

115TH CONGRESS
1ST SESSION

H. R. 4710

To amend the Public Health Service Act to establish a moratorium on the registration of certain new 340B hospitals and associated sites, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 21, 2017

Mr. BUCSHON (for himself and Mr. PETERS) introduced the following bill;
which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to establish a moratorium on the registration of certain new 340B hospitals and associated sites, and for other purposes.

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 “340B Protecting Ac-
5 cess for the Underserved and Safety-net Entities Act” or
6 the “340B PAUSE Act”.

1 **SEC. 2. MORATORIUM ON REGISTRATION OF CERTAIN NEW**
2 **340B HOSPITALS AND ASSOCIATED SITES.**

3 Section 340B(a) of the Public Health Service Act (42
4 U.S.C. 256b(a)) is amended—

5 (1) in paragraph (4)(L), by striking “A sub-
6 section (d) hospital” and inserting “Subject to para-
7 graph (11), a subsection (d) hospital”; and

8 (2) by adding at the end the following new
9 paragraph:

10 “(11) MORATORIUM ON REGISTRATION OF CER-
11 TAIN HOSPITALS AND ASSOCIATED SITES OF SUCH
12 HOSPITALS.—During the period beginning on the
13 date of the enactment of this paragraph, and ending
14 on the date that is 2 years after such date of enact-
15 ment—

16 “(A) an entity described in paragraph
17 (4)(L) shall not be considered a covered entity
18 under this section unless such entity had been
19 identified as a covered entity under the system
20 established under subsection (d)(2)(B)(iv) as of
21 the day before the date of the enactment of this
22 paragraph; and

23 “(B) in the case of an entity described in
24 paragraph (4)(L) that is identified as a covered
25 entity under such system, an off-site outpatient
26 facility, clinic, eligible off-site location, or asso-

1 ciated site of such entity (in this paragraph and
2 subsection (f) referred to as a potential ‘child
3 site’ of such entity) may not be identified under
4 such system as a child site of the covered entity
5 for purposes of this section unless such child
6 site was so identified under such system, with
7 respect to such covered entity, as of the day be-
8 fore the date of the enactment of this para-
9 graph.”.

10 **SEC. 3. DATA REPORTING TO IMPROVE THE TRANS-**
11 **PARENCY REGARDING HOW 340B HOSPITAL**
12 **COVERED ENTITIES PROVIDE CARE FOR PA-**
13 **TIENTS.**

14 Section 340B of the Public Health Service Act (42
15 U.S.C. 256b) is amended by adding at the end the fol-
16 lowing new subsection:

17 “(f) DATA REPORTING TO IMPROVE THE TRANS-
18 PARENCY REGARDING HOW HOSPITAL COVERED ENTI-
19 TIES PROVIDE CARE FOR PATIENTS.—

20 “(1) IN GENERAL.—Beginning on the date that
21 is 14 months after the date of the enactment of this
22 subsection, and annually thereafter, subject to sub-
23 paragraph (C), a covered entity described in sub-
24 paragraph (L) or (M) of subsection (a)(4), unless
25 otherwise indicated, shall report on the following,

1 with respect to the previous year, in such a manner
2 and form as specified by the Secretary:

3 “(A) The following information:

4 “(i) With respect to such covered enti-
5 ty and with respect to each child site of
6 such entity (as referenced in paragraph
7 (11)), the number and percentage of indi-
8 viduals who are dispensed or administered
9 drugs that are subject to an agreement
10 under this section, organized by form of
11 health insurance coverage of such individ-
12 uals (including at least by the Medicare
13 program under title XVIII of the Social
14 Security Act, the Medicaid program under
15 title XIX of such Act, health insurance
16 coverage offered in the individual or group
17 market or a group health plan (as such
18 terms are defined in section 2791), and
19 uninsured).

20 “(ii) With respect to each such child
21 site of such entity, the total costs incurred
22 at each such site and the cost incurred at
23 each such site for charity care as defined
24 in line 23 of worksheet S-10 to the Medi-
25 care cost report or in any successor form.

