**ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDER TO AID PUBLIC COMMENT**

***In the Matter of Caremark Rx, Zinc Health Services, et al. (Insulin)***
***File No. 221 0114; Docket No. 9437***

## I. Introduction

The Federal Trade Commission ("Commission") has accepted for public comment, subject to final approval, an Agreement Containing Consent Order ("Consent Agreement") from Express Scripts, Inc., Evernorth Health, Inc., Medco Health Services, Inc., and Ascent Health Services LLC (collectively, "ESI" or "ESI Respondents"). If and when the Commission issues the Decision and Order as final, the Consent Agreement settles (1) charges in *In the Matter of Caremark Rx, Zinc Health Services, et al.* ("Insulin Litigation") that ESI violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45 ("Section 5"), by anticompetitively and unfairly creating a system of competition that artificially prioritizes inflated rebates, and (2) the separate Commission investigation ("PBM Investigation") into ESI's business practices seeking to determine whether ESI unlawfully harmed pharmacy or PBM competition.[1]

Express Scripts is one of the nation's largest pharmacy benefit managers ("PBM"). Positioned at the center of the intricate and opaque pharmaceutical distribution chain, it wields significant influence over which drugs patients can access and at what price. Express Scripts administers PBM services on behalf of its plan sponsor clients, including employers that provide commercial insurance to their members. It creates drug formularies (lists of preferred drugs) as well as preferred pharmacy networks where members can go to fill their prescriptions. The Insulin Litigation alleges that ESI Respondents created a competition system that prioritizes the size of rebates over drugs' net price in winning clients, pushed insulin manufacturers to compete for preferred formulary coverage based on the size of rebates rather than net price, and shifted the cost of artificially inflated list prices to vulnerable patients. The PBM Investigation seeks to determine whether ESI violated Section 5 by requiring its clients' members to use its affiliated pharmacies or coercing unaffiliated pharmacies to accept unfavorable contractual terms.

The purpose of the Consent Agreement is to protect the public from ESI's anticompetitive conduct and deter others from engaging in similar anticompetitive conduct. Under the terms of the Proposed Decision and Order ("Proposed Order"), ESI will: (1) cease to discriminate against low-WAC[2] versions of a drug on its standard formularies; (2) provide a

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[1] Under the Consent Agreement, the Commission and ESI agree that the Consent Agreement is a global settlement that resolves the Commission's current concerns about ESI's business practices to the extent reflected in the Decision and Order. The release in the order excludes certain types of claims from its scope. For example, the release does not bar the Commission from bringing claims regarding business practices that ESI adopts after the Consent Agreement was signed or that were unknown to the Commission at the time, and it does not bar the Commission from bringing claims in the event it becomes aware of any agreement between ESI and its competitors.

[2] WAC, or wholesale acquisition cost, is the list price for a drug set by pharmaceutical manufacturers for wholesalers and direct purchasers.

standard offering to its plan sponsors that ensures that members will pay no higher than a drug's net cost; (3) provide full access to its Patient Assurance Program's insulin benefits to all members when a plan sponsor adopts a formulary that includes an insulin product covered by the Patient Assurance Program unless the plan sponsor opts out in writing; (4) provide a standard offering to all plan sponsors that allows the plan sponsor to transition off rebate guarantees and spread pricing; (5) delink, for its standard offering, drug manufacturers' compensation to ESI from list prices; (6) increase transparency for plan sponsors; (7) include certain terms in its standard offering to retail community pharmacies; (8) promote the standard offerings to plan sponsors and retail community pharmacies; and (9) reshore its group purchasing organization ("GPO") Ascent from Switzerland to the United States.

The Consent Agreement has been placed on the public record for 30 days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will review the comments received and decide whether it should withdraw, modify, or finalize the Proposed Order. The purpose of this analysis is to facilitate public comment on the Consent Agreement and Proposed Order to aid the Commission in determining whether it should make the Proposed Order final. This analysis is not an official interpretation of the Proposed Order or the Agreement Containing Consent Order and does not modify its terms.

