

115TH CONGRESS
2D SESSION

S. 2312

To provide a moratorium on registration of new non-rural section 340B hospitals and associated sites, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JANUARY 16, 2018

Mr. CASSIDY introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To provide a moratorium on registration of new non-rural section 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 “Helping Ensure Low-in-
5 come Patients have Access to Care and Treatment” or the
6 “HELP Act”.

1 **SEC. 2. MORATORIUM ON REGISTRATION OF NEW NON-**
2 **RURAL SECTION 340B HOSPITALS AND ASSO-**
3 **CIATED SITES.**

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

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

9 (2) by adding at the end the following:

10 “(11) MORATORIUM ON REGISTRATION OF CER-
11 TAIN HOSPITALS AND ASSOCIATED SITES OF SUCH
12 HOSPITALS.—During the 2-year period beginning on
13 the date of enactment of the Helping Ensure Low-
14 income Patients have Access to Care and Treatment
15 Act—

16 “(A) an entity described in paragraph
17 (4)(L) shall not be considered a covered entity
18 under this section unless such entity was a cov-
19 ered entity on December 31, 2017 (as evidenced
20 by the entity having been identified as a cov-
21 ered entity as of December 31, 2017, under the
22 covered entity identification system established
23 under subsection (d)(2)(B)(iv)); and

24 “(B) no site shall be added to the covered
25 entity identification system established under
26 subsection (d)(2)(B)(iv) or be permitted to

1 begin participating in the drug discount pro-
 2 gram under this section, as a ‘child site’ or oth-
 3 erwise, on the basis of association with a cov-
 4 ered entity described in paragraph (4)(L) un-
 5 less such site was identified as a child site as
 6 of December 31, 2017, under the system estab-
 7 lished under subsection (d)(2)(B)(iv).

8 “(12) REGULATIONS TO BE ISSUED DURING
 9 THE MORATORIUM PERIOD TO IMPLEMENT STATU-
 10 TORY REQUIREMENTS CLARIFYING HOSPITAL ELIGI-
 11 BILITY CRITERIA AND HOSPITAL CHILD SITE STAND-
 12 ARDS AND ENHANCING HOSPITAL TRANSPARENCY.—

13 “(A) ISSUANCE OF REGULATIONS.—

14 “(i) IN GENERAL.—During the mora-
 15 torium period under paragraph (11), the
 16 Secretary shall promulgate regulations
 17 through notice and comment rulemaking to
 18 implement the standards and requirements
 19 described in subparagraph (B).

20 “(ii) DEADLINE.—Such final regula-
 21 tions shall be promulgated and take ef-
 22 fect—

23 “(I) before the end date of the
 24 moratorium described in paragraph
 25 (11); or

1 “(II) in the event that any of
2 such regulations have not taken effect
3 by such end date, the moratorium
4 under subparagraph (11) shall be ex-
5 tended until such regulations are final
6 and effective.

7 “(iii) LIMITATION.—The authority to
8 promulgate regulations under this para-
9 graph is limited to setting forth the details
10 necessary and appropriate to carry out the
11 requirements of subparagraph (B) effi-
12 ciently, effectively, and in conformity with
13 such subparagraph.

14 “(B) STANDARDS AND REQUIREMENTS.—

15 “(i) HOSPITAL CHILD SITE STAND-
16 ARDS.—

17 “(I) IN GENERAL.—Hospitals de-
18 scribed in subparagraphs (L) and (M)
19 of paragraph (4) may register off-
20 campus outpatient facilities associated
21 with the hospital (also known as ‘child
22 sites’) to participate in the drug dis-
23 count program under this section (be-
24 ginning after the moratorium under
25 paragraph (11) ends), if—

1 “(aa) the site is listed on the
2 hospital’s most recently filed
3 Medicare cost report on a line
4 that is reimbursable under the
5 Medicare program (or, if the hos-
6 pital is a children’s hospital that
7 does not file a Medicare cost re-
8 port, the hospital submits to the
9 Secretary a signed statement cer-
10 tifying that the facility would be
11 correctly included on a reimburs-
12 able line of a Medicare cost re-
13 port if the hospital filed a cost
14 report);

15 “(bb) such cost report dem-
16 onstrates that the services pro-
17 vided at the facility have associ-
18 ated costs and charges for hos-
19 pital outpatient department serv-
20 ices under title XVIII of the So-
21 cial Security Act (or, if the hos-
22 pital is a children’s hospital that
23 does not file a Medicare cost re-
24 port, the hospital submits to the
25 Secretary a signed statement cer-

1 tifying that the services provided
2 at the facility include or consist
3 solely of outpatient services);

4 “(cc) the facility is wholly
5 owned by the covered entity;

6 “(dd) the Secretary has
7 made a determination, under the
8 process described in section
9 413.65(b) of title 42, Code of
10 Federal Regulations (or any suc-
11 cessor regulations), that the facil-
12 ity meets the Medicare provider-
13 based standards under section
14 413.65 of title 42, Code of Fed-
15 eral Regulations (or any suc-
16 cessor regulations);

17 “(ee) the facility provides a
18 full range of outpatient services,
19 in addition to drugs; and

20 “(ff) the facility adheres to
21 the charity care policy and any
22 sliding fee scale policy of the par-
23 ent hospital.

