program, but scarcely address the program's essential purpose. The Pilot Program that Plaintiffs aim to obstruct is designed to resolve a complex administrative problem arising at the intersection of two federal drug-pricing regimes: the "340B Program" and the IRA's "Drug Price Negotiation Program." Without the Pilot Program, drug manufacturers like AbbVie face substantial, irreparable harm, including because they have no ready way to comply with the overlapping requirements of these federal programs, will risk incurring penalties, and will pay duplicate price

concessions under both programs that are inconsistent with federal law. Ex. 1 (Aynilian Decl.) ¶¶ 12–13.

The federal 340B statute requires participating pharmaceutical manufacturers, like AbbVie, to offer their drugs at steep discounts to certain types of nonprofit healthcare providers called "covered entities." *See* 42 U.S.C. § 256b(a)(1). The net price manufacturers must offer to covered entities—known as the "ceiling price"—is set by statute. *See id.* § 256b(a)(2). For AbbVie, this price concession averages approximately sixty percent of the drug's commercial value, with some ceiling prices reaching just one penny per unit of drug. Ex. 2 (Scheidler Decl.) ¶ 3. The text of the 340B statute explicitly allows manufacturers to provide the 340B price through either upfront discounts or post-sale rebates. 42 U.S.C. § 256b(a)(1).

Some drug manufacturers, including AbbVie, are also subject to another, separate price-control regime called the "Drug Price Negotiation Program" (enacted within the IRA). *See id.* § 1320f. Under that statutory scheme, the Secretary of Health and Human Services sets a "maximum fair price" for certain selected drugs under Medicare. *See id.* § 1320f(a)(3). Manufacturers of selected drugs are then obligated to make the maximum fair price available whenever the drug is dispensed to Medicare-eligible individuals at hospitals and pharmacies. *Id.* §§ 1320f(c)(2), 1320f-2(a)(3). Many manufacturers will provide the maximum fair price through a rebate, as contemplated by CMS.[1] Failure to provide the maximum fair price when required subjects a manufacturer to significant civil monetary penalties that can reach into the ***millions of dollars per day***. *Id.* §§ 1320f-6(c), 1320f-2(a)(5).

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[1] *See* CMS, *Medicare Drug Price Negotiation Price Program: Final Guidance, Implementation of Section 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027*, at 43 (Oct. 2, 2024), https://tinyurl.com/ychztdfu ("2026 Guidance").

When the same drug dispense is eligible for both the 340B price and the maximum fair price—that is, when a Medicare beneficiary is a patient of a 340B covered entity—a manufacturer must provide the lower of the two discounts, *but not both*. 42 U.S.C. § 1320f-2(d). Such duplicate discounts are inconsistent with federal law. *Id.* And for good reason: If they were permitted, many manufacturers would pay more in discounts than the price of their drug. That could force manufacturers to exit the federal programs and likely jeopardize the programs' constitutionality. The agency administering the IRA's Drug Price Negotiation Program has made clear that, instead of policing these abuses itself, it is up to manufacturers to determine which price applies to any given dispense and to avoid impermissible duplicate discounts.[2]

On August 1, 2025, after widespread concern about the significant compliance burdens borne by manufacturers with a drug subject to both a 340B ceiling price and an IRA maximum fair price, HRSA issued a notice inviting such manufacturers to participate in a pilot program to provide 340B pricing through rebates, rather than through upfront discounts. 90 Fed. Reg. 36,163 (Aug. 1, 2025). Under that Program, "[c]overed entities are required to provide [claims] data"—i.e., basic data about the transaction—"to participating manufacturers in order for the manufacturers to provide rebates to effectuate the 340B discount on the entities' covered outpatient drug purchases." 90 Fed. Reg. 44,197, 44,198 (Sept. 12, 2025). This approach is in all important respects the same mechanism the government has implemented to effectuate the maximum fair price regime. Both 340B and IRA will be adjudicated through rebating, after the dispense to an eligible patient is made.

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[2] *See* 2026 Guidance, *supra*, at 231 ("CMS will not, at this time, assume responsibility for nonduplication of discounts between the 340B ceiling price and MFP."); *id.* at 54 ("Neither CMS nor the [system facilitating data flow between CMS, manufacturers, and providers] will verify that a claim was or was not billed as a 340B-eligible drug.").

The Pilot Program's critical component is that it enables manufacturers to obtain and analyze claims data—commonplace and widely used healthcare data that covered entities already generate and share with other entities—to identify which drug dispense is eligible for which price concession, if any. Ex. 1 (Aynilian Decl.) ¶¶ 10–12. Collecting and analyzing this data is the only feasible method for identifying when (and which) rebates are warranted and ensuring compliance with the Drug Price Negotiation Program's nonduplication provisions. *Id.* The Pilot Program will go into effect on January 1, 2026. 90 Fed. Reg. 38,165, 38,166 (Aug. 7, 2025).

In anticipation of that date, AbbVie has dedicated significant time and resources to implementing the Pilot Program. Operationalizing Imbruvica's maximum fair price and the Pilot Program has required AbbVie to work internally and with external vendors to design, build, and test a novel "effectuation and de-duplication plan" that will allow it to process claims data and issue refunds within CMS's required 14-day window. Ex. 1 (Aynilian Decl.) ¶¶ 2, 11–12.

Plaintiffs now ask this Court to second guess the wisdom of a rebate program created to address the compliance issues created by the overlap between the 340B Program and the Drug Price Negotiation Program. And Plaintiffs ask this Court to do so in less than one month, *see* Doc. 3 at 20, even though the agency announced the Pilot Program over four months ago, 90 Fed. Reg. 36,163, and even though covered entities participated in litigation before a different court regarding the scope of HRSA's authority to implement a rebate model, *Eli Lilly & Co. v. Kennedy*, 2025 WL 1423630, at *6 (D.D.C. May 15, 2025). An order from this Court bringing the nationwide Pilot Program to a grinding halt just days before it begins would subject AbbVie to significant, irreparable harms and legal risk. AbbVie therefore respectfully requests leave to intervene as a defendant.

ARGUMENT

I. AbbVie Meets The Requirements For Intervention As Of Right.

This Court should grant AbbVie's motion to intervene because deciding this case without AbbVie would impair AbbVie's ability to protect its interests. Fed. R. Civ. P. 24(a)(2). AbbVie satisfies the requirements for intervention because: (1) AbbVie has a concrete interest in the lawfulness of the Pilot Program; (2) deciding the action without AbbVie would impede AbbVie's ability to protect its interests; (3) the government does not adequately represent AbbVie's interests; and (4) AbbVie's motion is timely. *B. Fernández & Hnos., Inc. v. Kellogg USA, Inc.*, 440 F.3d 541, 544-45 (1st Cir. 2006).

Interest in the action. AbbVie possesses a concrete interest in this proceeding—one with a "sufficiently close relationship to the dispute between the original litigants and [the intervenor's] interest" so as to be obviously "direct" as opposed to "contingent." *Conservation L. Found. of New England, Inc. v. Mosbacher*, 966 F.2d 39, 42 (1st Cir. 1992).

Plaintiffs' lawsuit, if successful, will prevent AbbVie from participating in the Pilot Program. The Pilot Program is intended to help manufacturers, including AbbVie, ensure that they can provide the correct price concession when the 340B Program and Drug Price Negotiation Program intersect—thereby avoiding the risk of federal enforcement actions, steep civil penalties, and improper duplicate discounts that could effectively force AbbVie to pay double when selling certain products. AbbVie has already applied for and been accepted to the Pilot Program (and expended significant hours and resources preparing to implement the Program). Ex. 2 (Scheidler Decl.) ¶ 6; Ex. 1 (Aynilian Decl.) ¶¶ 2, 11–12, 17. Manufacturers like AbbVie—not Plaintiffs—bear the responsibility to comply with the 340B and IRA statutory obligations that the Pilot Program was designed to address. Blocking the Pilot Program from going into effect as planned would subject AbbVie to precisely the compliance risks that the federal government sought to

absolve. This direct and substantial interest is sufficient to warrant intervention. *See Fernández*, 440 F.3d at 545 ("An intervenor has a sufficient interest in the subject of the litigation where the intervenor's contractual rights may be affected by a proposed remedy."); *Daggett v. Comm'n on Governmental Ethics and Election Pracs.*, 172 F.3d 104, 110 (1st Cir. 1999) (finding a sufficient interest where the underlying proceeding threatened intervenor's ability to participate in a government program); *see also Mosbacher*, 966 F.2d at 43.

Threat to the interest. AbbVie's interest in the Pilot Program is threatened by this proceeding's outcome. AbbVie easily satisfies the "'practical' test of adverse effect" that the First Circuit employs when assessing this prong. *Daggett*, 172 F.3d at 110. That is because "'even a small threat' that [a movant's] interests could be jeopardized by the outcome of [a] case is 'ample reason for finding that [its] ability to protect [its] interest may be adversely affected.'" *Old Orchard Provisions, LLC v. Town of Old Orchard Beach*, 2023 WL 8540917, at *4 (D. Me. Dec. 11, 2023) (quoting *Cotter v. Mass. Ass'n of Minority L. Enf't Officers*, 219 F.3d 31, 35 (1st Cir. 2000)). Plaintiffs in this action seek to halt the Pilot Program. If Plaintiffs succeed in blocking the Program (whether temporarily or permanently), AbbVie's interest in avoiding the administrative and compliance burdens that underlie the Pilot Program will be adversely affected. *Daggett*, 172 F.3d at 110; *Fernández*, 440 F.3d at 545.

Adequacy of representation. AbbVie can also make the requisite "'minimal' showing that the representation afforded by a named party would prove inadequate." *Fernández*, 440 F.3d at 545. An intervenor makes this showing when "its interests are sufficiently different in kind or degree from those of the named party." *McDonough v. City of Portland*, 2015 WL 3755289, at *3 (D. Me. June 6, 2015). Courts routinely find government representation inadequate on this basis when the government "must account for a spectrum of governmental interests far broader than the

discrete commercial interests [a putative intervenor] seeks to protect." *Id.* at *4; *Mosbacher*, 966 F.2d at 44 (acknowledging "that a general agreement that 'regulations should be lawful does not necessarily ensure agreement in all particular respects,'" and "intervenors' interests in protecting their industries [may be] more narrowly focused than [a] governmental agency's interest in implementing the law"); *Utahns for Better Transp. v. U.S. Dep't of Transp.*, 295 F.3d 1111, 1117 (10th Cir. 2002) ("[T]he government's prospective task of protecting not only the interest of the public but also the private interest of the petitioners in intervention is on its face impossible." (cleaned up)).

The federal government-defendants cannot adequately represent AbbVie's interest in these proceedings. The government has no direct financial stake in the Pilot Program's implementation—it does not face the prospect of tens of millions of dollars in losses flowing from duplicative price concessions and civil penalties for compliance mistakes. *See* 42 U.S.C. § 1320f-2(d); *id.* § 256b(d)(1)(B)(vi); *see also* 90 Fed. Reg. 38,165. AbbVie's interest—as one of the manufacturers actually facilitating the Pilot Program and bearing related financial and compliance risks—is distinctly commercial and industry-based. If the Pilot Program is enjoined or delayed—even temporarily—AbbVie risks both improper duplicate discounts and penalties for noncompliance. And AbbVie will have expended substantial resources to implement the Pilot Program for naught. Even a modest delay in the Pilot Program's implementation would subject AbbVie to significant risk of unnecessary duplicate discounts. Whether or not the Pilot Program is enjoined, AbbVie's maximum fair price obligations ***will*** begin on January 1, 2026, and AbbVie's 340B discounting obligations will continue unimpeded. If Plaintiffs prevail, AbbVie will have no remedy for the compliance concerns that animated adoption of the Pilot Program in the first instance, and AbbVie will not be able to recoup losses that accrue, because federal law does not

otherwise provide a mechanism for recovering duplicate discounts paid on prior claims. These costs undercut AbbVie's business model and hurt its ability to invest in the research and development of life-saving medicines.

If the Court presumes adequate representation, that presumption is easily rebutted. *Daggett*, 172 F.3d at 111. AbbVie's burden in rebutting such a presumption "is not onerous." *McDonough*, 2015 WL 3755289, at *3. AbbVie "need only show that the government's representation *may* be inadequate, not that it is inadequate." *Id.* AbbVie carries any such burden because, as outlined above, AbbVie's unique commercial perspective on, and financial stake in, the Pilot Program differs markedly from the government's. As Plaintiffs themselves acknowledge, the government and manufacturers do not agree about the statutory framework for rebate models. *See* Doc. 3 at 2. And the government continues to litigate against manufacturers over the government's proper role in deciding whether manufacturers will deploy rebates or upfront discounts. *See Novartis v. Kennedy*, No. 25-5177 (D.C. Cir.). The government's "previous actions" thus demonstrate that it often disagrees with drug manufacturers and does not share AbbVie's view of the 340B statute or the role that rebates may play. That undercuts any assumption "that [the government] will zealously defend" AbbVie's interests. *Old Orchard Provisions*, 2023 WL 8540917, at *4; *see also Mosbacher*, 966 F.2d at 44 (finding inadequate representation by government when its actions in litigation left "fishing groups with the distinct feeling that the Secretary [was] less wholeheartedly dedicated to opposing the [plaintiff's] aims").

The government does not face the compliance and financial risks confronting AbbVie and lacks insight into the significant resources manufacturers have expended to implement the Pilot Program. It therefore cannot adequately represent AbbVie's interest in this litigation.

Timeliness. There can be no real dispute that AbbVie's motion is timely. AbbVie filed its notice only days after Plaintiffs filed their complaint and TRO motion and, thus, mere days after learning that its interest was imperiled. *See Daggett*, 172 F.3d at 108-09; *Old Orchard Provisions*, 2023 WL 8540917, at *3; *Dist. 4 Lodge of the Int'l Ass'n of Machinists and Aerospace Workers, Loc. Lodge 207 v. Raimondo*, 2021 WL 4616231, at *1 (D. Me. Oct. 6, 2021). Moreover, given the limited progress of this case as of the time of filing this motion, no party would be prejudiced by AbbVie's intervention. Indeed, no answer has been filed, no case management order has been issued, and no discovery has commenced. AbbVie would be prejudiced if its request is denied, as it would lose the opportunity to defend its unique interest in the Pilot Program before this Court. All these factors support finding that AbbVie's intervention here is timely.

Accordingly, because AbbVie meets all four requirements for intervention as of right, this Court should grant its motion to intervene under Rule 24(a).

II. Alternatively, Permissive Intervention Under Rule 24(b) Is Appropriate.

In the alternative, the Court should grant AbbVie permissive intervention under Rule 24(b). Rule 24(b) provides that "[o]n timely motion, the court may permit anyone to intervene who … has a claim or defense that shares with the main action a common question of law or fact." Fed. R. Civ. P 24(b)(1)(B). In weighing permissive intervention, "the court must consider whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights." *Id.* 24(b)(3). Courts "can [also] consider almost any factor rationally relevant" and "enjoy[] very broad discretion" in ruling on permissive intervention. *Daggett*, 172 F.3d at 113. That includes whether the putative intervenor would be helpful in fully developing a case and whether the putative intervenor's interests will be adequately represented by the existing parties. *Dinner Table Action v. Schneider*, 2025 WL 604885, at *2 (D. Me. Feb. 25, 2025); *Daggett*, 172 F.3d at 113.

AbbVie seeks to intervene to defend the validity of the Pilot Program, so it clearly has a defense that shares common questions of law or fact with the underlying action. *Dinner Table Action*, 2025 WL 604885, at *2. AbbVie's motion—filed within days of Plaintiffs' complaint—is timely and comes before any progression in this case. Under these circumstances, AbbVie's intervention would hardly cause undue delay or prejudice the original parties' rights. As detailed above, AbbVie's substantial interest in the Pilot Program is endangered by Plaintiffs' attempt to enjoin or vacate it and diverges significantly from the government's interests. AbbVie therefore will not be adequately represented in this proceeding.

This litigation cannot be properly resolved without involvement from participating manufacturers like AbbVie who bear the compliance obligations, financials risks, and operational burdens that will result from any change to the current Pilot Program. AbbVie's 340B expertise and unique perspective relative to Plaintiffs, who incorrectly suggest the Pilot Program deprives them of the right to access 340B-discounted drugs rather than merely changing how they receive that discount—will also aid the Court in weighing the merits. Thus, even if the Court concludes that intervention as of right is inappropriate, it should exercise its discretion to allow permissive intervention.

CONCLUSION

For the foregoing reasons, the Court should grant AbbVie's motion to intervene as of right or, alternatively, for permissive intervention.

Dated: December 10, 2025

Respectfully submitted,

/s/ Matthew S. Owen, P.C.

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was electronically filed with the Clerk of the Court via the Court's CM/ECF system, which sent notification of such filing to all counsel of record by electronic means.

/s/ Matthew S. Owen, P.C.
Counsel for AbbVie Inc. and Pharmacyclics LLC

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER, *Plaintiffs*, v. ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA, *Defendant*.	Case No. 2:25-cv-00600-JAW

DECLARATION OF PAUL AYNILIAN

I, Paul Aynilian, hereby make this declaration in lieu of an affidavit as permitted by 28 U.S.C. § 1746. I am aware that this declaration will be filed in the United States District Court for the District of Maine, and that it is the equivalent of a statement under oath. I, Paul Aynilian, declare as follows in support of AbbVie Inc.'s and Pharmacyclics LLC's motion to intervene as defendants and memorandum in opposition to Plaintiffs' motion for a temporary restraining order in the above-captioned action:

1. I am over the age of 21, under no disability, and competent to testify to the matters contained in this declaration.

2. I am the Director of Inflation Reduction Act ("IRA") Strategy at AbbVie Inc. ("AbbVie"). I have worked at AbbVie since 2018. I am responsible for developing AbbVie's plan to effectuate the "Maximum Fair Price" ("MFP") under the Inflation Reduction Act, including deduplication with 340B pricing. This responsibility includes working with technical groups within AbbVie like Information Technology, Finance, Accounting, Government Pricing, and third-party vendors to design, build, and test our effectuation and deduplication plan. Additionally, in my current role as well as previous roles, I have worked closely on the operational aspects of other federal healthcare programs, such as Medicare and Medicaid.

3. I understand that the IRA established the so-called Medicare Drug Price Negotiation Program ("DPNP"). The DPNP requires the Secretary of the U.S. Department of Health and Human Services ("HHS") to set a so-called MFP for certain selected drugs. A separate federal program, the 340B Program, requires manufacturers to offer drugs to certain "covered entities" at a statutorily calculated "ceiling price." For entities entitled to purchase drugs under the 340B Program, a manufacturer must offer the lower of a selected drug's MFP or the 340B ceiling price. I further understand that the IRA requires AbbVie to provide only the lower of the MFP and 340B ceiling price. AbbVie is not required to provide both price concessions on the same unit of drug. In other words, AbbVie is not required to pay duplicate discounts. It is my understanding that HHS has put the responsibility for preventing duplicate discounts on manufacturers.

4. I understand that the Centers for Medicare & Medicaid Services ("CMS") has issued Final Guidance setting forth how manufacturers are to comply with the DPNP.[1] CMS

[1] CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair*

requires manufacturers of selected drugs to submit Maximum Fair Price Effectuation Plans ("MFP Effectuation Plans") that detail how a manufacturer will comply with the DPNP and provide access to the MFP for selected drugs. As a part of that MFP Effectuation Plan, CMS requires manufacturers to detail a process for deduplication of MFP and 340B discounts. Any changes to that plan must be submitted to CMS.

5. AbbVie submitted an MFP Effectuation Plan in August 2025. AbbVie's MFP Effectuation Plan sets forth how AbbVie will comply with the IRA and identifies the use of the Health Resources & Services Administration ("HRSA")'s 340B Rebate Model Pilot Program ("Pilot Program") for deduplication.

6. I further understand the IRA to require manufacturers of selected drugs to provide the MFP only to MFP-eligible individuals, not everyone. To determine when manufacturers must provide the MFP, CMS has created the Medicare Transaction Facilitator ("MTF") to facilitate transmission of claims data from plans to manufacturers. Manufacturers use this data to identify dispenses of medication to MFP-eligible individuals and facilitate payments to dispensing entities by manufacturers who have chosen to provide the MFP through a rebate.[2] CMS created both a Data Module (DM) and Payment Module (PM) for the MTF. The MTF is a core component of implementing the DPNP.[3] Participation in the MTF-DM is mandatory for manufacturers such as AbbVie.[4] To effectuate MFP, CMS requires plan sponsors to provide claims data to the Drug Data

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Price in 2026, 2027, and 2028 at 212 (Sept. 30, 2025) ("IPAY 2028 Final Guidance"), https://tinyurl.com/uf86dc2f.

[2] *Id.* at 215.

[3] *See id.*

[4] *Id.*

Processing System ("DDPS") and subsequently the MTF, which is then transmitted to manufacturers to determine whether to make available the MFP (or 340B price).

7. It is also my understanding that CMS guidance has specified that manufacturers must provide access to the MFP in one of two ways: (1) prospectively ensuring that the price paid by the dispensing entity when acquiring the drug is no greater than the MFP; or (2) retrospectively providing reimbursement for the difference between the dispensing entity's acquisition cost and the MFP. With respect to the second option, CMS has stated that a manufacturer "may meet its statutory obligation under" the relevant provision of the IRA "to make the MFP available to dispensing entities by retrospectively transmitting payment for the difference between the dispensing entity's acquisition cost and the MFP (i.e., the MFP refund amount), within the 14-day prompt MFP payment window."[5]

8. I further understand that a drug manufacturer with a Medicare Drug Price Negotiation Program agreement that violates the requirements that CMS determines are "necessary" for program administration and compliance may be subject to fines of over one million dollars per day.[6] Further, CMS requires that drug manufacturers make MFPs available within the 14-day prompt pay window, or risk facing civil monetary penalties.[7]

9. The process CMS has mandated that manufacturers use for providing MFP refunds is incompatible with the way most drugs are sold at the 340B ceiling price. Under the 340B

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[5] *Id.* at 212.

[6] CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027* at 8 § 100 (Oct. 2, 2024) (providing examples of "substantive violations" that could trigger civil monetary penalties), https://tinyurl.com/4n245pt3.

[7] IPAY 2028 Final Guidance at 212.

Program, covered entities establish accounts with AbbVie that allow them to purchase medications at the 340B ceiling price. Covered entities generally do not provide either manufacturers or CMS data that would allow either to prevent duplicate discounts.

10. I understand that HHS recently announced the Pilot Program so pharmaceutical manufacturers can comply both with the 340B Program and the DPNP without providing duplicate discounts. Through the Pilot Program, AbbVie and other participating manufacturers will offer 340B pricing through a rebate mechanism instead of an upfront discount. This is so manufacturers can identify claims subject to both the MFP and 340B pricing and thus prevent duplicate price concessions between the 340B Program and DPNP. For the Pilot Program to function, covered entities must provide claims data to manufacturers.

11. AbbVie will, through its vendors Berkeley Research Group ("BRG") and its subsidiary Second Sight Solutions ("Second Sight") and their technology platform called "Beacon," compare 340B data submitted through the Pilot Program and MFP refund claims data received through the MTF, on a daily basis, to identify claims subject to both MFP and 340B pricing. I understand that "data submitted to Beacon's 340B rebate model platform is compared against data in Beacon's MFP platform, and utilized to appropriately price MFP refund requests."[8]

12. BRG and Second Sight are AbbVie's vendors providing data transmission services for both MFP effectuation and the 340B Pilot Program through their technology platform, Beacon.[9]

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[8] Beacon MFP Support Center, *Beacon MFP Frequently Asked Questions*, https://tinyurl.com/4btsetnx.

[9] *See, e.g.*, *id.* ("Beacon is an innovative technology platform that enables the Maximum Fair Price (MFP) program by ingesting, validating, pricing and transmitting MFP rebate requests. Dispensing entities utilize Beacon to research MFP rebate status, reconcile MFP refund payments and initiate good faith inquiries (GFI). Beacon is made available to dispensing entities at no cost by pharmaceutical manufacturers and is a distinct technology platform from the Medicare Transaction Facilitator (MTF)."); *see also* Beacon Channel Management, *Illuminating Pharmaceutical Pricing* ("Beacon enables 340B covered entities to access 340B pricing through the submission of eligible claims data."), https://tinyurl.com/25xfvsex.

It is my understanding that Beacon is the only platform that has been able to ultimately provide this service at this time given the technical complexities of building a system at the same time that HHS is building the MTF. HRSA has said that all ten manufacturers approved to execute a Pilot Program (as of December 8, 2025) in 2026 have listed Beacon as their platform to operationalize deduplication.[10] The Pilot Program is the only method that AbbVie is currently aware of that will allow AbbVie to identify claims subject to both 340B and MFP pricing, and prevent AbbVie from paying duplicate discounts with certainty.

13. It is my understanding that duplicate discounts will happen unless manufacturers can use a rebate model and obtain claims data. Without the Pilot Program, manufacturers lack the data necessary to identify if a unit dispensed under Medicare and subject to an MFP was purchased under the 340B Program, exposing manufacturers to costly duplicate discounts and steep monetary penalties. The primary available data field in MFP refund claims that will enable manufacturers to even attempt to predict potential duplicate discounts with 340B is the National Provider Identifier ("NPI"). But CMS specifically noted in its Final Guidance that the NPI alone provides an insufficient basis through which to de-duplicate claims.[11]

14. For example, if the wholesale acquisition cost for a drug is $1,000, the MFP is $500, and the 340B ceiling price is $250; a manufacturer would be forced to provide $1,250 in discounts on a drug that only cost $1,000. Claims data include important information, such as date prescribed, Rx number, fill number, quantity dispensed, and NPI, that allows manufacturers to prevent duplicate discounts.

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[10] HRSA, *Manufacturer 340B Rebate Model Plan Summaries*, https://www.hrsa.gov/opa/340b-model-pilot-program (last visited Dec. 8, 2025).

[11] IPAY 2028 Final Guidance at 254 § 40.4.5.

15. I have reviewed the declaration of Chad Golder, prepared on November 26, 2025 in support of Plaintiffs' motion for a temporary restraining order. It asserts that AHA believes "drug companies could comply with the Inflation Reduction Act and 340B's longstanding discount model by simply making the maximum fair price for Medicare negotiated drugs available prospectively as is currently done for drugs purchased under the 340B program." Doc. 7 at ¶ 20. I do not understand this observation to be an accurate restatement of manufacturers' options. Manufacturers must de-duplicate MFP and 340B discounts even if both are offered prospectively.[12]

16. The statement incorrectly suggests that duplicate 340B and MFP discounts are dependent on whether MFP is made available retrospectively or prospectively. Even if a manufacturer were to provide the purchase of a drug subject to an MFP prospectively that discount would still have to be validated through the MTF as going to an MFP-eligible individual and the manufacturer would still need to determine if that same claim was also the subject of a request for a 340B discount. Because the current status quo does not have a required time period in which covered entities must assert a claim is eligible for a 340B discount, there is no way to determine the duplicative discount within the 14-day period in which manufacturers must provide MFP, regardless of whether the MFP price is provided prospectively or retrospectively.

17. I understand that Plaintiffs' lawsuit, if successful, will prevent the Pilot Program from going into effect as planned on January 1, 2026. A temporary delay or permanent cancelation of the Pilot Program would adversely affect AbbVie. Without the Pilot Program, AbbVie will struggle to provide the correct price concession and meet its 340B-MFP nonduplication

[12] *See* IPAY20208 Final Guidance at 62-63. Additionally, providing prospective access to MFP requires specific documentation requirements for manufacturers that differ from retrospective access. *Id.* at 82 (Table 5).

obligations, putting it at risk of federal enforcement actions, steep civil penalties, and excess price concessions. AbbVie has also expended significant hours and resources to implement the Pilot Program.

18. Without the Pilot Program, I understand it has been estimated that manufacturers would lose an estimated $4 billion in duplicate 340B and DPNP discounts in 2026 alone.[13]

19. IQVIA has estimated the overlap between 340B and Medicare to be up to 40% of claims.[14] Further, IQVIA has estimated that duplicate discounts across other channels such as Medicaid and commercial represent a quarter of all 340B sales ($20-25 billion in 2021).[15]

20. U.S. revenue for Imbruvica through Q3 2025 was $507 million.[16]

* * *

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 10th day of December 2025.

/s/ *Paul Aynilian*
Paul Aynilian
Declarant

[13] BRG, *Implications for Duplication with the 340B Channel* at 2 (Oct. 2024), https://media.thinkbrg.com/wp-content/uploads/2024/10/23161214/BRG-Implications-for-Duplication-with-_the-340B-Channel-2024.pdf.

[14] IQVIA, *Can 340B Modifiers Avoid Duplicate Discounts in the IRA?* (Feb. 28, 2023), https://www.iqvia.com/-/media/iqvia/pdfs/us/white-paper/2023/can-340b-modifiers-avoid-duplicate-discounts-in-the-ira.pdf.

[15] IQVIA, *Uncover the Invisible Impacts of 340B Discounts* (Dec. 20, 2021), https://www.iqvia.com/locations/united-states/blogs/2021/12/uncover-the-invisible-impacts-of-340b-discounts#:~:text=Thinking%20about%20just%20the%20first,in%20addition%20to%20a%20rebate.

[16] AbbVie, *AbbVie Reports Third-Quarter 2025 Financial Results* at 7 (Oct. 31, 2025), https://investors.abbvie.com/news-releases/news-release-details/abbvie-reports-third-quarter-2025-financial-results.

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA,

Defendants.

Case No. 2:25-cv-00600-JAW

DECLARATION OF EDWARD SCHEIDLER

I, Edward Scheidler, hereby make this declaration in lieu of an affidavit as permitted by 28 U.S.C. § 1746. I am aware that this declaration will be filed in the United States District Court for the District of Maine, and that it is the equivalent of a statement under oath. I, Edward Scheidler, declare as follows in support of AbbVie Inc.'s and Pharmacyclics LLC's (collectively "AbbVie") motion to intervene as defendants and memorandum in opposition to Plaintiffs' motion for a temporary restraining order in the above-captioned action:

A. Background

1. I am over the age of 21, under no disability, and competent to testify to the matters contained in this declaration.

2. I am the Head of the 340B Center of Excellence at AbbVie. I have worked at AbbVie since 2004 and been responsible for AbbVie's 340B Program since 2017. My responsibilities include regularly engaging with the purchasers of AbbVie's pharmaceutical products concerning AbbVie's participation in the federal 340B Program, including with respect to AbbVie's relationships with commercial pharmacies (many of which are so-called "contract pharmacies"). I am familiar with the conditions of participation in federal healthcare programs, such as Medicare and Medicaid.

B. The Pilot Program

3. Manufacturers participating in the federal 340B Program (like AbbVie) must offer their medications at a statutorily calculated discounted price to certain nonprofit healthcare providers, known as "covered entities." *See* 42 U.S.C. § 256b. The average 340B discount across AbbVie's drug portfolio is over 60% of the drug's commercial price. For some drugs, the price is as low as one penny per unit.

4. Hospital covered entities are not restricted in how they use the revenue that they pocket from the 340B Program. From my experience, hospital covered entities simply put their 340B profits into their general operating budgets. Some covered entities might, at their own discretion, choose to voluntarily pass portions of their 340B discounts to certain patients. In my experience, such discounts are highly unusual: I'd estimate that less than 5%of 340B transactions (perhaps less than 2 or 3%) involve any sort of direct patient discount. In fact, some major contract pharmacy chains—including the vast majority of specialty pharmacies—refuse to cooperate with such patient discount programs. Thus, patients could not receive discounts for drugs purchased at those pharmacies even if the covered entity *wanted* to pass those discounts along. As a general rule, patients pay full price.

5. HRSA administers the 340B Program.[1] On August 1, 2025, HRSA proposed a Rebate Model Pilot Program ("Pilot Program") to test a rebate mechanism for delivering the 340B price.

6. AbbVie submitted its application for HRSA's Pilot Program on Monday, September 15, 2025. After a collaborative process with HRSA, the federal agency formally approved AbbVie's proposal for participating in the Pilot Program on October 30, 2025. Attached to this index as Exhibit A is a true and correct copy of HRSA's letter approving AbbVie for participation in the Pilot Program. AbbVie is set to start participating in the Pilot Program on January 1, 2026.

7. The Pilot Program is a limited pilot with 10 specific drugs. It is my understanding that the selected drugs make up a very small portion of drug sales conducted under the 340B Program (perhaps 2% of net sales or 5% of gross sales).

8. The drugs covered by the Pilot Program are those subject to the 340B discount as well as the "Maximum Fair Price" ("MFP") set by the Inflation Reduction Act's Drug Price Negotiation Program. AbbVie's Imbruvica is one such drug. I understand that one goal of the Pilot Program is to avoid duplicate discounts in which a purchaser receives, at the manufacturer's expense, both the 340B discount and the MFP.

9. Through the Pilot Program, all 340B claim activity must be submitted to obtain the 340B discount in the form of a rebate. For submitted claims, AbbVie will offer 340B discounts through a rebate mechanism rather than an upfront discount in order to identify claims subject to

[1] On February 11, 2025, President Trump issued Executive Order 14210, titled "Implementing the President's 'Department of Government Efficiency' Workforce Optimization Initiative." *See* 90 Fed. Reg. 9,669 (Feb. 11, 2025). On March 27, 2025, HHS announced it intended to restructure, including by creating an Administration for a Healthy America (or "AHA") which will have authority over, among other sub-agencies, HRSA. *See* Dep't of Health & Human Servs., *HHS Announces Transformation to Make America Healthy Again* (Mar. 27, 2025), https://www.hhs.gov/press-room/hhs-restructuring-doge.html.

340B pricing and prevent duplicate price concessions between the MFP and 340B ceiling price and to prevent other issues, such as the submission of duplicate Rx claims by separate covered entities. Because rebates facilitate deduplication, they are an effective way to address the compliance issues created by the overlap between the 340B Program and the Drug Price Negotiation Program. The net price that a covered entity pays remains the same whether they receive a discount upfront or as a rebate.

10. As an alternative, I understand some have proposed that deduplication could be facilitated via a proposed "government-backed clearinghouse" that CMS plans to use in the future for certain Medicare rebates. First, CMS has made clear that any data submitted to the 340B clearinghouse "would not be made available to external parties, including manufacturers and Part D plan sponsors,"[2] thus there is no option for manufacturers to use the clearinghouse to deduplicate MFP and 340B claims. Further, the earliest that clearinghouse will be available (on a voluntary basis, for testing only, and for a different federal program) is the fall of 2026. It remains unclear if it will ever be fully operational or if data submission will ever be mandatory. Moreover, a CMS clearinghouse is intended to help CMS identify 340B claims for purposes of calculating inflation rebates which is done after the year is completed—a very different timeline than required for 340B and MFP deduplication.

11. Even if CMS adopted a clearinghouse format, that would not alleviate covered entities from the obligation to generate and share claims data to facilitate 340B-MFP deduplication. Covered entities would still have to send the data somewhere so that process could be completed. A clearinghouse would change only where the covered entities send the data.

[2] 90 Fed. Reg. 32,352, 32,642 (July 16, 2025).

12. Further, manufacturers are best equipped to implement a rebate model. They have extensive operational experience with rebate programs and administer rebate programs across multiple federal and commercial markets. This existing infrastructure means that manufacturers can implement a rebate model that is predictable, scalable, and aligned with individual manufacturers' compliance requirements. Additionally, manufacturers are well positioned to accommodate the unique operational differences associated with medications included in HRSA's Pilot Program.

13. I also understand that HRSA has specified that under the Pilot Program, covered entities must continue to make purchases through their 340B wholesaler account. Manufacturers are to load commercial wholesale acquisition cost ("WAC") pricing in the 340B wholesaler account where purchases will be made by covered entities. Then, to obtain a rebate to the 340B ceiling price, covered entities must submit claims data to the manufacturer. Rebates will be calculated as WAC minus the 340B ceiling price on the date of dispense (date of service).

14. In approving AbbVie's proposal for the Pilot Program, HRSA specified the data fields that AbbVie collects from covered entities in order to receive a 340B rebate. AbbVie must collect claims data from covered entities to participate in the Pilot Program. Claims data from a medication dispense includes important information, such as date prescribed, Rx number, fill number, quantity dispensed, and the prescriber/rendering physician's national provider ID (NPI), that allows manufacturers to prevent duplicate discounts. The Pilot Program requires that participating manufacturers obtain data from covered entities to effectuate 340B rebates. The Pilot Program does not work without claims data. This data can be used to compare other types of rebates, such as the MFP, without denying the 340B rebate. But covered entities do not generally provide claims data voluntarily or upon request, which is why AbbVie attaches a claims data

provision as a condition of its 340B offer. Claims data is readily available to covered entities. In fact, claims data is ubiquitous in the healthcare industry and is the kind of information found in everything from hospital bills to insurance to Medicaid claims. Claims data is often required to substantiate non-340B healthcare transactions.

15. AbbVie does not require covered entities to engage with the Pilot Program. If a covered entity does not wish to participate in the pilot, it may send prescriptions to one of the specialty pharmacies capable of dispensing Imbruvica without disrupting patient care.

16. HRSA is preparing manufacturers, covered entities, and other stakeholders for the Pilot Program's effective date.

17. Second Sight Solutions ("Second Sight") is a software provider assisting AbbVie with its participation in the Pilot Program. The 10 manufacturers participating in the Pilot Program intend to use Second Sight's "Beacon" platform to support their participation.[3] I understand that Beacon is designed to provide covered entities with "invalidation codes" and manufacturer contact information when claims are denied, that Beacon does not collect or maintain "protected health information," and that the data it does collect is de-identified via HIPPA expert determination before it is submitted. *See* 45 C.F.R. § 164.514(b)(1).

18. It is my understanding that Second Sight conducted a live demonstration of the Beacon platform for HRSA on November 17, 2025. The platform is also available for testing through the Sandbox SDK environment. In addition, I understand that Second Sight publishes recorded walkthroughs of Beacon on its website and has updated Beacon's terms of access in response to feedback from covered entities, including accommodations for state and governmental

[3] HRSA, *Manufacturer 340B rebate model plan summaries*, https://www.hrsa.gov/opa/340b-model-pilot-program.

entities. Relatedly, Beacon is willing to negotiate its terms and conditions when covered entities identify conflicts with applicable state laws. In October and November 2025, hundreds of covered entities registered for Beacon and more than 2,300 individuals participated in Beacon's training sessions.

19. AbbVie provides covered entities with free access to Beacon to support claims data submissions, as well as technical support, customer service, and educational resources at no cost to covered entities. In addition, many covered entities work with "third party administrators" to identify claims for discounts under the 340B Program from past dispenses, as well as discounts available through other programs. Based on my experience, these third-party administrators may be willing and able to offset covered entities' administrative burdens by uploading necessary claims data directly to Beacon on the entities' behalf.

20. I have reviewed the declaration of Chad Golder, prepared on November 26, 2025 in support of Plaintiffs' motion for a temporary restraining order. It asserts that "[t]he AHA also is concerned about the terms and conditions that are associated with the Beacon software program" and that "AHA members have raised concerns about 1) allowing their claims data to be sold for profit, 2) cybersecurity and data privacy risks, and 3) strict limits on liability." Doc. 7 at ¶ 33. I have no reason to believe that the concerns he identifies are real or accurately described. Covered entities already use "340B ESP," a Second Sight Solutions product.[4] It is also my understanding that Beacon is conducting industry standard data security audits, with additional audits to begin after the system has been operational for several months, to substantiate the assurances made.[5]

[4] 340B ESP Help Center, *Frequently Asked Questions (FAQ)*, https://tinyurl.com/yc7mymmn.

[5] Beacon Trust Center, *Trust Center Frequently Asked Questions (FAQs)*, https://tinyurl.com/2nz7r38c.

21. In addition, the declaration of Chad Golder asserts that AHA believes "drug companies could comply with the Inflation Reduction Act and 340B's longstanding discount model by simply making the maximum fair price for Medicare negotiated drugs available prospectively as is currently done for drugs purchased under the 340B program." Doc. 7 at ¶ 20. I do not understand this observation to be an accurate restatement of manufacturers' options. Manufacturers must de-duplicate MFP and 340B discounts even if both are offered prospectively.[6]

22. In its Pilot Program announcement, HRSA cited the elimination of duplicate claim submissions under the 340B Program and the Drug Price Negotiation Program as a reason for collecting claims data and effectuating the 340B price through a rebate mechanism. 90 Fed. Reg. 36,163 (Aug. 1. 2025). Collecting claims data is the most efficient and accurate method of identifying when a rebate is warranted and ensuring compliance with the Inflation Reduction Act's nonduplication provisions because it enables manufacturers to quickly identify which dispenses are both maximum fair price–eligible and subject to 340B pricing. It is my understanding that duplicate discounts are inevitable unless manufacturers can use a rebate model and obtain claims data.

23. The Pilot Program is structured to prevent delays. My understanding is that rebates are due within 10 days of claim submission, so covered entities with standard wholesaler terms (typically 30 days) may receive rebates before payment is due. In addition, I understand that covered entities can use strategies such as "payer reimbursement" to pay wholesaler bills. HRSA

[6] *See* CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027* at 54-55, 22932 (Oct. 2, 2024), https://tinyurl.com/ychztdfu.

has clarified that non-payment may jeopardize a manufacturer's participation in the Pilot Program.[7]

24. It is my understanding that, when covered entities purchase drugs eligible for the 340B Program discount, they must pay to replenish the drug before they receive the revenue associated with a 340B eligible dispense—and a covered entity cannot replenish a drug until the dispenses for that drug reach a full package size. Moreover, a covered entity's payment from an external contract pharmacy usually is delayed 30 to 45 days, or more, based on the covered entity's contractual agreement with the pharmacy. As a result, it is possible that the Pilot Program will actually reduce the time that covered entities spend waiting to realize a drug discount.

25. Similarly, it is my understanding that covered entities have experience managing far greater administrative burdens and delays than those that covered entities fear will result from HRSA's Pilot Program. Many hospital pharmacies engage with outpatient Medicaid patients. For such patients, a hospital pharmacy dispenses a drug that it has already purchased, submits claim-level data, then waits for the State to adjudicate the request and pay the pharmacy. It is my understanding that this process may apply to all market products, whereas the Pilot Program involves only 10 drugs.

26. I have reviewed the declaration of Winfield S. Brown, prepared on November 30, 2025 in support of Plaintiffs' motion for a temporary restraining order. It asserts that HRSA has "not specified the consequences for drug companies that do not reimburse hospitals within ten days or that inappropriately deny rebates." Doc. 5 at ¶ 20. I have no reason to believe that this objection is accurate. Indeed, it is my understanding that HRSA's August 7, 2025 Notice clarified that the Office of Pharmacy Affairs may "revoke approval of a manufacturer plan at any time if a

[7] 90 Fed. Reg. at 36,164.

manufacturer is not in compliance with the criteria outlined in the 'Rebate Model Pilot Program Criteria.'"[8]

27. In addition, the declaration of Winfield S. Brown asserts that St. Mary's Regional Medical Center "will have to hire a new staff person if the rebate program is implemented." Doc. 5 at ¶ 21. I have no reason to believe that this concern, nor any similar concern, is legitimate. In my experience, most covered entities have personnel who handle claims data for eligibility determinations—or use vendors that can easily and rapidly interface with Beacon just as they do with other parties, like payers. Moreover, HRSA estimated that covered entities would spend approximately two hours per week on tasks related to the Pilot Program.[9] Based on my experience, I believe that HRSA's estimate is accurate.

28. AbbVie sells Imbruvica to covered entities nationwide, including in Maine. AbbVie expects to process rebate requests for Imbruvica from Maine-based covered entities under the Pilot Program.

29. Currently, AbbVie cannot tailor its Pilot Program plan on a state-by-state basis. The model must operate uniformly across all jurisdictions.

30. I understand that it has been estimated that without the Pilot Program, manufacturers would lose an estimated $4 billion to duplicate 340B and DPNP discounts in 2026 alone.[10]

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[8] *Id.* at 36,166.

[9] 90 Fed. Reg. 44,197, 44,198.

[10] BRG, *Implications for Duplication with the 340B Channel* at 2 (Oct. 2024), https://media.thinkbrg.com/wp-content/uploads/2024/10/23161214/BRG-Implications-for-Duplication-with-_the-340B-Channel-2024.pdf.

31. I understand that HRSA asked for public comments about the Pilot Program. Many of the comments submitted by hospital covered entities consisted of the same form letter sent by multiple organizations or multiple individuals within the same organization. By my department's count, one organization submitted a form letter at least 165 times, signed by at least 165 different people. That accounted for roughly 15% of the approximately 1,000 comments HRSA received.

* * *

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 10th day of December 2025.

/s/ Edward Scheidler
Edward Scheidler
Declarant

EXHIBIT A

Health Resources & Services Administration

Office of Special Health Initiatives
5600 Fishers Lane
Rockville, MD 20857

October 30, 2025

BY EMAIL
Helmuth Fendel
Vice President, Market Access Account Management & Trade
AbbVie, Inc.
Helmuth.Fendel@abbvie.com

Dear Helmuth Fendel:

The Office of Pharmacy Affairs (OPA) has received and reviewed AbbVie Inc./Pharmacyclics' (AbbVie) plan for participation in the 340B Rebate Model Pilot Program. The revised plan submitted on October 29, 2025, is approved for an implementation date of January 1, 2026.[1]

OPA has approved the data fields below for participating manufacturers to request from covered entities as part of the 340B Rebate Model Pilot Program. It should be noted that data requests are limited to these approved fields, and that no rebate claims may be denied for the absence of the optional fields outlined below.

Pharmacy Claims Data Fields	**Medical Claims Data Fields**
Date of Service	Date of Service
Date Prescribed	Claim Line Number
Rx number	Claim Number
Fill number	Unit of Measure
NDC-11	NDC-11
Quantity Dispensed	Quantity
Prescriber ID	Rendering Physician ID
Service Provider ID	Service Provider ID
340B ID	340B ID
RX BIN	Health Plan Name
RX PCN	Health Plan ID
Group Number ID (optional)	Health Plan ID Qualifier (optional)
	HCPCS Code (optional)
	HCPCS Modifiers (Up to 4) (optional)

During this initial phase of the Rebate Model Pilot Program, OPA is not allowing participating manufacturers to collect purchase data from covered entities, even as an optional field. However, OPA will instruct covered entities to purchase products subject to the pilot in their current 340B wholesale accounts

[1] As outlined in the *Federal Register Notice*, the scope of the 340B Rebate Model Pilot Program is limited to the NDC–11s included on the CMS Medicare Drug Price Negotiation Selected Drug List ("List") for 2026. The NDCs submitted in the revised plan are approved only to the extent they are published on the List. Please work to ensure that all NDCs in the revised plan are included on the List as 340B-rebates may not be offered for any NDC that does not appear on the List.

at the prices loaded by manufacturers (generally at WAC). OPA will also instruct covered entities to request rebates only after a purchase and to dispense 340B-rebate purchases solely to eligible 340B patients. Manufacturers should continue to work with their distribution partners to leverage data from wholesalers to monitor that the number of purchases made at WAC in those 340B wholesale accounts correspond to the number of rebates requested, whether through a chargeback feed or other report. Only NDCs that appear on the CMS Medicare Drug Price Negotiation Selected Drug List and have an approved plan in place, should list a WAC price in a 340B wholesale account. All other covered outpatient drugs should list the 340B ceiling price in the 340B wholesale account. OPA will evaluate covered entity and manufacturer compliance with the rebate model pilot as part of its 340B compliance audits.

Consistent with the August 7, 2025, *Federal Register notice,* manufacturers must provide covered entities with 60 calendar days' notice before implementation of an approved rebate model, with instructions for registering for any IT platforms. Notice should also provide details of the rebate plan as described in the *Federal Register notice* and also include how covered entities should submit unreplenished accumulations that occur prior to the implementation date of the approved rebate model; technical assistance for setting up files for submission, including data definitions for each allowable data field; a description of how the rebate will be calculated and paid; and details for how to seek assistance from both the IT vendor and the manufacturer contact. OPA will post a summary of AbbVie's plan to the OPA website.

As noted in the August 7, 2025, *Federal Register notice*, manufacturers must agree to provide OPA with reports detailing 340B-rebate purchases, and information related to claim delays and denials. In order to facilitate transfer of this data, OPA requests that AbbVie submit reports via Application Programming Interface (API) submissions to the 340B Prime Vendor, at least monthly. The attached file provides the requested fields. Please register at www.login.warehouse.apexus.com to create an account for reporting.

As a reminder, OPA reserves the right to revoke approval of AbbVie's participation in the 340B Rebate Model Pilot Program at any time if the manufacturer is not compliant with the plan as approved, including by denying rebates to covered entities for reasons not consistent with the August 7, 2025, *Federal Register notice* and not established in the approved plan.

HRSA plans to continue our collaboration with you in the coming months and as the pilot begins so that progress can be monitored and concerns addressed as they arise. Questions may be directed to 340BPricing@hrsa.gov.

Sincerely,



Krista M. Pedley, Pharm D, MS
RDML, USPHS Assistant Surgeon General
Director, Office of Special Health Initiatives

Attachment

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA,

Defendants.

Case No. 2:25-cv-00600-JAW

ASTRAZENECA PHARMACEUTICALS LP'S MOTION TO INTERVENE AND SUPPORTING MEMORANDUM OF LAW

AstraZeneca Pharmaceuticals LP ("AstraZeneca") hereby moves to intervene as defendant under Federal Rule of Civil Procedure 24 in the above-captioned matter. AstraZeneca is a biopharmaceutical company focusing on the discovery, development, manufacturing, and commercialization of medicines. AstraZeneca was accepted as a participant in the Health Resources & Services Administration's ("HRSA") Rebate Model Pilot Program ("Rebate Program Pilot"). Plaintiffs in this action seek to enjoin the Rebate Program. AstraZeneca seeks to intervene so that it may adequately represent its interests with respect to the Rebate Program Pilot.*

ARGUMENT

AstraZeneca seeks to intervene for the reasons set forth in the Motion to Intervene of AbbVie Inc. and Pharmacyclics LLC (collectively, "AbbVie"), and AstraZeneca fully incorporates by reference those arguments herein.

Like AbbVie, AstraZeneca has "an interest relating to the … transaction that is the subject of the action and is so situated that disposing of the action may as a practical matter impair … [AstraZeneca]'s ability to protect its interest." Fed. R. Civ. P. 24(a)(2). AstraZeneca participates in the 340B Drug Pricing Program. *See* Decl. of Chris Mancill (Mancill Decl.) ¶ 6 (a true copy attached as Exhibit 1). AstraZeneca manufactures Farxiga, one of ten drugs selected for "negotiation" and a "Maximum Fair Price" ("MFP") under the Drug Price Negotiation Program of the Inflation Reduction Act ("IRA"). *Id.* ¶ 9.

* AstraZeneca has sought all parties' position on this motion. At the time of this filing, Defendants had not yet responded to the request for their position. Plaintiffs represented that they will oppose the motion, and request a full twenty-one days to file their opposition. In light of the expedited schedule that Plaintiffs have sought for this case, and the need for resolution in advance of the Rebate Program Pilot's start date, AstraZeneca respectfully requests that any opposition to its motion to intervene be due by December 15, 2025, in line with the schedule set by the Court on December 8.

Under the IRA, drug manufacturers are required to offer covered entities the lower of the 340B price or the IRA's MFP within 14 days of the purchase of those drugs. *Id.* ¶ 10. Within that short timeframe, AstraZeneca is obligated to establish mechanisms for identifying the proper price of a drug and de-duplicating discounts such that it only offers the lower of the 340B price or MFP, not both. *Id.* ¶ 11. To facilitate its compliance with this obligation, AstraZeneca applied to participate in the Rebate Program Pilot, and HRSA approved AstraZeneca's rebate model and plan for participating in the program. *Id.* ¶ 14.

AstraZeneca's approved rebate model for Farxiga will enable AstraZeneca to identify in real time claims subject both to 340B pricing and to MFP pricing, enabling AstraZeneca to mitigate the risk of paying duplicate discounts. *Id.* ¶¶ 16-18. If the Rebate Program Pilot is temporarily or permanently enjoined, AstraZeneca will be unable to quickly and accurately identify whether a drug is eligible for 340B or MFP pricing, as it is required to do under the IRA and Section 340B. *Id.* ¶ 23. If the Rebate Program Pilot is temporarily or permanently enjoined, AstraZeneca will suffer substantial and irreparable financial harm, including the paying of duplicate discounts that cannot later be recovered. *Id.* ¶¶ 23, 25.

For these reasons and the reasons set forth in AbbVie's Motion to Intervene, AstraZeneca satisfies the criteria both for intervention as of right, pursuant to Federal Rule of Civil Procedure 24(a)(2), and for permissive intervention, pursuant to Rule 24(b). This Court should grant AstraZeneca's motion to intervene.

DATED: December 10, 2025

Respectfully submitted,

/s/ Jeffrey D. Talbert

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Attorneys for AstraZeneca Pharmaceuticals LP

* *Certifications for admission pro hac vice forthcoming*

CERTIFICATE OF SERVICE

I, Jeffrey D. Talbert, hereby certify that on December 10, 2025, I caused the foregoing Motion to Intervene to be filed via the Court's CM/ECF electronic filing system, which sent notice to all parties who have entered an appearance in this matter.

/s/ Jeffrey D. Talbert
Jeffrey D. Talbert

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER,

Plaintiffs,

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ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA,

Defendants.

Case No. 2:25-cv-00600-JAW

DECLARATION OF CHRIS MANCILL

I, Chris Mancill, hereby declare under penalty of perjury as follows:

1. I am over the age of 18. Except as expressly indicated, the facts stated herein are based upon my personal knowledge, including my experience in the pharmaceutical industry, my time working at AstraZeneca Pharmaceuticals LP, and my review of AstraZeneca business records. If called to testify, I could truthfully and competently testify to these facts. I provide this declaration in support of AstraZeneca's motion to intervene in this case.

2. I am the Senior Vice President & Head, U.S. Market Access at AstraZeneca, where I have been employed since 2024. I have over 30 years of experience in the pharmaceutical industry. During that time, my job responsibilities have included Global Government Affairs; Global Value Access; and Access, Reimbursement, and Patient Support.

3. In my position as Senior Vice President & Head, U.S. Market Access, I am responsible for leading market access, with a priority focus on ensuring that payers and health systems develop a deep understanding of the value of AstraZeneca's Oncology and BioPharmaceuticals portfolios and that appropriate patients are able to access our therapies when needed.

4. AstraZeneca is a global, science-led, patient-focused pharmaceutical company dedicated to transforming the future of healthcare by unlocking the power of what science can do for people, society, and the planet. AstraZeneca is committed to ensuring its life-changing and life-saving products and treatments are available to as many people as possible. AstraZeneca's drug accessibility work also includes co-pay assistance and patient assistance for financially needy patients.

5. AstraZeneca has, and continues to, research, develop, market, and sell pharmaceutical products in a wide variety of therapy areas, including oncology, biopharmaceuticals, cardiovascular, renal and metabolic, respiratory and immunology, and rare diseases. AstraZeneca also devotes considerable resources to researching and developing new vaccines and immune therapies.

6. AstraZeneca participates in the 340B Drug Pricing Program (340B Program), which requires pharmaceutical manufacturers to offer their products at steeply reduced prices to certain health care providers known as "covered entities."

7. AstraZeneca has participated in the 340B Program since 1993, when it first signed its pharmaceutical pricing agreement to enter the program.

8. To comply with its obligations under the 340B program, AstraZeneca offers its products at steep discounts to 340B-eligible covered entities. For example, a prescription for 90 tablets of AstraZeneca's product Farxiga retails for hundreds of dollars commercially, but can be purchased for less than a dollar with a 340B discount. AstraZeneca offers its products to 340B covered entities through wholesalers, just as it offers its products to other purchasers.

9. In 2022, Congress enacted the Inflation Reduction Act ("IRA"), which directed the Secretary of the Department of Health and Human Services to set a "Maximum Fair Price" ("MFP") for drugs that are selected as negotiation-eligible. For the first year of the program, which starts on January 1, 2026, AstraZeneca's product, Farxiga, was selected for "negotiation" and an MFP has been set for the product.

10. The IRA also requires manufacturers, including AstraZeneca, to offer covered entities the lower of the 340B price or the IRA's MFP—but not both discounts—within 14 days of the purchase of a selected drug.

11. I understand that CMS has stated that drug manufacturers, including AstraZeneca, are responsible for identifying whether a specific unit of a drug is eligible for 340B pricing or the MFP, and that the government requires drug manufacturers, including AstraZeneca, to establish processes and procedures for identifying 340B sales of selected drugs, so that de-duplication can

occur within the statutory timeframe. I also understand that a drug manufacturer must provide the government with its plan for "deduplicating" MFP and 340B discounts.

12. The Health Resources and Services Administration (HRSA) administers the 340B program. On August 1, 2025, HRSA announced an application process for a new 340B Rebate Model Pilot Program ("Rebate Pilot Program") under which drug manufacturers with selected drugs under the IRA would be allowed to use a rebate model to effectuate the 340B price. The purpose of this Rebate Pilot Program is to assist drug manufacturers with their obligation to deduplicate MFP and 340B discounts, as required under the IRA.

13. I understand that, under this rebate model, covered entities initially pay the WAC price for a 340B drug. Once the drug is dispensed to a 340B patient, the covered entity submits 340B claims data to the drug manufacturer, and the manufacturer provides a rebate for the difference between the WAC price and the 340B price. I understand that requiring covered entities to provide such 340B claim data, sometimes called claims data, will enable AstraZeneca to verify in real time that a specific unit of the drug is eligible for 340B pricing and that the purchaser did not already receive the MFP for it, if the MFP is lower than the 340B price.

14. On September 12, 2025, AstraZeneca applied to participate in the Rebate Pilot Program for Farxiga, its one selected drug for calendar year 2026. On October 30, 2025, HRSA informed AstraZeneca that it had approved AstraZeneca's plan for participating in the Rebate Pilot Program. A true and correct copy of HRSA's letter approving AstraZeneca's proposed rebate model for Farxiga is attached as **Exhibit A** to this declaration. AstraZeneca's rebate model is set to begin on January 1, 2026.

15. I understand that the Rebate Pilot Program is limited in scope, with only ten drugs initially eligible for inclusion. I understand that this is a small fraction of overall drugs eligible for purchase under the 340B program.

16. I understand that, since the Rebate Pilot Program application process opened, AstraZeneca has worked closely with Berkeley Research Group ("BRG") and its technology platform, known as "Beacon," to develop and validate its rebate model. Each day, Beacon compares a covered entity's 340B claims data to MFP refund claims data, identifying claims subject to both and thereby enabling the manufacturer to ensure it is only offering the lower of the two prices. Beacon uses specific data, including date prescribed, Rx (prescription) number, fill number, quantity dispensed, and the prescriber/rendering physician's national provider ID (NPI), to deduplicate claims. I understand that this data is industry standard and maintained by covered entities in the regular course of business.

17. Beacon is AstraZeneca's sole method of identifying claims subject to both 340B and MFP pricing in near-real time; it is a reliable way that AstraZeneca can avoid paying duplicate discounts.

18. I further understand that Beacon cannot operate without claims data, and that covered entities do not voluntarily provide this claims data to drug manufacturers. The Rebate Pilot Program enables manufacturers, like AstraZeneca, to collect claims data to which they otherwise would not have access.

19. AstraZeneca does not require covered entities to engage with the rebate model. If a covered entity does not wish to participate in the pilot program, it may still send prescriptions for its patients to a pharmacy.

20. Covered entities have free access to Beacon to submit claims data to AstraZeneca, and Beacon provides them with free customer service, technical support, and other resources. I further understand that many covered entities outsource submission of claims data via Beacon to third-party administrators.

21. AstraZeneca's approved rebate model under the Rebate Pilot Program is designed to provide rebates quickly, within ten days of claims data submission, to further minimize any impact on covered entities. I understand that this ten-day reimbursement window is a mandatory condition of program participation, and that AstraZeneca could face negative repercussions if it fails to comply with this requirement. *See* 90 Fed. Reg. 36,163, 36,164 (Aug. 1, 2025).

22. It is my understanding that AstraZeneca—and HRSA—have made every effort to minimize the Rebate Pilot Program's impact on covered entities, and both have been in communication with covered entities about the program's upcoming start date.

23. I understand that the Plaintiffs in this case seek to prevent the Rebate Pilot Program from going into effect as approved on January 1, 2026. A temporary delay or permanent cancellation of this program would cause AstraZeneca significant and irreparable harm. AstraZeneca has expended considerable time and resources in developing and validating its rebate model. Without the model, AstraZeneca will be left without a reliable mechanism for quickly and accurately identifying whether a drug is eligible for 340B or MFP pricing, as required under the Inflation Reduction Act. By our estimates, AstraZeneca will pay duplicate discounts of approximately $30-$50 million for Fiscal Year 2026 if the Pilot Program is unable to begin on January 1, 2026.

24. I have reviewed the declaration of Chad Golder, prepared on November 26, 2025 in support of Plaintiffs' motion for a temporary restraining order. The declaration asserts that AHA believes "drug companies could comply with the Inflation Reduction Act and 340B's longstanding discount model by simply making the maximum fair price for Medicare negotiated drugs available prospectively as is currently done for drugs purchased under the 340B program." Doc. 7 at ¶ 20. I respectfully disagree. If the MFP is offered prospectively, drug manufacturers will still have to deduplicate MFP and 340B prices after the drug has been administered. From AstraZeneca's perspective, AHA's proposal will not address the problem of MFP and 340B deduplication.

25. BRG has estimated that, without the Rebate Pilot Program, manufacturers would lose an estimate $4 billion in duplicate 340B and MFP discounts in 2026 alone.[1] I am not aware of any means by which AstraZeneca could later recover that money.

26. AstraZeneca sells Farxiga to covered entities in Maine. AstraZeneca expects that it will process rebate requests for AstraZeneca from Maine-based covered entities once its rebate model goes into effect. I understand from Beacon that the rebate model must operate uniformly nationwide, and that it cannot be tailored on a state-by-state basis.

I declare under penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct.

Executed this 10th of December 2025
in Wilmington, Delaware

/s/ *Chris Mancill*
Chris Mancill

[1] BRG, *Implications for Duplication with the 340B Channel* at 2 (Oct. 2024), https://media.thinkbrg.com/wp-content/uploads/2024/10/23161214/BRG-Implications-for-Duplication-with-_the-340B-Channel-2024.pdf.

EXHIBIT A

Health Resources & Services Administration

Office of Special Health Initiatives
5600 Fishers Lane
Rockville, MD 20857

October 30, 2025

BY EMAIL
Steven Chen
Director, US Policy
AstraZeneca Pharmaceuticals LP
steven.chen5@astrazeneca.com

Dear Steven Chen:

The Office of Pharmacy Affairs (OPA) has received and reviewed AstraZeneca Pharmaceuticals LP's (AstraZeneca) plan for participation in the 340B Rebate Model Pilot Program. The revised plan submitted on October 28, 2025, is approved for an implementation date of January 1, 2026.[1]

OPA has approved the data fields below for participating manufacturers to request from covered entities as part of the 340B Rebate Model Pilot Program. It should be noted that data requests are limited to these approved fields, and that no rebate claims may be denied for the absence of the optional fields outlined below.

Pharmacy Claims Data Fields	**Medical Claims Data Fields**
Date of Service	Date of Service
Date Prescribed	Claim Line Number
Rx number	Claim Number
Fill number	Unit of Measure
NDC-11	NDC-11
Quantity Dispensed	Quantity
Prescriber ID	Rendering Physician ID
Service Provider ID	Service Provider ID
340B ID	340B ID
RX BIN	Health Plan Name
RX PCN	Health Plan ID
Group Number ID (optional)	Health Plan ID Qualifier (optional)
	HCPCS Code (optional)
	HCPCS Modifiers (Up to 4) (optional)

During this initial phase of the Rebate Model Pilot Program, OPA is not allowing participating manufacturers to collect purchase data from covered entities, even as an optional field. However, OPA will instruct covered entities to purchase products subject to the pilot in their current 340B wholesale accounts

[1] As outlined in the *Federal Register Notice*, the scope of the 340B Rebate Model Pilot Program is limited to the NDC–11s included on the CMS Medicare Drug Price Negotiation Selected Drug List ("List") for 2026. The NDCs submitted in the revised plan are approved only to the extent they are published on the List. Please work to ensure that all NDCs in the revised plan are included on the List as 340B-rebates may not be offered for any NDC that does not appear on the List.

at the prices loaded by manufacturers (generally at WAC). OPA will also instruct covered entities to request rebates only after a purchase and to dispense 340B-rebate purchases solely to eligible 340B patients. Manufacturers should continue to work with their distribution partners to leverage data from wholesalers to monitor that the number of purchases made at WAC in those 340B wholesale accounts correspond to the number of rebates requested, whether through a chargeback feed or other report. Only NDCs that appear on the CMS Medicare Drug Price Negotiation Selected Drug List and have an approved plan in place, should list a WAC price in a 340B wholesale account. All other covered outpatient drugs should list the 340B ceiling price in the 340B wholesale account. OPA will evaluate covered entity and manufacturer compliance with the rebate model pilot as part of its 340B compliance audits.

Consistent with the August 7, 2025, *Federal Register notice,* manufacturers must provide covered entities with 60 calendar days' notice before implementation of an approved rebate model, with instructions for registering for any IT platforms. Notice should also provide details of the rebate plan as described in the *Federal Register notice* and also include how covered entities should submit unreplenished accumulations that occur prior to the implementation date of the approved rebate model; technical assistance for setting up files for submission, including data definitions for each allowable data field; a description of how the rebate will be calculated and paid; and details for how to seek assistance from both the IT vendor and the manufacturer contact. OPA will post a summary of AstraZeneca's plan to the OPA website.

As noted in the August 7, 2025, *Federal Register notice*, manufacturers must agree to provide OPA with reports detailing 340B-rebate purchases, and information related to claim delays and denials. In order to facilitate transfer of this data, OPA requests that AstraZeneca submit reports via Application Programming Interface (API) submissions to the 340B Prime Vendor, at least monthly. The attached file provides the requested fields. Please register at www.login.warehouse.apexus.com to create an account for reporting.

As a reminder, OPA reserves the right to revoke approval of AstraZeneca's participation in the 340B Rebate Model Pilot Program at any time if the manufacturer is not compliant with the plan as approved, including by denying rebates to covered entities for reasons not consistent with the August 7, 2025, *Federal Register notice* and not established in the approved plan.

HRSA plans to continue our collaboration with you in the coming months and as the pilot begins so that progress can be monitored and concerns addressed as they arise. Questions may be directed to 340BPricing@hrsa.gov.

Sincerely,



Krista M. Pedley, Pharm D, MS
RDML, USPHS Assistant Surgeon General
Director, Office of Special Health Initiatives

Attachment

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA,

Defendants.

Case No. 2:25-cv-00600-JAW

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA MOTION TO INTERVENE

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INTRODUCTION

Pharmaceutical Research and Manufacturers of America (PhRMA) moves to intervene as a defendant. PhRMA is an association that represents the Nation's leading biopharmaceutical research companies. Its members include eight of the nine companies whose plans were selected by the Health Resources & Services Administration (HRSA) for participation in the 340B Rebate Model Pilot Program (Pilot Program). *See* Ex. 1 (Stansel Decl.) ¶ 13. Plaintiffs have asked this Court to decide whether the agency's action creating that Pilot Program is lawful, and whether the Pilot Program may proceed. Because PhRMA and its members have protectable interests that will be directly impacted by this Court's answers to those questions, PhRMA is entitled to intervene as of right under Federal Rule of Civil Procedure 24(a)(2). In the alternative, PhRMA respectfully seeks permissive intervention under Rule 24(b)(1).[1]

LEGAL STANDARD

A party is entitled to intervene as of right in litigation if: (1) the motion to intervene is timely filed; (2) the proposed intervenor has "an interest relating to" the subject matter of the action; (3) the proposed intervenor is "so situated that disposing of the action may, as a practical matter impair or impede [its] ability to protect [that] interest;" and (4) the proposed intervenor's interests are not "adequately represent[ed]" by the "existing parties" to the suit. Fed. R. Civ. P. 24(a)(2); *see also Berger v. N.C. State Conf. of the NAACP*, 597 U.S. 179, 190 (2022). Even if a party is not entitled to intervene as a matter of right, permissive intervention may be granted when the proposed intervenor has "a claim or defense that shares with the main action a common

[1] PhRMA has sought all parties' position on this motion. At the time of filing, Defendants had not yet responded to the request for their position. Plaintiffs advised that they anticipate opposing the motion. PhRMA respectfully requests that any opposition to its motion to intervene be due by December 15, 2025, in line with the deadlines set for the motions to intervene by AstraZeneca and AbbVie.

question of law or fact," and the intervention will not "unduly delay or prejudice the adjudication of the original parties' rights." Fed. R. Civ. P. 24(b).

ARGUMENT

I. PhRMA Is Entitled To Intervene As Of Right.

PhRMA is entitled to intervene in this litigation because its motion is timely; PhRMA and its members have significant interests in the case; those interests will be affected by the outcome; and the current parties do not adequately represent PhRMA's interests.

First, PhRMA's motion is timely. This case is only nine days old. Plaintiffs filed their complaint and motion for temporary restraining order on December 1, and PhRMA is seeking intervention—alongside the other proposed intervenors—on the timeline ordered by the Court. *See Daggett v. Comm'n on Governmental Ethics and Election Pracs.*, 172 F.3d 104, 109 (1st Cir. 1999) (intervention motion filed within two weeks of complaint "easily met" Rule 24's timeliness requirement); *Ne. Patients Grp. v. Maine Dep't of Admin. & Fin. Servs.*, No. 1:20-CV-00468-NT, 2021 WL 1135019, at *3 (D. Me. Mar. 23, 2021) (intervention motion timely when filed two days after briefing schedule was set). No existing party would be prejudiced by PhRMA's intervention at this early stage, but PhRMA and its members would—for the reasons described below—be prejudiced if it cannot intervene at this time.

Second, PhRMA and its members have significant, protectable interests in this case. Those interests "bear a sufficiently close relationship to the dispute between the original litigants." *Conservation L. Found. of New England, Inc. v. Mosbacher*, 966 F.2d 39, 42 (1st Cir. 1992) (internal quotation marks omitted).

If Plaintiffs prevail, the Pilot Program will be halted—either temporarily or permanently. And PhRMA and its members have a direct interest in that Pilot Program. A key impetus for the Pilot Program was to ensure that manufacturers—including PhRMA's members—have a way to

simultaneously comply with their obligations under 340B and the Medicare Drug Price Negotiation Program come January 1, when manufacturers' obligations to offer the "maximum fair price" (MFP) kick in under the latter Program. *340B Program Notice: Application Process for the 340B Rebate Model Pilot Program; Correction*, 90 Fed. Reg. 38,165, 38,166 (Aug. 7, 2025). Absent the Pilot Program, those manufacturers, including PhRMA members, will not be able to deduplicate their MFP and 340B discounts, risking federal enforcement actions, civil penalties, costly duplicate discounts connected to their MFP obligations, and other harms. Ex. 2 (Paluzzi Decl.) ¶¶ 21, 24; Ex. 1 (Stansel Decl.) ¶ 18.

For example, PhRMA member Johnson & Johnson (J&J) participates in the 340B Program and must offer MFP refunds on two of its drugs, STELARA® and XARELTO®, starting on January 1. *See* Ex. 2 (Paluzzi Decl.) ¶¶ 4, 7. "In part to help meet its deduplication responsibilities, J&J planned to adopt a rebate model of its own initiative" in 2024. *Id.* ¶ 12. When HRSA refused to permit J&J to do so, J&J sued HRSA, in litigation that remains pending in the United States Court of Appeals for the D.C. Circuit. *Id.* § 13. HRSA later selected J&J for the Pilot Program. *Id.* ¶ 14. If Plaintiffs succeed in stopping the Pilot Program, even temporarily, J&J "estimates that it would be required to pay over a hundred million dollars in improper MFP refunds … on medications purchased at the 340B price." *Id.* ¶ 21. In addition, if J&J is prevented from implementing its rebate program, it will not be able to recoup the "substantial time and resources" it has invested since 2024 in developing and preparing for that program. *Id.* ¶ 24.

Other PhRMA members have the same or materially similar interests in the Pilot Program and, therefore, in this litigation. *See, e.g.*, Dkt. 39-1 (AstraZeneca Decl.) ¶¶ 23; Ex. 1 (Stansel Decl.) ¶¶ 13, 18.

Finally, the Pilot Program will "also … facilitate other aims[,]" including the gathering of information about rebate models "to inform [HRSA's] consideration of any future 340B rebate models consistent with the 340B statute and the Administration's goals." 90 Fed. Reg. at 38,165. PhRMA and its members have a direct stake in these goals of the Pilot Program too. PhRMA members—those in the Pilot Program and those not—have a strong interest in HRSA's ability to gather real-world information in a manner that will allow it to properly assess whether to expand the use of rebate models in the future. *See* Ex. 1 (Stansel Decl.) ¶¶ 19-21. Blocking the Pilot Program would significantly compromise that examination.