## II. Insulin Litigation

In September 2024, the FTC sued the three largest PBMs—Express Scripts, Caremark, and Optum—and their affiliated GPOs. The Complaint alleges that ESI Respondents have engaged in anticompetitive and unfair rebating practices that artificially inflated the list price of insulin drugs, impaired patients' access to lower list price products, and shifted the cost of high insulin list prices to vulnerable patients.

The Complaint alleges that ESI created a system of competition that prioritizes rebates over patient affordability. ESI has placed high-list price, high-rebate versions of insulin on its standard commercial formularies and excluded low-list price, low-rebate versions of the same drugs, even when the two versions had comparable net prices. This system benefits ESI, which keeps a portion of the inflated rebates and uses the rest to attract plan sponsor clients, while withholding drug-level price information from clients that would have allowed them to make more informed decisions about patients' share of drug cost. According to the Complaint, the inflated list prices hurt patients whose out-of-pocket payments are tied to the list price of the drug, such as patients in their deductible phase and those with coinsurance. While patients pay inflated prices, ESI is enriched by the rebates tied to each filled prescription.

The Complaint alleges unfair methods of competition and unfair acts or practices under Section 5 of the FTC Act.

## III. PBM Investigation

In fall 2023, the FTC opened an investigation to determine whether certain business practices of the three largest PBMs, including Express Scripts, violate the laws enforced by the FTC by unlawfully harming competition for pharmacy services. Prior to and since opening the

investigation, Staff has received comments from pharmacies, patients, and other market participants about ESI's business practices. The comments contend, among other allegations, that ESI uses its dominance to impose oppressive terms on unaffiliated pharmacies who need to join the PBMs' pharmacy networks, including reimbursement rates that make it uneconomical for unaffiliated pharmacies to dispense medications. In December 2023, the FTC issued a civil investigative demand to Express Scripts' parent company, The Cigna Group ("Cigna"), to investigate these concerns. That investigation has been ongoing.

## IV. Proposed Order

The Proposed Order, which lasts ten years from the Implementation Date, contains the following provisions:

Section I generally requires ESI to place low-WAC versions of high-WAC drugs on its four standard commercial formularies at no disadvantage to the high-WAC version. The provision includes exceptions to this requirement if (1) the low-WAC version is higher net cost than the high-WAC version, or (2) the drug manufacturer is unable to supply the low-WAC version "in sufficient quantities to meet expected demand."

This provision addresses allegations that ESI placed high-WAC versions of drugs on its standard commercial formularies and excluded low-WAC versions of the same drug, despite both versions having comparable net prices. According to the Insulin Complaint, this practice increased out-of-pocket costs to patients whose payments are based on list price (e.g., because the patient is in the deductible stage of their insurance or owes coinsurance calculated as a percentage of list price).

Section II contains several terms designed to protect patients from excessive out-of-pocket expenses. Specifically, Section II requires ESI to develop a "standard offering" to all plan sponsors that:

- Limits member out-of-pocket costs to be no higher than a drug's net cost;
- Prohibits member out-of-pocket costs from being tied to list price or any other benchmark higher than a drug's net cost; and
- Provides full access to ESI's programs that reduce out-of-pocket costs for members.

These provisions, collectively, would reduce out-of-pocket costs for those plans that adopt the standard offering, including by ensuring consumers generally benefit from the proportional amount of any rebate in coinsurance and deductible policies. In addition to providing the above options in its standard offering to all plan sponsors, Section II also requires all of Cigna's fully insured health plans to adopt the above protections on patient out-of-pocket expenses.

Under the "meeting competition" provision in Section XI, ESI would retain the flexibility to respond to specific client requests by offering customized services that do not comply with the

"standard offering." The plan sponsors may ultimately adopt a customized plan after being served with a notice of the standard offering and acknowledging receipt in writing. This "meeting competition" exemption does not apply to the requirements that Cigna fully insured health plans adopt the patient protections in Section II.

