

Bill Cassidy, M.D.

AMENDMENT NO. 2

Calendar No. 4

Purpose: To issue regulations to implement statutory requirements for clarifying hospital eligibility criteria and hospital child site standards and to enhance hospital transparency.

IN THE SENATE OF THE UNITED STATES—116th Cong., 1st Sess.

S. 1895

To lower health care costs.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. CASSIDY

Viz:

1 At the appropriate place, insert the following:

2 **SEC. ____ . REGULATIONS TO IMPLEMENT STATUTORY RE-**
3 **QUIREMENTS CLARIFYING HOSPITAL ELIGI-**
4 **BILITY CRITERIA AND HOSPITAL CHILD SITE**
5 **STANDARDS AND TO ENHANCE HOSPITAL**
6 **TRANSPARENCY.**

7 (a) IN GENERAL.—Section 340B(a) of the Public
8 Health Service Act (42 U.S.C. 256b(a)) is amended by
9 adding at the end the following:

10 “(11) REGULATIONS TO IMPLEMENT STATU-
11 TORY REQUIREMENTS CLARIFYING HOSPITAL ELIGI-

1 BILITY CRITERIA AND HOSPITAL CHILD SITE STAND-
2 ARDS AND ENHANCE HOSPITAL TRANSPARENCY.—

3 “(A) ISSUANCE OF REGULATIONS.—

4 “(i) IN GENERAL.—Not later than 1
5 year after the date of enactment of this
6 paragraph, the Secretary shall promulgate
7 regulations through notice and comment
8 rulemaking to implement the standards
9 and requirements described in subpara-
10 graph (B).

11 “(ii) DEADLINE.—Such final regula-
12 tions shall take effect on December 31,
13 2021.

14 “(iii) LIMITATION.—The authority to
15 promulgate regulations under this para-
16 graph is limited to setting forth the details
17 necessary and appropriate to carry out the
18 requirements of subparagraph (B) effi-
19 ciently, effectively, and in conformity with
20 such subparagraph.

21 “(B) STANDARDS AND REQUIREMENTS.—

22 “(i) HOSPITAL CHILD SITE STAND-
23 ARDS.—

24 “(I) IN GENERAL.—Hospitals de-
25 scribed in subparagraphs (L) and (M)

1 of paragraph (4) may register off-
2 campus outpatient facilities associated
3 with the hospital (also known as 'child
4 sites') to participate in the drug dis-
5 count program under this section, if—

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

20 “(bb) such cost report dem-
21 onstrates that the services pro-
22 vided at the facility have associ-
23 ated costs and charges for hos-
24 pital outpatient department serv-
25 ices under title XVIII of the So-

1 cial Security Act (or, if the hos-
2 pital is a children's hospital that
3 does not file a Medicare cost^A re-
4 port, the hospital submits to the
5 Secretary a signed statement cer-
6 tifying that the services provided
7 at the facility include or consist
8 solely of outpatient services);

9 “(cc) the facility is wholly
10 owned by the covered entity;

11 “(dd) the Secretary has
12 made a determination, under the
13 process described in section
14 413.65(b) of title 42, Code of
15 Federal Regulations (or any suc-
16 cessor regulations), that the facil-
17 ity meets the Medicare provider-
18 based standards under section
19 413.65 of title 42, Code of Fed-
20 eral Regulations (or any suc-
21 cessor regulations);

22 “(ee) the facility provides a
23 full range of outpatient services,
24 in addition to drugs; and

1 “(ff) the facility adheres to
2 the charity care policy and any
3 sliding fee scale policy of the par-
4 ent hospital.

5 “(II) DE-REGISTRATION.—If at
6 any time following registration one or
7 more of the standards listed above are
8 no longer satisfied, a registered hos-
9 pital shall immediately notify the Sec-
10 retary, de-register the facility, and
11 keep the facility from making any
12 purchases under the drug discount
13 program under this section or rep-
14 resenting to third parties that it may
15 purchase under such program.

16 “(ii) HOSPITAL ELIGIBILITY STAND-
17 ARDS FOR HOSPITALS NOT OWNED OR OP-
18 ERATED BY A UNIT OF STATE OR LOCAL
19 GOVERNMENT.—For purposes of subpara-
20 graphs (L)(i) and (M) of paragraph (4):

21 “(I) A private hospital has been
22 formally granted governmental powers
23 by a unit of State or local government
24 if—

1 “(aa) the Secretary receives
2 a certification from a State or
3 local governmental entity that
4 such governmental entity has for-
5 mally delegated, through State or
6 local statute or regulation or, if
7 permitted by applicable State or
8 local law, through a contract with
9 a State or local government, to
10 the hospital a power, described in
11 detail in the certification;

12 “(bb) the power delegated as
13 described in item (aa)—

14 “(AA) is a bona fide
15 power that is usually or ex-
16 clusively exercised by sov-
17 ereign governments, and is
18 not merely the power to pro-
19 vide health care services on
20 behalf of the government or
21 to otherwise act on behalf of
22 the government; and

23 “(BB) in the case of a
24 hospital, is limited to the
25 power to tax, issue govern-

1 ment bonds, or quarantine
2 individuals with commu-
3 nicable diseases; and *

4 “(cc) the certification de-
5 scribed in item (aa) is accessible
6 to the public as part of the infor-
7 mation describing the hospital in
8 the covered entity identification
9 system established under sub-
10 section (d)(2)(B)(iv) (provided
11 that such system specifies, for
12 each covered entity hospital,
13 whether it is publicly owned or
14 operated, a private nonprofit hos-
15 pital formally granted govern-
16 mental powers by a unit of State
17 or local government, or a private
18 nonprofit hospital with a contract
19 with a State or local government
20 to provide health care services to
21 low-income individuals who are
22 ineligible for Medicare and Med-
23 icaid).

