

Presidential Documents

Executive Order 13939 of July 24, 2020

Lowering Prices for Patients by Eliminating Kickbacks to Middlemen

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Purpose. One of the reasons pharmaceutical drug prices in the United States are so high is because of the complex mix of payers and negotiators that often separates the consumer from the manufacturer in the drug-purchasing process. The result is that the prices patients see at the point-of-sale do not reflect the prices that the patient's insurance companies, and middlemen hired by the insurance companies, actually pay for drugs. Instead, these middlemen—health plan sponsors and pharmacy benefit managers (PBMs)—negotiate significant discounts off of the list prices, sometimes up to 50 percent of the cost of the drug. Medicare patients, whose cost sharing is typically based on list prices, pay more than they should for drugs while the middlemen collect large “rebate” checks. These rebates are the functional equivalent of kickbacks, and erode savings that could otherwise go to the Medicare patients taking those drugs. Yet currently, Federal regulations create a safe harbor for such discounts and preclude treating them as kickbacks under the law.

Fixing this problem could save Medicare patients billions of dollars. The Office of the Inspector General at the Department of Health and Human Services has found that patients in the catastrophic phase of the Medicare Part D program saw their out-of-pocket costs for high-price drugs increase by 47 percent from 2010 to 2015, from \$175 per month to \$257 per month. Narrowing the safe harbor for these discounts under the anti-kickback statute will allow tens of billions in dollars of rebates on prescription drugs in the Medicare Part D program to go directly to patients, saving many patients hundreds or thousands of dollars per year at the pharmacy counter.

Sec. 2. Policy. It is the policy of the United States that discounts offered on prescription drugs should be passed on to patients.

Sec. 3. Directing Drug Rebates to Patients Instead of Middlemen. The Secretary of Health and Human Services shall complete the rulemaking process he commenced seeking to:

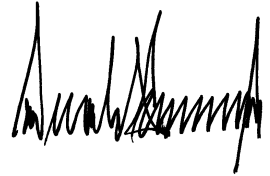
(a) exclude from safe harbor protections under the anti-kickback statute, section 1128B(b) of the Social Security Act, 42 U.S.C. 1320a–7b, certain retrospective reductions in price that are not applied at the point-of-sale or other remuneration that drug manufacturers provide to health plan sponsors, pharmacies, or PBMs in operating the Medicare Part D program; and

(b) establish new safe harbors that would permit health plan sponsors, pharmacies, and PBMs to apply discounts at the patient's point-of-sale in order to lower the patient's out-of-pocket costs, and that would permit the use of certain bona fide PBM service fees.

Sec. 4. Protecting Low Premiums. Prior to taking action under section 3 of this order, the Secretary of Health and Human Services shall confirm—and make public such confirmation—that the action is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs.

Sec. 5. General Provisions. (a) Nothing in this order shall be construed to impair or otherwise affect:

- (i) the authority granted by law to an executive department or agency, or the head thereof; or
 - (ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.
- (b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.
- (c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

A handwritten signature in black ink, appearing to be the signature of Donald Trump, located on the right side of the page.

THE WHITE HOUSE,
July 24, 2020.