1 “(B) The aggregate amount of gross reim-
2 bursement received by each such covered entity
3 (including child sites of such entity) described
4 in such subparagraph (L) or (M) for all drugs
5 purchased that are subject to an agreement
6 under this section and the entity’s aggregate
7 acquisition cost for such drugs.

8 “(C) In the case of covered entity de-
9 scribed in subparagraph (L) of subsection
10 (a)(4), at the time of application and recertifi-
11 cation (and at least annually thereafter), the
12 contract that is the basis for eligibility under
13 the requirement under clause (i) of such sub-
14 paragraph and any modifications to such con-
15 tract for purposes of review by the Secretary.

16 “(D) With respect to such covered entity
17 and with respect to each child site of such enti-
18 ty, the name of all third-party vendors or other
19 similar entities that the covered entity contracts
20 with to provide services associated with the pro-
21 gram under this section.

22 “(2) AVAILABILITY OF INFORMATION.—

23 “(A) IN GENERAL.—The Secretary shall
24 make data reported by covered entities under
25 subparagraphs (A), (C), and (D) of paragraph

1 (1) available on the public website of the De-
2 partment of Health and Human Services in an
3 electronic and searchable format, which may in-
4 clude the 340B Office of Pharmacy Affairs In-
5 formation System or a successor to such sys-
6 tem:

7 “(B) FORMAT.—Data made available
8 under subparagraph (A) shall be made available
9 in a manner that shows each category of data
10 reported both in the aggregate and identified by
11 covered entities described in subparagraphs (L)
12 and (M) of subsection (a)(4) and child sites of
13 such covered entities. In carrying out this para-
14 graph, with respect to data reported pursuant
15 to paragraph (1)(C), the Secretary shall ensure
16 that any proprietary information shall be re-
17 dacted from contracts submitted pursuant to
18 such paragraph (1)(C) before posting such
19 data.

20 “(3) INTERIM FINAL REGULATIONS.—The Sec-
21 retary shall issue interim final regulations no later
22 than the date that is 6 months after the date of the
23 enactment of this subsection, to carry out this sub-
24 section and shall finalize such regulations prior to

1 the end of the moratorium period to which sub-
2 section (a)(11) applies.

3 “(4) REPORTS TO CONGRESS.—

4 “(A) OIG REPORT.—Not later than 2
5 years after the date of the enactment of this
6 subsection, the Office of the Inspector General
7 shall submit to Congress a final report on the
8 level of charity care provided by covered entities
9 described in subparagraphs (L) and (M) of sub-
10 section (a)(4) and separately by child sites of
11 such covered entities, as reported in paragraph
12 (1)(A).

13 “(B) GAO REPORTS.—

14 “(i) INITIAL REPORT.—Not later than
15 1 year after the date of the enactment of
16 this subsection, the Comptroller General of
17 the United States shall submit to Congress
18 a report—

19 “(I) analyzing the State and local
20 government contracts intended to sat-
21 isfy the requirement under subsection
22 (a)(4)(L)(i) for a covered entity to
23 qualify as an entity described in sub-
24 paragraph (L) of subsection (a)(4);

1 “(II) assessing the amount of
2 care such contracts obligate such enti-
3 ty to provide to low-income individuals
4 ineligible for Medicare under title
5 XVIII of the Social Security Act and
6 Medicaid under title XIX of such Act;
7 and

8 “(III) analyzing how these con-
9 tracts define low-income individuals
10 and whether the Secretary reviews
11 such determinations.

12 “(ii) SUBSEQUENT REPORT.—Not
13 later than 2 years after the date of the en-
14 actment of this subsection, the Comptroller
15 General of the United States shall submit
16 to Congress a final report on the informa-
17 tion collected under paragraph (1)(B) re-
18 garding the difference between the aggre-
19 gate gross reimbursement and aggregate
20 acquisition costs received by each such cov-
21 ered entity (including child sites of such
22 entity) for drugs subject to an agreement
23 under this section.”.

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