24 “(II) A private hospital has a
25 contract with a State or local govern-

1 ment to provide health care services to
2 low-income individuals who are not
3 entitled to benefits under Medicare or
4 Medicaid if—

5 “(aa) the hospital submits a
6 copy of the contract to the Sec-
7 retary for review;

8 “(bb) the Secretary deter-
9 mines that the contract creates
10 an enforceable obligation for the
11 hospital to provide direct medical
12 care to low-income individuals in-
13 eligible for Medicare and Med-
14 icaid in an amount that rep-
15 resents at least 10 percent of the
16 hospital’s total costs of care; and

17 “(cc) the contract is avail-
18 able to the public as part of the
19 information describing the hos-
20 pital in the covered entity identi-
21 fication system established under
22 subsection (d)(2)(B)(iv).

23 “(III) If at any time a hospital
24 not owned or operated by a unit of
25 State or local government no longer

1 meets one or more requirements
2 under subclause (I) or (II), the hos-
3 pital shall immediately notify the Sec-
4 retary, dis-enroll from the drug dis-
5 count program under this section, and
6 stop making purchases under such
7 program and representing to third
8 parties that it may purchase under
9 such program.

10 “(iii) HOSPITAL TRANSPARENCY RE-
11 QUIREMENTS.—

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

17 “(aa) Claims for covered
18 outpatient drugs purchased
19 under the drug discount program
20 under this section shall be sub-
21 mitted to public and private
22 payors using the 340B modifier
23 established by the Secretary
24 under the prospective payment
25 system for hospital outpatient de-

1 department services, in conform-
2 ance with paragraph (22) of sec-
3 tion 1833(t) of the Social Secu-
4 rity Act, subsection (h) of 1847A
5 of such Act, subparagraph (F) of
6 section 1927(a)(5) of such Act,
7 and paragraph (5) of section
8 1857(g) of such Act, that is 'JG'
9 (or 'TB' in the case of a claim
10 for reimbursement under such
11 system submitted by a hospital
12 described in subparagraph (M) of
13 paragraph (4)).

14 "(bb) Such hospitals' shall
15 report to the Secretary on an an-
16 nual basis, in a form and manner
17 specified by the Secretary—

18 "(AA) the hospital's ag-
19 gregate annual revenue from
20 drugs purchased under the
21 program under this section,
22 minus its aggregate annual
23 acquisition costs for such
24 drugs broken out by hospital
25 and by each child site;

1 “(BB) the patient mix,
2 broken down by expected
3 payment source (including
4 at least the Medicare pro-
5 gram under title XVIII of
6 the Social Security Act, a
7 State plan under the Med-
8 icaid program under title
9 XIX of such Act, private in-
10 surance, and uninsured), for
11 each child site of the hos-
12 pital listed in the covered
13 entity information system
14 established under subsection
15 (d)(2)(B)(iv), the costs in-
16 curred at each site for char-
17 ity care (as described in line
18 23 of Worksheet S-10-Hos-
19 pital Uncompensated and
20 Indigent Care Data to the
21 Medicare cost report or as
22 reported in any successor
23 form);
24 “(CC) the percent of
25 total revenues at each site

1 derived from infusion or in-
2 jection of physician-adminis-
3 tered drugs; and
4 “(DD) with respect to
5 such hospital and each child
6 site of the hospital, the
7 names of all third-party ven-
8 dors or other similar entities
9 that the covered entity con-
10 tracts with to provide serv-
11 ices associated with the pro-
12 gram under this section
13 (broken down by covered en-
14 tity and by each child site).

15 “(II) PUBLIC AVAILABILITY.—
16 The Secretary shall make the infor-
17 mation reported to the Secretary
18 under subclause (I)(bb) available to
19 the public (with redactions of any in-
20 formation the Secretary determines to
21 be proprietary or confidential, and in
22 no case shall the report attribute spe-
23 cific discount information, including
24 the ceiling price, to any individual
25 drug product) in an annual compila-

1 tion of the reported information avail-
2 able on the internet website of the De-
3 partment of Health and Human Serv-
4 ices, and as part of the information
5 describing the hospital and the rel-
6 evant child site in the covered entity
7 identification system established
8 under subsection (d)(2)(B)(iv).”.

9 (b) REPORTS TO CONGRESS.—Section 340B of the
10 Public Health Service Act (42 U.S.C. 256b) is amended
11 by adding at the end the following:

12 “(f) REPORTS TO CONGRESS.—

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

20 “(2) GAO REPORTS.—

21 “(A) INITIAL REPORT.—Not later than 1
22 year after the date of the enactment of this
23 subsection, the Comptroller General of the
24 United States shall submit to Congress a re-
25 port—

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

7 “(ii) assessing the amount of care
8 such contracts obligate such entity to pro-
9 vide to low-income individuals ineligible for
10 Medicare under title XVIII of the Social
11 Security Act and Medicaid under title XIX
12 of such Act; and

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

16 “(B) SUBSEQUENT REPORT.—Not later
17 than 2 years after the date of the enactment of
18 this subsection, the Comptroller General of the
19 United States shall submit to Congress a final
20 report on the difference between the aggregate
21 gross reimbursement and aggregate acquisition
22 costs received by each such covered entity (in-
23 cluding child sites of such entity) for drugs sub-
24 ject to an agreement under this section.”.