PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of **Caremark Rx, LLC;** **Zinc Health Services, LLC;** **Express Scripts, Inc.;** **Evernorth Health, Inc.;** **Medco Health Services, Inc.;** **Ascent Health Services LLC;** **OptumRX, Inc.;** **OptumRx Holdings, LLC;** and **Emisar Pharma Services LLC.**	**Docket No. 9437**

RESPONDENTS' MOTION FOR DISCOVERY PURSUANT TO RULE 3.36

Pursuant to Rule 3.36 of the Commission's Rules of Practice, 16 C.F.R. § 3.36, Respondents Express Scripts, Inc., Evernorth Health, Inc., Medco Health Services, Inc., Ascent Health Services LLC, Caremark Rx, LLC, Zinc Health Services, LLC, OptumRx, Inc., OptumRx Holdings, LLC, and Emisar Pharma Services LLC (together the "Respondents") respectfully move for an order authorizing the issuance of a subpoena *duces tecum* to the Department of Health and Human Services ("HHS"), including its subsidiary agencies, such as the Centers for Medicare and Medicaid Services ("CMS") and the Indian Health Service ("IHS").

HHS oversees CMS, which administers health coverage to millions of Americans through programs including Medicare and Medicaid and is the single largest payer for health care services in the United States, and IHS, which oversees the federal health program for American Indians and native Alaskans. CMS and IHS health plans include prescription drug benefits and HHS has engaged in and benefited from conduct virtually identical to what is challenged in this case.

Likewise, HHS oversees health policy and regulations that directly impact drug pricing. The subpoena requests a clearly defined, relevant set of documents responsive to these material topics.

Complaint Counsel has informed Respondents that they intend to oppose this motion on relevance grounds. Information about health plans offered by the federal government, they say, is not relevant to the case "at all" because the allegations in the complaint relate only to health plans offered by commercial plan sponsors. This argument fails for at least four reasons.

- First, Complaint Counsel's assertion that the complaint addresses only commercial health plans is not correct. The relief sought in the complaint would sweep far more broadly and would clearly encompass government-sponsored health plans.
- Second, there is no meaningful substantive difference between government and commercial health plans with respect to the core allegations in the complaint. Just like commercial plan sponsors, the government manages its formularies to reduce overall costs and prefers drugs that carry rebates when they provide lower net costs.
- Third, HHS rulemaking and research likely will further support that the federal government itself has found that reducing rebates would cause health plan premiums to increase and that many consumers' out-of-pocket costs are already capped by legislation or regulation.
- Finally, Complaint Counsel had no objection to substantially similar requests issued previously in this case to other government agencies that sponsor health plans, including the Office of Personnel Management and the Department of Defense. Government-sponsored health plans cannot be relevant one minute and irrelevant the next.

I. INTRODUCTION

The FTC's Complaint alleges that Respondents' conduct—including the offering of closed formularies and the use of rebates—has increased prices and harmed consumers, including "government entities." Compl. ¶¶ 28, 125, 214-233. HHS, including CMS and IHS, oversees plans that provide prescription drug benefits that similarly use closed formularies and rebates. HHS has recognized publicly the value of negotiated rebates and enabled HHS to negotiate directly with manufacturers to lower plan drug costs.[1] Likewise, HHS routinely spearheads health policy and rulemaking relevant to key disputes in this case, including commissioning studies concerning drug pricing and proposing rules that implicate plan costs.

Respondents seek information to support their defenses that they could not obtain without a subpoena to HHS. This includes relevant evidence in HHS' possession concerning plan decisions and policy actions that underscore control of drug pricing by manufacturers, the "fairness" of formulary and rebate practices, and costs of insulin to consumers, which are issues central to this action.

II. ARGUMENT

The grant of a 3.36 motion for a subpoena is appropriate where the requested subpoena is: (1) "reasonably expected to yield information relevant to … [a respondent's] defenses"; (2) reasonable in scope; (3) specified with reasonable particularity; and (4) not reasonably obtainable by other means. *See* 16 C.F.R. §§ 3.31(c), 3.36(b), 3.37(a); *see also* Order Granting Respondents' Motion, *In re Caremark Rx, LLC*, Dkt No. 9437 (FTC Dec. 31, 2024) (granting 3.36 motion to

[1] *See, e.g.*, *Medicare Drug Price Negotiation Program Negotiates Prices for Initial Price Applicability Year 2026*, CMS.GOV (Aug. 15, 2024), https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026 (discussing estimated Medicare net savings in 2023 due to negotiation).

seek discovery on government agency experience "providing prescription drug benefits"). Respondents' proposed subpoena satisfies these requirements.

