II

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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as ''Helping Ensure Low-income Patients have Access to Care and Treatment'' or the ''HELP Act''.

SEC. 2. MORATORIUM ON REGISTRATION OF NEW NON-RURAL SECTION 340B HOSPITALS AND ASSOCIATED SITES.

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

(1) in paragraph (4)(L), by striking ''A subsection (d) hospital'' and inserting ''Subject to paragraph (11), a subsection (d) hospital''; and

(2) by adding at the end the following:

''(11) MORATORIUM ON REGISTRATION OF CERTAIN HOSPITALS AND ASSOCIATED SITES OF SUCH HOSPITALS.—During the 2-year period beginning on the date of enactment of the Helping Ensure Low-income Patients have Access to Care and Treatment Act—

''(A) an entity described in paragraph (4)(L) shall not be considered a covered entity under this section unless such entity was a covered entity on December 31, 2017 (as evidenced by the entity having been identified as a covered entity as of December 31, 2017, under the covered entity identification system established under subsection (d)(2)(B)(iv)); and

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

begin participating in the drug discount program under this section, as a 'child site' or otherwise, on the basis of association with a covered entity described in paragraph (4)(L) unless such site was identified as a child site as of December 31, 2017, under the system established under subsection (d)(2)(B)(iv).

''(12) REGULATIONS TO BE ISSUED DURING THE MORATORIUM PERIOD TO IMPLEMENT STATUTORY REQUIREMENTS CLARIFYING HOSPITAL ELIGIBILITY CRITERIA AND HOSPITAL CHILD SITE STANDARDS AND ENHANCING HOSPITAL TRANSPARENCY.—

''(A) ISSUANCE OF REGULATIONS.—

''(i) IN GENERAL.—During the moratorium period under paragraph (11), the Secretary shall promulgate regulations through notice and comment rulemaking to implement the standards and requirements described in subparagraph (B).

''(ii) DEADLINE.—Such final regulations shall be promulgated and take effect—

''(I) before the end date of the moratorium described in paragraph (11); or

''(II) in the event that any of such regulations have not taken effect by such end date, the moratorium under subparagraph (11) shall be extended until such regulations are final and effective.

''(iii) LIMITATION.—The authority to promulgate regulations under this paragraph is limited to setting forth the details necessary and appropriate to carry out the requirements of subparagraph (B) efficiently, effectively, and in conformity with such subparagraph.

''(B) STANDARDS AND REQUIREMENTS.—

''(i) HOSPITAL CHILD SITE STANDARDS.—

''(I) IN GENERAL.—Hospitals described in subparagraphs (L) and (M) of paragraph (4) may register off-campus outpatient facilities associated with the hospital (also known as 'child sites') to participate in the drug discount program under this section (beginning after the moratorium under paragraph (11) ends), if—

"(aa) the site is listed on the hospital's most recently filed Medicare cost report on a line that is reimbursable under the Medicare program (or, if the hospital is a children's hospital that does not file a Medicare cost report, the hospital submits to the Secretary a signed statement certifying that the facility would be correctly included on a reimbursable line of a Medicare cost report if the hospital filed a cost report);

"(bb) such cost report demonstrates that the services provided at the facility have associated costs and charges for hospital outpatient department services under title XVIII of the Social Security Act (or, if the hospital is a children's hospital that does not file a Medicare cost report, the hospital submits to the Secretary a signed statement cer-

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

"(cc) the facility is wholly owned by the covered entity;

"(dd) the Secretary has made a determination, under the process described in section 413.65(b) of title 42, Code of Federal Regulations (or any successor regulations), that the facility meets the Medicare provider-based standards under section 413.65 of title 42, Code of Federal Regulations (or any successor regulations);

"(ee) the facility provides a full range of outpatient services, in addition to drugs; and

"(ff) the facility adheres to the charity care policy and any sliding fee scale policy of the parent hospital.

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

more of the standards listed above are no longer satisfied, a registered hospital shall immediately notify the Secretary, de-register the facility, and keep the facility from making any purchases under the drug discount program under this section or representing to third parties that it may purchase under such program.