Section III ensures that ESI's standard offering, in the event of certain legislative or regulatory changes, will attribute patient payments made through the TrumpRx platform towards patient deductibles and out-of-pocket cost maximum amounts.

Section IV generally requires that ESI provide full access to its Patient Assurance Program to all members when a plan sponsor adopts a formulary that includes an insulin product covered by the Patient Assurance Program unless the plan sponsor opts out in writing. This provision offers further protections to insulin patients against high out-of-pocket costs.

Section V addresses allegations that ESI's use of rebates to compete for plan sponsor business—particularly where those rebates are not passed through to patients at the point of sale—can result in excessive patient out-of-pocket expenses. Specifically, Section V requires ESI's "standard offering" to plan sponsors to:

- Enable members to receive the benefit of any rebate or discounts at the point of sale, without charging a fee other than its actual cost to pre-fund any rebate, if applicable;

- Not provide to plan sponsors rebate guarantees or other guarantees of pre-determined amounts of compensation; and

- Not employ spread pricing (the practice of a PBM charging a plan sponsor a different amount for the purchase of a drug than the PBM reimburses the pharmacy).

The terms of Section V are subject to the "meeting competition" exemption detailed in Section XI of the Proposed Order.

Section VI addresses allegations that ESI benefits from placing higher list price products on its formularies by charging fees to manufacturers that are based on list price. Specifically, Section VI provides that compensation received by ESI from drug manufacturers related to ESI's "standard offering" to plan sponsors will not be based, directly or indirectly, on a drug's list price.

Section VII addresses allegations that ESI obscures net price information from plan sponsors. Specifically, Section VII increases transparency for plan sponsors by requiring ESI to provide as part of its standard offering an annual report disclosing each drug's costs and pharmacy claim-level reporting, as well as any compensation paid to consultants or brokers in connection with ESI's provision of pharmacy benefit services.

Section VIII addresses ESI's pharmacy reimbursement practices. Section VIII requires ESI to develop a standard offering to retail community pharmacies (defined as a pharmacy business with three or fewer retail stores) that will:

- Compensate retail community pharmacies based on the actual cost of acquiring prescription drugs plus a dispensing fee;

- Make additional payments for all non-dispensing services performed by a retail community pharmacy; and

- Not exclude any retail community pharmacy willing to agree to the terms and conditions for participation from its standard offering to retail community pharmacies.

Section IX provides that ESI will advertise its standard offerings; clearly and conspicuously disclose their existence and availability in material created to advertise, market, or otherwise promote its products to plan sponsors and retail community pharmacies; not disparage its standard offerings; and not require or coerce plan sponsors or retail community pharmacies to adopt terms that differ from its standard offerings.

Section X provides that ESI will move its GPO, Ascent, from Switzerland to the United States.

Section XI provides that nothing in Sections II, III, IV, V, and VIII shall prevent ESI from responding to a written request for terms other than the standard offering from a plan sponsor or retail community pharmacy. With respect to plan sponsors, if ESI and a plan sponsor agree to terms other than the standard offering, ESI must then obtain a written acknowledgement that the plan sponsor has received, read, and understood the explanation of benefits of the standard offering attached as Exhibit A to the Decision and Order. Cigna's fully-insured health plans are excluded from Section XI's "meeting competition" exception.

Section XII appoints a monitor for a term beginning shortly after the Order issues and ending three years after the Implementation Date (defined as no later than January 1, 2027). The monitor has the authority to observe ESI's compliance with the obligations set forth in the Proposed Order, to act in consultation with, and make inquiries on behalf of, the Commission or its Staff, and to make annual reports to the Commission.

Sections XIII, XIV, and XV contain provisions designed to ensure the effectiveness of the relief, including: obtaining information from ESI that it is complying with the Order; requiring ESI to submit compliance reports; and requiring ESI to notify the Commission of certain changes in its corporate structure.

Section XVI provides that ESI will cooperate with the ongoing Insulin Litigation, including by providing a certain number of witnesses for depositions and for trial.