

117TH CONGRESS
1ST SESSION

H. R. 5463

To increase reporting requirements and transparency requirements in the
340B Drug Pricing Program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 30, 2021

Mr. ROSENDALE introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To increase reporting requirements and transparency requirements in the 340B Drug Pricing Program, 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 “Drug Pricing Trans-
5 parency and Accountability Act”.

1 **SEC. 2. MORATORIUM ON REGISTRATION OF NEW NON-**
2 **RURAL SECTION 340B HOSPITALS.**

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:

9 “(11) MORATORIUM ON REGISTRATION OF CER-
10 TAIN HOSPITALS.—During the 2-year period begin-
11 ning on the date of the enactment of this para-
12 graph—

13 “(A) an entity described in paragraph
14 (4)(L) shall not be considered a covered entity
15 under this section unless such entity was a cov-
16 ered entity on such date (as evidenced by the
17 entity having been identified as a covered entity
18 as of such date under the covered entity identi-
19 fication system established under subsection
20 (d)(2)(B)(iv)); and

21 “(B) no site shall be added to the covered
22 entity identification system established under
23 subsection (d)(2)(B)(iv) or be permitted to
24 begin participating in the drug discount pro-
25 gram under this section, as a ‘child site’ or oth-
26 erwise, on the basis of association with a cov-

ered entity described in paragraph (4)(L) unless such site was identified as a child site as of December 31, 2020, 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

1 under subparagraph (11) shall be ex-
2 tended until such regulations are final
3 and effective.

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

11 “(B) STANDARDS AND REQUIREMENTS.—

12 “(i) HOSPITAL CHILD SITE STAND-
13 ARDS.—

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

23 “(aa) the site is listed on the
24 hospital’s most recently filed
25 Medicare cost report on a line

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

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

1 “(cc) the facility is wholly
2 owned by the covered entity;

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

14 “(ee) the facility provides a
15 full range of outpatient services,
16 in addition to drugs; and

17 “(ff) the facility adheres to
18 the charity care policy and any
19 sliding fee scale policy of the par-
20 ent hospital.

21 “(II) DE-REGISTRATION.—If at
22 any time following registration one or
23 more of the standards listed above are
24 no longer satisfied, a registered hos-
25 pital shall immediately notify the Sec-

1 retary, de-register the facility, and
2 keep the facility from making any
3 purchases under the drug discount
4 program under this section or rep-
5 resenting to third parties that it may
6 purchase under such program.

7 “(ii) HOSPITAL ELIGIBILITY STAND-
8 ARDS FOR HOSPITALS NOT OWNED OR OP-
9 ERATED BY A UNIT OF STATE OR LOCAL
10 GOVERNMENT.—For purposes of subpara-
11 graph (L)(i) of paragraph (4):

12 “(I) A private hospital has been
13 formally granted governmental powers
14 by a unit of State or local government
15 if the Secretary receives a certification
16 from a State or local governmental
17 entity that such governmental entity
18 has formally delegated, through State
19 or local statute or regulation or, if
20 permitted by applicable State or local
21 law, through a contract with a State
22 or local government, to the hospital
23 such a power, described in detail in
24 the certification.

1 “(II) A private hospital has a
2 contract with a State or local govern-
3 ment to provide health care services to
4 low-income individuals who are not
5 entitled to benefits under Medicare or
6 Medicaid if—

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

10 “(bb) the Secretary deter-
11 mines that the contract creates
12 an enforceable obligation for the
13 hospital to provide direct medical
14 care to low-income individuals in-
15 eligible for Medicare and Med-
16 icaid in an amount that rep-
17 represents at least 15 percent of the
18 hospital’s total costs for all items
19 and services furnished at such
20 hospital; and

21 “(cc) the contract is avail-
22 able to the public as part of the
23 information describing the hos-
24 pital in the covered entity identi-

1 fication system established under
2 subsection (d)(2)(B)(iv).