All these interests justify PhRMA's intervention. *See Daggett*, 172 F.3d at 110 (finding a sufficient interest where the underlying proceeding threatened intervenor's ability to participate in a government program); *see also Mosbacher*, 966 F.2d at 43; *Massachusetts Food Ass'n v. Massachusetts Alcoholic Beverages Control Comm'n*, 197 F.3d 560, 566 (1st Cir. 1999) (holding that trade association had a direct and concrete interest sufficient for intervention where its "members were subject to the very … regulation challenged by plaintiffs").

Third, for the reasons already given, this litigation directly impacts the interests of PhRMA and its members. *See Portland Cellular P'ship v. Inhabitants of the Town of Cape Elizabeth*, No. 2:14-cv-274, 2015 WL 12990147, at *2 (D. Me. Feb. 3, 2015) (when intervenor's interests are related, "[t]he third Rule 24(a)(2) factor requires little discussion"). "'[E]ven a small threat' that [a proposed intervenor's] interests could be jeopardized by the outcome of [a] case is 'ample reason for finding that [its] ability to protect [its] interest may be adversely affected.'" *Old Orchard Provisions, LLC v. Town of Old Orchard Beach*, No. 2:23-cv-272, 2023 WL 8540917, at *4 (D. Me. Dec. 11, 2023) (quoting *Cotter v. Mass. Ass'n of Minority L. Enf't Officers*, 219 F.3d 31, 35 (1st Cir. 2000)). And as just described, the threat here is large, not small. If Plaintiffs obtain their

requested relief (either temporarily or permanently), PhRMA's members' interests will be severely and adversely affected. *See supra*, at 2-4; *see also Daggett*, 172 F.3d at 110.

Fourth, PhRMA has shown that the representation of the existing parties "may be inadequate." *Mosbacher*, 966 F.2d 39, 43-44; *see also* Fed. R. Civ. P. 24(a)(2) "An applicant for intervention need only make a minimal showing that the representation afforded by existing parties likely will prove inadequate" to rebut the presumption that the government's representation is adequate to defend an agency action. *Pub. Serv. Co. of N.H. v. Patch*, 136 F.3d 197, 207 (1st Cir. 1998). Here, PhRMA's "interests are sufficiently different in kind or degree from those of" HRSA, *McDonough v. City of Portland*, 2015 WL 3755289, at *3 (D. Me. June 6, 2015), and PhRMA has made "a strong affirmative showing that the agency ... is not fairly representing its interests," *Patch*, 136 F.3d at 207 (internal quotation marks omitted) PhRMA's members have an undoubtedly concrete financial interest in this litigation – indeed, they have billions of dollars at stake. *See, e.g.*, *id.* (holding that proposed intervenor's interests "are sufficiently different from Portland's and that Portland's representation may be inadequate because Portland must account for a spectrum of governmental interests far broader than the discrete commercial interests [the proposed intervenor] seeks to protect"); *see* Ex. 1 (Stansel Decl.) ¶ 18. And PhRMA's members have already expended significant sums to prepare to initiate the Pilot Program on January 1, when the selected manufacturers' MFP obligations commence. *See id.* ¶ 16. HRSA, of course, seeks to defend the lawfulness of its Pilot Program, but it lacks these same monetary and timing-specific interests.

Separate and apart from this divergence, PhRMA satisfies this factor, because PhRMA members Novartis, Bristol Myers Squibb, Eli Lilly and Company, Sanofi, and J&J are currently adverse to the government in litigation about HRSA's claimed authority to decide whether and

when manufacturers may use rebates rather than up-front discounts to effectuate the 340B price for all of a manufacturer's drugs, not just those in the Pilot Program. *See Novartis et al. v. Kennedy*, No. 25-5177 (D.C. Cir.). As that pending case highlights, HRSA and these PhRMA members have divergent views about the role of rebates (and the role of HRSA in authorizing rebates) under the 340B statute. Given that circumstance, it cannot be assumed "that [the government] will zealously defend" PhRMA's interests or those of its members, *Old Orchard Provisions*, 2023 WL 8540917, at *4. Moreover, the adversity between HRSA and PhRMA members in related litigation underscores the inherent tension that arises where "an agency seeks to protect both the public interest and the interest of a private intervenor." *Mosbacher*, 966 F.2d at 44–45 (describing such a task as "on its face impossible" (quoting *Nat'l Farm Lines v. ICC*, 564 F.2d 381, 384 (10th Cir. 1977))).

Because PhRMA satisfies all the requirements for intervention as of right, this Court should grant its motion to intervene under Rule 24(a).

II. In The Alternative, PhRMA Should Be Permitted To Intervene Under Rule 24(b).

Alternatively, the Court should grant PhRMA permissive intervention under Rule 24(b). PhRMA's defenses share common questions of law and fact with this action, PhRMA will help fully develop the facts of this case, and PhRMA's intervention will not unduly delay or prejudice the litigation.

PhRMA "seek[s] to intervene to defend the" legality of the challenged agency action, "so [it] clearly ha[s] a 'defense that shares with the main action a common question of law or fact.'" *Dinner Table Action v. Schneider*, No. 1:24-CV-00430-KFW, 2025 WL 604885, at *2 (D. Me. Feb. 25, 2025) (quoting Fed. R. Civ. P. R. 24(b)(1)(B)). And because PhRMA's motion comes at the very start of the case, its intervention, especially alongside the other proposed intervenors,

would not cause undue delay or prejudice the original parties. Further, as already discussed, PhRMA's and its members' substantial interests in the Pilot Program are threatened by Plaintiffs' suit, and no existing party can adequately represent those interests. Finally, and perhaps most important, PhRMA and its members will provide facts and perspective on the operation of the 340B Program, its intersection with the Medicare Drug Price Negotiation Program, and the necessity of the Pilot Program that will aid the Court in assessing the merits, as well as the reasons why Plaintiffs' request for extraordinary preliminary relief should be denied.

CONCLUSION

For the forgoing reasons, the Court should grant PhRMA's motion to intervene as of right or, in the alternative, for permissive intervention.

Dated: December 10, 2025

Respectfully submitted,
/s/ Corin R. Swift

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Counsel for PhRMA

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was electronically filed with the Clerk of the Court via the Court's CM/ECF system, which sent notification of such filing to all counsel of record by electronic means.

/s/ Corin R. Swift
Corin R. Swift

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER,

Plaintiffs,
v.

ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA,

Defendants.

Case No. 2:25-cv-00600-JAW

DECLARATION OF JAMES C. STANSEL
IN SUPPORT OF PhRMA's MOTION TO INTERVENE

I, James C. Stansel, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1. I am Executive Vice President, General Counsel and Corporate Secretary of Pharmaceutical Research and Manufacturers of America (PhRMA). In this role, I supervise the work of PhRMA's law department, which supports PhRMA's public policy advocacy to represent its members' interests in matters before Congress, the Executive Branch, the Courts, and state legislatures and regulatory agencies.

2. I have held this position since 2016. I have personal knowledge of the facts stated herein. If called as a witness in this matter, I could and would competently testify to each of the facts set forth below.

3. PhRMA is a voluntary nonprofit corporation organized and existing under the laws of the State of Delaware that represents the Nation's leading biopharmaceutical research companies.

4. PhRMA's members are the country's leading innovative biopharmaceutical companies, which are focused on developing innovative medicines that transform lives and create a healthier world. Together, PhRMA's members are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. PhRMA member companies have invested more than $850 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States.

5. PhRMA's current members are Alkermes plc.; Amgen Inc.; Astellas Pharma; AstraZeneca; Bayer Corporation; Biogen; BioMarin Pharmaceutical Inc.; Boehringer Ingelheim Pharmaceuticals, Inc.; Bristol Myers Squibb; CSL; Daiichi Sankyo, Inc.; Eisai Inc.; Eli Lilly and Company; EMD Serono; Genentech; Genmab US, Inc.; Gilead Sciences, Inc.; GSK; Incyte Corporation; Ipsen Biopharmaceuticals, Inc.; Johnson & Johnson; Kyowa Kirin, Inc.; Lundbeck LLC; Merck & Co., Inc.; Neurocrine Biosciences, Inc.; Novartis Pharmaceuticals Corporation; Novo Nordisk Inc.; Otsuka America Pharmaceutical, Inc.; Pfizer Inc.; Sanofi; Sumitomo Pharma America; Takeda Pharmaceuticals USA, Inc.; and UCB, Inc.

6. PhRMA represents its members across the country concerning legislative, political, legal, and social issues in which the biopharmaceutical industry has an interest. PhRMA serves as the industry's principal policy advocate.

7. This lawsuit involves the 340B Drug Pricing Program (340B). 340B is a federal program that requires drug manufacturers to offer to sell certain drugs to "covered entities" at or below a specified statutory price. If manufacturers do not participate in 340B, the medicines they manufacture are not eligible for reimbursement from the federal government under Medicare Part B or Medicaid.

8. As part of my job responsibilities, I am familiar with PhRMA members' participation in 340B.

9. Many of PhRMA's member companies listed above participate in 340B. Those manufacturers provide to covered entities deeply reduced-priced drugs as part of the program. One study has found that through their participation in 340B, PhRMA's members annually provide reduced pricing worth more than $60 billion. *See* Adam Fein, *The 340B Program Reached $66 Billion in 2023—Up 23% vs. 2022: Analyzing the Numbers and HRSA's Curious Actions*, Drug Channels (Oct. 22, 2024), https://www.drugchannels.net/2024/10/the-340b-program-reached-66-billion-in.html.

10. Because PhRMA's members participate in 340B, they are directly affected by the operation of the program and by the regulatory requirements for participation. Accordingly, as a representative of its members' interests, PhRMA has a clear stake in the proper operation and application of 340B.

11. This lawsuit specifically concerns the 340B Rebate Model Pilot Program (Pilot Program), which the Health Resources & Services Administration (HRSA) announced via Federal Register notice on August 7, 2025. *See 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program; Correction*, 90 Fed. Reg. 38,165 (Aug. 7, 2025).

12. The Pilot Program allows an approved group of manufacturers to effectuate 340B price reductions through rebates to covered entities rather than upfront discounts. As part of my job responsibilities, I am familiar with the Pilot Program.

13. To date, HRSA has reviewed and approved rebate model plans under the Pilot Program that were proposed by the following PhRMA members: Amgen, AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, Johnson & Johnson, Merck, Novo Nordisk, and Novartis.

14. Consistent with the limited scope of the Pilot Program, these manufacturers all have drugs that have also been selected for the Inflation Reduction Act's (IRA) Medicare Drug Price Negotiation Program. The IRA requires covered manufacturers to offer a "maximum fair price" (MFP)—another statutorily mandated price reduction—on certain medicines. But the law prohibits having to provide both the MFP and 340B price reductions on the same prescription. And a manufacturer that fails to provide accurate pricing could face civil monetary penalties. *See* 42 U.S.C. § 1320f-6(a), (c).

15. PhRMA members sought approval to use rebate models in the Pilot Program to assist in compliance with the IRA and to avoid other 340B duplicate discounting. Under the manufacturers' rebate models approved by HRSA, manufacturers will pay cash rebates to covered entities for 340B-eligible prescriptions within 10 days of receiving basic claims data that confirms the prescription's eligibility for the 340B discount. *See* 90 Fed. Reg. at 38,166.

16. Since the PhRMA members' rebate programs were approved for the Pilot by HRSA this fall, these manufacturers have been preparing to implement their rebate programs. I understand that these preparations have required significant expenditures of time and money.

17. The Pilot Program begins on January 1, 2026, because the relevant manufacturers' obligations to offer the MFP under the IRA will begin on January 1, 2026.

18. Absent the Pilot Program, PhRMA's members stand to lose billions of dollars. Berkeley Research Group has estimated that, without the Pilot, manufacturers will pay $4 billion in duplicate 340B and MFP discounts in 2026 alone. *See* Berkeley Research Group, *Implications for Duplication with the 340B Channel* at 2 (Oct. 2024), https://media.thinkbrg.com/wp-content/uploads/2024/10/23161214/BRG-Implications-for-Duplication-with-_the-340B-Channel-2024.pdf. "[E]very dispense subject to a duplicate discount will represent a financial loss to the manufacturer … because the 340B discount and the MFP discount, when added together, exceed the drug's list price." *Id.*

19. In addition to these members selected for the Pilot Program, other PhRMA members have an interest in the Pilot.

20. As the agency explained, it "is introducing this pilot program to test the rebate model on a select group of drugs … in a methodical and thoughtful approach to ensure a fair and transparent 340B rebate model process for all stakeholders involved." *Id.* at 38,165. The information gathered during the Pilot will "inform [the agency's] consideration of any future 340B rebate models consistent with the 340B statute and the Administration's goals." *Id.*

21. Other PhRMA members who participate in the 340B Program, including those whose drugs have already been selected for MFP negotiation or may be subjected to an MFP in later years, are strongly interested in pursuing rebate models in the future. *See* PhRMA, Comment Letter on 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program; Correction at 1 (Sept. 8, 2025), https://cdn.aglty.io/phrma/global/resources/import/pdfs/Rebate%20Notice%20PhRMA%20Comments_FINAL.pdf (urging HRSA to permit broader rebates in the future). As a result, these

members too have a strong interest in ensuring that the agency will be able to use the Pilot Program to review and study the efficacy of rebate models.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. *See* 28 U.S.C. § 1746.

Executed on: December 10, 2025

/s/ James C. Stansel
James C. Stansel
Declarant

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA,

Defendants.

Case No. 2:25-cv-00600-JAW

DECLARATION OF LAUREN PALUZZI
IN SUPPORT OF PhRMA'S MOTION TO INTERVENE

I, Lauren Paluzzi, hereby make this declaration in lieu of an affidavit as permitted by 28 U.S.C. § 1746. I am aware that this declaration will be filed in the United States District Court for the District of Maine, and that it is the equivalent of a statement under oath. I, Lauren Paluzzi, declare as follows in support of the motion of the Pharmaceutical Research and Manufacturers of America ("PhRMA") to intervene as a defendant in the above-captioned action:

1. I am over the age of 21, under no disability, and competent to testify to the matters contained in this declaration.

2. I am employed as the Senior Director, Emerging Government Programs Operations and Strategies for Johnson & Johnson Health Care Systems Inc. ("J&J"). I have been employed by J&J since July 2016. In my current role, I oversee strategy and operations for J&J's participation in government programs, including 340B, and am responsible for preparing for Inflation Reduction Act ("IRA") implementation. I have been in this role since March 2024. J&J is a member of PhRMA.

3. In 2022, Congress passed the IRA, which established the Medicare Drug Price Negotiation Program ("Negotiation Program"). *See* 42 U.S.C. § 1320f. Under the Negotiation Program, the Secretary of Health and Human Services ("HHS") must publish annually a list of "selected drugs" and enter into agreements with their manufacturers to make those selected drugs available for Medicare Part D beneficiaries at the Maximum Fair Price ("MFP")—a mandatory discounted price point established through "negotiations" between the Centers for Medicare and Medicaid Services ("CMS") and the manufacturers. *See id*. The agreements require manufacturers to sell the selected drugs at the MFP. *Id.* § 1320f-2.

4. Effective January 1, 2026, two of J&J's medications, STELARA® and XARELTO®, will qualify as selected drugs and will remain so throughout calendar year 2026.

5. CMS has issued guidance setting out procedures for implementing the Negotiation Program in 2026 and 2027. *See* CMS, Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 (Oct. 2, 2024), https://bit.ly/3Y719J0. The IRA refers to each year the program operates as an "initial price applicability year" or "IPAY," so the CMS guidance is sometimes referred to as the "IPAY Guidance."

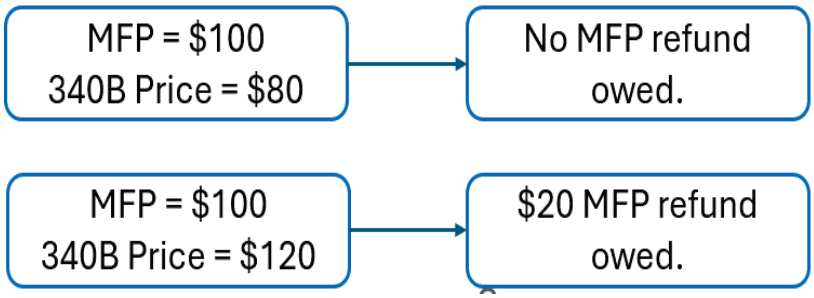
6. Under the IPAY Guidance, manufacturers can either charge dispensing entities the MFP for each purchase of a selected drug upfront or can provide a refund after the purchase for the difference between the entity's acquisition cost for the drug and the MFP. *See* IPAY Guidance § 40.4. CMS calls these reimbursement payments "MFP refunds." *See id.* Under the IPAY Guidance, manufacturers must transmit the MFP refund to the dispensing entity within 14 calendar days of the manufacturer's receipt of MFP Claim Data. *See* IPAY Guidance § 40.4.2. Drug manufacturers that fail to make MFPs available within the 14-day prompt pay window risk facing civil monetary penalties.

7. Separately, J&J participates in the federal 340B prescription drug pricing program ("340B Program"). Under the 340B Program, a manufacturer must enter into an agreement with the HHS Secretary providing that, in exchange for the manufacturer's right to participate in Medicare and Medicaid, the manufacturer must offer its outpatient drugs to certain healthcare providers, called "covered entities," at sharply reduced prices known as "ceiling prices." *See* 42 U.S.C. § 256b(a)(1).

8. Among other restrictions, the 340B Program prohibits covered entities from obtaining "duplicate discounts," which occur when a covered entity receives 340B pricing on a drug unit for which the manufacturer also pays a rebate under the Medicaid program. *See* 42 U.S.C. § 256b(a)(5)(A). Manufacturers are thus exempt from also paying a rebate to the applicable state Medicaid program on any unit of medication purchased at the 340B price.

9. Somewhat similarly, the IRA protects manufacturers from having to provide both the MFP and the 340B price on the same unit. *See* 42 U.S.C. § 1320f-2(d). Instead, manufacturers must offer 340B covered entities the lesser of the 340B price or the MFP for each unit of a selected drug dispensed to a 340B patient. *See id.* As a result, for units purchased at the 340B price, where

the 340B price is lower than the MFP, J&J owes the covered entity no MFP refund at all; where the 340B price is higher than the MFP, J&J owes the covered entity only the difference between the 340B price and the MFP. *See* IPAY Guidance § 40.4.5. By way of example, assume that the MFP for a particular drug was $100 and the 340B price was $80. In this situation, J&J would not have to pay any refund. But if the 340B price was $120, and the MFP was still $100, J&J would owe a $20 refund, that is, the difference between the higher 340B price and the MFP, as illustrated below.



10. However, if a manufacturer cannot confirm that a unit dispensed to a patient of a 340B entity was 340B-eligible within the 14-day MFP payment window, the IPAY Guidance requires manufacturers to issue to the covered entity the full MFP refund, which generally represents a selected drug's list price minus the MFP. *See id.* at 56; *id.* § 40.4.5.

11. Although J&J may later attempt to recoup these dollars from the covered entity if and when it discovers that the unit was 340B-eligible (often months later, if ever), the covered entity holds J&J's funds in the interim. Therefore, the result of CMS's guidance is that, for units that 340B covered entities purchase at a 340B-reduced price and then dispense to Medicare Part D beneficiaries who are patients of the 340B entity, J&J must pay the covered entity the full amount of the MFP refund—in essence, a duplicate discount—unless J&J can confirm the unit's 340B eligibility within the 14-day window.

12. In part to help meet its deduplication responsibilities, J&J planned to adopt a rebate model of its own initiative. In July 2024, J&J met with Health Resources and Services Administration ("HRSA") staff to discuss, among other things, its plans to implement a rebate model for certain purchasers of STELARA® and XARELTO®.

13. HRSA, however, took the position that J&J could not implement its own rebate program, and threatened to revoke J&J's Pharmaceutical Pricing Agreement if J&J proceeded with its rebate model without HRSA's prior approval to do so. In response, J&J (and other manufacturers) sued HRSA in November 2024, contending that rebate models were permissible under the 340B statute. That litigation remains pending in the United States Court of Appeals for the D.C. Circuit.

14. Meanwhile, on August 1, 2025, HRSA announced the Rebate Model Pilot Program ("Pilot Program") that Plaintiffs challenge in this case. J&J applied for, and was accepted into, the Pilot Program.

15. The Pilot Program is set to begin on January 1, 2026, the same day that STELARA® and XARELTO® will qualify as selected drugs under the Negotiation Program.

16. The Pilot Program allows manufacturers to provide 340B pricing through rebates. Critically, it enables manufacturers to obtain and analyze claims data to identify which drug dispense is eligible for which price concession, if any. This real-time data validation is what permits J&J to avoid paying unlawful duplicate discounts.

17. Claims data is commonplace and widely used healthcare data that covered entities already generate and share with payers and other government programs. Collecting and analyzing this data is the only feasible method for identifying when (and which) rebates are warranted and ensuring compliance with the Negotiation Program's nonduplication provisions. Without the Pilot

Program, J&J lacks the data necessary to identify whether a unit dispensed under Medicare and subject to an MFP was purchased under the 340B program, exposing J&J to costly duplicate discounts and potentially steep monetary penalties.

18. Although J&J has an existing policy requesting that certain covered entities submit standard claims data information to J&J within 45 days of dispensing a unit of a J&J drug, many covered entities have refused to submit claims data, or have submitted inaccurate or incomplete data. Moreover, even when that data is provided, it is done retroactively, after the covered entity has already received the 340B price on a unit. J&J is thus unable to rely on this data proactively to prevent duplication across the MFP and 340B prices.

19. Without real-time claims data, J&J is unable to confirm 340B status in a timely manner. Although J&J also accesses other third-party sources of information to identify limited instances of 340B-eligible claims, this information is sometimes inconsistent and often unavailable to J&J until months following a 340B-eligible dispense, meaning that J&J is unable to use it to comprehensively confirm 340B status.

20. Thus, even assuming the information available to J&J identifies all or even most 340B-eligible dispenses (which it does not), at best, J&J would still be required to pay both the 340B discount and MFP refund on virtually every unit purchased at the 340B price and dispensed by a covered entity to a Medicare Part D beneficiary, and would then have to attempt to retroactively recoup improperly paid duplicate discounts, as described below.

21. If Plaintiffs succeed in delaying or halting the Pilot Program, for purchases of STELARA® and XARELTO® in 2026, the company estimates that it would be required to pay over a hundred million dollars in improper MFP refunds to covered entities on medications purchased at the 340B price.

22. J&J's only available recourse to avoid these massive losses would be to use the fragmented information it is able to compile on 340B-eligible purchases to attempt to retroactively recoup improperly paid duplicate discounts. Retroactive efforts to track down duplicate discounts, however, would require a significant expenditure of time and expense and ultimately would be less effective than preventing duplicate discounts in the first instance.

23. Unless the Pilot Program goes into effect on January 1, 2026, J&J will simply not be able to comply with the overlapping requirements of the 340B program and the Negotiation Program, will risk incurring penalties for failure to comply, and will pay duplicate price concessions under both programs that are inconsistent with federal law.

24. In addition, J&J has devoted substantial time and resources to implementing the Pilot Program. Preparations began in mid-2024, when J&J first initiated plans to adopt a rebate program. Since that time, J&J has worked with external vendors to design, build, and test its rebate model platform. The Company has expended several million dollars and thousands of hours in anticipation of operationalizing a rebate program, whether through its own initiative or HRSA's Pilot Program.

25. Since HRSA's announcement of the Pilot Program, J&J has worked to ensure its rebate model platform will allow J&J to process claims data and issue refunds within the window specified by HRSA. J&J has expended hundreds more hours on testing for systems readiness, process, and compliance to ensure that the launch goes smoothly.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: December 10, 2025

Lauren Paluzzi

Lauren Paluzzi

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER, Plaintiffs, v. ROBERT F. KENNEDY, JR. Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA, Defendants.	Case No. 2:25-cv-00600-JAW

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.'S AND NOVO NORDISK INC.'S MOTION TO INTERVENE WITH INCORPORATED MEMORANDUM OF LAW

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Boehringer Ingelheim Pharmaceuticals, Inc. and Novo Nordisk Inc. hereby move for leave to intervene in this action pursuant to Federal Rules of Civil Procedure 24(a) and 24(b).

INTRODUCTION

Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer") and Novo Nordisk Inc. ("Novo Nordisk") (collectively, "the Manufacturers") move to intervene in this action to represent their distinct interests as manufacturers participating in the 340B Rebate Model Pilot Program ("pilot program"). The Manufacturers satisfy the requirements for intervention as of right pursuant to Federal Rule of Civil Procedure 24(a)(2). This motion is timely—filed only nine days after Plaintiffs filed their Complaint—and the Manufacturers will abide by any case deadlines, including the briefing schedule on Plaintiffs' motion for immediate relief.[1] The Manufacturers have a clear and substantial interest in the lawfulness of the pilot program that would be impaired if Plaintiffs succeed in delaying or halting the pilot program's implementation. The pilot program is necessary to ensure—consistent with federal statutory mandates—that manufacturers are not forced to provide steep and functionally unrecoverable duplicate discounts on their prescription drugs. Indeed, upending the pilot program at this late date will throw manufacturers' plans for deduplication, which are overseen by two federal agencies, into disarray—and effectively require the Manufacturers to pay duplicate discounts contrary to federal law. The federal Defendants cannot adequately represent the Manufacturers' commercial interests in ensuring that the pilot program begins as scheduled on January 1, 2026. In the alternative, the Manufacturers meet the standard for permissive intervention under Rule 24(b).[2]

[1] The Manufacturers are also prepared to coordinate with any other Intervenor-Defendants to avoid duplicative briefing to the extent possible.

[2] The Manufacturers have sought the parties' position on this motion. At the time of filing, Defendants have not yet responded. Plaintiffs stated they will oppose the motion. The Manufacturers respectfully request that any opposition to this motion be due by December 15, 2025, in line with the Court's December 8, 2025, Minute Order.

BACKGROUND

A pharmaceutical manufacturer participating in the 340B program must offer its products at a discount rate to statutorily defined "covered entities." The 340B statute expressly directs that this discount rate—known as the "ceiling price"—may be effectuated by either a front-end "discount" or back-end "rebate." 42 U.S.C. § 256b(a)(1). But the statute contains no requirement that covered entities pass through the discount to patients. 61 Fed. Reg. 43,549, 43,551 (Aug. 23, 1996) ("Section 340B does not limit the pricing behavior of covered entities.").

Both Boehringer and Novo Nordisk manufacture innovative pharmaceutical products that are covered by the 340B program. *See* Boehringer Ingelheim, Comment Letter on 340B Rebate Model Pilot Program Notice at 1 (Sept. 8, 2025) (Ex. A); Novo Nordisk, Comment Letter on 340B Rebate Model Pilot Program Notice at 2 (Sept. 8, 2025) (Ex. B). Beginning on January 1, 2026, several of these drug products will also be subject to a new requirement in the Inflation Reduction Act ("IRA") that directs manufacturers to provide Medicare beneficiaries access to the product at a discounted "maximum fair price" ("MFP"), as prescribed by the Centers for Medicare & Medicaid Services ("CMS"). *See* Ex. A at 1; Ex. B at 2; 42 U.S.C. § 1320f-2(a).

The separate discounts mandated by the IRA and 340B programs will often overlap—for example, when a Medicare patient receives treatment from a hospital that is a covered entity under the 340B program. The IRA addresses these scenarios by (1) directing manufacturers to offer only the *lower* of the MFP *or* the 340B ceiling price on a prescription, and (2) mandating that manufacturers "shall not be required to provide" both the MFP and 340B discounts. *See* 42 U.S.C. § 1320f-2(d). Manufacturers are further required to provide the MFP discount in the form of

reimbursement after the manufacturer receives notice that a patient is eligible.[3] Thus, if a covered entity purchases a product at the 340B price, and the product is later dispensed to an IRA-eligible patient, a duplicate discount may occur. A rebate model solves that problem by equipping manufacturers with a mechanism to prevent duplicate discounts, in accordance with the IRA, when the IRA's discount requirement takes effect in January 2026. *See* Ex. A at 1; Ex. B at 1.

On August 1, 2025, the Health Resources and Services Administration ("HRSA") announced the 340B Rebate Model Pilot Program "primarily to address" manufacturers' need to "de-duplicate" 340B and IRA discounts. 90 Fed. Reg. 38,165, 36,163 (Aug. 7, 2025). Accordingly, as initially created, the pilot program applies narrowly to a small group of drugs: those subject to IRA discounts beginning on January 1, 2026. *See id.* One of Boehringer's drugs (Jardiance®) and six of Novo Nordisk's drugs (Fiasp®; Fiasp FlexTouch®; Fiasp PenFill®; NovoLog®; NovoLog FlexPen®; and NovoLog PenFill®) fall within that category.[4] Under the pilot program, manufacturers will provide 340B discounts through a rebate after an initial purchase at market price, rather than through a discount at the time of purchase. *See* 90 Fed. Reg. at 36,163.

Boehringer and Novo Nordisk each applied to HRSA for authorization to operate a rebate model under the program. On October 30, 2025, HRSA approved the applications and authorized the Manufacturers to begin implementing their models on January 1, 2026. *See* Decl. of Christine Marsh, ¶¶ 33-34 ("Marsh Decl."); Decl. of Farruq Jafery, ¶ 24 ("Jafery Decl."). The Manufacturers also submitted an MFP effectuation plan to CMS, explaining that they would rely on the pilot to prevent duplication of IRA and 340B discounts. *See* Marsh Decl. ¶ 36; Jafery Decl. ¶ 25.

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[3] *See* Memorandum from CMS Deputy Admin. & Director of the Center for Medicare, *Medicare Drug Price Negotiation Program* at 127, Centers for Medicare & Medicaid Services (June 30, 2023), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.

[4] *See* CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 2023), https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf.

On December 1, 2025, more than a month after HRSA's approval orders, the Plaintiffs filed this action, contending that HRSA's pilot program violates the Administrative Procedure Act ("APA"). That same day, Plaintiffs moved for a temporary restraining order ("TRO"), seeking to enjoin the pilot program before it begins. To protect their substantial interests as participants in their rebate models, the Manufacturers now move to intervene.

ARGUMENT

I. The Manufacturers Are Entitled to Intervene as of Right Under Rule 24(a).

The Manufacturers may intervene as of right because: (1) the motion is timely; (2) the Manufacturers have a "concrete interest" in defending the lawfulness of the pilot program; (3) there is "a realistic threat that resolution of the pending action will hinder" the Manufacturers' ability to effectuate that interest; and (4) the federal Defendants do not adequately represent the Manufacturers' interests. *T-Mobile Ne. LLC v. Town of Barnstable*, 969 F.3d 33, 39 (1st Cir. 2020) (citing Fed. R. Civ. P. 24(a)).

Timeliness. The Manufacturers' motion to intervene—filed just nine days after Plaintiffs filed their Complaint—is timely. This case is still in "the initial stages." *Geiger v. Foley Hoag LLP Retirement Plan*, 521 F.3d 60, 64 (1st Cir. 2008). The federal Defendants have not filed their opposition to Plaintiffs' motion or any responsive pleading, and this Court has not ruled on any substantive motions. Courts regularly find motions to intervene timely in similar circumstances. *See, e.g.*, *Orkin v. Albert*, 557 F. Supp. 3d 252, 260 (D. Mass. 2021); *Ne. Patients Grp. v. Maine Dep't of Admin. & Fin. Servs.*, 2021 WL 1135019, at *3 (D. Me. Mar. 23, 2021).

Further, no party will be prejudiced if the Court allows the Manufacturers to intervene. The Manufacturers will observe all case deadlines, including the briefing schedule on Plaintiffs' motion for a TRO. *See, e.g.*, *S.R.C. by Cobbett-Walden v. Miller*, 2025 WL 3267608, at *2 (D. Mass. Nov. 24, 2025) (Plaintiffs not prejudiced "because this case is only at its initial stage" where

TRO briefed). Any urgency in this case is due to Plaintiffs' delay: Plaintiffs filed their complaint four months after HRSA announced the pilot program and more than one month after HRSA approved the Manufacturers' rebate models. In contrast, as discussed below, the Manufacturers would face significant prejudice if denied the opportunity to intervene. *See, e.g.*, *Littlefield v. U.S. Dep't of the Interior*, 318 F.R.D. 558, 560 (D. Mass. 2016) ("[G]iven the [intervenor's] undeniable and compelling interest in the outcome of th[e] litigation, their risk of prejudice is substantial.").

Significantly Protectable Interest. The Manufacturers have a "significantly protectable interest" at stake in this litigation that is "direct, not contingent," *Pub. Serv. Co. of N.H. v. Patch*, 136 F.3d 197, 205 (1st Cir. 1998) (quotations omitted), and "bear[s] a sufficiently close relationship to the dispute between the original litigants" over the legality of HRSA's pilot program, *Travelers Indem. Co. v. Dingwell*, 884 F.2d 629, 638 (1st Cir. 1989) (quotations omitted). The pilot program provides a mechanism that enables the Manufacturers to apply the correct discount under *either* the 340B program *or* the IRA program, as required by statute. Without the rebate model, the Manufacturers will face either substantial economic losses due to duplicate discounts, or potential penalties due to a failure to comply with the statutes' requirements. *See, e.g.*, *Conservation Law Foundation v. Mosbacher*, 966 F.2d 39, 42–43 (1st Cir. 1992) (sufficient interest to support intervention where movant is "the subject[] of the regulatory plan" and will face effects to "business, both immediately and in the future"); *Pub. Serv. Co. of N.H. v. Patch*, 173 F.R.D. 17, 27 (D.N.H. 1997), *aff'd*, 136 F.3d 197 (1st Cir. 1998) (intervenors had "sufficiently close relationship" because they had "a direct interest in the substance of the" regulatory action).

Impairment of Interest. Because the HRSA action challenged by Plaintiffs advances the Manufacturers' significantly protectable interests, those interests would be impaired if Plaintiffs' claims succeed. *See Daggett v. Comm'n on Governmental Ethics & Election Practices*, 172 F.3d

104, 110–11 (1st Cir. 1999) (requirement satisfied where disposition of the case could adversely affect the would-be intervenor's significantly protectable interest); *see also Portland Cellular P'ship v. Inhabitants of the Town of Cape Elizabeth*, 2015 WL 12990147, at *2 (D. Me. Feb. 3, 2015) (when intervenor's interests are related to the dispute, "[t]he third Rule 24(a)(2) factor requires little discussion"). A ruling in Plaintiffs' favor would invalidate or delay the pilot program, leaving the Manufacturers without a mechanism to prevent duplicate discounts—and causing Manufacturers substantial and unrecoverable economic losses.

Inadequate Representation. The Manufacturers satisfy the "minimal" requirement that the representation afforded by the existing parties "may be" inadequate. *Students for Fair Admissions, Inc. v. President & Fellows of Harvard Coll.*, 807 F.3d 472, 475 (1st Cir. 2015) (quoting *Trbovich v. United Mine Workers of Am.*, 404 U.S. 528, 538 n.10 (1972)). "The essential question," this Court has explained, "is whether the goals" of the existing governmental party "may" "differ from the goals of the Intervenors." *Animal Protection Inst. v. Martin*, 241 F.R.D. 66, 68 (D. Me. 2007) (Woodcock, J.); *see also Mosbacher*, 966 F.2d at 44 ("[a]n intervenor need only show that representation may be inadequate, not that it is inadequate").

The First Circuit historically has recognized a rebuttable presumption of adequate representation when a potential intervenor shares an ultimate goal with an existing party or when it "seeks to appear alongside a governmental body in defense of the validity of some official action." *T-Mobile*, 969 F.3d at 39. More recently, however, the Supreme Court has cast doubt on this presumption. *See Berger v. N.C. State Conf. of the NAACP*, 597 U.S. 179, 196–98 (2022); *see also Bost v. Ill. Bd. of Elections*, 75 F.4th 682, 688 n.3 (7th Cir. 2023) (*Berger* "called into question whether any presumption of adequate representation is appropriate"). Even if the presumption remains good law, it generally does not apply "[w]here the absentee's interest is similar to, but not

identical with, that of one of the parties." *Berger*, 597 U.S. at 197 (quotations omitted). Here, the federal Defendants' interests are far from "identical" to Manufacturers'. Rather, the interests of the two groups are distinct, in at least two critical ways.

First, the Manufacturers have substantial commercial interests in the pilot program that the federal Defendants do not. Unlike the government, the Manufacturers would face significant economic losses from duplicate discounts or risk civil penalties for failure to provide the correct discount if they are required to provide up-front 340B discounts after the IRA's requirements go into effect. *See* 42 U.S.C. § 1320f-2(d); *id.* § 256b(d)(1)(B)(vi). The Manufacturers thus have a particular financial interest in ensuring that their rebate models can operate on January 1, 2026. *See Animal Protection*, 241 F.R.D. at 70 ("there are private interests at stake, which the Intervenors stand to lose if [plaintiff] prevails in its action"). The Manufacturers also have expended substantial resources in modifying their 340B procedures to prepare for the program. Marsh Decl. ¶ 34; Jafery Decl. ¶ 26. Those procedures would be upended if the pilot program is enjoined.

Second, the federal Defendants must "bear in mind broader public-policy implications" and general concerns about the government's regulatory authority that the Manufacturers do not. *Berger*, 597 U.S. at 196; *see Animal Protection*, 241 F.R.D. at 70 ("While the [governmental party] may take into account the Intervenors' economic … interests, it must also weigh countervailing factors, such as the more broadly viewed public interest"). Instead, the Manufacturers "will focus on defending [this action] vigorously on the merits without an eye to crosscutting administrative concerns." *Berger*, 597 U.S. at 198. The Manufacturers also have a broader interest in defending their rebate models separate from the process HRSA employed in this action. Notably, Plaintiffs themselves rely on prior HRSA statements *rejecting* manufacturers' proposals for rebate models.

See, e.g., Mot. for TRO at 10; Complaint at 52. Particularly in light of HRSA's prior statements, manufacturers have a clear interest in presenting a vigorous defense of their rebate models.

Accordingly, courts have "often concluded that governmental entities do not adequately represent the interests of aspiring intervenors" where the government must represent the public interest, not the intervenor's unique private-sector interests. *Crossroads Grassroots Pol'y Strategies v. FEC*, 788 F.3d 312, 321 (D.C. Cir. 2015) (quoting *Fund For Animals, Inc. v. Norton*, 322 F.3d 728, 736 (D.C. Cir. 2003)); *see, e.g.*, *Mosbacher*, 966 F.2d at 44 (government's "judgments are necessarily constrained by [its] view of the public welfare," while regulated parties "may see their own interest in a different . . . light"); *NYNEX Corp. v. FCC*, 153 F.R.D. 1, 3 (D. Me. 1994) (interests not adequately represented where agency "defend[s] this case from the perspective of the overall national public welfare" and favorable ruling "may" result in "new regulations" detrimental to movant's interests).

To the extent any presumption of adequate representation applies, "the intervenor need only offer an adequate explanation as to why it is not sufficiently represented by the named party"—for example, by demonstrating "that its interests are sufficiently different in kind or degree from those of the named party." *B. Fernandez & Hnos., Inc. v. Kellogg USA, Inc.*, 440 F.3d 541, 546 (1st Cir. 2006) (quotations omitted). The Manufacturers' distinct financial interests described above are sufficient to overcome this presumption. *See, e.g.*, *McDonough v. City of Portland*, 2015 WL 3755289, at *4 (D. Me. June 16, 2015) (presumption overcome where government "must account for a spectrum of governmental interests far broader than the discrete commercial interests [a putative intervenor] seeks to protect").

Plaintiffs' TRO motion underscores the need for intervention. The Manufacturers have a financial interest in the uninterrupted implementation of their rebate models that Plaintiffs seek to

enjoin, and would be significantly and immediately harmed if they were precluded from using this mechanism to adjudicate 340B claims. Conversely, the federal Defendants do not suffer a similar harm if an injunction issues, since it is the Manufacturers (not the government) that are charged with implementing a mechanism that complies with the law as of January 1, 2026. Furthermore, the federal Defendants cannot provide information regarding the severe harm that would befall the Manufacturers if the program were enjoined, or the efforts the Manufacturers have undertaken prepare for the program's implementation date. Simply put, the Manufacturers, not HRSA, will suffer significant and immediate harm if the program is enjoined. And the federal Defendants' interests could deviate from those of the Manufacturers. As another court recognized, "[o]f course HRSA might treat" covered entities and manufacturers "differently," since "covered entities are the beneficiaries of the lower prices guaranteed by the 340B Program." *Johnson & Johnson Health Care Sys., Inc. v. Kennedy*, 2025 WL 1783901, at *13 (D.D.C. June 27, 2025). The Manufacturers thus must intervene to present critical information that the federal Defendants cannot.

Notably, a group of hospitals and hospital associations moved to intervene in related litigation in which drug manufacturers challenged HRSA's denial of earlier proposals for 340B rebate models, and those motions to intervene were granted. *See, e.g.*, Order, *Johnson & Johnson v. HHS*, No. 1:24-cv-3188, ECF 50 (D.D.C. May 15, 2025) (granting intervention under Rule 24(a)); Order, *Sanofi-Aventis U.S. LLC v. HHS*, No. 1:24-cv-3496, ECF 32 (D.D.C. Mar. 4, 2025) (same). In support of these motions, the would-be intervenors argued that HRSA could not adequately represent their "financial interests," nor could HRSA "adequately describe the impact that [the] proposed rebate model w[ould] have" on their businesses. Mot. to Intervene, No. 1:24-cv-3188, ECF 14-1 at 22-23 (D.D.C. Jan. 30, 2025); *see also* Mot. to Intervene, No. 1:24-cv-3496, ECF 23-1 at 17–19 (D.D.C. Feb. 5, 2025) (similar). The same is true here.

II. Alternatively, the Manufacturers Should Be Allowed to Intervene Under Rule 24(b).

Federal Rule of Civil Procedure 24(b) allows a court to permit intervention where the motion is timely, the movant has a claim or defense that shares with the main action a common question of law or fact, and intervention will not unduly delay or prejudice the adjudication of the original parties' rights. These requirements are "construed liberally." *Animal Protection*, 241 F.R.D. at 68. "The fact that the applicants may be helpful in fully developing the case is a reasonable consideration in deciding on permissive intervention." *Daggett*, 172 F.3d at 113.

The Manufacturers meet these requirements. They have timely moved for leave to intervene, such that granting this motion would not prejudice the original parties or delay this case. In addition, the defenses that the Manufacturers intend to raise will involve common questions of law or fact. For example, the Manufacturers' opposition will address the standards imposed by the APA, as well as the factual record that informed HRSA's decision to implement the pilot program and approve the Manufacturers' rebate model applications. Finally, as shown above, the Manufacturers have a substantial interest in the outcome of this litigation that cannot be adequately represented by the federal Defendants, and their intervention would be helpful in fully developing the case by adding a key perspective as entities subject to the 340B rebate model pilot program.[5]

CONCLUSION

The Manufacturers have a substantial and distinct interest in the outcome of this action and have timely moved for leave to intervene. This Court should grant the motion for intervention.

[5] Federal Rule of Civil Procedure 24(c) requires that a motion to intervene be accompanied by a responsive pleading. The Manufacturers request that this requirement be waived because the APA claims in this action likely will be resolved without the filing of an answer, and no party will suffer prejudice in the absence of a responsive pleading. *See Peaje Invs. LLC v. García-Padilla*, 845 F.3d 505, 515 (1st Cir. 2017) (recognizing flexibility in Rule 24(c)'s requirements, absent prejudice to any party).

Respectfully submitted,

/s/ Alfred C. Frawley IV

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Counsel for Boehringer Ingelheim Pharmaceuticals, Inc. and Novo Nordisk Inc.

December 10, 2025

CERTIFICATE OF SERVICE

I hereby certify that, on December 10, 2025, I caused the foregoing document to be filed with the Clerk of the Court of the United States District Court for the District of Maine using the Court's CM/ECF system.

/s/ Alfred C. Frawley IV
Alfred C. Frawley IV

Counsel for Boehringer Ingelheim Pharmaceuticals, Inc. and Novo Nordisk Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER, *Plaintiffs*, v. ROBERT F. KENNEDY, JR. Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA, *Defendants*.	Case No. 2:25-cv-00600-JAW

DECLARATION OF ALFRED C. FRAWLEY IV IN SUPPORT OF BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.'S AND NOVO NORDISK INC.'S MOTION TO INTERVENE

Alfred C. Frawley IV declares, under penalty of perjury and pursuant to 28 U.S.C. § 1746, as follows:

1. I am a member of the bars of Maine and Massachusetts, and I am at attorney at the law firm McCloskey, Mina, Cunniff & Frawley, LLC, counsel to Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer") and Novo Nordisk Inc. ("Novo Nordisk"). I submit this declaration and the attached exhibits in support of Boehringer's and Novo Nordisk's motion to intervene.

2. Attached as Exhibit A is a true and correct copy of a comment submitted by Boehringer on the 340B Program Notice, HHS Docket No. HRSA–2025–14619 (Sept. 8, 2025), available at https://www.regulations.gov/comment/HRSA-2025-0001-0873.

3. Attached as Exhibit B is a true and correct copy of a comment submitted by Novo Nordisk on the 340B Program Notice, HHS Docket No. HRSA–2025–14619 (Sept. 8, 2025), available at https://www.regulations.gov/comment/HRSA-2025-0001-0679.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: December 10, 2025

s/ Alfred C. Frawley IV
Alfred C. Frawley IV

EXHIBIT A

Boehringer Ingelheim

Boehringer Ingelheim USA
Corporation
900 Ridgebury Road
Ridgefield CT 06877

Via Regulations.gov

Thomas J. Engels
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Re: 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program Docket No. HRSA-2025-14619

Dear Administrator Engels:

Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer") thanks the Health Resources and Services Administration's ("HRSA" or "the Agency") for publishing the *340B Program Notice: Application Process for the 340B Rebate Model Pilot Program* ("Notice").[1] The Notice is an important development in the 340B program; Boehringer applauds HRSA for implementing a 340B rebate model. We welcome the opportunity to provide the following comments to further our shared goals of improving program integrity and ensuring the long-term viability of the 340B program. Boehringer adopts and incorporates by reference the comments on the Notice submitted by the Pharmaceutical Research and Manufacturers of America. We offer the following comments to elaborate and expand on certain issues raised by the Notice.

Boehringer is a leading research-driven biopharmaceutical company committed to innovation in areas of high unmet medical need. Accordingly, Boehringer has a significant interest in the effective administration of the 340B Drug Pricing Program. Moreover, as a manufacturer of JARDIANCE®, OFEV®, and TRADJENTA®, drugs selected for the Inflation Reduction Act ("IRA") price-setting program, Boehringer is committed to working with HRSA to successfully implement the 340B Rebate Model Pilot Program (the "Pilot").[2] The Pilot will improve program integrity and is critical to ensure nonduplication of the "maximum fair price" ("MFP") set under the IRA and the 340B ceiling price in an accurate manner, consistent with the requirements of section 1193(d)(1) of the Social Security Act.[3] Boehringer applauds HRSA for moving forward with the Pilot. Boehringer submits the following comments to ensure the smooth and efficient roll-out and expansion of the Pilot for all 340B stakeholders.

1. Minor Modifications and Flexibilities to Maximize Efficiency and Efficacy for Participating Manufacturers

A. *HRSA should approve proposed 340B rebate model applications on a rolling basis*

Boehringer encourages HRSA to approve proposed 340B rebate model applications on a rolling basis and to do so in advance of the stated October 15 deadline. In the Notice,

[1] 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program, 90 Fed. Reg. 38165 (Aug. 7, 2025)
[2] JARDIANCE® was selected for Initial Price Applicability Year ("IPAY") 2026 and is eligible for the Pilot under the Notice. OFEV® and TRADJENTA® were both selected for IPAY 2027 and are not currently eligible for the Pilot.
[3] 42 U.S.C § 1320f-2(d).

HRSA explains that "[a]pprovals will be made by October 15, 2025, for a January 1, 2026, effective date."[4] Approval of the 340B rebate model is critical to a manufacturer's ability to implement the MFP Effectuation Plan required by the Centers for Medicare & Medicaid Services ("CMS"), which must be submitted by September 1.[5] Moreover, access to a rebate model is critical to ensure nonduplication of the MFP and the 340B ceiling price as required by section 1193(d)(1) of the Social Security Act.[6] Knowing whether a 340B rebate model is a viable option to include in an MFP Effectuation Plan and in broader MFP/340B deduplication efforts is important to both manufacturers and CMS. The proposed October 15 deadline for approving Pilot applications falls *after* the CMS submission deadline. Until HRSA approves a pending application, manufacturers and CMS must undertake costly parallel-track approaches to developing MFP Effectuation Plans and MFP/340B deduplication strategies. If HRSA waits until October 15 to approve Pilot applications, manufacturers will not know if they are able to rely on a 340B rebate model for purposes of MFP/340B deduplication. To address this concern, HRSA should approve models on an accelerated timeline or on a rolling basis.

B. *HRSA should expand the Pilot to drugs selected for IPAY 2027 as soon as possible*

Boehringer encourages HRSA to expand the Pilot to apply to drugs selected for IPAY 2027 as soon as possible. As discussed above, the availability of a 340B rebate model is critical to developing and implementing an MFP/340B deduplication strategy and submitting an MFP Effectuation Plan to CMS. This concern is accentuated in future IPAYs because CMS will require manufacturers to submit portions of the MFP Effectuation Plans by June 1—three months earlier than the IPAY 2026 deadline.[7] Extending the Pilot to IPAY 2027 drugs well in advance of June 1, 2026, would thus maximize the efficacy of the Pilot and provide much-needed clarity.

2. **Potential Implementation Issues Not Yet Sufficiently Accounted for in the Pilot Design**

A. *HRSA must address the risk of duplicate discounts in the initial transition to a rebate model*

Boehringer is concerned that, during the transition to the 340B rebate model, covered entities could attempt to send claims data to the 340B rebate model for drugs purchased at the 340B price in the weeks before the January 1, 2026 effective date. Absent modifications to the Pilot, manufacturers will not be able to determine that these claims relate to drugs purchased at the 340B price and thus already subject to the 340B discount. We encourage HRSA to address this issue by requiring that covered entities submit purchase price data alongside 340B rebate claims. In addition, HRSA should clarify that covered entities should submit claims for 340B rebates only for drugs purchased on or after January 1, 2026 (i.e., drugs that were purchased at WAC or another wholesale price rather than drugs purchased at the 340B ceiling price).

B. *HRSA should authorize the collection of purchase data from covered entities*

Boehringer encourages HRSA to permit manufacturers to collect purchase data from covered entities as part of the Pilot. Providing this information through the Pilot would allow manufacturers to transmit accurate 340B rebates, improving program integrity. For example, if a manufacturer changes the WAC of an eligible product, having purchase data can ensure that 340B rebates accurately reflect the covered entity's purchase price. Moreover, permitting the collection of purchase data would not impose a significant

[4] 90 Fed. Reg. 31866.

[5] *See* CMS, Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 ("IPAY 2027 Final Guidance") at 285-286.

[6] 42 U.S.C § 1320f-2(d).

[7] *See* CMS, Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028 ("IPAY 2028 Draft Guidance") at 168.

additional burden on covered entities. They are required to maintain records as a condition of participation in the 340B program and they routinely collect purchase data in the regular course of business.

To ensure that manufacturers can provide accurate 340B rebates, Boehringer asks that HRSA allow the collection of the following purchase data:

- Wholesaler Name
- Wholesaler Account Number
- National Drug Code (collection permitted by Notice)
- Package Units
- Invoice Date
- Invoice Number
- National provider identifier of the pharmacy receiving physical shipment.
- 340B ID (collection permitted by Notice)

C. *HRSA should clarify how manufacturers may calculate the 340B rebate*

In the Notice, HRSA explains that a "'rebate' for purposes of this pilot program, means a reimbursement made from the manufacturer to the covered entity in the amount of the standard acquisition cost (i.e., wholesale acquisition cost) of a covered outpatient drug less the statutory 340B ceiling price."[8] This language suggests that WAC may be the only appropriate metric on which to base a rebate. But WAC may not reflect a covered entity's true purchase price. In certain instances, covered entities have agreements with manufacturers to purchase covered outpatient drugs at a price below WAC. Boehringer encourages HRSA to clarify that manufacturers may rely on WAC or, when available to the manufacturer, the actual acquisition cost when calculating the 340B rebate.

3. **Other Potential Modifications to the Pilot**

A. *HRSA should expand the Pilot to all drugs and payors*

While Boehringer appreciates HRSA's initial focus on implementing the Pilot for IRA selected drugs, we urge HRSA to work toward expanding the 340B rebate model to all 340B-eligible drugs.

1. A 340B rebate model is in the interests of all 340B program participants

A 340B rebate model can be implemented with minimal disruption to the current 340B distribution framework and will operate in a manner that protects the interests of all 340B program participants, including covered entities. Covered entities seeking to benefit from the 340B program have no grounds to object when reasonable conditions are imposed on their purchases of covered outpatient drugs to protect against duplicate discounts and other violations of federal law.

The 340B rebate model outlined in the Pilot is designed to mitigate concerns of covered entities "floating" the commercial cost of covered drugs. Under the 340B rebate model, Boehringer expects that rebate claims will be validated and paid within approximately seven to ten days of submission to the Beacon platform, with an outer limit of 10 days as required by the Notice. Under standard wholesaler payment terms, covered entities must generally pay for drug purchases within 30 days of purchase. As a result, covered entities that submit rebate claims promptly will obtain a rebate that allows them to net the 340B price on the sale well before the date on which their invoice is due to the

[8] 90 Fed. Reg. 31866.

wholesaler on the original purchase for Boehringer's JARDIANCE® product. In other words, although a covered entity will initially place an order at WAC under the 340B rebate model, the covered entity will not actually have to pay the non-340B price if it promptly submits a rebate claim, because it will receive the rebate before it needs to pay the invoice. Moreover, under Boehringer's 340B rebate model, the covered entity will deal directly with the manufacturer on the effectuation and administration of the 340B price, eliminating interaction with the distributor. This direct financial relationship between the entities subject to the requirements of 340B and governed by the respective agreements results in greater transparency and promotes program integrity.

In many respects, a 340B rebate model is similar to the virtual credit models that covered entities have voluntarily adopted and relied on for years. Under these virtual models, covered entities (or their contract pharmacies) purchase all medications at commercial prices and maintain a single inventory, without differentiating between 340B and non-340B products. The covered entity dispenses medications in the ordinary course and then identifies (after the fact) transactions that it maintains are eligible for 340B pricing. The covered entity sends that data—usually through a third-party administrator—to its distributor, which attempts to match the dispenses identified as 340B eligible with prior purchases of the same NDC and quantity. When the distributor successfully makes a match, it (i) "credit[s] the [covered entity's] non-340B commercial account for the difference" between the commercial and 340B price, and (ii) generates "a non-inventory purchase on the 340B covered entity bill-to/ship-to account."[9] Thus, rather than replenishing their inventories by having the distributor "physically shi[p]" drugs earmarked for 340B use, covered entities and contract pharmacies buy replacement drugs at the commercial price and then obtain the 340B price through a "financial credit" applied after the fact.[10] For example, when a covered entity enrolled in a virtual credit model program purchases a drug initially for $100 and later dispenses the drug to a 340B-eligible patient, "$100 will be credited to" the covered entity's "non-340B account" by the distributor "and then the entity will be invoiced for the 340B ceiling price … in [its] 340B account."[11]

The net effect of this virtual credit model is the same as a 340B rebate model: the covered entity orders drugs at commercial prices up front, then later receives the 340B price through a rebate after a third party validates the transaction. Court records and commercial literature show that covered entities have voluntarily participated in these virtual credit model programs for nearly a decade.[12] Indeed, PharmaForce stated in 2024 that "a lot" of its "customers . . . are using" the virtual credit model "successfully" and that many pharmacies now "require a credit-based replenishment model."[13] Likewise, Boehringer recently identified one covered entity that has shifted to making significant purchases at WAC and stated that it is doing so under a virtual credit model.

In support of these points, we attach the following documents as exhibits to this letter:

[9] AmerisourceBergen (now Cencora), *Inventory Synchronization Program Guide*, Doc. No. HS-110567, at 3, available at https://web.archive.org/web/20240426164057/https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/pdf/hgs-230633-isp-guide-12dec23-v2.pdf. PharmaForce, which offers a variety of 340B services for covered entities and pharmacies, has similarly identified the "adoption of credit-based replenishment models" as "a recent trend in 340B program" that "eliminates the need for physical inventory deliveries" and instead "us[es] a credit system within the pharmacy's retail account." PharmaForce, Credit-Based Replenishment: The Future of 340B? (accessed May 20, 2025), https://www.thepharmaforce.com/340b-credit-based-replenishment.aspx

[10] PharmaForce, Credit-Based Replenishment: The Future of 340B, at 5:52-6:12 (May 23, 2024), https://www.youtube.com/watch?v=T7yz-ZgjW2w ("PharmaForce Webinar").

[11] *Id.* at 5:25-5:38.

[12] *See, e.g.*, Memorandum of Law in Support of Defendant's Motion to Dismiss, *Fruth, inc. v. Cardinal Health, Inc.*, No. 3:23-cv-801, ECF No. 15, at *3 (S.D.W. Va. filed Mar. 18, 2024) (describing a similar "virtual replenishment" program operated by Cardinal Health and referring to allegation that plaintiff "began using" it "in March 2016"); PharmaForce Webinar, *supra*, at 24:20-24:32 (referring to Cardinal Health virtual credit model program).

[13] *See* PharmaForce Webinar, *supra*, at 24:05-24:23.

- **Exhibit A:** Letter from Boehringer Ingelheim to 340B Covered Entities (Nov. 1, 2024)
- **Exhibit B:** AmerisourceBergen Inventory Synchronization Program Guide
- **Exhibit C:** PharmaForce, "Credit-Based Replenishment: The Future of 340B?" Webinar Description
- **Exhibit D:** Transcript of PharmaForce 340B Credit-Based Replenishment Webinar
- **Exhibit E:** Memorandum of Law in Support of Defendants' Motion to Dismiss, Fruth Inc. v. Cardinal Health, 3:23-cv-00801 (S.D. W. Va. March 18, 2024)

2. HRSA should expand the 340B rebate model to cover all duplicate discounts

There is no rational reason for HRSA to prevent manufacturers from using a 340B rebate model to address Medicaid duplicate discounts and diversion. In the Notice, HRSA explains that a 340B rebate model as part of an approved Pilot application should not be used to deny claims "based on compliance concerns with diversion or Medicaid duplicate discounts."[14] This requirement unnecessarily allows covered entities to violate the 340B program's requirements.

As HRSA is aware, there is a longstanding problem of duplicative discounts in the 340B program. Currently, duplicate discounts can be applied to Medicaid fee-for-service rebates, Medicaid managed care rebates, commercial pharmacy benefit manager rebates, TRICARE retail refunds, patient coupons, and free drug vouchers. In addition, the IRA presents new risks of improper duplicate discounts, such as rebates necessary to effectuate the lower of the MFP or the 340B ceiling price, Part D inflation rebates, and Part B inflation rebates. The scope of this problem is significant: IQVIA estimates that duplicate discounts accounted for a staggering one-quarter of total 340B drugs sales in 2021, representing approximately $20-25 billion in total.[15] A 340B rebate model with consistent data exchange is by far the most efficient and transparent way to manage these interlocking programs. Nevertheless, the Pilot arbitrarily limits manufacturers to preventing duplicate discounts under the IRA—foreclosing an important compliance mechanism to ensure program integrity.

While HRSA has proposed other solutions to address Medicaid duplicate discounts and diversion, they are unlikely to be effective. Without providing access to a 340B rebate model, HRSA instead instructs manufacturers to address duplicate discounts and diversion in Medicaid through "the 340B statutory mechanisms, such as audits and administrative dispute resolution [("ADR")], for addressing such issues." But audits and ADR are ineffective at addressing Medicaid duplicate discounts and diversion. Audits are both time- and resource-intensive processes that were never intended to address the full scale of duplicate discounts and diversion. Under HRSA's final ADR rule, the Agency acknowledges that it "conducts 200 covered entity audits each fiscal year" on average.[16] These audits thus cover only a negligible percent of the more than 55,000 340B covered entities.[17] ADRs are similarly an ineffective process for addressing Medicaid duplicate discounts. Under the ADR Final Rule, manufacturers must seek and obtain approval from HRSA to conduct an audit *before* initiating ADR proceedings. If a manufacturer is able to conduct an audit, the ADR proceedings themselves are cumbersome and time consuming. According to HRSA's own published statistics, the Agency has issued only one ADR decision.[18] Moreover, the sheer quantity of individual 340B claims from an individual

[14] 90 Fed. Reg. 38166.
[15] IQVIA, Uncover the Invisible Impacts of 340B Discounts (Dec. 20, 2021) https://www.iqvia.com/locations/united-states/blogs/2021/12/uncover-the-invisible-impacts-of-340b-discounts.
[16] 89 Fed. Reg. 28643, 28644 (Apr. 19, 2024) ("Final ADR Rule").
[17] *See* Avalere Health, Key Stakeholders of the 340B Drug Discount Program (Jun. 16, 2023) https://advisory.avalerehealth.com/insights/key-stakeholders-of-the-340b-drug-discount-program ("In 2021, there were over 55,000 active 340B covered entities.").
[18] HRSA, 340B ADR Decision Summaries (Last Updated May 15, 2025) https://www.hrsa.gov/opa/340b-administrative-dispute-resolution/340b-adr-decision-summaries.

covered entity complicate the audit and ADR processes—complications that are solved by the 340B rebate model. Clearly, audits and ADRs are inadequate tools to address the scale of duplicate discounts and diversion in Medicaid.

Boehringer urges HRSA to reconsider the policy prohibiting manufacturers from using a 340B rebate model to identify duplicate discounts or diversion in Medicaid. The inability to address these instances of duplicated discounts undermines the 340B program's integrity and jeopardizes its long-term viability. Under the 340B statute, HRSA has a statutory obligation to "provide for improvements" by covered entities with the statutory requirements "in order to prevent diversion and violations of the duplicate discount provision."[19] Moreover, the 340B statute requires covered entities to maintain adequate records as a condition of participating in the program and obtaining the significant financial benefits of accessing manufacturers' drugs at dramatically reduced prices. Developing a mechanism like the 340B rebate model capable of identifying and remedying duplicate discounts in a manner that imposes few costs to HRSA is fully consistent with the statute and the requirements that Congress imposed to protect against abuses. In contrast, failing to extend that mechanism to duplicate discounts and diversion in Medicaid runs counter to these statutory directives. HRSA should thus allow a rebate model to address duplicate discounts.

3. Managing two separate 340B programs is burdensome and unnecessary

Given the limited scope of the Pilot, Boehringer will have to concurrently operate both a 340B rebate model for JARDIANCE® and a prospective 340B pricing system for all other products. This dual-model system will be unnecessarily burdensome and difficult to administer over the long term. What's more, this dual-model approach would, if maintained indefinitely, have the practical effect of warping incentives in the program by encouraging covered entities to prescribe drugs that are not subject to the Pilot to forgo data sharing with manufacturers. Accordingly, while we support the action HRSA has taken to launch the Pilot, we also encourage HRSA to promptly expand the Pilot to all 340B-eligible drugs.

* * *

Thank you for considering these comments. If you require any additional information or have questions, please contact Michael Penn, Head of Public Policy at (203)791-6680 or michael.penn@boehringer-ingelheim.com.

Sincerely,



Robert L. Anderson III
Vice President
Corporate Affairs
Boehringer Ingelheim Pharmaceuticals, Inc.

[19] 42 U.S.C. § 256b(d)(2).

Exhibit A – Letter from Boehringer Ingelheim to 340B Covered Entities (Nov. 1, 2024)

Boehringer Ingelheim

Date November 1, 2024
Page 01 | 04

UPDATE

Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer) is updating its 340B Program contract pharmacy policies

Notice to 340B Covered Entities: Effective December 2, 2024

Dear 340B Covered Entity:

Boehringer strongly supports the 340B program and is committed to maintaining and strengthening its mission for the patients we serve today and into the future. At the same time, Boehringer is concerned with the well-documented program integrity issues. We remain committed to the 340B program and believe this initiative will further strengthen the program and support its core mission to ensure patients have access to the medications they need.

I am writing to inform you that Boehringer is updating its 340B Program contract pharmacy policies. **Effective December 2, 2024, Boehringer will require the submission of claims data on 340B utilization filled at contract pharmacies for all covered entity types.** All specified claims data must be submitted on the 340B ESP™ platform within 45 days of the date of dispense.

- Our policy change applies to all covered entity types that do not have in-house pharmacy dispensing capabilities and have designated contract pharmacy location(s) per the 340B ESP™ platform. The FAQs below provide additional information on Boehringer's 340B policy.

If you have any questions regarding Boehringer's updated 340B Program contract pharmacy policy, please reach out to support@340besp.com.

Best regards,

DocuSigned by:
8FD6E7176DE8458...

Timmo Andersen
President U.S. Human Pharma
Boehringer Ingelheim Pharmaceuticals, Inc.

DocuSigned by:
Christine G. Marsh
20828E4D4469469...

Christine G. Marsh
Senior Vice President, Value & Access
Boehringer Ingelheim Pharmaceuticals, Inc.

Frequently Asked Questions

Q: Which products are subject to Boehringer's policy?
A: Boehringer's policy applies to all products attached in Exhibit A hereto. In addition, the list of applicable NDCs can be found at What NDCs do we look for? | 340B ESP – Help Center.

Q: What covered entity types are included in Boehringer's policy?
A: All covered entity types are subject to Boehringer's 340B contract pharmacy policy.

Q: What is an in-house ('entity-owned') pharmacy?
A: An in-house ('entity-owned') pharmacy is a pharmacy that is 100% owned by the 340B covered entity and listed as shipping addresses of the entity.

Q: My covered entity does not have in-house dispensing capabilities. Does my covered entity need to submit claims data for access to its designated contract pharmacy location(s)?
A: Yes. Any covered entity that does not have an in-house pharmacy capable of dispensing primary care 340B purchased products to its patients may designate a single contract pharmacy location to receive and dispense products purchased at the 340B price provided the covered entity submits limited claims data for that contract pharmacy location. The designated contract pharmacy must be registered on the HRSA OPAIS database as a contract pharmacy, located within a forty (40) mile radius of the covered entity parent site, and cannot be a central fill pharmacy. A wholly owned pharmacy may instead be designated as the single contract pharmacy location to receive and dispense 340B purchased primary care brands provided the covered entity submits limited claims data for that contract pharmacy location. The contract pharmacy must be registered on the HRSA OPAIS database as a contract pharmacy, located within forty (40) miles of the covered entity parent site and is not a central fill pharmacy.

Q: My covered entity has an in-house pharmacy that is capable of dispensing Boehringer's primary care products but does not have the capability to dispense OFEV. Can my entity designate a contract pharmacy that is approved to purchase and dispense OFEV?
A: Any covered entity that does not have an in-house pharmacy capable of dispensing specialty products may also designate one (1) specialty pharmacy from within Boehringer's limited distribution network for the sole purpose of receiving and dispensing OFEV at the 340B price to its patients provide the covered entity submits limited claims data for that specialty pharmacy location. A wholly owned pharmacy may instead be designated as a single contract pharmacy location to receive and dispense OFEV purchased at the 340B price provide the covered entity submits limited claims data for that specialty pharmacy location and it meets the contract pharmacy requirements as registered on the HRSA OPAIS database as a contract pharmacy and is not a central fill pharmacy.

Q: My covered entity was previously exempt from Boehringer's 340B contract pharmacy policy, is my entity required to submit claims data?
A: If your entity was previously exempt from Boehringer's policy, please reach out to support@340Besp.com for claims data requirements for your entity.

Q: My covered entity has an in-house pharmacy capable of dispensing Boehringer products. Is my covered entity required to submit claims data?
A: No, while submission of claims data is not required for 340B product dispensations at in-house pharmacies, covered entities may voluntarily submit claims level data for Boehringer products purchased at the 340B price and dispensed through their in-house pharmacies.

Q: My covered entity has a contract pharmacy relationship with a pharmacy that is owned by our health system ('wholly owned pharmacy'). Is this pharmacy subject to Boehringer's policy?
A: Yes, contract pharmacies that are wholly owned by the covered entity are subject to Boehringer's policy. A wholly owned pharmacy may be designated as the single contract pharmacy location provided it meets the contract pharmacy requirements as registered on the HRSA OPAIS database as a contract pharmacy of the

entity, is located within a forty (40) mile radius of the covered entity parent site, is not a central fill pharmacy, and the covered entity submits limited claims data for that contract pharmacy location.

Q: Does the pharmacy's location that I would like to designate as my contract pharmacy designation need to be within a forty (40) mile radius of my covered entity's parent location?
A: Yes, under Boehringer's policy, with the exception of OFEV, the single contract pharmacy designation that a covered entity has chosen to distribute Boehringer products must be within a forty (40) mile radius of the covered entity's parent location.

Q: My 340B covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy (e.g. six different pharmacy locations). Can my entity designate all locations of the same pharmacy?
A: No. Similar to guidance provided by HRSA in 1996, Boehringer's policy allows 340B covered entities to designate only a single contract pharmacy location within forty (40) miles of the covered entity. Contract pharmacy locations are registered individually on the HRSA database and 340B covered entities are permitted to designate only a single contract pharmacy location which corresponds to a single contract pharmacy registration with HRSA.

Q: Does Boehringer permit an entity to designate a single contract pharmacy that collectively replenishes Boehringer products based on the dispensing activity of other non-designated contract pharmacy locations?
A: No. Boehringer expects 340B products to be shipped directly to the same contract pharmacy location(s) in which the 340B product was dispensed to an eligible patient.

Q: Is Boehringer requiring covered entities to have a HIN registered for the contract pharmacy that they designate?
A: Yes, a contract pharmacy must have a HIN assigned to it for a covered entity to designate it as its single contract pharmacy. This information is important for Boehringer to manage its process with its wholesalers. Boehringer will not register a HIN on your behalf, however, if you need guidance or more information on how to get a HIN assigned to your contract pharmacy, please reach out to support@340besp.com. If you try to designate a contract pharmacy without a HIN in 340B ESP™, the system will notify you of this requirement and provide instructions for how to obtain a HIN.

Q. How do I ensure that my contract pharmacy designation takes effect on December 2, 2024?
A: If your covered entity wishes to designate a contract pharmacy, please allow up to ten (10) business days for the designation to take effect.

Q: What are the requirements for submission of 340B claims data?
A: Boehringer is utilizing Second Sight Solutions' 340B ESP™ platform (www.340Besp.com) to support claims collection on behalf of all entity types. Claims data must be submitted within forty-five (45) days of the date of dispense for the contract pharmacy to continue to access 340B pricing for all Boehringer products in Exhibit A. Please see 340B ESP™ for additional details on submitting claims data, including the limited set of required data fields.

Q: How often can my covered entity change its contract pharmacy designation?
A: 340B covered entities can elect a single contract pharmacy every twelve (12) months from the date of designation or more often if the designated contract pharmacy relationship is terminated from HRSA OPAIS database. Changes to the single contract pharmacy designation can only be made by visiting www.340besp.com/designations. Users that have registered an account with 340B ESP™ can navigate to the Entity Profile tab to make their contract pharmacy designation.