''(ii) HOSPITAL ELIGIBILITY STANDARDS FOR HOSPITALS NOT OWNED OR OPERATED BY A UNIT OF STATE OR LOCAL GOVERNMENT.—For purposes of subparagraphs (L)(i) and (M) of paragraph (4):

''(I) A private hospital has been formally granted governmental powers by a unit of State or local government if—

''(aa) the Secretary receives a certification from a State or local governmental entity that such governmental entity has formally delegated, through State or local statute or regulation or, if permitted by applicable State or

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

''(bb) the power delegated as described in item (aa)—

''(AA) is a bona fide power that is usually or exclusively exercised by sovereign governments, and is not merely the power to provide health care services on behalf of the government or to otherwise act on behalf of the government; and

''(BB) in the case of a hospital, is limited to the power to tax, issue government bonds, or quarantine individuals with communicable diseases; and

''(cc) the certification described in item (aa) is accessible to the public as part of the information describing the hospital in

the covered entity identification system established under subsection (d)(2)(B)(iv) (provided that such system specifies, for each covered entity hospital, whether it is publicly owned or operated, a private nonprofit hospital formally granted governmental powers by a unit of State or local government, or a private nonprofit hospital with a contract with a State or local government to provide health care services to low-income individuals who are ineligible for Medicare and Medicaid).

''(II) A private hospital has a contract with a State or local government to provide health care services to low-income individuals who are not entitled to benefits under Medicare or Medicaid if—

''(aa) the hospital submits a copy of the contract to the Secretary for review;

"(bb) the Secretary determines that the contract creates an enforceable obligation for the hospital to provide direct medical care to low-income individuals ineligible for Medicare and Medicaid in an amount that represents at least 10 percent of the hospital's total costs of care; and

"(cc) the contract is available to the public as part of the information describing the hospital in the covered entity identification system established under subsection (d)(2)(B)(iv).

"(III) If at any time a hospital not owned or operated by a unit of State or local government no longer meets one or more requirements under subclause (I) or (II), the hospital shall immediately notify the Secretary, dis-enroll from the drug discount program under this section, and stop making purchases under such program and representing to third

parties that it may purchase under such program.

"(iii) HOSPITAL TRANSPARENCY REQUIREMENTS.—

"(I) HOSPITAL REQUIREMENTS TO IDENTIFY SECTION 340B DRUGS.—In the case of covered entity hospitals described in subsections (L) and (M) of paragraph (4):

"(aa) Claims for covered outpatient drugs purchased under the drug discount program under this section shall be submitted to public and private payors using the 340B modifier established by the Secretary under the prospective payment system for hospital outpatient department services, in conformance with paragraph (22) of section 1833(t) of the Social Security Act, subsection (h) of 1847A, subparagraph (F) of section 1927(a)(5), and paragraph (5) of section 1857(g), that is

'JG' (or 'TB' in the case of a claim for reimbursement under such system submitted by a hospital described in subparagraph (M) of paragraph (4)).

''(bb) Such hospitals shall report to the Secretary on an annual basis, in a form and manner specified by the Secretary—

''(AA) the hospital's aggregate annual revenue from drugs purchased under the program under this section, minus its aggregate annual acquisition costs for such drugs broken out by hospital and by each child site;

''(BB) the patient mix, broken down by expected payment source (including at least the Medicare program under title XVIII of the Social Security Act, a State plan under the Medicaid program under title

XIX of such Act, private insurance, and uninsured), for each child site of the hospital listed in the covered entity information system established under subsection (d)(2)(B)(iv), the costs incurred at each site for charity care (as described in line 23 of Worksheet S–10—Hospital Uncompensated and Indigent Care Data to the Medicare cost report or as reported in any successor form);

''(CC) the percent of total revenues at each site derived from infusion or injection of physician-administered drugs; and

''(DD) with respect to such hospital and each child site of the hospital, the names of all third-party vendors or other similar entities

that the covered entity contracts with to provide services associated with the program under this section (broken down by covered entity and by each child site).

"(II) PUBLIC AVAILABILITY.—The Secretary shall make the information reported to the Secretary under subclause (I)(bb) available to the public (with redactions of any information the Secretary determines to be proprietary or confidential, and in no case shall the report attribute specific discount information, including the ceiling price, to any individual drug product) in an annual compilation of the reported information available on the internet website of the Department of Health and Human Services, and as part of the information describing the hospital and the relevant child site in the covered entity identification system established under subsection (d)(2)(B)(iv).".