3 “(III) If at any time a hospital
4 not owned or operated by a unit of
5 State or local government no longer
6 meets one or more requirements
7 under subclause (I) or (II), the hos-
8 pital shall immediately notify the Sec-
9 retary, dis-enroll from the drug dis-
10 count program under this section, and
11 stop making purchases under such
12 program and representing to third
13 parties that it may purchase under
14 such program.

15 “(iii) HOSPITAL TRANSPARENCY RE-
16 QUIREMENTS.—

17 “(I) HOSPITAL REQUIREMENTS
18 TO IDENTIFY SECTION 340B DRUGS.—
19 In the case of covered entity hospitals
20 described in subparagraph (L) of
21 paragraph (4):

22 “(aa) Claims for covered
23 outpatient drugs purchased
24 under the drug discount program
25 under this section shall be sub-

mitted 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’.

“(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;

1 “(BB) any dispensing
2 fees paid by the hospital or
3 child site to contract phar-
4 macies for such drugs;
5 “(CC) the patient mix,
6 broken down by expected
7 payment source (including
8 at least the Medicare pro-
9 gram under title XVIII of
10 the Social Security Act, a
11 State plan under the Med-
12 icaid program under title
13 XIX of such Act, private in-
14 surance, and uninsured indi-
15 viduals), for each such hos-
16 pital, and each child site of
17 the hospital listed in the
18 covered entity information
19 system established under
20 subsection (d)(2)(B)(iv), and
21 the costs incurred at each
22 such hospital and site for
23 charity care (as described in
24 line 23 of Worksheet S-
25 10—Hospital Uncompen-

1 sated and Indigent Care
2 Data to the Medicare cost
3 report or as reported in any
4 successor form);

5 “(DD) the percent of
6 total revenues (net of any
7 discounts) at each site de-
8 rived from infusion or injec-
9 tion of physician-adminis-
10 tered drugs, including any
11 associated items or services
12 furnished incident-to the ad-
13 ministration of such drugs;
14 and

15 “(EE) with respect to
16 such hospital and each child
17 site of the hospital, the
18 names of all third-party ven-
19 dors or other similar entities
20 (including split fee vendors
21 and contract pharmacies)
22 that the covered entity con-
23 tracts with to provide serv-
24 ices associated with the pro-
25 gram under this section

1 (broken down by covered en-
2 tity and by each child site).

3 “(II) PUBLIC AVAILABILITY.—

4 The Secretary shall make the infor-
5 mation reported to the Secretary
6 under subclause (I)(bb) available to
7 the public (with redactions of any in-
8 formation the Secretary determines to
9 be proprietary or confidential) in an
10 annual compilation of the reported in-
11 formation available on the internet
12 website of the Department of Health
13 and Human Services, and as part of
14 the information describing the hos-
15 pital and the relevant child site in the
16 covered entity identification system
17 established under subsection
18 (d)(2)(B)(iv).”.

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

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

23 “(F) 340B CLAIMS MODIFIER.—

24 “(i) IN GENERAL.—All claims sub-
25 mitted to a Medicaid fee-for-service pro-

1 gram or a medicaid managed care organi-
2 zation (as defined in section
3 1903(m)(1)(A)) for reimbursement of a
4 unit of a covered outpatient drug subject
5 to an agreement under section 340B of the
6 Public Health Service Act shall include the
7 340B modifier established by the Secretary
8 under the prospective payment system for
9 hospital outpatient department services
10 under section 1833(t) that is ‘JG’ or the
11 Submission Clarification Code of ‘20’ de-
12 veloped by the National Council for Pre-
13 scription Drug Programs (NCPDP).

14 “(ii) DATA SHARING.—Each single
15 State agency shall make available to a
16 manufacturer of a covered outpatient drug
17 any fee-for-service or managed care claim
18 for reimbursement for a unit of such drug
19 for the purpose of verifying the propriety
20 of any claim for a rebate payment under
21 an agreement under subsection (b) with re-
22 spect to such drug. At the manufacturer’s
23 request, in lieu of making such a claim
24 available to the manufacturer, the single
25 State agency may instead provide a list of

1 claims (and relevant data concerning each
2 claim) for covered outpatient drugs that
3 were purchased under an agreement under
4 section 340B of the Public Health Service
5 Act or other summary data specified by
6 the manufacturer.