Exhibit A

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ATROVENT®

COMBIVENT®RESPIMAT®

CYLTEZO®

GLYXAMBI®

JARDIANCE®

JENTADUETO®

JENTADUETO XR ®

MICARDIS®

MICARDIS HCT®

OFEV®

PRADAXA®

SPIRIVA® HandiHaler®

SPIRIVA® RESPIMAT®

STIOLTO® RESPIMAT®

STRIVERDI® RESPIMAT®

SYNJARDY®

SYNJARDY XR®

TRADJENTA®

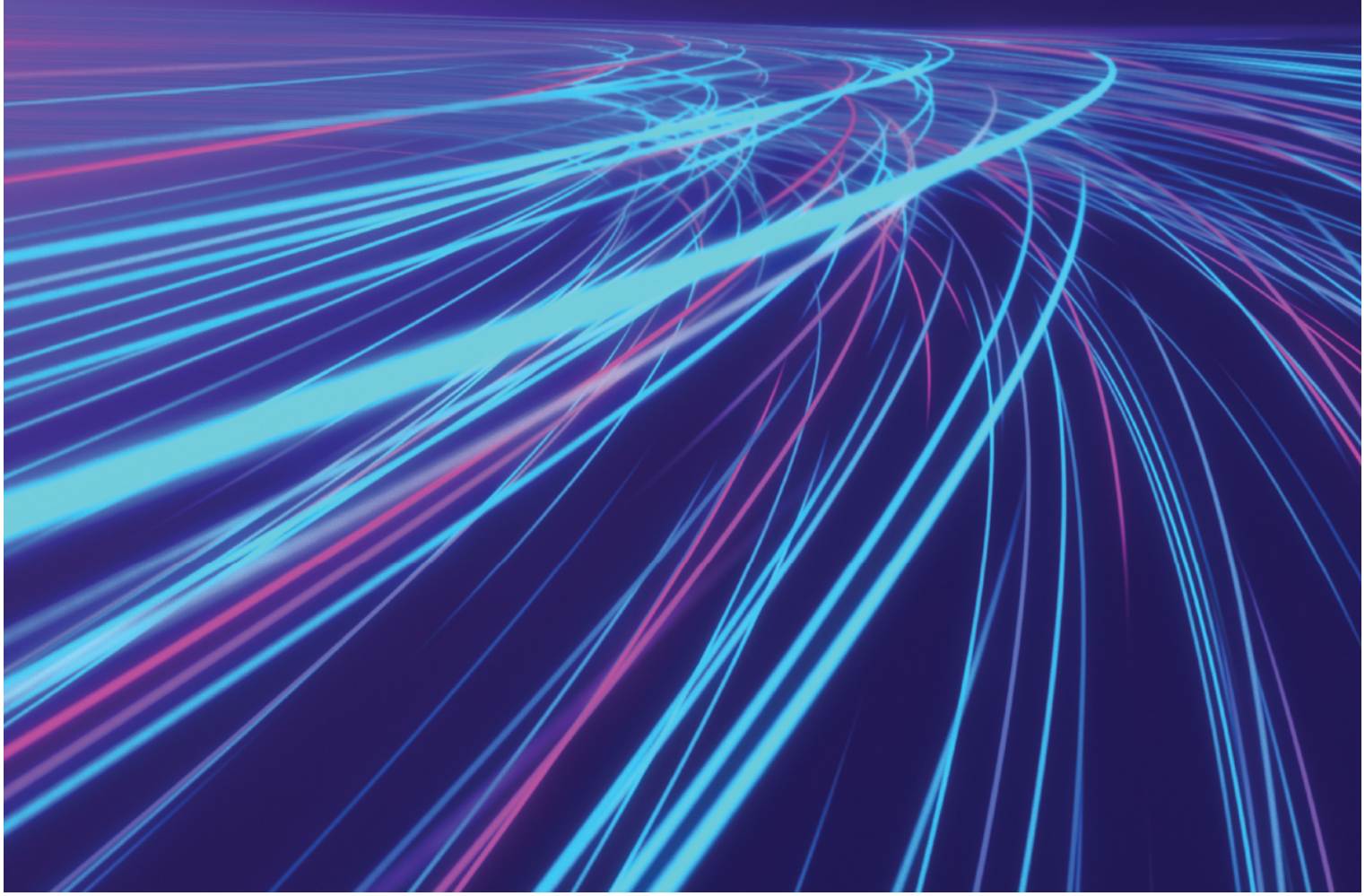
TRIJARDY XR®

VIRAMUNE XR®

Exhibit B – AmerisourceBergen Inventory Synchronization Program Guide

AmerisourceBergen

Inventory Synchronization Program guide



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ISP order flow 4

ISP benefits 4

Drug Supply Chain Security Act (DSCSA) 5

ISP considerations 5

Non-ISP orders 5

Pricing methodology 6

Enrollment process 6

Ongoing ISP support 7

Inventory Synchronization Program guide

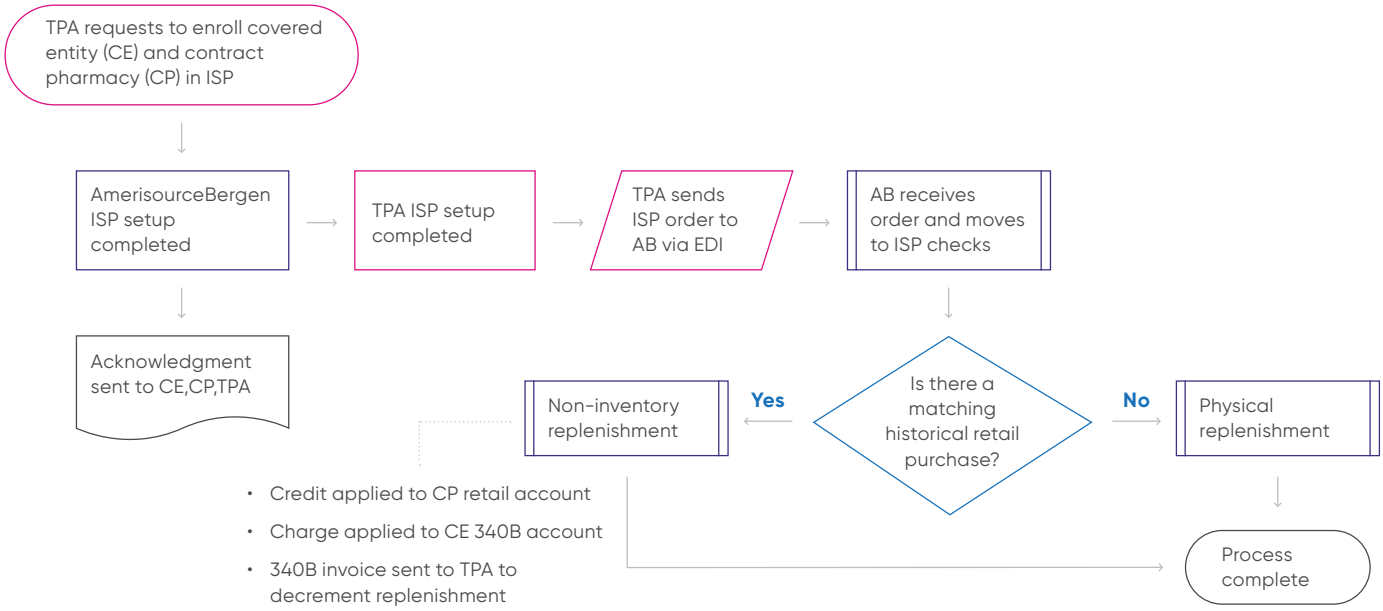
Overview

The Inventory Synchronization Program (ISP) is a solution provided by AmerisourceBergen for 340B contract pharmacies and covered entities. It enables these pharmacies to receive virtual replenishment of products instead of physical replenishment, aiming to improve patient access and optimize the supply chain by reducing unnecessary product returns. You may also hear this referred to as a form of credit-based replenishment model.

To participate in ISP, a 340B contract pharmacy must have an AmerisourceBergen primary distribution agreement and covered entities must purchase eligible replenishment products from AmerisourceBergen. The program operates similarly to the current process, where Third-Party Administrators (TPAs) submit replenishment orders to AmerisourceBergen on behalf of covered entities for eligible contract pharmacies. Upon receiving an ISP order, AmerisourceBergen validates each line by searching for a matching historical purchase for the same NDC and quantity on the pharmacy's non-340B commercial account and provides a response to the TPA indicating the fulfillment disposition (ISP acceptance, rejection, or partial fulfillment).

A successful ISP transaction occurs when the matching historical purchase is found. This results in creating a non-inventory purchase on the 340B covered entity bill-to/ship-to account and generates a credit on the pharmacy's non-340B commercial account for the difference in price. Items that do not have a matching historical purchase cannot be eligible for ISP and can be filled with physical replenishment or dropped, depending on the TPA's desired configuration option.

ISP order flow



ISP considerations

CII-CV and drop ship excluded

Manufacturer restrictions apply

Default setup replenishes non-ISP items with physical inventory following standard process

Key

- AmerisourceBergen
- Third Party Administrator (TPA)

ISP benefits

ISP is intended to enhance patient access and provide a more efficient supply chain operation by alleviating unnecessary returns. ISP enables stakeholders to achieve quicker reconciliation of program dispensations with daily non-inventory replenishments (if desired). Through ISP, 340B opportunity can be realized as soon as full package accumulations are obtained without physical shipments. This avoids lost value due to allocations, product shortages, or unnecessary product returns, and reduces labor burden for stores to receive-in 340B product.



Drug Supply Chain Security Act (DSCSA)

Additionally, when DSCSA is enforced, multi-supplier shipments could be disastrous for a retail pharmacy. Some pharmacies may have challenges with single daily delivery, tote consolidation due to single wholesaler configuration, and inability to return 340B product at full list price. ISP transactions create non-inventory purchases that don't require serialization. Only physically replenished product requires serialization.

ISP considerations

Non-ISP orders

- All 340B products are eligible for the ISP solution except CII-V and drop ship items
- Manufacturer restrictions still apply, regardless of participation in ISP
  - Visit our website for additional details on manufacturer restrictions
- When an order includes items that cannot match to historical purchases, ISP default configuration will create a physical replenishment
  - TPAs have the option to exclude items that cannot be processed through ISP from the order, eliminating the need for physical replenishments
  - For a change of this nature, the TPA must consult with the ISP team and determine best approach forward considering operational processes

Pricing methodology

- When an NDC/quantity is processed through ISP, the amount credited to the pharmacy's account is based on the difference between the current 340B price at the time the ISP order is received by AmerisourceBergen and the original purchase cost paid by the pharmacy
- The ISP credit transaction uses a "last in, first out" method, starting at five days from the order date to a maximum of 180 days

Enrollment process

In order to enroll an account in ISP, there are a few requirements that must be met.

Prerequisites	• Pharmacy must use AmerisourceBergen as primary wholesaler • TPA readiness (ISP pilot complete) • Must not be a SmartSource account
Covered entity and contract pharmacy participation	• TPA to confirm 340b accounts and covered entity and contract pharmacy's desire to participate
Enrollment request*	• TPA submits enrollment request to ISP@amerisourcebergen.com • Set up completed by AmerisourceBergen within two business days

* ISP enrollment process will be confirmed during pilot program and may vary by TPA

- **TPA readiness**
  TPAs must be live with AmerisourceBergen and ISP, having completed a pilot project and being prepared for roll-out
- **Confirmation of participation**
  TPAs need to confirm the desire of both the covered entity and contract pharmacy to participate in ISP
- **Submitting the request**
  The TPA submits a request to ISP@amerisourcebergen.com, providing necessary information such as covered entity and contact details, 340B government ID, and contract pharmacy and contact details
- **ISP configuration**
  AmerisourceBergen completes the ISP configuration, typically within a few business days
- **Acknowledgment from AmerisourceBergen**
  AmerisourceBergen sends an acknowledgment to the covered entity, contract pharmacy, and TPA; this acknowledgment includes information about ISP, links for more details, and confirms that the accounts are now ready to receive ISP orders when the TPA is prepared
  - AmerisourceBergen can process both standard orders and ISP orders
  - TPAs may have their own turnaround times for completing the ISP setup on their side; however, AmerisourceBergen's setup must be completed first



Ongoing ISP support

General ISP information and ISP enrollment requests: ISP@amerisourcebergen.com

Technical issues: EDISupport@amerisourcebergen.com

New bill-to / ship-to account requests: AmerisourceBergen340Bonboarding@amerisourcebergen.com

ISP frequently asked questions

ISP order flow

AmerisourceBergen

Exhibit C – PharmaForce, “Credit-Based Replenishment: The Future of 340B?” Webinar Description

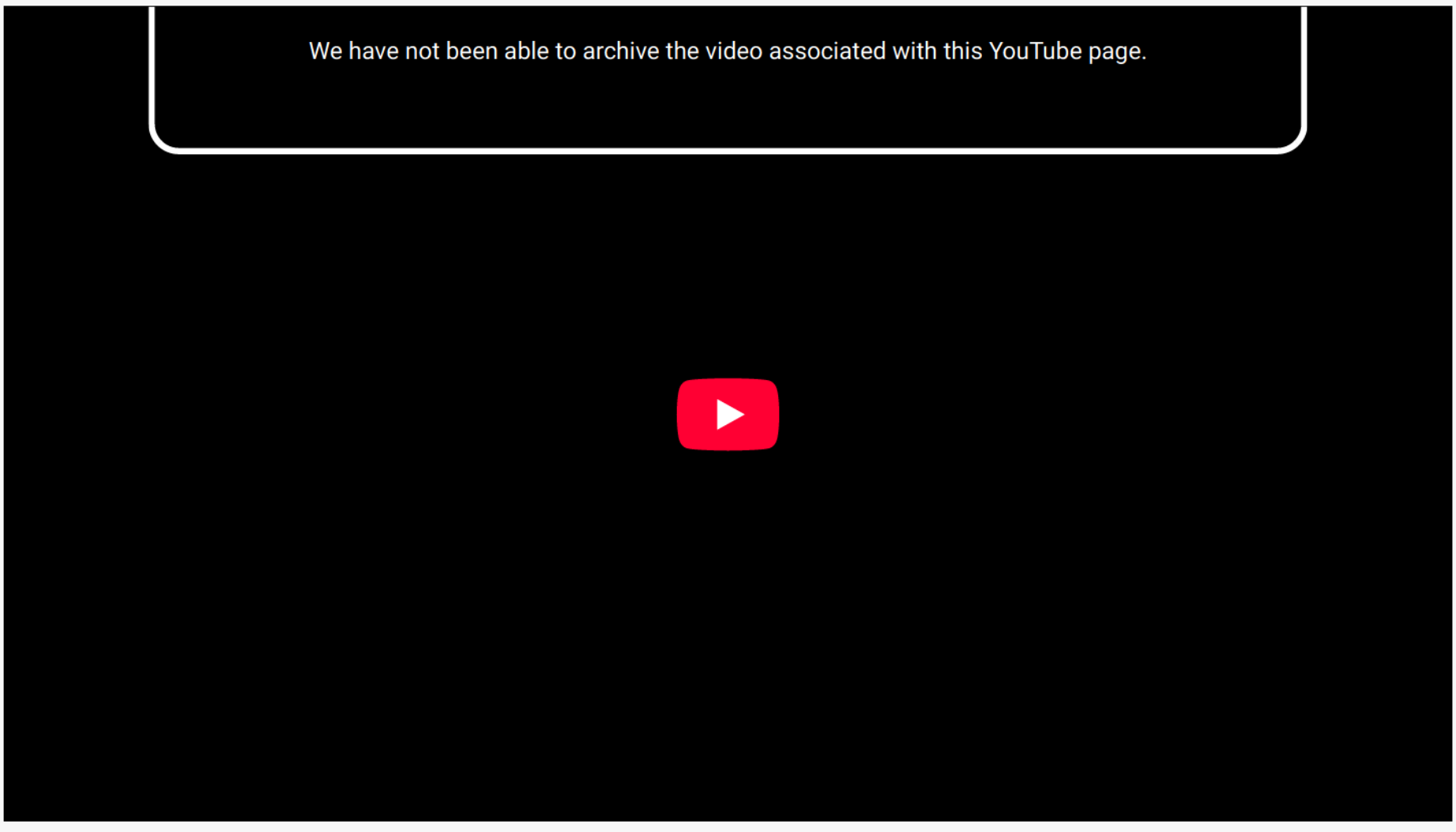
Webinar

Webinar

Credit-Based Replenishment: The Future of 340B?

Contract Pharmacy programs offer significant cost advantages within a 340B program. However, establishing a successful program presents challenges, including Third-Party Administrator (TPA) selection, wholesaler choice, implementation complexities, and pharmacy partner selection. A recent trend in 340B program optimization is the adoption of credit-based replenishment models with contracted pharmacies. This approach eliminates the need for physical inventory deliveries, using a credit system within the pharmacy's retail account instead.

This session will explore the benefits of credit-based replenishment models and their potential suitability for your program.



We will delve into:

- **Understanding Credit-Based Replenishment:** A clear explanation of the model and

Who should attend:

- Covered entities in the 340B program
- Finance Directors
- Program Managers

programs.

- **Maximizing Savings and Streamlining Inventory:**How credit-based models can boost 340B cost savings while minimizing pharmacy inventory burden.
- **Reduced Returns and Expirations:**Strategies for minimizing returns and drug expiration risks associated with pharmacies.
- **DSCSA Compliance and Future Potential:**Ensuring compliance with the Drug Supply Chain Security Act (DSCSA) and exploring the potential of credit-based models as the future of 340B virtual replenishment.

- HR Managers/Directors
- Anyone interested in learning more about the 340B program

Presented By



ANTHONY VELASQUEZ
Chief Product Officer

PharmaForce™

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SOC for Service Organizations | Service Organizations™

340B OFFERINGS

Contract Pharmacy

Cash Cards

Referral Claim Capture

RxGateway

PBM OFFERINGS

Pharmacy Benefits Management

Pharmacy Benefits Administration

Prescription Savings Solutions

Additional Tools & Resources

WEBINARS

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Exhibit D – Transcript of PharmaForce 340B Credit-Based Replenishment Webinar

Transcript of PharmaForce Webinar — Credit Based Replenishment: The Future of 340B?

https://www.youtube.com/watch?v=T7yz-ZgjW2w
Accessed and Transcribed May 30, 2025

Time Stamp: 00:00 – 07:30

Justin Rolling: Thanks, Anthony. Thanks everybody for joining with us again for our monthly webinars. We always appreciate our reoccurring attendees and everyone that's new, the first timers on the call. We appreciate your attendance. So, we do these once a month. We provide content that is discussing what's going on in the 340B world. We hope you all find this very beneficial. I am Justin Rolling, the vice president of national sales and I am Anthony's co-writer on the webinars. He's the content guy. I think I'm here for more of the comment release.

Anthony Velasquez: Here for the minute.

Justin Rolling: That's right. But so, we'll go through 30 minutes and then please ask any questions. We'll have the chat box, the Q &A. And Anthony and I will go through those in the end, but I will pass it on to the great Anthony Velasquez.

Anthony Velasquez: Thank you, Justin. Hey, you know what I was thinking? I saw a YouTube video of a guy who was like driving and doing like a conference meeting, but had like a green screen in the background so it looked like he was in his house. So…

Justin Rolling: I tried that. I couldn't—

Anthony Velasquez: I need to get you one of those.

Alright, thank you everyone for joining. As you all have known for the for probably going on two years now, maybe we have been doing these webinars once a month. The last couple of weeks I have been sorry, the last couple of months I have been doing several webinars on the everything that was going on a policy level related to the 340B program. Things going on with the state level regulations, things going on at a national level.

All of those things. And this month I have a really, really good topic on credit-based replenishment. Some of you might be aware of what this is and might be doing it in a 340B program. Some of you might not know what this is, but in my opinion, I think this is going to be the future of 340B as it relates to the replenishment of drugs at contract pharmacies. So, I'm going to share with you what this is, where we see this going as a company, some things that were involved in as a company in the 340B space. So, let's go ahead and get started. Thank you to everyone who is joining, you know, for the first time and those of you that are regulars and joining these webinars. Okay, my rule number one that I always say before I start these is nothing in this presentation should be constituted as legal advice.

This is all for educational purposes. Please work with your team on deciding what you do for your 340B program and things that you implement for your 340B program. Okay.

Now let's go ahead and get started. Credit based replenishment. We're going to talk about five things today. We're going to talk about what is it and how does it work.

We're going to talk about how do you set up a credit-based replenishment model, the benefits, how it relates to DSCSA compliance. I know that that's, that was a hot topic at the end of 2023 and then it got pushed back another year and it's going to come around. It comes around like clockwork.

And then is this the future of 340B? I want to leave you some comments and thoughts on that. So, let's go ahead and get into what is it and how does it work. All right.

So, what is this? Traditionally in 340B, the contract pharmacy arrangement has been, you know, has not changed much. The third-party administrator is receiving claims from the switch. The third-party administrator is then capturing those claims. And then placing orders on behalf of the entity for the contract pharmacy and those orders are then arrived to the contract pharmacy in a tote delivery that has a label that says this is from the 340B account. The pharmacist or pharmacy receives that they open it, and they put the drug on the shelf. Right?

Very traditional contract pharmacy model that has been around since, you know, since the beginning of time of this contract pharmacy program replenishment model. Now this credit-based replenishment is a little bit different because what it does is a … wholesaler enabled mechanism is what I like to call it. So, the wholesaler is able to, if they participate or provide this as a feature, mechanism, that allows for the purchase of a 340B product. Right?

So, you as the covered entity are still invoiced for the 340B product. That 340B product though, instead of being physically delivered and shipped to the contract pharmacy location is in certain instances, if it meets certain eligibility, credited to the non 340B account.

Let me say that one more time. You place an order for a product or the TPA in the traditional model will place an order will say you accumulated a bottle of a package of Levemir. We're going to order a package of Levemir. But instead of that product physically arriving at your store, as a contract pharmacy recipient, the value of that product that a non 340B price will be placed on your non 340B account.

So, if the product to keep a simple is $100, $100 will be credited to your 340B account—to your non 340B account—and then the entity will be invoiced for the 340B ceiling price that is in their 340B account. Okay. So, I hope I did a good job explaining that and I hope that that was clear, but it's essentially a financial transaction. So again, charges the ceiling price to the covered entity still. The covered entity still invoiced as normal. No problem. But the product does not physically ship to the contract pharmacy. The order is placed as normal as I said. And then you have to pick the designated store, the designated contract pharmacy location, designated non-340B account in order for the financial credit to -- to be applied. Okay.

So, I hope I hope I hope that all makes sense. Justin, did that makes sense to you? I know you're not you're not in the weeds like I am, but I just want to show that that I explained that in a way that makes sense.

Justin Rolling: That was great.

Anthony Velasquez: Okay, perfect.

All right. Now, what are other things to know about this is, I mean, it's not a free for all. There is some limited it's limited to a look back period, depending on the wholesaler. So, for example, usually the wholesaler will receive the order and see if that product has had a purchase in the last six months. Okay?

If that product has been purchased in the last six months, there's other rules that that that will be checked. But if it has been and it meets all those eligibility criteria, then the product is eligible for this credit-based replenishment model.

Okay, so I hope I hope that that was clear. There are certain exclusions on the on the model. So, it's control substance … are excluded from the model. Drop ship items are excluded from the model and things like that. Because it is based on look back period, if it's the first time that that pharmacy is buying an NDC, for example, an NDC being purchased for the first time it was 340B eligible, that order is placed on the 340B account, then that will not be subject to the credit-based replenishment eligibility. Okay?

…

Time Stamp: 11:40 – 13:28

Anthony Velasquez: … And then your pharmacies yelling at you as a covered entity. Why did this happen and and are upset. So it reduces all that. It removes that because in this case the credit will be placed on the retail account of the independent pharmacy. Okay?

Number two, it improves the pharmacy cash flow. In a world where independent pharmacies are really hurting for cash flow and are being pushed out by some of the bigger chains and things like that. This is a big topic in the world of contract pharmacy is how do you help and how do you help pharmacies with a cash flow. That's why we're big proponents of a pay on replenishment model here at pharma force. We we think that is a model that is both pharmacy-friendly and entity-friendly in the sense that it really helps the pharmacy and that, you know, in a pay on dispense model the pharmacy is out of the drug because they dispense it to the 340B patient. They have to pay the revenue associated with that prescription within a 30-day invoicing period. And they might not get paid by the PBM in you know, a 45, 60, or even greater number of days.

So, in a pay on dispense model, it creates pharmacy cash flow issues for the pharmacy. And I've heard that I've been part of those conversations with pharmacy owners. So, this model, just like the pay on replenishment model, is what I would consider pharmacy-friendly in the sense it

improves the pharmacy cash flow. You're not buying these very expensive products or, you know, these expensive products are not being replenished and then sitting on the shelf. Right

…

Time Stamp: 22:40 – 24:29

Anthony Velasquez: … there's going to be a very tight mechanisms in place that are going to make it, add some operational burden and difficulty on pharmacies to manage all of this, but the credit based replenishment model is so good. And so to be in the counterpoint of the operational difficulty that that that this this new drug supply chain act is going to add, because if you are able to reduce the number of products that are physically shipped, then you are lessening the burden on the pharmacy the entity and all parties involved in that process. So, I think this model just because I'm a big, you know, proponent and supporter of the credit based replenishment model is something that myself and my team are very much in support of. What I have heard from the contract pharmacies how much they love this model. And, and especially from pharmacies that have what have worked in both. This is going to be another major major added benefit to this. I'm not going to say it's going to fix everything, I'm going to say is, you know, it's still not going to lead to some challenges but for the most part, it seems like it will be very helpful in this model. So, the question— and Justin, we're going to say something? I saw you unmuted yourself.

Justin Rolling: Yeah, just in the sales process what we're what we're running into is that the covered entities are saying that their independent pharmacies are basically pushing or are going to require a credit based replenishment model. I know we have a lot of customers that are using this with the contract pharmacies successfully but it's it seems to be almost a demand at this point, even some switching wholesalers from – I know McKesson is not doing credit based replenishment, Cardinal ABC are – and these pharmacies are moving to those wholesalers that offer credit credit-based replenishments just going to look out as a covered entity with your contract pharmacies their independence, reach out to them I guess get ahead of it talk to them and talk through this process if it was if it was me I would be doing that. Yep.

Exhibit E – Memorandum of Law in Support of Defendants' Motion to Dismiss, *Fruth Inc. v. Cardinal Health*, 3:23-cv-00801 (S.D. W. Va. March 18, 2024)

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT HUNTINGTON

FRUTH, INC. and FRUTH PHARMACY, INC.,	)	
Plaintiffs,	)	
vs.	)	Civil Action No. 3:23-cv-00801 Honorable Robert C. Chambers
CARDINAL HEALTH, INC., CARDINAL HEALTH 411, INC., CARDINAL HEALTH 110, LLC, and CARDINAL HEALTH 112, LLC,	)	
Defendants.	)	

MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANTS' MOTION TO DISMISS

I. INTRODUCTION

This case arises from disputes between a pharmacy chain (Plaintiffs Fruth, Inc. and Fruth Pharmacy, Inc. (together, "Fruth")) and its wholesale distributor (Defendants Cardinal Health, Inc., Cardinal Health 411, Inc., Cardinal Health 110, LLC, and Cardinal Health 112, LLC (collectively, "Cardinal Health")). The biggest dispute, but one not referenced in Fruth's Complaint, is the fact that Fruth owes Cardinal Health millions of dollars for product it has received but failed to pay for. But that is an issue for another day. This motion is concerned with the two disputes at issue in Fruth's Complaint: (1) Fruth's claim that Cardinal Health short-changed it in the way Cardinal issued credits to Fruth when Fruth sold drugs under the federal government's 340B discount drug-pricing program; and (2) Fruth's claim that Cardinal Health improperly hiked prices on drugs.

Neither of these claims provide Fruth with any recognizable cause of action. Fruth's Complaint tries every cause of action Fruth can think of, but none fit. Breach of contract is not

viable because the contract between Fruth and Cardinal Health, attached to Fruth's Complaint, does not forbid, or require, Cardinal Health to do anything that Fruth claims Cardinal Health did or did not do. Fruth's claims for fraud – which Fruth phrases both in terms of inducement and concealment – do not fly either because they are simply repackaged versions of Fruth's breach of contract claim. Fruth's claim for conversion is also nothing more than a repackaged version of its claim for breach of contract. Fruth's claim for unjust enrichment is barred because Fruth's relationship with Cardinal Health is governed by an express contract. And Fruth's claim for an accounting is barred because the parties do not have the type of relationship that allows this claim.

For all these reasons, and as more fully explained below, Fruth's Complaint should be dismissed in its entirety.

II. FACTUAL BACKGROUND

A. The parties' contractual relationship.

Fruth alleges that "[a]t all times relevant to this action, Cardinal Health served as Fruth's primary wholesale pharmaceutical supplier, commonly called a 'wholesaler,' for all of Fruth's retail pharmacy locations owned, managed, or operated." (Compl. at ¶ 58.) Fruth also alleges that its relationship with Cardinal Health was originally governed by a Prime Vendor Agreement dated December 2009, and was renewed in another Prime Vendor Agreement dated November 2016, both of which are attached to Fruth's Complaint as Exhibits A and B, respectively. (*Id.* at ¶ 59, 83.) The November 2016 Prime Vendor Agreement ("PVA") controls here. (*See id.* at ¶ 229.)

B. Fruth's participation in the 340B program.

As Fruth alleges in its Complaint, it is a "contract pharmacy" under the federal government's 340B discount drug-pricing program. (Compl. at ¶ 9.) That means that Fruth contracts with health care facilities that qualify as "covered entities" under the 340B program to

provide drugs at or below a statutory "ceiling price" to eligible patients. (*Id*. at ¶ 2-4, 46.) Fruth buys those drugs from wholesalers like Cardinal Health. (*Id*. at ¶ 9.)

Fruth's allegations focus on the true-up process that occurs between Fruth and Cardinal Health when Fruth sells drugs at 340B prices. As Fruth alleges, this true-up process is necessary because Fruth buys all drugs from Cardinal Health at wholesale prices and does not know before dispensing the drugs which of them will be dispensed through the 340B program. (*Id*. at ¶ 6.) To make Fruth whole, Cardinal Health issues credits or ships replacement product to Fruth for the drugs Fruth sells at discounted 340B prices. (*Id*. at ¶ 10.) When credits are issued in lieu of replacement product, the process is known as "virtual replenishment." (*Id*.)

C. The "virtual replenishment" process.

Fruth alleges that it began using virtual replenishment in March 2016 when it voluntarily enrolled in a new "340B Invoice Credit Program" offered by Cardinal Health, in which "a software program was used to identify prior invoices that could be used to credit Fruth's account . . . rather than shipping physical 340B drugs." (*Id*. at ¶ 77-78.) Fruth states that, "[u]nder Cardinal's 340B Invoice Credit Program, after a [third-party administrator] places an order for a drug on behalf of a covered entity, and after Fruth dispenses the drug, Cardinal is required to either issue a credit to Fruth (if Fruth purchased the drug within the last 12 months), or send Fruth a replacement drug (if Fruth did not purchase the drug within the last 12 months)." (*Id*. at ¶ 96.)

Fruth acknowledges that "[t]he 2016 PVA does not specifically reference Cardinal's invoice credit program applicable to drugs dispensed . . . under the 340B Program," but it alleges that "the parties intended to include Cardinal's invoice credit program applicable to drugs dispensed . . . under the 340B Program in the 2016 PVA." (*Id*. at ¶ 89-90.) Fruth alleges Cardinal Health led it to believe that 340B credits "would be handled in the same manner in which credits

for returns are handled under the [PVA]," specifically in Cardinal Health's "Returned Goods Policy" attached as Exhibit C to the PVA. (*Id*. at ¶ 60, 72, 75.) Fruth also alleges that the virtual replenishment process is governed by the pricing terms in Section 3 of the PVA. (*Id*. at ¶ 91-93.)

D. Fruth's complaints concerning 340B credits.

Fruth alleges that "in or about February of 2020, Fruth's current Vice President of Pharmacy, Mr. Andy Becker, insisted that Cardinal Health provide a report detailing the credits issued to Fruth for drugs dispensed under the 340B Program." (*Id*. at ¶ 99.) Fruth alleges that "[i]n or about March of 2020, Cardinal Health ultimately provided a report reflecting credits issued to Fruth for drugs dispensed under the 340B Program." (*Id*. at ¶ 100.) Although Fruth alleges that "the report was vague and confusing and failed to include critical information," it alleges that "Fruth's review of the reports provided by Cardinal Health, combined with a financial reconciliation of 340B Program transactions, confirms that Cardinal Health has improperly withheld substantial sums of money owed to Fruth arising out of the 340B Program." (*Id*. at ¶ 101.)

Fruth alleges it obtained further information concerning problems with 340B credits after discussing the matter with other chain drug stores starting in April 2022. (*Id*. at ¶ 105-115.) Fruth claims to have discovered through these discussions "that it was receiving less than what it was owed (by way of invoice credits) under Cardinal Health's 340B Invoice Credit Program because Cardinal Health was using historical and outdated invoices." (*Id*. at ¶ 106.) Fruth alleges that Cardinal Health should have been "using the most recent cost of a pharmaceutical drug dispensed by Fruth under the 340B Program" and that by instead relying on "historical invoices that reflect outdated drug costs when issuing a credit to Fruth," Cardinal Health "created a delta between the amount of credit Fruth actually received from Cardinal Health for drugs dispensed under the 340B Program and the amount of credit that Fruth should have received under Cardinal Health's 340B

Invoice Credit Program." (*Id.* at ¶ 117-119.) Fruth alleges that Cardinal Health's issuance of insufficient credits spanned the time-frame between March 2016 and June 2022. (*Id.* at ¶ 116.)

E. Fruth's complaints concerning Cardinal Health's price increases.

Section 11.4 of the PVA provides that "Cardinal Health guarantees that the invoice price paid by [Fruth] on 'Benchmark Source Program Purchases' (as defined below) shall not increase by more than one percent (1.00%) during a given Contract Year." (*Id.* at ¶ 173; PVA at § 11.4.1.) Fruth alleges that "Cardinal failed to comply with Section 11.4.1 of the 2016 PVA because it increased its prices for generic drugs in amounts greater than one percent (1.00%) of the manufacturer prices during contract years." (Compl. at ¶ 175.)

Specifically, Fruth takes issue with "Cardinal's calculation methodology and interpretation of Section 11.4 of the 2016 PVA," which Fruth claims is "inconsistent with the express language of the contract and the intent of the parties." (*Id.* at ¶ 190.) Fruth claims that an unnamed "Cardinal representative" explained Cardinal Health's calculation methodology as follows:

> 191. Specifically, Cardinal's representative advised that Cardinal groups certain drugs into "CardKeys" and then identifies the total quantity of product shipped to Fruth for a particular "CardKey" for a contract year (November 1 through October 31). Cardinal then takes the quantity of product shipped to Fruth for the entire contract year and multiplies it by the catalog price as of November 1. Cardinal then takes the same quantity of product shipped to Fruth for the contract year and multiplies it by the catalog price as of October 31. Cardinal then takes the sum from the November 1 calculation, adds a one percent price increase (as allegedly permitted under the 2016 PVA) and then compares it to the sum from the October 31 calculation. If the sum from the October 31 calculation is less, then Cardinal's representative admitted that Cardinal believes that it did not raise prices greater than 1%, and its practices are consistent with the 2016 PVA.

EXHIBIT B

September 8, 2025

Federal eRulemaking Portal: https://www.regulations.gov

Thomas J. Engels
Administrator
Health Resources and Services Administration
Department of Health and Human Services
5600 Fishers Lane
Mail Stop 08W05A
Rockville, MD 20857

Re: 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program (HRSA-2025-14619)

Dear Administrator Engels:

Novo Nordisk Inc. ("NNI") appreciates the opportunity to provide the following comments on HRSA's August 7, 2025, 340B Rebate Model Program Notice. NNI is a member of the Pharmaceutical Research and Manufacturers of America ("PhRMA"); unless otherwise noted, our comments echo and incorporate by reference the comments submitted by PhRMA on this matter.

NNI is a global health care company committed to improving the lives of those living with serious chronic conditions, including diabetes, rare bleeding disorders, growth disorders, and obesity. The Novo Nordisk Foundation, our majority stakeholder, is among the top five largest charitable foundations in the world. Accordingly, our company's mission and actions reflect the Foundation's vision to contribute significantly to research and development that improves the lives of people and sustainability of society.

HRSA has taken an important step in developing a robust rebate mechanism for 340B. For too long, the point-of-purchase discount model has been insufficient to meet the operational demands of the 340B Drug Pricing Program ("340B Program"), exacerbating manufacturers' exposure to illegal and improper duplicate discounting and diversion that takes money away from patient benefits. In this first step toward transparency and accountability, HRSA has not only proposed a means by which to address illegal "maximum fair price" duplication and multiple discounts on the same claim, but sent a clear message that the 340B Program must operate fairly for all stakeholders. NNI looks forward to working with HRSA to refine the Rebate Model Pilot Program and see it appropriately expanded (most immediately by including IPAY 2027 drugs in the pilot as soon as possible in 2026) to address broader program noncompliance.

Pharmaceutical price decreases are generally made available to purchasers and payors in two ways: as *upfront discounts* at the time the product is purchased, and through *rebates* sought and paid after the initial sale. Upfront discounts are appropriate when the right to the concession turns on the character of the purchaser (e.g., GPO member, VA hospital). Rebates, on the other hand, are almost universally utilized when critical information about the *patient* (e.g., insurance carrier) is not known at the time the provider or pharmacy purchased the product. Indeed, all payor concessions—both government and commercial—operate via rebate because eligibility for payor reimbursement—and therefore a manufacturer concession—is not known until *after* the product has been dispensed. The Medicaid and Medicare Part D programs are great examples of how manufacturer concessions in the form of rebates are only forthcoming once the character of the patient is known (e.g., a Medicaid beneficiary or a member of a Part D PDP).

340B implicates both character tests: eligibility for 340B-discounted product depends not only on the "covered entity" status of the purchaser, but also on the status as "patient" of the individual to whom the covered entity dispenses the product. 42 U.S.C. §256b(a)(5)(B). 340B is additionally complicated because 340B pricing also depends on the *non-existence* of other price concessions that would disqualify it (e.g., Medicaid rebates, "maximum fair price" rebates). 42 U.S.C. §256b(a)(5)(A), 42 U.S.C. §1320f-2(d). Rebates, therefore, are the natural means of effectuating 340B discounts. Providing 340B rebates based on the submission of reasonable eligibility evidence will promote transparency and compliance with the program.

As a general principle, 340B concessions should be paid only after the covered entity and the manufacturer agree that: (1) the covered entity is eligible, (2) the individual is a 340B patient, and (3) no disqualifying concessions exist. A 340B rebate mechanism may present a "shift" in the way 340B has operated for many years, as HRSA notes, but such a reasonable shift has been a long time coming.

As a manufacturer of selected drugs in IPAY 2026 (the insulin aspart products), NNI appreciates that HRSA is providing this critical and timely solution. Nevertheless, NNI encourages HRSA to expand the use of rebates in the coming months to all covered outpatient drugs, to determine patient eligibility, and to scrub for illegal and improper duplicate discounting. To that end, NNI supports the successful administration of the Pilot as a proving ground for these other critical uses.

In particular, access to the Pilot should be granted to IPAY 2027 selected drugs as soon as it becomes apparent that the Pilot can function for IPAY 2026 selected drugs. As a manufacturer with products in both the IPAY 2026 and IPAY 2027 selected drug sets, NNI encourages HRSA to quickly permit NNI to add its IPAY 2027 drugs to the Pilot as soon as possible. At the very least, HRSA should act in this regard in time to allow NNI to incorporate reliance on the Pilot well in advance of our "maximum fair price" implementation plan deadline of September 1, 2026.

NNI would like to focus on five specific suggestions to improve the operation of the 340B Rebate Model Pilot Program (in addition to those put forward by NNI's trade association, PhRMA):

1. **Ten calendar days to provide payment is impracticable.** The proposal requires payment of 340B rebates within ten calendar days after data submission; NNI urges HRSA to require payment within ten *business* days after data submission. Because processing and payment cannot occur on weekends or holidays, in limited circumstances ten calendar days may not be enough time to turn 340B refunds, particularly around the Thanksgiving and Christmas holidays. Commercial banks will not process Automated Clearing House ("ACH") payments on weekends or holidays, making a ten calendar day requirement functionally impracticable. NNI is committed to prompt payment of eligible rebates, and to avoiding any unreasonable cashflow concerns that covered entities may experience. Ten business days is still a very quick turnaround for provider rebates.
2. **Manufacturers need product purchase data to accurately determine the 340B rebate.** The proposal does not include purchase data in its set of required claim fields; NNI requests that HRSA permit plans to require submission of critical product purchase data. The calculation of a rebate requires at least two pieces of information: the price at which a unit was originally purchased, and the net price to which the purchaser is entitled. By subtracting the latter from the former, a rebate per unit can be calculated. Manufacturers need data showing the price the covered entity paid for an eligible unit of utilization in order to determine the rebate amount. Because WAC (or a covered entity's purchase price) can change over time, for example, the covered entity must make clear in its rebate request its actual purchase price. Furthermore, it should be made clear that units purchased at the 340B ceiling price (before effectuation of the Pilot, for instance) should not be eligible for refunds. NNI recommends that the following data elements also be submitted in a rebate request: (i) Wholesaler Name, (ii) Wholesaler Account Number, (iii) NDC-11, (iv) Invoice Date, (v) Quantity, (vi) Invoice Number, (vii) Ship-to Pharmacy (NPI), (viii) 340B ID, and (if applicable) (ix) GPO identifier.
3. **HRSA should clarify the rebate calculation basis.** The proposal does not address the specific rebate calculation methodology; NNI suggests that HRSA make clear that the rebate per unit be calculated with reference to more specifically defined data points. As HRSA is aware, the relevant component prices—e.g., WAC/GPO and 340B ceiling price—are not static. For this reason, HRSA should establish a uniform method of rebate calculation. Specifically, NNI suggests that the *WAC at the time of purchase,* the *GPO price at the time of purchase,* and the *then-applicable 340B ceiling price* be the component price points. For instance, if a covered entity purchased a unit on December 20, dispensed the unit on January 3, and sought a rebate on January 30, the calculated rebate for that unit would be (a) the WAC/GPO price on December 20, less (b) the 340B ceiling price in effect in the fourth quarter. Use of any other moment in time (e.g., date of dispense, date of rebate invoice submission, date of rebate payment) could lead to attempts to manipulate or game the rebate process.

4. **Manufacturers need medical benefit data to accurately determine the 340B rebate.** The proposal does not accommodate medical benefit utilization; NNI suggests that the data necessary to process physician-administered drugs be added to the Pilot. Because the Pilot currently accommodates only IPAY 2026 selected drugs, and although those drugs are primarily self-administered, the proposal does not include the data fields necessary to process medical benefit products. Nevertheless, NNI is concerned that some covered entities will seek rebates on units administered as part of the medical benefit (*e.g.* as will be true for some emergency room and specialty clinic dispenses). NNI therefore recommends that the following data elements be available for use in the Pilot: (i) Health Plan ID, (ii) Health Plan Name, (iii) Health Plan ID Qualifier, (iv) Service Provider ID (NPI), (v) NDC-11, (vi) Quantity, (vii) Date of Service, (viii) Rendering Physician ID, (ix) Claim Number, (x) Claim Line Number, (xi) HCPCS Code, (xii) HCPCS Code Modifiers (up to 4), (xiii) 340B ID, and (xiv) Unit of Measure.
5. **HRSA should assert the supremacy of its pilot over conflicting state laws.** As HRSA is aware, several states have recently passed laws purporting to prohibit the use of rebate models and bar the submission to manufacturers of 340B claims data. HRSA should clearly state that any such laws are preempted by this federal initiative. Indeed, HRSA should protect the integrity of its oversight of the 340B Program generally by declaring *any* state law interference with the operation of the 340B program to be in direct conflict with the federal regime and preempted. At a minimum, however, HRSA should speak to the irreconcilable conflict these state laws present regarding rebates and data submission and declare the federal program's supremacy over them.

Novo Nordisk supports the 340B Rebate Model Pilot Program, and the direction toward transparency, compliance, and integrity to which it points. We are committed to the Pilot's successful launch and administration.

Sincerely,

Jennifer Duck
Vice President, Public Affairs
Novo Nordisk Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER, *Plaintiffs,* v. ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA, *Defendants.*	Case No. 25-cv-00600-JAW

DECLARATION OF CHRISTINE MARSH

I, Christine Marsh, declare as follows pursuant to 28 U.S.C. § 1746:

1. I am Senior Vice President, Value and Access for Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer"), and have held that position since July 2019. I submit this declaration in opposition to Plaintiffs' motion for a preliminary injunction.

2. As Senior Vice President, Value and Access, I am responsible for, among other things, collaborating with a broad range of Boehringer departments to ensure that Boehringer medicines are accessible to patients, including Medicare Part D and Medicaid enrollees. I have

direct oversight over the integrity and compliance of Boehringer's participation in the 340B program. Prior to my current position, I served as Senior Vice President, Market Access and Vice President, Managed Markets Sales at Boehringer, and in senior strategic leadership roles at Boehringer (where I have worked in various capacities since 1999), and Roxane Laboratories. In these roles, I have gained significant experience regarding pricing and government contracting for pharmaceutical products.

3. This declaration is based on my personal knowledge, including knowledge I have gained from others at Boehringer and company documents.

Boehringer's Jardiance® Products

4. Boehringer has a long history of research and development of novel pharmaceutical products. In 2020 alone, the Boehringer family of companies (consisting of Boehringer Ingelheim Pharmaceuticals, Inc. and related entities globally) invested $4.2 billion in pharmaceutical research and development, covering work on approximately 100 projects across all phases of the research process, many of which addressed unmet medical needs. Those investments increased to $7 billion in 2024, a year in which more than 66 million people globally benefitted from therapies developed by the Boehringer family of companies.[1]

5. One of the medications that has resulted from Boehringer's investments is empagliflozin—a medication used to lower blood sugar in adults with type 2 diabetes and to reduce the risk of cardiovascular death in those adults and adults with heart failure—which Boehringer manufactures and sells under the trade name Jardiance®.

[1] *See* Boehringer Ingelheim, *Boehringer Ingelheim Reaches More Patients in 2024 And Prepares New Medicine Launches* (Feb. 4, 2025), https://www.boehringer-ingelheim.com/about-us/who-we-are/2024-results-research-and-development-investment-rise.

6. Boehringer markets Jardiance® in the United States under a license for the patents claiming empagliflozin and its uses. Boehringer owns title to its Jardiance® products (i.e., the physical, retail-packaged tablets) and exercises its rights to possess, sell, and otherwise dispose of those products, including by determining when and on what terms to make them available to others.

Boehringer's Participation in Medicare, Medicaid, and 340B

7. Boehringer makes Jardiance® and all its other drugs—numbering more than 20—available through Medicaid and Medicare.

8. Through the Medicaid program, Boehringer provides significant rebates, often above federally mandated amounts, on its products to states that provide health coverage to low-income individuals and families.

9. Through the Medicare program, Boehringer makes its drugs available to people aged 65 and older and certain individuals with disabilities. The Medicare program is divided into multiple parts that provide various benefits to beneficiaries. As relevant to Jardiance®, under Medicare Part D, the Centers for Medicare and Medicaid Services ("CMS") partially reimburses private insurance plans who provide coverage for self-administered prescription drugs to Medicare beneficiaries. *See* 42 U.S.C. § 1395w-101 *et seq.*

10. Together, Medicare and Medicaid account for nearly half of the total U.S. prescription drug market.[2]

11. To receive coverage for drugs under the Medicare Part B and Medicaid programs, federal law requires that manufacturers participate in the 340B Program. *See* 42 U.S.C. § 1396r-

[2] HHS Office of the Inspector General, *Drug Spending* (Dec. 16, 2024), https://oig.hhs.gov/reports/featured/drug-spending/.

8(a)(1). Boehringer thus participates in the 340B Program, and Jardiance® is a drug that is subject to the 340B Program.

12. Under the 340B Program, pharmaceutical manufacturers must offer drugs at a reduced price—referred to as the "340B ceiling price"—to a statutorily defined set of healthcare providers, known as "covered entities." These covered entities can, in turn, dispense drugs acquired at a reduced cost to patients while billing the patients' insurance for the full, non-discounted cost of the product. Covered entities retain the difference between the reimbursement paid by the patient's insurer and the lower acquisition cost obtained through the 340B Program. The 340B Program is administered by the Health Resources and Services Administration ("HRSA").

13. While the 340B statute requires that manufacturers offer discounts to covered entities, it permits manufacturers to effectuate their 340B "offers" in at least two ways: through a "discount" or a "rebate." 42 U.S.C. § 256b(a)(1).

14. The initial purpose of the 340B Program—as described in a report by the House Energy and Commerce Committee—was to enable covered entities "to stretch limited federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[3] But the 340B statute does not require covered entities to use the funds generated through the 340B Program to provide additional free or reduced-cost care to patients. In fact, there are virtually no limitations on how covered entities can use the resources obtained through the 340B Program. As a result, a 2023 study found that 69% of the disproportionate share hospitals

[3] House Energy and Commerce Committee. (1992). Report to Accompany H.R. 2980, The Medicaid Drug Rebate Amendments of 1992.

that participate in the 340B Program provided less charity care than the national average for all hospitals.[4]

15. Since its creation, the 340B Program has evolved from a small program intended to help a limited number of safety net health providers into the second-largest prescription drug program in the country, now surpassed only by the prescription drug benefit in Medicare Part D. When the program first launched in 1992, fewer than 100 hospitals enrolled, and by 2009, the 340B Program accounted for $4 billion in total sales. Since then, however, the growth has exploded. In 2023, the 340B Program accounted for $66 billion in total sales—a 23% increase from the year before.[5]

16. This massive growth has been driven in part by an increase in duplicate discounts (*i.e.*, seeking both a 340B discount and another discount) and diversion of 340B drugs (*i.e.*, transferring or selling a 340B-priced drug to individuals who are not patients of the covered entity). The scope of this problem is significant: HRSA issued "a total of 1,536 findings to address covered entity noncompliance … from fiscal years 2012 through 2019."[6] IQVIA, an industry data provider, estimates that duplicate discounts accounted for one-quarter of total 340B drugs sales in 2021, representing approximately $20-25 billion in total.[7] These duplicate discounts impose significant costs on pharmaceutical manufacturers. But these costs are not limited to manufacturers: a recent

[4] Alliance for Integrity & Reform, *Charity Care at 340B Hospitals is on a Downward Trend* (Oct 2023), https://340breform.org/wp-content/uploads/2024/03/2023-Charity-Care-Report-Final-1.pdf.

[5] HRSA, *2023 340B Covered Entity Purchases*, https://www.hrsa.gov/opa/updates/2023-340b-covered-entity-purchases.

[6] *See* U.S. Gov't Accountability Off., *GAO-21-107, Drug Pricing Program: HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements* 13 (Dec. 14, 2020)

[7] IQVIA, *Uncover the Invisible Impacts of 340B Discounts* (Dec. 20, 2021) https://www.iqvia.com/locations/united-states/blogs/2021/12/uncover-the-invisible-impacts-of-340b-discounts.

study found that 8% of the total increase in employer-based health insurance premiums can be attributed to increased 340B costs.[8]

Boehringer's Need for the Rebate Model Pilot

17. On August 29, 2023, CMS selected Jardiance® for inclusion in the Inflation Reduction Act's ("IRA") Drug Price Negotiation Program (the "IRA Program"). Under the IRA Program, Medicare selects a certain number of drugs each year and imposes a "maximum fair price" ("MFP") for each selected product.

18. Once a drug is selected into the IRA Program, manufacturers must sign a form agreement written by CMS and submit a data package to the Agency including information about the selected drug, such as costs related to research and development, production, and commercialization. 42 U.S.C. § 1320f-3(e). On the basis of this and other information, CMS develops and transmits an initial MFP offer to the manufacturer. *Id*. § 1320f-3(b)(2)(B). By statute, CMS's offer may not exceed a statutory ceiling.

19. For a Medicare Part D drug like Jardiance®, the MFP must be at least 25% to 60% below the drug's market-based price. Id. § 1320f-3(c). The statute additionally directs CMS to "aim[] to achieve the lowest [MFP] for each selected drug." 42 U.S.C. § 1320f-3(b)(1).

20. If a manufacturer fails to sign CMS's agreement—or an addendum to the agreement memorializing the agreed-upon MFP—the manufacturer is subject to a significant excise tax on all U.S. sales of the selected drug. *See* 26 U.S.C. § 5000D. The tax is initially calculated as 186% of the drug's sale price but increases to 1,900% after nine months of non-compliance. *See id*. § 5000D(a), (b)(1), (d). A manufacturer's only other option for avoiding the tax in this scenario

[8] Neal Masia et al., *The 340B Drug Purchasing Program and Commercial Insurance Premiums* (May 2025) available at https://www.npcnow.org/sites/default/files/2025-05/340B%20and%20Employer%20Costs%20White%20Paper.pdf.

is to withdraw *all* of its products (not just the selected drug) from Medicare and Medicaid entirely. *Id*. § 5000D(c). Since Medicare and Medicaid combined account for such a significant portion of the prescription drug market, total withdrawal is not economically feasible for a manufacturer like Boehringer.

21. In August 2024, roughly one year after CMS selected Jardiance® for inclusion in the IRA Program, CMS announced that the MFP for Jardiance® would be $197 for a 30-day supply.[9] That price reflects a 66% discount off Jardiance®'s list price.[10]

22. The MFP for Jardiance® (and all other drugs selected for the IRA Program's first year) takes effect on January 1, 2026. *See* 42 U.S.C. § 1320f(b). Starting on that date, Boehringer will be required by statute to "provide access" to Jardiance® to Medicare beneficiaries at the MFP. 42 U.S.C. § 1320f-2(a)(1). If Boehringer fails to comply with that access requirement, it is subject to a civil monetary penalty equal to ten times the difference between the MFP and the price actually charged, multiplied by the number of violative units. *Id.* § 1320f-6(a).

23. Jardiance® is subject to both the 340B Program and the IRA Program. The IRA includes a special pricing provision that governs drugs subject to both of those programs. Under this provision, the manufacturer of a drug subject to both the 340B Program and the IRA Program must provide the drug at the lower of the 340B ceiling price or the MFP but cannot be required to provide the discount under the 340B Program and the discount under the IRA Program. *See* 42 U.S.C. § 1320f-2(d). Accordingly, as CMS recently explained, the IRA requires manufacturers to

[9] CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (Aug. 2024), https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf.

[10] *Id*.

"ensur[e] compliance with the statutory requirement to avoid duplication of the MFP and the 340B ceiling price for a selected drug."[11]

24. Moreover, the MFPs established under the IRA Program apply only to Medicare beneficiaries. Patients covered by Medicaid or private insurers, or who are uninsured, are not eligible to receive drugs at the MFP. By contrast, covered entities can receive the 340B ceiling price for any patient regardless of the patient's health insurer. As a practical matter, that means that manufacturers must provide the lower of the MFP or 340B ceiling price only to the subset of patients of a 340B covered entity who are covered by Medicare. Manufacturers must also offer the 340B ceiling price to a covered entity for all its patients who are not Medicare beneficiaries.

25. Boehringer sells its drugs to wholesalers in bulk quantities. When Boehringer makes these sales, it is impossible to know which providers will dispense the drugs, which patients will receive them, and who will ultimately pay for the drug. Thus, Boehringer generally cannot know *ex ante* which pricing rules will apply to each unit of product.

26. Manufacturers generally comply with their pricing obligations under the IRA Program (and contracts in the private market) by following a two-step process. First, the manufacturer charges a uniform price—known as wholesale acquisition cost ("WAC") or list price—when it sells its drugs to wholesalers. Second, the manufacturer pays after-the-fact rebates to pharmacies and other dispensing entities that cause the final price, net of rebates, to equal the legally required price. For example, if the WAC for a drug subject to the IRA Program were $100, and the MFP for that drug were $40, the manufacturer would pay a $60 rebate to the dispensing

[11] CMS, *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026* (June 30, 2023) at 26, https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.

pharmacy.[12] This two-step approach allows manufacturers to provide the correct price to a wide range of dispensing entities, despite not knowing who those entities will be when the drug products first enter the stream of commerce.

27. To provide access to MFPs set under the IRA Program, CMS has developed a "Medicare Transaction Facilitator" ("MTF") that will share data with manufacturers about claims for products subject to an MFP from dispensing entities (e.g., pharmacies). In return, the MTF can facilitate rebate payments from the manufacturers to the dispensing entities. In general, once a covered entity has dispensed a drug to a Medicare beneficiary, the MTF will send information about the claim to the manufacturer. Once the manufacturer ensures that the claim is valid, it is required to provide a rebate to the dispensing entity equal to the difference between the acquisition cost of the drug and the MFP.[13] In most cases, Boehringer will provide a rebate equal to the difference between the drug's WAC and the drug's MFP. Once the manufacturer has provided this rebate to the dispensing entity, it has met its statutory obligation to provide access to the MFP.

28. A key challenge for manufacturers providing access to the MFP is that neither manufacturers nor covered entities know which patient is a Medicare beneficiary eligible for the MFP until *after* a claim has been processed. While covered entities rely on various distribution models to obtain drugs at the 340B ceiling price, the acquisition cost of a covered entity is typically not WAC but rather the much lower 340B ceiling price. However, when a dispensing entity

[12] In the context of the IRA Program, CMS describes the payments from manufacturers to dispensing entities as a "refund," but the payments are retrospective and functionally indistinguishable from a rebate. *See generally*, CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028* (Sep. 30, 2025), https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf.

[13] *See id.* at 215.

submits a claim to the MTF for a rebate, there is generally no way for either the dispensing entity or the manufacturer to know that the claim involves a drug initially purchased at the 340B ceiling price. But to meet its statutory obligation to provide access to the MFP, the manufacturer must still provide a rebate to the dispensing entity equal to the difference between WAC and MFP. Since the covered entity, working through the dispensing entity, acquired the drug at a price below WAC, it would benefit from a duplicate discount in this scenario.

29. For example, if a product's WAC is $100, its MFP is $40, and its 340B ceiling price is $30, the dispensing entity may submit a claim for an MFP rebate and obtain $60 from the manufacturer. But since the manufacturer sold the dispensed drug through its wholesaler to the covered entity for $30 (the 340B ceiling price), the net result is that the manufacturer has *lost* $30 in the transaction (i.e., the $60 rebate paid to the dispensing entity minus the $30 acquisition cost of the covered entity). In other words, in this scenario, the manufacturer has received a *negative price* by paying a duplicate discount.

30. This duplicate discount would occur because determining which claims are subject to the 340B price is a process that the covered entity—which often contracts with an independent dispensing entity—determines after the drug has been dispensed. As a result, there is no way for manufacturers to prevent duplicate discounts between the 340B price and the MFP across all claims submitted to the MTF.

31. The most accurate way to avoid these duplicate discounts is to utilize the provision in the 340B statute authorizing manufacturers to offer the 340B ceiling price through a retrospective rebate (the same mechanism which is used to effectuate the MFP under the IRA Program). Accordingly, a rebate model is the only mechanism currently available to prevent the provision of all duplicate 340B and IRA discounts.

32. In the absence of a 340B rebate model, manufacturers do not have adequate data to identify those duplicate discounts. Accordingly, Boehringer has urged HRSA to authorize a 340B rebate model, which will allow covered entities to obtain the 340B ceiling price for covered drugs only if they provide manufacturers with sufficient information to identify and prevent duplicate discounts.

33. HRSA announced the rebate model pilot program in the Federal Register on August 1, 2025, observing that manufacturers sought such a rebate model "primarily to address 340B and Maximum Fair Price (MFP) deduplication." 90 Fed. Reg. 36,163, 36,163 (Aug. 1, 2025). Boehringer timely submitted an application to participate in the pilot program, and HRSA, which administers the 340B Program, approved Boehringer's application on October 30, 2025.

34. Boehringer intends to implement the rebate model pilot program beginning on January 1, 2026, as authorized by HRSA. To prepare for implementation of the rebate model, Boehringer has made significant organizational changes including changing IT infrastructure, contracting with additional vendors, developing new banking-payment processes, and adding additional headcount. These efforts have cost Boehringer millions of dollars.

35. Boehringer has also worked closely with HRSA and Beacon Channel Management to develop and implement a rebate model. In particular, Boehringer and Beacon Channel Management have developed processes to simplify the data submission process for covered entities and to ensure prompt payment of any validated claims within 10 days—meaning that covered entities will promptly receive the full benefit of the 340B Program's discounts. Boehringer has also worked closely with HRSA to make targeted adjustments to business rules to address concerns from covered entities, including solutions for unreplenished dispensed product during the initial transition period. To fully plan for these changes, Boehringer has also developed

a robust compliance framework to ensure compliance with all current HRSA and CMS requirements relating to the 340B rebate model and MFP effectuation.

36. Boehringer has informed CMS of its intent to use the rebate model pilot program to de-duplicate the MFP and the 340B price. Boehringer has also shared information with covered entities about the functioning of its proposed rebate model pilot on October 31, 2025 by physical mailing and email notification when the covered entity's email address was available—well in advance of the January 1, 2026 effective date.

37. In the absence of a rebate model, Boehringer is not aware of a mechanism by which to accurately deduplicate the discounts provided under the IRA and 340B programs.[14] Thus, if Boehringer cannot proceed with the 340B Rebate Model Pilot Program, Boehringer will have no viable alternative to implement the IRA's statutory prohibition on duplicate discounts. Although the Plaintiffs have proposed alternative approaches, those approaches would not solve the problem of duplicate discounts.

38. First, providing access to the MFP *prospectively* to every dispensing entity in the country, as the Plaintiffs have suggested, is administratively impossible and would expand the IRA Program well beyond its limits. Since only Medicare beneficiaries are eligible for the MFP, manufacturers would need to scrutinize every claim for every transaction in which their eligible products are dispensed to determine which claims do not involve Medicare beneficiaries. For

[14] In a similar vein, a 340B rebate model could help address other 340B Program integrity issues including duplicate discounts with the Medicaid program and drug diversion. Current methods for addressing duplicate discounts between the Medicaid and 340B Program, including covered entity audits and administrative dispute resolution, are insufficient to fully address the scope of the duplicate discount problem. Despite a 340B rebate model's potential to address this concern, HRSA in the notice announcing the 340B rebate model pilot expressly prohibited participating manufacturers from denying claims "based on compliance concerns with diversion or Medicaid duplicate discounts." 90 Fed. Reg. 38165, 38166 (Aug. 7, 2025). While Boehringer will comply with this requirement, we have urged HRSA to reconsider this policy.

those claims, manufacturers would then need to initiate after-the-fact chargebacks to recoup the difference between the MFP and WAC. This system would impose significant burdens on manufacturers, covered entities, and every other dispensing entity that does not participate in the 340B Program.

39. Second, there is no mandatory claims clearinghouse that contains the information necessary to avoid duplicate discounts between the 340B ceiling price and the MFP. While CMS did create a clearinghouse for Medicare Part D 340B claims, it did so for voluntary submissions only. 90 Fed. Reg. 49,266, 49,932 (Nov. 5, 2025). Here again, manufacturers would not have sufficient information to prevent duplicate discounts for *all* Medicare claims. While a mandatory claims data repository identifying every 340B eligible claim could help address duplicate discounts, no such repository currently exists.

40. Accordingly, if the Court enjoins use of the rebate model pilot, Boehringer will suffer significant economic harm due to duplicate discounts. Berkeley Research Group estimates that manufacturers would lose $4 billion in duplicate 340B and MFP discounts in 2026 alone absent the rebate pilot program.[15] In addition, Boehringer will have to invest considerable resources to develop methodologies to avoid duplication of the 340B ceiling price and MFP through other, less accurate means. It is highly unlikely that Boehringer could ever recoup these costs—and even attempting to do so would be a costly, time-consuming process. These harms will jeopardize Boehringer's ability to continue to invest in research and development of new medicines to treat patients.

[15] BRG, *Implications for Duplication with the 340B Channel* (Oct. 2024) at 2, https://media.thinkbrg.com/wpcontent/uploads/2024/10/23161214/BRG-Implications-for-Duplication-with-_the-340B-Channel-2024.pdf.

The Rebate Model Pilot Will Not Harm 340B Covered Entities

41. The rebate model pilot program has been carefully designed to ensure that covered entities will not be harmed.

42. First, the pilot program is limited to a small subset of drug products, for the purpose of assessing the benefits and drawbacks of the rebate model. Out of thousands of drug products and dozens of drug manufacturers covered by the 340B Program, only ten IRA selected drugs produced by nine manufacturers are included in the rebate model pilot program.

43. Second, I understand that the narrow set of data that is required to be submitted by covered entities is limited, industry-standard data that covered entities maintain in the ordinary course of business. HRSA approved limited data fields for covered entity submissions, including information about the distribution of the drug product (date of service, prescription number, quantity, etc.), the provider (identifying the physician and service provider), and insurance information.[16] I understand that HRSA already required covered entities to maintain accurate records of this information and that HRSA or drug manufacturers could audit those records.[17] Furthermore, HRSA has required that drug manufacturers provide technical support and customer service to covered entities regarding the rebate platform, and manufacturers must bear the administrative costs they incur in implementing the pilot program.[18]

44. Moreover, the program provides robust protections for any claims data that is submitted. The pilot program requires that the software platform used to gather this limited data

[16] HRSA, *340B Rebate Model Pilot Program* (Dec. 2025), https://www.hrsa.gov/opa/340b-model-pilot-program.

[17] HRSA, *Program Integrity* (Sept. 2025), https://www.hrsa.gov/opa/program-integrity.

[18] *See* HRSA, *Notice 2025-14998* (Sept. 8, 2025), https://www.regulations.gov/document/HRSA-2025-0001-0001.

incorporate controls to ensure that the data are handled and stored appropriately.[19] In particular, the software platform must have "mechanisms in place to protect patient identifying information," and must also maintain the data in a manner that complies with all applicable privacy and data security laws.[20] I understand that the software operator that will process rebates received an Expert Determination confirming that it is compliant with HIPAA and does not collect or maintain identifiable protected health information.[21] Boehringer's policy is compliant with these requirements and implements HRSA's guardrails.

45. Third, rebates must be paid promptly under the pilot: Boehringer has committed to paying rebates within 10 days of submission of a complete rebate request. Thus, covered entities that promptly submit rebate requests will not be required to "float" any funds. Under standard wholesaler payment terms, covered entities must generally pay for drug purchases within 30 days of purchase. As a result, covered entities that submit rebate claims promptly will obtain a rebate that allows them to net the 340B price on the sale well before the date on which their invoice is due to the wholesaler on the original purchase. In other words, although a covered entity will initially place an order at a standard commercial price under the 340B rebate model, the covered entity will not actually have to pay the non-340B price if it promptly submits a rebate claim, because it will receive the rebate before it needs to pay the invoice.

46. Fourth, the pilot program includes further safeguards to minimize the disruption to covered entities. For instance, manufacturers must provide 60 days' notice for covered entities

[19] *See id.*

[20] *Id.*

[21] Beacon Channel Management, *Rebate Model Frequently Asked Questions*, https://support.beaconchannelmanagement.com/en/articles/9589827-rebate-model-frequently-asked-questions.

before implementation of a rebate model. Boehringer issued this notice to covered entities on October 31, 2025. Furthermore, Boehringer, like other drug manufacturers, will allow covered entities to continue ordering the drugs through their existing distribution mechanisms, which will prevent delays or disruptions in the flow of drugs to covered entities and patients.[22]

47. Fifth, HRSA has stated that it will closely monitor the pilot program to understand how a rebate model system functions in practice and to ensure that participants comply with the 340B Program's requirements.[23] HRSA's Office of Pharmacy Affairs ("OPA") has selected manufacturers to participate in the pilot and will monitor its execution—for example by requiring these manufacturers, including Boehringer, to submit regular data to OPA. OPA will also solicit feedback from covered entities, provide a mechanism for stakeholders to submit comments, and facilitate the provision of "real-time reconciliation reports" for covered entities to stay apprised of the rebate status of submitted claims in real time.[24] OPA has reserved the right to terminate any drug manufacturer from the pilot program if it fails to meet the program's requirements, such as by failing to provide rebates in a timely manner.[25]

48. Further, many covered entities already voluntarily use a model similar to the rebate model in the 340B context. That model is commonly referred to as a "virtual credit model." Under this model, covered entities (or their contract pharmacies) purchase all medications at commercial

[22] *See* HRSA, Notice 2025-14998 (Sept. 8, 2025), https://www.regulations.gov/document/HRSA-2025-0001-0001.

[23] *See* HRSA, *340B Rebate Model Pilot Program* (Dec. 2025), https://www.hrsa.gov/opa/340b-model-pilot-program.

[24] *See* HRSA, Notice 2025-14998 (Sept. 8, 2025), https://www.regulations.gov/document/HRSA-2025-0001-0001.

[25] HRSA, *340B Webinar 12-4-2025*, https://www.youtube.com/watch?v=Iw0kxqi74PE; HRSA, *340B Rebate Model Pilot Program* (Dec. 2025), https://www.hrsa.gov/opa/340b-model-pilot-program.

prices (such as WAC) and maintain a single inventory, without differentiating between 340B and non-340B products. The covered entity dispenses medications in the ordinary course and then identifies (after the fact) transactions that it maintains are eligible for 340B pricing. The covered entity sends that data—usually through a third-party administrator—to its distributor, which attempts to match the drug transactions identified as 340B eligible with prior purchases of the same NDC and quantity. When the distributor successfully makes a match, it (i) "credit[s] the [covered entity's] non-340B commercial account for the difference" between the commercial and 340B price, and (ii) generates "a non-inventory purchase on the 340B covered entity bill-to/ship-to account."[26] Thus, rather than replenishing their inventories by having the distributor "physically shi[p]" drugs earmarked for 340B use, covered entities and contract pharmacies buy replacement drugs at the commercial price and then obtain the 340B price through a "financial credit" applied after the fact.[27] For example, when a covered entity enrolled in a virtual credit model program purchases a drug initially for $100 and later dispenses the drug to a 340B-eligible patient, "$100 will be credited to" the covered entity's "non-340B account" by the distributor "and then the entity will be invoiced for the 340B ceiling price … in [its] 340B account."[28]

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[26] AmerisourceBergen (now Cencora), Inventory Synchronization Program Guide, Doc. No. HS-110567, at 3, available at https://web.archive.org/web/20240426164057/https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/pdf/hgs-230633-isp-guide-12dec23-v2.pdf. PharmaForce, which offers a variety of 340B services for covered entities and pharmacies, has similarly identified the "adoption of credit-based replenishment models" as "a recent trend in 340B program" that "eliminates the need for physical inventory deliveries" and instead "us[es] a credit system within the pharmacy's retail account." PharmaForce, Credit-Based Replenishment: The Future of 340B? (accessed May 20, 2025), https://www.thepharmaforce.com/340b-credit-based-replenishment.aspx

[27] PharmaForce, Credit-Based Replenishment: The Future of 340B, at 5:52-6:12 (May 23, 2024), https://www.youtube.com/watch?v=T7yz-ZgjW2w ("PharmaForce Webinar").

[28] *Id.* at 5:25-5:38.

49. The net effect of this virtual credit model is the same as a 340B rebate model: the covered entity orders drugs at commercial prices up front, then later receives the 340B price through a rebate after a third party validates the transaction. Court records and commercial literature show that covered entities have voluntarily participated in these virtual credit model programs for nearly a decade.[29] Indeed, PharmaForce stated in 2024 that "a lot" of its "customers . . . are using" the virtual credit model "successfully" and that many pharmacies now "require a credit-based replenishment model."[30] Likewise, Boehringer recently identified one covered entity that has shifted to making significant purchases at WAC and stated that it is doing so under a virtual credit model.

[29] See, e.g., Memorandum of Law in Support of Defendant's Motion to Dismiss, *Fruth, inc. v. Cardinal Health, Inc.*, No. 3:23-cv-801, ECF No. 15, at *3 (S.D.W. Va. filed Mar. 18, 2024) (describing a similar "virtual replenishment" program operated by Cardinal Health and referring to allegation that plaintiff "began using" -it "in March 2016"); PharmaForce Webinar, supra, at 24:20-24:32 (referring to Cardinal Health virtual credit model program).

[30] *See* PharmaForce Webinar, supra, at 24:05-24:23.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this Tenth (10th) day of December, 2025.

Christine G. Marsh
Senior Vice President, Value and Access
Boehringer Ingelheim Pharmaceuticals, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER, *Plaintiffs,* v. ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA, *Defendants.*	Case No. 25-cv-00600-JAW

DECLARATION OF FARRUQ JAFERY

Pursuant to 28 U.S.C. § 1746, I, Farruq Jafery, state as follows:

1. I am over the age of eighteen, and I am competent to provide this declaration.

2. I am the Vice President, Pricing, Contract Operations & Reimbursement at Novo Nordisk Inc. ("Novo Nordisk").

3. Since September 2009, I have been responsible for governance of all of Novo Nordisk's pricing, contracting, and reimbursement strategies and execution of pricing strategies and operations for the US business. I am a strategic partner to senior and executive management

responsible for facilitating and executing pricing and contracting strategy for the organization. I am knowledgeable and have access to information about Novo Nordisk's pricing, marketing, and business practices for its portfolio of prescription drugs.

4. I have spent 16 years at Novo Nordisk in pricing, contract operations, and reimbursement. I have significant experience with the federal 340B Program, particularly as it relates to Medicare Parts B and D. I am also deeply involved in Novo Nordisk's efforts to address abuses of the 340B Program and to meet its obligations under the Inflation Reduction Act, including to identify and avoid impermissible "duplicate discounts."

5. Before joining Novo Nordisk, I served as Director, Contracts & Pricing, at Astellas Pharma US for four years and Associate Director, Contract Development & Administration at Wyeth Pharmaceuticals for five years.

6. Through these roles, I have been deeply involved in pricing, contracting, and reimbursement decisions for pharmaceutical products.

7. Novo Nordisk is a leading global biopharmaceutical company. Its history spans more than a century, beginning with two small Danish companies, Nordisk Insulinlaboratorium and Novo Terapeutisk Laboratorium, which merged in 1989. The company has discovered and developed innovative medicines and delivery systems, many of which are used to treat the unmet medical needs of people living with serious chronic disease. Novo Nordisk prides itself on discovering and developing innovative medicines and making them accessible to patients throughout the world.

8. Novo Nordisk's focus is on diabetes and other serious chronic diseases such as obesity and rare blood and endocrine diseases. The company currently offers for sale across the United States and in 170 countries around the world a number of life-saving and life-enhancing

pharmaceutical products for providing diabetes care, obesity care, hemophilia care, growth hormone therapy, and care in other therapeutic areas.