SEC. 3. 340B CLAIMS MODIFIER.

(a) MEDICAID.—Section 1927(a)(5) of the Social Security Act (42 U.S.C. 1396r–8(a)(5)) is amended by adding at the end the following:

"(F) 340B CLAIMS MODIFIER.—

"(i) IN GENERAL.—All claims submitted to a Medicaid fee-for-service program or a medicaid managed care organization (as defined in section 1903(m)(1)(A)) for reimbursement of a unit of a covered outpatient drug subject to an agreement under section 340B of the Public Health Service Act shall include the 340B modifier established by the Secretary under the prospective payment system for hospital outpatient department services under section 1833(t) that is 'JG' or the Submission Clarification Code of '20' developed by the National Council for Prescription Drug Programs (NCPDP).

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

of any claim for a rebate payment under an agreement under subsection (b) with respect to such drug. At the manufacturer's request, in lieu of making such a claim available to the manufacturer, the single State agency may instead provide a list of claims (and relevant data concerning each claim) for covered outpatient drugs that were purchased under an agreement under section 340B of the Public Health Service Act or other summary data specified by the manufacturer.

''(iii) REPORT.—Each single State agency shall publish an annual report on utilization of covered outpatient drugs subject to an agreement under section 340B of the Public Health Service Act by the Medicaid fee-for-service program or a medicaid managed care organization (as defined in section 1903(m)(1)(A)) during the preceding calendar year. The State agency shall not include confidential patient-specific, drug-specific, or manufacturer-specific information in any such annual report.''.

(b) MEDICARE.—

(1) MEDICARE PART B.—

(A) HOSPITAL OUTPATIENT DEPARTMENT SERVICES.—Section 1833(t) of the Social Security Act (42 U.S.C. 1395l) is amended by adding at the end the following paragraph:

''(22) 340B CLAIMS MODIFIER.—All claims submitted under the system under this subsection for reimbursement of a unit of a covered outpatient drug subject to an agreement under section 340B of the Public Health Service Act shall include the 340B modifier established by the Secretary under such system that is 'JG' (or 'TB' in the case of a claim for reimbursement under such system submitted by a hospital described in subparagraph (M) or (N) of section 340B(a)(4) of the Public Health Service Act or a rural sole community hospital described in subparagraph (O) of such section).''.

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

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

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

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

''(5) 340B CLAIMS MODIFIER.—All claims submitted to a Medicare Advantage organization or a PDP sponsor under this part and part D, respectively, for reimbursement of a unit of a covered outpatient drug subject to an agreement under section 340B of the Public Health Service Act shall include the 340B modifier established by the Secretary under the prospective payment system for hospital outpatient department services under section 1833(t) that is 'JG' or the Submission Clarification Code of '20' developed by the National Council for Prescription Drug Programs (NCPDP).''.

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

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

(c) EFFECTIVE DATE.—The amendments made by this section take effect on the date that is 6 months after the date of enactment of this Act and apply to claims submitted on or after that date.

SEC. 4. REPORTS TO CONGRESS.

Section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended by adding at the end the following:

''(f) REPORTS TO CONGRESS.—

''(1) OIG REPORT.—Not later than 2 years after the date of the enactment of this subsection, the Office of the Inspector General shall submit to Congress a final report on the level of charity care provided by covered entities described in subparagraphs (L) and (M) of subsection (a)(4) and separately by child sites of such covered entities.

''(2) GAO REPORTS.—

''(A) INITIAL REPORT.—Not later than 1 year after the date of the enactment of this subsection, the Comptroller General of the United States shall submit to Congress a report—

''(i) analyzing the State and local government contracts intended to satisfy the requirement under subsection (a)(4)(L)(i) for a covered entity to qualify as an entity described in subparagraph (L) of subsection (a)(4);

''(ii) assessing the amount of care such contracts obligate such entity to provide to low-income individuals ineligible for Medicare under title XVIII of the Social Security Act and Medicaid under title XIX of such Act; and

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

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

gross reimbursement and aggregate acquisition costs received by each such covered entity (including child sites of such entity) for drugs subject to an agreement under this section.''.

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