Respondents have met these requirements for the following requests, which are substantially similar to previously authorized (and unopposed by Complaint Counsel) discovery requests issued in this litigation to other federal government agencies:

- All Documents and Data related to the potential use, use, quality, or value of closed Formularies, preferred Formulary status, or Formulary tiering, negotiated by, or obtained for any Medicare or IHS plan;
- All Documents and Data related to the use of Rebates received by, on behalf of, or in connection with any Medicare or IHS plan, including without limitation Documents and Data relating to the impact of Rebates on Pharmacy Benefit Plan costs to federal agencies, and to use or not use Rebates to reduce premiums or other dimensions of member cost, provide point-of-sale discounts for members, expand benefits, or otherwise deliver value to members, to HHS, or to other federal agencies;
- All Documents and Data related to any analysis or decision-making concerning the Formulary treatment of any Insulin Product for any Medicare or IHS plan, including without limitation the inclusion or exclusion of low WAC Insulin Products from Formularies, member costs for Insulin Products, and the List Prices, net Prices, or costs paid for Insulin Products over time;
- Documents and Data sufficient to show the Rebates or discounts negotiated by, obtained for, or paid to any CMS or IHS plan for Insulin;
- All Documents and Data related to competition between PBMs to supply services in connection with any Medicare plan, including without limitation any comparisons between Pricing or quality of services provided by PBMs.

See Order Granting Respondents' Motion, *In re Caremark Rx, LLC*, Dkt No. 9437 (FTC Dec. 31, 2024) (allowing for unopposed subpoena to the U.S. Office of Personnel Management); Order Granting Respondents' Motion, *In re Caremark Rx, LLC*, Dkt No. 9437 (FTC Dec. 31, 2024) (allowing for unopposed subpoena to the U.S. Department of Defense).

In addition to previously approved requests, Respondents have likewise met these requirements for the following requests, which are specific to information in the possession of HHS:

- All Documents and Data received from or provided to Insulin Manufacturers or PBMs between 2017-2019 concerning any proposed or considered change in manufacturer list prices, such as WAC reduction, alternative generic strategy, or additional "new" NDC introduction plans, including without limitation materials discussing any burden to FDA or HHS from such list pricing proposals;

- All models, analyses, and empirical evidence used to examine costs, associated with the withdrawal of the 2019 proposed changes to the HHS Safe Harbor rule, 42 C.F.R. 1001.952;

- Documents and Data sufficient to show the actual or anticipated impact of the Inflation Reduction Act out-of-pocket Insulin Product price cap for Medicare plans, including without limitation observed cost increases, shifts, or changes resulting from participation in the CMS Part D Senior Savings Model;

- All Documents discussing the actual or anticipated impact of the Inflation Reduction Act out-of-pocket Insulin Product price cap with Insulin Manufacturers or PBMs;

- All Documents and Data concerning models, analyses, and empirical evidence on the difference between drug manufacturers pharmaceutical list prices in foreign markets and the United States, including but not limited to the September 2020 HHS ASPE Research Report Comparing Insulin Prices in the U.S. to Other Countries.

A. The Requested Discovery Is Relevant

The broad relief sought in the complaint would apply to all of Respondents' formularies and all benefit plans that Respondents' clients design and offer—whether or not those clients are so-called "commercial" clients or government clients. *See* Compl., Notice of Contemplated Relief. In relevant part, the complaint seeks to "[p]rohibit Respondents from excluding or disadvantaging low WAC versions of high WAC drugs made by the same manufacturers whenever the Respondent covers the high WAC drug on a formulary." *Id.* The complaint also seeks to "[p]rohibit Respondents from designing—or assisting with designing—a benefit plan that bases patients' deductibles or coinsurance on the list price, rather than the net cost after rebates." *Id.* Neither of these requests for relief is limited to commercial plan sponsors and would seemingly apply equally to government plan sponsors.

