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(Original Signature of Member)

115TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

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.

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IN THE HOUSE OF REPRESENTATIVES

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

\_\_\_\_\_  
**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.”.