9. Novo Nordisk has nine products subject to the Inflation Reduction Act's Drug Price "Negotiation" Program. For initial price applicability year ("IPAY") 2026, beginning January 1, 2026, the following six products will be subject to a "maximum fair price" ("MFP") imposed by the Centers for Medicare & Medicaid Services ("CMS"): FIASP® vial, FIASP® Flextouch®, FIASP® Penfill®, NovoLog® vial, NovoLog® FlexPen®, and NovoLog® PenFill®.[1] Beginning on January 1, 2026, Novo Nordisk will be required by federal law to offer those products at the MFP imposed by CMS under the terms of the Inflation Reduction Act.

10. Novo Nordisk participates in the 340B Program. As required by federal law, the company offers its drugs at deeply discounted 340B prices. Covered entities have no right to access manufacturers' drugs at discounted prices except as specifically provided under the terms of the 340B Program, which is overseen by the Health Resources and Services Administration ("HRSA").

11. Rebates are standard practice in the pharmaceutical industry. They are a common feature of drug pricing and a ubiquitous means by which discounts are extended on pharmaceutical products to secure coverage for our products on formularies. Rebates are drug discount mechanisms used to reduce the overall costs of prescription drugs and improve their affordability to patients. In determining the price paid for a drug, it is essential to consider whether a rebate is provided.

12. In the commercial context, when a characteristic of the patient is relevant in

[1] CMS considers these six products to be one "selected drug" for purposes of the Inflation Reduction Act's Drug Price "Negotiation" Program. Novo Nordisk has challenged this determination in litigation. The 340B Rebate Model Pilot Program applies to all of these products.

determining the price to be extended by the manufacturer, rebates are generally the tool used to offer the discount. For instance, if a manufacturer contracts with an insurer to offer discounts on units dispensed to the insurer's covered patients, the coverage characteristic is relevant to the extension of the discount. In this example, a rebate is the appropriate way to track and pay discounts consistent with the terms of the contract. Conversely, a rebate might not be used if nothing about the patient is determinative—if, for instance, a manufacturer contracted with a hospital for a discounted price without regard to whom the drugs are dispensed.

13. Rebates are particularly appropriate in the 340B context for two reasons. First, a characteristic of the patient is highly relevant to the right to the discount. 340B covered entities may only transfer and dispense drugs subject to the 340B price to their *patients* as defined by law.

14. Second, rebates are especially appropriate in the 340B context because of how the 340B Program has evolved. When Congress first enacted the 340B statute in 1992, it did so with the expectation that covered entities would provide the discounted medications to indigent and uninsured patients who visited their facilities for treatment. In recent years, however, covered entities have been permitted to use what is referred to as a "replenishment model." Under this model, covered entities have taken advantage of the 340B Program by contracting with large, for-profit commercial pharmacies that are often located far away from the covered entity's facilities. The pharmacy dispenses drugs to the pharmacy's customers at the regular price. The pharmacy and the covered entity then later determine whether, in their view, the customer qualifies as a "patient" of the covered entity and, if the customer does, the covered entity seeks to "replenish" the unit of the drug originally sold to the pharmacy customer at the regular price by purchasing a new unit of the drug at the discounted 340B price. The covered entity and the pharmacy pocket the difference, and the patient (or the patient's insurance company) do not see any discount.

Because covered entities often do not pass on discounts to patients at the point of sale, the 340B Program has become a mechanism for covered entities and their contract pharmacies to engage in arbitrage for their own financial benefit at the expense of patients.

15. This "replenishment" system also operates to allow other abuses of the 340B Program. It is often the case that a covered entity will claim that a pharmacy customer is a "patient" of the covered entity even when the prescription is not written in connection with a service provided by the covered entity itself. There is also a significant risk of "duplicate discounts," meaning that manufacturers provide a discount at the 340B price for a medication that is also subject to a rebate or another discount. The 340B statute prohibits Medicaid "duplicate discounts" and transfers of 340B drugs to non-patients, but significant problems arise because covered entities do not transfer drugs purchased at discounted prices to contract pharmacies and patients at the point of sale. Instead, they regularly demand access to the discounted 340B price long after the pharmacy has dispensed a drug to its pharmacy customer.

16. The challenges in policing abuses of the 340B Program have become even more important with the implementation of the Inflation Reduction Act. Under that statute, manufacturers like Novo Nordisk are required to provide drugs to Medicare beneficiaries at a price dictated by the government, referred to as the "maximum fair price."

17. The statute expressly provides that manufacturers, including Novo Nordisk, must provide only the *lower* of the "maximum fair price" or the discounted 340B price, but not both. The law affirmatively protects manufacturers from being required to pay duplicate discounts in this way.

18. Duplicate discounts cause substantial harm to manufacturers. Because the discounts are so significant, when Novo Nordisk provides more than one discount on the same

drug unit, it may even be effectively forced to sell the drug at a loss for certain products.

19. Yet the agency charged with overseeing the maximum fair price regime, CMS, has made clear that it expects manufacturers to police this kind of illegal duplicate discounting. According to CMS, it "is not charged with verifying or otherwise reviewing whether a particular drug claim is 340B-eligible." CMS, Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028 (September 30, 2025) ("IPAY 2028 Final Guidance") § 40.4.5. Instead, CMS has made clear that manufacturers must work with others in the pharmaceutical supply chain "to facilitate access to the lower of the [maximum fair price] and the 340B ceiling price, wherever applicable." *Id.*

20. Because of how the 340B Program operates, there is no ready or plausible way to identify duplicate discounts at the point of sale. Precisely because of the widespread use of "replenishment" practices, and because covered entities have an incentive not to be transparent with manufacturers, it is virtually impossible for manufacturers to know when a product that is subject to maximum fair price might *later* be identified by a covered entity as eligible for replenishment at the 340B discounted price. The only practical way to satisfy the statutory requirements is for manufacturers to have a short period of time after a drug is dispensed, and a request for a 340B discount is made, to determine whether the request for the discounted 340B price might result in an impermissible duplicate discount.

21. The federal 340B statute expressly contemplates that manufacturers are permitted to offer their drugs at 340B prices through the provision of rebates. For that reason, Novo Nordisk carefully investigated using a rebate model to ensure that covered entities would be able to access drugs at the 340B price without causing Novo Nordisk to pay a duplicate discount.

22. HRSA announced the availability of a voluntary 340B Rebate Model Pilot Program for drugs on the CMS Medicare Drug Price Negotiation Selected Drug List for year 2026 on July 31, 2025.

23. Consistent with HRSA's announcement, Novo Nordisk submitted a proposal to HRSA and sought approval to implement a rebate model, consistent with the terms of the 340B statute and the agency's pilot program.

24. HRSA approved Novo Nordisk's use of a rebate model on October 30, 2025.

25. Novo Nordisk has relied significantly on HRSA's decision approving Novo Nordisk's proposed rebate model, as well as HRSA's promise that it would implement a 340B rebate model pilot program. Novo Nordisk has structured its 340B rebate model to comply specifically with HRSA's requests, and it has done so in order to be in a position to avoid duplicate discounts under the Inflation Reduction Act, as federal law provides.

26. Novo Nordisk incurred substantial costs in preparing the 340B rebate model to ensure compliance with the Inflation Reduction Act. Novo Nordisk retained Second Sight Solutions to help effectuate the 340B rebate model through the use of the Beacon 340B technology platform ("Beacon 340B platform"). Novo Nordisk has borne significant costs and has dedicated myriad resources associated with establishing technical assistance and manufacturer points of contact, preparing IT systems to receive 340B rebate model data, evaluating contractual arrangements with supply chain entities to facilitate data flow, and engaging the services of multiple outside professionals, including project managers and legal counsel. Novo Nordisk estimates its total cost to implement the rebate model in 2025 and 2026 to be approximately $10 million.

27. If Novo Nordisk is unable to implement a rebate model to address duplicate

discounts on January 1, 2026, it faces substantial harm. In the absence of an operational rebate model on January 1, 2026, Novo Nordisk would not have any viable means to identify and weed out duplicate "maximum fair price" and 340B claims. Novo Nordisk is not aware of any readily available alternative model that would be possible to implement that would effectively identify duplicate claims.

28. Even if an alternative deduplication mechanism could be implemented, Novo Nordisk could not simply flip a switch to immediately proceed with that alternative deduplication methodology. It would take substantial time and resources to stand up an alternative model. That would be substantially burdensome. The company has been preparing its systems, processes, and personnel in reliance on the 340B rebate model. A pivot or delay in the rebate model at this time would require Novo Nordisk to create, test, train on, and implement a wholly separate process to deduplicate claims. During that time, Novo Nordisk may be required to operate without a reliable method to deduplicate claims, meaning the company would be forced, contrary to the law, to pay duplicate discounts. Either outcome threatens substantial losses or exposure to penalties.

29. Novo Nordisk's model, effectuated through the Beacon 340B platform, ensures the confidentiality of patient information: "data elements under HIPAA are de-identified through a HIPAA compliant hashing process known as SHA-3 hashing." Beacon Support Center, Rebate Model Frequently Asked Questions, https://support.beaconchannelmanagement.com/en/articles/9589827-rebate-model-frequently-asked-questions. The Beacon 340B platform adds another layer of security called a "salt," which is applied before the hashing process and before any data is uploaded to Beacon. *Id.* Notably, "[t]his process was granted an Expert Determination and meets the definition of a De-Identified Data Set under HIPAA. This means that Beacon does not collect or maintain identifiable PHI." *Id.*

30. Novo Nordisk avoids any harm to covered entities by ensuring its 340B rebate model is consistent with the 340B statute and HRSA's requirements, which provide that each manufacturer's plan "should ensure that all rebates are paid to the covered entity (or denied, with documentation in support) within 10 calendar days of data submission." 90 Fed. Reg. 38165, 38166 (Aug. 7, 2025). Ten calendar days is not a hardship and would not result in any harm to covered entities: providers and dispensaries often wait much longer for standard insurance reimbursement, and as noted above, covered entities typically seek to secure the 340B prices for drugs that have already been dispensed to pharmacy customers. A recent white paper published by IQVIA has concluded that the 340B Rebate Model is not expected to negatively impact Covered Entity cash flow (https://www.iqvia.com/locations/united-states/library/white-papers/how-will-a-rebate-model-impact-cash-flow-in-the-340b-drug-pricing-program).

I declare under penalty of perjury that the foregoing is true and correct.

Executed on December 10, 2025.

Signed by:
Farruq Jafery
2CA6D64E44D841F...

Farruq Jafery

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA.

Defendants.

Case No. 2:25-cv-00600-JAW

BRIEF FOR PROPOSED INTERVENORS ABBVIE, INC., PHARMACYCLICS, LLC, ASTRAZENECA PHARMACEUTICALS LP, PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA (PHRMA), BOEHRINGER INGELHEIM PHARMACEUTICALS INC., AND NOVO NORDISK INC. IN OPPOSITION TO PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER[1]

[1] Proposed Intervenors file this opposition pursuant to the schedule set during the Court's December 8, 2025 telephone conference. ECF 31.

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INTRODUCTION

Plaintiffs' motion for emergency relief should be denied. Months ago, on August 1, 2025, the government announced it intended to launch a Pilot Program to test how drug manufacturers could use a rebate model to provide reduced prices to eligible healthcare providers (called "covered entities") participating in the federal 340B Program. The 340B Program allows covered entities to buy steeply discounted drugs from manufacturers participating in Medicaid and Medicare Part B, but they can dispense those drugs only to their own eligible patients and cannot generate duplicate discounts or rebates. 42 U.S.C. § 256b. The relevant federal statute expressly authorizes the use of ***either*** "discounts" or "rebates" to afford 340B prices—there is no dispute here that a 340B rebate model is substantively lawful. *Id.* § 256b(a).

And a 340B rebate mechanism is needed now more than ever. Congress recently imposed new, competing obligations on certain manufacturers. The Inflation Reduction Act (IRA) created the "Drug Price Negotiation Program" (DPNP), which initially requires nine manufacturers to offer certain drugs to hospitals and pharmacies treating Medicare-covered individuals at a "maximum fair price" (MFP) that HHS sets. Because Medicare patients often fill their prescriptions at 340B covered entities (or their off-site contract pharmacies), manufacturers often must determine ***which*** of those two prices applies to a dispensing event: 340B or MFP? By statute, manufacturers must provide ***only*** the lower price, not ***both*** discounts. Failure to provide the correct price within fourteen days exposes manufacturers to severe monetary penalties. The Pilot Program challenged here was primarily designed to enable manufacturers to comply with their statutory obligations that commence in under three weeks. Those manufacturers cannot make the required 340B or MFP determination on their own; they need claims data from the covered entities and their pharmacies. As explained below and in the proposed Intervenors' declarations, without the Pilot Program, manufacturers could not fully satisfy their deduplication obligations and would face

losses exceeding $4 billion in 2026 alone, in addition to the risk of severe monetary penalties.[2]

Plaintiffs waited until December—more than a month after manufacturers' individual rebate models were approved and less than a month before the Pilot Program starts and manufacturers' penalty-backed statutory obligations kick in—to sue and seek emergency relief. They claim the agency embarked on the Pilot Program without engaging in inapplicable notice-and-comment or fully explaining its cost-benefit calculus. But the agency's decisions to establish a pilot program and accept Intervenors into it were not arbitrary and capricious. To the contrary, they represent, after months of discussion, the bare minimum the agency could do to reconcile overlapping statutory pricing obligations that were thrust upon manufacturers and that manufacturers lack other viable means to satisfy. The agency adequately explained its reasoning. And if more explanation were needed, the proper remedy would be to require ***more agency explanation***, not an injunction.

Just as importantly, the balance of equities disfavors an injunction. The Pilot Program will apply to a limited number of products (accounting for approximately 2% of the 340B Program's total value).[3] Importantly, the Pilot Program will not change what discounts Plaintiffs receive from the 340B Program or create a cash-flow problem. And contrary to Plaintiffs' contentions, covered entities already collect, maintain, and routinely transmit the claims data at issue, rendering claims that covered entities will face millions of dollars in compliance costs both speculative and unsupported. Even indulging Plaintiffs' estimates, however, there is no doubt that granting

[2] All proposed Intervenors seek leave to participate at the December 19, 2025 hearing and intend to present argument through one counsel. Proposed Intervenors are AbbVie, Inc., Pharmacyclics, LLC, AstraZeneca Pharmaceuticals LP, Pharmaceutical Research & Manufacturers of America (PhRMA), Boehringer Ingelheim Pharmaceuticals Inc., and Novo Nordisk Inc. *See* ECF 36, 39, 45, 50. PhRMA is a trade association representing eight of the nine manufacturers in the Pilot Program, as well as other interested members.

[3] There is a dispute over the exact number of medications involved in the Pilot Program, as CMS aggregated six of Novo Nordisk's medications and treated them as a single product. That dispute is irrelevant to Plaintiffs' motion.

emergency relief would subject Intervenors to vastly greater harms. Without the ability to collect claims data and effectuate the 340B price through a rebate model, Intervenors risk accruing debilitating penalties under the DPNP and providing enormous duplicate discounts that are inconsistent with federal law. The nine participating manufacturers will lose $4 billion in 2026 alone if enjoined from implementing their agency-approved rebate models. And that figure just covers losses attributable to duplicate discounts; it does not account for statutory penalties and the time, labor, and resources spent preparing for their new DPNP obligations and the Pilot Program.

Finally, Plaintiffs' request for emergency relief is untimely. They have known about the Pilot Program since the agency's announcement on August 1. Although individual rebate models were first approved in October, Plaintiffs' suit does not engage with the specifics of those individual rebate plans. Plaintiffs contest the propriety of the Pilot Program as a whole. Plaintiffs' suit is thus a belated challenge to the agency's August 1 decision to have a rebate pilot at all. Plaintiffs' unjustified and prejudicial delay alone justifies denying emergency relief.

Plaintiffs' motion for emergency relief threatens grave harm to Intervenors and the public interest while providing Plaintiffs no corresponding benefit. It should be denied.

BACKGROUND

A. The 340B Pricing Program and the Inflation Reduction Act.

1. The Pilot Program concerns two overlapping federal drug-pricing programs. The first is the 340B Program, which requires manufacturers participating in Medicaid and Medicare Part B to offer drugs "at a ceiling price" to certain enumerated healthcare providers known as "covered entities" that serve indigent and uninsured patients. 42 U.S.C. § 256b. The "ceiling price" is set by a statutory formula and is often pennies on the dollar. *See id.* § 1396r-8(c); *see also, e.g.*, ECF 36-2, ¶ 3. The second is the new DPNP created by the IRA. The DPNP requires HHS to set a "maximum fair price" (MFP) for certain drugs. CMS, *Medicare Drug Price Negotiation Program:*

Selected Drugs for Initial Price Applicability Year 2026 (Aug. 15, 2024), https://tinyurl.com/2wf6wv8t. Manufacturers must make selected drugs available to certain Medicare-covered individuals at the MFP. *See* 42 U.S.C. §§ 1320f(a), (c)(2), 1320f-2(a)(3). Failure to provide the MFP exposes a manufacturer to civil monetary penalties reaching into the millions per day. *Id.* §§ 1320f-6(c), 1320f-2(a)(5). HHS has agreed that a manufacturer may satisfy its MFP obligation by using a rebate mechanism—that is, by "retrospectively transmitting payment for the difference between the dispensing entity's acquisition cost and the MFP (*i.e.*, the MFP refund amount)," within fourteen days.[4] That rebate-based approach makes sense because manufacturers sell their drugs in bulk, when it is impossible to know which particular drugs, if any, will later be sold to MFP-eligible patients.

2. The DPNP creates a new problem for manufacturers, like Intervenors, who produce drugs subject to both the MFP and the 340B ceiling price. Starting January 1, 2026, such manufacturers must provide the lower of the two prices—***but not both,*** which combined could be so ruinously steep as to produce a negative price. *See id.* § 1320f-2(d). The DPNP is explicit on that point: Manufacturers "shall not be required to provide" both the MFP and the 340B price. *Id.* Such "duplicate discounts" are therefore inconsistent with federal law. But the government has disclaimed responsibility for identifying and deduplicating MFP-340B dispenses, leaving manufacturers to shoulder that burden.[5]

Manufacturers do not have the information necessary to determine whether a given prescription was 340B-eligible. To meet their new statutory obligations, manufacturers subject to

[4] CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028* (Sept. 30, 2025) ("IPAY2028 Final Guidance") at 212, https://tinyurl.com/uf86dc2f.

[5] *See* CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027* (Oct. 2, 2024) ("2026 Guidance") at 54-55, 229-32, https://tinyurl.com/ychztdfu.

the DPNP need "claims data" to determine which discount (if any) to issue within the fourteen-day payment window. Claims data is transaction-level data about a given drug "dispense," *i.e.*, furnishing a drug to a patient. Covered entities already use claims data to determine whether their past drug dispenses were 340B-eligible. ECF 36-2, ¶¶ 19, 27. For purposes of the MFP (but not 340B), manufacturers must use the "Medicare Transaction Facilitator" (MTF), a new system that facilitates data transmission from plans to manufacturers.[6] Under HHS guidance, manufacturers must collect and analyze certain claims data submitted through the MTF to determine whether the MFP is owed on any given drug dispense. IPAY2028 Final Guidance, *supra* note 3, at 216-19. But the limited claims data from the MTF does not enable manufacturers to determine whether a drug dispense is also subject to a 340B discount. ECF 36-1, ¶ 13. So it is functionally impossible to use existing systems to determine whether the MFP or the 340B price applies—and thus prevent duplicate discounts—without claims data concerning 340B eligibility. *See id.*; ECF 36-2, ¶ 22.

B. HRSA's Rebate Model Pilot Program.

The 340B statute expressly contemplates manufacturers making the 340B price available either through an upfront "discount" or an after-the-fact "rebate." 42 U.S.C. § 256b(a)(1). In response to widespread concern from manufacturers about their new deduplication obligations, HHS announced the Pilot Program to test a rebate model for effectuating the 340B price to covered entities while ensuring manufacturers are not burdened with duplicate discounts. *See* 90 Fed. Reg. 36,163 (Aug. 1, 2025). While the statute clearly contemplates broader rebate models, the Pilot Program is currently limited to manufacturers with competing MFP and 340B pricing obligations and only to those manufacturers' DPNP-selected drugs. CMS, *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026* (Aug. 15, 2024),

[6] IPAY2028 Final Guidance, *supra*, at 215 (Sept. 30, 2025) ("IPAY2028 Final Guidance"); *see also* ECF 36-1, ¶ 6.

https://tinyurl.com/5bcw2z4a.

Under the Pilot Program, the manufacturers will initially sell the selected drugs to 340B covered entities at the commercial price. Those manufacturers will then review certain data to determine whether the MFP or the 340B price applies: (1) the limited claims data from the MTF relevant to establishing DPNP eligibility; and (2) certain claims data from the covered entity (which the covered entity ***already collects*** in the regular course) relevant to establishing an entitlement to a 340B discount. Covered entities will submit their claims data to manufacturers through a platform called Beacon, which "precisely mirrors" a platform covered entities (including some of Plaintiffs here) already use in their 340B operations. Ex. 1 (Vandervelde Dec.), ¶ 8. From that review, the manufacturer will know whether to issue a rebate effecting the MFP or the 340B price. This is currently the only accurate and reliable method of identifying claims subject to 340B pricing, preventing duplicate discounts, and ensuring statutory compliance. ECF 36-2, ¶ 22.

The Pilot Program is also a way for HRSA to explore improvements to existing 340B procedures. In its Notice, HRSA explained that the Pilot Program would enable it "to better understand the merits and shortcomings of the rebate model from stakeholders' perspectives," and that the Program would "inform [its] consideration of any future 340B rebate models." 90 Fed. Reg. at 36,164. Such consideration is valuable as some manufacturers seek to implement rebate models as a method of ensuring covered entities' compliance with the 340B statutory scheme more broadly. *See* Ex. 2 (Banks Decl.), ¶¶ 7, 10–11.

The Pilot Program will begin in less than three weeks, on January 1. *Id.* HRSA chose that date because that is when the DPNP's MFP goes into effect, and thus when the potential for duplicate discounts begins. Intervenors, after investing thousands of hours and millions of dollars, are set to implement their HRSA-approved rebate models on January 1. *See* ECF 36-1, ¶ 17; ECF

39-1, ¶ 23; ECF 45-2, ¶ 24; ECF 50-5, ¶¶ 25–26.

LEGAL STANDARD

Plaintiffs seek an "extraordinary and drastic remedy" used "sparingly and only in a clear and plain case." *Doe ex rel. Doe v. Portland Pub. Schs.*, 701 F. Supp. 3d 18, 32 (D. Me. 2023) (cleaned up). Whether Plaintiffs' motion seeks a TRO or a preliminary injunction, the standard is the same. *Id.* Plaintiffs must demonstrate a likelihood of success on the merits, a likelihood of irreparable harm, that a balance of the equities favors them, and that the public interest favors granting emergency injunctive relief. *Id.* Plaintiffs must make a "clear showing" for each factor. *Starbucks Corp. v. McKinney*, 602 U.S. 339, 346 (2024); *see Doe*, 701 F. Supp. 3d at 32.

ARGUMENT

I. PLAINTIFFS ARE UNLIKELY TO SUCCEED ON THE MERITS.

Plaintiffs have tried and failed to stop 340B rebate models before, and this suit is simply their latest bite at that apple. *See Eli Lilly & Co. v. Kennedy*, 2025 WL 1423630, at *9 n.11 (D.D.C. May 15, 2025); *Johnson & Johnson Health Care Sys. Inc. v. Kennedy*, No. 24-cv-3188 (D.D.C. June 27, 2025), ECF 68.[7] Indeed, these are repeat players with similar arguments. *See Johnson & Johnson*, ECF 68 at 23 (Plaintiff AHA contending that"[c]omplying with the rebate policies will inflict substantial administrative costs" and interfere with Dallas County Medical Center's mission "to help its patients"). Here, they insist that the Pilot Program is arbitrary and capricious because (1) HRSA changed its longstanding disapproval of rebates without explanation, (2) HRSA failed to respond to comments, (3) the Pilot Program is unjustified by cost-benefit balancing, and (4) HRSA ignored better alternatives. These arguments fail. The Pilot Program is a targeted initiative

[7] *See also Eli Lilly v. Kennedy*, No. 24-cv-3220 (D.D.C. March 4, 2025), ECF 34; *Bristol Myers Squib v. Kennedy*, No. 24-CV-3337 (D.D.C. March 5, 2025), ECF 37; *Novartis Pharms. Corp. v. Kennedy*, No. 25-CV-117 (D.D.C. March 5, 2025), ECF 30; *Sanofi-Aventis U.S. LLC v. HHS*, No. 24-cv-3496, (D.D.C. March 20, 2025), ECF 38.

necessary to facilitate the nonduplication provisions of the 340B Program and the DPNP, and it is informative to HRSA's consideration of rebate models in the 340B Program more broadly.

A. HRSA Addressed A New Problem Consistent With Its Past Positions.

HRSA has not reversed its former views, disavowed earlier agency action, or rescinded earlier regulations. Rather, it has conceived of a targeted approach to test a model for addressing a new, urgent deduplication problem that the IRA created.

HRSA did not announce the Pilot Program in a vacuum; the Pilot Program is a response to a recent legal development—the IRA's creation of the DPNP. The IRA created new, onerous deduplication obligations for manufacturers, and those obligations go into effect on January 1. Under the IRA's new regime, it is critical that the selected manufacturers be able to collect claims data so that they can, within the fourteen-day deadline, identify claims subject to 340B pricing and prevent duplicate discounts for the same dispense. ECF 36-2, ¶ 22. Currently, the Pilot Program is the only mechanism for manufacturers to do so. If manufacturers cannot use this mechanism, they will lack the data necessary to accurately identify claims subject to both programs, exposing them to costly duplicate discounting. ECF 36-2, ¶ 22. So it can hardly be said that HRSA drew no "rational connection" between the looming duplicate-discount problem and a pilot designed to combat duplicate discounts. *FDA v. Wages & White Lion Invs., L.L.C.*, 604 U.S. 542, 567 (2025) (cleaned up). Given the January 1 deadline, HRSA reasonably determined that ***now*** is the time for further investigation of a rebate model. The agency explained as much, noting that it wanted "to address 340B and [MFP] deduplication." 90 Fed. Reg. at 36,163. This is HRSA responding to a ***new*** problem for the ***first*** time—not HRSA changing its mind. The agency's judgment calls were thus reasonable and reasonably explained. That is all the Administrative Procedure Act requires.

Plaintiffs also misstate HRSA's pre-IRA position on rebates. HRSA has never categorically rejected the propriety of a rebate system—much less any particular pilot program to

test that model. Nor could it: The 340B statute explicitly authorizes "rebate[s]." 42 U.S.C. § 256b(a)(1). HHS has administered another 340B rebate program, the AIDS Drug Assistance Program (ADAP), since 1998. *See* 62 Fed. Reg. 45,823 (Aug. 29, 1997); 63 Fed. Reg. 35,239 (June 29, 1998). Several manufacturers discussed 340B rebate models with HRSA long before August 2025, *Eli Lilly & Co.*, 2025 WL 1423630, at *6 (describing a months-long back-and-forth with manufacturers). HRSA has claimed authority to approve or disapprove of any specific rebate proposal and said it needed more information before it could do so. *Id.* at *8; *Johnson & Johnson Health Care Sys. Inc. v. Kennedy*, 2025 WL 1783901, at *3-4 (D.D.C. June 27, 2025). The Pilot Program does not contradict that position.

Plaintiffs claim that HRSA "stopped drug companies from enacting similar [rebate] programs" as recently as last year, ECF 3 at 1, but that is wrong. In the cited action, HRSA took the position that it was not approving particular proposals ***yet***.[8] Further, the rebate policies at issue in those prior actions included proposals seeking to implement 340B rebates for ***all*** 340B drug transactions. *Eli Lilly & Co.*, 2025 WL 1423630, at *6. The Pilot Program, by contrast, implements 340B rebates for a very limited number of DPNP-selected drugs. Any suggestion that the Pilot Program is an agency about-face is false.

Plaintiffs are also wrong about the legal doctrine applicable to an agency's change in position. They claim that "when an agency reverses its prior policies, as here, … the APA requires 'more detailed justification than what would suffice for a new policy created on a blank slate.'" ECF 3 at 9-10 (quoting *FCC v. Fox Television Studios*, 556 U.S. 502, 515 (2009)). But in *Fox*, the Supreme Court held that an agency generally "need ***not*** demonstrate to a court's satisfaction that the reasons for the new policy are ***better*** than the reasons for the old one," and that "the agency

[8] ECF 1, ¶¶ 40-51; ECF 10-1; ECF 10-4; ECF 10-5.

need ***not*** always provide a more detailed justification than what would suffice for a new policy created on a blank slate." 556 U.S. at 515 (some emphasis added). Even if HRSA changed its mind (it did not), the question is simply whether it "display[ed] awareness that it ***is*** changing [its] position" and offered "good reasons for the new policy." *Id.* Here, the agency satisfied that standard. HRSA acknowledged that the Pilot Program would take 340B pricing mechanisms in a different direction. *See* 90 Fed. Reg. at 36,163-64 (noting that rebates may "shift how the 340B Program has operated"). And it offered good reasons for testing rebates. The DPNP created an urgent problem that a 340B rebate model would address, and broader rebate-model talks were ongoing, so a pilot program would help all parties "better understand the merits and shortcomings of the rebate model" and would inform "consideration[s] of any future 340B rebate models." *Id.* at 36,164.

HRSA was likewise "cognizant that longstanding policies may have engendered serious reliance interests." *White Lion*, 604 U.S. at 570 (cleaned up). Indeed, HRSA considered Plaintiffs' asserted reliance in choosing to test rebates on a limited set of 340B drugs, with agency-approved plans and guidelines, rather than to endorse rebates outright.[9] Nor can Plaintiffs' reliance interests trap HHS's policy in amber when Congress has expressly authorized rebates, *see* 42 U.S.C. § 256b(a)(1), and has created a ***new*** statutory problem that rebates solve, *id.* § 1320f-2(d).

B. HRSA Was Not Required To Respond To Comments.

Plaintiffs make much of the fact that HHS did not respond to the approximately 1,000 comments submitted about the Pilot Program.[10] But they fail to explain why any response was

[9] 90 Fed. Reg. at 36,164 ("OPA is introducing this pilot program to test the rebate model on a select group of drugs … in a methodical and thoughtful approach to ensure a fair and transparent 340B rebate model process for all stakeholders involved.").

[10] Many of the comments Plaintiffs invoke consisted of the same letter sent numerous times. One entity even submitted the exact same letter at least 165 times, accounting for roughly 15% of all comments. ECF 36-2, ¶ 31.

necessary. Indeed, Plaintiffs never quite say whether they challenge the August 1 Notice or HRSA's acceptance of Intervenors' rebate proposals, but neither action required notice and comment. The APA distinguishes legislative rules (made through rulemaking) from orders (made through adjudication). *See* 5 U.S.C. § 551(4)–(7). Legislative rules generally require notice and comment. *Id.* § 553. Orders merely interpreting a statutory mandate do not. *Blanca Telephone Co. v. FCC*, 743 F.3d 860, 867 (D.C. Cir. 2014).

If Plaintiffs are challenging the August 1 Notice that announced the Pilot Program, they do not contend that it is a "legislative rule" subject to notice and comment. The Notice was a non-binding policy statement with no standalone legal effect. *See* 90 Fed. Reg. at 36,164. Given that status, HRSA was not required to solicit comments on the Notice in the first place, and therefore was not subject to any APA obligation to publish responses to such comments. *See City of Portland v. EPA*, 507 F.3d 706, 714-15 (D.C. Cir. 2007) (observing that "whether EPA adequately responded to these comments makes no difference because the Agency had no obligation to respond to them in the first place"). In any event, the Pilot Program will ***generate*** the very information Plaintiffs seek. As HRSA explained, by participating in the Pilot Program HRSA and industry stakeholders will gain valuable experience and information on the operational benefits and downsides of rebates. 90 Fed. Reg. at 36,163-64.

If Plaintiffs are challenging the approvals of manufacturers' individual Pilot Program applications, those are adjudicatory "orders" implementing the IRA's pricing scheme that are not subject to the APA's notice-and-comment requirements, and they are voluntary ones at that. The agency "adjudicate[d] [] facts in particular cases," namely whether a specific drug manufacturer's proposed model was adequate for participation in the Pilot Program. *See, e.g.*, *Franks v. Salazar*, 816 F. Supp. 2d 49, 59 (D.D.C. 2011). The application-and-approval process underscores the time-

limited and narrow nature of the Pilot Program. Plaintiffs supply no authority supporting the claim that HRSA was required to publish responses to public comments before completing those adjudications. Nor do Plaintiffs identify unanswered questions about the proposed rebate models. HRSA explained that the approved "plans all met the requirements as stated in the" August 1 Notice.[11] Nothing more would be required under the APA. *See Hudson v. FAA*, 192 F.3d 1031, 1034, 1036 (D.C. Cir. 1999); *see also Housatonic River Initiative v. EPA*, 75 F.4th 248, 266-67 (1st Cir. 2023).

C. A Cost-Benefit Analysis Supports The Pilot Program.

Plaintiffs next challenge HRSA's cost-benefit analysis by grossly inflating their projected costs while entirely ignoring manufacturers' far greater costs if the Pilot Program does not go into effect. Plaintiffs dispute HRSA's estimate of a $200 million annual burden for covered entities, arguing that this figure "grossly understates the true cost." ECF 3 at 13. They put the number closer to $400 million and argue that HHS failed to properly account for the Pilot Program's administrative costs. *Id.* at 13-14, 17. That estimate is implausible, as the Pilot Program runs on a software, Beacon, that "precisely mirrors" a software that covered entities (including some of Plaintiffs here) have used for years. Ex. 1, ¶ 8. Even crediting Plaintiffs' inflated and unsubstantiated $400 million estimate, that figure is dwarfed by the ***over $4 billion*** in duplicate discounts manufacturers will provide in 2026 alone absent the Pilot Program. *See* ECF 36-1, ¶ 18, ECF 39-1, ¶ 25, ECF 45-1, ¶ 18, ECF 50-4, ¶ 40.[12] This disparity becomes even starker when accounting for the substantial civil monetary penalties—potentially millions of dollars per day—that manufacturers face for failing to satisfy their DPNP obligations. 42 U.S.C. §§ 1320f-6(c),

[11] HRSA, *340B Rebate Model Pilot Program*, https://www.hrsa.gov/opa/340b-model-pilot-program.

[12] BRG, *CMS October 2024 Final Guidance for MFP Effectuation in 2026-2027: Implications for Duplication with the 340B Channel*, https://tinyurl.com/kt6nzhak.

1320f-2(a)(5). Moreover, in the context of the 340B Program as a whole, Plaintiffs' alleged costs constitute a de minimis fraction of the tens of billions of dollars in 340B discounts covered entities receive.[13] The purported $400 million burden would be distributed across more than 60,000 covered entities nationwide,[14] whereas only nine manufacturers would bear over $4 billion in losses.

Plaintiffs contend that HRSA failed to "identify benefits [of the Pilot Program] that bear a rational relationship to the … costs imposed," and therefore that "no such analysis happened for ***any*** of the significant costs inherent to the Rebate Program." ECF 3 at 13 (internal quotation marks omitted). This too is false. In its Pilot Program announcement, HHS cited the elimination of duplicate discounts under the 340B Program and DPNP as the driving force behind effectuating the 340B price through a rebate. 90 Fed. Reg. at 36,163. Preventing illegal duplicate discounts is an obvious benefit that bears a rational relationship to any costs imposed—even if Plaintiffs disagree. Plaintiffs therefore do not demonstrate a likelihood of success on the merits by alleging that HRSA arbitrarily ignored the Pilot Program's costs and benefits.[15]

D. Plaintiffs Cannot Show HRSA Had Viable Alternatives To Consider.

Plaintiffs erroneously contend that HRSA never considered alternatives to a rebate model or the Pilot Program. They first vaguely claim that "IRA/340B deduplication could be done via a

[13] *See* U.S. Senate Committee on Health, Education, Labor & Pensions, *Congress Must Act to Bring Needed Reforms to the 340B Drug Pricing Program* (April 4, 2025) at 2, https://tinyurl.com/2rey6ybw ("Cassidy Senate Report") (noting that in 2023, covered entities received $124 billion in drugs (at wholesale acquisition cost), yet paid only $66 billion); HRSA, *2024 340B Covered Entity Purchases*, https://tinyurl.com/6jbbhynf (noting even greater numbers for 2024).

[14] *See* HRSA, Search Covered Entities, https://340bopais.hrsa.gov/SearchCe (displaying 63,740 active covered entities) (last visited Dec. 6, 2025).

[15] Although Plaintiffs briefly reference substantive unreasonableness, their motion includes no argument under Count IV of their Complaint as a basis for emergency relief. *See* ECF 3 at 2. Even if this claim were properly before the Court, courts review substantive unreasonableness deferentially. *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). They "simply ensure[] that the agency has acted within a zone of reasonableness." *Id.* As demonstrated above, the Pilot Program is within that zone, and Plaintiffs provide no basis for concluding otherwise.

government-backed 'clearinghouse' to exchange information between covered entities and drug companies." ECF 3 at 15. This is a smokescreen. Plaintiffs do not demonstrate that such a clearinghouse could be created and implemented before the MFP goes into effect on January 1. *Id.*; ECF 1, ¶¶ 88, 154. Indeed, the earliest any such clearinghouse allegedly could be available (on a voluntary basis and for testing only) is the ***fall*** of 2026—well after drug manufacturers must confront their new deduplication obligations under the 340B Program and DPNP. ECF 36-2, ¶ 10. And even then, data will not be available to manufacturers and will not enable timely 340B-MFP deduplication. *Id.* Because the clearinghouse will not be operational before January 1, it is not a viable alternative that HRSA needed to consider. *Nat'l Shooting Sports Found. v. Jones*, 716 F.3d 200, 215 (D.C. Cir. 2013) ("[A]n agency must consider only significant and viable and obvious alternatives." (cleaned up)).

Plaintiffs next contend HRSA could have given the Pilot Program a more limited scope. ECF 3 at 16. But the Pilot Program ***is*** limited in scope—just not in the ways Plaintiffs would prefer. The Pilot Program applies to only a limited number of 340B drugs that will ***already*** be receiving steep discounts under the IRA. There is hardly a "swath" of drugs at issue as Plaintiffs insist, ECF 1, ¶ 5, and it is difficult to imagine that a pilot program involving "a smaller subset of drugs" would be effective, ECF 3 at 16. HRSA could not have limited the Pilot Program to fewer drugs selected for the DPNP without defeating the program's central purpose: facilitating 340B-MFP deduplication. Nor could HRSA rationally have implemented a pilot program exempting some covered entities. ECF 3 at 16. A pilot program with that limitation would not meet HRSA's stated 340B-MFP deduplication goal, rendering it self-defeating. *See Nat'l Shooting Sports Found.*, 716 F.3d at 215.

Finally, although Plaintiffs assert that HRSA "ignored every possible alternative proposed"

and that "the outcome was predetermined" because HRSA did not explicitly or publicly weigh them against the Pilot Program, ECF 3 at 16, HRSA "need not consider every alternative proposed nor respond to every comment made." *Nat'l Shooting Sports Found.*, 716 F.3d at 215; *see also Thompson v. Clark*, 741 F.2d 401, 408 (D.C. Cir.1984) (providing that an agency was not required to "respond to every comment, or [] analyze every issue or alternative raised by the comments, no matter how insubstantial"). This is particularly so where, as here, the proposed alternatives are not viable because they do not address the central concern that motivated the agency's proposal in the first place. *See Nat'l Shooting Sports Found.*, 716 F.3d at 215.

II. THE EQUITABLE FACTORS FAVOR INTERVENORS.

A. An Injunction Will Irreparably Harm Intervenors.

Within three weeks, on January 1, Intervenors will find their drugs subject to competing 340B and DPNP discounts without a clear way to identify the right price. Absent the ability to implement their HRSA-approved rebate models, manufacturers will inevitably provide duplicate discounts totaling over $4 billion. ECF 36-1, ¶¶ 13, 18. That figure does not account for the substantial penalties—potentially millions per day—for which the IRA provides. *Id.* ¶ 13. No viable alternative exists that Intervenors could implement in the little time remaining before their statutory obligations commence. As explained above, Plaintiffs' purported alternatives are neither feasible before January 1, nor capable of enabling manufacturers to satisfy their DPNP obligations, even if they were available. Enjoining the Pilot Program would therefore inflict irreparable harm on Intervenors—who have no burden to establish such harm in the first place—by forcing them to provide billions of dollars in duplicate discounts inconsistent with the IRA.

B. Plaintiffs Will Not Suffer Any Harm Absent Emergency Relief.

Plaintiffs cannot demonstrate that the Pilot Program will harm them. Covered entities sell manufacturers' drugs at regular prices then replenish their stocks at deeply discounted 340B prices.

And covered entities will receive the ***same*** 340B price under the Pilot Program as they do now. If they think manufacturers are not providing the 340B price when it is required, the 340B statute provides remedies. *See* 42 U.S.C. § 256b(d)(3)(A); 42 C.F.R. § 10.21(a). Any administrative burden they might incur while going through necessary deduplication procedures is driven by statutory requirements and dwarfed by the windfall they receive under the relevant statutes.

Plaintiffs cite no decision from this District or the First Circuit holding that their (exaggerated) administrative costs justify the emergency relief sought. Plaintiffs rely only on a stay opinion from a Fifth Circuit motions panel (which, they fail to note, was later vacated by a merits panel that was itself vindicated by the Supreme Court). ECF 3 at 17; *see Wages & White Lion Invs., LLC v. U.S. FDA*, 16 F.4th 1130, 1142 (5th Cir. 2021), *stay vacated*, 41 F.4th 427 (5th Cir. 2022), *rev'd*, 90 F.4th 357 (5th Cir. 2024) (en banc), *rev'd*, 604 U.S. 542 (2025).

Plaintiffs also misattribute their costs to the Pilot Program. Any administrative costs associated with collecting and providing claims data are unavoidable. The deduplication problem arises from the IRA and thus ***must*** be solved—which the agency itself has acknowledged, while declining to take on the deduplication burden. *See* 42 U.S.C. § 1320f-2(d); 2026 Guidance at 54-55, 230-32. The only feasible and accurate solution is the use of claims data. *See* 90 Fed. Reg. at 36,165. In other words, Plaintiffs will ultimately have to share claims data with ***someone***—be it the manufacturers or the government. Indeed, collecting and providing claims data is not a new obligation. Plaintiffs are already obligated by the 340B statute to maintain auditable records "sufficient to demonstrate continued compliance with 340B requirements," *i.e.*, claims data. *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 463 (D.C. Cir. 2024) (quoting 75 Fed. Reg. 10,272, 10,274 (March 5, 2010)). Additionally, the 340B statute ***already permits*** manufacturers to condition 340B sales on the provision of claims data—whether they use a rebate model or not.

See id. at 460-64; *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 703-06 (3d Cir. 2023); *Johnson & Johnson*, 2025 WL 1783901, at *15. In this way, too, Plaintiffs' objections to providing claims data are hardly traceable to the Pilot Program.

Manufacturers have also streamlined this process. Most covered entities routinely collect and transmit claims data to their third-party administrators ("TPAs") who use such data to facilitate 340B-priced purchasing on their behalf. Manufacturers are providing free-to-covered entities software, Beacon, which "precisely mirrors" the software that covered entities and their TPAs already use for 340B purchasing. Ex. 1, ¶¶ 7–8; *see also* 90 Fed. Reg. at 36,164 (requiring that "all costs for data submission through an Information Technology (IT) platform be borne by the manufacturer …."). Covered entities (or their TPAs) can use that same underlying claims data for submission to Beacon for the Pilot Program. Ex. 1, ¶¶ 7–8. Providing standard claims data for the Pilot Program's limited number of drugs to the same vendor is thus unlikely to burden covered entities with significant additional costs. If, as Plaintiffs say, covered entities hire new personnel, *see* ECF 3 at 14, that is an inefficiency they choose to undertake. The Pilot Program simply relies on a process many covered entities are already using—providing claims data to substantiate claims—and will not impose any undue administrative burdens on covered entities.

Plaintiffs claim irreparable harm from the time gap between dispensation and receipt of rebates—which they disingenuously characterize as "interest-free loans" from covered entities to drug manufacturers—but such problems are overstated and of Plaintiffs' own making. ECF 3 at 3, 20. The Pilot Program may actually ***improve*** Plaintiffs' payment terms and many covered entities will not have to make the initial full-priced outlay at all. Rebates in the Pilot Program are due within ten days of validated claims submissions, whereas covered entities' payments to wholesalers are typically not due for thirty days. *See* 90 Fed. Reg. at 36,164–65 (stating that

manufacturers will be expelled for failure to promptly pay rebates). So covered entities that promptly validate their claims should receive rebates before payment is due. ECF 36-2, ¶ 23. Financing costs for covered entities, if any, should either be improved or at most be negligible.[16]

If there are cash-flow disruptions, that is a result of Plaintiffs' preferred inventory system. Covered entities almost exclusively choose to operate on an inventory management system called the "replenishment model," through which a covered entity dispenses drugs, charges its patients the full price, and, after a sufficient number of 340B-eligible dispenses occur, places an order for replenishment drugs at a discount (essentially a rebate-in-kind). ECF 36-2, ¶ 24. Waiting for the requisite number of dispenses before submitting claims lengthens the payment lag about which Plaintiffs complain. But even under the replenishment model, if covered entities or their TPAs promptly submit claims data, covered entities would receive rebates before payment is due. *Id.*

C. The Balance of Equities And The Public Interest Favor Intervenors.

The equities favor Intervenors. The affected manufacturers stand to lose more than $4 billion next year in duplicate discounts, plus substantial civil monetary penalties. Covered entities across the country allegedly stand to lose a fraction of that, if anything at all. And denying Plaintiffs' motion will mean only that Plaintiffs are required to transmit data they already collect and provide in the same manner. Plaintiffs should not be rewarded with the extraordinary relief of a temporary restraining order for bringing their long-running (and unsuccessful) challenges of 340B rebate models to a new forum.

Nor is the public interest served by blocking lawful agency actions that are necessary for congressional commands to be executed. *See NCTA – Internet & Television Ass'n v. Frey*, 2020

[16] IQVIA, *How Will a Rebate Model Impact Cash Flow in the 340B Drug Pricing Program?* (Aug. 27, 2025) at 1, https://tinyurl.com/58v5sjf6 ("[F]inancing costs under the 340B rebate model are small and unlikely to be a barrier to its use by covered entities.").

WL 2529359, at *3 (D. Me. May 18, 2020). That is especially true here, where the agency is testing a policy designed to address an urgent problem, the agency action at issue was published four months prior to the filing of this litigation, and Plaintiffs sought emergency relief a month before Intervenors begin to face debilitating statutory penalties and enormous duplicate discounts. Moreover, because covered entities typically do not use windfalls from federal statutory discounts to pass savings on to patients,[17] the public has no interest in allowing covered entities to reap massive duplicate discounts from manufacturers. Here, the public is best served by preventing abuse of federal drug-pricing discount programs. The Court will not serve the public interest by enjoining the Pilot Program while it adjudicates Plaintiffs' meritless claims.

D. Plaintiffs' Motion For Emergency Relief Is Untimely And Unreasonable.

Plaintiffs employ a sleight-of-hand about what agency action is at issue. An APA lawsuit must challenge a final agency action. *Glob. Tower Assets, LLC v. Town of Rome*, 810 F.3d 77, 82 (1st Cir. 2016). But Plaintiffs studiously avoid identifying *which* agency action they challenge: the August 1 announcement of the Pilot Program, or HRSA's subsequent individualized adjudications approving Intervenors' specific rebate proposals?

The gravamen of Plaintiffs' motion is that HRSA's decision to hold a rebate pilot program was not reasonably explained. The agency's decision to hold the Pilot Program was announced in the August 1 Notice, yet Plaintiffs waited until December to file suit—less than a month before Intervenors' penalty-backed statutory obligation to deduplicate MFP and 340B discounts kicks in—and seek emergency relief. Plaintiffs offer no justification for the months-long delay.

[17] *E.g.*, *AbbVie Inc. v. Drummond*, -- F. Supp. 3d --, 2025 WL 3048929, at *9 (W.D. Okla. Oct. 31, 2025); Cassidy Senate Report, *supra*; U.S. Government Accountability Office, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* (June 21, 2018), https://tinyurl.com/25dnnbfs; U.S. Government Accountability Office, *Manufacturer Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement* (Sept. 23, 2011), https://tinyurl.com/8m83dzm8; U.S. Department of Health and Human Services, Office of Inspector General, *Contract Pharmacy Arrangements in the 340B Program* (Feb. 4, 2014), https://tinyurl.com/56s6p7w7.

Plaintiffs' untimely motion should be denied for that reason alone. *See We the People PAC v. Bellows*, 512 F. Supp. 3d 74, 97 (D. Me. 2021) (Woodcock, J.) (rejecting emergency relief request where "Plaintiffs have provided no reason why they waited until now to request" such relief).

Nor do Plaintiffs explain why, even assuming HRSA should have provided additional explanation, the appropriate remedy would be a ***multi-billion dollar injunction*** rather than a remand for supplemental reasoning. *Central Me. Power Co. v. FERC*, 252 F.3d 34, 48 (1st Cir. 2001) ("A reviewing court that perceives flaws in an agency's explanation is not required automatically to set aside the inadequately explained order."); *see also Town of Weymouth v. Mass. Dep't of Env't Prot.*, 973 F.3d 143, 146 (1st Cir. 2020).

CONCLUSION

Plaintiffs' motion for emergency relief should be denied.

Dated: December 15, 2025

Respectfully submitted,

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EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA,

Defendants.

Case No.: 2:25-cv-00600-JAW

DECLARATION OF AARON VANDERVELDE

December 15, 2025

1. I, Aaron Vandervelde, hereby make this declaration in lieu of an affidavit as permitted by 28 U.S.C. § 1746. I am aware that this declaration will be filed in the United States District Court for the District of Maine, and that it is the equivalent of a statement under oath. I, Aaron Vandervelde, declare as follows in support of AbbVie Inc.'s and Pharmacyclics LLC's (collectively "AbbVie") memorandum in opposition to Plaintiffs' motion for a temporary restraining order in the above-captioned action and motion to intervene as defendants:

2. I am over the age of 21, under no disability, and competent to testify to the matters contained in this declaration. I am the Chief Executive Officer of Second Sight Solutions ("Second Sight"), a technology solution provider that operates the 340B ESP and Beacon platforms. 340B ESP is a platform that enables 340B Covered Entities to submit claims data to manufacturers for dispenses from a Covered Entity's off-site contract pharmacies. It is currently in operation and has been for several years. Beacon enables 340B Covered Entities to access 340B pricing through a direct discount payment made upon receipt of eligible purchase and claims data. Beacon is designed to facilitate 340B rebate models as well as manufacturers' effectuation of the "Maximum Fair Price" (MFP) under the Inflation Reduction Act's (IRA) Drug Price Negotiation Program (DPNP). I am intimately familiar with 340B ESP's and Beacon's technology, the mechanisms through which 340B Covered Entities utilize each platform and the contractual terms associated with Covered Entities' use of each platform. I have extensive experience with both the 340B program and the pharmaceutical supply chain and have authored numerous reports

and testified in federal court and in arbitration on matters pertaining to the 340B program and the pharmaceutical supply chain.

3. On August 1, 2025, HRSA proposed a Rebate Model Pilot Program ("Pilot Program") to test a rebate mechanism for delivering the 340B price. On October 30, 2025, HRSA formally approved eight manufacturer proposals for participation in the Pilot Program, all of which are utilizing my organization's Beacon platform. Since then, HRSA has approved an additional manufacturer proposal, also using the Beacon platform. Since the August 1 proposal, representatives from my organization have met with HRSA officials on five occasions to discuss preparations for the launch of the Pilot Program.

4. I understand that Plaintiffs in this matter allege that "HRSA has not even bothered to test the software platform on which this program is supposed to run." Doc. 1 at ¶ 10. Plaintiffs' allegation ignores a 90-minute demonstration of the Beacon platform that I led on November 17, 2025 for key personnel at HRSA. The HRSA team observed the functionality of the platform and had the opportunity to ask questions and confirm their understanding of the platform.

5. I understand that Plaintiffs similarly allege that certain entities have warned HRSA of "significant technical issues" with the Beacon platform due to a "lack of testing." *Id.* ¶ 123. Second Sight launched the Beacon platform in September 2024 and began engaging with 340B Covered Entities and their third-party technology vendors through in-person meetings, online webinars, documentation and direct engagement. To date, Second Sight has hosted over 50 webinars and meetings with thousands of participants focused on educating the 340B covered entity community on how to utilize Beacon. Second Sight has

established direct data transfer capabilities with Third Party Administrators ("TPAs")—specialized consultants who administer elements of the 340B program such as claims submission on behalf of covered entities—that include a "sandbox" environment that enables TPAs to submit test data to Beacon and perform other standard testing scenarios. Similarly, 340B Covered Entities that register with Beacon have the ability to establish account profiles, set data submission configurations and test sample files for successful submission to Beacon.

6. In any event, I am not aware of any 340B program requirement for HRSA to formally test technologies and processes used to operationalize the 340B program. Even in prior pilot programs, such as the 2001 Alternative Methods Demonstration Projects that broadened the use of contract pharmacies for certain Covered Entities, I am not aware of any formal testing conducted by HRSA.

7. I also understand that Plaintiffs allege that the Pilot Program will create significant administrative costs for Covered Entities. Doc. 1 at ¶ 11. To this point, I note that the Beacon platform is free of charge to Covered Entity users. Additionally, Second Sight has voluntarily incorporated technology to allow TPAs working on behalf of Covered Entities to submit data directly to the Beacon platform to ease any administrative burden on Covered Entities. This technology is also free of charge to both Covered Entities and TPAs. To date, Second Sight has established direct data connections with 30 TPAs and is working to establish direct data connections with additional TPAs. These 30 account for more than 98% of direct TPA data submissions to the 340B ESP platform, indicating strong engagement with the Beacon platform.

8. In further response to the allegation of administrative cost and burden, I offer that the technology to submit data through the Beacon platform precisely mirrors the technology used to collect the same data through 340B ESP, which has been in use since 2020, including by entities that challenge the Pilot Program in this litigation.

9. Plaintiffs state that HRSA's August proposal for the Pilot Program included a series of "criteria," and that drug companies had the option of deviating from the criteria if they provided justification. The Plaintiffs allege that HRSA has not indicated whether it approved any drug company applications that deviated from these criteria. HRSA clearly states on its public-facing website that approved plans "met the requirements as stated" in its proposal.[1] The approved manufacturer plans are publicly available on the Beacon website and provide details on how each manufacturer aligned to HRSA's guidance.[2] Importantly, the manufacturer plans are structured such that Covered Entities can submit one combined claims file for all drugs subject to the Pilot Program, comprised of nothing beyond the limited data elements that HRSA has disclosed on its public-facing website, in request for 340B rebates. They need not tailor their submissions to each of the nine manufacturers.

10. Plaintiffs state that the Pilot Program was not needed to prevent duplication between 340B and MFP discounts because alternative options existed. I understand that Plaintiff AHA claimed in a prior comment letter that CMS could simply rely on the Medicare Transaction Facilitator for this purpose. AHA notes that "drug companies [could]

[1] https://www.hrsa.gov/opa/340b-model-pilot-program

[2] https://cm.beaconchannelmanagement.com/pages/resources

make access to the [maximum fair price] for Medicare negotiated drugs available *prospectively* as is currently done for drugs purchased under the 340B Program." Doc. 1 at ¶ 88. AHA posits that dispensing entities would submit certain data to CMS' Medicare Transaction Facilitator (MTF), which would then verify that the dispensing entity purchased the drug at the correct price. If the purchase was made at the incorrect price, the MTF could facilitate a transfer of funds between the drug company and the dispensing entity to rectify the error. In my experience working with the Medicare Transaction Facilitator as the sole manufacturer-selected technology provider supporting MFP effectuation, this suggested alternative is misleading and demonstrates confusion with clearly stated CMS guidance. The suggestion that the MTF would determine "correct" and "incorrect" pricing conflicts with CMS's statements that "the obligation to calculate and pay an appropriate amount to ensure the dispensing entity has access to the MFP rests with the Primary Manufacturer"[3] and "CMS is not charged with verifying or otherwise reviewing whether a particular drug claim is a 340B-eligible claim."[4] Based on observations made during extensive platform testing between Beacon MFP and the MTF, the MTF's platform was not scoped to include, nor did it demonstrate, capabilities to independently assess pricing determinations or 340B eligibility. Additionally, the AHA

[3] CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028 at 214 (Sept. 30, 2025) ("IPAY 2028 Final Guidance")*, https://edit.cms.gov/files/document/ipay-2028-final-guidance.pdf

[4] CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028 at 65 (Sept. 30, 2025) ("IPAY 2028 Final Guidance"),* https://edit.cms.gov/files/document/ipay-2028-final-guidance.pdf

assertion that the MTF could independently "facilitate a transfer of funds" between the manufacturer and the covered entity to address 340B deduplication is false. The MTF did not demonstrate this capability. In fact, the payment of MFP refunds goes only in one direction, from the manufacturer, through the MTF Payment Module, to the dispensing entity.

11. Another alternative presented is a "clearinghouse" that CMS has proposed for purposes of de-duplication between 340B and Medicare inflation rebates. The earliest that this clearinghouse will be available (on a voluntary basis and for testing only) is fall of 2026. It remains unclear if it will ever be fully operational or if data submission will ever be mandatory. 340B Covered Entities typically do not share claims data voluntarily: When manufacturers attempted to collect 340B claims on a voluntary basis through Second Sight's 340B ESP platform in 2020, fewer than one percent of Covered Entities provided any submissions voluntarily, even after the functionality had been available for a year. Certain manufacturers subsequently mandated that 340B Covered Entities submit claims data through 340B ESP, which largely explains why 340B ESP receives large quantities of data submissions from TPAs, notwithstanding Covered Entities' reluctance to share such data.

12. Plaintiffs also allege that HRSA should have designed the Pilot Program to be smaller in scope. This belies the fact that the few drugs included within the Pilot Program encompass a small share of 340B program sales today. My organization has calculated that these few drugs account for only two percent of program sales when

measured at the 340B price, and five percent when measured at the list price (wholesale acquisition cost).

13. I understand that Plaintiffs allege that Second Sight's Terms of Use and Privacy Policy are designed to benefit Second Sight and any pharmaceutical manufacturer that elects to utilize Beacon to effectuate the Pilot Program. Second Sight has developed standardized platform terms that are applied uniformly to ensure consistent program administration at national scale. The platform terms establish a set of rights for both Second Sight, as the technology provider, and 340B Covered Entities, as the platform users. Second Sight has engaged directly with 340B Covered Entities to modify the Terms where Covered Entities identified conflicts with applicable law, including accommodations for state and governmental entities. To date, over 8,000 340B Covered Entities have initiated registration on Beacon and agreed to the Terms of Use and Privacy Policy, including entities that now challenge those very terms in this litigation.

14. I understand that Plaintiffs raise concerns regarding the security and confidentiality of any protected health information (PHI) and personally identifiable information (PII) collected as part of the administration of the Pilot Program. Second Sight does not collect PHI within Beacon and has received an Expert Determination from Dr. Brad Malin certifying that the information the platform collects meets the definition of a De-identified Dataset under HIPAA.[5] Second Sight does collect limited PII as part of the

[5] Dr. Malin is the Accenture Professor of Biomedical Informatics, Biostatistics, and Computer Science and Vice Chair for Research in Vanderbilt University Medical Center's Department of Biomedical Informatics. *See* Bradley Malin, *Biography*, Vanderbilt Univ. Med. Ctr. Dept. of Biomedical Informatics, https://www.vumc.org/dbmi/person/bradley-malin-phd.

registration process and has appropriate safeguards in place to ensure compliance with applicable state and federal laws. Additional information regarding the platform's security framework is available to all Beacon users in our Trust Center.

15. I understand that Plaintiffs also allege that HRSA is allowing Second Sight to "harvest and sell the patient data that Covered Entities must provide as part of the rebate program." Doc. 1 at ¶ 121. As noted above, Second Sight does not collect PHI nor does it collect any data that would allow it to identify an individual patient. Rather, 340B Covered Entities will submit to Beacon virtually the same data elements that they currently submit to Second Sight via 340B ESP. Since its launch in 2020, 340B Covered Entities have submitted over 25,000,000 340B claims to Second Sight via 340B ESP under similar terms to Beacon. Second Sight has never sold these data to a third party nor does Second Sight intend to sell the 340B claims data collected via Beacon. Instead, Second Sight will utilize the 340B claims data for the purposes outlined in its terms, including to address the enormous volume of duplicate discounts that exist between the 340B program and Medicare's MFP, and under the rules of the Pilot Program.

I declare under the penalty of perjury that the foregoing is true and correct.

Executed this 15th day of December, 2025 at Washington, D.C.

/s/ Aaron Vandervelde

Aaron Vandervelde

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA,

Defendants.

Case No. 2:25-cv-00600-JAW

PhRMA'S LIMITED SUPPLEMENTAL OPPOSITION TO PLAINTIFFS' MOTION FOR TEMPORARY RESTRAINING ORDER

v.

Proposed Intervenor Pharmaceutical Research and Manufacturers of America (PhRMA) submits this opposition to Plaintiffs' motion for a temporary restraining order to further explain how its members would be harmed by an injunction halting the 340B Rebate Pilot Program, as well as to specifically address the unique harms that PhRMA's members would suffer. These harms further tip the balance of equities against granting the relief Plaintiffs seek.

As the joint opposition explains, the Pilot Program was prompted in part by the Inflation Reduction Act's requirement that certain manufacturers offer selected drugs to eligible Medicare beneficiaries at a "maximum fair price" (MFP). For the eight PhRMA members selected by the Health Resources and Services Administration (HRSA) for participation in the Pilot Program, that MFP obligation kicks in on January 1, 2026. *See* ECF No. 45-1 (Stansel Decl.) ¶ 17. And therefore so does the Pilot Program. *Id.* For the reasons outlined in the Proposed Intervenors' opposition and the declarations of PhRMA's members, the manufacturers (including eight of PhRMA's members, *see id.* ¶ 13) selected for the Pilot Program will be severely and irreparably harmed if the Pilot Program is enjoined, *see* ECF No. 72 Part II.A; ECF No. 45-2 (Paluzzi Decl.) ¶¶ 21–25 (explaining harm to Johnson & Johnson); Ex. 2 (McCarthy Decl.) ¶¶ 18-24 (outlining harm to Bristol Myers Squibb Company); Ex. 3 (McCrudden Decl.) ¶¶ 16-23 (describing harm to Novartis Pharmaceuticals Corporation).

Additional manufacturers will be subject to the IRA's MFP requirement starting in 2027, *see* Ctrs. for Medicare & Medicaid Servs., *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2027* (January 2025), https://www.cms.gov/files/document/factsheet-medicare-negotiation-selected-drug-list-ipay-2027.pdf, and more still in subsequent years, *see* 42 U.S.C. § 1320f-1(a). These manufacturers, some of which are PhRMA members, thus have a strong interest in HRSA's ability—through the

Pilot Program—to study the efficacy of rebate models and to consider expanding the rebate Pilot to manufacturers whose drug products will be subject to the IRA's MFP requirement in later years. *See* ECF No. 45-1 (Stansel Decl.) ¶ 21. These manufacturers too could be harmed if the Pilot Program is halted and HRSA is prevented from studying rebate models in furtherance of expanding the Pilot Program in future years.

Other PhRMA members who participate in the 340B Program would be harmed as well. PhRMA members, including Gilead Sciences, are interested in pursuing a 340B rebate model in the future to address other longstanding statutorily prohibited 340B duplicate discounts and diversion of 340B drugs to ineligible patients. As explained in the joint opposition, the 340B statute expressly authorizes manufacturers to offer the 340B price via either "discounts" or "rebates." 42 U.S.C. § 256b(a). And a rebate model "would help prevent prohibited duplicate discounts" across 340B and Medicaid, and it would help prevent "diversion of 340B drugs to patients not eligible for the 340B Program." Ex. 1 (Banks Decl.) ¶ 9. If the Plaintiffs are granted the relief they request and the Pilot Program is stopped, then HRSA may be impeded from gathering the information to support the use of rebate models across the 340B program, harming PhRMA members who wish to pursue those models in the future.

Dated: December 15, 2025

Respectfully submitted,

/s/ Daniel L. Rosenthal
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Counsel for PhRMA

v.

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was electronically filed with the Clerk of the Court via the Court's CM/ECF system, which sent notification of such filing to all counsel of record by electronic means.

Dated: December 15, 2025

/s/ Daniel L. Rosenthal
Daniel L. Rosenthal

v.

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER, *Plaintiffs*, v. ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA, *Defendants*.	Case No. 2:25-cv-00600-JAW

DECLARATION OF KRISTIE BANKS

I, Kristie Banks, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1. I am Vice President of U.S. Market Access at Gilead Sciences. In this role, I lead end-to-end market access functions to ensure optimal access to both newly launched and established products in the U.S.

2. I have held this position since 2021, and have been with Gilead Sciences for more than 17 years. I have personal knowledge of the facts stated herein. If called as a witness in this matter, I could and would competently testify to each of the facts set forth below.

3. Gilead is a research-based biopharmaceutical company that discovers, develops, and commercializes innovative medicines in areas of unmet medical need. Gilead's therapeutic areas of focus include HIV/AIDS, liver diseases, cancer, and inflammation.

4. Gilead is a member of PhRMA.

5. Gilead participates in the 340B Drug Pricing Program (340B Program). Under the 340B Program, a manufacturer is required to enter into an agreement with the HHS Secretary that provides that—in exchange for the manufacturer's right to participate in Medicare and Medicaid—the manufacturer must offer its covered outpatient drugs to certain healthcare entities, called "covered entities," at sharply reduced prices. *See* 42 U.S.C. § 256b(a)(1).

6. Among other requirements, the 340B Program prohibits covered entities from obtaining what are called "duplicate discounts." A duplicate discount arises when a covered entity receives 340B pricing on a prescription fill for which the manufacturer also pays a rebate under the Medicaid program. *See id.* § 256b(a)(5)(A). Manufacturers are therefore exempt from paying a rebate to the relevant state Medicaid program for any prescription fill that a covered entity purchased at the 340B price.

7. A 340B rebate model would help prevent prohibited duplicate discounts, as well as diversion of 340B drugs to patients not eligible for the 340B Program. As I understand the rebate model, covered entities initially pay the Wholesale Acquisition Cost (WAC) for a 340B drug. After the drug is dispensed to a 340B-eligible patient, the covered entity would submit 340B-relevant claims data to the manufacturer, and the manufacturer would promptly provide a rebate—in the amount of the difference between the WAC price and the 340B price. Requiring covered entities to provide the 340B claims data allows the manufacturer to verify, accurately and efficiently, that the drug unit dispensed is eligible for 340B pricing and to ensure that a Medicaid rebate is not paid

on that drug unit. For example, data elements such as prescription number and date of fill are critical for validation purposes.

8. Gilead is not among the manufacturers who applied for the 340B Rebate Model Pilot Program (Pilot Program) at issue in this case, and Gilead does not currently employ a 340B rebate model.

9. However, Gilead is interested in pursuing a 340B rebate model in the future, because a 340B rebate model would help prevent prohibited duplicate discounts and diversions by confirming 340B eligibility of prescription fills.

10. I understand that one of the purposes of the Pilot Program is "to test the rebate model on a select group of drugs … in a methodical and thoughtful approach to ensure a fair and transparent 340B rebate model process for all stakeholders involved." *340B Program Notice: Application Process for the 340B Rebate Model Pilot Program; Correction*, 90 Fed. Reg. 38,165, 38,165 (Aug. 7, 2025). I also understand that the information gathered during the Pilot Program will "inform [the agency's] consideration of any future 340B rebate models consistent with the 340B statute and the Administration's goals." *Id.*

11. Because Gilead is interested in pursuing a 340B rebate model in the future, Gilead has an interest in the Pilot Program. If the Pilot Program is blocked, the Health Resources and Services Administration (HRSA) may not be able to gather the information it needs to further develop its understanding of the rebate model and the role that rebate models can play in facilitating 340B transparency and sustainability. Without that information, HRSA might be reluctant to expand the Pilot Program or otherwise to endorse the use of the rebate model by Gilead and other manufacturers.

///

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. *See* 28 U.S.C. § 1746.

Executed on: December 15, 2025

DocuSigned by:
Kristie Banks
3B4BECBA5AB74F3...

Kristie Banks, Vice President of U.S. Market Access
Gilead Sciences, Inc.
Declarant

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA,

Defendants.

Case No. 2:25-cv-00600-JAW

DECLARATION OF JUSTIN McCARTHY

I, Justin McCarthy, declare as follows:

1. I am over the age of 18. Except as expressly indicated, the facts stated below are based upon my personal knowledge, my experience in the pharmaceutical industry, my work at Bristol Myers Squibb Company (BMS), and the knowledge base and business records of the company, upon which I have relied.

2. I am Senior Vice President and Head of Market Access, Pricing, and Value Demonstration at BMS. In my current position, I am responsible for leading a team that executes market access and pricing strategy and operations, including implementation of government

pricing programs—including but not limited to the 340B and Inflation Reduction Act (IRA) Medicare Drug Price Negotiation Program (DPNP) programs—for BMS's entire portfolio of products.

3. BMS is a global biopharma company that is pursuing bold science to define what's possible for the future of medicine and the patients it serves. Its mission is to discover, develop, and deliver innovative medicines that help patients prevail over serious diseases. Consistent with that mission, BMS works to ensure that its products and treatments are available to as many patients as possible.

BMS'S PARTICIPATION IN THE 340B PROGRAM

4. To qualify for federal reimbursement under Medicaid and Medicare Part B for its covered outpatient drugs, a drug manufacturer must, among other requirements, enter into an agreement known as the Pharmaceutical Pricing Agreement (PPA). A manufacturer's execution of the PPA indicates its commitment to participate in the 340B Drug Pricing Program. If the Secretary of the Department of Health and Human Services (HHS) terminates a manufacturer's PPA, federal reimbursement under Medicaid and Medicare Part B is unavailable for the manufacturer's drugs.

5. BMS has entered a PPA and participated in the 340B Program since the program's inception decades ago.

6. Through the 340B Program, BMS provides its covered outpatient drugs to certain hospitals and clinics known as covered entities. BMS's drugs are provided to these covered entities at or below a price specified by a statutory formula. This 340B "ceiling price" results in significant price reductions on BMS's products for covered entities: The 340B price for some drugs can be as low as a penny per unit.

BMS'S PARTICIPATION IN THE DRUG PRICE NEGOTIATION PROGRAM

7. BMS's product Eliquis qualifies as a selected drug under the IRA's DPNP and will be subject to a "maximum fair price" (MFP) starting on January 1, 2026.

8. Under HHS guidance implementing the IRA, HHS permits manufacturers like BMS to either offer dispensing entities the MFP for a selected drug at the time of purchase or provide a refund after the purchase for the difference between the entity's acquisition cost and the MFP. The latter is referred to as "MFP refunds." A manufacturer must provide the MFP refund to the dispensing entity within 14 days of the manufacturer receiving claims data (which enables the manufacturer to verify MFP eligibility) through a data portal set up by HHS. If the manufacturer does not pay the MFP refund within 14 days, it risks a significant civil monetary penalty.

9. The IRA protects manufacturers like BMS from having to offer both the 340B price and the MFP on the same unit of a selected drug. Manufacturers instead need only provide covered entities that dispense an eligible prescription the lower of the MFP and the 340B price. As a result, commencing on January 1, BMS must provide the lower of the MFP or the 340B ceiling price on a unit of Eliquis, but not both discounts. If BMS does not provide the correct price, it risks significant civil monetary penalties.

10. In cases where BMS is unable to determine within the 14-day MFP refund window whether an MFP-eligible unit was eligible for the 340B price, it must issue the covered entity an MFP-based refund—usually a selected drug's commercial price minus the MFP. Although BMS may try to recover any refund overpayment where the unit was already sold at the 340B price, it usually does not have access to the claims data necessary to determine whether the unit was also 340B eligible.

11. Covered entities generate claims data in the regular course of business that is often shared with public and private payors. Such claims data identify the dispensing pharmacy, the identity of the prescriber, and the prescription identification number assigned to each prescription, for example. Such claims data is the only means by which BMS can accurately match two prescriptions to each other, and thereby identify whether a given prescription for which an MFP refund is claimed also is eligible for the 340B price. That matching is what is necessary to determine whether on a given prescription any rebate is owed, and if so, the rebate amount, as required by the IRA.

12. HHS has specifically disclaimed any responsibility for identifying whether a given prescription on which an MFP refund also is eligible for the 340B price, leaving manufacturers to do so. Without 340B claims data accompanying a dispensing entity's request for an MFP refund, a 340B-eligible unit can be identified only after it has been dispensed, piecing together data from other sources, and very often well after the 14-day MFP payment deadline HHS mandated. In practice, this means that it is impossible to identify a unit as 340B-eligible by HHS's deadline for paying the MFP refund. As a result, without access to claims data manufacturers like BMS will end up either inadvertently—and unlawfully—failing to offer the lower of the MFP and 340B price or, conversely, having to offer both in violation of the statute.