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

20 (b) MEDICARE.—

21 (1) MEDICARE PART B.—

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

1 “(22) 340B CLAIMS MODIFIER.—All claims sub-
2 mitted under the system under this subsection for
3 reimbursement of a unit of a covered outpatient
4 drug subject to an agreement under section 340B of
5 the Public Health Service Act shall include the 340B
6 modifier established by the Secretary under such
7 system that is ‘JG’ (or ‘TB’ in the case of a claim
8 for reimbursement under such system submitted by
9 a hospital described in subparagraph (M) or (N) of
10 section 340B(a)(4) of the Public Health Service Act
11 or a rural sole community hospital described in sub-
12 paragraph (O) of such section).”.

13 (B) OTHER PART B CLAIMS.—Section
14 1847A of the Social Security Act (42 U.S.C.
15 1395w–3a) is amended by adding the following
16 new subsection:

17 “(h) 340B CLAIMS MODIFIER.—All claims submitted
18 under this part (other than under the prospective payment
19 system for hospital outpatient department services under
20 section 1833(t)) for reimbursement of a unit of a covered
21 outpatient drug subject to an agreement under section
22 340B of the Public Health Service Act shall include the
23 340B modifier established by the Secretary under such
24 payment system that is ‘JG’.”.

1 (2) MEDICARE ADVANTAGE AND MEDICARE
2 PART D.—Section 1857(e) of the Social Security Act
3 (42 U.S.C. 1395w–27(e)) is amended by adding at
4 the end the following new paragraph:

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

17 (3) REPORT ON UTILIZATION UNDER MEDICARE
18 PART B.—The Secretary of Health and Human
19 Services shall publish an annual report on utilization
20 under part B of title XVIII of the Social Security
21 Act (42 U.S.C. 1395j et seq.) of covered outpatient
22 drugs purchased subject to an agreement under sec-
23 tion 340B of the Public Health Service Act (42
24 U.S.C. 256b) during the preceding calendar year.
25 The Secretary shall not include confidential patient-

1 specific, drug-specific, or manufacturer-specific in-
 2 formation in any such annual report.

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

7 **SEC. 4. REPORTS TO CONGRESS.**

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

11 “(f) REPORTS TO CONGRESS.—

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

19 “(2) GAO REPORTS.—

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

1 **SEC. 5. MEDICARE REQUIREMENT FOR HOSPITALS RE-**
2 **GARDING 340B DRUG INFORMATION.**

3 (a) IN GENERAL.—Section 1866(a)(1) of the Social
4 Security Act (42 U.S.C. 1395cc(a)(1)) is amended—

5 (1) in subparagraph (X), by striking “and” at
6 the end;

7 (2) in subparagraph (Y), by striking the period
8 at the end and inserting “, and”; and

9 (3) by inserting after subparagraph (Y), the fol-
10 lowing new subparagraph:

11 “(Z) in the case of a hospital that is a covered
12 entity under subsection (a)(4) of section 340B of the
13 Public Health Service Act, to include in any cost re-
14 port submitted to the Secretary under this title in-
15 formation on—

16 “(i) the aggregate acquisition costs of the
17 hospital for drugs, the purchase of which were
18 attributed to the hospital, during the period
19 covered by such cost report and for which the
20 hospital received a discount under such section
21 340B; and

22 “(ii) the aggregate revenues the hospital
23 received from all payors for such drugs,
24 disaggregated by insurance status (including
25 the Medicare program, the Medicaid program,

1 the Children’s Health Insurance Program, pri-
2 vate health insurance, and uninsured).”.

3 (b) EFFECTIVE DATE.—The amendments made by
4 subsection (a) shall apply to contracts entered into or re-
5 newed on or after the date of the enactment of this Act.

○