

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 Caremark Rx, L.L.C. and Zinc Health Services, LLC (collectively, “Caremark” or “Caremark 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 Caremark violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, by anticompetitively and unfairly creating a system of competition that artificially prioritizes inflated rebates, and (2) the separate Commission investigation (“PBM Investigation”) into Caremark’s business practices seeking to determine whether Caremark unlawfully harmed pharmacy or PBM competition.¹

Caremark 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. Caremark 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 Caremark 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 Caremark 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 Caremark’s anticompetitive conduct and deter others from engaging in similar anticompetitive conduct. Under the terms of the Proposed Decision and Order (“Proposed Order”), Caremark will: (1)

¹ Under the Consent Agreement, the Commission and Caremark agree that the Consent Agreement is a global settlement that resolves the current concerns of the Commission, to the extent reflected in the Decision and Order, about Caremark’s business practices. 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 Caremark 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 Caremark and its competitors.

cease to discriminate against low-WAC² versions of a drug on its standard formularies; (2) provide a standard offering to its plan sponsors that ensures that members will get the benefits of their share of rebates at the point of sale; (3) in the event of certain legislative and regulatory changes, provide a standard offering to its plan sponsors that counts patient payments on TrumpRx toward patient deductibles and out-of-pocket maximums, for covered drugs and drugs with most favored nation pricing; (4) create a Copay Certainty Program that caps members' out-of-pocket costs on insulin, and provide full access to the Copay Certainty Program's insulin benefits to all members when a plan sponsor adopts a formulary that includes an insulin product covered by the program, unless the plan sponsor opts out in writing; (5) provide a standard offering to all plan sponsors that allows the plan sponsor to transition off rebate guarantees and spread pricing; (6) delink, for its standard offering, drug manufacturers' compensation to Caremark from list prices; (7) increase transparency for plan sponsors; (8) include certain terms in its standard offering to retail community pharmacies; (9) allow pharmacies in its networks to work with pharmacy hub service providers; (10) promote the standard offerings to plan sponsors and retail community pharmacies; and (11) maintain its group purchasing organization ("GPO") Zinc's activities in 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 Caremark 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 Caremark created a system of competition that prioritizes rebates over patient affordability. Caremark 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 Caremark, 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

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

price of the drug, such as patients in their deductible phase and those with coinsurance. While patients pay inflated prices, Caremark 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 Caremark, 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 Caremark's business practices. The comments contend, among other allegations, that Caremark 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 Caremark's parent company, CVS Health Corporation ("CVS Health"), 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 Caremark 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 is listed as "Currently in Shortage" in the U.S. Food & Drug Administration's Drug Shortage Database at the time the formulary takes effect or within the 18 months prior to the formulary decision.

This provision addresses allegations that Caremark 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 Caremark to develop a "standard offering" to all plan sponsors that:

- Ensures member out-of-pocket costs are no higher than the plan sponsor's contracted rate minus any rebates;
- Prohibits member out-of-pocket costs from being tied to list price or any other benchmark higher than the plan sponsor's contracted rate minus any rebates; and

- Provides full access to Caremark’s programs that reduce out-of-pocket costs for members.

These provisions, collectively, would reduce out-of-pocket costs for members of 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 fully insured health plans offered by Aetna (owned by CVS Health) to adopt the above protections on patient out-of-pocket expenses.

Under the “meeting competition” provision in Section XII, Caremark 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 Aetna fully insured health plans adopt the patient protections in Section II.

Section III ensures that Caremark’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, so long as the drug product is covered under the plan sponsor’s benefit design or certified as the most favored nation price.

The terms of Section III are subject to the “meeting competition” exemption detailed in Section XII of the Proposed Order.

Section IV requires Caremark to create a Copay Certainty Program that caps members’ out-of-pocket costs on insulin to \$25 for a prescription claim with a 0-34 days’ supply, \$50 for a prescription claim with a 35-68 days’ supply, and \$75 for a prescription claim with a 69 or longer days’ supply. Section IV requires that Caremark provide full access to this program to all members when a plan sponsor adopts a formulary that includes an insulin product covered by the program, unless the plan sponsor opts out in writing. This provision offers further protections to insulin patients against high out-of-pocket costs.

The terms of Section IV are subject to the “meeting competition” exemption detailed in Section XII of the Proposed Order.

Section V addresses allegations that Caremark’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 Caremark’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 XII of the Proposed Order.

Section VI addresses allegations that Caremark 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 Caremark from drug manufacturers related to Caremark’s “standard offering” to plan sponsors will not be based, directly or indirectly, on a drug’s list price.

Section VII addresses allegations that Caremark obscures net price information from plan sponsors. Specifically, Section VII increases transparency for plan sponsors by requiring Caremark 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 Caremark’s provision of pharmacy benefit services.

Section VIII addresses Caremark’s pharmacy reimbursement practices. Section VIII requires Caremark to develop a standard offering to retail community pharmacies (defined as a retail pharmacy business with three or fewer store locations) 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.

The terms of Section VIII are subject to the “meeting competition” exemption detailed in Section XII of the Proposed Order.

Section IX addresses Caremark’s practices relating to third party digital pharmacy service providers known as hubs. Section IX prohibits Caremark from imposing or enforcing, or threatening to impose or enforce, any rule, agreement, or policy that prohibits or restricts a pharmacy’s engagement with a hub, so long as the pharmacy complies with law, regulation, and certain rules for transparency. Caremark also may not take any other action to interfere with the ability of a pharmacy to engage with a hub.

The provision includes exceptions for certain circumstances. Caremark may take action with documented evidence that: the pharmacy is on a federal or state exclusion list, has been flagged by regulators, or is suspected of fraud, waste, or abuse; the action is required by law; or the action is taken pursuant to a client agreement or at a client’s written request, provided Caremark does not require, coerce, or create a default option for such agreements or requests, nor

materially misrepresent hubs to clients. Caremark must report all such actions to the Monitor quarterly, retain supporting documents, and post a notice of Section IX on its pharmacy portal.

In addition, Section IX provides that Caremark must apply its audit selection criteria equally to all pharmacies of the same type, including CVS affiliates.

Section X provides that Caremark 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 XI provides that Caremark will maintain the operations of its GPO, Zinc, in the United States.

Section XII provides that nothing in Sections II, III, IV, V, and VIII shall prevent Caremark from responding to a written request for terms other than the standard offering from a plan sponsor or retail community pharmacy. If Caremark receives a written request from a plan sponsor for terms that differ from the standard offering, Caremark must include in its response the standard offering and a written acknowledgement (Exhibit A to the Decision and Order) that the plan sponsor has received, read, and understood the explanation of benefits of the standard offering. If Caremark and the plan sponsor ultimately agree on terms that differ from the standard offering, the plan sponsor must sign and return the acknowledgment. Aetna's fully-insured health plans are excluded from Section XII's "meeting competition" exception.

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

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