115TH CONGRESS
1ST SESSION

S. 2042

To authorize a joint action plan and report on drug waste.

IN THE SENATE OF THE UNITED STATES

OCTOBER 31, 2017

Ms. KLOBUCHAR (for herself, Mr. GRASSLEY, Mr. DURBIN, and Mrs. SHAHEEN) introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To authorize a joint action plan and report on drug waste.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Reducing Drug Waste Act of 2017''.

SEC. 2. FINDINGS.

Congress finds as follows:

(1) On May 23, 2017, the Department of Health and Human Services, acting through the Office of the Inspector General in a letter to Senators Klobuchar, Durbin, and Shaheen, found that dif-

ferent vial sizes in addition to those currently approved and marketed in the United States could sometimes significantly reduce the amount of drug discards, or waste, from single-use vials.

(2) The Office of Inspector General analyzed 20 single-use vial drugs with the highest amounts of identifiable reimbursement for discarded drugs during 2013 and 2014 and found that the Medicare Part B program paid $11,600,000,000 for these drugs, $2,100,000,000 of which was for drugs billed in increments of other-than-full vials, and $195,000,000, or nearly 10 percent, of the $2,100,000,000 billed in increments of other-than-full vials was reimbursed for discarded drugs.

(3) During the Food and Drug Administration's review process for a drug's safety and efficacy before a drug is approved for marketing in the United States, the Food and Drug Administration reviews the manufacturer's proposed vial size.

(4) As of January 1, 2017, the Centers for Medicare & Medicaid Services requires all physicians, hospitals, and other providers submitting claims to Medicare to separately identify the discarded amount of a drug from a single-use vial (the JW modifier) on its claim for reimbursement by

Medicare. The new requirement does not change the amount the providers are reimbursed for single-use drugs.

(5) An October 2017 investigation by ProPublica found that many pharmaceutical companies produce eye-drops in over-sized doses, in some cases more than twice what the eye can hold, resulting in drug waste and excess spending.

SEC. 3. JOINT ACTION PLAN AND REPORT ON DRUG WASTE.

(a) JOINT ACTION PLAN.—The Commissioner of Food and Drugs, in coordination with the Administrator of the Centers for Medicare & Medicaid Services, shall develop a joint action plan, in consultation with healthcare providers and patient advocates (including relevant Federal advisory committees) that—

(1) utilizes data from Medicare claims on how much of a single-use drug was not administered, examines single-use vial sizes in other countries, and analyzes the drug approval process for alternative vial size safety and efficacy approaches, to reduce drug waste and better manage costs with respect to drug vial sizes and other drug delivery systems, as appropriate; and

(2) includes quantifiable metrics and specific timelines.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Commissioner of Food and Drugs, in coordination with the Administrator of the Centers for Medicare & Medicaid Services, shall submit to Congress the joint action plan described in subsection (a) and a report containing recommendations for any legislative action needed to reduce drug waste and better manage costs with respect to drug vial sizes and other drug delivery systems, as appropriate.

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