24 “(II) DE-REGISTRATION.—If at
25 any time following registration one or

1 more of the standards listed above are
2 no longer satisfied, a registered hos-
3 pital shall immediately notify the Sec-
4 retary, de-register the facility, and
5 keep the facility from making any
6 purchases under the drug discount
7 program under this section or rep-
8 resenting to third parties that it may
9 purchase under such program.

10 “(ii) HOSPITAL ELIGIBILITY STAND-
11 ARDS FOR HOSPITALS NOT OWNED OR OP-
12 ERATED BY A UNIT OF STATE OR LOCAL
13 GOVERNMENT.—For purposes of subpara-
14 graphs (L)(i) and (M) of paragraph (4):

15 “(I) A private hospital has been
16 formally granted governmental powers
17 by a unit of State or local government
18 if—

19 “(aa) the Secretary receives
20 a certification from a State or
21 local governmental entity that
22 such governmental entity has for-
23 mally delegated, through State or
24 local statute or regulation or, if
25 permitted by applicable State or

1 local law, through a contract with
2 a State or local government, to
3 the hospital a power, described in
4 detail in the certification;

5 “(bb) the power delegated as
6 described in item (aa)—

7 “(AA) is a bona fide
8 power that is usually or ex-
9 clusively exercised by sov-
10 ereign governments, and is
11 not merely the power to pro-
12 vide health care services on
13 behalf of the government or
14 to otherwise act on behalf of
15 the government; and

16 “(BB) in the case of a
17 hospital, is limited to the
18 power to tax, issue govern-
19 ment bonds, or quarantine
20 individuals with commu-
21 nicable diseases; and

22 “(cc) the certification de-
23 scribed in item (aa) is accessible
24 to the public as part of the infor-
25 mation describing the hospital in

1 the covered entity identification
2 system established under sub-
3 section (d)(2)(B)(iv) (provided
4 that such system specifies, for
5 each covered entity hospital,
6 whether it is publicly owned or
7 operated, a private nonprofit hos-
8 pital formally granted govern-
9 mental powers by a unit of State
10 or local government, or a private
11 nonprofit hospital with a contract
12 with a State or local government
13 to provide health care services to
14 low-income individuals who are
15 ineligible for Medicare and Med-
16 icaid).

17 “(II) A private hospital has a
18 contract with a State or local govern-
19 ment to provide health care services to
20 low-income individuals who are not
21 entitled to benefits under Medicare or
22 Medicaid if—

23 “(aa) the hospital submits a
24 copy of the contract to the Sec-
25 retary for review;

1 “(bb) the Secretary deter-
2 mines that the contract creates
3 an enforceable obligation for the
4 hospital to provide direct medical
5 care to low-income individuals in-
6 eligible for Medicare and Med-
7 icaid in an amount that rep-
8 resents at least 10 percent of the
9 hospital’s total costs of care; and

10 “(cc) the contract is avail-
11 able to the public as part of the
12 information describing the hos-
13 pital in the covered entity identi-
14 fication system established under
15 subsection (d)(2)(B)(iv).

16 “(III) If at any time a hospital
17 not owned or operated by a unit of
18 State or local government no longer
19 meets one or more requirements
20 under subclause (I) or (II), the hos-
21 pital shall immediately notify the Sec-
22 retary, dis-enroll from the drug dis-
23 count program under this section, and
24 stop making purchases under such
25 program and representing to third

1 parties that it may purchase under
2 such program.

3 “(iii) HOSPITAL TRANSPARENCY RE-
4 QUIREMENTS.—

5 “(I) HOSPITAL REQUIREMENTS
6 TO IDENTIFY SECTION 340B DRUGS.—

7 In the case of covered entity hospitals
8 described in subsections (L) and (M)
9 of paragraph (4):

10 “(aa) Claims for covered
11 outpatient drugs purchased
12 under the drug discount program
13 under this section shall be sub-
14 mitted to public and private
15 payors using the 340B modifier
16 established by the Secretary
17 under the prospective payment
18 system for hospital outpatient de-
19 partment services, in conform-
20 ance with paragraph (22) of sec-
21 tion 1833(t) of the Social Secu-
22 rity Act, subsection (h) of
23 1847A, subparagraph (F) of sec-
24 tion 1927(a)(5), and paragraph
25 (5) of section 1857(g), that is

1 'JG' (or 'TB' in the case of a
2 claim for reimbursement under
3 such system submitted by a hos-
4 pital described in subparagraph
5 (M) of paragraph (4)).

