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(Original Signature of Member)

116TH CONGRESS
2D SESSION

H. R. _____

To modify reporting requirements under the Controlled Substances Act.

IN THE HOUSE OF REPRESENTATIVES

Ms. CASTOR of Florida introduced the following bill; which was referred to the
Committee on _____

A BILL

To modify reporting requirements under the Controlled
Substances Act.

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 “Preventing Pill Mills
5 Through Data Sharing Act”.

6 **SEC. 2. REPORTING REQUIREMENTS.**

7 (a) RECORDS AND REPORTS OF REGISTRANTS.—Sec-
8 tion 307 of the Controlled Substances Act (21 U.S.C. 827)
9 is amended—

1 (1) in subsection (d), by striking “(d)(1)” and
2 all that follows through the end of paragraph (1)
3 and inserting the following:

4 “(d)(1)(A) Except as provided in subparagraph (B),
5 every person registered under section 303 shall, not less
6 frequently than monthly, make reports to the Attorney
7 General through the Automated Reports and Consolidated
8 Orders System, or any subsequent automated system de-
9 veloped by the Drug Enforcement Administration to mon-
10 itor controlled substances, of every sale, delivery, or other
11 disposal by the person of any controlled substance, identi-
12 fying by the registration number assigned under this title
13 the person or establishment (unless exempt from registra-
14 tion under section 302(d)) to whom such sale, delivery,
15 or other disposal was made.

16 “(B) Subparagraph (A) shall not apply to—

17 “(i) the retail sale or delivery of a controlled
18 substance by a pharmacy registered under section
19 303 to another pharmacy registered under that sec-
20 tion to fulfill a specific patient need, as defined in
21 section 581 of the Federal Food, Drug, and Cos-
22 metic Act (21 U.S.C. 360eee); or

23 “(ii) the retail dispensing of a controlled sub-
24 stance by a pharmacy registered under section 303.

1 “(C) A person registered under section 303 that does
2 not sell, deliver, or otherwise dispose of a controlled sub-
3 stance during a month shall not be required to submit a
4 report for that month under subparagraph (A).”; and

5 (2) in subsection (f)—

6 (A) in paragraph (1)—

7 (i) in the matter preceding subpara-
8 graph (A)—

9 (I) by striking “manufacturer
10 and distributor registrants” and in-
11 sserting “persons registered under sec-
12 tion 303”; and

13 (II) by striking “selected”;

14 (ii) in subparagraph (A)—

15 (I) by inserting “or pharmacy”
16 after “distributor”; and

17 (II) by inserting before the pe-
18 riod at the end the following: “to
19 whom controlled substances are dis-
20 tributed”; and

21 (iii) in subparagraph (B), by striking
22 “opioids” and inserting “controlled sub-
23 stances”;

24 (B) in paragraph (2)—

1 (i) by striking “made available not
2 later” and inserting the following: “made
3 available—

4 “(A) not later”;

5 (ii) by striking the period at the end
6 and inserting a semicolon; and

7 (iii) by adding at the end the fol-
8 lowing:

9 “(B) in a format that allows the raw data to be
10 queried and sorted for analytical purposes; and

11 “(C) in a manner such that the information
12 may be accessed simultaneously by more than 1 user
13 at each registered location of a specific manufac-
14 turer, distributor, or pharmacy.”; and

15 (C) in paragraph (3)—

16 (i) in subparagraph (A), by striking
17 “registered manufacturers and distribu-
18 tors” and inserting “persons registered
19 under section 303”; and

20 (ii) in subparagraph (B), by striking
21 “registered manufacturer or distributor”
22 and inserting “person registered under sec-
23 tion 303”.

24 (b) PENALTIES.—

1 (1) IN GENERAL.—Section 402 of the Con-
2 trolled Substances Act (21 U.S.C. 842) is amend-
3 ed—

4 (A) in subsection (a), by striking para-
5 graph (17) and inserting the following:

6 “(17) in the case of a person registered under
7 section 303, to fail to review the most recent infor-
8 mation, directly related to the customers of the per-
9 son, made available by the Attorney General in ac-
10 cordance with section 307(f).”; and

11 (B) in subsection (c)(1)(B), by striking
12 clause (ii) and inserting the following:

13 “(ii) In the case of a violation described in clause (i)
14 committed by a person registered under section 303 and
15 related to the reporting of suspicious orders of controlled
16 substances, failing to maintain effective controls against
17 diversion of such substances, or failing to review the most
18 recent information made available by the Attorney General
19 in accordance with section 307(f), the penalty shall not
20 exceed \$100,000.”.

21 (2) TECHNICAL AND CONFORMING AMEND-
22 MENT.—Section 402(a)(16) of the Controlled Sub-
23 stances Act (21 U.S.C. 842(a)(16)) is amended by
24 striking “section 825 of this title” and inserting
25 “section 305”.

1 (c) AUTOMATED REPORTS AND CONSOLIDATED OR-
2 DERS SYSTEM.—Section 503(c)(1) of the Controlled Sub-
3 stances Act (21 U.S.C. 873(c)(1)) is amended—

4 (1) by inserting after “of States” the following:
5 “, and to the Committee on the Judiciary of the
6 Senate, the Committee on Health, Education, Labor,
7 and Pensions of the Senate, the Caucus on Inter-
8 national Narcotics Control of the Senate, the Com-
9 mittee on the Judiciary of the House of Representa-
10 tives, and the Committee on Energy and Commerce
11 of the House of Representatives,”;

12 (2) by inserting after “registrants,” the fol-
13 lowing: “including unusual volumes of controlled
14 substances that are disposed of rather than sold,
15 and unusual numbers of deleted transactions of high
16 volumes of controlled substances,”; and

17 (3) by striking “contained in schedule II,”.

18 **SEC. 3. REGULATIONS AND GUIDANCE.**

19 Not later than 90 days after the date of enactment
20 of this Act, the Attorney General shall—

21 (1) amend part 1304 of title 21, Code of Fed-
22 eral Regulations, to implement the amendments
23 made by section 2, including the requirements
24 that—

1 (A) persons registered under section 303
2 of the Controlled Substances Act (21 U.S.C.
3 823) make the reports under section 307(d)(1)
4 of that Act (21 U.S.C. 827(d)(1)) on a monthly
5 basis; and
6 (B) the reports described in subparagraph
7 (A) include all controlled substances; and
8 (2) issue guidance to persons described in para-
9 graph (1)(A) to clarify the meaning of each of the
10 data sets contained in the Automated Reports and
11 Consolidated Orders System.