Respondents seek to defend themselves in this litigation by, among other things, proving that the conduct alleged in the Complaint—the use of rebates, client preference for lowest net costs, and the adoption of closed formularies—is procompetitive and is not unfair. The adoption of rebates and closed formulary products by HHS plans, which must balance market realities, public health costs, and clinical considerations, is plainly relevant to Respondents' defenses. *See* Order Granting Respondents' Motion*, In re Caremark Rx, LLC*, Dkt No. 9437 (FTC Dec. 31, 2024) (granting 3.36 motion to seek discovery on the federal agency the Office of Personnel Management in "providing prescription drug benefits"); *see also In re MSC Software Corp.*, 2002 WL 31433985, at *2 (FTC May 9, 2002) (granting 3.36 motion to seek discovery on parts of the government, including the DoD, as a user of an at-issue product); *In re Axon Enterprise, Inc*., 2020 WL 5701022, at *1 (FTC Sept. 17, 2020) (granting 3.36 motion when government actor was a customer).

FTC's allegations directly concern the "fairness" of conduct incorporated into HHS plan oversight activity. The government not only relies on PBMs to administer plan offerings, it also engages in its own rebate negotiations and weighs costs and benefits of formulary decisions, including decisions in response to drug manufacturer WAC increases and product launches. Contrary to Complaint Counsel's assertion, the government performs these functions as a plan sponsor in much the same way that commercial plan sponsors do. Evidence showing that the government – like commercial plan sponsors – actively engages in and promotes the kind of conduct that the complaint attacks is highly relevant, as it will constitute an admission that the federal government itself disagrees with the complaint.

HHS rulemaking and research is also relevant to the allegedly unfair conduct at issue. For instance, the Complaint criticizes PBMs for supposedly being "addicted to rebates," but Respondents contend that is false and that rebates lower costs for client plan sponsors. *See* Compl.

¶ 193. HHS rulemaking to repeal the safe harbor for rebates to PBMs, making rebates unavailable to Medicare plans, was projected to increase federal spending by billions of dollars and increase enrollee premiums, and the rule was subsequently delayed from taking effect.[2] The Complaint's alleged harms also focus on affordability of out-of-pocket costs of consumers. *See* Compl. ¶¶ 259, 266, 273. This claim largely ignores out-of-pocket cost caps available to consumers, including cost caps studied by HHS and available under the 2022 Inflation Reduction Act for over one million Medicare Part D beneficiaries.[3]

The Complaint is also premised on the notion that PBM rebate practices are the driving cause for drug manufacturer pricing decisions. *See* Compl. ¶ 259. This claim ignores the fact that HHS research has found that there is a significant imbalance between high U.S. drug pricing as compared to prices manufacturers set for the rest of the world, which, as acknowledged in a recent presidential executive order, may suggest that manufacturers charge high prices in the US to subsidize the low prices they charge in foreign markets.[4]

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[2] *See* Office of the Actuary, *Proposed Safe Harbor Regulation*, CMS (Aug. 30, 2018), https://www.cms.gov/research-statistics-data-and-systems/research/actuarialstudies/downloads/proposedsafeharborregulationimpact.pdf; *see also* Congressional Budget Office, *Incorporating the Effects of the Proposed Rule on Safe Harbors for Pharmaceutical Rebates* (May 2019), https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf (evaluating costs of a since delayed HHS rule on point-of-sale rebates); Safe Harbor Regulations, HHS-OIG, https://oig.hhs.gov/compliance/safe-harbor-regulations/ (discussing timeline of rule delay).

[3] *See, e.g.*, *Part D Senior Savings Model*, CMS NEWSROOM (Mar. 11, 2020), https://www.cms.gov/newsroom/fact-sheets/part-d-senior-savings-model; Sayed et al., *Insulin Affordability and the Inflation Reduction Act: Medicare Beneficiary Savings by State and Demographics*, ASPE (Jan. 24, 2023), https://aspe.hhs.gov/reports/insulin-affordability-ira-data-point.

[4] *See, e.g.*, RAND Health Care, *Comparing Insulin Prices in the U.S. to Other Countries,* ASPE (Sept. 2020), https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/196281/Comparing-Insulin-Prices.pdf ("Even with a 50-percent rebate amount as assumed … our finding suggest that U.S. insulin prices would have been considerably higher (about four times higher) than those in other countries"); *see also* White House Executive Order, *Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients* (May 12, 2025), https://www.whitehouse.gov/presidential-actions/2025/05/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients/ ("drug manufacturers deeply discount their products to access foreign markets, and subsidize that decrease through enormously high prices in the United States."); *see also* HHS, International Prescription Drug Price Comparisons: Estimates Using 2022 Data, ASPE (Feb. 2024), https://aspe.hhs.gov/sites/default/files/documents/277371265a705c356c968977e87446ae/international-price-comparisons.pdf.