THE 340B REBATE MODEL PILOT PROGRAM

13. In order to address these concerns, BMS proposed to the Health Resources and Services Administration (HRSA) that it be allowed to implement a rebate model that would, among other things, allow for de-duplication of MFP pricing and 340B pricing. When HRSA refused to approve the request, BMS filed a lawsuit. In August 2025, during the pendency of that lawsuit and in part to address manufacturers' concerns, HRSA announced a 340B Rebate Model Pilot Program (Pilot Program). The agency invited certain manufacturers, including BMS, to participate in it.

14. Under the Pilot Program, a covered entity will pay for a drug at the commercial price, known as the wholesale acquisition cost (WAC). Within 10 days of submitting the requisite claims data, the covered entity will receive a rebate reflecting the difference between the WAC and the 340B price. The Pilot Program will only cover drugs selected for the DPNP, or, in other words, drugs subject to an MFP.

15. BMS submitted a rebate plan for Eliquis—its product that is subject to an MFP—and was accepted into the Program. BMS's approval letter is attached as Exhibit A. The Pilot Program is BMS's only available option for deduplicating 340B and MFP pricing.

16. Under the Pilot Program, covered entity claims data will enable BMS to identify units for which both an MFP refund and a 340B rebate have been claimed, and then issue a rebate based on the lower of the two prices (if no rebate has yet been paid).

If a discount based on the MFP or 340B price has already been paid and a claim for the other price comes in afterwards, the covered entity claims data will enable BMS to "true up" the amount due based on whichever price is lower, and either issue a supplemental rebate payment to achieve the lower price or deny the second rebate claim as duplicative of the first rebate

payment. The Pilot Program will thus ensure that BMS timely complies with its obligations under the DPNP without resulting in duplicate pricing obligations.

17. The Pilot Program aligns with the primary commercial model that manufacturers use with their non-340B customers, where eligibility for a reduced price is not determined until after the product is purchased. It is standard commercial practice to provide price reductions through a rebate when a given unit's eligibility for the reduced price is not known at the time of sale.

BMS WILL SUFFER HARM IF THE PILOT PROGRAM IS ENJOINED

18. If the Pilot Program does not go into effect on January 1, 2026, BMS will suffer significant and irreparable harm.

19. BMS has expended significant time and resources in preparing for and implementing the Pilot Program, including the design, testing, and operational readiness of the rebate model. This process required collaboration across Market Access, Finance, Treasury, IT, Policy, and other functions within BMS, as well as coordination with external partners to ensure systems, processes, and stakeholders are fully prepared.

20. In addition, for 2024 through 2026, BMS has committed over ten million dollars and thousands of hours to designing, developing, and testing the infrastructure supporting its pilot program. Significant investments have been made to operationalize the BEACON platform for the rebate model, including enhancements to internal pricing, banking, and related systems. BMS has also ensured its platform can process claims data and issue rebates to covered entities within the 10-day window mandated by HSRA, dedicating substantial time to compliance testing ahead of the January 1, 2026, launch.

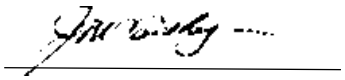
21. Without the ability to implement its pilot program, BMS will lack the information needed to identify units for which both an MFP rebate and a 340B price concession have been claimed, which will significantly increase the likelihood of duplicate price concessions for Eliquis. Each duplicate price concession costs BMS significant revenue that it would otherwise receive absent the unlawful duplicate price concession.

22. If the Pilot Program is enjoined, BMS estimates it will be forced to pay more than $100 million in improper duplicate 340B and MFP discounts in 2026 that it would not otherwise be obligated to pay under the Pilot Program. In addition, without the Pilot Program enabling BMS to review and de-duplicate claims data, BMS faces the risk of incurring significant civil monetary penalties for failure to provide the correct price required by federal law.

23. This lost revenue could otherwise be used by BMS to fund programs like research and development into new lifesaving drug therapies; to offer critical patient support, education, and access programs; and to impact patient health around the world by advancing access to innovative treatments for patients in more low- and middle-income countries.

24. In short, an injunction delaying implementation of the Pilot Program will cause widespread disruption to manufacturers' efforts to comply with their statutory obligations and cause significant and irreparable harm to BMS.

I declare under penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct.



Executed on December 15, 2025

EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER, *Plaintiffs*, v. ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA, *Defendants*.	Case No. 2:25-cv-00600-JAW

DECLARATION OF SHANNON MCCRUDDEN

I, Shannon McCrudden, declare as follows:

1. I am over the age of 18. Except as expressly indicated, the facts stated herein are based upon my personal knowledge, including my experience in the pharmaceutical industry, my work at Novartis Pharmaceuticals Corporation (Novartis),

and my review of the business records of the company. If called to testify, I could truthfully and competently testify to those facts.

2. Novartis is a global innovative medicines company. Its mission is to reimagine medicine to improve and extend people's lives. Consistent with that mission, Novartis works to ensure that its products and treatments are available to as many patients as possible.

3. I am the Vice President of Managed Markets Finance at Novartis, where I have been employed since July 27, 2015. I have over 10 years of experience in the pharmaceutical industry. During that time, I have had various responsibilities for Commercial Contracting, Contract Operations, and Pricing.

4. In my current position, I lead Novartis's Managed Markets Finance function, and I am responsible for Contract Operations, Government Reporting, Federal & State Programs, Medicaid, Fair Market Value, and Governance.

BACKGROUND

5. Drug manufacturers wishing to participate in Medicaid and Medicare Part B must also participate in the federal 340B Drug Pricing Program. Under the 340B Program, manufacturers must offer their covered outpatient drugs to covered entities at or below a "ceiling price" mandated by a statutory formula. This results in significant price reductions on purchases of drug products by covered entities. Novartis participates in the 340B Program, and thus must offer 340B discounts to covered entities on purchase of its drug products, including its heart medicine ENTRESTO®.

6. Recently, ENTRESTO® was selected by the federal government for participation in the Inflation Reduction Act (IRA)'s Medicare Drug Price Negotiation Program. Starting January 1, 2026, Novartis must make a statutorily mandated "maximum fair price" (MFP) for ENTRESTO available to Medicare Part D beneficiaries through the pharmacies that dispense those prescriptions.

7. Manufacturers subject to the Drug Price Negotiation Program may offer such dispensing entities the MFP for a selected drug by providing a refund after purchase. The refund—called an "MFP refund"—reflects the difference between the amount the dispensing entity paid for the unit and the MFP. A manufacturer must provide the MFP refund to the dispensing entity within 14 days of receiving Drug Price Negotiation Program claims data that purportedly enables the manufacturer to verify MFP eligibility through an HHS-created portal. A manufacturer faces the risk of a significant civil monetary penalty if it fails to pay the MFP refund within the 14-day window.

8. Under the IRA, manufacturers must make the drug available to dispensing entities at the lesser of [1] the MFP, or [2] the 340B price. Manufacturers need not offer *both* MFP pricing and a 340B discount on the same unit. That said, if a manufacturer is unable to determine within the 14-day MFP refund window whether a unit subject to an MFP is also eligible for the 340B discount, it must provide the dispenser an-MFP-based refund. Such a scenario could lead to duplicate price concessions.

9. Accurately and quickly identifying when drugs are subject to both MFP and 340B pricing requirements is thus critically important. But to do that, manufacturers also need basic claims data relating to the units for which a 340B discount is sought, so that

the manufacturers can identify those prescriptions that are present in *both* the MFP and 340B claims data sets. This 340B claims data includes information like the name of the drug, the name of the dispensing pharmacy, the prescriber's identity, and the prescription identification number assigned to each prescription.

10. Without this 340B-related claims data, manufacturers will be unable to accurately identify units as 340B-eligible by HHS's 14-day deadline for paying the MFP refund. Manufacturers will likely end up either [1] offering duplicative MFPs and 340B prices or [2] failing to offer the lower of the MFP and 340B price. Either way, the federal statutes would not be operating as Congress intended.

THE 340B REBATE MODEL PILOT PROGRAM

11. To address this issue, Novartis sought permission from the Health Resources and Services Administration (HRSA) to adopt a rebate model that among other uses, would allow for deduplication of MFP pricing and 340B pricing. HHS refused to approve its request, and Novartis subsequently challenged HHS's decision.

12. On August 1, 2025, HRSA announced the 340B Rebate Model Pilot Program (Pilot Program). The Pilot Program implements a limited rebate program in order to allow manufacturers to deduplicate 340B and Drug Price Negotiation Program pricing. Covered entities will pay for participating drugs at the commercial price, known as the wholesale acquisition cost (WAC), and then submit basic claims data relating to the claimed 340B discount. If the drug purchase qualifies for the 340B discount, the covered entity will receive a rebate within 10 days of submission of the claims data, reflecting the difference between the WAC and the 340B price.

13. The Pilot Program is consistent with standard industry practice where a customer's eligibility for a reduced price on a given unit is not known at the time the customer purchases the product. Where that is the case, the price concession is effectuated only after the recipient has provided documentation demonstrating eligibility for the discount on a given unit. The manufacturer typically provides that discount through a post-purchase rebate, once the requisite data has been supplied and validated.

14. Novartis applied for, and was accepted into, the Pilot Program commencing April 2026. Exhibit A (Approval Letter). The Pilot Program will cover its ENTRESTO® product, which will be subject to an MFP starting January 1, 2026.

15. The Pilot Program will provide Novartis with the data it needs to ensure compliance with overlapping statutory directives. Paired with the MFP refund model and associated claims data, Novartis will be able to determine which discount, if any, is required on a particular unit, and thus make sure the appropriate price is charged for a given unit within the 14-day MFP refund window.

NOVARTIS WILL SUFFER HARM WITHOUT THE PILOT PROGRAM

16. Novartis will face irreparable harm if the Pilot Program is enjoined.

17. Novartis has expended a great deal of effort, time, and money preparing for and implementing the Pilot Program.

18. In 2025, Novartis spent an estimated $1 million and devoted significant employee hours to implement the Pilot Program. In doing so, Novartis, among other things, created an effectuation plan for the project implementing the Pilot Program; defined the project's requirements; secured funding for the project; ran vendor and

system integrator selection processes; worked with vendors to design and build its own platform to implement the Pilot Program; and established methodologies for payment processing and for duplicate claim identification.

19. Novartis employees also collaborated amongst all internal and external stakeholders to align process, system, and legal decisions; coordinated internally with senior leadership to make key decisions for the project; authored the plan for implementing the Pilot Program that was submitted to, and approved by, HRSA; and ensured Novartis's internal systems were updated and synced to accommodate its pilot platform.

20. Novartis has also spent time and money testing its platform to ensure compliance with HRSA's requirements. To do so, Novartis entered into contracts with Berkley Research Group (BRG) and Riparian to design, build, and implement the rebate model pilot to ensure compliance with HRSA's requirements.

21. Without the Pilot Program, Novartis risks incurring significant civil monetary penalties for failure to provide the correct price under federal law. These penalties pose a significant legal, operational, and reputational risk to Novartis, and if imposed, would stigmatize the company and label it a wrongdoer. That damage would have long-lasting effects. Moreover, if Novartis is prevented from implementing its pilot program, it will lack sufficient data to identify units for which both an MFP rebate and 340B discount have been claimed. That will lead to a significant increase in duplicate price concessions for single units of ENTRESTO and therefore will reduce profits for Novartis.

22. Novartis's lost revenue would otherwise fund critical programs, such as clinical trials, patient access programs, research and development for new medications and for improving its existing drugs, and education efforts. The lost revenue, for example, will negatively affect Novartis's ability to invest in its pipeline innovation products that the company hopes will treat a wide range of conditions and unmet needs, including solid tumors, hematology, immunology, neuroscience, and cardiovascular. That will be to the detriment of the public, and vulnerable patients in particular, who desperately need innovative drugs and new treatments.

23. The lost revenue also will hinder Novartis's ability to recruit and maintain talent and build relationships with the stakeholders necessary to develop pharmaceuticals that patients need. Those harms are irreparable; once research and development opportunities are lost or delayed, it is impossible to recoup the lost investment.

I declare under penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct.

/s/ Shannon McCrudden
Shannon McCrudden
Vice President of Managed Markets Finance
Novartis Pharmaceuticals Corporation

Executed on December 15, 2025.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. ROBERT F. KENNEDY, JR. SECRETARY of the U.S. Department of Health and Human Services, *et al.*, Defendants.	No. 2:25-cv-600-JAW

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION[1]

[1] Counsel for Defendants conferred with counsel for Plaintiffs, and the parties have agreed to litigate the Motion for a Temporary Restraining Order, *see* Doc. No. 3, as a Preliminary Injunction Motion on the schedule the Court has entered, *see* Doc. Nos. 31, 32.

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INTRODUCTION

Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, requires pharmaceutical manufacturers participating in Medicare Part B and Medicaid to sell drugs at reduced prices to certain healthcare providers known as "covered entities." The statute provides that "the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary [of Health and Human Services (HHS)]) to the manufacturer for covered outpatient drugs" may not exceed a ceiling price set by a statutory formula. *See* 42 U.S.C. § 256b(a)(1). Manufacturers sign a pharmaceutical pricing agreement with the Secretary of HHS signifying their intent to participate in the 340B Program and memorializing their obligation to offer covered entities drugs for purchase at or below the ceiling price.

Until now, with the exception of State AIDS Drug Assistance Programs, participating manufacturers have provided upfront discounts—meaning that covered entities would purchase drugs from manufacturers at the ceiling price. But recent inquiries from stakeholders, and developments in the statutory and regulatory landscape, have prompted the agency to consider whether a rebate model might offer advantages. Under a rebate model, covered entities would purchase drugs at their retail price, or wholesale acquisition cost, and then submit a rebate claim to the manufacturer for the difference between that price and the 340B ceiling price.

The statute plainly gives the agency the authority to choose between rebates or discounts. *See* 42 U.S.C. § 256b(a)(1) (stating that "the amount required to be paid (taking into account any rebate or discount, *as provided by the Secretary*") may not exceed the ceiling price (emphasis added)). But recognizing that the 340B Program has operated via upfront discounts for a long time, and wanting to learn more about the advantages and disadvantages of a rebate model, HHS decided to test the rebate model on a small scale. It established a 340B Rebate Model Pilot Program to test the model on ten specific drugs. It then solicited comments from stakeholders along with applications from manufacturers of those ten drugs seeking to participate in the program. After reviewing the comments and applications, the agency approved eight manufacturers to begin selling the chosen drugs to

covered entities under a rebate model as of January 1, and one manufacturer to do the same as of April 1. The agency's actions here amount to a reasonable way to test an action that is plainly authorized by statute.

Yet Plaintiffs—covered entities and associations representing them—seek emergency relief from this Court to thwart the implementation of the Pilot Program, alleging that the program is substantively unreasonable in violation of the Administrative Procedure Act (APA). But under the APA, Plaintiffs must challenge discrete, final agency action, not broad, ongoing programs or policies. *See Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 882 (1990). At most, Plaintiffs may seek to challenge the agency's approval of the nine manufacturers' applications to offer 340B prices for select drugs through a rebate mechanism. But the 340B statute gives the agency discretion to choose between rebates or discounts, and it provides no standards for a court to judge the exercise of that discretion. So the decisions to approve those manufacturers' applications is "committed to agency discretion by law" and is therefore unreviewable. 5 U.S.C. § 701(a)(2).

Even if the approvals were subject to review under the APA, they can only be set aside if they were "arbitrary" or "capricious." *Id.* § 706(2)(A). But these decisions were neither—the agency considered all important aspects of the problem, took into account any reliance interests and costs of covered entities, weighed possible alternatives, and factored in perspectives of other stakeholders before deciding to approve the manufacturers' applications.

Finally, Plaintiffs have failed to show irreparable harm, and the balance of equities and public interest weigh in the Government's favor. Therefore, Plaintiffs' motion for a preliminary injunction should be denied.

BACKGROUND

I. Statutory and Regulatory Background

Medicare is a federal medical insurance program for people ages sixty-five and older and for younger people with certain disabilities. *See* 42 U.S.C. §§ 1395 *et seq*. Medicaid is a joint federal and state program that provides medical coverage for people with limited resources or certain disabilities. *See id.* §§ 1396 *et seq*.

A. The Section 340B Program

Since 1990, pursuant to the Medicaid Drug Rebate Program, pharmaceutical manufacturers that participate in Medicaid have been required to "provide rebates to States on their Medicaid drug purchases." *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 114 (2011); *see* 42 U.S.C. § 1396r-8. These rebates provide States with a discount, which for most "brand-name drugs" is equivalent to the difference between the average wholesale price and the lowest price at which the manufacturer sells the drug, known as the "best price." *See id.* § 1396r-8(c); 42 C.F.R. pt. 447.

The creation of the Medicaid Drug Rebate Program gave rise to a concern that manufacturers had reduced the discounts they were giving to safety-net providers in order to raise the "best price" figures for their drugs under Medicaid and lower their rebate payments to States. *See* H.R. Rep. No. 102-384(II), at 10-12 (1992). Congress responded by creating the 340B Program to govern the prices that drug manufacturers may charge providers that offer health care to underserved individuals, *see* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967 (codified at 42 U.S.C. § 256b), and it later expanded the scope of that program, *see* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, tit. VII, subtitle B, § 7101, 124 Stat. 119, 821 (2010). Within the Department of HHS, the Health Resources and Services Administration (HRSA) administers the 340B Program on behalf of the Secretary.

Under Section 340B, pharmaceutical manufacturers participating in Medicaid and in Medicare Part B (which covers certain outpatient drugs) "must offer discounted drugs to covered entities,

dominantly, local facilities that provide medical care for the poor." *Astra USA,* 563 U.S. at 115; *see* 42 U.S.C. § 256b(a)(1), (3), (4). Covered entities include, for example, federally qualified health centers, certain children's hospitals and free-standing cancer hospitals, critical access hospitals, rural referral centers, black lung clinics, and other federally funded health care entities. 42 U.S.C. § 256b(a)(4). The discounts provided through the 340B Program help covered entities "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12. In particular, it gives them extra revenue from serving insured patients because covered entities "turn a profit when insurance companies reimburse them at full price for drugs that they bought at the 340B discount." *Sanofi Aventis U.S. LLC v. U.S. Dep't of Health & Hum. Servs.*, 58 F.4th 696, 699 (3d Cir. 2023), *entering judgment*, 2023 WL 1325507 (3d Cir. Jan. 30, 2023). And it allows them "to give uninsured patients drugs at little or no cost." *Id.*

Section 340B implements these discounted-pricing requirements through "uniform agreements that recite the responsibilities [Section] 340B imposes, respectively, on drug manufacturers and the Secretary of HHS." *Astra USA*, 563 U.S. at 113. These "are not transactional, bargained-for contracts" but rather "simply incorporate statutory obligations and record the manufacturers' agreement to abide by them." *Id.* at 113, 118. As relevant here, Section 340B directs the Secretary to enter into agreements providing that "the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs . . . purchased by a covered entity" may not exceed a specified ceiling price. 42 U.S.C. § 256b(a)(1). For covered outpatient drugs, the ceiling price is equivalent to the average manufacturer price less the rebate the manufacturer provides to States. *Id.* § 256b(a)(1)–(2); 42 C.F.R. § 10.10.

Section 340B also imposes substantive requirements on covered entities that choose to participate in the program, prohibiting (1) duplicate discounts and (2) the diversion of drugs purchased under the 340B Program. 42 U.S.C. § 256b(a)(5). To prevent duplicate discounts, the statute specifies that a covered entity shall not request a discount for a drug that is already subject to a separate

Medicaid rebate requirement. *Id.* § 256b(a)(5)(A). And to prevent diversion, the statute specifies that "a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B). Disputes between manufacturers and covered entities may be resolved through an administrative process. *See id.* § 256b(d)(3); 42 C.F.R. §§ 10.20-10.24.

To ensure compliance, Section 340B requires a covered entity to permit both the Secretary and the manufacturer to audit the entity's records. *Id.* § 256b(a)(5)(C). Congress authorized the Secretary to impose sanctions against covered entities—including civil monetary penalties, removal from the 340B Program, and referral to other federal agencies for appropriate action—for diversion, duplicate discounts, or other violations of Program requirements. *Id.* § 256b(d)(2)(B)(v).

If a manufacturer fails to comply with its 340B requirements, the Secretary of HHS may terminate the manufacturer's pharmaceutical pricing agreement, "which terminates as well the manufacturer's eligibility for Medicaid coverage of its drugs," and may impose civil penalties. *Astra USA*, 563 U.S. at 115–16; *see* 42 U.S.C. §§ 256b(d)(1)(B)(vi), 1396r-8(b)(4)(B)(i), (v).

B. The Medicare Drug Price Negotiation Program

In the Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818, Congress gave the Secretary authority to negotiate the prices that Medicare pays for pharmaceutical products that lack generic competition and that account for a disproportionate share of Medicare's expenses. 42 U.S.C. §§ 1320f(a), 1320f-1(b), (d), (e). The Medicare Drug Price Negotiation Program applies only to manufacturers that choose to participate in Medicare and Medicaid and governs only the prices that Medicare pays for certain drugs. *See id.* § 1320f-1(b), (d). If negotiations for a selected drug are successful, the manufacturer memorializes its agreement to make the drug available to Medicare beneficiaries at the negotiated price, called the "Maximum Fair Price." *Id.* § 1320f-2(a). In the first negotiation cycle, the Secretary reached agreements for negotiated prices with participating drug companies for ten selected drugs, and those prices take effect January 1, 2026.

Under the Inflation Reduction Act's "nonduplication" provision, manufacturers must provide access to the lower of the Maximum Fair Price or the 340B ceiling price to covered entities—but not both. *Id.* § 1320f-2(d). Deduplication refers to the process of preventing such duplicate discounts.

II. Factual Background

On July 31, 2025, HRSA issued a press release announcing the availability of a 340B Rebate Model Pilot Program for the ten drugs on the Centers for Medicare & Medicaid Services (CMS) Medicare Drug Price Negotiation Selected Drug List for year 2026.[2] In the press release, HRSA explained that it was seeking to test the rebate model "in a methodical and thoughtful" way "to ensure a fair and transparent 340B rebate model process." *See* HRSA Press Release.

The next day, HRSA published a notice in the Federal Register announcing the application process for the Pilot Program. *See* 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program, 90 Fed. Reg. 36,163 (Aug. 1, 2025). The notice explained that the agency had received inquiries from manufacturers related to different proposed rebate models for the 340B Program, primarily to address 340B and Maximum Fair Price deduplication, but also to facilitate other aims including preventing diversion.

Indeed, manufacturers previously tried to implement rebate models unilaterally, *see, e.g.*, *Eli Lilly & Co. v. Kennedy*, 2025 WL 1423630 (D.D.C. May 15, 2025), *appeal filed sub nom. Novartis Pharms. Corp. v. Kennedy*, No. 25-5117 (D.C. Cir. May 21, 2025); *consolidated with Johnson & Johnson Health Care Sys. Inc. v. Kennedy*, 2025 WL 1783901 (D.D.C. June 27, 2025), *appeal filed*, No. 25-5236 (D.C. Cir. June 30, 2025). In that litigation, as here, the Government's position is that implementing a rebate model requires agency approval. *See* 42 U.S.C. § 256b(a)(1).

In the notice, HRSA explained that the point of the Pilot is to test the rebate model in a thoughtful manner and help the agency better understand the merits and shortcomings of the rebate

[2] *See* Press Release, HRSA, HRSA Announces Application Process for the 340B Rebate Model Pilot Program and Request for Public Comment (July 31, 2025), https://www.hrsa.gov/about/news/press-releases/rebate-model-pilot-program ("HRSA Press Release").

model, as well as inform considerations for any future rebate models. 90 Fed. Reg. at 36,163–64. The potential scope of the program would be limited to the ten drugs included on the Medicare Drug Price Negotiation Selected Drug List for year 2026. Those drugs represent only 2% of 340B sales. *See* Decl. of Chantelle Britton ¶ 22 ("Britton Decl."). The notice solicited comments from stakeholders and applications from manufacturers of the selected drugs. It also set forth requirements for manufacturers' plans for participation. Comments were due September 8, 2025, *see* 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program; Correction, 90 Fed. Reg. 38,165 (Aug. 7, 2025), and applications were due the following week, on September 15, 2025. Manufacturers whose plans were approved would have to give covered entities at least 60 calendar days' notice before implementation of an approved rebate model. HRSA also addressed questions about the Pilot Program on its website.[3]

In response to the notice, HRSA received more than 1,100 comments and nine applications from manufacturers. On October 30, 2025, HRSA announced eight manufacturers that were approved to participate in the Pilot Program with a January 1, 2026 effective date. A ninth manufacturer was later approved to participate in the Program beginning on April 1, 2026. The January 1, 2026, effective date applicable to the majority of participants was chosen to align with the date that negotiated prices for those same drugs would take effect under the Medicare Drug Price Negotiation Program.

III. This Litigation

On December 1, 2025—approximately four months after HRSA first announced the 340B Rebate Model Pilot Program and one month after the agency announced the approval of certain manufacturers' applications—Plaintiffs filed this lawsuit to challenge the 340B Rebate Model Pilot Program under the APA. *See* Compl., Doc. No. 1. That same day, Plaintiffs moved for a temporary restraining order, arguing that the Pilot Program violates the APA because it is arbitrary and capricious

[3] HRSA, 340B Drug Pricing Program, FAQs, https://www.hrsa.gov/opa/faqs?categories=All&keywords= (last visited Dec. 15, 2025).

and substantively unreasonable. *See* Mot. for a TRO with Incorporated Mem. of Law, Doc. No. 3 ("Pls.' Br."). Plaintiffs seek an order prohibiting the Pilot Program from going into effect pending a final ruling on the merits of this case.

STANDARD OF REVIEW

A preliminary injunction is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). A "plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Id.* at 20. The third and fourth factors "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). The plaintiff bears the burden of demonstrating those requirements. *Nieves-Marquez v. Puerto Rico*, 353 F.3d 108, 120 (1st Cir. 2003).

To "demonstrate likelihood of success on the merits, plaintiffs must show 'more than mere possibility' of success—rather, they must establish a 'strong likelihood' that they will ultimately prevail." *Sindicato Puertorriqueño de Trabajadores v. Fortuño*, 699 F.3d 1, 10 (1st Cir. 2012) (per curiam) (citation omitted). And a preliminary injunction cannot issue on the basis of speculative or possible harm. Rather, the moving party must establish that irreparable harm is "*likely* in the absence of an injunction." *Winter*, 555 U.S. at 22.

ARGUMENT

Plaintiffs challenge the establishment and implementation of the 340B Rebate Model Pilot Program, but that is an impermissible programmatic challenge under *Lujan*, 497 U.S. at 882 (holding that a program is not an "agency action" within the meaning of 5 U.S.C. § 702, much less a "final agency action" within the meaning of 5 U.S.C. § 704). In the same vein, the notice announcing the Pilot Program and soliciting comments and applications is not itself final agency action: if no manufacturers had applied (or no applications had been approved), the Pilot Program would have no

effect on anyone. At most, Plaintiffs may seek to challenge the agency's approval of the nine manufacturers' applications to offer 340B prices for select drugs through a rebate mechanism. Because the 340B statute gives the Secretary of HHS discretion to choose between rebates or discounts, and provides no standard by which to judge the exercise of that discretion, the decision to approve those applications is committed to agency discretion by law and thus unreviewable. Even if the approvals were subject to review under the APA, they can only be set aside if they were "arbitrary" or "capricious." 5 U.S.C. § 706(a)(2)(A). But these decisions were neither: the agency made a reasonable decision "to test the rebate model," which many stakeholders had been requesting, "on a select group of drugs . . . in a methodical and thoughtful" way to ensure fairness for all stakeholders. 90 Fed. Reg. at 38,165. And it did so after considering important aspects of the problem, including any reliance interests, costs, and alternatives raised in the comments. Finally, Plaintiffs have failed to show irreparable harm, and the balance of the equities and public interest weigh in the Government's favor.

I. The Government is Likely to Succeed on the Merits

A. The Pilot Program is Not Discrete, Final Agency Action Subject to Review Under the APA

At the outset, Plaintiffs broadly seek to challenge HRSA's establishment and implementation of the 340B Rebate Model Pilot Program. *See generally* Compl., Prayer for Relief (seeking to "set aside" the Pilot Program); Pls.' Br. at 20 (asking this Court to prohibit the Pilot Program from going into effect).

The APA requires Plaintiffs to challenge discrete and final agency action, not seek "*wholesale* improvement of [a] program by court decree." *Lujan*, 497 U.S. at 891; *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (explaining that final agency action marks the completion of the agency's decision-making process and the decision is one that determines rights or obligations, or from which legal consequences will flow). In *Lujan*, the plaintiffs challenged a series of land-use decisions, which they referred to as the "land withdrawal review program." 497 U.S. at 890. The Supreme Court rejected the challenge, holding that the plaintiffs must "direct [their] attack against some particular 'agency

action' that causes [them] harm." *Id.* at 891. The Court explained that the so-called "program" was not an identifiable final agency action but shorthand for the agency's ongoing "operations . . . in reviewing withdrawal revocation applications and the classifications of public lands and developing land use plans as required by [statute]." *Id.* at 890. The Court stressed that any "flaws in the entire 'program'—consisting principally of the many individual actions referenced in the complaint, and presumably action yet to be taken as well—cannot be laid before the courts for wholesale correction under the APA." *Id.* at 893.

Other courts have applied these principles to conclude that, because "'an on-going program or policy is not, in itself, a final agency action under the APA,' [a court's] jurisdiction does not extend to reviewing generalized complaints about agency behavior." *Cobell v. Kempthorne*, 455 F.3d 301, 307 (D.C. Cir. 2006) (citation omitted). Similarly, "implementation" of such a program or policy "is neither agency action nor final agency action subject to judicial review under the APA." *Vill. of Bald Head Island v. U.S. Army Corps of Eng'rs*, 714 F.3d 186, 195 (4th Cir. 2013). These APA limitations serve to "protect agencies from undue judicial interference with their lawful discretion, and to avoid judicial entanglement in abstract policy disagreements which courts lack both expertise and information to resolve." *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 66 (2004) ("*SUWA*").

Under these principles, Plaintiffs' challenge as they frame it cannot proceed. The Pilot Program itself is not a circumscribed, discrete agency action subject to review under the APA. As in *Lujan*, the program does not refer to a particular agency order or regulation. Rather, it is shorthand for the agency's continuing operations in administering the 340B Program—principally through agreements with individual manufacturers to effectuate 340B prices, which Congress specified may be achieved through rebates or discounts "as provided by the Secretary." 42 U.S.C. § 256b(a)(1).

Moreover, "implementation" of the Pilot Program is neither agency action nor final agency action. *See Vill. of Bald Head Island*, 714 F.3d at 195. No rights or obligations are determined by the existence of the program itself. *See Bennett*, 520 U.S. at 177–78. Similarly, the notice announcing the

Pilot Program and soliciting comments and applications is not final agency action either: if no manufacturers had applied or been approved, the Pilot Program would have no effect. Yet the key question Plaintiffs invite the Court to answer is "why it is necessary to implement the program this way," Pls.' Br. at 10; *see also id.* at 20 (requesting that the Court prohibit Defendants from implementing the program). That is precisely the kind of question that federal courts are not suited to answer. *See SUWA*, 542 U.S. at 66.

What Plaintiffs really take issue with is the agency's decisions to allow nine drug manufacturers to offer 340B pricing for ten selected drugs via rebates. Those approvals constitute informal agency actions—specifically, informal agency adjudications. *See, e.g.*, *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402 (1971) (decision of the Secretary of Transportation to approve the routing of an interstate highway through Overton Park was informal agency action); *Camp v. Pitts*, 411 U.S. 138, 142 (1973) (decision concerning applications for new banking authorities was informal agency action); *see also Izaak Walton League of Am. v. Marsh*, 655 F.2d 346, 361 n.37 (D.C. Cir. 1981) ("Informal adjudication is a residual category including all agency actions that are not rulemaking and that need not be conducted through 'on the record' hearings."). Because those approvals are final agency actions, *see Bennett*, 520 U.S. at 177–78, Plaintiffs may seek to challenge those decisions. *See* Compl. ¶ 29 (challenging HRSA's establishment and implementation of the Pilot Program, as well as its approval of drug company applications). But Plaintiffs cannot "seek *wholesale* improvement of this program by court decree," *Lujan*, 497 U.S. at 891.

B. The Decisions to Approve the Applications to Participate in the Pilot Program are Committed to Agency Discretion by Law

The decision to effectuate 340B prices via rebates is committed to agency discretion by law. Agency action "committed to agency discretion by law" is exempt from APA review. *See* 5 U.S.C. § 701(a)(2); *Heckler v. Chaney*, 470 U.S. 821, 830–31 (1985). A statute need not expressly preclude review for the agency's action to be committed to agency discretion. Rather, "[a] statute [may be] drawn so that a court would have no meaningful standard against which to judge the agency's exercise

of discretion." *Heckler*, 470 U.S. at 830. In that case, the statute leaves nothing for the courts to review. The Supreme Court applied these principles in *Webster v. Doe* to a statute allowing the director of the CIA to terminate an employee whenever he "shall *deem* such termination necessary or advisable in the interests of the United States." 486 U.S. 592, 600 (1988). Because that assessment was "the Director's alone" to make, the statute "foreclose[d] the application of any meaningful judicial standard of review." 486 U.S. 592, 600, 603 (1988); *see also Lincoln v. Vigil*, 508 U.S. 182, 192 (1993) (allocation of funds from a lump-sum appropriation was committed to agency discretion because of the absence of instructions regarding how to spend it); *CC Distribs., Inc. v. United States*, 883 F.2d 146, 153 (D.C. Cir. 1989) (statute directing the Secretary of Defense to procure services from the private sector if less expensive—except for services the Secretary "determines must be performed by military or governmental personnel"—left the decision of which services must be performed by government employees to the Secretary's determination).

The 340B statute directs the Secretary of HHS to enter into agreements with drug manufacturers to effectuate the 340B ceiling price, "taking into account any rebate or discount, *as provided by the Secretary*." 42 U.S.C. § 256b (emphasis added). The relevant definition for the term "provide" is "to have as a condition" or to "stipulate." *Provide*, Merriam-Webster.com, https://www.merriam-webster.com/dictionary/provide. The statute therefore contemplates that the Secretary will set "as a condition" or "stipulate" whether the 340B price will be achieved through rebates or discounts. *See also Eli Lilly & Co. v. Kennedy*, 2025 WL 1423630, at *9 (D.D.C. May 15, 2025) (adopting this construction of the statute). Moreover, the statute provides no guidelines by which to judge the Secretary's choice. And the legislative history confirms this understanding of the text: the House Committee on Energy and Commerce report accompanying the 1992 legislation noted that 340B price reductions "would be implemented, *at the discretion of the Secretary*, either by a point-of-purchase discount, a rebate, or other mechanism." H.R. Rep. No. 102-384(II), at 8, 12, 16 (emphasis added). As in *Webster*, the decision at issue is the Secretary's alone to make. *See Webster*, 486 U.S. at

603. And because the statute does not provide a benchmark against which to measure the agency's exercise of discretion in making that decision, arbitrary and capricious review does not apply.

C. Even if the Decisions to Approve the Applications Were Reviewable, They Do Not Violate the APA

Even if review were not precluded here, the agency's decisions can be overturned only if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Review under the "arbitrary and capricious" standard is "narrow," and the ultimate question is whether the agency's action was reasonable. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009). Review should be particularly circumscribed here because the statute "exudes deference" to the Secretary's determination as to whether to effectuate 340B prices via rebates or discounts, *see Webster*, 486 U.S. at 600, and the approvals are designed to test the rebate model on a small scale to minimize the costs and risks of such information gathering.

To comply with the arbitrary and capricious standard, the agency must examine the relevant data and articulate a satisfactory explanation for its action including a "rational connection between the facts found and the choice made." *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962). Moreover, an agency is free to change its position so long as it displays awareness that it is doing so, shows that there are good reasons for the new policy, and takes any serious reliance interests into account. *See Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221–22 (2016). In conducting its review, the Court should consider "whether there has been a clear error of judgment," *Bowman Transp., Inc. v. Ark.-Best Freight Sys., Inc.*, 419 U.S. 281, 285 (1974) (quoting *Volpe*, 401 U.S. at 416). But "a court is not to substitute its judgment for that of the agency." *Fox Television Stations, Inc.*, 556 U.S. at 513–14 (citation omitted).

Here, the agency's decisions to approve the manufacturers' applications readily satisfy how courts apply the arbitrary and capricious standard in the context of informal agency adjudications.[4]

[4] *See, e.g.*, *Royal Siam Corp. v. Chertoff*, 484 F.3d 139, 148 (1st Cir. 2007) ("In the absence of an error of law—and we see none here—this case comes down to straight abuse-of-discretion review. Under that standard, the outcome is foreordained."); *Neustar, Inc. v. FCC*, 857 F.3d 886, 900 (D.C. Cir. 2017)

First, as explained in the agency's notice, the agency previously received a significant amount of feedback from both manufacturers and covered entities regarding rebate models, and recognized that a rebate model "could fundamentally shift how the 340B Program has operated for over 30 years." 90 Fed. Reg. at 36,164. Still, the agency wanted to better understand the merits and shortcomings of a rebate model from stakeholders' perspectives, and to inform consideration of any future 340B rebate models consistent with the 340B statute and the Administration's goals. *Id.* So it designed a thoughtful pilot program that was limited in scope to only ten drugs that account for only 2% of 340B sales, *see* Britton Decl. ¶ 22,[5] to test "a fair and transparent 340B rebate model process for all stakeholders involved." 90 Fed. Reg. at 36,164. Further, because one of the goals of the Pilot Program is to address 340B and Maximum Fair Price deduplication, the agency chose to limit the scope of the Pilot to the ten drugs with negotiated Maximum Fair Prices set to take effect on January 1, 2026, due to their inclusion in the Medicare Drug Price Negotiation Program. After reviewing applications to participate in the Pilot Program from manufacturers of those drugs, as well as comments received from stakeholders including covered entities, the agency carefully balanced the equities and then decided which specific aspects of each application to approve. *See* Britton Decl. ¶ 12–14. Those decisions were reasonable.

1. In opposition, Plaintiffs first argue that the agency's actions were arbitrary and capricious because Defendants offered no reasonable explanation for instituting the Pilot Program and ignored reliance interests by healthcare providers. Pls.' Br. at 9–11. But as explained above, the agency did offer a reasonable explanation: "[d]ue to the significant amount of feedback received from (or on behalf of) manufacturers and covered entities regarding implementation of rebate models," the agency

(although Petitioner raised legitimate concerns that might have justified a different decision by the agency, the Court was "not to substitute [its] judgment for that of the [agency] . . . . Rather, the question [of whether the agency acted arbitrarily and capriciously] is more narrow").

[5] *Compare Clifford v. Pena*, 77 F.3d 1414, 1418 (D.C. Cir. 1996) ("[T]here is nothing improper in receiving declarations that merely illuminate reasons obscured but implicit in the administrative record[.]" (citation modified)) *with Overton Park, Inc*, 401 U.S. at 419 (discouraging reliance on "mere[] 'post hoc' rationalizations" (citation omitted)).

wanted to test the merits and shortcomings of a rebate model, including whether it was beneficial in addressing "340B and Maximum Fair Price (MFP) deduplication" and "the prevention of 340B Medicaid duplicate discounts and diversion." 90 Fed. Reg. at 38,165. That course of action is consistent with the agency's long-held positions that it must make provision for the method of obtaining the 340B statutory ceiling price, and that rebate models require more study. Consistent with those positions, the agency has not previously rejected rebate models, and has not now made a final decision about the efficacy or desirability of such models but simply announced an effort to obtain real-world data.

Still, the agency did consider the reliance interests of covered entities. It recognized that "rebate models could fundamentally shift how the 340B Program has operated for over 30 years." *Id.* So it limited the scope of the Pilot Program to a small set of manufacturers and a limited number of drugs in order to minimize the impact on covered entities. *See* Britton Decl. ¶ 5. Collectively, the ten drugs chosen for the Pilot represent only 2% of total sales in the 340B program; 340B pricing on all other drugs (representing 98% of total 340B sales) will continue to be offered through upfront discounts. And only one of the drugs selected for the Pilot Program was in the top 20 of 340B drug products purchased by covered entities in 2024. *See* Britton Decl. ¶ 22. The agency determined that further limiting the Pilot Program, either by reducing the number of drugs or covered entities in it, would interfere with the agency's ability to collect sufficient information on which to evaluate the merits and shortcomings of a rebate model. *See* Britton Decl. ¶ 22–25.

2. Plaintiffs next attack the agency's failure to respond to the comments received on the notice. Pls.' Br. at 11. Although they (correctly) do not argue that the agency was required to undertake notice and comment as a procedural matter, they assert that the agency's failure to respond to the comments is a substantive violation of the APA. Not so. As the Supreme Court held in *Perez v. Mortgage Bankers Association*, an agency's obligation to "consider and respond to significant comments received during the period for public comment" is part of the three-step procedure for notice-and-comment

rulemaking pursuant to Section 553 of the APA. 575 U.S. 92, 96 (2015). But the agency was not engaging in rulemaking here. *See supra* Argument Section I.A.[6] And even if it were, without a procedural requirement to solicit comments in the first place, the agency incurs no obligation to respond to comments, even "significant" ones. *Perez*, 575 U.S. at 96 (distinguishing between rules subject to notice-and-comment, which require that the agency respond to significant comments, and those that do not).

To be sure, if an agency chooses to solicit comments, those comments could highlight an important aspect of the problem. And an agency's failure to consider an important aspect of the problem could show that its decision was arbitrary and capricious as a substantive matter. *See Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). But the agency did not exhibit any such failure here. Contrary to Plaintiffs' contention, the agency did in fact consider the comments it received on the notice. *See, e.g.*, Britton Decl. ¶ 12. Comments submitted by different stakeholders with diverse viewpoints advocated for different changes to the program. With those diverging views in mind, the agency made reasonable judgment calls in approving applications for the Pilot Program. For example, covered entities decried having to "float" billions of dollars to drug companies during the ten-day period while awaiting their rebates, while drug manufacturers requested a longer timeframe for processing claims. *See* Britton Decl. ¶ 26. Ultimately, the agency retained the ten-day timeframe to minimize the financial impact on covered entities, reasoning that those entities would likely receive rebate payments before their invoices from wholesalers came due. *See* Britton Decl. ¶ 27–30.

As another example, in response to concerns about the denial of claims and disputed claims, the agency is planning to create a mechanism for covered entities to report to HRSA when the covered entity is unable to secure a rebate, and covered entities will be able to raise these types of issues through

[6] For that reason, Plaintiffs' reliance on *W. Coal Traffic League v. Surface Transp. Bd.*, 998 F.3d 945 (D.C. Cir. 2021) and *Marasco & Nesselbush, LLP v. Collins*, 6 F.4th 150 (1st Cir. 2021) is misplaced. *See* Pls.' Br. at 12.

the 340B Administrative Dispute Resolution process. *See* Britton Decl. ¶ 31–32. HRSA also provided a number of guardrails to mitigate these concerns, including severely limiting the bases for the denial of claims and requiring manufacturers to provide a rationale and specific documentation for any claim denials. *Id.* And Manufacturers are required to provide a customer service component and a point of contact to engage with covered entities in good faith regarding questions or concerns. *See* Britton Decl. ¶ 43.

In addition, the agency sought to balance the interests of covered entities and manufacturers by imposing several requirements on manufacturers regarding the IT platform used to collect and store rebate claims data. *See* Britton Decl. ¶ 42–43. For instance, manufacturers were required to provide covered entities at least 60 days' notice before implementing the rebate model with instructions for registering with any IT platform. *See id.* They also had to provide a technical assistance component and ensure that the data is secure, protected, and limited to the elements identified by HRSA as necessary for providing 340B rebates. *See id.*

The agency remains committed to evaluating "data and reports received from the participating manufacturers" and "covered entity and other stakeholder feedback" in order to assess the effectiveness of the Pilot in light of the issues raised by commenters. *See* 90 Fed. Reg. at 38,166.

3. Third, Plaintiffs claim that the agency ignored the scale of the Pilot Program's costs, including as compared to its benefits. *See* 90 Fed. Reg. at 38,165–66. But the agency did consider costs to covered entities, including upfront costs, administrative costs, and non-monetary costs. *See* Britton Decl. ¶ 34–41; *see also* Req. for Emergency Approval – Assessment of Administrative Burden 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, & Supporting Statement, Doc. Nos. 10-29, 10-30.[7] The agency tried to minimize those costs as much as possible by, among other things,

[7] The agency is currently examining the comments alleging an under-estimation of administrative costs in response to its Paperwork Reduction Act Notice. *See* Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-0111-Extension, 90 Fed. Reg. 44,197 (Sep. 12, 2025). The agency will address those concerns in the context of finalizing that notice. *See* Britton Decl. ¶ 35.

limiting the scope of the Pilot to ten drugs, requiring manufacturers to pay rebates within ten calendar days of submission, approving unit-level rebates, limiting the allowable data fields covered entities would need to submit to request a rebate, and imposing the costs of running the IT platform on manufacturers. *See* Britton Decl. ¶¶ 5, 27–30, 38, 43. Ultimately, the agency predicted that the Pilot Program would not have a significantly negative impact on patient care and determined that the potential significant benefits of the Pilot Program, not least of which is to test a rebate model that the Secretary is authorized by statute to adopt, outweighed the costs associated with it. *See* Britton Decl. ¶¶ 34, 41. That was a reasonable determination. The agency relied on its expertise to make a predictive judgment about costs and then made a policy decision about whether those costs were worth bearing. Such judgments are afforded substantial deference. *See FCC. v. Fox Television Stations, Inc.*, 556 U.S. 502, 521 (2009); *FCC v. Nat'l Citizens Comm. for Broad.*, 436 U.S. 775, 814 (1978).

4. Plaintiffs further argue that Defendants failed to consider alternative options. On the contrary, the agency did consider alternatives proposed by commenters. *See* Britton Decl. ¶ 21. For example, HRSA rejected alternatives like the Medicare Transaction Facilitator because that methodology does not test the concept of a rebate model, and testing that model to effectuate the 340B ceiling price was the agency's chief aim. *See id.* And there is no clear legal authority in the 340B statute for those alternatives. Moreover, HRSA considered and rejected proposals to further limit the scope of the Pilot to a smaller subset of drugs. Only a very small percentage of drugs are currently included in the Pilot Program and further restricting that number would interfere with the agency's ability to collect sufficient information on which to evaluate the viability of a broader rebate model. *See* Britton Decl. ¶ 22–23.

HRSA likewise considered commenters' suggestions to limit the Pilot Program to a subset of covered entities or only to covered entities that volunteered to participate. The 340B Program contains a wide variety of covered entity types, ranging from federally qualified health centers, certain children's hospitals and free-standing cancer hospitals, critical access hospitals, rural referral centers, black lung

clinics, and other federally funded health care entities. 42 U.S.C. § 256b(a)(4). HRSA did not limit the Pilot Program to a subset of those covered entities because it was important to the agency that manufacturers be able to structure their rebate programs to test the model for as broad a variety of covered entities as possible. *See* Britton Decl. ¶ 24.

5. Finally, Plaintiffs assert that the agency improperly sought a predetermined result. But they offer no support for that allegation, much less the support needed to overcome the presumption of regularity afforded agency action. *See United States v. Chem. Found., Inc.*, 272 U.S. 1, 14–15 (1926) ("The presumption of regularity supports the official acts of public officers, and . . . that they have properly discharged their official duties."). Indeed, the initiation of a Pilot Program does not conclusively determine anything. It is meant to "better understand the merits and shortcomings of the rebate model from stakeholders' perspectives, and to inform [agency] consideration of any future 340B rebate models." 90 Fed. Reg. at 38,165. In any event, the APA does not impose "an open-mindedness test." *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 591 U.S. 657, 685 (2020).

For these reasons, Plaintiffs' arbitrary and capricious claim should fail.

II. Plaintiffs Have Failed to Show Irreparable Harm

Plaintiffs must also show that a preliminary injunction is needed "to prevent a real threat of [irreparable] harm." *Matos ex rel. Matos v. Clinton Sch. Dist.*, 367 F.3d 68, 73 (1st Cir. 2004). "A finding of irreparable harm must be grounded on something more than conjecture, surmise, or a party's unsubstantiated fears of what the future may have in store." *Charlesbank Equity Fund II v. Blinds to Go, Inc.*, 370 F.3d 151, 162 (1st Cir. 2004); *see also Winter*, 555 U.S. at 22 ("[A party] seeking preliminary relief [must] demonstrate that irreparable injury is *likely* in the absence of an injunction"). In other words, "speculative injury" is not enough. *Narragansett Indian Tribe v. Guilbert*, 934 F.2d 4, 6–8 (1st Cir. 1991) (citation modified).

Significantly, Plaintiffs do not claim that the rebate model reduces the amount of their 340B discounts. Nor could they, as that amount is set by the statute and the challenged agency action here merely changes how those discounts are disbursed in a way that is clearly authorized by the 340B

statute. Rather, Plaintiffs principally focus on three theories of harm: 1) increased upfront costs; 2) increased administrative costs; and 3) harm to their missions. None of these asserted harms rises to the level of irreparable harm.

First, with respect to increased upfront costs, Plaintiffs have failed to show that they face irreparable harm from the ten-day period between submitting their claims and receiving their rebates. Although they allege that they do not have significant amounts of cash on hand, they do not explain why a ten-day payment window will cause them irreparable harm, particularly given the limited scope of the Pilot Program and the likelihood that, for most purchases of the ten drugs included in the Pilot Program, covered entities will receive rebates before their payment is due to the wholesaler. *See* Britton Decl. ¶ 30. And while Plaintiffs allege that there could be significant delays between ordering drugs and dispensing them, manufacturers will pay unit-level rebates rather than package-level rebates, so covered entities will not have to wait to dispense an entire package before requesting a rebate. *Id.* ¶ 29. And in any event, most drugs included in the Pilot Program are dispensed as a full package size and do not sit on the shelf for long periods of time. *See id.* ¶ 28. All of these features should mitigate any financial strain on covered entities by minimizing or eliminating the need to wait long periods of time between ordering drugs and requesting rebates.

Plaintiffs also speculate that they'll have to float their capital to drug manufacturers for unknown periods of time "with no enforceable guarantee of repayment," Pls.' Br. at 17. But as explained above, manufacturers are required to ensure that all rebates are paid to the covered entities, or denied with documentation in support, within ten days of data submission. 90 Fed. Reg. at 36,165. And HRSA has limited the grounds on which manufacturers can deny claims and reserves the right to revoke approval of a manufacturer plan at any time if the manufacturer fails to comply with the Pilot Program's criteria. *Id.* at 36,164. Plaintiffs' unsupported fears that manufacturers will fail to "reimburse hospitals within ten days" or "inappropriately deny rebates" are therefore too speculative to support irreparable harm. *See, e.g.*, Decl. of Winfield S. Brown ¶ 20, Doc. No. 5 ("Brown Decl.");

Decl. of Sean M. Fadale ¶ 21, Doc. No. 6 ("Fadale Decl.") ("I am also concerned that the drug companies will not reimburse [Plaintiff] within ten days because Defendants have not set out clear consequences for late or unfairly denied rebates."); Decl. of Alan W. O'Neil ¶ 17, Doc. No. 9 (similar).

Plaintiffs next contend that they face irreparable harm from increased administrative costs. But Plaintiff Maine Hospital Association states only in a vague and conclusory fashion that its members have "serious concerns" about the Pilot Program, including their inability to fund the administrative costs necessary to comply with it. Decl. of Jeffrey Austin ¶ 14, Doc. No. 4. That assertion is not enough to establish standing, much less irreparable harm. *See, e.g.*, *Cacchillo v. Insmed, Inc.*, 638 F.3d 401, 404 (2d Cir. 2011) ("[T]o establish standing for a preliminary injunction, a plaintiff cannot rest on . . . mere allegations, as would be appropriate at the pleading stage." (citation modified)). For their part, Plaintiffs St. Mary's Regional Medical Center and Nathan Littauer Hospital and Nursing Home aver that each will have to hire a new staff person if the program is implemented. *See* Brown Decl. ¶ 21; Fadale Decl. ¶ 22. But neither establishes that those burdens are sufficiently weighty to constitute irreparable harm, especially given the financial benefits that flow to Plaintiffs due to 340B discounts. *See Sierra Club v. Larson*, 769 F. Supp. 420, 422 (D. Mass. 1991) ("To establish irreparable harm there must be an actual, viable, presently existing threat of *serious* harm." (emphasis added)).

Finally, Plaintiffs assert that the Pilot Program will cause irreparable harm to their missions, as they face financial uncertainty and may have to delay maintenance on hospital facilities and cut back on health-promoting services. But these fundamentally economic harms do not threaten the very "survival" of Plaintiffs' businesses, as they must to qualify as irreparable, particularly given the limited scope of the Pilot. *Coastal Cntys. Workforce, Inc. v. LePage*, 284 F. Supp. 3d 32, 59 (D. Me. 2018), *appeal dismissed*, 2018 WL 3440030 (1st Cir. Mar. 2, 2018); *see also Dr. Jose S. Belaval, Inc. v. Perez-Perdomo*, 465 F.3d 33, 36 n.2 (1st Cir. 2006) (explaining that the plaintiff had "filed documents . . . indicating that it was on the brink of financial ruin"). To the extent Plaintiffs attempt to bolster their claims of

irreparable harm by relying on injuries to patients, that fails as well. Plaintiffs may not rely on alleged harms to third parties to demonstrate irreparable harm. The "issuance of a preliminary injunction requires a showing of irreparable harm *to the movant* rather than to one or more third parties." *CMM Cable Rep., Inc. v. Ocean Coast Props., Inc.*, 48 F.3d 618, 622 (1st Cir. 1995); *see also Winter*, 555 U.S. at 20 ("A plaintiff seeking a preliminary injunction must establish . . . that *he* is likely to suffer irreparable harm in the absence of preliminary relief." (emphasis added)). Thus, Plaintiffs have failed to establish irreparable harm.

III. The Balance of Equities and Public Interest Favor the Government

Even if Plaintiffs could establish irreparable harm, they have not shown that "the balance of equities and consideration of the public interest" favor a preliminary injunction. *Id.* at 32. Where, as here, the government is the defendant, these factors "merge." *Nken*, 556 U.S. at 435.

As the First Circuit has recognized, "[a]ny time a [government] is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." *Dist. 4 Lodge of Int'l Ass'n of Machinists & Aerospace Workers Loc. Lodge 207 v. Raimondo*, 18 F.4th 38, 47 (1st Cir. 2021) (quoting *Maryland v. King*, 567 U.S. 1301, 1303 (2012)). That is particularly true here, where Congress has explicitly granted the Secretary of HHS the authority to choose between rebates or discounts in administering the 340B program. Pursuant to that authority, the agency has decided to test the viability of one of those options in a way designed to limit adverse impacts on covered entities. Moreover, the agency's choice is motivated in part to help regulated parties address deduplication between 340B prices and negotiated prices under the Medicare Drug Price Negotiation Program, where the first set of negotiated prices is set to take effect on January 1. Regulatory agencies "must be given ample latitude to 'adapt their rules and policies to the demands of changing circumstances.'" *State Farm*, 463 U.S. at 42. And while Plaintiffs claim that the balance of the equities and the public interest favor them because there is no public interest in the perpetuation of unlawful agency action, Pls.' Br. at 19, that argument only presupposes the success of their incorrect view of the merits. Accordingly, the balance of equities and public interest favor the Government.

IV. Any Relief Must Be Limited to the Named Plaintiffs and Members the Associational Plaintiffs Have Chosen to Identify for Purposes of Standing[8]

If the Court is inclined to grant Plaintiffs' motion, it should limit any injunction to the named Plaintiffs and the members that the American Hospital Association (AHA) and Maine Hospital Association (MHA) have chosen to identify who have standing.

1. At the outset, this Court cannot grant relief as broadly as Plaintiffs request. Plaintiffs request that this Court prohibit Defendants from implementing the Pilot Program pending a final judgment on the merits, *see id.* at 20, which, apart from being improper for the reasons explained above, *see supra* Argument Section I.A., would extend relief to covered entities who are neither parties to this litigation nor members of the associational Plaintiffs. But as the Supreme Court recently made clear, federal courts are not authorized to issue universal injunctions—injunctions that extend relief beyond the parties to the litigation. *Trump v. CASA, Inc.*, 606 U.S. 831, 856 (2025).

Traditionally, "when a federal court finds a remedy merited, it provides party-specific relief, directing the defendant to take or not take some action relative to the plaintiff." *United States v. Texas*, 599 U.S. 670, 693 (2023) (Gorsuch, J., concurring). That practice comports with the "founding-era understanding that courts 'render a judgment or decree upon the right of the litigant[s]." *Id.* (citation omitted) (Gorsuch, J., concurring). Relief drawn in this way ensures that federal courts respect the limits of their authority under Article III "to decide cases and controversies and avoid trenching on the power of the elected branches to shape legal rights and duties more broadly." *Id.* at 694; *see also Doran v. Salem Inn, Inc.*, 422 U.S. 922, 931 (1975) ("[N]either declaratory nor injunctive relief can directly interfere with enforcement of contested statutes or ordinances except with respect to the particular federal plaintiffs.").

Accordingly, any equitable remedy should apply only to the named parties. *See California v. Texas*, 593 U.S. 659, 672 (2021) (remedies "ordinarily operate with respect to specific parties" rather

[8] The Court has asked the parties to address whether the American Hospital Association (AHA) has associational standing. Defendants do not contest that the AHA has standing to seek relief on behalf of its members. *See Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977).

than "on legal rules in the abstract" (citations omitted)); *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994) (observing that the "general rule" is that equitable relief "should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs" (citation omitted)).

2. In the context of associational plaintiffs, this means that relief should extend only to the members that the associations have chosen to identify and for whom the associations have established standing. That latter showing would entail, for example, establishing not only that the member participates in the 340B program but also that it administers a drug that has been approved for a rebate model and would face irreparable harm absent preliminary relief. *See Summers v. Earth Island Inst.*, 555 U.S. 488, 499–500 (2009) ("[T]he Court has required plaintiffs claiming an organizational standing to identify members who have suffered the requisite harm.").

Limiting a remedy to the members the associational plaintiffs have identified for standing purposes comports with the limitations on extending relief to nonparties outlined above. *See CASA*, 606 U.S. at 856. This Court cannot circumvent that prohibition indirectly by extending relief to nonparties who are represented by a party, other than through properly established associational standing or class certification under Rule 23. *See Smith v. Bayer Corp.*, 564 U.S. 299, 315 (2011) ("[A] properly conducted class action . . . can come about in federal courts in just one way—through the procedure set out in Rule 23."). Neither associational Plaintiff has sought or obtained class certification, and the AHA has identified just four of its thousands of members for standing purposes. *See* Compl. ¶ 13. For its part, the MHA has identified only one member. *See id.* ¶ 14. The AHA and MHA cannot end-run all three of those limits—*CASA*, Rule 23, and associational standing requirements—by obtaining an injunction barring the Government from effectuating 340B pricing through rebates for members whose membership is unknown.

Limiting the remedy in this way also appropriately leaves the breadth of the remedy those plaintiffs can receive in their own hands. Nothing prevents the AHA or the MHA from naming as

many of its members as it wishes so that each member can benefit from any relief the Court orders. Likewise, nothing prevents those Plaintiffs' members from seeking to litigate this case as a class action. Thus, any remedy should only extend to cover the specific identified members for which the associations have shown irreparable harm, and should be tailored only to address the irreparable harms shown by those specific members.

V. Any Relief Should Be Accompanied by a Bond

Defendants also respectfully request that any injunctive relief be accompanied by a bond under Federal Rule of Civil Procedure 65(c), which provides that "[t]he court may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained."

CONCLUSION

For the foregoing reasons, this Court should deny Plaintiffs' motion for a preliminary injunction.

Dated: December 15, 2025

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. ROBERT F. KENNEDY, JR. SECRETARY of the U.S. Department of Health and Human Services, *et al.*, Defendants.	No. 2:25-cv-600-JAW

DECLARATION OF CHANTELLE BRITTON

I, Chantelle Britton, M.P.A., M.S., declare as follows pursuant to 28 U.S.C. § 1746:

1. I am the Director of the Office of Pharmacy Affairs (OPA). OPA is part of the Health Resources and Services Administration (HRSA), an agency within the U.S. Department of Health and Human Services (HHS). OPA has delegated authority to administer the 340B Program, which is codified in statute at 42 U.S.C. § 256b or Section 340B of the Public Health Service Act. OPA is responsible for the day-to-day administration of the 340B Program. I make this declaration based on personal knowledge and information provided to me by my staff in the course of my official duties as the Director of OPA.

2. Pursuant to 42 U.S.C. § 256b(a)(1), "[t]he Secretary [of HHS] shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (*taking into account any rebate or discount, as provided by the Secretary*) to the manufacturer for covered outpatient drugs . . . does not exceed" the statutorily-defined ceiling price (emphasis added). This provision, which has been in the statute since the 340B Program's inception in 1992, has been interpreted by HHS as providing the legal authority for effectuating the 340B ceiling price by either a rebate or discount mechanism.

3. Notwithstanding that statutory authority to operationalize rebates and set conditions for rebates in the 340B Program,[1] covered entities have historically purchased covered outpatient drugs in the 340B Program at upfront discounted prices rather than through back-end rebates, with few exceptions.

4. After receiving a significant amount of feedback from (or on behalf of) manufacturers and covered entities regarding implementation of rebate models, OPA recently became interested in testing the merits and shortcomings of a rebate model, including whether it was beneficial in addressing 340B and Maximum Fair Price (MFP)[2] deduplication and the prevention of 340B Medicaid duplicate discounts and diversion. For the past several years, drug manufacturers have been aggressively pursuing the unilateral implementation of widespread 340B rebate models, insisting that a rebate model would have minimal impact on covered entities and patients and is necessary to address a wide variety of perceived program integrity concerns. Covered entities have argued just as hard in opposition to rebate models, asserting that a rebate model would adversely impact covered entities cash flow, negatively impact patients' access to drugs and services and that manufacturers' program integrity concerns are overblown. Given these hyperbolic positions, OPA felt it necessary to test rebates to see how the mechanism would impact the 340B Program and its stakeholders. The purpose of the rebate Pilot Program was also to help OPA consider any future 340B rebate models consistent with the 340B statute and the Administration's goals.

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[1] *See* 42 U.S.C. § 256b(a)(1); *see also Eli Lilly & Co. v. Kennedy*, 2025 WL 1423630 (D.D.C. May 15, 2025), *appeal filed*, No. 25-5221 (D.C. Cir. June 13, 2025); *Johnson & Johnson Healthcare Sys. Inc. v. Kennedy*, 2025 WL 1783901 (D.D.C. June 27, 2025), *appeal filed*, No. 25-5236 (D.C. Cir. June 30, 2025).

[2] Maximum Fair Price refers to the negotiated price under the Medicare Drug Price Negotiation Program (MDPNP). *See* 42 U.S.C. §§ 1320f(c)(2). Under the MDPNP "nonduplication" provision, manufacturers that agree to a Maximum Fair Price are not required to provide a covered entity access to the negotiated Maximum Fair Price under that agreement if the drug is also subject to a 340B agreement and the 340B ceiling price is lower than the Maximum Fair Price. 42 U.S.C. § 1320f-2(d). Deduplication refers to the process a manufacturer uses to assess its obligation to provide access to the Maximum Fair Price under the MDPNP nonduplication provision.

5. OPA recognized that a rebate model would be a significant shift from how the 340B program has been operating, so it sought to test the rebate model on a small scale to help it better understand the merits and shortcomings of a rebate model from stakeholders' perspectives while minimizing disruption to covered entities. It therefore limited the scope of the Pilot Program to the manufacturers with Medicare Drug Price Negotiation Program (MDPNP) Agreements with the Centers for Medicare & Medicaid Services (CMS) for the ten selected drugs for initial price applicability year 2026, in order to test the viability of rebates as an option for effectuating 340B ceiling prices.

6. Limiting the scope of the Pilot Program to the manufacturers of the ten drugs on the MDPNP Selected Drug List for 2026 was intended to allow OPA to better understand the merits and shortcomings of the rebate model from stakeholders' perspectives, including those of manufacturers seeking to address 340B and MFP deduplication.

7. On August 1, 2025, OPA published in the Federal Register a notice titled "340B Program Notice: Application Process for the 340B Rebate Model Pilot Program." 90 Fed. Reg. 36,163 (Aug. 1, 2025).

8. The notice announced the availability of a 340B Rebate Model Pilot Program as a voluntary mechanism for qualifying drug manufacturers to effectuate the 340B ceiling price through a rebate rather than upfront discount on select drugs to all covered entities, and to collect comments on the structure and application process of the Pilot. The notice also contained the criteria for manufacturers' plans to implement a rebate model and set out expectations for continued participation in the Pilot.

9. A technical correction to the notice was published on August 7, 2025, which extended the 30-day comment period by a week to September 8, 2025. 90 Fed. Reg. 38,165 (Aug. 7, 2025).

10. Applications were due on September 15, 2025, the week following the deadline for the submission of comments.

11. In response to the notice, OPA received more than 1,100 comments and applications from each of the nine manufacturers that were eligible to participate in the Pilot.

12. OPA reviewed the comments and considered suggestions and concerns raised therein when evaluating the applications.

13. Each of the nine plans for implementation of rebate models in connection with the Pilot Program submitted by the manufacturers addressed general requirements, reporting requirements, and criteria pertaining to rebates and data. OPA carefully reviewed each plan and sought revisions and clarifications on a number of topics having to do with claims submission, billing, rebate calculation, and inventory management before deciding whether to approve the plans.

14. As further explained below, OPA carefully balanced the equities and took into consideration a variety of factors, including impacts on covered entities and concerns raised in comments, in making decisions on which specific aspects of the plans that it would approve.

The January 1, 2026 Effective Date

15. The August 1, 2025 notice announced that approved manufacturer plans would take effect on January 1, 2026.

16. The January 1 effective date was chosen to align with the effective date of the first set of negotiated prices under the MDPNP, which are set to take effect on January 1, 2026. Starting January 1, manufacturers participating in MDPNP will be implementing 340B prices and Maximum Fair Price deduplication. A 340B rebate mechanism is one way that drug manufacturers can deduplicate 340B prices and Maximum Fair Price. Many drug manufacturers participating in the MDPNP stated that a 340B rebate mechanism is their preferred method to achieve deduplication.

17. At least as far back as 2024, it was widely known that OPA was considering requests from multiple drug manufacturers to implement rebate models. OPA determined that the five-month lead-time from the announcement of the Pilot to effective date was sufficient for covered entities to prepare for implementation of the Pilot, particularly given the limited scope of the Pilot.

18. OPA also required plans to allow for 60 calendar days' notice to covered entities and other impacted stakeholders before implementation of a rebate model, with instructions for registering for any IT platforms. Sixty days was more than sufficient time for covered entities to prepare for the Pilot given that the Pilot was limited in scope, the pharmacy and medical claims information being collected was limited to information that most covered entities already collect, and the Pilot was structured to use existing 340B purchasing accounts.

19. Although the notice stated that OPA's approvals of manufacturer plans would be made by October 15, 2025, the lapse in appropriations applicable to some components of HHS prevented OPA from meeting that goal. Instead, OPA announced eight manufacturers that were approved to participate in the Pilot on October 30, 2025 for a January 1, 2026 effective date. The ninth manufacturer was later approved by OPA to participate in the Pilot beginning on April 1, 2026, even though this manufacturer advised OPA that a January 1 effective date for its participation in the Pilot Program was preferred for its alignment with the effective date of the MFP for its selected drug under the MDPNP.

Alternatives to a Rebate Pilot

20. While alternatives to the Pilot were raised by commenters, OPA did not adjust the concept for its Pilot after considering these comments. Many commenters proposed alternatives that would have maintained the status quo of effectuating ceiling prices through upfront discounts or were otherwise counter to the central aim of the Pilot, which was to test whether rebates were feasible across other covered entity types besides AIDS Drug Assistance Programs. Some suggested alternatives were clearly outside the scope of OPA's legal authority or relied on questionable legal authority.

21. For example, commenters proposed OPA create a government-backed, third-party "clearinghouse" to collect data from drug manufacturers and covered entities, to deduplicate 340B prices and Maximum Fair Price under the MDPNP, and to address manufacturers' program integrity

concerns with the 340B program. Commenters asserted that examples of these "clearinghouses" already exist, such as the Medicare Transaction Facilitator, which facilitates manufacturer effectuation of Maximum Fair Price for drugs selected for negotiation under the MDPNP. OPA rejected those suggestions because those methodologies do not test the concept of a rebate, and testing the rebate methodology to effectuate the 340B ceiling price was OPA's chief aim. Moreover, there is no clear legal authority in the 340B statute for OPA to create the type of clearinghouses suggested by the commenters.

The Scope of the Pilot Program

22. OPA also rejected proposals to further limit the scope of the Pilot Program. The Pilot, which encompasses only the selected drugs of the manufacturers in the MDPNP for IPAY 2026, was narrowly tailored by design. The ten drugs that are in the Pilot Program represent ten Labeler Codes and 83 National Drug Codes (NDCs) of the 904 active Labeler Codes and 47,541 NDCs in the 340B Program. Sales in the 340B Program in 2024 totaled $81.4B. The ten drugs that are subject to the Pilot Program account for only 2% of that total. Further, of the drugs in the Pilot Program, only one, Stelara, was in the top 20 of 340B drug products purchased by covered entities in 2024.

23. Commenters suggested further restricting the number of drugs in the Pilot. OPA rejected that suggestion because reducing the number of drugs in the Pilot would interfere with one of the Pilot's goals of addressing manufacturer concerns regarding 340B-MFP deduplication. Under the MDPNP, manufacturers that agree to a Maximum Fair Price are not required to provide a covered entity access to the negotiated Maximum Fair Price under that agreement if the drug is also subject to a 340B agreement and the 340B ceiling price is lower than the Maximum Fair Price. 340B-MFP deduplication refers to the process of preventing duplicate discounts. Since the drugs with MFPs in effect under the MDPNP for CY 2026 are the only drugs eligible for the Pilot, further limiting the number of drugs would have not afforded a 340B rebate option for each of the ten drugs for which manufacturers are seeking deduplication. Reducing the number of drugs included would also interfere

with the agency's ability to collect sufficient information on which to evaluate the viability of a broader rebate model.

24. Commenters suggested that manufacturers' rebate proposals should be limited to only a subset of covered entities or to only covered entities that volunteered to participate. OPA rejected this suggestion. The 340B Program contains a wide variety of covered entity types, ranging from federally qualified health centers, certain children's hospitals and free-standing cancer hospitals, critical access hospitals, rural referral centers, black lung clinics, and other federally funded health care entities. 42 U.S.C. § 256b(a)(4). Because another important goal of the Pilot is to collect information on the experience of a wide variety of covered entity types with the rebate model, OPA decided that manufacturers should be able to structure their rebate programs for as broad a variety of covered entities as manufacturers deemed necessary to appropriately test the model.

25. The scope of the Pilot is already extremely limited because only ten drugs are included. Further limiting its scope would undermine the agency's goal of information gathering.

Drug Costs

26. Several covered entity commenters indicated that the Pilot would have a significant financial impact because it would require covered entities to "float" billions of dollars to drug manufacturers. They contended that this would occur because 340B purchases would be made at the higher wholesale acquisition cost (WAC) price and they would only be made whole later when the rebate was paid, which OPA required to be paid within ten calendar days of submission. In contrast, drug manufacturers asserted that given the short ten-day time frame for processing claims, the financial impact would be minimized as it was likely that covered entities would receive rebate payments before payment would be due by the covered entity to the wholesaler for most purchases. Several drug manufacturers also requested a longer time frame for processing claims with some wanting OPA to extend the ten days to fourteen days.

27. Given the wide variety of assertions on this topic, OPA opted for the shorter payment window, in part, to address covered entity concerns regarding cash flow and determined that it would be necessary to collect data from the Pilot to make an informed decision about any necessary future changes. OPA was of the view that the impact on covered entities would be lessened by maintaining the shorter ten-day time frame for processing claims and by the extremely limited scope of the Pilot.

28. Moreover, most drugs included in the Pilot would not "sit on the shelf for long[] periods of time before being dispensed" as Plaintiffs claim. Compl. ¶ 85. Rather, the majority of drugs included in the Pilot are dispensed as a full package size (i.e., dispensed as one prescription), which minimizes, or altogether eliminates, the necessity to wait long periods of time between ordering a package and submitting a rebate request.

29. Any financial strain on covered entities will be further mitigated by the fact that manufacturers will pay unit-level rebates rather than package-level rebates. Said another way, for purchases from which multiple dispenses will be drawn, covered entities will not have to wait to dispense an entire package before being able to request a rebate; instead, if applicable, they may do so after the first dispense from the package (e.g., a rebate may be requested for 30 tablets dispensed out of a bottle of 100 tablets).

