

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

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Reducing Drug Waste
5 Act of 2017”.

6 **SEC. 2. FINDINGS.**

7 Congress finds as follows:

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

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

5 (2) The Office of Inspector General analyzed 20
6 single-use vial drugs with the highest amounts of
7 identifiable reimbursement for discarded drugs dur-
8 ing 2013 and 2014 and found that the Medicare
9 Part B program paid \$11,600,000,000 for these
10 drugs, \$2,100,000,000 of which was for drugs billed
11 in increments of other-than-full vials, and
12 \$195,000,000, or nearly 10 percent, of the
13 \$2,100,000,000 billed in increments of other-than-
14 full vials was reimbursed for discarded drugs.

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

20 (4) As of January 1, 2017, the Centers for
21 Medicare & Medicaid Services requires all physi-
22 cians, hospitals, and other providers submitting
23 claims to Medicare to separately identify the dis-
24 carded amount of a drug from a single-use vial (the
25 JW modifier) on its claim for reimbursement by

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

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

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

10 (a) **JOINT ACTION PLAN.**—The Commissioner of
11 Food and Drugs, in coordination with the Administrator
12 of the Centers for Medicare & Medicaid Services, shall de-
13 velop a joint action plan, in consultation with healthcare
14 providers and patient advocates (including relevant Fed-
15 eral advisory committees) that—

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

24 (2) includes quantifiable metrics and specific
25 timelines.

1 (b) REPORT.—Not later than 1 year after the date
2 of enactment of this Act, the Commissioner of Food and
3 Drugs, in coordination with the Administrator of the Cen-
4 ters for Medicare & Medicaid Services, shall submit to
5 Congress the joint action plan described in subsection (a)
6 and a report containing recommendations for any legisla-
7 tive action needed to reduce drug waste and better manage
8 costs with respect to drug vial sizes and other drug deliv-
9 ery systems, as appropriate.

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