In short, PBM Respondents seek discovery concerning the facts, studies, and analysis by HHS that bears directly on disputed issues in this case. *See In re 1-800 Contacts, Inc.*, 2016 WL 6609774, at *4-5 (FTC Oct. 28, 2016) (explaining that relevant discovery from the FTC includes "reports, studies, and analyses of competitive conditions" in the relevant market and analyses of "sales and prices" in the relevant market); *see also In re 1-800 Contacts, Inc.*, 2016 WL 7634657, at *3-5 (FTC Dec. 20, 2016) (granting 3.36 motion seeking facts supporting policy statements); *see also In the Matter of Intel Corp.*, 2010 WL 2544424, at *4 (FTC June 9, 2010) (granting 3.36 motion seeking background on data relating to the relevant market published by a government agency); *see also In the Matter of Union Oil Co. of California*, 2004 WL 3239430, at *1 (FTC Dec. 7, 2004) (granting 3.36 motion for discovery related to government actor's considerations in its regulatory process).

B. The Discovery Is Reasonable In Scope, Stated With Particularity, And Cannot Be Otherwise Obtained

The requested discovery is reasonable in scope and stated with particularity. 16 C.F.R. §§ 3.36(b)(1), 3.37(a). The requested discovery is limited to discrete topics and specific types of materials to allow identification of readily accessible responsive materials. The requests are also narrowly tailored to support Respondents' defenses, rebut the FTC's allegations, and will impose only a limited burden. *In re Intel Corp.*, 2010 WL 2544424, at *3 (FTC June 9, 2010). The documents sought are held by HHS, including CMS and IHS, including non-public information related to the HHS' determination on how to structure rebate negotiations and how to allocate the savings from rebates, the decision on how to place drugs on their formulary and related rationale, and other relevant internal evidence related to the allegations of pricing harms in this case. Beyond the requested subpoena, Respondents cannot otherwise obtain these materials.

The ESI Respondents moved for discovery under Rule 3.36 in December 2024 for similar information about the health plans offered or managed by the U.S. Office of Personnel Management and U.S. Department of Defense. Complaint Counsel took no position on those motions at that time. Complaint Counsel now objects to substantially similar requests to HHS. To the extent that Complaint Counsel is attempting to engage in gamesmanship to delay the Respondents' ability to obtain this highly relevant discovery, their opposition should be rejected.

III. CONCLUSION

An order should issue authorizing the subpoena attached as Exhibit A.

Dated: September 17, 2025

Respectfully submitted,

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Counsel for Caremark Rx, LLC and Zinc Health Services, LLC

CONFERENCE STATEMENT

Pursuant to Paragraph 4 of the Amended Scheduling Order entered in this matter on September 8, 2025, I hereby certify that counsel for Respondents Express Scripts, Inc., Evernorth Health, Inc., Medco Health Services, Inc., Ascent Health Services LLC, Caremark Rx, LLC, Zinc Health Services, LLC, OptumRx, Inc., OptumRx Holdings, LLC, and Emisar Pharma Services LLC, the moving parties, conferred with Complaint Counsel on September 15, 2025, in an effort in good faith to resolve by agreement the issues raised by the motion and have been unable to reach such an agreement.

/s/ Daniel J. Howley
Counsel for Express Scripts, Inc., Evernorth Health, Inc., Medco Health Services, Inc., and Ascent Health Services LLC

PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of **Caremark Rx, LLC;** **Zinc health services, LLC;** **Express Scripts, Inc.;** **Evernorth Health, Inc.;** **Medco Health Services, Inc.;** **Ascent Health Services LLC;** **OptumRx, Inc.;** **OptumRx Holdings, LLC;** and **Emisar Pharma Services LLC.**	**Docket No. 9437**

[PROPOSED] ORDER ON RESPONDENTS' MOTION FOR DISCOVERY PURSUANT TO RULE 3.36

Upon consideration of the Respondents' Motion for Discovery Pursuant to Rule 3.36:

IT IS HEREBY ORDERED that the Respondents' motion is GRANTED.