30. OPA acknowledges that adopting the rebate mechanism for even this limited set of drugs will be a significant change for covered entities. However, covered entities derive substantial financial benefits from the 340B spread, which is additional revenue representing the difference between the cost of a drug and what a covered entity is reimbursed by a third-party payer—e.g., covered entities turn a profit when serving insured patients because insurance companies reimburse them at full price for drugs that they bought at the 340B discount. A ten-day lag before a covered entity is made whole, on balance, does not strike OPA as being as calamitous as covered entities portray, particularly if, as manufacturer commenters state, the rebate in most instances will be paid before the purchase invoice from a wholesaler for the WAC amount is due. The Pilot will allow OPA

to collect data to evaluate whether rebates are paid before a purchase invoice is due and to evaluate more generally the impact of rebates on covered entities.

31. Commenters were also concerned about delays in receiving rebates, as well as disputed claims and improperly denied claims. OPA has provided a number of guardrails to mitigate these concerns. These include, but are not limited to: 1) severely limiting the bases for the denial of claims; 2) requiring manufacturers to provide a rationale and specific documentation for any claim denials; 3) requiring manufacturers to have processes in place for the good faith resolution of disputes; and 4) requiring manufacturers to report to OPA information related to claim delays and denials.

32. In addition, OPA is planning to create a mechanism through which covered entities will be able to report to OPA when the covered entity is unable to secure a rebate and covered entities will be able to raise these types of issues through the 340B Administrative Dispute Resolution process. Given that these safeguards provide covered entities with protections that exceed the protections that covered entities maintain outside of the Pilot, OPA determined that the dispute process was sufficient and that the suggestions from commenters to address alleged unaccounted-for costs caused by perceived gaps in the dispute resolution system were unnecessary.

33. Finally, OPA recognized that covered entities could be due partial credit for 340B purchases made under the upfront discount system when covered entities transition to a rebate mechanism. Under the current upfront discount system, covered entities cannot claim the 340B price until they have dispensed a full package size. For example, if the package size for a given drug is 100 pills, if a covered entity has only dispensed 25 pills to one patient, the covered entity must wait until it dispenses the rest of the 75 pills to other patients before claiming the 340B discount. In this example, a covered entity can't claim the 340B price until it has "accumulated" the full package size by providing all 100 pills to 340B eligible patients. OPA worked with manufacturers to ensure that there was a mechanism for covered entities to obtain the 340B price for any drugs that the covered entity may not have accumulated a full package size on January 1, 2026, when they are transitioned to a rebate model.

Administrative Costs and Other Burdens

34. Commenters also raised concerns about administrative costs. As explained above, covered entities that choose to participate in the 340B program derive a significant financial benefit from it. Their participation in the 340B Program is voluntary and has always entailed certain compliance, operational, and other costs. OPA designed the Pilot Program with the aim of minimizing any additional administrative costs and burdens attributable to the Pilot and ultimately determined that the potential significant added benefits of the Pilot—gathering information on the feasibility of rebates, helping to collect data for future rebate models consistent with the 340B statute and Administration priorities, improving transparency, addressing manufacturer concerns about 340B-MFP deduplication, and facilitating the prevention of 340B Medicaid duplicate discounts and diversion—outweighed these costs.

35. OPA is currently examining the comments alleging an under-estimation of administrative costs in the context of the Paperwork Reduction Act Notice, 90 Fed. Reg. 44,197 (Sept. 12, 2025). OPA will address those concerns in the context of finalizing that notice.

36. As for the need to provide claims data to receive rebates, most covered entities already provide the type of claims data they will need to provide under the Pilot. Since at least 2021, in connection with manufacturer contract pharmacy policies, many covered entities have been submitting claims data to 340B ESP, an IT platform owned by the company Second Sight Solutions, which also operates the rebate model IT platform. OPA purposefully did not require covered entities to submit any new pharmacy and medical data elements beyond which most were already submitting either as part of the manufacturer contract pharmacy claims submission process or which most had readily available through third party administrators.

37. For example, OPA rejected proposals from manufacturers to require submission of a set of data tied to the purchase of the drug (e.g., specific invoice data, detailed wholesaler account information, and purchase account information) to avoid creating additional burdens on covered

entities as this element was not something that could be easily produced by many covered entities at this juncture. While covered entities have access to their purchase records, they do not routinely tie those records to individual dispensing records. Requiring this reconciliation would create a significant administrative burden on covered entities.

38. To elaborate, in all the plans, manufacturers sought to collect purchase data from covered entities. Manufacturers relayed that the purchase data was necessary to improve the integrity of the Pilot. They also claimed it was needed to provide visibility into 340B transactions. In particular, manufacturers thought this data would allow them to verify that the claims data submitted by covered entities showed that the drug was purchased at WAC, thus triggering the request for a rebate. In addition, manufacturers wanted to verify that there were purchases made to warrant a rebate request. OPA considered the request from manufacturers but ultimately decided against approving the collection of purchase data. It did so to avoid placing undue burden on covered entities as this information is not readily available to attach as part of the claims submission and would cause additional burden for covered entities to produce. OPA was also of the view that manufacturers could, at this juncture, use information provided by their wholesale partners to determine that there were sufficient WAC purchases to compare with rebate requests. The final approval letters to manufacturers reflected OPA's reasoned thinking on this issue and that purchase data was not necessary at this initial phase of the Pilot.

39. As another example, in all of the plans, manufacturers sought to collect medical claims data from covered entities. This was in addition to the pharmacy claims data that OPA was requiring covered entities to submit to obtain a rebate payment under the Pilot. Regarding this request, OPA considered the justification provided by the manufacturers and agreed that the data would be necessary to effectuate 340B rebates for physician-administered drugs. Medical claims data include different data than pharmacy claims data due to how the drug is received by the patient: instead of the RX number that would be supplied by a pharmacy dispense, the medical claims corresponding data field would be

the claim number. This is the type of data that is generated when a drug is administered by a physician as opposed to being dispensed at a pharmacy. In addition, OPA found that the medical claims data was analogous to pharmacy claims data used to identify 340B eligible claims and would therefore not cause additional burden for covered entities to produce as part of their claims submission when requesting a rebate.

40. Public comments submitted in response to the notice also identified the concern that the rebate model would cause difficulties with state Medicaid programs that reimburse at actual acquisition cost (AAC) and difficulties in providing sliding fees to uninsured patients. Under the upfront discount model, covered entities receive pricing files with 340B ceiling prices from wholesalers that feed the pharmacy billing systems, which allow covered entities to bill at AAC and allow for sliding fees that share savings with eligible patients. This would not exist under the rebate model because the 340B ceiling price will no longer be present in the pricing files from wholesalers for drugs in the rebate model. The WAC price, not the 340B ceiling price, will appear in the pricing files. Therefore, as OPA reviewed the plans, it became apparent that covered entities would need a separate pricing file to understand better what their ultimate rebated amount would be to help them plan. OPA requested that each manufacturer work to provide a supplemental pricing file with the 340B ceiling prices to assist covered entities with the Medicaid billing requirements and assist with providing patients with the shared savings. This file will be available for download on the rebate model's IT platform. The 340B OPAIS pricing component is also available for verification of the accuracy of the manufacturer provided files.

41. OPA considered the non-monetary costs associated with moving to a rebate model. Covered entities have asserted that a rebate model would affect patient care by limiting the availability of drugs and by reducing the benefits covered entities derive from participating in the 340B Program. Manufacturers have argued that implementation of a rebate model would not affect patient care, will not affect patient access to drugs, and will not affect covered entity participation in the 340B Program.

OPA does not believe that the rebate model will have a significantly negative impact on patient care as the rebate model is designed only to change the form of the 340B discount, not restrict the savings received by 340B covered entities for the drugs included in the Pilot. OPA does not think a ten-day lag in receiving a rebate payment will harm patients or communities that indirectly benefit from the 340B Program. These types of concerns are the reason, in part, why OPA greatly restricted the scope of the Pilot, so that it could further evaluate any unforeseen consequences of a Pilot without endangering the entire 340B Program.

Concerns about the Beacon Software Platform

42. To balance the interests of covered entities and manufacturers, OPA imposed several requirements on manufacturers participating in the Pilot regarding the IT platform a manufacturer would use to collect and store rebate claims data.

43. Manufacturers were required to, among other requirements: 1) provide covered entities and other impacted stakeholders with 60 calendar days' notice before implementation of the rebate model, with instructions for registering with any IT platform; 2) provide a technical assistance/customer service component and ensure that opportunities to engage with the manufacturer in good faith regarding questions or concerns are made available to covered entities through both the IT platform and a point of contact at the manufacturer; 3) ensure that the IT platform has assurances in place to ensure that the data is secure and protected and collection of the data is limited to the elements identified by OPA as necessary for providing 340B rebates pursuant to section 340B(a)(1) of the PHSA; 4) ensure that the IT platform has mechanisms in place to protect patient identifying information, which is required to be maintained in a manner consistent with the Health Insurance Portability and Accountability Act of 1996 and any other applicable privacy and data security laws; 5) ensure that the IT platform will have the capacity to receive data that will filter and use only the data required to effectuate the rebate (e.g., if drugs other than the selected drugs under the MDPNP included within the Pilot Program are submitted, the IT platform will be able to identify

and discard unneeded data); and 6) ensure that the IT platform will have the capability to provide real-time reconciliation reports for covered entities to be informed of the rebate status of submitted claims.

44. All manufacturers that were approved by OPA to participate in the Pilot selected Beacon Channel Management (Beacon) as their chosen IT platform. OPA did not select Beacon or in any way influence the selection of Beacon. Beacon is a private company that is an ancillary stakeholder in the 340B space, but OPA has no legal authority over Beacon. Although OPA cannot compel Beacon to act in a certain manner, it reserves the right to revoke approval of a manufacturer plan at any time if the manufacturer fails to comply with the program's criteria, including by failing to ensure its IT platform is complying with the above requirements. Also, the health care and pharmaceutical sectors are heavily regulated, and numerous federal and state laws beyond the 340B statute already exist to address unlawful conduct regarding privacy and data security.

45. There are many third-party contractors that operate in furtherance of the 340B Program. These stakeholders include wholesalers, specialty distributors, contract pharmacies, third party administrators, consultants, auditors, and pharmacy benefit managers, among others. The use of Beacon is entirely consistent with these other aspects of the 340B Program. As is the case with Beacon, OPA exercises no regulatory oversight over these stakeholders. While OPA is aware of many contracts or agreements that covered entities, for example, may enter into with these stakeholders, OPA is not involved in negotiating, setting, or even reviewing beforehand the terms and conditions of these private agreements and would only become involved to the extent there is activity that conflicts with a covered entity's (or a manufacturer's) 340B obligations. Although the Beacon IT platform is not entirely new to most covered entities because of their experience with 340B ESP (the IT platform many covered entities use in connection with manufacturer contract pharmacy policies), OPA understood that purchasing covered outpatient drugs via rebates would be a new endeavor. Consequently, OPA stipulated the requirements listed above and other guardrails to minimize the compliance costs and administrative burden for covered entities adopting the new rebate mechanism.

46. To conclude, each manufacturer seeking approval to join the Pilot made its own business decision regarding the IT platform it would use to facilitate its participation. While OPA did not select Beacon, after reviewing the manufacturer plans, it believed there were potential advantages to having all manufacturers in the Pilot using the same IT platform. In submitting and adjudicating rebate claims, covered entities would only need to acclimate to one IT service provider rather than multiple service providers with different digital platforms and rules of engagement. OPA believed a single IT platform would further minimize any perceived or actual burden on covered entities.

OPA Will Ensure Compliance and Evaluate the Pilot Program Moving Forward

47. Since announcing the approved manufacturer plans, OPA has met with various stakeholders to discuss the Pilot. Compliance and evaluation of the Pilot will be part of OPA's ongoing work. Compliance with 340B obligations by manufacturers and covered entities will be assessed through data reporting by the manufacturers and through audits for both covered entities and manufacturers. Evaluation of the Pilot will also be conducted through data and reports received from the participating manufacturers on the effectiveness of the model and covered entity and other stakeholder feedback.

48. OPA continues to encourage stakeholders to reach out with their questions and concerns, and OPA is engaging with trade organizations that represent covered entities and manufacturers regularly. OPA is collecting questions and regularly updating the OPA website that houses frequently asked questions to clarify issues that can be resolved prior to implementation.

49. OPA is also working closely with CMS to understand how the implementation of the Pilot may impact the Medicaid and Medicare programs. OPA is working with CMS to receive feedback from their stakeholders about how these stakeholders believe the Pilot is working.

50. Finally, OPA is designing a mechanism by which covered entities and manufacturer stakeholders can begin to submit their feedback once the Pilot is operational in January.

In accordance with 28 U.S.C. § 1746, I declare, under penalty of perjury, that the above information is true and correct to the best of my knowledge and belief.

Signed this 15th day of December 2025.

Chantelle V. Britton -S

Digitally signed by Chantelle V. Britton -S
Date: 2025.12.15 20:24:09 -05'00'

Chantelle Britton, M.P.A., M.S.
Director
Office of Pharmacy Affairs
Health Resources and Services Administration

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA,

Defendants.

Case No. 2:25-cv-00600-LEW

REPLY OF PROPOSED INTERVENORS ABBVIE INC., PHARMACYCLICS, LLC, ASTRAZENECA PHARMACEUTICALS LP, PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA (PHRMA), BOEHRINGER INGELHEIM PHARMACEUTICALS INC., AND NOVO NORDISK INC. IN SUPPORT OF MOTIONS TO INTERVENE

The motions to intervene filed by Proposed Intervenors—AbbVie Inc., Pharmacyclics, LLC, AstraZeneca Pharmaceuticals LP, Pharmaceutical Research & Manufacturers Association of America (PhRMA), Boehringer Ingelheim Pharmaceuticals Inc., and Novo Nordisk Inc. ("Manufacturers")—should be granted. As those motions demonstrate, Manufacturers are entitled to intervene as of right because this suit puts their concrete legal and financial interests immediately at stake. In the alternative, the Court should grant permissive intervention to allow Manufacturers to defend their interests. Plaintiffs' opposition does nothing to refute that showing.

I. THE COURT SHOULD GRANT INTERVENTION AS OF RIGHT.

A. Manufacturers' Concrete Interests Are Directly Threatened By Plaintiffs' Suit.

Manufacturers—not Plaintiffs—are the parties directly regulated by the challenged government action in this case. As the Supreme Court has explained in the analogous standing context, when a party "is himself an object of the action (or foregone action) at issue … , there is ordinarily little question" that the party suffers an injury. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561-62 (1992). So if anything, Manufacturers' interest in the suit is ***more*** direct than Plaintiffs', who are not directly regulated by HRSA's Pilot Program, but only by the private decisions that Manufacturers make downstream of that Program. Plaintiffs cite no case holding that a directly regulated party lacks a cognizable interest in a regulation's legality while collaterally impacted parties do have one. Plainly, Manufacturers' concrete interests are at issue here.

Nor do Plaintiffs dispute that Manufacturers are subject to competing statutory obligations that impose staggering costs—duplicate discounts to the tune of $4 billion on the one hand, or the risk of civil penalties of millions of dollars per day on the other. ECF 36-2 ¶ 30; 42 U.S.C. § 1320f-2(a)(2), (d). To avoid those harms, Manufacturers must determine which federally mandated price applies—the 340B price or the Maximum Fair Price (MFP)—and offer the lower

of the two. 42 U.S.C. §§ 1320f-6(c), 1320f-2(a)(5); ECF 36-2 ¶ 30. Those statutory obligations commence—and thus the threat of debilitating financial losses arises—in less than three weeks on January 1, 2026. If Plaintiffs are successful in this case, then Manufacturers will be exposed to statutory penalties or enormous duplicate discounts that they could never recover.

The harm to Manufacturers' concrete interests is real, not contingent. The rebate model endorsed by HRSA's Pilot Program is the only way for Manufacturers to accurately and efficiently prevent duplicate discounts, and thus comply with their statutory obligations, while avoiding statutory penalties or the loss of billions of dollars in improper discounts. ECF 36-1 ¶¶ 12-13; ECF 36-2 ¶¶ 10-11, 22. The launch of that Program, and Manufacturers' participation in it, is imminent. HRSA has formally approved Manufacturers' rebate models, which will commence on January 1, 2026.[1] *E.g.*, ECF 36-2, Ex. A. Manufacturers undoubtedly have a direct and substantial interest in the Pilot Program's fate, and that interest is more than sufficient to warrant intervention. *Daggett v. Comm'n on Governmental Ethics & Election Pracs.*, 172 F.3d 104, 110 (1st Cir. 1999).

Plaintiffs offer three arguments to sidestep those obvious risks. ***First,*** Plaintiffs speculate that the Pilot Program is unnecessary to avoid duplicate discounts, pointing out that Novartis's participation in the Pilot Program does not begin until April 1, 2026. ECF 76 at 3. That is beside the point. Novartis experienced a delay in approval due to technical issues; that does not mean that it will not suffer harm in the form of duplicate discounts during that delay. ECF 75-1 ¶ 19.

[1] For these reasons, *Pub. Serv. Co. of N.H. v. Patch*, 136 F.3d 197 (1st Cir. 1998), does Plaintiffs little good. *Patch* involved groups of New Hampshire residents, including non-profit citizen groups and merchant associations, who were consumers of electricity and sought to intervene in state electrical-utility proceedings. *Id.* at 203-04. The court found intervention unwarranted because the groups had an "undifferentiated, generalized interest in the outcome" of the proceedings; and "every electricity consumer in New Hampshire and every person who does business with any electricity consumer yearns for lower electric rates." *Id.* at 205. By contrast, Manufacturers' interests are unique to them. The general public does not sell pharmaceutical drugs subject to federal price regulations. Nor does any member of the general public have a Pilot Program plan approved by HRSA. Nor does any member of the general public seek the opportunity to implement a rebate model to address duplicate discounts across 340B and Medicaid and help prevent diversion of 340B drugs to patients not eligible for the 340B Program.

Any further delay in the implementation date would not be tolerable, even for Novartis. And whatever the situation faced by one company may be, Manufacturers have made clear ***they*** cannot avoid either paying statutory penalties or debilitating extra discounts absent the Pilot Program, meaning Plaintiffs' requested emergency relief would irreparably harm Manufacturers. *See Philip Morris USA Inc. v. Scott*, 561 U.S. 1301, 1304 (2010) (Scalia, J., in chambers) ("If expenditures cannot be recouped, the resulting loss may be irreparable."); *Am. Pub. Health Ass'n v. NIH*, 145 F.4th 39, 55 (1st Cir. 2025) (same).

Second, Plaintiffs try to say that Manufacturers' deduplication dilemma hinges on the "assumption" that covered entities will always seek both 340B and MFP discounts. ECF 76 at 3. But it is no mere "assumption" that Manufacturers will face overlapping discounts for the same drug transactions. Manufacturers must deduplicate discounts to achieve the correct prices. Congress set these obligations, and Plaintiffs cannot wave them away by calling it an "assumption" that Manufacturers will face the very situation contemplated—and prohibited—by Congress.

Plaintiffs' argument is also inconsistent with how the 340B and MFP systems work in practice. Right now, Plaintiffs typically receive the 340B price at the time they purchase medications. The 340B medicine is shipped to the covered entity's pharmacy (or its contract pharmacy), which places the medications in its single, common inventory and sells them to patients, including 340B patients and non-340B patients, at commercial prices. After the dispense is determined to be 340B-eligible, a replenishment order is placed and the 340B drug is shipped to the pharmacy. *See Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 457 (D.C. Cir. 2024) (describing these practices). Beginning in 2026 for IRA-selected drugs, those pharmacies, as "dispensing entities," will submit data to the Medicare Transaction Facilitator (MTF); and Manufacturers will use that post-dispensing transaction data to determine whether the MFP

applies.[2] Plaintiffs—who are a group of ***some hospitals***, not pharmacies—are in no position to prevent all "dispensing entities"—not hospitals—throughout the Nation from submitting duplicative discounts on claims submitted to the MTF. In other words, Plaintiffs cannot represent to the Court that they themselves will prevent deduplication from occurring.

Third, Plaintiffs suggest that with no way to deduplicate discounts, Manufacturers can simply rely on the government to abstain from enforcing the statute and seeking millions in civil penalties. They have no basis for that speculation. Manufacturers cannot afford to make a multi-billion-dollar gamble that the government will do nothing if it believes manufacturers are violating federal law. To the contrary, courts "presume that the government will enforce the law." *Cayuga Nation v. Tanner*, 824 F.3d 321, 331 (2d Cir. 2016); *see also FCC v. Schreiber*, 381 U.S. 279, 296 (1965) (noting the "presumption" that federal agencies "will act properly and according to law").[3]

B. Manufacturers' Interests Are Not Adequately Represented.

Manufacturers' interests are not adequately represented by the government. On this point, Plaintiffs gloss over the proper legal standard. The Supreme Court, the First Circuit, and this Court have made clear that an intervenor need only show that government representation "***may*** be inadequate, not that it ***is*** inadequate." *Conservation L. Found. of New England, Inc. v. Mosbacher*, 966 F.2d 39, 44 (1st Cir. 1992) (citing *Trbovich v. United Mine Workers*, 404 U.S. 528, 538 n.10

[2] Centers for Medicare and Medicaid Services, *Medicare Transaction Facilitator (MTF) for Dispensing Entities*, https://tinyurl.com/2bbutmaw.

[3] Plaintiffs' last-ditch contention that Manufacturers' interest is somehow "contingent" on other state lawsuits lacks merit. Manufacturers have been accepted into a government program—a "here-and-now" legal interest—and this lawsuit seeks to undo that. If states are passing laws that also burden participation in the Pilot Program, that does not make Manufacturers' interest contingent. And in any event, Manufacturers are successfully litigating preemption challenges against those state laws based on the Pilot Program. *See, e.g.*, *AbbVie Inc. v. Neronha*, No. 1:25-cv-388 (D.R.I. Sept. 12, 2025), ECF 18 at 38 (Rhode Island conceding that, "by its own terms, [Rhode Island's law] will pose no obstacle to AbbVie's ability to participate in the Rebate Pilot Program"); *PhRMA v. Arel*, No. 2:25-cv-600 (D. Vt. Sept. 2, 2025), ECF 22 at 12-14 (Vermont consenting to an injunction of its rebate-model prohibition); *id.*, ECF 46 at 13 (Vermont conceding that its law "does not restrict data requests if the claims or utilization data sharing is required by HHS, which will be the case under any rebate plans HHS approves" (cleaned up)).

(1972)) (emphasis added); *see also McDonough v. City of Portland*, 2015 WL 3755289, at *4 (D. Me. June 16, 2015) ("It is apparent that [a private party's] interests are sufficiently different from [the City of] Portland's and that Portland's representation *may* be inadequate because Portland must account for a spectrum of governmental interests far broader than the discrete commercial interests [the private party] seeks to protect.").

Manufacturers have overcome the "low hurdle" necessary to show inadequate representation. *Canadian Nat'l Ry. Co. v. Montreal, Me. & Atlantic Ry., Inc.*, 2010 WL 5168003, at *7 (D. Me. Dec. 14, 2010); *McDonough*, 2015 WL 3755289, at *3 (burden to show potentially inadequate governmental representation "not onerous"). Manufacturers have commercial interests that differ from the federal government's. And Manufacturers offer a unique perspective on the Pilot Program's operation because they are the ones that will operate under the Program. Further still, Manufacturers—not Plaintiffs—are the parties who have the actual evidence of the real-world impact of the Program (or its absence), which bears on the equitable and public interest factors of injunctive relief, as well as the merits. Manufacturers also have a unique perspective on deduplication in general, as the government has made clear it will not undertake the work necessary to deduplicate 340B and MFP discounts; that burden will fall on Manufacturers alone. Thus, Manufacturers "certainly [have] more to lose" than the named defendants here. *B. Fernández & Hnos., Inc. v. Kellogg USA, Inc.*, 440 F.3d 541, 547 (1st Cir. 2006). And Manufacturers have an interest "different in kind" from the government's. *McDonough*, 2015 WL 3755289, at *3.[4]

[4] Plaintiffs also insist upon an undefined, heightened standard for intervening when the government is a party. In doing so, they casually brush aside *Berger v. N.C. State Conf. of the NCAAP*, 597 U.S. 179, 195-98 (2022), where the Supreme Court cast serious doubt on a "presumption" of adequate governmental representation or on courts imposing a heightened standard in such cases. The Supreme Court itself has never applied Plaintiffs' preferred test; instead, the Court has long "held that a movant's burden [to intervene along the government] 'should be treated as ***minimal***.'" *Id.* at 196 (quoting *Trbovich*, 404 U.S. at 538 n.10 (emphasis added)). The cases from this District cited above are consistent with *Berger* and *Trbovich*. By contrast, Plaintiffs' Rule 24 caselaw—all of which predates *Berger*—is no longer a reliable guide to assessing intervention motions like this one. *See Cuevas v. United States*, 778 F.3d 267, 272-73 (1st Cir. 2015) (noting that this Court follows Supreme Court dicta).

Further, Manufacturers and the government do not see eye-to-eye on all 340B rebate issues. The briefing already filed here underscores that point. Manufacturers provide distinct evidence and arguments regarding the harm that would result if the Pilot Program were enjoined.[5] And the government is alone in arguing that application approvals are committed to its unlimited, "unreviewable" discretion. While the government emphasizes the limited scope of this Pilot Program, Manufacturers have an interest in defending rebate models broadly. Moreover, the government's "candor in taking no position on the petition for intervention" supports Manufacturers' position that the government is unlikely to represent their independent "special interests[.]" *Mosbacher*, 966 F.2d at 44; *see* ECF 74. Finally, if an injunction is granted, the government will continue to implement the relevant statutes and be relatively unaffected, while Manufacturers will lack an adequate mechanism to deduplicate discounts.

II. THE COURT SHOULD GRANT PERMISSIVE INTERVENTION.

Alternatively, the Court should grant permissive intervention. The Court has "broad discretion" to "consider almost any factor rationally relevant," like how a party's "own resources, expertise and personal experience" can shed additional light on the legal issues and "develop[] the case" in ways that the government might not. *Daggett*, 172 F.3d at 113; *see Dinner Table Action v. Schneider*, 2025 WL 604885, at *2 (D. Me. Feb. 25, 2025). Manufacturers will do just that. The Court will benefit from their expertise and experience operating within the 340B Program.

Permissive intervention is particularly appropriate in this case. Covered entities (like Plaintiffs) are repeat players that have successfully intervened in 340B-related cases around the

[5] Contrary to Plaintiffs' suggestion, extra-record evidence is permitted in APA cases to address the equitable factors relevant to determining whether to grant injunctive relief. *See, e.g.*, *Am. Sci. & Eng'g, Inc. v. Kelly*, 69 F. Supp. 2d 227, 235 n.13 (D. Mass. 1999) ("Evidence outside the record may be looked to, however, in cases where relief is at issue, especially at the preliminary injunction stage' . . . ." (quoting *Esch v. Yeutter*, 876 F.2d 976, 991 (D.C. Cir. 1989))).

country on the side of state officials.[6] Covered entities often make the same arguments in support of their own intervention that Manufacturers make here—for example, claiming that they offer a unique perspective on the 340B Program and that the government would not adequately represent their private, commercial interests.[7] In light of that, they can hardly complain about permissive intervention by Manufacturers in this case. "After all, in the law, what is sauce for the goose is normally sauce for the gander." *Heffernan v. City of Paterson*, 578 U.S. 266, 272 (2016).

Finally, Manufacturers will not delay this case's proceedings. The Court "retains the authority to govern the progress of the case," and intervention will not "impede progress or diffuse the focus of the case." *Canadian*, 2010 WL 5168003, at *8. Manufacturers will continue to comply with whatever schedule the Court sets and present their arguments in a coordinated and efficient manner.

CONCLUSION

The motions to intervene should be granted.

[6] *See e.g.*, *AbbVie Inc. et al. v. Murrill*, 6:23-CV-01307, ECF 58, (W.D. La. Mar. 7, 2024); *Pharmaceutical Research and Manufacturers of America v. Bailey et al.*, 2:24-CV-04144-MDH, ECF 60 (Nov. 25, 2024); *AstraZeneca Pharmaceuticals LP v. Bailey et al.*, 2:24-CV-04143-MDH, ECF 67 (W.D. Mo. Nov. 15, 2024); *Novartis Pharmaceuticals Corp. v. Bailey et al.*, 2:24-CV-04131-MDH, ECF 62 (W.D. Mo. Nov. 14, 2022); *Pharmaceutical Research and Manufacturers of America v. McClain et al.*, 4:21-CV-00864, ECF 22 (E.D. Ark. May 3, 2022); *AstraZeneca Pharmaceuticals LP v. McClain*, 4:24- CV-00268, ECF 50 (E.D. Ark. Aug. 13, 2024); *Pharmaceutical Research & Manufacturers of America v. Landry*, 6:23-CV-00997, ECF 26 (W.D. La. Nov. 8, 2023); *AstraZeneca Pharmaceuticals LP v. Landry*, 6:23-CV-01042, ECF 29 (W.D. La. Nov. 9, 2023); *see also Eli Lilly & Co. v. Kennedy*, 2025 WL 1423630, at *1 (D.D.C. May 15, 2025) (noting several covered entities' intervention in suit brought by manufacturers against the government).

[7] *See, e.g.*, *AbbVie Inc. et al. v. Murrill*, 6:23-CV-01307, ECF 30-1 (W.D. La. Jan. 19, 2024) at 15-16 ("Although [Louisiana Primary Care Association]'s interest in defending and enforcing [a state law regulating the 340B Program] may appear to align with the interests of the [government] Defendant, the Defendant also does not adequately represent the interests of LPCA and its members. … Defendant's interests are not … wholly aligned with LPCA members' interests. … Finally, LPCA can provide the Court with the unique perspective of community-based 340B covered entities, … a perspective which neither Plaintiffs nor Defendant can offer because they are not health care providers.").

Dated: December 17, 2025

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was electronically filed with the Clerk of the Court via the Court's CM/ECF system, which sent notification of such filing to all counsel of record by electronic means.

/s/ Matthew S. Owen, P.C.
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. ROBERT F. KENNEDY, JR. SECRETARY of the U.S. Department of Health and Human Services, *et al.*, Defendants.	No. 2:25-cv-600-LEW

NOTICE REGARDING PORTIONS OF THE ADMINISTRATIVE RECORD

On December 19, 2025, this Court heard argument on Plaintiffs' motion for a preliminary injunction, Doc. No. 3, in the above captioned matter. The Court had questions about the Administrative Record and what it would show, so Defendants have compiled a sample of some of the materials that will be included in the Administrative Record to give the Court a better sense of the depth of the agency's consideration of the issues, as further articulated in the declaration submitted with Defendants' preliminary injunction opposition, *see* Decl. of Chantelle Britton, Doc. No. 71-1. These materials are not comprehensive; Defendants will compile a complete Administrative Record and produce a certified index of that record at the appropriate time.

Defendants also respectfully submit that, even if the Court were to find a failure to comply with the Administrative Procedure Act at final judgment, the appropriate remedy would be to remand to the agency for further consideration or explanation without setting aside the agency's decisions. *See Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985) ("[T]he proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation."); *Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 60 (D.C. Cir. 2015) ("[B]edrock principles of administrative law preclude us from declaring definitively that the Secretary's decision was arbitrary and capricious without first affording her an opportunity to articulate, if possible, a better explanation" (citation

modified)); *see also Town of Weymouth v. Massachusetts Dep't of Env't Prot.*, 973 F.3d 143, 146 (1st Cir. 2020) (remanding without vacatur); *Central Maine Power Co. v. FERC*, 252 F.3d 34, 48 (1st Cir. 2001) ("A reviewing court that perceives flaws in an agency's explanation is not required automatically to set aside the inadequately explained order."). Because that is the relief Plaintiffs would theoretically be entitled to at final judgment, it is not appropriate to grant the broader relief of enjoining the agency's decisions at this preliminary stage. In other words, because a preliminary injunction is meant to preserve the status quo until a court can grant an effective remedy, *see Delaware State Sportsmen's Ass'n, Inc. v. Delaware Dep't of Safety & Homeland Sec.*, 108 F.4th 194, 200–01 (3d Cir. 2024), any preliminary relief should not go beyond what Plaintiffs may be entitled to at final judgment.

Dated: December 22, 2025

Respectfully submitted,

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UNITED STATES DISTRICT COURT

DISTRICT OF MAINE

_____

AMERICAN HOSPITAL ASSOCIATION et al.,
Plaintiffs

CIVIL ACTION
Docket No: 2:25-cv-00600-LEW

-versus-

ROBERT F. KENNEDY, JR., SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,
Defendants

_____

Transcript of Proceedings

Pursuant to notice, the above-entitled matter came on for **Oral Argument** held before **THE HONORABLE LANCE E. WALKER**, United States District Court Judge, in the United States District Court, Edward T. Gignoux Courthouse, 156 Federal Street, Portland, Maine, on the 19th day of December, 2025 at 11:03 a.m. as follows:

Appearances:

For the Plaintiffs: Lawrence (Rush) Atkinson, Esquire
Melissa Hewey, Esquire
Jenifer N. Hartley, Esquire

For the Defendants: Elisabeth Neylan, Esquire (Via Zoom)

Tammy L. Martell, RMR, CRR
Official Court Reporter

(Prepared from manual stenography and computer-aided transcription)

(Open court.)

THE COURT: Good morning, everyone. We're here in the matter of the American Hospital Association, et al., versus Robert F. Kennedy, Jr., Secretary of the U.S. Department of Health and Human Services, et al. This is civil case No. 2:25-cv-600-LEW.

Counsel, could I have you all enter your appearance for the record, please, starting with the plaintiffs.

MR. ATKINSON: Good morning, Your Honor, Rush Atkinson on behalf of the plaintiffs. With me at counsel's table is Melissa Hewey and Jenifer Hartley.

THE COURT: Good morning.

MS. NEYLAN: Good morning, Your Honor, Elisabeth Neylan on behalf of the United States.

THE COURT: Good morning. All right. I'll hear from the plaintiffs. My understanding is from since way back when two days ago when I inherited this case, my understanding is that the parties -- this came to the Court on a motion for temporary restraining order, but as the Government, I think, indicated, maybe all counsel did, that the attorneys have conferred and we're proceeding to litigate the motion for TRO as a preliminary injunction motion.

MR. ATKINSON: That's correct, Your Honor.

THE COURT: Great.

MR. ATKINSON: So, Your Honor, good morning. We --

the plaintiffs here are seeking a preliminary injunction because the Government's new program, a sea change in a 30-year status quo, plainly violates the APA and would cause irreparable harm to safety net hospitals across the country like St. Mary's Medical Center.

The unrebutted declarations before the Court explain that the average Maine hospital has less than 11 days of cash on hand. For many, that money and its operating capital come from the 340B program. It's used to fund programs like opioid addiction treatment, mental health services, and other needs for underserved patients.

So the defendants are trying to unlawfully enact a program that would impose hundreds of millions of dollars in costs upon safety net hospitals, and that would mean cuts to services provided via the 340B savings. And that's already started happening, Your Honor, because money to fund those services is now having to be diverted in anticipation of this new administrative burden set to take real effect on January 1st.

As Your Honor wrote in the -- in the opinion issued yesterday, this case relies entirely on the administrative record, and that is a nonexistent record. It is a threadbare notice and a few nonresponsive FAQs. And so instead what the defendants have done is tried to submit a post hoc declaration, which the Supreme Court has repeatedly explained cannot fill the gap. So every point in that litigation affidavit just

illustrates how the defendants failed to reasonably explain the actual record.

THE COURT: You're referring to the Britton declaration?

MR. ATKINSON: That's correct, Your Honor. And so even the Britton declaration wouldn't save this record because it concedes that they -- they failed to consider costs. That alone would warrant the entry of a preliminary injunction based on State Farm and the Supreme Court's case in Michigan v. EPA.

Calling a program a pilot, like the defendants try to argue, doesn't save the -- it doesn't save it from the legal requirements of the APA, and it's actually not accurate here.

This change affects every safety net hospital in the country that participates in the 340B program. And this isn't some tiny experiment which is made a little bit more obvious through the fact that the number of drug companies that wanted to intervene in this case.

So plaintiffs here, Your Honor, are only asking to preserve a 30-year status quo temporarily. And we believe, Your Honor, this case can be heard expeditiously on the merits, likely in time for the second April -- second deadline that defendant HRSA has selected, which is April 4th, 2026. We think we can do this case in that time period. And that's all we're asking for today, Your Honor.

So as Your Honor noted, the parties have agreed to

litigate this as a motion for a preliminary injunction, but the -- the standard is the same as the TRO. The four part -- it's a four-part test, the most important of which is likelihood of success on the merits. And here the plaintiffs are extremely likely to prevail on the merits given the numerous APA violations.

I have sort of put them into five buckets, Your Honor: The failure to address cost; the failure to provide a reasonable explanation contemporaneously; the failure to provide more detailed justification for a -- a change in policy as required under Supreme Court precedent; the failure to consider other important aspects of the problem; and the failure to consider obvious and less burdensome alternatives.

And so -- but based on the admissions in the Government's response filed this week, the most straightforward violation is probably the failure to appropriately consider costs.

The Government did not address costs in its notice or in its FAQs. It has a $200 million calculation of administrative -- $200 million calculation of administrative costs in a memo that the defendants sent OMB in August of 2025, but it doesn't have any explanation of how it calculated or why it calculated it that way. $200 million in administrative costs is both stunning and a wild undercount.

So many of the 1,100 comments that Defendant HRSA received noted the administrative burden was going to be much much

higher, and defendants never responded to any of those -- those comments publicly, and that threadbare notice in fact wrongly said that it didn't have to respond. But what this week's declaration conceded was that they didn't even consider those costs at the time before approving the drug -- the drug companies' rebate programs on October 30th and November 14th.

The litigation affidavit at paragraph 35 says that they are, quote, currently examining the comments alleging an underestimation of administrative costs. That's just another way of saying they didn't consider the costs at the time. And that --

THE COURT: So they're saying that they're in the process of considering those costs but they were not considered before implementing the rebate program.

MR. ATKINSON: Exactly right, making the final agency decision that's reviewable here, and that should end the inquiry under State Farm. The Supreme Court in Michigan v. EPA held an agency must consider cost including, most importantly, cost of compliance, before deciding whether regulation is appropriate and necessary. That's at 576 U.S. 759.

And, you know, there are other courts like Mexican Gulf Fishing, a Fifth Circuit case, 60 F.4th at 973, that talk about the inner -- the importance of cost in the context of State Farm.

That is really enough for this Court to consider for

purposes of our motion today, but of course that's not the only failure here.

The defendants have tried to save itself by offering this Britton declaration, but let me start by saying the FCC -- the Supreme Court in FCC versus Prometheus Radio Station [sic] says a decision has to be both reasonable and reasonably explained, and Director Britton's post hoc rationalization is clearly impermissible.

The Supreme Court most recently in DHS v. Regents of University of California but going back to Overton Park, have said that post hoc rationalizations via affidavits cannot substitute for contemporaneous decisionmaking. And that's because the contemporaneous decisionmaking needs to be reviewed by a court and a party -- and the parties and avoid a moving target.

THE COURT: Should I not consider the Britton declaration at all or should I consider it for the limited purpose of demonstrating how badly the government -- the agency failed to comply with the APA?

MR. ATKINSON: So it can be both, Your Honor. It can be -- it can be -- there is a concession in there that you can consider, but for purposes of substituting judgment if it cannot produce a contemporaneous decisionmaking record, that is -- that is -- does not fill the gap under FCC v. Prometheus Radio Station [sic]. So, you know, that is -- that's the

second APA violation.

The third here is that this involves a change in policy. Defendants are not writing on a blank slate, and when that happens the Supreme Court has been extremely clear in multiple Supreme Court decisions over the last ten years, in Encino Motorways v. Navarro [sic], in FCC v. Fox Television Stations, and again in the Regents case, that when that happens a switch in policy requires a, quote, more detailed justification.

It's not a heightened burden of proof, Your Honor, but it does -- it's a requirement to say more about the agency's thinking than it otherwise would if it was writing on a blank slate.

So the justification requires, one, identifying the engendered reliance interests from the old rule; two, measuring the significance of those reliance interests; and three, measuring those reliant interests against the competing policy.

So here that would involve thinking about, for example, how rural hospitals have relied on upfront discounts for budget reasons or managed cash on hand. Here there is nothing, not even in the Britton declaration, that does that. And the only detail justification that the defendants point to is one single sentence in the contemporaneous record that rebates could, quote, fundamentally shift 340B policy. That's not even a -- that's not even a justification, that's just an observation. And so they have just utterly failed, under the Supreme Court

precedent, to provide that more detailed justification.

So the last two points, Your Honor, about -- of APA violations are that the Government has -- or the Government, as the Britton declaration highlights, they just haven't addressed other significant aspects of this problem as required under State Farm.

They haven't contemplated, for example, nonmonetary costs for access to medication by patients. They haven't considered dispute resolutions. In fact, there is another concession in the Britton declaration that they have not set up a dispute res -- resolution mechanism, even though they told the drug companies last year that that was something that was critical to any rebate model.

They also --

THE COURT: How is that relevant to my analysis of the argument now, the fortuity that they took a particular position in litigation, how does that impact the resolution of the pending motion?

MR. ATKINSON: So, Your Honor, you don't need to reach it. There are just multiple -- there is a multi, you just consider would this improve the plaintiffs' likelihood of success on the merits, that's it. And so given the I think the five buckets of APA violations, I think the plaintiffs plainly established they're very likely to prevail on that -- on that prong.

So -- and I think the only one I'll hit very briefly is just similar to the failure to address important aspects of the problem, they haven't considered the reasonable alternatives.

The only thing that we see is a post hoc justification from the Britton declaration about why they didn't consider a less massive pilot program. You know, why not -- why do you have to choose ten of the largest and most expensive drugs in America to, quote, a pilot program to see if this rebate works. There is no explanation in the contemporaneous record. There is a post hoc justification that, you know, minimal in the declaration, but that's not -- that should not be considered by Your Honor.

So, taken in sum, the Government -- the -- the Government has utterly failed its duties under the APA and so the plaintiffs are very likely to proceed -- to succeed on the merits, which then leads us to the other questions of -- the other questions of -- other four prongs, you know.

With respect to --

THE COURT: Can we -- before we move on --

MR. ATKINSON: Yeah.

THE COURT: Are we ready to move on from the merits argument?

MR. ATKINSON: I am, Your Honor.

THE COURT: Okay. Let me, before you do that, I have got a couple of questions about that. So as you know in these

types of cases reasonableness is a very low standard that most agencies take fulsome advantage of when they're promulgating rules or making changes to policy, and as I was reading the plaintiffs' submissions it struck me that claims on improper calculations or under analyzed costs, aren't those really impermissibly elevating the standard for whether the agency acted arbitrarily or capriciously?

MR. ATKINSON: No, Your Honor, they're not. There are sort of two -- two points to that. One is under Prometheus in the Supreme Court's decision it's not just reasonable, it has to be reasonably explained. So right now what Your Honor should really be focussed on is what was said contemporaneously, what was the thinking. No public -- no post hoc rationalizations.

THE COURT: Is that what you're focused on?

MR. ATKINSON: I would say that's the first prong because there is nothing for us, as plaintiffs, to object to. Your Honor is like, well, what is the standard for reasonableness? It is -- there is -- it's a relatively low standard, but plaintiffs get to argue, based on the record that is put before them, that the Government still has not met that standard. Here we have nothing to argue against because nothing was said and nothing has been said that is admissible for the purposes of the administrative record.

THE COURT: And my understanding from the submissions

is that what we can expect by way or what qualifies as a reasonable explanation is amplified if there is introduced the idea of a reliance interest in -- in the change; is that right?

MR. ATKINSON: It's -- it's exactly right. The justification certainly has to be more fulsome.

THE COURT: All right. Can you elaborate for me your argument about the less burdensome alternatives. As I understand it at least, doesn't the agency just have to consider those alternatives, not that it has to seize upon the alternatives that the plaintiffs prefer?

MR. ATKINSON: No, it certainly doesn't have to select just by default the alternatives that the plaintiffs prefer. It does have to consider and explain them. Here there is sort of two sets of alternative -- less burdensome alternatives that should have been considered, at least.

One is one that is less burdensome vis-a-vis the number of drugs that are involved, and why do you need to use all ten versus one or versus a drug that isn't one of the ten most expensive under Medicare? Two -- I guess there are actually three, Your Honor. Two is why choose -- why do all 14,600 340B providers have to be involved in this, quote, unquote, pilot? That's not typically how a pilot is implemented. It's implemented in a discrete fashion either on a voluntary basis or other some smaller subset. The drug companies got to volunteer in, but it's compulsory for any 340B provider. So

why does it have to be that way? There is no explanation for why 14,600 people have to -- have to be -- or 14,600 providers have to be included.

THE COURT: So your argument presently isn't so much about the substantive reasonableness of that agency decision, it's that it wasn't appropriately or properly explored and explained by the agency?

MR. ATKINSON: Correct. I think, Your Honor, there is no -- there is no real record -- I mean there are some -- there is something that we can sort of glance at, but the majority of the plaintiffs' case right now is that we should be able to see the agency's thinking, see the agency's as explained contemporaneously as required, so that we can then make a substantive case against here, a most substantive case.

THE COURT: All right. And so what evidence is there -- I guess your argument -- so I had a question regarding the evidence that the agency didn't even consider what the plaintiffs characterize as, quote, a host of important parts of the problem including less burdensome alternatives, all the issues that we've been talking about, the IT difficulties, the ADR process that the agency offers that they're going to stand up and -- and analyze. Those sound to me like policy arguments ultimately. I just want to button that down a bit. You're not asking me to resolve those policy arguments by substituting my admittedly limited knowledge in this area for that of the

agency, what you're saying is, is that they haven't -- they, the agency, it hasn't offered any reasoned explanation for the change; is that right?

MR. ATKINSON: Exactly right, Your Honor. We're only asking that -- we would not ask you to substitute your own policy judgment, that's not the proper role of this Court in the -- for those matters. What we are asking you is to assess whether they have fulfilled the A -- their requirements under the APA to show -- demonstrate both reasonableness in their policymaking, so the outer bounds, but really the most important thing here is was it reasonably explained. That's -- for the purposes of the TRO, that should be the main focus of the Court, I would recommend.

THE COURT: All right. Could you touch on irreparable harm for me, because I'm interested about that.

MR. ATKINSON: Yes, of course, Your Honor.

So, Your Honor, the parties absolutely agree that this program will impose at minimum hundreds of millions of dollars of costs on the covered entities. That's a pretty stunning total for a program that only covers ten drugs. Plaintiff AHA has submitted that its estimate for its members is actually $400 million next year in administrative burden costs.

The three -- three of the individual plaintiff hospitals in this case, including St. Mary's, have submitted declarations that they will have to hire full-time employees just to deal

with this administrative burden. One of the plaintiffs, Unity Health Center, estimates the compliance costs for it -- its small facility to be about a hundred thousand dollars. That's 20 percent of its entire 340B savings for the year.

So the Supreme Court held this year in NIH v. American Public Health Association that the loss of money is typically not considered irreparable harm but that changes if the funds cannot be recouped and thus are -- are thus irrevocably expended. That's at 145 S. Ct. 2658. And because this is an APA case, Your Honor, there is no way to recoup those costs against the Government, and so that would qualify under NIH as irreparable harm, a hundred -- you know, hundreds of millions of dollars for -- for the plaintiff hospitals here.

There is also a second nonmonetary harm that is absolutely irreparable in this case, and that's the impact that these -- this program is going to have to services. St. Mary's is going to, as demonstrated -- or as explained in its declaration, is faced with having, based on the cut and these -- these burdens of the 340B program, it's going to force it to eliminate -- limit and discontinue free drug infusion programs in their behavioral health services.

Plaintiff Dallas County Medical Center has already suspended a program for mental health in schools and it's going to have to be -- it's looking like it's going to have to cut an unprofitable service line like remote oncology services.

There's also a -- a separate set of harms to the plaintiffs participation in the 340B program and that's it's partnerships with pharmacies that allow it to expand its reach. Pharmacies like Walgreens and Walmart. And what we submitted to Your Honor in the reply brief, along with another declaration, is sort of late-breaking news. That these large pharmacies have announced that they're going to suspend their partnerships with hospital -- with 340B hospitals, meaning that 340B -- hospitals are not going to be able to distribute their 340B drugs through these two of the largest pharmacies in America. That's going to have devastating effects on their ability to recoup -- to qualify 340B savings, to capture that. And that's another type of serious irreparable harm that's going to happen on January -- well, on January 1st.

So I think, Your Honor, there is more than enough evidence in the record to establish irreparable harm here on this particular case.

Relatedly on the balance of equities, I just don't --

THE COURT: Before you move on --

MR. ATKINSON: Yes.

THE COURT: -- I apologize, let me ask you a couple of questions about irreparable harm. So there are two related topics that interest me here, and one is I understand your argument regarding why categorically the harm that might befall the plaintiffs is irreparable, meaning not able to be

recovered, should it be determined that the rebate program is unlawful. I want to explore the idea of speculative damages.

It seems to me that a component part of the damages claimed by the plaintiffs is, it may be realistic or cynical depending on how one looks at it, that the plaintiffs are going to be put in the position of perhaps having to wait on slow payments for the rebates or be entangled in a situation in which the pharmaceutical company denies payment for one reason or another and then of course the ensuing agency ADR process, for lack of a better term.

I would like to know how those aren't speculative damages?

In other words, they project, and quite understandably, the frustration that will come along with plaintiffs having to stand up something like a series of claims departments to process those payments, and I'll get to the administrative cost of doing that. But separately I would like you to address how those aren't to be considered speculative in nature.

MR. ATKINSON: So I think, Your Honor, the -- the delay, the inevitable delay that we all concede will happen for payments, so let's call that the carry cost, right, I -- there is at least a ten-day window.

THE COURT: Mm-hmm.

MR. ATKINSON: That is not speculative because that we can all -- we all -- I think all parties can see that it will happen by design, so that's a cost that can be considered.

THE COURT: So the float. The float.

MR. ATKINSON: The float, the float, Your Honor, yes, exactly.

THE COURT: Right.

MR. ATKINSON: The float is certainly, you know, undoubtedly true, whether it's, you know, $54 billion over ten days or $54 billion over however many other days, that's really beside the point, but the float itself, the size of the float set aside, it certainly is a cost to be considered.

The -- whether or not there will be chicanery by the drug companies and they'll slow roll, I don't think you need to reach that, Your Honor. I don't think there -- I think there are other harms that are more irreparable and more -- and more immediate that you can -- that satisfy irreparable harm here.

THE COURT: All right. Thank you.

MR. ATKINSON: Your Honor had a question about administrative costs or sorry?

THE COURT: No. No, I don't, thank you.

MR. ATKINSON: Okay. Your Honor, on the -- on the balance of equities in the public interest, I think that's relatively straightforward here. The public interest -- the defendants don't contest that there is no public interest in continuing unlawful agency action. There is obvious public interest in making sure government agencies follow the rules that they're -- that govern their actions, but here there's

also a second public interest not to interfere with patient care. I would cite you to the First -- First Circuit's opinion in Rio Grande Community Health Center v. Rullan, 397 F.3d at 77 for that.

And then in terms of the equities, Your Honor, again the plaintiffs here are just trying to maintain the status quo, it's a 30-year status quo, while this Court fully considers the merits of the -- of the case. That's the quintessential purpose of a preliminary injunction, to -- to freeze the status quo in place.

And moreover, in this particular case Defendant HRSA has approved part of the program to go into effect on April 4th, and that's -- as I said at the beginning of my remarks, Your Honor, we believe the merits in this case can be decided by then.

THE COURT: All right. Can you talk to me about the -- whether the harm that the bene -- the plaintiffs project will be the result of the rebate program, whether they can be characterized as substantial? And by that I mean sort of a more qualitative effort than I saw in the papers to explain how, for example, those costs, whether they be the administrative costs or the float costs, would threaten to, say, shutter the business of any of the plaintiffs.

MR. ATKINSON: Yeah, Your Honor, I want to -- that's a good point, Your Honor, I should have addressed it. First off,

the -- the Government's brief makes it sound like imminent, you know, closure of a hospital is the standard for irreparable harm. That's not at all what it is; it's substantial costs.

I think, Your Honor, for purposes of this -- of this case, you know, the parties agree that hospitals are going to -- to accumulate millions of dollars of burden in administrative costs and -- and the float every week. That is -- that's conceded. The $200 million estimate from the -- from the -- the defendants alone would make that, and its unrefuted that AHA's calculation of $400 million is unrefuted in the record.

How does that $400 million, like what does that mean? It means that they're going to have to hire employees to track every distribution of a drug and make sure that it's logged correctly, that it's entered into this new platform, and that they then have to chase the drug companies for the rebate. I mean it's -- it's going to be a massively administrative, time-intensive process that's not going to be able to be done in two hours, as even the $200 million projection sort of assumed, it's going to be multiples of that. You're -- the stakes will be so high there will be for every single plaintiff it's going to be millions of dollars of money.

They can't just like, you know, do it on a whim or do it on a wing, they've got to actually hire full-time employees to make sure that they are correctly documenting the 340B drugs, making sure they're being administered. As soon as they've

been administered, putting those -- you know, putting that claim into the rebate -- into the rebate machinery of the software. So I think that is -- that is what the -- that's how you get to, you know, hundreds of millions of dollars so fast, because the stakes are so high.

THE COURT: So I don't want to be overly punctilious on the point --

MR. ATKINSON: Yes.

THE COURT: -- but millions of dollars means a lot to me, I'm just wondering --

MR. ATKINSON: Oh, sure.

THE COURT: -- comparatively speaking.

MR. ATKINSON: Let me --

THE COURT: Yes.

MR. ATKINSON: That's fair. Let me give you a sense of like what it means on the micro level --

THE COURT: Yes, thank you.

MR. ATKINSON: -- for these particular plaintiffs.

THE COURT: Mm-hmm.

MR. ATKINSON: So defense -- or Plaintiff Dallas County Medical Center saves about 1.1 million annually through the 340B program. They use that money to do things like replace the roof on its center. They're trying to break even this year. They haven't made a profit since COVID. They're going to have to hire two full-time employees for the rebate

program and in -- and then they're also going to have to pay increasing vendor fees.

That increased cost -- so those costs are going to make -- force them to cut unprofitable service lines, like remote oncology clinic. There is just no money. And delay -- they're going to have to delay things like $35,000 to fix a boiler in their maintenance room. That's in -- I can point you to the docket entry eight, that's the DCMC declaration.

For St. Mary's, St. Mary's lost about $4 million last year and it's about to project a similar loss this year. It saves about 3.3 million annually through 340B. And so hiring a full-time employee, which again we're talking about probably a hundred thousand dollars, is going to cut into its 340B savings and force it to limit and discontinue services.

So we are talking about hospitals, these are rural hospitals, Your Honor, safety net hospitals, they are operating on the most razor thin of margins. A hundred thousand dollars means a lot to you and me, and it also means a heck of a lot to these individual plaintiffs here.

THE COURT: All right. So --

MR. ATKINSON: Umm.

THE COURT: Pardon me.

MR. ATKINSON: Oh.

THE COURT: Go ahead.

MR. ATKINSON: Sorry, I would just point you to one

other fact or one other data point in the record. This is in the docket entry four at paragraph nine from the Maine Health -- Hospital Association.

THE COURT: Mm-hmm.

MR. ATKINSON: 94 percent of Maine's hospitals are at medium or high risk of closure based on '93 -- 2023 financials. So it's not just these individual plaintiffs where a hundred thousand dollars or a million dollars means something, it's to most hospitals in the State of Maine.

THE COURT: All right, thank you. How -- how should I weigh -- as a related question, how should I weigh the benefit plaintiffs receive from the 340B discounts against the additional administrative costs?

MR. ATKINSON: Yeah, I was -- I was pretty stunned by that argument in the Government's brief. That was not --

THE COURT: Stunned because it was so good or?

MR. ATKINSON: No, it's because that's absolutely not considered. It's not say like, oh, you can take it. That's not a -- that's not an argument for -- for administrative law. And they've cited no case to that. They've cited no principle.

This is a program enacted by Congress to do exactly -- to help give a lifeline to safety net hospitals.

The idea that, you know, there's some -- I won't use a pejorative, but I can think of a few that -- you know, for people that benefit from the Government subsidy that are

providing the service is absolutely incorrect, Your Honor, and I don't think -- and I don't think it should be given any weight whatsoever.

THE COURT: All right. I want you to touch upon the other factors, if you would like, but before we do that and I fear that I may not remember to ask you a question about the nature of the relief sought. I'm aware that Judge Woodcock previously had asked the parties to brief that issue, and I was curious as to whether you could expand on that for me.

MR. ATKINSON: Yes, Your Honor. Judge Woodcock was asking about in light of the CASA case --

THE COURT: CASA, right.

MR. ATKINSON: -- from the Supreme Court, you know, what -- how does that affect the scope of relief, and footnote ten, as he rightfully noted in -- in CASA, carves out APA cases. And Justice Kavanaugh explains in that -- in that case that the set-aside provision under Section 706 still remains. That has been reaffirmed by the Supreme Court by the Chief Justice in the NIH case that was issued this summer. So the set-aside authority, which we -- which -- so we're -- sometimes it's called temporary vacature on a TRO, or a preliminary injunction, still remains, and five justices have said as much in the last year. And we cite to you in -- in the reply, Your Honor, a number of courts that have -- have used that authority, district courts.

There is a -- there is a second consideration that the Government in its response argues that really -- it ignores the temporary vacature question and it -- it says for a PI, a preliminary injunctive relief, it should only be the individually identified parties named by an organizational plaintiff. Here it would be AHA and MHA. And that's just -- they just ignore the First Circuit's decision in Doe from this year, Your Honor, which -- which rejected squarely that argument and found that any -- a PI should extend in an organizational plaintiff to all members that are -- you know, that are subject -- or that would benefit from that PI that are within the sort of remit of the subject matter, and so here it would be all -- for AHA all 2,000 AHA members that participate in 340B, and it's -- I believe it's 26 of the 32 hospitals in Maine that are members of MHA. So that would be the proper scope of the P -- the PI -- of a PI, but -- or if it's an APA case you can just do a temporary vacature which would -- would extend beyond the plaintiffs, we -- we acknowledge, but that is accepted by the -- by the Chief Justice.

THE COURT: Thank you.

MR. ATKINSON: Your Honor, I only had one other brief point on the -- the defendant's argument about justiciability here, which was, you know, they argue that this is beyond the Court's review -- reviewability. They cite two cases, they cite Heckler v. Chaney and Webster v. Doe. They then ignore

the Supreme Court's decision in -- in Weyerhaeuser where -- from 2018 which held there is a strong presumption in favoring review of administrative action even when there is agency discretion. And the court's quite explicit saying that there is no exception where there is a, quote, meaningful standard against which to judge the agency's exercise of discretion. That was reaffirmed in Department of Commerce v. New York the following year by the Supreme Court.

And defendants here -- it's a peculiar argument to see again in the -- in the briefs because the defendants for decades have accepted there is a meaningful standard under 340B for assessing whether to adopt the discount mod -- offer a discount or a rebate and that's that the secretary must choose the option, quote, most effective and most efficient from the standpoint of each type of covered entity, closed quote. That's from the House Report 102-384(II) at 16. That shouldn't be a surprise, Your Honor, because the defendants quote that report extensively including the same page, they -- when they talk about discretion.

So the Defendant HRSA itself has used that standard in the context of making 340B policy about rebates going back to 1997. They used it in -- I can direct you to 62 Fed Reg four -- 45823 and 24, and that was when it establish -- it adopted a small rebate program for AIDS medication, it was sort of a unique set of circumstances.

Moreover, the defendants conceded in litigation this year brought by the drug companies that this was a reviewable -- a reviewable standard, and that's the Eli Lilly case, 20 -- 2025 Westlaw 1423630 at 11 through 14. They -- they acknowledge this is reviewable as arbitrary and capricious. And then similarly the -- Judge Friedrich in the -- in the DC district court accepted that standard and went on to find that an agency -- the agency HRSA's failure to provide a reasoned explanation, that's a common theme here, was arbitrary and capricious and set aside that standard. So I would just say that argument about reviewability just doesn't hold up to the record here.

Happy to answer any other questions, Your Honor, but -- but -- now or later.

THE COURT: Thank you.

MR. ATKINSON: Thank you, Your Honor.

THE COURT: Appreciate it. Attorney Neylan.

MS. NEYLAN: Good morning, Your Honor. May it please the Court. This case is about HRSA's decisions to allow nine manufacturers to effectuate the 340B price of ten select drugs via rebates.

There are three main reasons why the Government should prevail here. First, the statute commits the decision to effectuate 340B prices by rebates or discounts to the agency's discretion by law; second, if review were not completely

foreclosed, review under the arbitrary and capricious standard is highly deferential to agency determinations, and these decisions easily satisfy that standard; and finally, plaintiffs have failed to establish irreparable harm or that the balance of the equities in the public interest tip in their favor, so their motion should be denied.

If the Court were to disagree, any remedy must be limited to the identified members of the associational plaintiffs who have established standing and irreparable harm.

So turning to -- to my first point, the 340B statute plainly gives the agency discretion to effectuate 340B prices via rebates or discounts, and it provides no standard by which to judge the exercise of that discretion so the decisions are committed to agency discretion by law.

In that regard, the 340B statute parallels the language at issue in the Webster case which gave the director of the CIA discretion to terminate a CIA employee when he deemed that termination was necessary or advisable in the interests of the United States.

So, because the text is clear, we don't think it's necessary for the Court to wade into the legislative history; but to the extent the Court finds it helpful, the better reading of the legislative history is that Congress granted the secretary discretion to choose between rebates or discounts, and it expected that his decision would be informed by his

determination of the most effective and efficient mechanism for covered entities. So there is nothing inconsistent with the agency's past practice or positions with that -- with that understanding.

For instance, certainly the secretary can act consistently with that expectation, as it did when it brought the state AIDS drug assistance programs, you know, within the fold of the 340B program.

And also, Your Honor, this argument is not inconsistent with any position that the Government took in the Eli Lilly litigation.

So as a factual matter, the agency's position there was that the agency had not rejected any of the manufacturer's rebate proposals, rather our position continues to be that manufacturers cannot implement rebate models unilaterally but require the secretary's pre-approval. And so the issue in that litigation was whether requiring pre-approval was arbitrary or capricious. Of course we had said no, but that's a separate issue than what's at issue here, which is once the secretary approves a rebate model whether that decision is reviewable.

And then, you know, just because we didn't advance an arbitrary -- a committed to agency discretion by law argument in that separate context of that separate issue does not preclude us from doing so here.

And then I'll just briefly respond to plaintiff's point

about the -- this Friedrich's determination as to the Sanofi company in that litigation.

So although it's not, you know, particularly relevant for present purposes, I'll just flag that the agency's position was and continues to be that it had not rejected any manufacturers' proposals. Although Judge Friedrich largely agreed with the Government, it disagreed as to Sanofi, and found that it -- you know, the agency's violation letter constituted a -- a rejection.

We submit that -- respectfully that that determination misread the letter, which merely reiterated that if Sanofi were to implement a rebate model unilaterally that would be a statutory violation but it's proposal was still under review with the agency.

Turning to my second point. If the Court could review the secretary's decision here, it should be especially circumscribed given the amount of discretion that Congress entrusted the agency with under the statute, and even under typical arbitrary and capricious review the standard is highly deferential to agency determinations. Basically, the agency's decisions have to be reasonable.

Here the agency easily satisfies that standard. It did everything it was supposed to do. It considered all important aspect of the problem including any reliance interests, costs, benefits, alternatives, and engaged in reasoned decisionmaking

in deciding which specific aspects of manufacturers plans to approve.

THE COURT: All right. How do I -- how do I come to that conclusion independently based on the administrative record? And to put too not fine a point on it at this preliminary injunction stage, and without the benefit of a fully developed record, what evidence constitutes the administrative record before the Court as of today and is that evidence submitted on the docket?

MS. NEYLAN: Right, Your Honor. Well, I'll begin by -- by explaining that plaintiffs are wrong that the agency's declaration costs used post hoc rationalizations.

So, first of all, it's not at all improper for the Court to consider declarations that illuminate the reasons implicit in the record and the agency's contemporaneous decisionmaking, especially in an emergency posture like this one. You know, that's the Clifford v. Pena case. And then so Overton Parks, you know, concerned with post hoc rationalizations are just not at issue here because the declarations clearly explain the agency's contemporaneous decisionmaking and Overton Parks also recognized --

THE COURT: Well, well, well, hold on. So I'm open to the possibility that the declarations characterize, summarize, or point me in the direction of contemporaneous administrative agency action. I would like -- I'm less interested in the sign

than I am the location. Where is the administrative record that I'm supposed to review here?

MS. NEYLAN: Yes, Your Honor. So at this point in -- in the litigation of course there is -- there is the notice, which set out, you know, criteria that manufacturer plans had to comply with. There's also the agency's announcement of the approvals of those plans, which clearly states that the plans complied with the criteria in the notice. And as stated in Overton Park in informal adjudications agencies do not need to make formal findings as they typically only involve paper submissions by the parties.

So even though agencies have to provide some explanation for their decisions, it doesn't need to be elaborate. And as explained by the Supreme Court in the FCC v. Fox case, an agency's determination must be upheld if its path may be reasonably discerned.

THE COURT: All right.

MS. NEYLAN: So here --

THE COURT: Right, so let's get to it. I -- from what I can deduce from the filings, there seems to be a sentence or two upon which the agency chiefly relies that it is a catchall provision that assures me that the agency has carefully contemplated, considered, meditated on, and resolved against the plaintiffs everything bad and good about the competing proposals, and the net of that is they've decided to move ahead

with the rebate program. I'm wondering if that's sufficiently -- a sufficiently articulated reasoned explanation of the agency's action?

MS. NEYLAN: Well, Your Honor, we would push back against that characterization of the record. You know, we think it's clear that the agency's review of the comments was informing its specific -- its consideration of specific aspects --

THE COURT: Where is that in the record? Where is that in the record?

MS. NEYLAN: Well, so first, Your Honor, I think it's in -- so it is more fulsomely explained in the declaration, but also I think it's implicit in the -- in the ultimate aspects of the claims that were approved.

So, for example, as explained in paragraph 38 of the declaration, manufacturers were pushing to require additional data be submitted beyond what most covered entities already collect, and the agency determined that that would be an additional burden that wasn't necessary at this juncture and so it declined to approve those requests.

Similarly, manufacturers wanted longer to process rebate claims and covered entities thought that even ten days was -- was too many, so the agency determined that ten days was reasonable and wouldn't negatively impact covered entities.

THE COURT: What do you -- what are you read --

MS. NEYLAN: And following --

THE COURT: What are you reading from right now? Is this --

MS. NEYLAN: So that --

THE COURT: Is this the Britton declaration?

MS. NEYLAN: Yes, Your Honor, that's declaration paragraph 27.

THE COURT: All right. In light of DHS versus Regents am I precluded from considering any of the substantive explanations contained in the Britton declaration?

MS. NEYLAN: No, Your Honor, because the declarations merely illuminate the agency's contemporaneous decisionmaking process. Whether there could be a more fulsome administrative record compiled down the road I think is a -- is a question that -- that we would have to address later on.

THE COURT: All right. So I don't want to go on too much of an existential goose chase here, but let me ask you this: Is there any place a lowly district judge could go right now as I'm considering the motion for a temporary restraining order which reflects the administrative record which supports the contentions offered through the Britton declaration?

So what I mean by that is assume for the sake of this question that I cannot and will not rely on any of the representations made in the Britton declaration. Is there anything else I can fasten my eyes on to satisfy myself that

the agency has achieved the very low bar set out in the APA in providing a reasoned explanation for the change to the rebate program?

MS. NEYLAN: Yes, Your Honor, I think -- I think the notice would be a helpful starting point as that articulated good reasons for the pilot program, including information gathering, testing the concept of a rebate mechanism for the 340B program, evaluating its effectiveness at achieving goals including preventing diversion and achieving deduplication, you know, both between 340B and the Medicaid rebates and between 340B and the Medicare drug association price program.

And -- and again, you know, in the notice the agency acknowledges, yes, we know that this is a -- is a shift from -- from how things have been done. It's not a change in policy position, though, because the agency hasn't conclusively determined that rebate mechanisms are -- are better than -- than upfront discounts, it's merely wanting to -- to test that concept in a -- you know, to test the concept that's plainly authorized under the statute, and so it designed the pilot in a very limited way including only two percent of drugs -- two percent of sales of the 340B program to -- to test it and minimize the burden on covered entities.

And then also, Your Honor, you know, the notice announced criteria that manufacturers plans would have to comply with. And so when the -- when the agency, after engaging in a back

and forth with manufacturers about specific aspects of plans and revising those plans, in deciding ultimately to approve the plans, it announced, okay, these are the plans that -- that comply with the -- with the criteria we've announced and -- and are therefore approved.

So I think there is -- I think the declaration is helpful, but I think that otherwise the agency complied with what was required in terms of articulating decisions in an informal adjudicatory context and --

THE COURT: So the notice is -- and I don't have the language of the notice in front of me, but as I recall it's a sentence or two and it basically says the agency acknowledges that this will be a fundamental shift in the way that payments are made and received, something like that, nevertheless we're going forward with the rebate program. That doesn't strike me as a particularly comprehensive reasoning as to why the change is supported and whether the agency has considered all of the countervailing issues. Are -- are you --

MS. NEYLAN: Well, again --

THE COURT: -- is the -- is the argument -- is the agency's argument essentially, well, we're going to -- by the time this litigation is concluded we're surely going to have an administrative record that has more meat on the bones than currently is the case, for now the Britton declaration will have to do. Is that essentially the agency's argument?

MS. NEYLAN: Well, again, Your Honor, I think the -- the point of the pilot is information gathering, and so in the notice it invited comments to -- to highlight, you know, important aspects of the problem including unanticipated -- unanticipated administrative costs and -- and things like that. So I think that's consistent with the agency's position that it's trying to gather real-world data to make an informed decision in the future regarding whether a broader rebate mechanism might have advantages in the --

THE COURT: All right.

MS. NEYLAN: -- in the --

THE COURT: All right, so that touches on something that I wanted to ask you. So it sounds to me like the repeated emphasis on the notion that this is a pilot program -- I wanted to ask you an open-ended question about that, who cares? How should that weigh in my thinking about this case and the arguments advanced by the agency? What relevance does it have that it's a pilot program?

And what I'm gathering from one of your answers is it may have some relevance to this idea that as your counterpart pointed out that the agency is in the process of considering certain things but hasn't fully considered them yet, which is an odd position to be in on an APA challenge.

So is -- is the -- is there any particular relevance to the notion that this is a pilot program?

MS. NEYLAN: Two points in response to that, Your Honor. First, I think the -- the agency's decision to do what it clearly has statutory authority to do in a limited way underscores its reasonableness here and its commitment, you know, both to giving manufacturers tools to -- to adapt to a changing regulatory landscape and also to minimize burdens on covered entities I think the agency is trying to walk a fine line.

And then also, Your Honor, we would push back on plaintiffs' characterization of the record that the agency did not consider or properly weigh costs and benefits. You know, the declaration at paragraphs 12 and 34 clearly shows that the agency considered costs including administrative costs and nonmonetary and other costs.

And, you know, plaintiffs quibble with whether the agency might have underestimated costs, but again, Your Honor, a lot of this entails predictive judgments within the areas -- within the agency's areas of expertise which are afforded considerable deference under FCC v. Fox and FCC v. National Citizens Communication for Broadcasting [sic], and so, you know, the agency's also committed to evaluating the pilot on an ongoing basis and to adjusting if -- if necessary.

But the agency's determination that covered entities would not be severely negatively impacted from the upfront costs, particularly given that most covered entities will be

reimbursed with their rebates before their bills to the wholesalers become due, and given that, you know, on the topic of administrative costs that participation in the 340B program has always entailed compliance in administrative and operational costs. And, you know, the pilot program requires the collection of information that most covered entities are already collecting in the context of their contract pharmacies, so --

THE COURT: So, so, so Ms. -- Ms. Neylan, if I could, I agree with you for the -- under the general proposition that if -- if we were merely talking about to what extent the agency is owed deference by the Court you -- you'd find no argument from -- from me.

If this was merely a back and forth on the wisdom or folly of the policy decisions that the agency made in this particular lane, I'm not going to get into the middle of those types of disputes and mediate them to a conclusion. That's not what troubles me here.

I think there is a step that we're missing before we get there, and that is whether there is anything in the, as it were, administrative record -- I -- frankly, last night a question that I put to some of my staff is what is the administrative record here? What am I reviewing other than a sentence or two in the notice and the announcement that the rebate program was going to go into effect? And so I'm not

trying to trap you with this question.

I heard in your last answer, I think, that you keep referring and relying, quite understandably, on representations made through declarations which have been filed with the Court, which is all well and good unless I'm not to look at those declarations as being a contemporaneous, reasoned explanation of the agency's action, which is sort of what I'm thinking right now. How am I supposed to conclude otherwise?

MS. NEYLAN: Your Honor, I -- I understand the -- I understand the question, but I think the -- the statements in the declaration clearly demonstrate that they are highlighting the agency's contemporaneous decisionmaking process. They're not saying -- the statements are not -- you know, they do not amount to saying, well, these are -- you know, these are good reasons that we've recently come up with for -- for why we acted this way, they're saying, no, this is what we were considering at the time. You know, we did review the comments, we did understand the -- the concerns that were highlighted therein, and those concerns informed our adjudication of the -- the manufacturers applications. And --

THE COURT: I'm not -- I'm not -- I'm not even taking issue right now necessarily with -- with whether that's true or not. I'll accept for -- for the sake of our exchange that that may be true, that the Britton declaration, and the others, support a relatively fair characterization of what the agency

considered and --

MS. NEYLAN: Mm-hmm.

