

115TH CONGRESS
2D SESSION

S. 3565

To amend title XI of the Social Security Act to include additional covered recipients for transparency reports required of manufacturers of opioids.

IN THE SENATE OF THE UNITED STATES

OCTOBER 10, 2018

Mrs. McCASKILL (for herself and Mr. CASSIDY) introduced the following bill;
which was read twice and referred to the Committee on Finance

A BILL

To amend title XI of the Social Security Act to include additional covered recipients for transparency reports required of manufacturers of opioids.

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 “Opioid Advocacy
5 Transparency Act of 2018”.

6 **SEC. 2. ADDITIONAL COVERED RECIPIENTS FOR TRANS-**
7 **PARENCY REPORTS REQUIRED OF MANUFAC-**
8 **TURERS OF OPIOIDS.**

9 (a) IN GENERAL.—Section 1128G(e) of the Social
10 Security Act (42 U.S.C. 1320a–7h(e)) is amended—

1 (1) in paragraph (6)—

2 (A) in subparagraph (A)—

3 (i) in the matter preceding clause (i),
4 by inserting “and subject to subparagraph
5 (C)” after “subparagraph (B)”; and

6 (ii) by adding at the end the following
7 new clause:

8 “(vi) A relevant patient advocacy or-
9 ganization (as defined in subparagraph
10 (D)) or a foundation established by such
11 an organization.”; and

12 (B) by adding at the end the following new
13 subparagraphs:

14 “(C) LIMITATION.—Clause (vi) of subpara-
15 graph (A) shall only apply with respect to infor-
16 mation required to be submitted under this sec-
17 tion by an applicable manufacturer that is the
18 manufacturer of a covered drug, device, biologi-
19 cal, or medical supply that is an opioid (as de-
20 fined in section 102 of the Controlled Sub-
21 stances Act (21 U.S.C. 802)).

22 “(D) RELEVANT PATIENT ADVOCACY OR-
23 GANIZATION.—For purposes of subparagraph
24 (A)(vi), the term ‘relevant patient advocacy or-
25 ganization’ means an organization engaged in

1 advocacy on issues related to opioids (as so de-
2 fined), including patient use of and access to
3 opioids, the use of opioids for the treatment of
4 pain, and opioid addiction treatment.”; and

5 (2) in paragraph (10)(B)—

6 (A) in clause (i), by striking “A transfer”
7 and inserting “Subject to clause (xiii), a trans-
8 fer”; and

9 (B) by adding at the end the following new
10 clause:

11 “(xiii) In the case of a covered recipi-
12 ent described in paragraph (6)(A)(vi), a
13 transfer of anything of value to the covered
14 recipient by an applicable manufacturer
15 described in paragraph (6)(C), unless the
16 aggregate amount transferred to, requested
17 by, or designated on behalf of the covered
18 recipient by the applicable manufacturer
19 during the calendar year exceeds \$4,000.
20 For calendar years after 2024, the dollar
21 amount specified in the preceding sentence
22 shall be increased by the same percentage
23 as the percentage increase in the consumer
24 price index for all urban consumers (all
25 items; U.S. city average) for the 12-month

1 period ending with June of the previous
2 year.”.

3 (b) TREATMENT OF CERTAIN PAYMENTS OR OTHER
4 TRANSFERS OF VALUE MADE BY PHARMACEUTICAL
5 TRADE ASSOCIATIONS.—Section 1128G(a)(1) of the So-
6 cial Security Act (42 U.S.C. 1320a–7h(a)(1)) is amended
7 by adding at the end the following new subparagraph:

8 “(C) TREATMENT OF CERTAIN PAYMENTS
9 OR OTHER TRANSFERS OF VALUE BY PHARMA-
10 CEUTICAL TRADE ASSOCIATIONS.—For pur-
11 poses of this section, the provisions that apply
12 to an applicable manufacturer with respect to a
13 payment or other transfer of value described in
14 subparagraph (A) shall also apply to a pharma-
15 ceutical trade organization (as defined by the
16 Secretary) but only with respect to a payment
17 or other transfer of value described in such sub-
18 paragraph provided to a covered recipient de-
19 scribed in subsection (e)(6)(A)(vi) (or to an en-
20 tity or individual at the request of or designated
21 on behalf of a covered recipient described in
22 such subsection).”.

23 (c) EFFECTIVE DATE.—The amendments made by
24 this section shall apply with respect to information re-
25 quired to be submitted under section 1128G of the Social

1 Security Act (42 U.S.C. 1320a-7h) on or after January
2 1, 2024.

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