IT IS HEREBY FURTHER ORDERED that the Respondents are authorized to issue the subpoena to the U.S. Department of Health and Human Services attached as Exhibit A to the motion.

ORDERED: _____

Jay L. Himes
Administrative Law Judge

Date: _____

CERTIFICATE OF SERVICE

I hereby certify that no portion of this filing was drafted by generative artificial intelligence ("AI") (such as ChatGPT, Microsoft Copilot, Harvey AI) and that on September 17, 2025, I filed the foregoing document electronically using the FTC's E-Filing system, which will send notification of filing to:

April Tabor
Secretary
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm H-113
Washington, DC 20580
ElectronicFilings@ftc.gov

The Honorable Jay Himes
Office of Administrative Law Judges
Federal Trade Commission
600 Pennsylvania Ave. NW, Rm. H-110
Washington, DC 20580
oalj@ftc.gov

I also certify that I caused the foregoing document to be served via email to:

Bradley S. Albert
Lauren Peay
Rebecca L. Egeland
Federal Trade Commission
600 Pennsylvania Avenue, NW
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Counsel Supporting the Complaint

Respectfully submitted,

/s/ Daniel J. Howley
Counsel for Express Scripts, Inc., Evernorth Health, Inc., Medco Health Services, Inc., and Ascent Health Services LLC

EXHIBIT A

Subpoena for Production of Documentary Material

PUBLIC

Provided by the Secretary of the Federal Trade Commission, and
Issued Pursuant to Commission Rule 3.34(b), 16 C.F.R. § 3.34(b)(2010)

1. TO

General Counsel
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

2. FROM

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

This subpoena requires you to produce and permit inspection and copying of designated books, documents (as defined in Rule 3.34(b)), or tangible things, at the date and time specified in Item 5, and at the request of Counsel listed in Item 9, in the proceeding described in Item 6.

3. PLACE OF PRODUCTION

Rule Garza Howley LLP
901 7th St., NW Suite 600
Washington, DC 20001
202.843.9280

4. MATERIAL WILL BE PRODUCED TO

Counsel for Respondents Express Scripts, Inc., Evernorth Health, Inc., Medco Health Services, Inc., and Ascent Health Services LLC

5. DATE AND TIME OF PRODUCTION

6. SUBJECT OF PROCEEDING

In re Caremark Rx, LLC, et al. (Insulin), FTC Dkt. No. 9437.

7. MATERIAL TO BE PRODUCED

See attached Request for Production of Documentary Material, General Counsel, Department of Health and Human Services, 200 Independence Avenue, S.W., Washington, DC 20201

8. ADMINISTRATIVE LAW JUDGE

The Honorable Jay L. Himes
Federal Trade Commission
Washington, D.C. 20580

9. COUNSEL AND PARTY ISSUING SUBPOENA

Counsel for Respondents Express Scripts, Inc., Evernorth Health, Inc., Medco Health Services, Inc., and Ascent Health Services LLC
Rick Rule, Esq.
Rule Garza Howley LLP
901 7th St., NW Suite 600
Washington, DC 20001
202.843.9280

DATE SIGNED

SIGNATURE OF COUNSEL ISSUING SUBPOENA

INSTRUCTIONS AND NOTICES

The delivery of this subpoena to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply. This subpoena does not require approval by OMB under the Paperwork Reduction Act of 1980.

PETITION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any petition to limit or quash this subpoena be filed within the earlier of ten days after service thereof or the time for compliance therewith. The original and twelve copies of the petition must be filed with the Secretary of the Federal Trade Commission, and one copy should be sent to the Commission Counsel named in Item 9.

YOUR RIGHTS TO REGULATORY ENFORCEMENT FAIRNESS

The FTC has a longstanding commitment to a fair regulatory enforcement environment. If you are a small business (under Small Business Administration standards), you have a right to contact the Small Business Administration's National Ombudsman at 1-888-REGFAIR (1-888-734-3247) or www.sba.gov/ombudsman regarding the fairness of the compliance and enforcement activities of the agency. You should understand, however, that the National Ombudsman cannot change, stop, or delay a federal agency enforcement action.

The FTC strictly forbids retaliatory acts by its employees, and you will not be penalized for expressing a concern about these activities.