6 "(bb) Such hospitals shall
7 report to the Secretary on an an-
8 nual basis, in a form and manner
9 specified by the Secretary—

10 "(AA) the hospital's ag-
11 gregate annual revenue from
12 drugs purchased under the
13 program under this section,
14 minus its aggregate annual
15 acquisition costs for such
16 drugs broken out by hospital
17 and by each child site;

18 "(BB) the patient mix,
19 broken down by expected
20 payment source (including
21 at least the Medicare pro-
22 gram under title XVIII of
23 the Social Security Act, a
24 State plan under the Med-
25 icaid program under title

1 XIX of such Act, private in-
2 surance, and uninsured), for
3 each child site of the hos-
4 pital listed in the covered
5 entity information system
6 established under subsection
7 (d)(2)(B)(iv), the costs in-
8 curred at each site for char-
9 ity care (as described in line
10 23 of Worksheet S-10—
11 Hospital Uncompensated
12 and Indigent Care Data to
13 the Medicare cost report or
14 as reported in any successor
15 form);

16 “(CC) the percent of
17 total revenues at each site
18 derived from infusion or in-
19 jection of physician-adminis-
20 tered drugs; and

21 “(DD) with respect to
22 such hospital and each child
23 site of the hospital, the
24 names of all third-party ven-
25 dors or other similar entities

1 that the covered entity con-
2 tracts with to provide serv-
3 ices associated with the pro-
4 gram under this section
5 (broken down by covered en-
6 tity and by each child site).

7 “(II) PUBLIC AVAILABILITY.—

8 The Secretary shall make the infor-
9 mation reported to the Secretary
10 under subclause (I)(bb) available to
11 the public (with redactions of any in-
12 formation the Secretary determines to
13 be proprietary or confidential, and in
14 no case shall the report attribute spe-
15 cific discount information, including
16 the ceiling price, to any individual
17 drug product) in an annual compila-
18 tion of the reported information avail-
19 able on the internet website of the De-
20 partment of Health and Human Serv-
21 ices, and as part of the information
22 describing the hospital and the rel-
23 evant child site in the covered entity
24 identification system established
25 under subsection (d)(2)(B)(iv).”.

1 **SEC. 3. 340B CLAIMS MODIFIER.**

2 (a) **MEDICAID.**—Section 1927(a)(5) of the Social Se-
 3 curity Act (42 U.S.C. 1396r–8(a)(5)) is amended by add-
 4 ing at the end the following:

5 “(F) **340B CLAIMS MODIFIER.**—

6 “(i) **IN GENERAL.**—All claims sub-
 7 mitted to a Medicaid fee-for-service pro-
 8 gram or a medicaid managed care organi-
 9 zation (as defined in section
 10 1903(m)(1)(A)) for reimbursement of a
 11 unit of a covered outpatient drug subject
 12 to an agreement under section 340B of the
 13 Public Health Service Act shall include the
 14 340B modifier established by the Secretary
 15 under the prospective payment system for
 16 hospital outpatient department services
 17 under section 1833(t) that is ‘JG’ or the
 18 Submission Clarification Code of ‘20’ de-
 19 veloped by the National Council for Pre-
 20 scription Drug Programs (NCPDP).

21 “(ii) **DATA SHARING.**—Each single
 22 State agency shall make available to a
 23 manufacturer of a covered outpatient drug
 24 any fee-for-service or managed care claim
 25 for reimbursement for a unit of such drug
 26 for the purpose of verifying the propriety

1 of any claim for a rebate payment under
2 an agreement under subsection (b) with re-
3 spect to such drug. At the manufacturer’s
4 request, in lieu of making such a claim
5 available to the manufacturer, the single
6 State agency may instead provide a list of
7 claims (and relevant data concerning each
8 claim) for covered outpatient drugs that
9 were purchased under an agreement under
10 section 340B of the Public Health Service
11 Act or other summary data specified by
12 the manufacturer.

13 “(iii) REPORT.—Each single State
14 agency shall publish an annual report on
15 utilization of covered outpatient drugs sub-
16 ject to an agreement under section 340B
17 of the Public Health Service Act by the
18 Medicaid fee-for-service program or a med-
19 icaid managed care organization (as de-
20 fined in section 1903(m)(1)(A)) during the
21 preceding calendar year. The State agency
22 shall not include confidential patient-spe-
23 cific, drug-specific, or manufacturer-spe-
24 cific information in any such annual re-
25 port.”.

