ADVOCATES FOR COMMUNITY HEALTH

July 28, 2023

The Honorable John Thune
511 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Debbie Stabenow
731 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Shelley Moore Capito
172 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Tammy Baldwin
702 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Jerry Moran
521 Dirksen Senate Office Building
Washington, D.C. 20510

The Benjamin L. Cardin
509 Hart Senate Office Building
Washington, D.C. 20510

RE: 340B Request for Information
Submitted electronically Bipartisan340BRFI@email.senate.gov

Dear Senators Thune, Stabenow, Capito, Baldwin, Moran, and Cardin,

Thank you for the opportunity to submit information regarding the 340B program, and specifically how it benefits community health centers (CHCs). Advocates for Community Health (ACH) is a national membership organization comprised of leading federally qualified CHCs focused on health equity and innovation to drive health care systems, policies, and health programs. Our members serve over 2 million people and provide high-quality, comprehensive primary health care, mental health services, preventive care, and social services to patients most in need.

As required by Section 330 of the Public Health Service Act, CHCs are committed to serving all individuals regardless of their insurance status or availability to pay. The 340B program helps CHCs serve as health care lifelines for millions of Americans. By allowing the purchase of drugs at a discounted price, the 340B program enables CHCs to serve more patients, at a higher level of complexity, than they otherwise could. As required by law and regulation, and as core to our mission, CHCs reinvest every dollar of program income back into patients. We are proud to re-invest 340B savings into initiatives like medication adherence programs, outreach workers for hard-to-reach populations, and population health projects that improve individual and community health. Health center use and engagement in the 340B program exemplifies the intent behind its creation: to maximize federal investment and expand care to underserved communities as effectively as possible.

Unfortunately, health centers' ability to access and leverage this vital program is eroding, and time is of the essence. The 340B program is being steadily eroded by the actions of state policymakers, pharmaceutical companies, and pharmacy benefit managers, to the detriment of the nation's safety net providers. The following issues are the most pressing:

- **Contract Pharmacy Arrangements**: 340B covered entities are permitted to dispense 340B drugs to patients through contracting with external pharmacies, as opposed to in-house pharmacies. This is particularly helpful in rural communities, where health centers may be farther apart and access to a local pharmacy is a better way to facilitate patient access to care. Drug manufacturers are increasingly imposing restrictions on the use of contract pharmacies under the 340B drug pricing program, in an effort to narrow the program, hindering access to care for vulnerable populations. The contract pharmacy arrangements that do remain are often set up to overcompensate pharmacies, and do not allow for maximum accrual of savings to the benefit of patients.

- **PBM and Insurance Company Reimbursement**: Pharmacy benefit managers (PBMs) and insurance companies impose policies that dramatically reduce health center savings from the 340B program. For example, they may treat 340B providers differently than other providers in terms of reimbursement, participation in standard or preferred networks or inventory management systems, or they may interfere in a patient's choice to receive drugs from a 340B pharmacy. This behavior reduces health centers' savings from the program and impacts the provision of patient care.

- **State Medicaid Program Action**: Several states have enacted or plan to enact policies that would lessen or eliminate health center savings from the 340B program. For example, in January 2019, California's governor signed an executive order to create a single-purchaser system for prescription drugs in California, which will ultimately transition pharmacy services in Medi-Cal Managed Care to fee-for-service. This transition eliminated the savings that health centers receive from the 340B program in Medi-Cal Managed Care, all of which goes back into the community to support access to care and patient programming.

We appreciate your continued support to safeguard and strengthen the 340B Program. As requested, please see our responses below to your 340B Request for Information.

1. ***What specific policies should be considered to ensure HRSA can oversee the 340B program with adequate resources? What policies should be considered to ensure HRSA has the appropriate authority to enforce the statutory requirements and regulations of the 340B program?***

   Under our 340C proposal (detailed in our response to Answer #6), we recommend that HRSA be given regulatory authority to enforce clear guardrails for the 340B program, including reinvestment of savings, internal compliance protocols, and reporting requirements. We propose that covered entities receive audits every three years, with a

one-year lookback period. For effective audits that enforce the statutory requirements and regulations of the 340B program, we further recommend:

a) *High standard of burden for approval of pharmaceutical manufacturer audits*. These audits often place a high burden on CHCs to audit 340B drug prescriptions, which often takes away from patient care resources. HRSA should be the primary arbiter of program requirements.

b) *Desktop audits.* We strongly recommend interim desktop audits (sometimes called a "tabletop exercise"), with smaller sample sizes to help entities identify problems or misunderstandings before they escalate.