TRAVEL EXPENSES

Use the enclosed travel voucher to claim compensation to which you are entitled as a witness for the Commission. The completed travel voucher and this subpoena should be presented to Commission Counsel for payment. If you are permanently or temporarily living somewhere other than the address on this subpoena and it would require excessive travel for you to appear, you must get prior approval from Commission Counsel. Witness travelers can contact the FTC travel office for guidance at (202) 326-3299 or travel@ftc.gov. PLEASE NOTE: Reimbursement for necessary transportation, lodging, and per diem expenses cannot exceed the maximum allowed for such expenses by an employee of the federal government.

A copy of the Commission's Rules of Practice is available online at http://bit.ly/FTCsRulesofPractice. Paper copies are available upon request.

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RESPONDENTS' SUBPOENA *DUCES TECUM* ATTACHMENT TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Pursuant to Rules 3.34 and 3.36 of the Federal Trade Commission's Rules of Practice (16 C.F.R. §§ 3.34, 3.36), Respondents Express Scripts, Inc., Evernorth Health, Inc., Medco Health Services, Inc., Ascent Health Services LLC, Caremark Rx, LLC, Zinc Health Services, LLC, OptumRx, Inc., OptumRx Holdings, LLC, and Emisar Pharma Services LLC (together the "Respondents"), by and through their attorneys, request that the Department of Health and Human Services ("HHS"), including the Centers for Medicare and Medicaid Services ("CMS") and the Indian Health Service ("IHS"), and its staff produce all documents, electronically stored information, and other materials in their possession, custody, or control that are responsive to the requests made below.

DEFINITIONS

1. "Action" means the above-captioned litigation, *In the Matter of Caremark Rx, LLC, et al.*, FTC Docket No. 9437 (F.T.C.).
2. The terms "all," "any," and "each" shall be construed as encompassing any and all; and "every" means each and every.
3. The terms "and" and "or" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of the discovery request all responses that might otherwise be construed to be outside of its scope. The use of the singular form of any word includes the plural and vice versa.
4. "CMS" means the Centers for Medicare and Medicaid Services, a sub-agency of HHS.
5. The terms "concerning" and "regarding" mean to comprise, reflect, record, memorialize, embody, discuss, contradict, evaluate, consider, review or report on, concern, refer to, or relate to the subject matter of the Request or to have been created, generated or maintained in connection with or as a result of the subject matter of the Request.
6. "Data" shall mean any recorded information, including but not limited to, all spreadsheets, databases, images, audio or video files, logs, metadata, or any other material that captures information. "Data" encompasses structured data (such as databases or tables), unstructured data (such as email or word processing files), and any embedded or associated metadata. It shall also include all drafts, versions, deletions, and hidden or deleted information, whether stored on local computers, servers, cloud storage, mobile devices, or other data storage locations.
7. The terms "discuss" or "discussing" means in whole or in part constituting, containing, describing, or addressing the designated subject matter, regardless of the length of the

treatment or detail of analysis of the subject matter, but not merely referring to the designated subject matter without elaboration. In addition, a Document that "discusses" another Document includes the other Document itself (e.g., a Document that "discusses" an agreement or contract includes the agreement or contract itself). Further, these terms include any operating or financial Data about the designated subject matter where such data are separately set out as in a chart, listing, table, or graph.

8. "Document(s)" mean any information, on paper or in electronic format, including written, printed, recorded, and graphic materials of every kind, in the possession, custody, or control of HHS. The term "Documents" includes, without limitation: computer files; email messages; text messages; instant messages and chat logs; group chats; voicemails and other audio files; calendar entries; schedulers; drafts of documents; metadata and other bibliographic or historical Data describing or relating to documents created, revised, or distributed electronically; notes of Meetings or telephone calls; and copies of documents the originals of which are not in the possession, custody, or control of HHS. This term includes the transmittal or transfer of communications and information (in the form of facts, ideas, inquiries, or otherwise) by any means, including email, instant messages, text messages, iMessages, WhatsApp Messages, Telegram, and Signal messages. "Document(s)" include the original and, separately, each non-identical copy (including, but not limited to, non-identical copies containing unique notes, inserted material, or attachments).
9. "FDA" means the U.S. Food and Drug Administration, a sub-agency of HHS.
10. "Formulary" means a Payor's, Health Care Provider's or PBM's list of medicines, drugs, or pharmaceutical products that are approved to be prescribed, covered, or reimbursed at a

hospital, in a particular health system, or under the pharmaceutical benefit of a health insurance policy.

