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.

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 the “340B Protecting Access for the Underserved and Safety-Net Entities Act” or the “340B PAUSE Act”.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,
SEC. 2. MORATORIUM ON REGISTRATION OF CERTAIN NEW
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 sub-
section (d) hospital” and inserting “Subject to para-
graph (11), a subsection (d) hospital”; and

(2) by adding at the end the following new
paragraph:

“(11) MORATORIUM ON REGISTRATION OF CER-
TAIN HOSPITALS AND ASSOCIATED SITES OF SUCH
HOSPITALS.—During the period beginning on the
date of the enactment of this paragraph, and ending
on the date that is 2 years after such date of enact-
ment—

“(A) an entity described in paragraph
(4)(L) shall not be considered a covered entity
under this section unless such entity had been
identified as a covered entity under the system
established under subsection (d)(2)(B)(iv) as of
the day before the date of the enactment of this
paragraph; and

“(B) in the case of an entity described in
paragraph (4)(L) that is identified as a covered
entity under such system, an off-site outpatient
facility, clinic, eligible off-site location, or asso-
ciated site of such entity (in this paragraph and subsection (f) referred to as a potential ‘child site’ of such entity) may not be identified under such system as a child site of the covered entity for purposes of this section unless such child site was so identified under such system, with respect to such covered entity, as of the day before the date of the enactment of this paragraph.”.

SEC. 3. DATA REPORTING TO IMPROVE THE TRANSPARENCY REGARDING HOW 340B HOSPITAL COVERED ENTITIES PROVIDE CARE FOR PATIENTS.

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

“(f) Data Reporting to Improve the Transparency Regarding How Hospital Covered Entities Provide Care for Patients.—

“(1) In general.—Beginning on the date that is 14 months after the date of the enactment of this subsection, and annually thereafter, subject to subparagraph (C), a covered entity described in subparagraph (L) or (M) of subsection (a)(4), unless otherwise indicated, shall report on the following,
with respect to the previous year, in such a manner
and form as specified by the Secretary:

“(A) The following information:

“(i) With respect to such covered enti-
ty and with respect to each child site of
such entity (as referenced in paragraph
(11)), the number and percentage of indi-
viduals who are dispensed or administered
drugs that are subject to an agreement
under this section, organized by form of
health insurance coverage of such individ-
uals (including at least by the Medicare
program under title XVIII of the Social
Security Act, the Medicaid program under
title XIX of such Act, health insurance
coverage offered in the individual or group
market or a group health plan (as such
terms are defined in section 2791), and
uninsured).

“(ii) With respect to each such child
site of such entity, the total costs incurred
at each such site and the cost incurred at
each such site for charity care as defined
in line 23 of worksheet S–10 to the Medi-
care cost report or in any successor form.
“(B) The aggregate amount of gross reimbursement received by each such covered entity (including child sites of such entity) described in such subparagraph (L) or (M) for all drugs purchased that are subject to an agreement under this section and the entity’s aggregate acquisition cost for such drugs.

“(C) In the case of covered entity described in subparagraph (L) of subsection (a)(4), at the time of application and recertification (and at least annually thereafter), the contract that is the basis for eligibility under the requirement under clause (i) of such subparagraph and any modifications to such contract for purposes of review by the Secretary.

“(D) With respect to such covered entity and with respect to each child site of such entity, the name 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.

“(2) AVAILABILITY OF INFORMATION.—

“(A) IN GENERAL.—The Secretary shall make data reported by covered entities under subparagraphs (A), (C), and (D) of paragraph

“
(1) available on the public website of the Department of Health and Human Services in an electronic and searchable format, which may include the 340B Office of Pharmacy Affairs Information System or a successor to such system:

“(B) FORMAT.—Data made available under subparagraph (A) shall be made available in a manner that shows each category of data reported both in the aggregate and identified by covered entities described in subparagraphs (L) and (M) of subsection (a)(4) and child sites of such covered entities. In carrying out this paragraph, with respect to data reported pursuant to paragraph (1)(C), the Secretary shall ensure that any proprietary information shall be redacted from contracts submitted pursuant to such paragraph (1)(C) before posting such data.

“(3) INTERIM FINAL REGULATIONS.—The Secretary shall issue interim final regulations no later than the date that is 6 months after the date of the enactment of this subsection, to carry out this subsection and shall finalize such regulations prior to
the end of the moratorium period to which sub-
section (a)(11) applies.

“(4) REPORTS TO CONGRESS.—

“(A) OIG REPORT.—Not later than 2
years after the date of the enactmen 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 sub-
section (a)(4) and separately by child sites of
such covered entities, as reported in paragraph
(1)(A).

“(B) GAO REPORTS.—

“(i) 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 sat-
ify the requirement under subsection
(a)(4)(L)(i) for a covered entity to
qualify as an entity described in sub-
paragraph (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.

“(ii) 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 information collected under paragraph (1)(B) regarding 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.”.