We also recommend a strong commitment to phased compliance, whereby entities are given the opportunity to engage in corrective action, but should they fail to come into compliance, be excluded from 340B purchases for a set period of time. We also recommend that entities demonstrating gross negligence and/or failure to follow policies and procedures should also be excluded from the program for a set period of time. For precedent, you can look to the Health Center program, in which health centers struggling with compliance lose eligibility for Federal Tort Claims Act status for up to one year.

HRSA has consistently requested funding to fully staff its audit teams. Our recommendations to shore up the oversight and efficacy of the 340B program are contingent on providing HRSA with adequate resources to conduct comprehensive oversight. Resources should be allocated equitably to ensure equal enforcement and not used for 340B entity audit purposes.

2. ***What specific policies should be considered to establish consistency and certainty in contract pharmacy arrangements for covered entities?***

Under our 340C proposal, entities that agree to higher levels of transparency and accountability are eligible for arrangements with contract pharmacies to dispense 340B drugs. 340B covered entities are permitted under current law to dispense 340B drugs to patients through contracting with external pharmacies. This practice is particularly helpful in rural communities, where health centers may be farther apart and access to a local pharmacy is a better way to facilitate patient access to care. Unfortunately, drug manufacturers are increasingly imposing unlawful restrictions on the use of contract pharmacies under the 340B drug pricing program, hindering access to care for vulnerable populations. To date, at least 16 manufacturers have instituted contract pharmacy restrictions.[1] Therefore, we recommend:

[1] https://www.amerisourcebergen.com/provider-solutions/340b-advisory-services/340b-manufacturer-updates

a) *Codify contract pharmacy access*: Congress should codify entities' right to use contract pharmacies when necessary to provide access to medications for patients. Additionally, entities should be permitted to use however many contract pharmacies are appropriate. Such necessity can be assessed during existing audit protocols and schedules.

b) *Clarifying agency guidance*: We recommend that Congress direct HRSA to issue policy guidance and regulation regarding the use of contract pharmacies by covered entities that outlines the requirements, limitations, and compliance expectations.

c) *Protecting health centers against exploitative arrangements*: We further recommend Congress give HRSA the authority to cap the percentage of 340B savings that contract pharmacies can receive, in order to ensure that benefits accrue to covered entities for the benefit of patients. Given the imbalance of power between national pharmacy chains and CHCs, for example, we recommend HRSA issue template agreements that outline these requirements and other limitations on contract restrictions that negatively impact CHCs and our patients.

3. ***What specific policies should be considered to ensure that the benefits of the 340B program accrue to covered entities for the benefit of patients they serve, not other parties?***

a) *Keep 340B savings in the hands of covered entities*. First, as touched on in our answer to #2, Congress must reduce the 340B savings accruing to third parties, including PBMs, insurers, states, third party administrators, and contract pharmacies. The primary limitation of 340B savings accruing to our patients is the number of other entities leveraging their market power to take it for themselves.

i. PBM/insurers: Congress should prevent discrimination against 340B entities by PBMs and insurers seeking to reduce reimbursement. These actions undermine the intent of the 340B program. Patients should be protected against exclusions, terms, and conditions, and should have a choice about how they receive a 340B drug. This protection would ensure that patients benefit from the 340B program, as opposed to PBMs and insurance companies.

ii. States: Congress should direct CMS to prohibit unilateral state decisions that go against the intent of the 340B program, and ensure all 340B entities that meet certain accountability and transparency requirements have the decision to bill Medicaid for 340B drugs at wholesale acquisition cost (WAC).

iii. Third party administrators (TPAs): There should be a reasonable cap on the admin fees TPAs can charge, and/or oversight to ensure that their use of 340B savings aligns with their partner entity.

b) *Institute new reporting requirements*. Under our 340C proposal, we recommend entities submit annual reports to HRSA that include community benefit as reported on the health center's IRS form 990, and evidence of tangible benefit to patients, which could include critical staffing, service expansion, infrastructure investments and/or access to

medications, among other initiatives.

4. ***What specific policies should be considered to ensure that accurate and appropriate claims information is available to ensure duplicate discounts do not occur?***

   We share in the desire and the responsibility to prevent duplicate discounts. While the best practices for sharing claims information varies by region and payer, Congress and HRSA must ensure absolute confidentiality of the data and that it is never used for discriminatory purposes. Further, they must clarify whose primary responsibility it is to review the claims, and over what time period.