11. "Health Care Provider" refers to any doctor, hospital, clinic, or other Person or entity that provides health care services.
12. "IHS" means the Indian Health Service, a sub-agency of HHS.
13. "Insulin Manufacturers" means any pharmaceutical manufacturer or other company that manufactures or market Insulin Products, including but not limited to Sanofi S.A. or its U.S. subsidiary Sanofi-Aventis U.S. LLC; Eli Lilly and Company; Novo Nordisk A/S; Viatris Inc.; Biocon Biologics Ltd.; MannKind Corporation; Civica Rx; or any subsidiary thereof.
14. "Insulin Product" means each insulin pharmaceutical and related device, equipment, or other mechanical part approved by the U.S. Food and Drug Administration to treat diabetes, including those Insulin Products marketed in pen, cartridge, or vial presentations in the United States.
15. "List Price" means the WAC price at which an Insulin Product is listed.
16. "Medicare" means the prescription drug benefit program offered and managed by CMS.
17. "Meeting" means an assembly of two or more people, in-person or via telephone, voiceover-IP, video, video conferencing, or other similar means of communication.
18. "Payor" means any entity, other than the receiving patient, that pays or reimburses in whole or in part for the administration or sale of a pharmaceutical product. Payors include, but are not limited to, Plan Sponsors, federal and state government programs such as TRICARE, Medicare, and Medicaid; private insurers and health-maintenance organizations (HMOs); and health-and-welfare funds.

19. "PBM" or "Pharmacy Benefit Manager" means any entity that negotiates Rebate agreements; creates or manages a Formulary; or otherwise deals with pharmaceutical manufacturers or sellers and serves as a third-party administrator of a Payor's or Plan Sponsor's Pharmacy Benefit Plan.
20. "Person" includes HHS, including CMS and IHS, and means any natural person, corporate entity, sole proprietorship, partnership, association, governmental entity, or trust, including any individuals employed by, serving as the agent of, or are otherwise contracted or affiliated with the Person or any subsidiaries thereof.
21. "Pharmacy" refers to any entity, including mail-order vendors, retail vendors, hospitals, clinics, and inpatient facilities, that dispenses pharmaceutical products to patients, including pursuant to a prescription issued by a Health Care Provider.
22. "Pharmacy Benefit Plan" means a plan that provides insurance coverage to a patient for certain drugs from Pharmacies and other drug sources, often service by a PBM.
23. "Plan Sponsor" means the financial entities (e.g., Self-Funded employers, insurance companies, union health plans) that pay for prescription drugs through Pharmacy Benefit Plans.
24. "Price" or "Pricing," when used with regard to one or more products, means the amount charged by the supplier for such product(s) or the amount paid by the buyer of such product(s) to the seller, whether or not the seller is the manufacturer of the product(s). The terms "price" and "pricing" also include amounts denominated as price, gross price, net price, average price, unit price, effective price, dead net price, Rebate, package price, bundled price, discount, credit, charge or chargeback, allowance, debit, or any other payment

or receipt of anything of value incurred in whole or in part as a result of the sale of the applicable product.

25. "Rebate" means a retrospective payment returning a portion of the List Price paid for a drug to the direct or indirect purchaser.
26. The terms "relate," "related to," and "relating to" mean, in whole or in part, addressing, analyzing, concerning, constituting, containing, commenting on, discussing, describing, identifying, referring to, reflecting, reporting on, stating, or dealing with.
27. "HHS," "You," "Your," or "Yours" means the Department of Health and Human Services and any other Person acting or purporting to act on behalf of or under the direction, authorization, or control of HHS, including staff and advisors and employees of HHS, including CMS and IHS.
28. "Wholesale Acquisition Cost" or "WAC" means the pharmaceutical manufacturer's price for a drug to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, Rebates or reductions in Price, as reported in wholesale price guides or other publications of drug pricing data.

GENERAL INSTRUCTIONS

1. Respondents seek production of the Documents set forth in the numbered Requests below that are in Your possession, custody, or control. A Document is to be deemed in Your possession, custody, or control if You (a) own such Document in whole or in part; (b) have a right by contract, statute or otherwise, to use, access, inspect, examine, or copy such Document on any terms; or (c) have an express or implied understanding that You may use, access, inspect, examine or copy such Document on any terms.