THE COURT: -- the reason it decided the way it did. My question is more fundamental. A declaration filed with the court a day or two ago is not a contemporaneous administrative record that reflects what was happening at the time, and I take it that you would agree with that; but your argument is that I'm permitted to now, with the benefit of the declaration provided by the agency, rely on them as the stand-in for the actual administrative record.

MS. NEYLAN: That's correct, Your Honor. I think that that's appropriate at this preliminary stage of the proceedings. And -- and I also think again it's implicit in the -- in the notice and the subsequent approvals what the agency was -- was considering and -- and addressing when it made its approvals and so, you know, again we would say that in informal adjudications that the agency's decisionmaking does not have to be -- does not have to be elaborate and -- and here we think that its path can be reasonably discerned.

THE COURT: Is it arbitrary or capricious for an agency to be currently examining important factors when the agency program goes into effect?

MS. NEYLAN: Your Honor, is Your Honor referring to the -- the question about the estimation of administrative costs?

THE COURT: Right. So if the agency hasn't finished its assessment of an important factor or any important factor relevant to the agency action that they've already taken, how is that not arbitrary and capricious under the APA and guidance from Supreme Court case law?

MS. NEYLAN: Well, no, Your Honor, I don't think it's arbitrary and capricious that the -- the agency is committed to continuing to evaluate the -- the pilot and its -- and its implications. Again I think at a juncture as we are now, which is before the -- the pilot has taken effect, a lot of the aspects of the program entailed predictive judgments, but the agency made those predictive judgments reasonably, explained them the best that it could, and then made a policy choice. And -- and I don't -- I don't think that the Court is -- is meant to say, yes, those choices, and I don't think that the agency's reasonableness in doing so is at all undermined by, you know, its commitment to an ongoing evaluation process.

THE COURT: Well, how can you claim to have considered administrative costs if you don't know how much it will cost because the agency hasn't finished its analysis?

MS. NEYLAN: I think some of those questions in terms of quantifying specifics and -- and -- well, to begin, I think some of the questions in terms of quantifying the -- the specifics are going to be revealed, you know, once the -- once the program is underway. I think that's part of the point of

the pilot program is to be able to more concretely quantify these aspects, but, again, the agency did consider administrative costs. It concluded that the administrative burden wouldn't be significantly high in part because covered entities already collect this data. You know, the costs of running the IT platform are borne by the manufacturers, covered entities are already using a similar IT platform in the context of their -- their contract pharmacies.

And so, you know, it's not that the agency didn't consider administrative costs, the question now is, okay, well, what will the amount of the administrative costs be? And again plaintiffs also provide a sort of speculative estimate, which for the reasons I mentioned there is reason to -- to doubt whether -- whether that will be the case or not, but -- but the agency did consider them and concluded that the significant benefits of the pilot program at this point, you know, outweigh those -- those costs.

THE COURT: So in Michigan --

MS. NEYLAN: Particularly --

THE COURT: So -- so in Michigan versus the EPA the Supreme Court held that agencies must consider costs, and so my question is under the APA is it your position that the agency calculate costs before implementing the rebate program?

MS. NEYLAN: I think our -- so I think that the agency does have an obligation to consider the costs, and I think that

it complied with that obligation here.

THE COURT: Is there a difference between considering the costs and analyzing the costs?

MS. NEYLAN: Does Your Honor when Your Honor says, you know, analyzing the costs, does that refer to quantifying the costs? I'm just trying to understand the question.

THE COURT: So -- right. So considering the costs, you -- you might be able to generally considering the costs without expending too many calories trying to understand what the costs are, and I'm not sure how useful that would be or how faithful it would be to Supreme Court precedent. So my question is, is the agency required simply to consider costs and move on to the goal it wants to achieve by implementing the rebate program or should it analyze the costs? That is, try to figure out what the costs actually are before they start? Before they implement the program?

MS. NEYLAN: Well, even so, Your Honor, the agency did analyze the costs, you know, in the context of complying with the -- the Paper Reduction Act. You know, again as explained in the declaration, the agency is evaluating comments that -- that state that it -- it might have underestimated those costs and will respond appropriately to those comments in the context of -- of finalizing that notice. But -- but again, you know, under the APA the ultimate question is whether the agency's course of action was reasonable, and here I think the agency's

prediction as to costs, you know, relevant to the benefits of the program was not unreasonable.

THE COURT: So I -- this -- I almost promise this will be my last question in this line of questioning. How can the agency claim to have considered the administrative costs if the agency doesn't know how much it will cost because the agency isn't yet finished with its analysis?

MS. NEYLAN: Because the agency reasonably determined that especially in light of the benefits covered entities incur by virtue of participating in the pilot program, you know, including when covered entities dispense a drug that they have bought at a 340B discount to an insured patient and then get reimbursed for the full amount, thereby turning a profit, you know, the agency -- and again that -- that the covered entities wouldn't suffer significantly because of the -- the upfront cost of the drugs, you know, given the limited ten-day window, given other -- other aspects, including that manufacturers will pay per unit level rebates rather than package level rebates and these drugs don't sit on the shelf for -- for long periods of time. And so, you know, any additional administrative burden associated with the pilot program, which again the agency did its best to minimize, you know, I think -- I think the agency's ultimate conclusion to forge ahead with the pilot was -- was reasonable in light of all of those considerations.

THE COURT: All right. So I think you've stated that

it's permissible for the Court to -- in this emergency posture to consider the declarations as something of a substitute -- temporary substitute for the actual administrative record as to what the agency believes the administrative record will later show. Do I have that right or did I mischaracterize that?

MS. NEYLAN: I would -- I would caveat that, Your Honor, by -- by stating that, you know, even under normal circumstances it's -- it's proper to consider a declaration that's merely meant to, you know, illuminate what's implicit in the record and highlight the agency's contemporaneous decisionmaking.

You know, at this juncture, I would -- I would have to confer with -- with my client as to what any sort of down-the-road administrative record might entail.

THE COURT: And what prevents the agency from identifying the part of the administrative record which could, at least for purposes of the present motion, address the likelihood of success on the merits argument?

In other words, why are we relying so heavily on a summary or a characterization by others through their declarations and not also maybe in addition to those declarations pointing the Court to the administrative record?

MS. NEYLAN: Well, Your Honor, I mean I'll reiterate that -- that, you know, the Court is welcome to look at the -- at the notice and the approvals, which are --

THE COURT: Is that -- okay, I just want to be sure I understand so -- so that you and I are both working in the same universe here. Is that -- when we say the administrative record, is that what you're referring me to? The notice?

MS. NEYLAN: I would refer to the -- the notice, the -- the frequently asked questions on the -- on the website, and, you know, the announcement of the -- the approvals of the plan.

THE COURT: Okay. And that's it?

MS. NEYLAN: And -- and I would include the declaration in that as well, for now.

THE COURT: Okay, understood. Thank you. All right. Thank you, counsel, you can move on to the other parts of the argument. I think those are the questions I had.

MS. NEYLAN: Yes, Your Honor. So, you know, finally, you know, similar for the reasons that we have been -- we had been touching on, plaintiffs have failed to establish irreparable harm, you know, or that the balance of the equities in the public interests tip in their favor.

I would like to highlight that there are equities on all sides here, Your Honor. The United States has a sovereign interest in being able to take lawful actions to effectuate federal statutes and agencies must be afforded flexibility to adapt a change in regulatory and statutory landscapes.

One of the reasons why the agency, you know, chose the

effective date of January 1st is to align with when the first set of negotiated prices under the Medicare Drug Price Negotiation Program are meant to take effect because manufacturers have a concern about achieving deduplication between the two programs.

And so, you know, the Government's position is that effectuating 340B prices through rebates is one tool that they can use to -- to achieve that goal and so it's, you know, perfectly reasonable for the -- the agency to -- to have these -- you know, to set the effective dates to begin evaluating that purpose.

And then -- and of course there are equities on the -- on the side of the manufacturers as well who, you know, are trying to comply with, you know, various obligations and, you know, also are -- are working on research and development and other, you know, important -- important goals that serve the public interest.

And then on remedy, Your Honor, you know, the plaintiffs' request for relief is overbroad. So after CASA the Court cannot issue universal -- universal injunctions because relief is only supposed to extend to the specific parties in the case.

Granted, CASA left open the question of whether the APA authorizes broad preliminary relief, but I'll note at the outset that the same preliminary injunction standard applies to stays under Section 705 because a Section 705 stay is a

provisional remedy in the nature of a preliminary injunction. And then also CASA was informed by Article III limitations on the Court's remedial power. So consistent with those limitations relief should extend no further than -- than necessary to the particular federal plaintiffs.

Moreover, in grafting equitable relief the Court must consider what is necessary, what is fair, and what is workable. In the context of associational plaintiffs, a remedy limited to the associational plaintiffs members who have demonstrated standing and irrevocable harm comports with -- with all of those principles.

You know, especially because it's not clear from plaintiffs' submissions which of their members administer drugs that are included in the pilot program. And, you know, certainly if -- if any of their members only administer Entresto, which is the one drug whose participation is starting on April 1st, those members have not established imminent irreparable harm.

And then finally Doe v. Trump, which -- which plaintiffs mention and also cited in their -- page 14 of their reply brief, is not to the contrary. The Court specifically noted that the issue of the scope of the injunction with respect to unidentified members wasn't raised below and could be addressed on remand; and second, it seemed like the Court disagreed with defendant's position that the organizations had only identified

two members who had shown standing and irreparable harm.

THE COURT: Thank you, counsel, anything else?

MS. NEYLAN: No, Your Honor.

THE COURT: All right. Thank you very much.

MR. ATKINSON: Your Honor, just a few remarks in reply. First, I want to start with the notice, Your Honor, and the probative value of that in light of the Britton declaration.

THE COURT: Mmm.

MR. ATKINSON: Most of the Britton declaration is a response to the comments. The comments came after the dec -- the notice. So unless Director Britton has a time machine, she can -- her comments about -- I mean her explanation about the comments cannot be illuminating the notice, that just doesn't make -- that doesn't logically follow.

The -- you know, with respect to the other parts of the, quote, unquote, the administrative record, the FAQs say nothing about decisionmaking and the reasons for it, the approvals say nothing about the reasons for making these decisions. So there is nothing that can be illuminated by the Britton declaration; it should not be considered even at this stage.

I think counsel conceded that she cannot say there is more records forthcoming, and so therefore it's not, you know -- I mean I don't think you -- I think under DHS you cannot consider it, but even if you were inclined to, you can't suggest there

is anything in the record in the way of e-mails or internal memoranda that would be coming at this stage.

Counsel referred to emergency in -- in an effort to try to get latitude a couple of times. For example, the emergency application to OMB. That's an -- that's an emergency of their own making. You know, they had three years to comply with this -- with the IRA, if that's what they're suggesting. You know, why they waited until August to file something with OMB there is no explanation for.

So, I think that that is -- I think that that should offer them no latitude. I don't -- and I don't think they've cited to a case that suggests that emergency allows them deviation from the strictures of the APA.

The Chief Justice in D -- in Regents said that the, quote, the Government should turn square corners in dealing with the people. That's at 591 U.S. at 24. And that's in the context of these post hoc litigation affidavits it has to lay the proper foundation, the proper explanation that shows that it was both reasonable and reasonably explained. So I don't think that they've -- you know, that they have come even close to turning that square cord that chief -- excuse me, the square corner that the Chief Justice required.

Similarly, Your Honor, just a couple of other points. The -- with respect to the balance of equities, I fully didn't grasp the -- the argument from the Government, but I don't

believe that the drug companies' interests are permissible to allow, you know, latitude to not follow the rules under the APA, but I don't think the drug companies' interests are anything -- or should be any value in the balance of equities here.

And then finally on the evaluating costs. There is a difference between a commitment to monitoring costs as the program is implemented, and I think that's what Ms. Neylan was suggesting the agency is committed to. That's a very different question from whether it before implementing the program considered costs, and that has not been done here. That's a concession. And the rule is you have to consider costs before making the decision to implement this program that's going to impose, by its own estimate, $200 million, and that's a wild undercount. So they have not -- they have not fulfilled any of their obligations in this -- in this situation.

I'm obviously happy to answer any other questions from Your Honor at this stage.

THE COURT: Thank you, counsel.

MR. ATKINSON: Thank you.

THE COURT: All right. Counsel, thank you all for your submissions and arguments today and for answering my questions so thoughtfully. That was a great help to the Court.

I'll have the matter under advisement and I expect to have a -- a decision to you very soon. I'm not going to hem myself

in by predictions, but I would predict there is a better than even money chance there will be a decision before the holiday next week, all right. Thank you, we're in recess.

(Time noted: 12:15 p.m.)

C E R T I F I C A T I O N

I, Tammy L. Martell, Registered Merit Reporter, Certified Realtime Reporter, and Official Court Reporter for the United States District Court, District of Maine, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

Dated: December 22, 2025

/s/ Tammy L. Martell

Official Court Reporter

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER, *Plaintiffs*, v. ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA, *Defendants*.	Case No. 2:25-cv-00600-JAW

ASTRAZENECA PHARMACEUTICAL LP'S SUPPLEMENTAL FILING OF RECORDS REFLECTING AGENCY APROVAL OF PILOT PROGRAM PROPOSAL

AstraZeneca Pharmaceuticals LP respectfully submits the attached documents reflecting consideration of and approval by the Health Resources and Services Administration (HRSA) of AstraZeneca's submitted plan for the 340B Rebate Model Pilot Program. *See* Declaration of Sky Adams, Exhibit A (Ex. A). AstraZeneca submits these documents to provide the Court with a fuller picture of the agency's consideration of the relevant issues. Among other things, these documents indicate the agency's consideration of the program's potential costs for covered entities, including:

1. HRSA voicing concern about whether AstraZeneca's shift to a rebate model could lead covered entities "to pay significantly higher prices on prescription drugs at the time of purchase," Ex. A at 1;

2. AstraZeneca's response to such concerns, Ex. A at 7-9;

3. A presentation by AstraZeneca to John Brooks, Deputy Administrator and the Chief Policy and Regulatory Officer, Center for Medicare, which included a slide deck detailing the ways in which the "Rebate Model can address different degrees of cash flow concerns for covered entities," Ex. A at 20;

4. A presentation by AstraZeneca to Tom Engels, Administrator of HRSA, which included slides detailing the ways in which the "Rebate model will not burden selected covered entities," and the "Rebate Model can address different degrees of cash flow concerns for covered entities," Ex. A at 25, 27;

5. HRSA voicing additional concerns about whether AstraZeneca's proposed model for the pilot program addresses covered entities' acquisition costs, Ex. A at 32; and

6. AstraZeneca's revised plan, which addressed HRSA's concern, Ex. A at 33-35.

Dated: December 23, 2025

Respectfully submitted,

/s/ Jeffrey D. Talbert

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CERTIFICATE OF SERVICE

I, Jeffrey D. Talbert, hereby certify that on December 23, 2025, I caused the foregoing document to be filed via the Court's CM/ECF electronic filing system, which sent notice to all parties who have entered an appearance in this matter.

/s/ Jeffrey D. Talbert

Jeffrey D. Talbert

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER, *Plaintiffs*, v. ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA, *Defendants*.	Case No. 2:25-cv-00600-JAW

DECLARATION OF SKY ADAMS

I, Sky Adams, hereby declare under penalty of perjury as follows:

1. I am over the age of 18. Except as expressly indicated, the facts stated herein are based upon my personal knowledge, including my time working at AstraZeneca Pharmaceuticals LP and my review of AstraZeneca business records. If called to testify, I could truthfully and competently testify to these facts. I provide this declaration in support of AstraZeneca's supplemental filing, submitted herewith.

2. I am the Legal Director for Market Access at AstraZeneca, where I have been employed since 2020. In my position, I am responsible for leading and coordinating on issues of market access, including legal issues and litigation related to the federal 340B program.

3. Exhibit A is a true and accurate copy of the documents related to approval by the Health Resources and Services Administration (HRSA) of AstraZeneca's submitted plan for the 340B Rebate Model Pilot Program.

4. The documents in Exhibit A include:

- A letter dated December 10, 2024, from HRSA to Joris Silon, Senior Vice President, U.S. President, AstraZeneca Pharmaceuticals LP, regarding AstraZeneca's planned rebate model for DSH covered entities purchasing Farxiga.
- A letter dated December 17, 2024 from AstraZeneca Pharmaceuticals LP to Chantelle V. Britton, Director, Office of Pharmacy Affairs, HRSA, regarding AstraZeneca's planned rebate model for DSH covered entities purchasing Farxiga.
- A slide deck presented by AstraZeneca to John Brooks, Deputy Administrator and the Chief Policy and Regulatory Officer, Center for Medicare, on February 19, 2025.
- A slide deck presented by AstraZeneca to Tom Engels, Administrator of the Health Resources & Services Administration, on March 17, 2025.
- A letter dated October 21, 2025, from HRSA to Chris Mancill, Senior Vice President, Market Access, AstraZeneca Pharmaceuticals LP, requesting revisions to AstraZeneca's plan.
- AstraZeneca's Revised 340B Rebate Model Pilot Program Application, signed on October 24, 2025.
- A letter dated October 30, 2025, from HRSA to Steven Chen, Director, US Policy, AstraZeneca Pharmaceuticals LP, approving AstraZeneca's revised plan for participation in the 340B Rebate Model Pilot Program, and an accompanying spreadsheet listing the approved data collection fields.

5. All of the attached documents were submitted to the agency prior to its approval of AstraZeneca's plan for participating in the program.

I declare under penalty of perjury pursuant to 28 U.S.C. § 1746 that the foregoing is true and correct.

Executed this 23rd of December 2025
in Wilmington, Delaware

/s/ *Sky Adams*
Sky Adams

EXHIBIT A

HRSA
Health Resources & Services Administration
Office of Special Health Initiatives
5600 Fishers Lane
Rockville, MD 20857

December 10, 2024

BY EMAIL
Joris Silon
Senior Vice President, U.S. President
AstraZeneca Pharmaceuticals LP
Joris.Silon@astrazeneca.com

Dear Joris Silon:

The Health Resources and Services Administration (HRSA) is reviewing the information submitted in your November 18, 2024, correspondence, regarding AstraZeneca Pharmaceuticals, LP's (AstraZeneca) proposal to implement a 340B rebate model. You indicated that AstraZeneca intends to implement its proposed rebate model in 2025 for Farxiga, however, AstraZeneca may include additional drugs in the future. In addition, the rebate model would initially apply only to disproportionate share hospitals (DSH), but AstraZeneca is weighing whether to apply the model to all covered entities.

The 340B statute states that "[t]he Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, *as provided by the Secretary*) to the manufacturer" shall not exceed the statutory ceiling price formula. 42 U.S.C. § 256b(a)(1) (emphasis added). To date, the Secretary has not provided for such rebate as proposed by AstraZeneca. Therefore, while this correspondence should not be construed as either a final approval or disapproval of AstraZeneca's proposal, implementing such a proposal at this time would be inconsistent with the statutory requirements for the 340B Program.

While HRSA continues to review your proposed rebate model, HRSA requests responses to the following questions:

1. AstraZeneca currently employs a replenishment model for 340B sales and intends to shift to the rebate model. This shift would disrupt how the 340B Program has operated for over thirty years. As a result of this shift, covered entities, including those which primarily serve rural and underserved populations, may need to pay significantly higher prices on prescription drugs at the time of purchase.
    a. Has AstraZeneca conducted an evaluation of the impact of this proposal on the scope and breadth of health care access for patients served by affected covered entities?
    b. Has AstraZeneca conducted an analysis of the extent of the additional burden and/or costs to the affected covered entities, particularly those that

are the sole or primary source of health care in a rural or underserved community?

c. AstraZeneca has claimed that the rebate model will enable covered entities to receive rebate payments prior to wholesaler payment. Any brief delay in submitting or processing rebate claims could result in covered entities paying significantly higher prices. Has AstraZeneca conducted an analysis of how many rebate claims will be able to be paid prior to wholesaler payment?

2. AstraZeneca states that it will require covered entities to submit rebate claims to the rebate platform.
   a. What specific claims level information would covered entities be required to submit?
   b. What other parties, if any, would AstraZeneca share the claims data with?
   c. Is there a timeframe covered entities must submit data from time of dispense to be eligible for the 340B rebate?
   d. What protections and safeguards would AstraZeneca plan to implement to ensure such information would be used in support of the 340B Program?
   e. What protections and safeguards would AstraZeneca plan to implement to ensure the privacy and security of such information?

3. AstraZeneca indicates that it plans to implement the rebate model for Farxiga initially but reserves the right to implement for other drugs in the future. Similarly, AstraZeneca states the model will initially apply only for DSH covered entities.
   a. How would changes to the model be communicated to covered entities?
   b. How much notice would covered entities expect if AstraZeneca decided to expand the number of drugs or covered entity types to which the model applies?
   c. Why were DSH covered entities selected for this model?

4. If AstraZeneca identifies a potential 340B duplicate discount, how will the rebate claim be adjudicated?
   a. What is the timeframe that AstraZeneca will process any such adjudication?
   b. What reconsideration or appeals process will AstraZeneca implement?
   c. Will AstraZeneca automatically deny covered entities' 340B rebate claims if AstraZeneca believes a Medicaid rebate was already paid?
   d. Will AstraZeneca automatically deny Medicaid rebate claims if AstraZeneca believes a covered entity's 340B rebate claims have already been paid?

5. What are the specific reasons that will lead AstraZeneca to reject claims?
   a. Will AstraZeneca make these reasons publicly available in advance of adjudication of claims?
   b. Will covered entities receive claim-by-claim information from AstraZeneca

regarding which claims were rejected and on what basis?

c. What reconsideration or appeals process will AstraZeneca implement to ensure covered entities receive any 340B discounts that are due as required by statute?

6. With respect to the use of pharmacies with which covered entities contract:
   a. Will covered entities need to demonstrate that they purchased individual drugs subject to the rebate claim at wholesale acquisition cost?
   b. Will this process require covered entities to maintain a separate stock of drugs at the contract pharmacy?
   c. If so, how does AstraZeneca plan to ensure this process does not functionally deny covered entities access to the 340B price required by the statute given the additional upfront cost and administrative burden for covered entities, particularly low-margin safety net providers?

7. Would the rebate be paid at the package level or at the dispense level?
   a. Would rebates be paid to covered entities as soon as there is a full package or will covered entities receive a rebate based on the quantity dispensed per claim?
   b. How would AstraZeneca engage with covered entities with respect to these specifics of their prescription drug acquisition and distribution practices?

8. Under this proposal, how would AstraZeneca treat current unreplenished accumulations?

9. Under the AstraZeneca plan, covered entities would be required to submit claims data to both 340B ESP and the rebate platform? HRSA has received a number of reports of technical and customer service difficulties with 340B ESP. How would AstraZeneca ensure covered entities could submit claims without technical difficulties or delays and would be able to access customer support with any significant issues with the Beacon platform?

Please send your responses to 340BPricing@hrsa.gov.

Sincerely,

Chantelle V. Britton, M.P.A., M.S.
Director, Office of Pharmacy Affairs



AstraZeneca Pharmaceuticals, LP
1800 Concord Pike
Wilmington, DE 19850

December 17, 2024

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VIA ELECTRONIC MAIL

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Re: HRSA's December 10, 2024 Letter to AstraZeneca Regarding a Rebate Model

Dear Director Britton,

I write on behalf of AstraZeneca Pharmaceuticals L.P. (AstraZeneca) in response to your letter of December 10, 2024, regarding AstraZeneca's expected implementation of our Planned Rebate Model ("Rebate Model") for disproportionate share hospital (DSH) Covered Entities purchasing FARXIGA®® (dapagliflozin).[1]

AstraZeneca appreciates your engagement on this issue and hopes the information provided below satisfies questions from the Health Resources and Services Administration ("HRSA") regarding AstraZeneca's Rebate Model. AstraZeneca understands that these questions do not relate to AstraZeneca's statutory authorization to implement a Rebate Model, but rather relate to the operation and impact of such a Rebate Model. AstraZeneca hopes to implement its Rebate Model as smoothly as possible and without disruption to Covered Entities and the operation of the 340B Program. AstraZeneca has spent significant time, effort, and resources planning its Rebate Model in a way that will minimize such disruption for providers and have no impact on patients. The answers provided below reflect that intent.

Prior to answering HRSA's questions, AstraZeneca would also like to note that, notwithstanding HRSA's assertion that its December 10, 2024, letter is not a final approval or disapproval of AstraZeneca's Rebate Model, the letter reflects a categorical determination that the

[1] AstraZeneca is not currently planning to implement this Rebate Model for any other drug though we reserve the right to do so in the future.

HRSA Administrator and the US Department of Health and Human Services Secretary have statutory authority to approve (or reject) any Rebate Models. AstraZeneca disagrees with HRSA and instead reads the 340B statute to allow AstraZeneca to proceed with a Rebate Model at its discretion (without HRSA pre-approval). HRSA's letter is a final agency action on the question of whether HRSA has authority under the 340B statute to approve Rebate Models.

As explained during AstraZeneca's meeting with HRSA on November 14, 2024, and in its letter of November 18, 2024, AstraZeneca decided to implement the Rebate Model due to how the 340B Program has changed in recent years. The Rebate Model is necessary for manufacturers to comply with the IRA requirements to provide a "maximum fair price" ("MFP") on selected products. Without implementing a new means of effectuating discounts, manufacturers will be unable to avoid duplicate discounts between the 340B Program and IRA and also will not have sufficient time to ensure that they comply with the IRA requirement to charge the lower of the 340B price and the MFP on qualifying 340B sales of drugs subject to MFP requirements under the IRA. The existing replenishment system does not provide manufacturers sufficient data or time to determine which units are eligible for MFP and/or 340B pricing.

The Rebate Model is also necessary to improve transparency into the 340B program. New technologies, such as replenishment models, replaced physical inventories as a way to track 340B drug sales. This now prevalent method of "replenishment" has rendered tracking 340B claims and utilization nearly impossible. Moreover, drug distribution models have shifted significantly with the growth of PBMs further reducing transparency in the system. The Rebate Model is a solution to each these inherent compliance dilemmas and information gaps.

The 340B Program has undergone rapid and continuous change since its inception. Despite HRSA's assertion, there is no single manner in which "the 340B Program has operated for over thirty years," nor would AstraZeneca's implementation of a Rebate Model disrupt how the 340B Program has operated during that time. The 340B Program continues to evolve and is now the second largest government pharmaceutical program in the country, with approximately $124 billion in annual purchases at list price. As explained in our November 18 letter, the 340B Program has seen nearly 20 percent year-over-year growth over the last five years and AstraZeneca is concerned this growth is not benefitting patients at a level proportionate to program growth.

AstraZeneca's Rebate Model is the direct result of these evolutions. AstraZeneca strongly believes that the Rebate Model is a statutorily permissible way to adapt the 340B Program in light of recent statutory changes driven by the IRA, and it will help restore the integrity of the Program by increasing real-time transparency and mitigating the risk of abuse, including duplicate discounts and diversion.

As a showing of good faith and cooperation with HRSA, AstraZeneca has not yet provided Covered Entities with notice of its intention to implement the Rebate Model, but AstraZeneca hopes to provide Covered Entities with such notice in early 2025 for an April 2025 implementation date. AstraZeneca thanks HRSA for its continued engagement on this matter, and we look forward to working with the agency on the implementation of this Rebate Model and other efforts to increase 340B Program integrity.

I. Legal Authority Regarding Rebate Models

In its December 10, 2024, letter to AstraZeneca, HRSA asserted that the 340B statute requires a drug manufacturer to receive the Secretary's approval before implementing a Rebate Model. HRSA advised AstraZeneca that, "[t]o date, the Secretary has not provided for such rebate as proposed by AstraZeneca. Therefore, while this correspondence should not be construed as either a final approval or disapproval of AstraZeneca's proposal, implementing such a proposal at this time would be inconsistent with the statutory requirements for the 340B Program." Particularly in light of the request for approval in its November 18 letter, AstraZeneca interprets the December 10 letter as setting forth HRSA's final, definitive interpretation of the 340B statute, including a definitive interpretation that the 340B statute (1) allows HRSA to determine whether manufacturers may use a Rebate Model, and (2) requires Secretary approval prior to a manufacturer implementing a Rebate Model.

AstraZeneca strongly disagrees with HRSA's interpretation of the 340B statute in this regard.[2] The 340B statute provides that the HHS "Secretary [must] enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary)" by Covered Entities is at or below the ceiling price set for the specific 340B drug at issue. 42 U.S.C. § 256b(a)(1). This provision sets forth the requirements for the Pharmaceutical Pricing Agreement ("PPA") that HRSA enters into with a manufacturer. Also notable, the statute specifically refers to and accounts for potential "rebate[s] or discount[s]." *Id.* AstraZeneca's PPA with HRSA does not address Rebate Models or any other mechanism for offering 340B prices on AstraZeneca drugs. Because the PPA is silent on a price-effectuation mechanism, AstraZeneca is free to choose a reasonable mechanism that it deems most appropriate.

[2] AstraZeneca offers just a brief overview of its interpretation of applicable law in this letter, which should not be construed to waive any other argument. AstraZeneca provides this overview in an effort to facilitate cooperation with HRSA, and it retains all legal rights to make any additional legal arguments, such as the relevance of the words "as provided by the Secretary," and to challenge any final agency action in the future.

AstraZeneca's reading of the 340B statute aligns with the opinions of at least two federal courts of appeals.[3] These decisions hold that the 340B statute vests manufacturers with discretion to implement reasonable conditions when offering 340B drugs to Covered Entities, so long as the manufacturer makes a meaningful offer to Covered Entities to purchase its covered outpatient drugs at 340B prices.[4] The proposed Rebate Model complies with this standard.

II. Responses to HRSA's Questions Regarding the Rebate Model

In its December 10 letter, HRSA asked AstraZeneca a number of questions about the operation and impact of its Rebate Model. AstraZeneca interprets these questions as asking about the effects of the model rather than AstraZeneca's authority to implement such a model. Accordingly, AstraZeneca does not believe its answers to these questions have any bearing on the legality of its implementation of a Rebate Model or on HRSA's ability to approve such a model prior to its implementation. AstraZeneca nevertheless provides responses to HRSA's questions below as a show of good faith.

1. **AstraZeneca currently employs a replenishment model for 340B sales and intends to shift to the Rebate Model. This shift would disrupt how the 340B Program has operated for over thirty years. As a result of this shift, Covered Entities, including those which primarily serve rural and underserved populations, may need to pay significantly higher prices on prescription drugs at the time of purchase.**

   The Public Health Service ("PHS") Act has always contemplated rebates as a valid mechanism to effectuate the 340B discount. Additionally, HRSA already allows for the 340B price to be effectuated through rebates and has done so for more than two decades since a 1998 Federal Register Notice regarding AIDS Drug Assistance Program ("ADAP") 340B rebates. Under the prevalent virtual inventory model of replenishment, the first purchase is always at WAC and the 340B discount is only realized following dispense, 340B qualification, and finally product replenishment. A rebate virtual inventory model follows a very similar process where the initial purchase is at WAC and the 340B price is realized after the purchase but, importantly, the rebate virtual inventory model eliminates the requirement for product shipment replenishment and can enable faster turnaround of the discount. At a minimum, a rebate virtual inventory model will be net-neutral from a cash flow perspective for the purchasing entity.

[3] *See Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452 (D.C. Cir. 2024); *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696 (3d Cir. 2023).
[4] *Novartis*, 102 F.4th at 459, 461; *Sanofi*, 58 F.4th at 705.



a. Has AstraZeneca conducted an evaluation of the impact of this proposal on the scope and breadth of health care access for patients served by affected Covered Entities?

AstraZeneca's policy does not change or limit the ability of a Covered Entity to access the 340B price for AstraZeneca products. To the extent that a Covered Entity generates profit/margin on the purchase and reimbursement for our products, the Rebate Model does not impact that ability. Covered Entities and patients will continue to access AstraZeneca products.

b. Has AstraZeneca conducted an analysis of the extent of the additional burden and/or costs to the affected Covered Entities, particularly those that are the sole or primary source of health care in a rural or underserved community?

Yes. The Rebate Model will require Covered Entities to submit data that we understand is readily available to Covered Entities. Based on our analysis, these entities already must maintain this information as a requirement for 340B program participation, and these entities already submit such data to technology platforms and payors today. Covered Entities will be asked to provide information, described in detail below, that they already collect in the normal course of business and regularly report to AstraZeneca (through 340B ESP) and other stakeholders in the supply chain. In addition, wholesalers would continue to distribute drugs, Covered Entities could continue to utilize contract pharmacies (consistent with applicable AstraZeneca policies), and third-party administrators ("TPAs") still will be used to identify eligible 340B claims.

c. AstraZeneca has claimed that the Rebate Model will enable Covered Entities to receive rebate payments prior to wholesaler payment. Any brief delay in submitting or processing rebate claims could result in Covered Entities paying significantly higher prices. Has AstraZeneca conducted an analysis of how many rebate claims will be able to be paid prior to wholesaler payment?

As it is the case in today's model, if a Covered Entity fails to provide the data necessary to support 340B pricing, there could be a delay in the effectuation of the 340B price. Under both models, AstraZeneca has no control over the entity's submission of data. AstraZeneca has established performance metrics with its service provider to ensure timely processing of data submission by covered entities as well as payments to covered entities that will typically enable payment within seven to ten days of submission of data. Although AstraZeneca does not have visibility to the confidential agreements between the wholesalers and their customers, it is our understanding that they generally have 30-day payment terms. As noted in our meeting on November 14, and in our

November 18 letter, for Covered Entities that dispense or administer FARXIGA® shortly after purchase and submit the required information in a timely manner, those Covered Entities should be able to obtain 340B rebates on these units ***before*** their payment is due to wholesalers on the underlying purchase. Obtaining rebates before payment is due should be more financially beneficial to Covered Entities than the current chargeback model. AstraZeneca does not expect that implementation of the Rebate Model will impose significant additional burden or cost on Covered Entities. AstraZeneca has evaluated the time involved in registering for and learning to use the Beacon platform and then managing it on a regular basis. Although Covered Entities will be given adequate notice to adjust to using the Beacon platform.

2. **AstraZeneca states that it will require Covered Entities to submit rebate claims to the rebate platform.**

   a. *What specific claims level information would Covered Entities be required to submit?*

As noted in our meeting on November 14, and in our November 18 letter, the Rebate Model will provide a Covered Entity with the 340B discount through a direct payment to the Covered Entity after the Covered Entity submits eligible purchase and dispense information (Submission Data). The Submission Data is the same data that the Covered Entity maintains and uses to access 340B prices through the current model (See Table Below for fields required by the Beacon Platform and those currently available in NCPDP files). As a result, the Rebate Model will not create additional burden for Covered Entities. Upon receipt of the Submission Data, AstraZeneca will typically pay the rebate to the Covered Entity within 7 to 10 days. The Submission Data is the same data that the Covered Entity maintains and uses to access 340B prices through the current model.

Submission Data:

Beacon Field	NCPDP Standard	HRSA Standard
340b_id		Parent 340B ID
date_prescribed	414-DE	
date_of_service	401-D1	
fill_number	403-D3	
ndc_11	407-D7	
prescriber_id	411-DB	
quantity	442-E7	
bin_number	101-A1	
rx_number	402-D2	
pcn_number	104-A4	
service_provider_id	201-B1	

b. What other parties, if any, would AstraZeneca share the claims data with?

AstraZeneca will not share the Rebate Claim Data submitted by DSH Covered Entities with any party beyond AstraZeneca, unless necessary to address a duplicate discounting issue with a third-party payor or to address potential diversion with an auditor or HRSA.

c. Is there a timeframe Covered Entities must submit data from time of dispense to be eligible for the 340B rebate?

DSH Covered Entities will be required to submit the above data elements to the Beacon platform within 45 days of the date of the dispense of FARXIGA®. This timeline is consistent with the time period in which Covered Entities must submit limited claims data today under AstraZeneca's policy.

d. What protections and safeguards would AstraZeneca plan to implement to ensure such information would be used in support of the 340B Program?

Second Sight Solutions (a wholly-owned subsidiary of BRG that manages the Beacon platform), has taken numerous steps to ensure information submitted to the platform is used solely in support of the 340B program. Specifically, when Covered Entities register to use the platform, they will agree to certain Terms of Use related to the

platform. Those Terms of Use set forth how Beacon, Second Sight Solutions, and manufacturers, such as AstraZeneca, can use the information submitted to the platform.

e. What protections and safeguards would AstraZeneca plan to implement to ensure the privacy and security of such information?

AstraZeneca and its partner, Second Sight Solutions, provide comprehensive and robust data security. Additional information on the Beacon security protocols can be found here: https://beaconchannelmanagement.com/pages/trust-center

3. AstraZeneca indicates that it plans to implement the Rebate Model for FARXIGA® initially but reserves the right to implement for other drugs in the future. Similarly, AstraZeneca states the model will initially apply only for DSH Covered Entities.

a. How would changes to the model be communicated to Covered Entities?

Notifications will be effectuated with, at a minimum, 30 days' notice within the Beacon platform

b. How much notice would Covered Entities expect if AstraZeneca decided to expand the number of drugs or covered entity types to which the model applies?

Sufficient notice, but at a minimum 30 days

c. Why were DSH Covered Entities selected for this model?

As reported by HRSA, purchases under the 340B program in 2023, were 24% higher than the prior year; 78% of those purchases were made by DSH hospitals. In connection to the significant growth and share of 340B purchases, DSH hospitals. make up the majority of large contract pharmacy networks.

4. If AstraZeneca identifies a potential 340B duplicate discount, how will the rebate claim be adjudicated?

Within the Beacon platform, any claim that is not eligible for 340B rebate payment will be tagged with an appropriate reason code for entities to view.

a. What is the timeframe that AstraZeneca will process any such adjudication?

The Beacon platform will not adjust or otherwise impact 340B rebates paid to Covered Entities as the result of identifying a 340B duplicate discount. Once "MFP" goes into effect, BRG anticipates that the platform could be utilized to account for duplicate discounts on Medicare Parts D utilization to which the "MFP" applied.

b. What reconsideration or appeals process will AstraZeneca implement?

The Beacon platform employs a robust entity support team that will address disputed payments. Additional details may be found here: https://beaconchannelmanagement.com/pages/support-center

c. Will AstraZeneca automatically deny Covered Entities' 340B rebate claims if AstraZeneca believes a Medicaid rebate was already paid?

No. The 45-day window for claim submission will ensure that 340B rebates are paid before any Medicaid rebates are paid, thereby eliminating the need to deny Covered Entities rebate claims. Instead, the Beacon platform will provide AstraZeneca with real-time access to data with which AstraZeneca can work with the Medicaid program to eliminate duplicative Medicaid rebates on a Medicaid transaction.

d. Will AstraZeneca automatically deny Medicaid rebate claims if AstraZeneca believes a covered entity's 340B rebate claims have already been paid?

If AstraZeneca identifies that a 340B rebate was paid on a unit for which a Medicaid rebate is being requested, AstraZeneca would not pay the Medicaid rebate on that claim in accordance with the 340B and Medicaid statutes.

5. What are the specific reasons that will lead AstraZeneca to reject claims?

As of launch on the early part of 2025, the Beacon platform will validate basic elements of a 340B transaction: that the product was purchased by the Covered Entity, that the product was dispensed or administered by the Covered Entity, and that required information was timely submitted.

Specifically, the Beacon platform will validate that:

(i) purchases were made by an eligible 340B DSH Covered Entity,
(ii) FARXIGA® was dispensed from either:
   a. an eligible 340B DSH Covered Entity registered in the OPAIS database or
   b. a registered contract pharmacy designated in the ESP system, and

(iii) purchase and claim data were submitted within 45 days from the date of the dispense or administration of FARXIGA®.

If the Beacon platform is unable to determine that these requirements were met, it would not validate the claim and inform the Covered Entity of the reason for the rejection.To support these validations, the Beacon platform may reject claims for various reasons, for example, if a Covered Entity's 340B ID was not active in OPAIS at the time of the invoice purchase date, or if a claim was dispensed from a pharmacy not registered on the OPAIS database or designated in the 340B ESP system. As discussed below, the Beacon platform will inform Covered Entities of the reason for any rejection, and Covered Entities will have the ability to request reconsideration of the determination.

a. *Will AstraZeneca make these reasons publicly available in advance of adjudication of claims?*

Through its notification to Covered Entities as well as information available on the Beacon platform, AstraZeneca will inform Covered Entities of the above validation requirements. Further, the Beacon platform will inform a Covered Entity that experiences a rejection of the reason the claim was not validated by the system.

b. *Will Covered Entities receive claim-by-claim information from AstraZeneca regarding which claims were rejected and on what basis?*

Yes. The Beacon platform will provide an explanation for the reason for the rejection of each claim.

c. *What reconsideration or appeals process will AstraZeneca implement to ensure Covered Entities receive any 340B discounts that are due as required by statute?*

The Beacon system includes a reconsideration process, allowing Covered Entities to provide additional information supporting their position. Reconsideration requests will be managed by the Beacon system in the first instance. Disputes that cannot be resolved will be escalated to an AstraZeneca team member that will engage with the Covered Entity in good faith to work through any issues.

6. With respect to the use of pharmacies with which Covered Entities contract:

a. *Will Covered Entities need to demonstrate that they purchased individual drugs subject to the rebate claim at wholesale acquisition cost?*

No. DSH Covered Entities will need to submit to the Beacon platform the Relevant Data listed in 2 a). These data elements are made available by every major wholesaler to DSH Covered Entities. Requiring a Covered Entity to demonstrate that it purchased the drug is important to ensuring that AstraZeneca does not provide the 340B price when MFP has been effectuated already.

b. Will this process require Covered Entities to maintain a separate stock of drugs at the contract pharmacy?

No, as with the prevalent virtual inventory model today, the pharmacy does not need to segregate its inventory based on the purchase price.

c. If so, how does AstraZeneca plan to ensure this process does not functionally deny Covered Entities access to the 340B price required by the statute given the additional upfront cost and administrative burden for Covered Entities, particularly low-margin safety net providers?

Not applicable.

7. Would the rebate be paid at the package level or at the dispense level?

a. Would rebates be paid to Covered Entities as soon as there is a full package or will Covered Entities receive a rebate based on the quantity dispensed per claim?

For FARXIGA® 340B utilization, the package level and the dispense level are identical. Rebates will be paid on NDC-11 packages consistent with how 340B prices are determined today.

b. How would AstraZeneca engage with Covered Entities with respect to these specifics of their prescription drug acquisition and distribution practices?

AstraZeneca's vendor Second Sight Solutions has already engaged the Covered Entity community with several webinars and solicits daily requests for information from Covered Entities. In addition, DSH Covered Entities will have access to a broad range of resources on the Beacon Support Center website https://beaconchannelmanagement.com to facilitate their use of the platform. The Beacon Support Center also supports direct customer engagement through an in-application chat feature as well as call center and email support. DSH Covered Entities can also register for a series of live webinars hosted by the Beacon Support Center.

8. **Under this proposal, how would AstraZeneca treat current unreplenished accumulations?**

AstraZeneca encourages all DSH Covered Entities to place 340B replenishment orders for all eligible utilization with dates of service that precede our implementation date prior to the launch of the Rebate Model. Additionally, as noted above, because FARXIGA® packages will have package sizes that align with the unit of dispense, Covered Entities generally should not have partially-accumulated package sizes of the product.

9. **Under the AstraZeneca plan, Covered Entities would be required to submit claims data to both 340B ESP and the rebate platform? HRSA has received a number of reports of technical and customer service difficulties with 340B ESP. How would AstraZeneca ensure Covered Entities could submit claims without technical difficulties or delays and would be able to access customer support with any significant issues with the Beacon platform?**

The Beacon platform will offer several means for customer support for any Covered Entities that have questions when using the platform. These channels will include direct customer engagement through an in-application chat feature as well as call center and email support, in addition to a broad range of resources on the Beacon Support Center website. Additionally, AstraZeneca understands that BRG has more than doubled the size of its customer support team in anticipation of the launch of the Beacon system.

* * * * *

AstraZeneca hopes the above information is helpful to HRSA in its continuing evaluation of AstraZeneca's Rebate Model. As AstraZeneca currently plans to announce its Rebate Model to Covered Entities in early 2025 for an April 2025 implementation date, AstraZeneca respectfully requests HRSA consider this submission in an expedited manner. AstraZeneca thus respectfully asks HRSA to provide a response by January 2, 2025.

Please be advised that much of the information referenced and discussed in this letter is proprietary and confidential and is not subject to disclosure under the Freedom of Information Act ("FOIA") pursuant to 5 U.S.C. § 552(b)(4) ("FOIA Exemption 4"). The legal protection of such confidential commercial material is also claimed under the applicable provisions of the Trade Secrets Act, 18 U.S.C. § 1905. AstraZeneca respectfully requests HRSA treat this letter as confidential commercial information and not subject to disclosure. If any information contained in this letter is requested under FOIA or otherwise, AstraZeneca requests that HRSA notify

AstraZeneca

AstraZeneca of the request and afford AstraZeneca the opportunity to subject objections to any disclosure.

Sincerely,

Joris Silon
Joris Silon (Dec 17, 2024 17:42 EST)

Joris Silon
SVP, U.S. President
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AZ - Draft Response to 12.10 HRSA Letter FINAL(7409811.6)

Final Audit Report 2024-12-17

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AstraZeneca

Meeting with John Brooks: 340B Rebate Model

Chris Mancill, SVP, Market Access

Dan Wygal, VP, US Corporate & Government Affairs

Sarah Arbes, head of US Federal Affairs & Policy

Claudia Vainstein, Executive Director, Contract Operations

Sky Adams, Senior Counsel

Steven Chen, Director, US Policy



1

Unavoidable duplicate discounts under IRA and 340B

- Inflation Reduction Act established a 'maximum fair price' (MFP) as the negotiated price of a Medicare Part D drug
- Manufacturers must provide the lower of the MFP price versus the 340B price
- Duplicate discounts are unavoidable in the current system
  - MFP effectuation must occur within 14 days
  - 340B eligibility is determined in months
- Final CMS guidance (IPAY2027)[1] puts the process of removing duplicate discounts on manufacturers
- Manufacturers are also required to submit their proposed process for implementing MFP to CMS by September 2025

[1] Memo from CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 (October 2, 2024)*

2

Rebate models solve for duplicate discounts

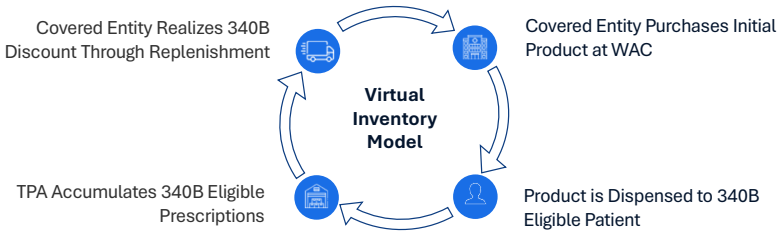
- AstraZeneca intends to implement the Beacon Rebate Model for its MFP selected product FARXIGA
- Rebate models are compliant with federal law and expressly permitted in the 340B Statute
- Model is necessary to meet current requirements under the IRA and 340B statute [2]
  - CMS requirement of a system effectuating MFP
  - Prohibition on duplicate discounts between MFP and 340B
- Rebates are a standard settlement method for healthcare transactions (e.g., payments to PBMs, GPOs)

[2] Section 340B of the federal Public Health Service Act, 42 U.S.C. § 256b

3

Beacon

The virtual inventory model endorsed by HRSA[1] provides a blueprint for a 340B rebate model



The initial dispense to a 340B eligible patient is not necessarily filled with a product purchased at the 340B price

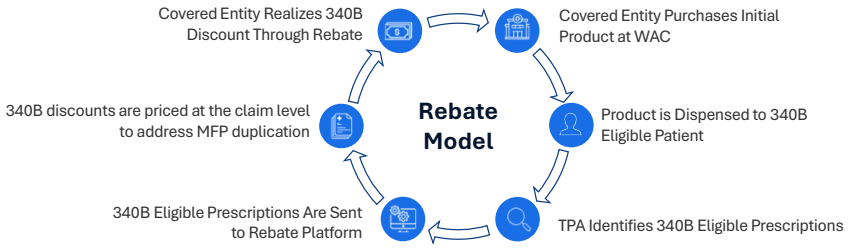
The economic value associated with 340B pricing is only realized upon full accumulation of an NDC-11 – which could be weeks or months after initial purchase

1. HRSA FAQ ID 1352

4

Beacon

A rebate model would ensure no MFP duplication while addressing other challenges stemming from the current chargeback system



Covered entities still purchase initial inventory at WAC

Following accumulation of sufficient 340B eligible prescriptions, a rebate is issued to the covered entity and associated with the initial WAC purchase

Manufacturers gain access to claims level data prior to issuing rebate allowing for proper calculation of the 340B discount and ensuring no duplication across all channels

5

Beacon

The Rebate Model can address different degrees of cash flow concerns for covered entities

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Improve payment processing

The current model always requires dispensing and full accumulation, The Rebate Model can bypass these, processing payment faster than the current model

The current model relies on shipment of new, reduced-price inventory to realize the 340B discount while a direct rebate payment eliminates product logistics

Product Logistics 02
Simplify & Process Clarity

03 Payment timelines
Mitigate cash flow impact

Wholesaler payment terms typically extend 14 to 30 days from purchase. The Rebate Model can enable payments to Covered Entities prior to wholesaler invoicing.

6

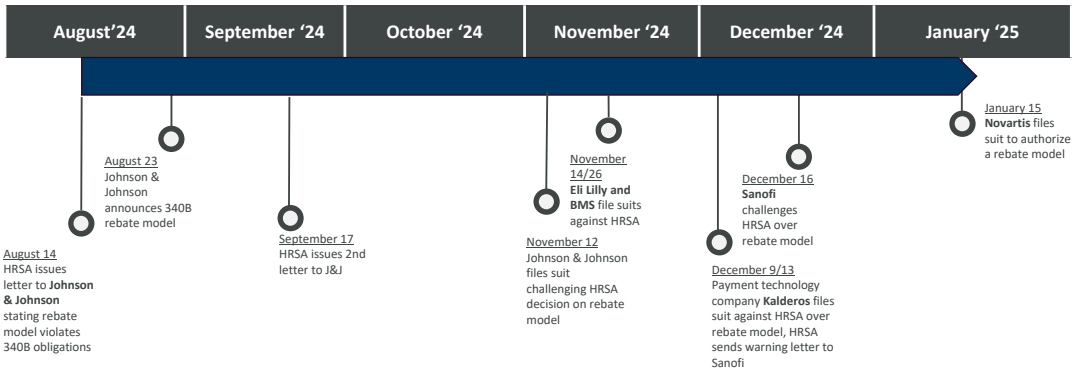
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7

HISTORY OF REBATE MODEL

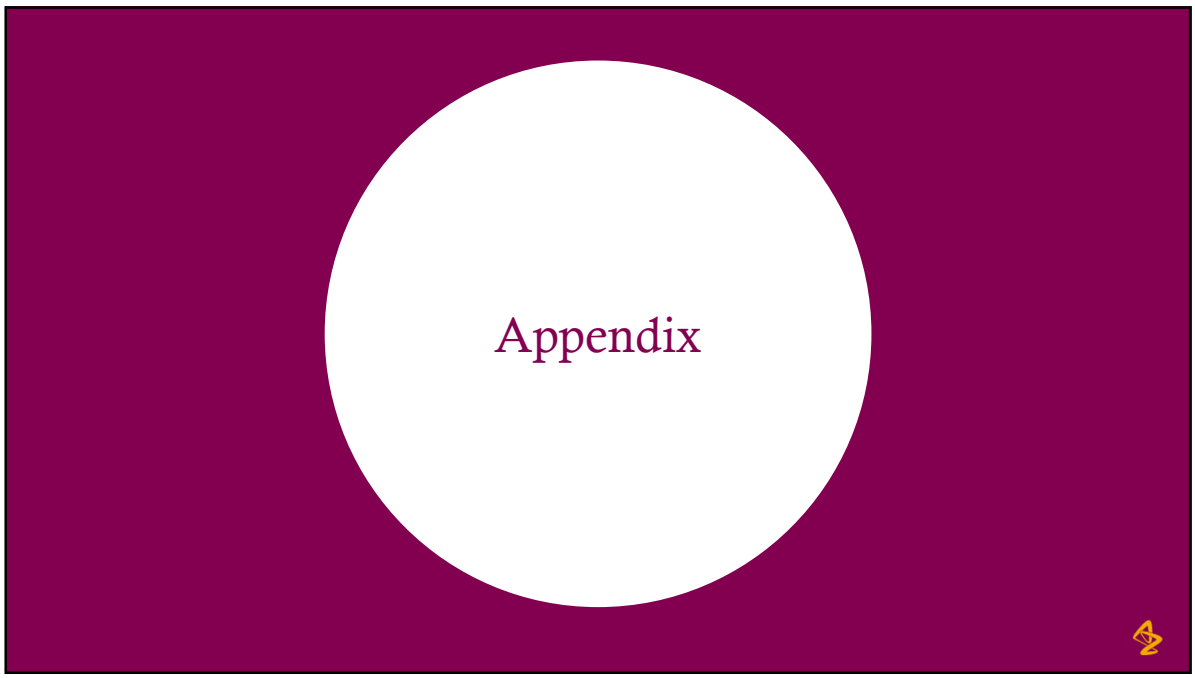
Timeline of HRSA and pharmaceutical manufacturers interactions



8



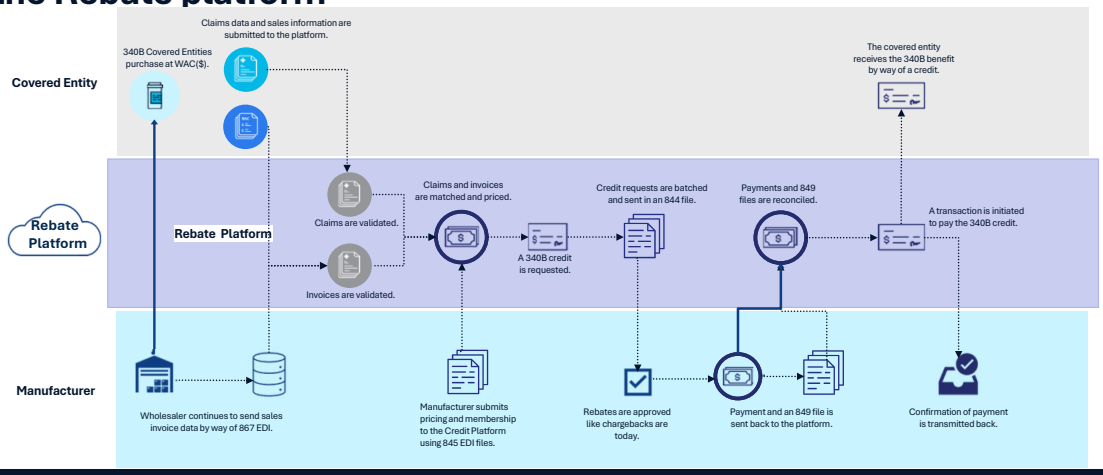
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10

Beacon

Rebate payments are made directly to 340B covered entities via the Rebate platform



11

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AstraZeneca

Meeting with HRSA: 340B Rebate Model

Chris Mancill, SVP, Market Access

Dan Wygal, VP, US Corporate & Government Affairs

Sarah Arbes, Head of US Federal Affairs & Policy

Jessica Matthias, Senior Director, Market Access Operations

Sky Adams, Senior Counsel

Steven Chen, Director, US Policy

March 17, 2025



1

Unavoidable duplicate discounts under IRA and 340B

- Inflation Reduction Act established a 'maximum fair price' (MFP) as the negotiated price of a Medicare Part D drug
- Manufacturers must provide the lower of the MFP price versus the 340B price
- Duplicate discounts are unavoidable in the current system
  - MFP effectuation must occur within 14 days
  - 340B eligibility is determined in months
- Final CMS guidance (IPAY2027)[1] puts the process of removing duplicate discounts on manufacturers
- Manufacturers are also required to submit their proposed process for implementing MFP to CMS by September 2025

[1] Memo from CMS, *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 (October 2, 2024)*

2

Rebate models solve for duplicate discounts

- AstraZeneca intends to implement the Beacon Rebate Model for its MFP selected product FARXIGA
- Rebate models are compliant with federal law and expressly permitted in the 340B Statute
- Model is necessary to meet current requirements under the IRA and 340B statute [2]
  - CMS requirement of a system effectuating MFP
  - Prohibition on duplicate discounts between MFP and 340B
- Rebates are a standard settlement method for healthcare transactions (e.g., payments to PBMs, GPOs)

3

[2] Section 340B of the federal Public Health Service Act, 42 U.S.C. § 256b

3

Rebate model will not burden selected covered entities

Cash Flow Positive

Under the Rebate Model, AstraZeneca will pay the rebate to the Covered Entities via ACH, within 7 to 14 days from receipt of the Submission Data, as compared to today's wholesaler payment terms ranging from 14 to 30 days.

340B Discount divorced from Inventory Management

A direct cash payment is issued to the Covered Entity upon verification of 340B eligible prescriptions.

Leverage Existing Data

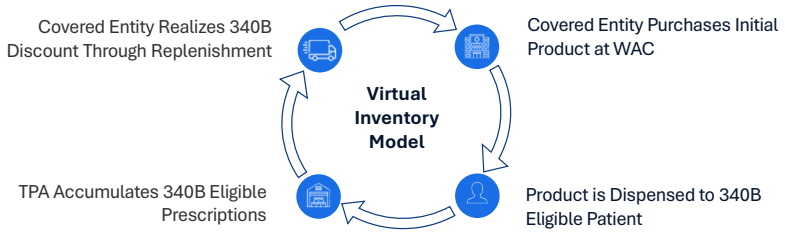
The Rebate Model will require Covered Entities to submit data required today for 340B program participation.

Beacon Field	NCPDP Standard	HRSA Standard
340b_id		Parent 340B ID
date_prescribed	414-DE	
date_of_service	401-D1	
fill_number	403-D3	
ndc_11	407-D7	
prescriber_id	411-DB	
quantity	442-E7	
bin_number	101-A1	
rx_number	402-D2	
pcn_number	104-A4	
service_provider_id	201-B1	

4

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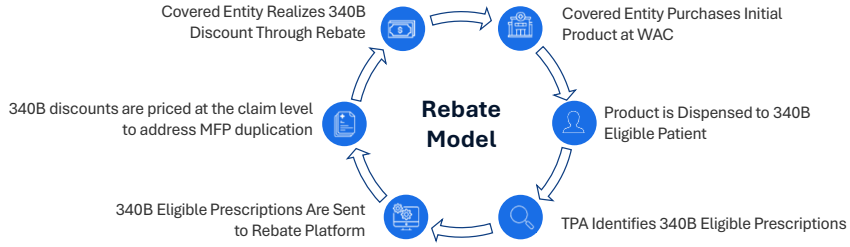
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- The Rebate Model simply allows a manufacturer to avoid duplication of MFP and 340B discounts

8

8

Timeline of AZ engagements with HHS and HRSA

- Nov. 14, 2024 - Meeting with HRSA and HHS OGC
- Nov. 18, 2024 - Follow-up letter to Rear Admiral Pedley
- Dec. 10, 2024 - HRSA letter to AZ
- Dec. 17, 2024 - AZ response to HRSA letter
- Jan. 21, 2025 - AZ follow-up letter to John Brooks
- Feb. 19, 2025 - Meeting with John Brooks
- Mar. 17, 2025- Meeting with John Brooks

9

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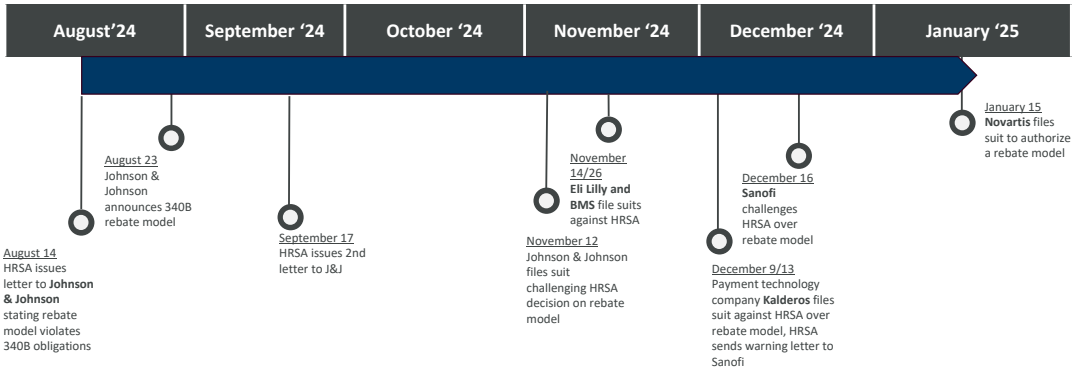
Appendix

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10

HISTORY OF REBATE MODEL

Timeline of HRSA and pharmaceutical manufacturers interactions

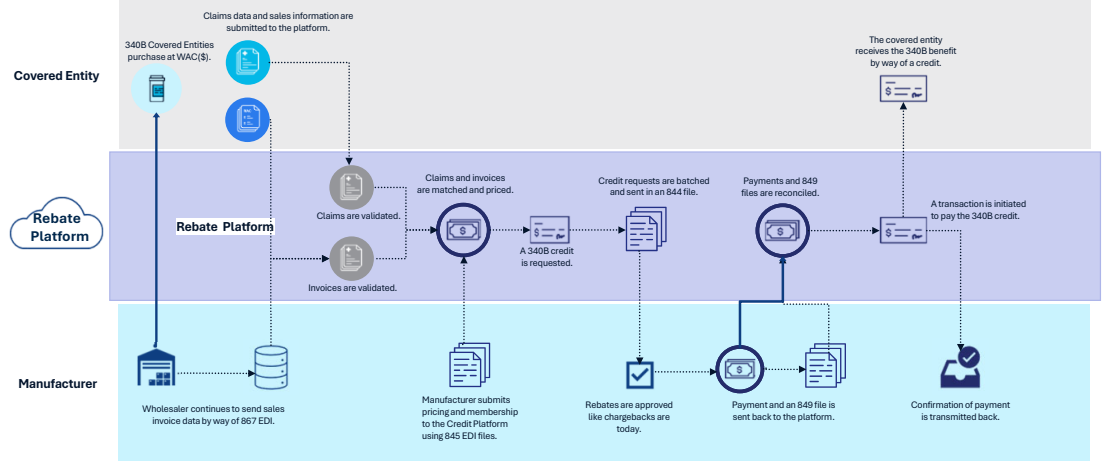


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Beacon

Rebate payments are made directly to 340B covered entities via the Rebate platform



12

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13

13

HRSA
Health Resources & Services Administration
Office of Special Health Initiatives
5600 Fishers Lane
Rockville, MD 20857

October 21, 2025

BY EMAIL
Chris Mancill
Senior Vice President, Market Access
AstraZeneca Pharmaceuticals, LP
Chris.mancill@astrazeneca.com

Dear Chris Mancill:

The Office of Pharmacy Affairs (OPA) has received and reviewed AstraZeneca Pharmaceuticals LP's (AstraZeneca) plan for participation in the 340B Rebate Model Pilot Program and is requesting additional information. OPA recognizes that the stated October 15, 2025, date for approval of rebate plans has passed due to the lapse in Federal appropriations affecting certain agency operations, but OPA is now working expeditiously to review plans as soon as possible. In order to complete our evaluation of AstraZeneca's plan, OPA requests that AstraZeneca provide the following revisions and clarifications.

OPA has reviewed AstraZeneca's request to collect certain medical claims data that was in addition to the data fields identified in the August 7, 2025, Federal Register Notice. After review, OPA recognizes that some medical claims data is required to effectuate rebates for physician-administered drugs. Therefore, to the extent a claim qualifies as a pharmacy claim or medical claim, the updated table below reflects the allowable data fields AstraZeneca may collect on its IT platform from covered entities.

Pharmacy Claims Data Fields	**Medical Claims Data Fields**
Date of Service	Date of Service
Date Prescribed	Claim Line Number
Rx number	Claim Number
Fill number	Unit of Measure
NDC-11	NDC-11
Quantity Dispensed	Quantity
Prescriber ID	Rendering Physician ID
Service Provider ID	Service Provider ID
340B ID	340B ID
RX BIN	Health Plan Name
RX PCN	Health Plan ID

AstraZeneca has also requested the collection of purchase data. During the initial phase of the Rebate Pilot Program, OPA will not approve plans that require purchase data to be submitted with the claims data. It is OPA's understanding that manufacturers can use information provided by their wholesale

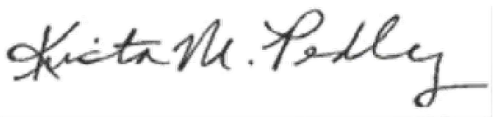
partners to verify the appropriate number of WAC purchases in the 340B wholesale account for Rebate Pilot Program drugs, relative to the number of 340B rebates requested. OPA's expectation is that all Rebate Pilot Program drugs will continue to be ordered through the 340B wholesale account to assist with manufacturers' visibility into 340B eligible purchases.

In addition, OPA requests the following revisions and clarifications of AstraZeneca's plan:

- Please provide an AstraZeneca point of contact and email address, for covered entities who have questions to be posted on the OPA website summary of AstraZeneca's plan, if approved.
- Please clarify if all purchases will occur at the same acquisition cost, such as WAC, or if covered entities' acquisition cost will vary by contract.
- Please clarify that the rebate will be calculated based on the WAC and 340B ceiling price as of the date of dispense.
- Please clarify if covered entities will be provided with an opportunity to resubmit data if denied for incomplete or missing data.
- Please clarify how wasted or undispensed units should be characterized during claims submission.
- Please clarify how rebate requests for cash or uninsured patients should be characterized during claims submission.
- Public comments submitted from the August 7, 2025, *Federal Register Notice*, identified the concern that the rebate model would cause difficulties with Medicaid billing at actual acquisition cost (AAC) and difficulties in providing sliding fees to uninsured patients. Currently, covered entities receive pricing files with 340B ceiling prices from wholesalers that feed the pharmacy billing systems, which allow covered entities to bill at AAC and allow for sliding fees that share savings with eligible patients. OPA requests that AstraZeneca work with its wholesale partners to provide a supplemental pricing file with the 340B ceiling prices for Farxiga NDCs to assist covered entities with the Medicaid billing requirements and assist with providing patients with the shared savings.
- AstraZeneca's plan indicates that claims will be deemed eligible if the unit amount on the 340B claim does not exceed WAC purchases made during the 340B rebate pilot. It should be noted that covered entities operating under a virtual replenishment model are starting with a neutral inventory so they may not have WAC purchases made at the beginning of the pilot period for their initial purchase. AstraZeneca should consider this during the initial phase of the pilot period.

Please provide the requested information and confirm that AstraZeneca accepts the allowable data fields outlined in this letter and that AstraZeneca will ensure wholesalers provide a supplemental pricing file for covered entities' billing use, no later than **October 24, 2025,** to **340BPricing@hrsa.gov**. In recognition of the short response request, OPA can be available for a virtual meeting to discuss any questions you may have prior to the response deadline.

Sincerely,



Krista M. Pedley, Pharm D, MS
RDML, USPHS Assistant Surgeon General
Director, Office of Special Health Initiatives

AstraZeneca's 340B Rebate Model Pilot Program Plan: FARXIGA®

This proposal includes the provision of the 340B price as a unit-based rebate for FARXIGA® dispensed outpatient by all 340B entity types and their designated contract pharmacies, regardless of payer, with the rebate effectuated by the Beacon technology platform. The proposed start date is January 1, 2026, with an announcement date no later than 10/31/25. We propose a quarterly call with the agency to discuss progress.

340B Rebate Model Pilot Program Criteria

General Requirements

1. All costs associated with development, implementation, and administration of the Beacon Platform will be borne by AstraZeneca and not passed onto the Covered Entities.

2. AstraZeneca will provide 60 calendar days' notice to covered entities, and other impacted stakeholders, before implementation of a rebate model with instructions for registering on the Beacon Platform.

3. Covered Entities will be able to order FARXIGA® at the Wholesale Acquisition Cost (WAC) under their 340B wholesaler account. AstraZeneca expects Covered Entities to only purchase FARXIGA® packages, that are intended to receive 340B rebates, via this WAC based contract in the 340B account.

4. AstraZeneca will provide technical assistance, customer service, educational resources, and a free entity-user platform that enables search functionality and reconciliation reporting through Beacon – a technology platform operated by Second Sight Solutions. Entities will have opportunities to engage in good faith regarding questions directly through Beacon's customer support team. Certain inquiries may be escalated to AstraZeneca for resolution.

5. AstraZeneca and its partner, Second Sight Solutions, provide comprehensive and robust data security. Additional information on Beacon's security protocols can be found here: https://beaconchannelmanagement.com/pages/trust-center. The collection of the data is limited to the elements listed below that are necessary for providing 340B rebates pursuant to section 340B(a)(1) of the PHSA.

6. The Beacon Platform has mechanisms in place to protect patient identifying information in a manner consistent with the Health Insurance Portability and Accountability Act of 1996 and any other applicable privacy and data security laws.

Reporting Requirements

7. Covered Entities will be required to submit the data elements to the Beacon platform within 45 days of the date of the dispense of FARXIGA®. Covered Entities will also be provided an opportunity to resubmit data within the same 45-day window if it was originally denied for incomplete or missing data. Allowances for extenuating circumstances and other exceptions, including adjustments for when a claim status changes to 340B outside of the 45-day window, will be considered according to AstraZeneca's standard business practices. 340B submitted claims in error should be reversed as soon as discovered, and credits for such reversals will be used to offset future 340B rebate payments. This process will be transparent to entities in the Beacon platform and the Beacon customer support team will be available to resolve inquiries.

8. The Beacon Platform will have the capacity to receive data, filter, and use only the data required to effectuate the rebate.

9. The Beacon Platform will have the capability to provide real-time reconciliation reports for Covered Entities to be informed of the rebate status of submitted claims. Each quarter, Beacon will also provide all registered Covered Entities with a 340B pricing file containing the 340B ceiling price for each FARXIGA® NDC to assist with Medicaid billing requirements.

10. AstraZeneca will provide periodic reports as specified by OPA.

Rebates

11. FARXIGA® rebates will be paid at the unit level. The calculated rebate will be the difference between WAC and the 340B ceiling price at the date of dispense.

12. AstraZeneca will pay rebates via the Beacon platform to the Covered Entity (or deny with supporting documentation) within 10 calendar days of data submission.

13. AstraZeneca will use 340B and MFP claims data elements to conduct deduplication. When duplication is identified, adjustments will be made to the MFP rebate. This approach is described further in AstraZeneca's MFP effectuation plan for IPAY 2026, as submitted to CMS. Good faith questions/concerns will be addressed by the Beacon customer support team.

14. AstraZeneca's Plan will ensure that 340B rebates are only paid on sales of FARXIGA®, regardless of payer. 340B claim submissions by Covered Entities will be deemed eligible for rebate payments when the following criteria have been met:
    a) The NDC on the 340B claim is one of the NDCs incorporated into AstraZeneca's 340B rebate model pilot.
    b) The date of dispense occurs during the 340B rebate model pilot period.
    c) The dispensing pharmacy or site of administration is registered with HRSA as an eligible 340B covered entity location
    d) The 340B claim has not already been submitted by another 340B covered entity.

    AstraZeneca will monitor the number of 340B claims relative to the number of WAC purchases and will communicate instances of misalignment to HRSA. AstraZeneca will allow a grace period for Covered Entities operating under a virtual replenishment model and starting with a neutral inventory.

Data

15. AstraZeneca will utilize Beacon to collect the data required by the US Department of Health and Human Services for purposes of this pilot. This includes Pharmacy and Medical claims data as outlined below. For avoidance of doubt, Covered Entities should populate the BIN/PCN fields with "CASH" for uninsured or cash patients.

    Pharmacy Claims Data:

    a) Date of Service
    b) Date Prescribed
    c) RX Number
    d) Fill Number

e) 11 Digit National Drug Code (NDC)
f) Quantity Dispensed
g) Prescriber ID
h) Service Provider ID
i) 340B ID
j) Rx Bank Identification Number (BIN)
k) Rx Processor Control Number (PCN)

Medical Claims Data:

a) Date of Service
b) Claim Line Number
c) Claim Number
d) Unit of Measure
e) 11 Digit National Drug Code (NDC)
f) Quantity
g) Rendering Physician ID
h) Service Provider ID
i) 340B ID
j) Health Plan Name
k) Health Plan ID

Any questions regarding AstraZeneca's plan should be directed to 340B@astrazeneca.com.