5. ***What specific policies should be considered to implement common sense, targeted program integrity measures that will improve the accountability of the 340B program and give health care stakeholders greater confidence in its oversight?***

   The ACH 340C proposal (detailed below)[2] imposes accountability and transparency standards on participating entities. Please see our response to question 6 for more information.

   We also believe Congress could consider restricting eligibility for the 340B program with more specific criteria, including more effective measures of service to the uninsured. Health centers are the nation's primary care safety net and serve the uninsured and underinsured; however, we could also meet new criteria proposed by Congress that was based on particular payer mix or patients under a certain percentage of the Federal Poverty Level.

6. ***What specific policies should be considered to ensure transparency to show how 340B health care providers' savings are used to support services that benefit patients' health?***

   As we have referenced, ACH has developed a proposal to ensure that participating entities can access the benefits of the program, while ensuring greater accountability and transparency.

   This proposal creates a new subset of the 340B program called "340C." Entities can opt-in to 340C, through which they receive protections from the actions that are reducing their savings, and in return are required to reinvest all savings into the populations they serve.

[2] https://advocatesforcommunityhealth.org/wp-content/uploads/2023/02/340C-One-Pager%5EJ-as-of-2.16.23.pdf

340C is completely voluntary – anyone who participates in 340B may choose to participate in 340C. The proposal maintains key provisions of the original 340B program, including the prime vendor, certification processes, and a prohibition on resale of drugs.

If entities opt to participate in 340C, they are subject to detailed accountability and transparency standards, including the following:

- Any funds generated shall be reinvested into program operations, patient care, and other community benefits, as determined by the covered entity leadership and governing board, to the populations served.
- Entities shall submit annual reports attesting to these requirements.
- Participants are subject to audits of records that establish their compliance.

In return for agreeing to these standards, entities will have access to:

- Reimbursement at wholesale acquisition cost (WAC) for all Medicaid drugs,
- Protection against discriminatory network and reimbursement actions by health insurers and PBMs, which undermine the intent of the 340B program, and
- Unlimited use of contract pharmacies as necessary.

Enclosed, please find:

- An outline of 340C.
- Proposed legislative language for our 340C proposal.
- A letter from 104 national, state, and local organizations outlining the challenges health centers face in the 340B program and recommending the 340C proposal.

We appreciate your support and the opportunity to provide 340B program recommendations. We look forward to working with you on these important issues.

For more information, please contact me at apearskelly@advocatesforcommunityhealth.org or you can contact Stephanie Krenrich, Senior Vice President Policy and Government Affairs, at skrenrich@advocatesforcommunityhealth.org.

Sincerely,

Amanda Pears Kelly
Chief Executive Officer
Advocates for Community Health

Opt-in Accountability Program for Covered Entities: 340C

Overview

The 340B Program is a vital lifeline for federally qualified health centers, rural hospitals, and recipients of federal grant dollars. Unfortunately, it is slowly being eroded by the actions of state policymakers, pharmaceutical companies, and pharmacy benefit managers.

Reform of 340B is long overdue, and health centers and other safety net entities cannot wait any longer. Advocates for Community Health looks forward to working with Congress on full-scale reform and offers the "340C" proposal as a stopgap mechanism for certain covered entities to restore the benefits of the 340B program as soon as possible.

Accountability and Transparency

The draft 340C proposal is designed such that entities opt-in to a subsidiary program based on the 340B foundation. Under the proposal, any funds generated from the 340B program must be reinvested into program operations, patient care, and other appropriate and beneficial activities, as determined by the covered entity leadership, to the populations served. The bill also adds required internal protocols, including review of 340B savings as part of annual audit and tax reporting processes managed by the governing board. Finally, the bill adds new reporting requirements from participating entities on both overall community benefit and tangible evidence of patient benefit. Entities are subject to regular audits of records that establish their compliance with these requirements.

Benefit parameters

Entities that meet accountability standards are entitled to:

- The option to receive Medicaid reimbursement at adequate levels for drugs purchased for Medicaid patients;
- Protection against discriminatory network and reimbursement actions by health insurers and pharmacy benefit managers;
- Use contract pharmacies as necessary for patient access.