2. In addition to the specific instructions set forth below, these Requests incorporate by reference all provisions of the Protective Order Governing Confidential Material, as entered by Chief Administrative Law Judge Chappell on October 1, 2024 ("Protective Order"). Subject to a valid claim of privilege, please produce the entire document if any part of that Document is responsive.
3. Any alteration of a responsive Document, including any marginal notes, handwritten notes, underlining, stamps, drafts, revisions, modifications, and other versions of a responsive Document is a separate and distinct Document and it must be produced in addition to the unaltered responsive Document.
4. No part of a Request may be left unanswered, or Documents not produced, merely because a different portion of a Request is objected to. Where an objection is made to any Request, or subpart thereof, the objection must state with specificity all grounds for the objection. If an objection is made to any Request, the response shall state whether Documents are being withheld from production on the basis of such objection, or whether inspection and production of the responsive Documents will occur not withstanding such objection.
5. For any Document withheld or redacted, in whole or in part, based on any claim of privilege or work product protection, You shall, pursuant to 16 C.F.R. § 3.38A and any additional provisions as detailed in the Protective Order, produce a privilege log that describes the nature of Documents, communications, or tangible things not produced or disclosed, in a manner that will enable Counsel for Respondents to assess the claim of privilege.
6. If no Document responsive to a Request exists, please state so in Your response.
7. Each Document should be produced in the manner, form and position in which it is kept in the ordinary course of business.

8. Unless otherwise stated, each request covers Documents and information from January 1, 2017, through the close of fact discovery in this Action.

REQUESTS FOR PRODUCTION

DOCUMENT REQUEST NO. 1

All Documents and Data related to the potential use, use, quality, or value of closed Formularies, preferred Formulary status, or Formulary tiering, negotiated by, or obtained for any Medicare or IHS plan.

DOCUMENT REQUEST NO. 2

All Documents and Data related to the use of Rebates received by, on behalf of, or in connection with any Medicare or IHS plan, including without limitation Documents and Data relating to the impact of Rebates on Pharmacy Benefit Plan costs to federal agencies, and to use or not use Rebates to reduce premiums or other dimensions of member cost, provide point-of-sale discounts for members, expand benefits, or otherwise deliver value to members, to HHS, or to other federal agencies.

DOCUMENT REQUEST NO. 3

All Documents and Data related to any analysis or decision-making concerning the Formulary treatment of any Insulin Product for any Medicare or IHS plan, including without limitation the inclusion or exclusion of low WAC Insulin Products from Formularies, member costs for Insulin Products, and the List Prices, net Prices, or costs paid for Insulin Products over time.

DOCUMENT REQUEST NO. 4

Documents and Data sufficient to show the Rebates or discounts negotiated by, obtained for, or paid to any CMS or IHS plan for Insulin Products.

DOCUMENT REQUEST NO. 5

All Documents and Data related to competition between PBMs to supply services in connection with any Medicare plan, including without limitation any comparisons between Pricing or quality of services provided by PBMs.

DOCUMENT REQUEST NO. 6

All Documents and Data received from or provided to Insulin Manufacturers or PBMs between 2017-2019 concerning any proposed or considered change in manufacturer list prices, such as WAC reduction, alternative generic strategy, or additional "new" NDC introduction plans, including without limitation materials discussing any burden to FDA or HHS from such list pricing proposals.

DOCUMENT REQUEST NO. 7

All models, analyses, and empirical evidence used to examine costs, associated with the withdrawal of the 2019 proposed changes to the HHS Safe Harbor rule, 42 C.F.R. 1001.952.

DOCUMENT REQUEST NO. 8

Documents and Data sufficient to show the actual or anticipated impact of the Inflation Reduction Act out-of-pocket Insulin Product price cap for Medicare plans, including without limitation observed cost increases, shifts, or changes resulting from participation in the CMS Part D Senior Savings Model.

DOCUMENT REQUEST NO. 9

All Documents discussing the actual or anticipated impact of the Inflation Reduction Act out-of-pocket Insulin Product price cap with Insulin Manufacturers or PBMs.

DOCUMENT REQUEST NO. 10

All Documents and Data concerning models, analyses, and empirical evidence on the difference between drug manufacturers pharmaceutical list prices in foreign markets and the United States, including but not limited to the September 2020 HHS ASPE Research Report Comparing Insulin Prices in the U.S. to Other Countries.

Dated: September 17, 2025

Respectfully submitted,

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