1 (b) MEDICARE.—

2 (1) MEDICARE PART B.—

3 (A) HOSPITAL OUTPATIENT DEPARTMENT
4 SERVICES.—Section 1833(t) of the Social Secu-
5 rity Act (42 U.S.C. 1395l) is amended by add-
6 ing at the end the following paragraph:

7 “(22) 340B CLAIMS MODIFIER.—All claims sub-
8 mitted under the system under this subsection for
9 reimbursement of a unit of a covered outpatient
10 drug subject to an agreement under section 340B of
11 the Public Health Service Act shall include the 340B
12 modifier established by the Secretary under such
13 system that is ‘JG’ (or ‘TB’ in the case of a claim
14 for reimbursement under such system submitted by
15 a hospital described in subparagraph (M) or (N) of
16 section 340B(a)(4) of the Public Health Service Act
17 or a rural sole community hospital described in sub-
18 paragraph (O) of such section).”.

19 (B) OTHER PART B CLAIMS.—Section
20 1847A of the Social Security Act (42 U.S.C.
21 1395w–3a) is amended by adding the following
22 new subsection:

23 “(h) 340B CLAIMS MODIFIER.—All claims submitted
24 under this part (other than under the prospective payment
25 system for hospital outpatient department services under

1 section 1833(t)) for reimbursement of a unit of a covered
2 outpatient drug subject to an agreement under section
3 340B of the Public Health Service Act shall include the
4 340B modifier established by the Secretary under such
5 payment system that is ‘JG’.”.

6 (2) MEDICARE ADVANTAGE AND MEDICARE
7 PART D.—Section 1857(e) of the Social Security Act
8 (42 U.S.C. 1395w–27(e)) is amended by adding at
9 the end the following new paragraph:

10 “(5) 340B CLAIMS MODIFIER.—All claims sub-
11 mitted to a Medicare Advantage organization or a
12 PDP sponsor under this part and part D, respec-
13 tively, for reimbursement of a unit of a covered out-
14 patient drug subject to an agreement under section
15 340B of the Public Health Service Act shall include
16 the 340B modifier established by the Secretary
17 under the prospective payment system for hospital
18 outpatient department services under section
19 1833(t) that is ‘JG’ or the Submission Clarification
20 Code of ‘20’ developed by the National Council for
21 Prescription Drug Programs (NCPDP).”.

22 (3) REPORT ON UTILIZATION UNDER MEDICARE
23 PART B.—The Secretary of Health and Human
24 Services shall publish an annual report on utilization
25 under part B of title XVIII of the Social Security

1 Act (42 U.S.C. 1395j et seq.) of covered outpatient
2 drugs purchased subject to an agreement under sec-
3 tion 340B of the Public Health Service Act (42
4 U.S.C. 256b) during the preceding calendar year.
5 The Secretary shall not include confidential patient-
6 specific, drug-specific, or manufacturer-specific in-
7 formation in any such annual report.

8 (c) EFFECTIVE DATE.—The amendments made by
9 this section take effect on the date that is 6 months after
10 the date of enactment of this Act and apply to claims sub-
11 mitted on or after that date.

12 **SEC. 4. REPORTS TO CONGRESS.**

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

16 “(f) REPORTS TO CONGRESS.—

17 “(1) OIG REPORT.—Not later than 2 years
18 after the date of the enactment of this subsection,
19 the Office of the Inspector General shall submit to
20 Congress a final report on the level of charity care
21 provided by covered entities described in subpara-
22 graphs (L) and (M) of subsection (a)(4) and sepa-
23 rately by child sites of such covered entities.

24 “(2) GAO REPORTS.—

1 “(A) INITIAL REPORT.—Not later than 1
2 year after the date of the enactment of this
3 subsection, the Comptroller General of the
4 United States shall submit to Congress a re-
5 port—

6 “(i) analyzing the State and local gov-
7 ernment contracts intended to satisfy the
8 requirement under subsection (a)(4)(L)(i)
9 for a covered entity to qualify as an entity
10 described in subparagraph (L) of sub-
11 section (a)(4);

12 “(ii) assessing the amount of care
13 such contracts obligate such entity to pro-
14 vide to low-income individuals ineligible for
15 Medicare under title XVIII of the Social
16 Security Act and Medicaid under title XIX
17 of such Act; and

18 “(iii) analyzing how these contracts
19 define low-income individuals and whether
20 the Secretary reviews such determinations.

21 “(B) SUBSEQUENT REPORT.—Not later
22 than 2 years after the date of the enactment of
23 this subsection, the Comptroller General of the
24 United States shall submit to Congress a final
25 report on the difference between the aggregate

1 gross reimbursement and aggregate acquisition
2 costs received by each such covered entity (in-
3 cluding child sites of such entity) for drugs sub-
4 ject to an agreement under this section.”.

○