Regards,

Chris Mancill (24-Oct-2025 15:16:30 EDT)

Chris Mancill

Senior Vice President, Market Access

AstraZeneca

Health Resources & Services Administration

Office of Special Health Initiatives
5600 Fishers Lane
Rockville, MD 20857

October 30, 2025

BY EMAIL
Steven Chen
Director, US Policy
AstraZeneca Pharmaceuticals LP
steven.chen5@astrazeneca.com

Dear Steven Chen:

The Office of Pharmacy Affairs (OPA) has received and reviewed AstraZeneca Pharmaceuticals LP's (AstraZeneca) plan for participation in the 340B Rebate Model Pilot Program. The revised plan submitted on October 28, 2025, is approved for an implementation date of January 1, 2026.[1]

OPA has approved the data fields below for participating manufacturers to request from covered entities as part of the 340B Rebate Model Pilot Program. It should be noted that data requests are limited to these approved fields, and that no rebate claims may be denied for the absence of the optional fields outlined below.

Pharmacy Claims Data Fields	**Medical Claims Data Fields**
Date of Service	Date of Service
Date Prescribed	Claim Line Number
Rx number	Claim Number
Fill number	Unit of Measure
NDC-11	NDC-11
Quantity Dispensed	Quantity
Prescriber ID	Rendering Physician ID
Service Provider ID	Service Provider ID
340B ID	340B ID
RX BIN	Health Plan Name
RX PCN	Health Plan ID
Group Number ID (optional)	Health Plan ID Qualifier (optional)
	HCPCS Code (optional)
	HCPCS Modifiers (Up to 4) (optional)

During this initial phase of the Rebate Model Pilot Program, OPA is not allowing participating manufacturers to collect purchase data from covered entities, even as an optional field. However, OPA will instruct covered entities to purchase products subject to the pilot in their current 340B wholesale accounts

[1] As outlined in the *Federal Register Notice*, the scope of the 340B Rebate Model Pilot Program is limited to the NDC–11s included on the CMS Medicare Drug Price Negotiation Selected Drug List ("List") for 2026. The NDCs submitted in the revised plan are approved only to the extent they are published on the List. Please work to ensure that all NDCs in the revised plan are included on the List as 340B-rebates may not be offered for any NDC that does not appear on the List.

at the prices loaded by manufacturers (generally at WAC). OPA will also instruct covered entities to request rebates only after a purchase and to dispense 340B-rebate purchases solely to eligible 340B patients. Manufacturers should continue to work with their distribution partners to leverage data from wholesalers to monitor that the number of purchases made at WAC in those 340B wholesale accounts correspond to the number of rebates requested, whether through a chargeback feed or other report. Only NDCs that appear on the CMS Medicare Drug Price Negotiation Selected Drug List and have an approved plan in place, should list a WAC price in a 340B wholesale account. All other covered outpatient drugs should list the 340B ceiling price in the 340B wholesale account. OPA will evaluate covered entity and manufacturer compliance with the rebate model pilot as part of its 340B compliance audits.

Consistent with the August 7, 2025, *Federal Register notice*, manufacturers must provide covered entities with 60 calendar days' notice before implementation of an approved rebate model, with instructions for registering for any IT platforms. Notice should also provide details of the rebate plan as described in the *Federal Register notice* and also include how covered entities should submit unreplenished accumulations that occur prior to the implementation date of the approved rebate model; technical assistance for setting up files for submission, including data definitions for each allowable data field; a description of how the rebate will be calculated and paid; and details for how to seek assistance from both the IT vendor and the manufacturer contact. OPA will post a summary of AstraZeneca's plan to the OPA website.

As noted in the August 7, 2025, *Federal Register notice*, manufacturers must agree to provide OPA with reports detailing 340B-rebate purchases, and information related to claim delays and denials. In order to facilitate transfer of this data, OPA requests that AstraZeneca submit reports via Application Programming Interface (API) submissions to the 340B Prime Vendor, at least monthly. The attached file provides the requested fields. Please register at www.login.warehouse.apexus.com to create an account for reporting.

As a reminder, OPA reserves the right to revoke approval of AstraZeneca's participation in the 340B Rebate Model Pilot Program at any time if the manufacturer is not compliant with the plan as approved, including by denying rebates to covered entities for reasons not consistent with the August 7, 2025, *Federal Register notice* and not established in the approved plan.

HRSA plans to continue our collaboration with you in the coming months and as the pilot begins so that progress can be monitored and concerns addressed as they arise. Questions may be directed to 340BPricing@hrsa.gov.

Sincerely,



Krista M. Pedley, Pharm D, MS
RDML, USPHS Assistant Surgeon General
Director, Office of Special Health Initiatives

Attachment

Claim submission date	340B ID	NDC-11 Purchased	Quantity	Unit WAC price	Unit 340B ceiling price	Unit MFP	Rebate amount	Rebate Date Paid	Rejection Reason

Dunn Isaacson Rhee

December 23, 2025

Hon. Lance E. Walker
Chief U.S. District Judge
Edward T. Gignoux U.S. Courthouse
156 Federal Street
Portland, Maine 04101

Re: AstraZeneca Pharmaceuticals LP's "Supplemental Filing of Records Reflecting Agency Approval of Pilot Program Proposal" (ECF Doc. 88)

Dear Chief Judge Walker:

Following Defendants' unauthorized sur-reply submission, non-party AstraZeneca has now added its own belated submission. It was improper for a party to submit belated materials, and it is more so for a drug company that was denied intervention. With the January 1, 2026 effective date rapidly approaching, Plaintiffs do not wish to waste this Court's resources with a lengthy response. We simply note that, like Defendants' submission yesterday, AstraZeneca's documents only underscore the many Administrative Procedure Act failings with Defendants' Rebate Program. For example:

- The bulk of AstraZeneca's submission contains documents that pre-date the Rebate Program—when Defendants were *objecting* to drug companies' unilateral efforts to impose a rebate model. Accordingly, AstraZeneca's documents underscore that, as Plaintiffs have alleged, Defendants never adequately addressed reliance interests or explained their change in position just a year later. *E.g.*, ECF Doc. 1 ¶¶ 43–44, 110; *see also* ECF Doc. 3 at 4–5.
- AstraZeneca cites its *own* private presentations to the government in early 2025. These are not a substitute for a Defendant agency's explanations of costs and benefits of the Rebate Program, especially following *two* public comment periods. *E.g.*, *Ohio v. EPA*, 603 U.S. 279, 293–94 (2024) (holding EPA "ignored an important aspect of the problem" where "commenters posed

Dunn Isaacson Rhee LLP
401 9th Street, NW
Washington, DC 20004
(202) 240-2900

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this concern to EPA during the notice and comment period, [but] EPA offered no reasoned response" (quotation omitted)).

- None of AstraZeneca's documents address the hundreds of millions of dollars in *administrative costs* that Plaintiffs and their members will pay (and are paying now) as a result of Defendants' unlawful Rebate Program—a cost that the government *has admitted* that it did not adequately consider. *See* ECF Doc. 1 ¶¶ 144 & n.12, 145, 149; ECF Doc. 75-1 (Britton Decl.) ¶ 35.

These documents obviously do not, as AstraZeneca suggests, "indicate the agency's consideration of the program's potential costs for covered entities." ECF Doc 88 at 1. We are of course happy to provide any additional submissions should the Court find such briefing helpful.

Respectfully submitted,

/s/ L. Rush Atkinson

Karen L. Dunn*
L. Rush Atkinson*
Lyle W. Gruby*
Jenifer N. Hartley**
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UNITED STATES DISTRICT COURT

DISTRICT OF MAINE

AMERICAN HOSPITAL ASSOCIATION, et al.,	)	
Plaintiffs,	)	
v.	)	No. 2:25-cv-00600-LEW
ROBERT F. KENNEDY, JR., SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,	)	
Defendants.	)	

ORDER ON MOTION FOR PRELIMINARY INJUNCTION

Like the old adage, "crawl, walk, run," the Administrative Procedure Act's (APA) arbitrary and capricious standard imposes vanishingly minimal requirements that a federal agency must satisfy before launching a new program or policy. Those minimal requirements are simply that the agency action be reasonable and reasonably explained. Thus, before a new program that affects the rights and privileges of the public can be up and running, the agency must undertake the basic task of developing a contemporaneous record of the relevant factors it considered and provide a reasoned explanation for its course of action.

This axiomatic principle of administrative law is no less applicable in the context of administering complex federal drug pricing laws. With the laudable goal of resolving competing congressional directives to offer price concessions to certain "covered entities"

under both the longstanding 340B Program and the nascent Inflation Reduction Act's Drug Price Negotiation Program, the Health Resources and Services Administration (HRSA) plans to launch a hastily assembled 340B Rebate Model Pilot Program (the Rebate Program) on January 1, 2026, to "deduplicate" these price concessions. Although the HRSA is empowered by statute to achieve the de-duplication objective through a rebate model, and although it applies to only a subset of drugs sold to 340B covered entities, it marks a departure from the Agency's decades-long practice of requiring upfront discounts on 340B eligible drugs, and the Agency's roll out has involved a rather threadbare administrative record that likely fails to consider and reasonably explain the impact of a rebate model on 340B hospitals, who rely on upfront price concessions to stretch few resources as far as possible to serve rural and poor communities. The APA likely requires more from Defendants. For the reasons explained below, Defendants are preliminarily enjoined from implementing the Rebate Program pending further order.

BACKGROUND

In 1990, Congress created the Medicaid drug pricing rebate program to lower the cost of pharmaceuticals reimbursed by the States under Medicaid. The program conditions Medicaid and Medicare Part B coverage for a pharmaceutical companies' (hereafter "manufacturers") products on the manufacturer's participation in rebate agreements with the Secretary of Health and Human Services (HHS). By participating, manufacturers are contractually bound to pay rebates to state Medicaid programs at the statutorily determined price for certain drugs.

In 1992, Congress separately enacted Section 340B of the Public Health Service Act to assist "covered entities" (i.e., safety-net healthcare providers serving the most vulnerable populations) with their drug-acquisition costs. Pub. L. No. 102-585 § 602 (1992). Under Section 340B, manufacturers enter into pricing agreements with the Secretary in exchange for having their drugs covered by Medicaid and Medicare Part B. 42 U.S.C. § 1396r-8(a)(1); *id.* § 256b(a). In these 340B agreements, manufacturers agree to provide upfront discounts to 340B covered entities, such as Plaintiffs. Critical to understanding this unfolding narrative is the fact that Medicaid and the 340B Program are different programs imposing different pricing constraints on participating manufacturers.

Since the inception of the 340B drug pricing program, HRSA has required drug manufacturers to provide 340B discounts at the time of sale, colloquially called "upfront discounts," *id.* § 256b(a)(1); Section 602 Guidance, 58 Fed. Reg. 27289, 27291-92 (May 7, 1993), in order to "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive resources." H.R. Rep. No. 102-384(II) at 12 (1992). As recently as last year, HRSA rejected several manufacturers' proposal to switch to a rebate model, taking the position that an upfront discount model is superior and the switch would be disruptive to the operation of the 340B program. *See* Compl. ¶¶ 43–46, 48; Ex. 1 at -66; Ex. 4 at -292; Ex. 5 at -342.

However, in the state-administered Medicaid context, a rebate model is standard. In the Inflation Reduction Act of 2022 (IRA), Congress established the Medicare Drug Price Negotiation Program, which authorizes the Secretary to negotiate a "Maximum Fair Price" (MFP) that Medicare pays for certain eligible drugs. Inflation Reduction Act of

2022, Pub. L. No. 117-169, 136 Stat. 1818; U.S.C. §§ 1320f(a), 1320f-1(b), (d), (e). State Medicaid programs generally pay more than the MFP when administering Medicaid but receive a rebate from manufacturers to ensure that they pay only the MFP on behalf of qualifying patients.

Because several drugs are subject to both the Medicaid MFP and the 340B price concession, there is the potential (commonly realized) that manufacturers are mistakenly subjected to duplicative price concessions when a MFP rebate is claimed for a drug that a covered entity purchased at the 340B price.[1] Where MFP and 340B price concessions overlap, the IRA's "nonduplication" provision requires drug manufacturers to provide the lower of the 340B ceiling price and the MFP to covered entities, but not both. 42 U.S.C. § 1320f-2(d). There does not appear to be any dispute that a well-designed program would avoid duplication, and the parties generally refer to this objective as the "de-duplication" objective.

On July 31, 2025, HRSA announced the 340B Rebate Program, which would allow certain drug manufacturers to charge their drug's wholesale price to 340B covered entities and later issue a rebate to reflect the statutorily required discount price and achieve the de-duplication objective. *See* Press Release, HRSA, HRSA Announces Application Process for the 340B Rebate Model Pilot Program and Request for Public Comment (July 31,

[1] Section 340B covered entities also serve Medicaid participants and may dispense drugs to Medicaid participants that they purchased at the 340B discount price. When a Medicaid program seeks and receives the MFP rebate on these prescriptions, manufacturers will have provided a duplicative discount. Such loses spread across the entire 340B network add up to substantial sums of money that should have been realized by the manufacturers rather than the 340B entities or state Medicaid programs.

2025), https://www.hrsa.gov/about/news/press-releases/rebate-model-pilot-program (last visited Dec. 29, 2025). The next day, August 1, 2025, HRSA published notice of the new program in the Federal Register, inviting drug manufacturers to submit applications to participate. Rebate Program Application Notice, 90 Fed. Reg. 36163 (Aug. 1, 2025). HRSA's Notice explained the purpose of the Rebate Program was to address concerns over duplicate discounting by drug manufacturers attempting to ensure that covered entities receive only the 340B upfront discount or the IRA's Medicaid MFP, but not both. Corr. Rebate Program Application Notice, 90 Fed. Reg. 38165 (August 7, 2025). Between October 30 and November 14, 2025, HRSA approved rebate applications from nine eligible drug manufacturers for ten covered drugs. Although the applications concern only ten covered drugs, the anticipated program will be implemented across the entire population of 340B covered entities, all of whom will need to free up money to pay the much higher wholesale drug prices and implement new internal processes to pursue the rebates.[2]

On December 1, 2025, the American Hospital Association (AHA) and the Maine Hospital Association (MHA), along with several of AHA's and MHA's members, (collectively, "Plaintiffs") filed their Complaint (ECF No. 1) and Motion for Temporary Restraining Order (ECF No. 3), seeking to enjoin implementation of the Rebate Program.

[2] In addition to the preceding background concerning the legislative landscape and the deduplication effort, Plaintiffs' claims rely on a collection of facts associated with the nature and quality of the administrative record and the nature and quality of the harms that will be visited upon them by the Rebate Program. I relate those particularized facts in the preliminary injunction discussion that follows.

Plaintiffs allege that Federal Defendants'[3] establishment and implementation of the 340B Rebate Program violates the Administrative Procedure Act (APA) and ask this Court to declare the program unlawful under § 706 of the APA. Compl. ¶¶ 52-62, 130-175. Because the parties have all been heard on the propriety of emergency injunctive relief, including at a December 19, 2025 hearing, I construe Plaintiffs' Motion as a request for a preliminary injunction rather than a temporary restraining order. The parties have conferred and agree to proceed on this basis. Opp'n at n.1 (ECF No. 75).

DISCUSSION

The parties' briefs raise the issues of justiciability as well as the question of whether Plaintiffs can meet all four of the preliminary injunction factors. I therefore begin this discussion with the issue of whether Plaintiffs' claims present a justiciable controversy (they do) before turning to whether preliminary injunctive relief is warranted. Because I conclude that relief is warranted on the record presently before me, I necessarily conclude with a discussion of the appropriate nature and scope of relief.

A. JUSTICIABILITY

Before reaching the merits, I first briefly address Defendants' two arguments against judicial review: HRSA's promulgation of the Rebate Program is not final agency action and the decision to effectuate 340B prices through rebates is committed to agency

[3] Robert F. Kennedy, Jr. in his official capacity as Secretary of the U.S. Department of Health and Human Services; Thomas J. Engels, in his official capacity as Administrator of Health Resources and Services Administration (HRSA); the U.S. Department of Health and Human Services (HHS); and the United States of America. *Compl.* ¶¶ 19-23.

discretion by law. I reject both arguments because they mischaracterize the nature of Plaintiffs' claims. First, Defendants pettifog on the distinction between their general authority to administer a rebate model program and the approved applications that comprise the Rebate Program itself. As Defendants concede, however, the application approvals do constitute final agency action, which by their nature are reviewable under the APA. *See* 5 U.S.C. § 704. Second, Defendants maintain that because the Public Health Service Act provides the Secretary with the discretion to effectuate the 340B ceiling prices through either rebates or discounts, without a benchmark against which to judge the Secretary's choice, Congress committed that decision to the Secretary alone and the judicial branch must avert its gaze, judicial review being unavailable. Opp'n at 11-13. According to Defendants, that unreviewable discretion extends to the Agency's decision to approve the nine drug manufacturers' applications to participate in the Rebate Program. *Id.*

Assuming without questioning the Secretary's discretion to choose between discounts and rebates to effectuate 340B price concessions, see *Webster v. Doe*, 486 U.S. 592 (1988), the Agency's approval of the drug manufacturers' individual applications is reviewable under the APA. Judicial review of the approvals, including the scope of the resulting program and the expedited pace of its implementation, is entirely consistent with the APA's strong presumption of judicial review, and the longstanding practice of narrowly reading the agency discretion exception "to those rare administrative decisions traditionally left to agency discretion." *Dept. of Homeland Security v. Regents of the Univ. of Cal.*, 591 U.S. 1, 17 (2020) (citations omitted). Accordingly, judicial review of the Agency's

approval of the nine applications to participate in the "Rebate Program," is appropriate under the APA.

B. THE PRELIMINARY INJUNCTION FACTORS

The extraordinary and drastic remedy of a preliminary injunction requires a showing of four elements: (1) substantial likelihood of success on the merits; (2) a high likelihood of irreparable harm if injunctive relief is not granted; (3) a balance of equities tips in the movant's favor; and (4) the injunctive relief is in the public interest. *See Voice of the Arab World, Inc. v. MDTV Med. News Now, Inc.*, 645 F.3d 26, 32 (1st Cir. 2011) (citing *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). The last two factors "merge when the Government is the party opposing the preliminary injunction." *Nken v. Holder*, 556 U.S. 418, 435 (2009). The most important of the four elements is the likelihood of success on the merits—which is considered the "sine qua non" of the inquiry. *Ryan v. U.S. Immigr. & Customs Enf't*, 974 F.3d 9, 18 (1st Cir. 2020) (quoting *New Comm Wireless Servs., Inc. v. SprintCom, Inc.*, 287 F.3d 1, 9 (1st Cir. 2002)).

As explained below, the anemic administrative record alone supports a conclusion that Plaintiffs have made a strong showing of likelihood of success, at least as matters stand today. Additionally, Plaintiffs' showing of economic impact and disruption to services is substantial and, paired with such a strong showing on the merits, sufficient to demonstrate irreparable injury. With these initial factors tilting the board decisively in Plaintiffs' direction, the remaining factors easily slide in Plaintiff's favor.

1. Likelihood of Success on the Merits

The APA's arbitrary-and-capricious standard requires that agency action be both reasonable and reasonably explained. "An agency's decision is arbitrary and capricious if the agency relied on improper factors, disregarded 'an important aspect of the problem, offered an explanation that runs counter to the evidence,' or when a reasonable explanation for the agency's decision cannot be discerned." *Gulluni v. Levy*, 85 F.4th 76, 82 (1st Cir. 2023) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)); *accord Melone v. Coit*, 100 F.4th 21, 29-30 (1st Cir. 2024). Judicial review under this standard is deferential, and a court may not substitute its own policy judgment for that of the agency. *State Farm*, 463 U.S. at 43. "A court simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *Federal Communications Comm'n v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021); *accord Fam. Plan. Assoc. of Me. v. U.S. Dept. of Health and Human Srvs.*, 466 F. Supp. 3d 259, 266-67, 269 (D. Me. 2020).

a. The administrative record

A significant flaw with Defendants' institution of the Rebate Program relates to the paucity of the administrative record. Defendants present for review a July 31, 2025 press release, an August 1, 2025 Federal Register Notice (correction issued August 7), the Agency website's FAQs, a letter to the Office of Management and Budget (OMB), and a few documents and correspondence related to HRSA's approval of AbbVie Inc.'s and Janssen Pharmaceuticals, Inc. and Janssen Biotech, Inc.'s applications to participate in the Rebate Program. To fill the yawning void in this administrative "record," Defendants also

offer as a load-bearing beam to carry the weight of their argument the Declaration of Chantelle Britton (ECF No. 75-1), Director of the Agency's Office of Pharmacy Affairs, which Defendants aver is permissible for the court to consider to "illuminate reasons obscured but implicit in the administrative record." Opp'n at 14 n.5 (quoting *Clifford v. Pena*, 77 F.3d 1414, 1418 (D.C. Cir. 1996)).

"It is a 'foundational principle of administrative law' that judicial review of agency action is limited to 'the grounds that the agency invoked when it took the action.'" *Regents of the Univ. of Cal.*, 591 U.S. at 20 (quoting *Michigan v. EPA*, 576 U.S. 743, 758 (2015)). And while an agency may later "elaborate" on those grounds, it "may not provide new ones." *Id.* at 21 (citing *Camp v. Pitts*, 411 U.S. 138, 143 (1973) (per curiam)). "In other words, an agency must stand by the reasons it provided at the time of its decision and cannot rely on post-hoc rationalizations developed and presented during litigation." *In re Fin. Oversight and Mgmt. Bd. for P.R.*, 37 F.4th 746, 761 (1st Cir. 2022); *see also Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 419 (1971); *State Farm*, 463 U.S. at 50.

Despite Defendants' representations to the contrary, the Britton Declaration largely presents post hoc rationalizations absent from the administrative record, precisely the non-cotemporaneous explanations excluded from consideration in APA challenges. *See Regents of the Univ. of Cal.*, 591 U.S. at 23; *Am. Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 539 (1981) ("the post hoc rationalizations of the agency . . . cannot serve as a sufficient predicate for agency action"); *Overton Park*, 401 U.S. at 419 (rejecting "litigation affidavits" from agency officials as "merely '*post hoc*' rationalizations"); *Cal.*

v. U.S. Dept. of Educ., 132 F.4th 92, 99 (1st Cir. 2025) (rejecting litigation affidavit's "newfound claim of clarity" as post hoc rationalization). To the extent that this tatty administrative record is ambiguous, I consider the Britton Declaration for clarity, but because the record is mostly silent on salient considerations that would guide any rational policy-making process, Director Britton's representations are, for the most part, of no use. *Clifford*, 77 F.3d at 1418.

Finally, amicus AstraZeneca Pharmaceuticals LP offered documents and correspondence related to HRSA's approval of its Rebate Program application. *See* Sky Adams Decl. (ECF No. 88-1). The vast majority of these documents are AstraZeneca's own, and though I appreciate that AstraZeneca is a beneficiary of the Rebate Program, its contributions do not constitute the administrative agency record. To the extent they include HRSA's own documents, it is curious why the Agency did not incorporate them into the administrative record, let alone submit them for consideration. In any event, information presented in this filing is at best circumstantial evidence of what the Agency might have considered, not evidence that it did. Moreover, the animating principle behind the prohibition of post hoc rationalization in APA cases is that democratically unaccountable federal agencies wielding executive power to carry out congressional objectives must do their own homework, build an administrative record, and then demonstrate the application of something resembling a thought process in regard to what the record contains (more on that to follow).

b. Failure to provide a reasonable explanation or address significant reliance interests

Plaintiffs allege Defendants' failure to address significant reliance interests is fatal to the Rebate Program. Specifically, Plaintiffs' point to Defendants' failure to even state how 340B entities' more than thirty-year reliance interests in a discount model weighs against the Rebate Program's de-duplication goal. Mot. at 11. Plaintiffs further assert Defendants have failed to meet the APA's requirement of a reasoned explanation for their policy shift because they fail to offer genuine justifications for why the Rebate Program as designed was necessary to achieve its de-duplication goal, what costs and benefits might be relevant, or how patients could be affected. *Id.* at 10.

Defendants counter that they did reasonably explain the policy change and consider reliance interests. In its August 7, 2025 Federal Register Notice, HRSA explained that the purpose and nature of the Rebate Program is based on feedback from drug manufacturers and covered entities about addressing the de-duplication problem and to test the merits and shortcomings of a rebate model. Opp'n at 14-15; Corr. Rebate Program Application Notice, 90 Fed. Reg. 38165 (Aug. 7, 2025). Defendants also maintain that they did consider these reliance interests, pointing to a Federal Register Notice acknowledging the "fundamental[ ] shift" a rebate model offers, and explaining that the Agency has limited the scope of the Rebate Program to a pilot covering only 2% of total drug sales in the 340B

program.[4] Opp'n at 15; Corr. Rebate Program Application Notice, 90 Fed. Reg. 38165 (Aug. 7, 2025); Britton Decl. ¶¶ 5, 22-25.

When an agency changes position on prior policy that has engendered serious reliance interests, it is arbitrary and capricious to ignore the facts and circumstances engendered by that prior policy. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009); *Smiley v. Citibank (S.D.) N.A.*, 517 U.S. 735, 742 (1996). In these circumstances, "agencies are free to change their existing policies as long as they provide a reasoned explanation for the change, display awareness that they are changing position, and consider serious reliance interests." *Food and Drug Admin. v. Wages & White Lion Invs., LLC*, 604 U.S. 542, 568 (2025) (citations and quotations marks omitted). In considering reliance interests the agency must "assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." *Regents of the Univ. of Cal.*, 591 U.S. at 33.

At the threshold, Defendants concede Plaintiffs' "decades of industry reliance" in the 340B discount model is significant. *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016). What matters then is simply whether the Agency (1) reasonably explained its change in position, (2) displayed awareness of its change, and (3) considered Plaintiffs' serious reliance interests. It is clear the Agency has displayed awareness that the Rebate

[4] Plaintiffs dispute Defendants' characterization of the Rebate Program as "limited" or a "pilot." According to Plaintiffs, at least in its current iteration, the Rebate Program is a "pilot" in name only because it applies nationwide, mandating approximately 14,600 340B entities to participate in the Rebate Program for ten of the most commonly used drugs. *See* Compl. ¶¶ 7, 56; Reply at 9.

Program constitutes a shift in policy, and Plaintiffs do not contest this factor. On the remaining two factors, I find Plaintiffs are likely to succeed on the merits of their reliance interest claim but that their reasoned explanation claim is a closer call that I need not wade into at the preliminary injunction stage because Defendants' failure to address reliance interests is fatal to a January 1, 2026 rollout of the Rebate Program.

First, there is no evidence in the administrative record that Defendants considered Plaintiffs significant reliance interests. Defendants rely on a single sentence in their August 7, 2025 Federal Register Notice acknowledging "rebate models could fundamentally shift how the 340B Program has operated for over 30 years." Opp'n at 15 (quoting Corr. Rebate Program Application Notice, Fed. Reg. 38165 (August 7, 2025)). This is problematic for several reasons. First, the sentence does not support Defendants' contention that they considered 340B entities' reliance interests. Noting a change in a program's operation is not the same as recognizing that the change will impact 340B entities in detrimental ways. Furthermore, it does not evidence that HRSA weighed any reliance interest against the competing de-duplication policy concern or the proposed de-duplication approach favored by the participating manufacturers. *Regents of the Univ. of Calif.*, 591 U.S. at 33. Indeed, the record's silence on reliance interests reverberates throughout HRSA's approval of all nine Rebate Program applications. Defendants are left only to rely on post-hoc rationalizations in the Britton Declaration, which cannot substitute for the contemporaneous record. Accordingly, without anything more from the administrative record, the Britton Declaration does not "merely illuminate" the reasons "implicit in the administrative record," but rather offers impermissible non-contemporaneous explanations

precluded from consideration. *See U.S. Dept. of Educ.*, 132 F.4th at 99 ("this newfound claim of clarity approaches the sort of 'post hoc rationalization' that we cannot allow").

Although a closer call, it stands to reason Defendants have also failed to provide a reasoned explanation for the Rebate Program, at least in regard to design components. Arbitrary and capricious review is a minimal standard, and a reviewing court is only to assess "whether the [agency's] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Overton Park*, 401 U.S. at 416. Plaintiffs' allegations that the Rebate Program lacks "genuine justifications," Mot. at 10, seem to invite me to make a policy judgment in place of the Agency, something I cannot do. *State Farm*, 463 U.S. at 43. Defendants explain that the Rebate Program is based on resolving the deduplication problem, and it is not the provenance of the courts to second guess that determination, only to probe whether the Agency's consideration and explanation remained "within a zone of reasonableness." *Prometheus Radio Project*, 592 U.S. at 423. I agree with Defendants' explanation of my limited role regarding review of agency action, but exercising deference would be manifestly easier if there was any meaningful administrative record for me to review. It seems impossible to conclude that HRSA reasonably explained its policy change when the administrative record is entirely silent on a relevant factor—the 340B hospitals' reliance interests. And given the Agency's failure to consider significant reliance interests, I cannot say that the administrative record necessarily offers a reasonable explanation for the Defendants' establishment of the Rebate Program, though I need not wade into this at the preliminary injunction stage because Defendants' failure to address reliance interests is alone fatal to the Rebate Program.

c. Failure to consider relevant costs

Plaintiffs argue that Defendants ignored the costs associated with the Rebate Program, including administrative costs, the costs of paying full price for covered drugs and awaiting a rebate (sometimes referred to as "floating" costs), and other non-monetary costs. Pls.' Mot. at 12-15. Defendants counter they did consider these costs, citing the August 7, 2025 Federal Register Notice, their Emergency Letter to OMB, and the Britton Declaration. Opp'n at 17-18. Defendants aver the Agency's determination that the benefits of the Pilot Program outweigh those costs is entitled to substantial deference. *Id.* at 18.

A regulation is arbitrary and capricious "if the agency 'failed to consider an important aspect of the problem,'" which "includes, of course, considering the costs and benefits associated with the regulation." *Mexican Gulf Fishing Co. v. U.S. Dept. of Com.*, 60 F.4th 956, 973 (5th Cir. 2023) (quoting *State Farm*, 463 U.S. at 43). As part of its analysis, the agency must identify benefits that "bear a rational relationship to the . . . costs imposed." *Id.* "Consideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages and the disadvantages of agency decisions." *Michigan*, 576 U.S. at 753.

Fatal to Defendants' counterargument is their own admission that the Agency is "currently examining" administrative costs. Opp'n at 17 n.7. In other words, Defendants have not yet considered an important aspect of the problem, rather they are still evaluating administrative costs. Specifically, while in its letter to OMB, the agency initially estimated $200 million in compliance costs to 340B entities, the agency is still reviewing public "comments alleging an under-estimation of administrative costs . . . and will [later] address

those concerns." Britton Decl. ¶ 35 (citing Paperwork Reduction Act Notice, 90 Fed. Reg. 44197 (Sep. 12, 2025)). This failure to consider administrative costs before approving the manufacturers' applications under the Rebate Program is fatal under the APA. *Michigan*, 576 U.S. at 759-60.

The administrative record is also silent on the cost of floating the full price of covered drugs until 340B entities receive their rebate. Defendants only response is more post hoc rationalization in the Britton Declaration that the Agency's decision to limit the scope of the Rebate Program to ten drugs and require drug manufacturers to pay rebates within ten calendar days demonstrate their consideration of the burden that will be placed on 340B entities to float upfront costs. Britton Decl. ¶¶ 5, 27-30, 34, 38, 41. Similarly, the non-monetary costs to 340B entities, including the impact these additional prices might have on their long-term viability represents another unaddressed "important aspect of the problem." *State Farm*, 463 U.S. at 43.

Defendants' call for judicial deference on this determination rings hollow. Their bald assertion that the benefits of the Rebate Program outweigh any negative impact associated with floating the full price of covered drugs, Britton Decl. ¶¶ 34, 41, smacks of "clairvoyance" rather than the kind of "exercise in logic" deserving of judicial deference. *Fox Television Stations*, 556 U.S. at 521. Particularly as here where financial forecasts about what costs the 340B entities can bear for a certain period is not predicated on any specialized or expert knowledge of the Agency. *FCC v. Nat'l Citizens Comm. for Broad.*, 436 U.S. 775, 815 (1978). Even supposing it were, Defendants make no argument that such a determination is within their expertise aside from the naked claim that we should

simply take their word for it. Furthermore, any colorable argument to that effect is belied by the absence of any evidence in the administrative record about upfront costs, particularly considering the numerous public comments estimating hundreds of millions of dollars in additional costs to 340B hospitals they might struggle to pay under a rebate model.[5] *See, e.g.*, Austin Decl. ¶¶ 13-14 (ECF No. 4); Brown Decl. ¶¶ 14, 20 (ECF No. 5); Fadale Decl. ¶¶ 14-15, 21 (ECF No. 6).

For the foregoing reasons, the administrative record's silence on Defendants' efforts to consider and reasonably explain the relevant costs associated with the Rebate Program offer independent grounds to conclude that Plaintiffs have demonstrated a likelihood of success on the merits.

d. Other relevant factors and pertinent aspects

Plaintiffs also assert that Defendants' failure to address public comments, less costly alternatives, and issues with the electronic database used to collect and store rebate claims data and the rebate dispute resolution mechanism also invalidate the Rebate Program. Defendants maintain they are not required to respond to public comments and that they did consider these aspects of the problem.

In establishing and implementing the Rebate Program, Defendants were not required to respond to public comments. *Cf.* 5 U.S.C. § 553; *Perez v. Mortgage Bankers Assoc.*, 575 U.S. 92, 96 (2015). To the extent the public comments highlighted an

[5] I do not mean to suggest that Defendants must weigh the burdens imposed on each and every entity that makes up the Public Health Service. However, the fact that the "pilot" program impacts them all calls for something more than casual indifference to localized impacts.

important aspect of the problem, they may be evidence of an agency's failure to reasonably explain its position, which I already addressed in relation to reliance interests and costs. *State Farm*, 463 U.S. at 43. Plaintiffs' arguments concerning less costly alternatives, the dispute resolution mechanism, and the rebate database all venture into the territory of asking for a policy judgment against the Agency. *Id.* In other words, digging into these arguments likely requires policy considerations about the nature and scope of the Rebate Program and the effectiveness of some of its component parts. Considering that Plaintiffs are likely to succeed on the merits without wading into these trickier issues, my analysis of the merits stops here.

2. Irreparable Harm

Plaintiffs allege irreparable harm for the costs they will incur from the Rebate Program between floating the upfront costs of covered drugs (far in excess of the costs they will ultimately be responsible for), hiring additional staff to process and track rebate claims, and cutting back or altogether abandoning certain programs and services. Mot. at 16-19. Defendants contend Plaintiffs' costs associated with the Rebate Program are not irreparable because they are speculative, mitigated by the benefits they will receive from the Rebate Program, and impermissibly rely on alleged harm to third parties. Opp'n at 19-22.

Irreparable harm is "a cognizable threat" of "a substantial injury that is not accurately measurable or adequately compensable by money damages" to the movant. *Ross-Simons of Warwick, Inc. v. Baccarat, Inc.*, 102 F.3d 12, 19 (1st Cir. 1996). Although it need not "be fatal to [the movant's] business," *id.* at 18, it "must be grounded on something more than conjecture, surmise, or a party's unsubstantiated fears of what the

future may have in store." *Charlesbank Equity Fund II v. Blinds to Go, Inc.*, 370 F.3d 151, 162 (1st Cir. 2004). "The costs of complying with challenged regulations have been recognized as irreparable given the obstacles faced when suing for monetary damages." *Cal. v. Kennedy*, No. 25-12019-NMG, 2025 WL 2807729, at *6 (D. Mass. Oct. 1, 2025) (citing *Rosario-Urdaz v. Rivera-Hernandez*, 350 F.3d 219, 222 (1st Cir. 2003)).

Plaintiffs demonstrate irreparable harm. AHA members alone estimate $400 million in compliance costs, the downstream effect causing them to cut back services and suspend partnerships with drug distributors. Mot. at 16-19; Reply at 11-12; Golder Suppl. Decl. ¶¶ 2-4; Austin Decl. ¶¶ 10-13; Brown Decl. ¶ 18; Fadale Decl. ¶ 18. These claims are not unsubstantiated fears of what the future might hold. Nor do Plaintiffs' speculative concerns about delayed receipt and inappropriate denial of rebates from drug manufacturers defeat the meritorious aspects of their irreparable harm claim. Furthermore, because Plaintiffs raise an APA challenge, they cannot recover any damages for the costs incurred from the Rebate Program should it later be invalidated—a claim on which they are likely to succeed. Accordingly, their inability to recoup those costs in this context demonstrates irreparable harm. *Kennedy*, 2025 WL 2807729, at *6.

3. Balance of Equities and Public Interest

Plaintiffs maintain that the balance of equities and public interest weigh in their favor for several reasons, including the public's interest in preserving the reach of the Public Health Service to provide critical medical services, particularly when weighed against the lack of public interest in an agency carrying out a likely unlawful action. Mot. 19-20. Defendants assert that there is strong public interest in implementing the Rebate

Program to address the de-duplication problem and assess the benefits of a rebate model. Opp'n at 22.

The balance of equities and public interest weigh in Plaintiffs' favor. Most importantly, a preliminary injunction would preserve the status quo and preserve the reach of 340B entities to continue serving the public's significant interest in receiving critical medical services. *See Starbucks Corp. v. McKinney*, 602 U.S. 339, 344 (2024); *Rio Grande Cmty. Health Ctr., Inc. v. Rullan*, 397 F.3d 56 (1st Cir. 2005). Moreover, considering that Plaintiffs are likely to succeed on the merits of their APA claims, Defendants' arguments concerning equities and public interest in the Rebate Program are necessarily diminished. To be clear, Defendants' authority to administer a rebate model program is not in question, only the quality of the Rebate Program's current rollout effort in light of the APA.

4. Summation

As complicated as certain aspects of this case might seem, it boils down to a simple principle. Defendants cannot fly the plane before they build it. The Agency's failure to abide basic requirements of the APA, Plaintiffs' irreparable injury should the program go into effect, as well as the balance of equities weighing in Plaintiffs favor, all counsel against permitting the Rebate Program to take flight on January 1, 2026.[6] That, of course, is not to say that a rebate model is impermissible. Congress clearly gave Defendants that option. The problem is that the Defendants' failed to follow the APA's basic blueprint in

[6] April 1, 2026, for the application approved for Novartis Pharmaceuticals Corporation. *See* Opp'n at 7.

assembling the Rebate Program. For these reasons, Defendants are preliminarily enjoined from implementing this iteration of the Rebate Program pending further order.

C. SCOPE OF PRELIMINARY RELIEF

1. Preliminary Injunction

Defendants' cite *Trump v. CASA, Inc.*, 606 U.S. 831 (2025), for the proposition that the breadth of this preliminary injunction is limited to the specific identified association members of AHA and MHA or that the remedy should be tailored only to address the irreparable harm shown by specific members of these associations. Opp'n at 23-25. First, *Casa* declined to "resolve[ ] the distinct question whether the [APA] authorizes federal courts to vacate federal agency action." *CASA*, 606 U.S. at 847 n.10. Second, the First Circuit has already rejected Defendants argument that the remedy here must be limited to the "members whom the organizations identified in seeking associational standing." *Doe v. Trump*, 157 F.4th 36, 80 (1st Cir. 2025).

The APA authorizes federal courts to "hold unlawful and set aside agency action," 5 U.S.C. § 706(2), including by "issu[ing] all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings," *id.* § 705. Defendants fundamentally misunderstand the nature of this 'set aside' authority, which "'empower[s] the judiciary to act directly against the challenged agency action.'" *Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 838 (2024) (KAVANAUGH, J., concurring) (quoting J. Mitchell, *The Writ-of-Erasure Fallacy*, 104 VA. L. REV. 933, 1012 (2018)). Moreover, courts have long understood the APA to authorize vacatur and the Supreme Court has yet

to dictate otherwise. *Id.* at 839; s*ee also Assoc. of Am. Univ. v. Dept. of Defense*, No. 25-11740-BEM, 2025 WL 2899765, at *29 (D. Mass. Oct. 10, 2025) (citing cases); *Doe v. Trump*, 796 F. Supp. 3d 599, 603 (N.D. Cal. 2025) (citing cases). As a result, the preliminary injunction in this case—based in part on a finding that the government's application approvals likely violated the APA—need not be limited to Plaintiffs. Instead, the Court has authority to preliminarily set aside those agency actions comprising the Rebate Program. *See CASA*, 606 U.S. at 873 (KAVANAUGH, J., concurring) (noting that even after *CASA*, district courts may "grant or deny the functional equivalent of a universal injunction—for example, by . . . preliminarily setting aside or declining to set aside an agency rule under the APA"); 5 U.S.C. § 705.[7]

2. Bond Requirement

In this case, a nominal bond is appropriate. Although the APA has no bond requirement, *id.* § 705, "the district courts in this circuit have generally required a bond," *Maine v. U.S. Dept. of Agric.*, 778 F. Supp. 3d 200, 237 (D. Me. 2025). Defendants face no material loss from enjoining the implementation of the Rebate Program, Plaintiffs' lawsuit concerns the public interest, and Plaintiffs are likely to succeed on the merits of their claim. *See Crowley v. Local No. 82, Furniture & Piano Moving*, 679 F.2d 978, 999-1000 (1st Cir. 1982). Accordingly, Plaintiffs must post a bond of $1,000.[8]

[7] Of course, the broad latitude the APA affords courts to fashion relief does not necessarily preclude more limited remedies, including remand for further consideration by the agency consistent with a court order. *See*, *e.g.*, *State Farm*, 463 U.S. at 59.

[8] This District and other district courts within the First Circuit have similarly required a nominal bond in this amount. *See Maine*, 778 F. Supp. 3d at 238; *Nationwide Payment Sols., LLC v. Plunkett*, 697 F. Supp.

CONCLUSION

For the foregoing reasons, Plaintiffs' Motion (ECF No. 3) is GRANTED. Defendants are enjoined from implementing the nine individual applications that comprise the 340B Model Rebate Pilot Program pending further order. Furthermore, within seven days of the date of this order, Plaintiffs are ORDERED to provide security in the amount of $1,000.

SO ORDERED.

/s/ Lance E. Walker
Chief U.S. District Judge

Dated this 29th day of December, 2025.

2d 165, 173 (D. Me. 2010); *Nw. Selecta, Inc. v. Sec'y of the Dep't Agric. of P.R.*, No. 22-1092-RAM, 2022 WL 17985926, at *7 (D.P.R. Dec. 29, 2022). I see no reason to depart from this precedent.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. ROBERT F. KENNEDY, JR. SECRETARY of the U.S. Department of Health and Human Services, *et al.*, Defendants.	No. 2:25-cv-600-LEW

MEMORANDUM IN SUPPORT OF MOTION FOR A STAY PENDING APPEAL OR, IN THE ALTERNATIVE, AN ADMINISTRATIVE STAY OF PRELIMINARY INJUNCTION

Defendants respectfully request a stay pending appeal of this Court's December 29, 2025 order, Doc. No. 90, which granted Plaintiffs' motion for a preliminary injunction. In the alternative, Defendants ask the Court for an administrative stay of the preliminary injunction to allow the First Circuit to rule on the government's forthcoming motion for a stay pending appeal in that Court. The Department of Health and Human Services (HHS) acted reasonably in approving its limited 340B Rebate Pilot Program (the "Pilot Program"). After considering covered entities' reliance interests and compliance costs, HHS determined that those concerns were outweighed by the need to study the efficacy of 340B rebates and by the desirability of offering rebates as a method to deduplicate 340B and Medicare Drug Negotiation Program discounts. This Court erred in concluding otherwise by characterizing HHS's declaration, which explained its contemporaneous thinking for these informal adjudications, as "largely . . . post-hoc rationalizations," Doc. No. 90 at 10, and by demanding a higher level of specificity in the agency's consideration of compliance costs than what courts have required. Those fundamental errors of administrative law fatally undermine its injunction.

The government respectfully requests a stay pending appeal or an immediate administrative stay in the alternative. To prevent disruption of industry preparation to implement a pair of significant

programs scheduled to take effect on January 1, the government respectfully requests a ruling on this motion as soon as possible so that the government may seek relief from the First Circuit if necessary. If the Court is inclined to deny the motion, the government respectfully requests that the Court do so without waiting for a response from Plaintiffs. The government plans to seek relief from the First Circuit by December 30, 2025 at 6:00 pm if the Court has not ruled by then. *See Boston Parent Coal. for Acad. Excellence Corp. v. School Comm.*, 996 F.3d 37, 44 (1st Cir. 2021). Plaintiffs oppose this motion.

"[T]he factors regulating the issuance of a stay are . . . (1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987).

These factors weigh decisively in favor of a stay.

First, as explained in Defendants' brief in opposition to Plaintiffs' preliminary injunction motion and at argument, Defendants are likely to succeed on the merits. An agency's decisions can be overturned only if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Review under the "arbitrary and capricious" standard is "narrow," and the ultimate question is whether the agency's action was reasonable. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009). Review should be particularly circumscribed here because the statute "exudes deference" to the Secretary's determination as to whether to effectuate 340B prices via rebates or discounts, *see Webster*, 486 U.S. at 600, and the approvals are designed to test the rebate model on a small scale to minimize the costs and risks of such information gathering.

Here, the agency's decisions to approve the manufacturers' applications readily satisfy the arbitrary and capricious standard as applied by courts in the context of informal agency adjudications.[1]

[1] *See, e.g.*, *Royal Siam Corp. v. Chertoff*, 484 F.3d 139, 148 (1st Cir. 2007) ("In the absence of an error of law—and we see none here—this case comes down to straight abuse-of-discretion review. Under that standard, the outcome is foreordained."); *Neustar, Inc. v. FCC*, 857 F.3d 886, 900 (D.C. Cir. 2017) (although Petitioner raised legitimate concerns that might have justified a different decision by the

As explained in the agency's notice, the agency had previously received a significant amount of feedback from (and on behalf of) both manufacturers and covered entities regarding rebate models, and recognized that a rebate model "could fundamentally shift how the 340B Program has operated for over 30 years." 90 Fed. Reg. at 36,164. Indeed, for the past several years, drug manufacturers have been aggressively pursuing the unilateral implementation of widespread 340B rebate models, and covered entities have argued just as hard in opposition to rebate models. Given these divergent positions, HHS felt it necessary to test rebates to better understand the merits and shortcomings of a rebate model from stakeholders' perspectives, while minimizing disruptions to covered entities, and to inform the agency's consideration of any future 340B rebate models consistent with the 340B statute and the Administration's goals. *Id.* So it designed a thoughtful Pilot Program that was limited in scope to test "a fair and transparent 340B rebate model process for all stakeholders involved." 90 Fed. Reg. at 36,164. Further, because one of the goals of the Pilot Program is to address manufacturer concerns regarding 340B and Maximum Fair Price deduplication, HHS chose to limit the scope of the Pilot to the ten drugs with negotiated Maximum Fair Prices set to take effect on January 1, 2026, which account for only 2% of 340B sales. After reviewing applications to participate in the Pilot Program submitted by manufacturers of those drugs, and considering comments received from stakeholders including covered entities, the agency carefully balanced the equities and then decided which specific aspects of each application to approve. Those decisions were reasonable.

1. In refusing to consider HHS's explanation for approving the rebate applications, this Court erred. In an informal adjudication, "the APA does not specifically require the agency to explain its decision" or provide "a written explanation on the record." *Neighborhood Ass'n of the Back Bay, Inc. v. Federal Transit Admin.*, 463 F.3d 50, 60 n.4 (1st Cir. 2006) (citing *Pension Benefit Guaranty Corp. v. LTV Corp.*, 496 U.S. 633, 655–56 (1990); *Camp v. Pitts*, 411 U.S. 138, 142 n. 3 (1973)). Rather, in such circumstances, "if the agency's path may reasonably be discerned," its decision should be sustained.

agency, the Court was "not to substitute [its] judgment for that of the [agency] . . . . Rather, the question [of whether the agency acted arbitrarily and capriciously] is more narrow").

FCC v. Fox Television Stations, Inc., 556 U.S. 502, 513–14 (2009); *see also Diaz-Valdez v. Garland*, 122 F.4th 436, 443 (1st Cir. 2024). Here, the agency's declaration explaining its contemporaneous decision-making satisfies that standard. *See* Decl. of Chantelle Britton, Doc. No. 75-1.

This Court abused its discretion in concluding otherwise. *See Koon v. United States*, 518 U.S. 81, 100 (1996) ("A district court by definition abuses its discretion when it makes an error of law."). As the Supreme Court has explained, when an informal adjudication does not produce the sort of record that would permit "effective judicial review," a court appropriately should "obtain from the agency, either through affidavits or testimony, such additional explanation of the reasons for the agency decision as may prove necessary." *Camp*, 411 U.S. at 143; *see Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 419–20 (1971). In these circumstances, "the administrative record may be supplemented, if necessary, by affidavits, depositions, or other proof of an explanatory nature," so long as "the new material" is "explanatory of the decisionmakers' action at the time it occurred," rather than a "new rationalization[]." *Sierra Club v. Marsh*, 976 F.2d 763, 772 (1st Cir. 1992) (cleaned up). Such "illuminat[ions]" of the reasons for agency action are routinely accepted by courts. *Olivares v. TSA*, 819 F.3d 454, 464 (D.C. Cir. 2016).

Here, the decision documents are operational documents that simply outline the terms of the approved rebate program. *See, e.g.*, Doc. No. 36-2 at 14–15. The approval letters do not indicate why HHS acted. *Cf.* Doc. No. 36-2 at 14–15. Instead, the agency has "provide[d] an adequate explanation for [its] action" in the form of a declaration, which is the "only way there can be effective judicial review." *Overton Park*, 401 U.S. at 420. In other words, considering the agency's declaration—which "provided the court with an explanation for the agency's action submitted by the officer who had the authority to act on the application[s]"—was appropriate. *See Bagdonas v. Department of Treasury*, 93 F.3d 422, 426 (7th Cir. 1996). That type of explanation does not violate the *Chenery* principle or the record-review rule. Rather, a "court may properly uphold the [agency]'s decision on the basis of affidavits or testimony by the administrator who made the decision concerning his reasoning at the time of the

decision." *Sierra Club*, 976 F.2d at 772 (quoting *Manhattan Tankers, Inc. v. Dole*, 787 F.2d 667, 672 n. 6 (D.C.Cir.1986)); *see also id.* at 772–73 (collecting cases). And that is exactly what HHS did.

This Court misunderstood the agency's declaration as an improper post-hoc rationalization. *But see Sierra Club*, 976 F.2d at 774 (citing *Overton Park*, 401 U.S. at 420) (acknowledging that affidavits "containing post-hoc explanations" may be considered critically by courts). But this Court did not offer any reason to think that the Britton Declaration, offered by a key "official[] who participated in the decision," *Overton Park*, 401 U.S. at 420, did anything other than what it purported to do: explain the agency's contemporaneous thinking. Britton's declaration "explained" how her office "took into consideration a variety of factors, including impacts on covered entities and concerns raised in comments, in making decisions on which specific aspects of the plans that it would approve." Doc. No. 75-1 at 3. There is no basis to dismiss that explanation as a post-hoc litigation rationale.

This Court also faulted the Britton Declaration because it included "rationalizations absent from the administrative record," Doc. No. 90 at 10. That conclusion was error. First, HHS still "is in the process of compiling the administrative record for this case," Doc. No. 85-1 at 2, so the Court cannot know what it will eventually comprise. But more importantly, this is not a case "[w]hen an agency's initial explanation indicates the determinative reason for the final action taken," *DHS v. Regents of Univ. of Cal.*, 591 U.S. 1, 21 (2020) (cleaned up), and then the agency sought to "provide new ones." Doc. No. 90 at 10 (quoting *Regents*, 591 U.S. at 21).

This point is even more pronounced in the context of a preliminary injunction. Plaintiffs filed suit on December 1, 2025, and HHS has not yet assembled the administrative record or prepared a certified index. *Cf.* Doc. No. 85 (only partial administrative record assembled). Plaintiffs pushed for immediate relief without waiting for the administrative record. In such circumstances, courts must consider the available evidence regardless of whether it would ultimately be admissible at trial. *See, e.g.*, *Mullins v. City of New York*, 626 F.3d 47, 52 (2d Cir. 2010) (hearsay admissible at preliminary injunction stage). *Cf University of Texas v. Camenisch*, 451 U.S. 390, 395 (1981) (the decision of whether to award

preliminary injunctive relief is often based on "procedures that are less formal and evidence that is less complete than in a trial on the merits."). This Court's understanding of the record-review rule does not comport with the ordinary practice of fully considering all available information before rendering a decision on a preliminary injunction.

2. This Court also erred in misunderstanding how HHS estimated and weighed compliance costs. HHS received and considered comments about the administrative costs plaintiffs would bear in participating in rebate pilots. It took steps to minimize any burden by rejecting manufacturers' proposals that covered entities submit more specific and thus more burdensome information to claim rebates. It noted that "most covered entities already provide the type of claims data" to their contract pharmacies that "they will need to provide under the Pilot." Doc. No. 75-1 ¶ 36. And it "considered the non-monetary costs associated with moving to a rebate model." *Id.* ¶ 41. Ultimately, HHS made the determination that the benefits of running the Pilot Program outweighed these costs.

This Court faulted HHS for continuing to consider the compliance costs. Doc. No. 90 at 16–18. Specifically, the Court pointed to a notice HHS issued pursuant to the Paperwork Reduction Act to collect information about the burdens of submitting rebate claims and other associated administrative tasks. *See* Doc. No. 90 at 16. This Court reasoned that HHS could not have properly considered compliance burdens if it was still studying them. *Id.* That conclusion does not follow from its premise.

The Paperwork Reduction Act generally requires federal agencies to examine the burden on the public before it conducts or sponsors any collection of information. But the Act also provides for emergency approval of agency plans to collect information when normal review procedures are not practical. 44 U.S.C. § 3507(j)(1); *see* 5 C.F.R. § 1320.13. HHS availed itself of that option here, obtaining approval to launch the rebate program on January 1 while undertaking a more extensive study of compliance costs. To hold that HHS acted unlawfully by proceeding before that more

extensive study is complete, as this Court did, is inconsistent with Congress's express acknowledgement that sometime agencies may proceed on two tracks when considering compliance costs. *See* 44 U.S.C. § 3507(j)(1).

Here, HHS did what agencies must often do: it made a predictive judgment based on the best information available to it. Making a decision without "perfect empirical or statistical data . . . is not unusual in day-to-day agency decisionmaking." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 427 (2021). Nor is that type of decision improper, *id.* at 427–28; to the contrary, agencies are entitled to increased deference when it comes to matters implicating predictive judgments. *See National Citizens Comm.*, 436 U.S. at 813–14. Accordingly, HHS considered how many hours would be required to collect information necessary to submit rebate claims. And it expressly concluded that "the benefits of the pilot . . . outweighed these costs." Doc. No. 75-1 at 10.

Plaintiffs believe that they will need to spend more time to claim rebates, *e.g.*, Doc. No. 7 at 9, but they fail to explain this conclusory assertion, *see, e.g.*, Doc. No. 10-8 at 14. That failure is striking in light of the substantial overlap between the information required to obtain rebates and the information covered entities already submit to their contract pharmacies. *See* Doc. No. 75-1 at 10–11. Moreover, some of the bases plaintiffs assert for their inflated views of compliance costs did not materialize in the approved proposals. *Compare* Doc. No. 10-8 at 14 (raising concerns about different IT platforms, *with* Doc. No. 75-1 at 14 all manufacturers selected same IT platform). These underbaked objections fail to show that HHS took an "[ir]rational view of the record," and thus the agency's decision must be sustained. *Atieh v. Riordan*, 797 F.3d 135, 138 (1st Cir. 2015).

3. This Court erred as well in concluding that the "administrative record is also silent on the cost of floating the full price of covered drugs until 340B entities receive their rebate." Doc. No. 90 at 17. But the Court only reached that conclusion by discounting the Britton Declaration. *See id.* Had this Court properly looked to the agency's explanation, it would have found that HHS designed the rebate program to account for such concerns. *See* Doc. No. 75-1 at 7–9.

Second, Defendants will be irreparably harmed absent a stay, and the equities strongly favor a stay. "Any time a government is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." *District 4 Lodge of the Int'l Ass'n of Machinists v. Raimondo*, 18 F.4th 38, 47 (1st Cir. 2021) (cleaned up). Here, Congress explicitly granted HHS authority to choose between rebates or discounts in administering the 340B program,[2] and this Court disabled the agency from making that choice and "improperly intrud[ed]" on the Executive Branch's authority and ability to enforce the law, *Trump v. CASA, Inc.*, 606 U.S. 831, 859 (2025) (cleaned up). HHS is also injured by the inability to test manufacturers' claims that the rebate model could reduce alleged fraud in the program.

In contrast, plaintiffs have shown no irreparable harms. Plaintiffs will obtain the same 340B discounts they are entitled to under the statute. They will receive rebates within 10 days of submitting claims, and they have not shown that such a minor delay will cause them significant harm, especially given the limited scope of the Pilot Program and the likelihood that for most purchases covered entities will receive rebates before any payment is due to the wholesaler. *See* Doc. No. 75-1 at 7. Nor can plaintiffs rely on compliance burdens to overcome the serious harms to the government and the public interest resulting from the injunction, especially when plaintiffs have not shown how submitting the same kinds of information they already provide to contract pharmacies, *id.* at 10–11, could possibly create a significant burden. And to the extent that plaintiffs speculate about harm resulting from manufacturers' denial of rebate claims, they fail to recognize that HHS "severely limit[ed] the bases for the denial of claims." *Id.* at 9; *see also Narragansett Indian Tribe v. Guilbert*, 934 F.2d 4, 6–7 (1st Cir. 1991) ("[S]peculative injury does not constitute a showing of irreparable harm.").

In the alternative, Defendants are entitled to an administrative stay. An administrative stay "minimize[s] harm while an appellate court deliberates" whether to issue a stay pending appeal by

[2] *See* 42 U.S.C. § 256b(a)(1); *see also Eli Lilly & Co. v. Kennedy*, 2025 WL 1423630 (D.D.C. May 15, 2025), *appeal filed*, No. 25-5221 (D.C. Cir. June 13, 2025); *Johnson & Johnson Healthcare Sys. Inc. v. Kennedy*, 2025 WL 1783901 (D.D.C. June 27, 2025), *appeal filed*, No. 25-5236 (D.C. Cir. June 30, 2025).

preserving the status quo. *United States v. Texas*, 144 S. Ct. 797, 798 (2024) (Barrett, J., concurring). Here, the status quo was that manufacturers would begin offering rebates and using the rebate program to deduplicate Negotiation Program discounts starting January 1. *See, e.g.*, *Oregon v. Trump*, 154 F.4th 1161, 1164 (9th Cir. 2025) (looking to situation before injunctive relief granted). Disrupting the status quo would seriously complicate the years-long progress towards the rollout of negotiated prices for Medicare drugs and force manufacturers to scramble to comply with their various pricing obligations. Immediate relief is necessary to avoid that result while the First Circuit considers the government's forthcoming stay motion.

Dated: December 29, 2025

Respectfully submitted,

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UNITED STATES DISTRICT COURT

DISTRICT OF MAINE

AMERICAN HOSPITAL ASSOCIATION, et al.,	)	
Plaintiffs,	)	
v.	)	No. 2:25-cv-00600-LEW
ROBERT F. KENNEDY, JR., SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,	)	
Defendants.	)	

ORDER ON MOTION FOR STAY PENDING APPEAL

The matter returns to the Court on Defendants' Motion to Stay Preliminary Injunction Pending Appeal (ECF No. 92). Yesterday, I granted Plaintiffs a preliminary injunction that enjoins Defendants from implementing a pilot rebate program that, based on a preliminary assessment, Defendants never bothered to stand up in the first place, including by failing to develop a meaningful administrative record. Order on Mot. for Prelim. Inj. (ECF No. 90).

Pursuant to the Federal Rules of Appellate Procedure, a party appealing the entry of a preliminary injunction by the District Court may seek a stay of the injunction pending appeal. Fed. R. App. P. 8(a). Ordinarily, the party must first request such relief from the District Court. Fed. R. App. P. 8(a)(1)(A). To secure a stay, "the moving party need not

persuade the court that it is likely to be reversed on appeal." *Canterbury Liquors & Pantry v. Sullivan*, 999 F. Supp. 144, 150 (D. Mass. 1998). However, "more than a mere possibility of relief is required." *Nken v. Holder*, 556 U.S. 418, 434 (2009) (internal quotation marks omitted). The provision of a stay pending appeal is a discretionary matter attuned to the circumstance of the case at hand. *Id*. at 433. The exercise of that discretion is guided by the moving party's ability to convincingly demonstrate the following: (1) likelihood of success on appeal; (2) irreparable harm absent injunctive relief; (3) a lack of substantial injury to others having an interest in the decision under appeal; and (4) service of the public interest. *Id.* at 434; *see also State of New Jersey v. Trump*, 131 F.4th 27, 33-34 (1st Cir. 2025); *Arborjet, Inc. v. Rainbow Treecare Sci. Advancements Inc*., 794 F.3d 168, 171 (1st Cir. 2015).

Of these elements, the "first two factors are the most critical," *Respect Maine PAC v. McKee*, 622 F.3d 13, 15 (1st 2010), but failure to "show a strong likelihood of success" on appeal is an independent basis for denial of an injunction pending appeal. *Id*.; *Acevedo-Garcia v. Vera-Monroig*, 296 F.3d 13, 16 (1st Cir. 2002) (per curiam); *In re Elias*, 182 F. App'x 3 (1st Cir. 2006) (per curiam).

Defendants state that a stay is needed to "prevent disruption of industry preparation to implement a pair of significant programs scheduled to take effect on January 1." Mot. to Stay Mem. at 1 (ECF No. 92-1). In fact, the preliminary injunction preserves the status quo and granting the requested stay would produce the far greater disruption to administration of the 340B program at large. Moreover, as explained in the Order on appeal, given the anemic administrative record, advancing the pilot rebate program on this

timetable is likely an arbitrary undertaking. For these reasons, I find that Defendants are unlikely to secure the relief that they seek in the First Circuit; that they do not face an irreparable injury of their own due to the preliminary injunction; that substantial injuries would flow to others from the grant of a stay; and that the public's interest is not on the line if the requested stay is denied. Indeed, there is no apparent, actual urgency to the January 1 start date and, based on my preliminary assessment of the record, the Defendants would be better off attending to the minimal administrative steps the APA imposes in order to fortify the pilot rebate program rather than attempting to lower the bar for administrative action in service to "industry preparation" interests.

Defendants' Motion to Stay Preliminary Injunction Pending Appeal (ECF No. 92) is DENIED.

SO ORDERED.

Dated this 30th day of December, 2025.

/s/ Lance E. Walker
Chief U.S. District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, THE MAINE HOSPITAL ASSOCIATION, ST. MARY'S REGIONAL MEDICAL CENTER, NATHAN LITTAUER HOSPITAL & NURSING HOME, UNITY MEDICAL CENTER, and DALLAS COUNTY MEDICAL CENTER,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., Secretary of the U.S. Department of Health and Human Services, THOMAS J. ENGELS, Administrator, Health Resources and Services Administration, THE HEALTH RESOURCES AND SERVICES ADMINISTRATION, THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and THE UNITED STATES OF AMERICA,

Defendants.

Case No. 2:25-cv-00600-LEW

PROPOSED INTERVENORS' JOINT NOTICE OF APPEAL TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

Proposed Intervenors AbbVie Inc., Pharmacyclics LLC, AstraZenaca Pharmaceuticals LP, Boehringer Ingelheim Pharmaceuticals, Inc., Novo Nordisk Inc., and Pharmaceutical Research and Manufacturers of America, appeal to the United States Court of Appeals for the First Circuit from the order of the United States District Court for the District of Maine, entered in this case on December 18, 2025, denying Proposed Intervenors' motions to intervene. Doc. 83.

The parties to the order appealed from and the names and addresses of their respective

attorneys are as follows:

Dated: December 30, 2025

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was electronically filed with the Clerk of the Court via the Court's CM/ECF system, which sent notification of such filing to all counsel of record by electronic means.

/s/ *Kwaku Akowuah*
Kwaku Akowuah

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. ROBERT F. KENNEDY, JR. SECRETARY of the U.S. Department of Health and Human Services, *et al.*, Defendants.	No. 2:25-cv-600-LEW

JOINT MOTION FOR VACATUR AND REMAND

The Parties, having conferred since the Court issued its Order Granting Motion for Preliminary Injunction ("PI Order"), ECF No. 90, jointly and respectfully move for the Court to order vacatur and remand of the agency actions challenged in this matter on the same bases underlying the PI Order.

In support of this joint motion, the parties state the following:

1. Plaintiffs filed their Complaint on December 1, 2025. Compl., ECF No. 1. They allege that "the 340B Rebate Model Pilot Program" announced by Defendants in August 2025 violates the Administrative Procedure Act ("APA"), and they ask this Court to declare the program unlawful, enjoin its implementation, and set it aside under § 706 of the APA. *Id.* ¶¶ 52-62, 130-75, Request for Relief. The Complaint asserted five claims that establishment and implementation of "the 340B Rebate Model Pilot Program" and approval of drug manufacturer applications to participate in that program were arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law. *Id.* ¶¶ 130-75.
2. Since the filing of the Complaint, the Parties briefed Plaintiffs' motion for a temporary restraining order, ECF No. 3, which was converted into a motion for preliminary

injunction, *see* PI Order. The Court granted Plaintiffs' motion and enjoined Defendants "from implementing the nine individual applications that comprise the 340B Model Rebate Pilot Program pending further order." *Id.* at 24. Defendants sought a stay of that injunction, ECF No. 92, and the Court denied a stay. ECF No. 96. Defendants appealed the PI Order and subsequently sought a stay from the First Circuit, which denied the request. Order Denying Motion for Stay (First Circuit Order), Case No. 25-2236 (1st Cir.), Doc. No. 00118387963. Defendants have since dismissed their appeal. ECF Nos. 109, 110.

3. Defendants' response to the Complaint was due on February 3, 2026, and, on unopposed motion from Defendants, the Court extended that deadline by 30 days. ECF Nos. 112, 113.

4. The Parties have conferred about next steps in this litigation. After discussion, the Parties ask that the Court order vacatur and remand of the challenged administrative actions. Courts "commonly grant such motions, preferring to allow agencies to cure their own mistakes rather than wasting the courts' and the parties' resources reviewing a record that both sides acknowledge to be incorrect or incomplete." *Ethyl Corp. v. Browner*, 989 F.2d 522, 524 & n. 3 (D.C. Cir. 1993) (citing cases). The Parties agree that, in the circumstances of this case, judicial economy and the interests of the Parties would be best served by a vacatur and remand order rather than further litigation.

5. The Court's PI Order concluded that Plaintiffs' claims are justiciable and that Plaintiffs are likely to succeed on the merits of their claims. PI Order at 6-8, 9-19. Specifically, the Court identified two defects in the portion of the administrative record submitted at the preliminary injunction stage—(1) a failure to provide a reasonable explanation or address significant reliance interests and (2) a failure to consider relevant costs. *Id.* at 12-18. The Court reserved judgment on other potential defects raised by Plaintiffs. *Id.* at 18-19.

6. The First Circuit subsequently denied Defendants' request for a stay of the Court's preliminary injunction, crediting the Court's order as "a careful and thorough decision" that properly resolved the likelihood of success of Plaintiffs' claims. First Circuit Order at 1. The First Circuit, like this Court, concluded that "the preview of the administrative record" demonstrated defects in the agency's explanation and consideration. *Id.* at 3-6.
7. Since this Court and the First Circuit issued these orders, Defendants have considered the documents that would comprise the full administrative record in this matter. Defendants do not believe the full administrative record would change the outcome of this litigation at summary judgment. As a result, the Parties agree that further motions practice would not be fruitful, and instead, it would serve the best interests of judicial economy and the Parties to vacate the challenged actions with a remand to the Health Resources and Services Administration. *See, e.g.*, *Bennett v. Murphy*, No. 14-cv-10275-FDS, 2016 WL 1449571, at *1 (D. Mass. Apr. 13, 2016) ("Voluntary remands are commonly granted because they allow agencies to correct their own mistakes without expending the resources of the court in reviewing a record that is admittedly incomplete or incorrect.").
8. The Parties agree that the vacatur and remand should cover the following agency actions:
    a. The 340B Rebate Model Pilot Program Application Notice, 90 Fed. Reg. 36163 (Aug. 1, 2025);
    b. The Corrected 340B Rebate Model Pilot Program Application Notice, 90 Fed. Reg. 38165 (Aug. 7, 2025);
    c. The approvals of 340B rebate program applications from nine eligible drug manufacturers (Briston Myers Squibb, Immunex Corp., Astra Zeneca AB, Pharmacyclics, Merck Sharp Dohme, Boehringer Ingelheim, Novo Nordisk Inc., Jansssen Biotech/Janssen Pharmaceuticals, and Novartis Pharmaceuticals Corp.) for ten covered drugs announced between October 30 and November 14, 2025.

9. The Parties have further discussed next steps for the agency following remand. The Parties agree that, if Defendants decide to begin a new 340B rebate program, Defendants will issue a new notice, including soliciting new applications. Furthermore, the Parties agree that Defendants will solicit comments either prior to or concurrently with a new notice, or both. Furthermore, Defendants agree to set any effective date for any new 340B rebate program to no earlier than 90 days following the public announcement of any approval of drug manufacturer applications—to avoid the prospect of any extremely expedited future litigation.

Based on the foregoing, the Parties jointly request that this Court vacate the agency actions listed in paragraph 8 and remand the matter to the agency.[1] The Parties further request that all subsequent deadlines in this case be vacated and the matter be closed.

Dated: February 5, 2026

Respectfully submitted,

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[1] It is the position of the Department of Justice that the APA does not authorize a court to vacate an agency action, and that if vacatur is an available remedy, then like all equitable remedies, such relief must be subject to traditional equitable limitations, including the principle of party-specific relief. The Department acknowledges, however, that there is substantial authority opposing this position in some circuits, though the Supreme Court has not ruled on the issue. In jointly requesting with Plaintiffs that the Court vacate the challenged agency actions, the Department agrees not to pursue this position in this specific case, but it reserves the right to continue to advance this position in other cases. Plaintiffs disagree with the Department's general position regarding courts' authority under the APA, *see, e.g.*, ECF No. 82 at 13-14, but agree that this dispute is irrelevant here given the Parties' joint request for vacatur of the challenged agency actions.

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Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT

DISTRICT OF MAINE

AMERICAN HOSPITAL ASSOCIATION, *et al.*,	)	
Plaintiffs	)	
v.	)	No. 2:25-cv-00600-LEW
ROBERT F. KENNEDY, JR., SECRETARY of the U.S. Department of Health and Human Services, et al.,	)	
Defendants	)	

ORDER

This matter is before the Court on the parties' Joint Motion for Vacatur and Remand (ECF No. 114). On December 1, 2025, Plaintiffs filed their Complaint alleging that the 340B Rebate Model Pilot Program violated the Administrative Procedure Act (APA) and moved for a Temporary Restraining Order[1] to prevent the Rebate Program from taking effect on January 1, 2026. *See* Compl. (ECF No. 1), Mot. for TRO (ECF No. 3). On December 29, 2025, I preliminarily enjoined Defendants from implementing the Program. *See* Order on Mot. for Prelim. Inj. (ECF No. 90). In so doing, I concluded that Plaintiffs' were likely to succeed on the merits of their claims that Defendants were required to but did not consider significant reliance interests and costs, based on Defendants' preview of the administrative record. *Id.* at 9-18. Defendants requested a stay of the preliminary

[1] Plaintiffs' request was converted into a motion for a preliminary injunction.

injunction pending appeal, which the First Circuit denied. Defendants' have since dismissed their appeal.

Defendants now represent that, following the decisions of both this Court and the First Circuit, they do not believe the full administrative record would change the outcome of this litigation at summary judgment. *See* J. Mot. for Vacatur & Remand ¶ 7. The parties agree that the agency actions comprising the Rebate Program should be vacated and remanded to the Department of Health and Human Services, to "allow [the agency] to correct [its] own mistakes without expending the resources of the court in reviewing a record that is admittedly incomplete or incorrect." *Bennett v. Murphy*, No. 14-cv-10275, 2016 WL 1449571, at *1 (D. Mass. Apr. 13, 2016).

It is therefore ORDERED that the 340B Rebate Model Pilot Program Application Notice, 90 Fed. Reg. 36,163 (Aug. 1, 2025), the Corrected 340B Rebate Model Pilot Program Application Notice, 90 Fed. Reg. 38,165 (Aug. 7, 2025), and the approvals of applications from drug manufacturers submitted pursuant to those notices (announced between October 30 and November 14, 2025) are VACATED and REMANDED to the agency. The Joint Motion for Vacatur and Remand (ECF No. 114) is GRANTED.

SO ORDERED.

Dated this 10th day of February, 2026.

/S/ Lance E. Walker
Chief U.S. District Judge

CERTIFICATE OF SERVICE

This is to certify that the foregoing Joint Appendix has been served via the Court's CM/ECF filing system in compliance with Rule 25(b) and (c) of the Federal Rules of Appellate Procedure, on May 5, 2026, on all registered counsel of record, and has been transmitted to the Clerk of the Court.

/s/ Matthew S. Owen
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