Implementation

340C is not a new program, but an opt-in alternative that shares the same core foundation as the 340B program. The 340C proposal includes key provisions of the original 340B program, including the prime vendor, certification processes, and a prohibition on resale of drugs. It provides HRSA regulatory authority to implement the legislation and authorizes appropriations in such sums as necessary.

LEGISLATIVE PROPOSAL

Sec. 340C PUBLIC HEALTH SERVICE ACT: LIMITATION ON PRICES OF DRUGS PURCHASED BY CERTAIN COVERED ENTITIES.

(a) REQUIREMENTS FOR AGREEMENT WITH SECRETARY.

(1) IN GENERAL.—The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs which requires that:

(A) the amount required to be paid to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of this section, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2), at the time of purchase. (This amount is referred to in this section as the 'ceiling price');

(B) the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price;

(C) all discounts anticipated by this statute shall be realized by such covered entities at the time they purchase 340B eligible drugs from drug wholesalers or drug manufacturers, at the ceiling prices described herein, unless the covered entity requests to have the discounts provided as a rebate after the drugs were purchased;

(D) such drugs are shipped without any delay or precondition to any licensed pharmacy or pharmacies that have entered into written agreement(s) with a covered entity that authorizes such licensed pharmacy or pharmacies to:

(i) perform dispensing activities to 340B eligible patients of the covered entity, and

(ii)receive and account for all 340B discounted drugs purchased by the covered entity, compliant with all applicable Federal and State laws, rules and regulations;

(E) the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities described in this section may permissibly be required to pay for the drug (referred to in this section as the 'ceiling price').

(2) REBATE PERCENTAGE DEFINED.

(A) IN GENERAL.—For a covered outpatient drug purchased in a calendar quarter, the ''rebate percentage'' is the amount (expressed as a percentage) equal to—

(i) the average total rebate required under section 1927(c) of the Social Security Act with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by

(ii) the average manufacturer price for such a unit of the drug during such quarter.

(B) OVER THE COUNTER DRUGS.—

(i) IN GENERAL.—For purposes of subparagraph (A), in the case of over the counter drugs, the ''rebate percentage'' shall be determined as if the rebate required under section 1927(c) of the Social Security Act is based on the applicable percentage provided under section 1927(c)(3) of such Act.

(ii) DEFINITION.—The term ''over the counter drug'' means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law).

(3) COVERED ENTITY DEFINED.

In this section, the term ''covered entity'' means

(A) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act);
(B) An entity receiving a grant under section 256a [1] of this title.
(C) A family planning project receiving a grant or contract under section 300 of this title.
(D) An entity receiving a grant under subpart II 1 of part C of subchapter XXIV (relating to categorical grants for outpatient early intervention services for HIV disease).
(E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV.
(F) A black lung clinic receiving funds under section 937(a) of title 30.
(G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act [42 U.S.C. 701(a)(2)].
(H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.
(I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act [25 U.S.C. 1651 et seq.].
(J) Any entity receiving assistance under subchapter XXVI (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).
(K) An entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2) 1 of this title (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).
(L) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act [42 U.S.C. 1395i–4(c)(2)]), and that
    (i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which 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 title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] or eligible for assistance under the State plan under this subchapter;

(4) REQUIREMENTS FOR COVERED ENTITIES IN THIS SECTION.

(A) PROHIBITING DUPLICATE DISCOUNTS OR REBATES.—

(i) IN GENERAL.—A covered entity shall not request payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act.

(ii) ESTABLISHMENT OF MECHANISM.—The Secretary shall establish a mechanism to ensure that covered entities comply with clause (i). If the Secretary does not establish a mechanism within 12 months under the previous sentence, the requirements of section 1927(a)(5)(C) of the Social Security Act shall apply.

(B) PROHIBITING RESALE OF DRUGS.—With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

(C) REINVESTMENT OF SAVINGS – Any funds generated from the benefits conferred under this section shall be reinvested into program operations, patient care, and other appropriate and beneficial activities, as determined by the covered entity leadership, to the populations served.

(D) INTERNAL COMPLIANCE PROTOCOLS—

(i) A covered entity must receive approval from its governing board (in the case of Federally-qualified health centers as defined in section 1905(l)(2)(B) of the Social Security Act, the board required under section 330(H) of the Public Health Service Act) on the use of the 340B savings as part of its review of the entity's community benefit reporting in its annual tax return.

(ii) A covered entity must also report on the use of 340B savings to its governing board as part of regular financial auditing processes.

(E) AUDITING.—

(i) A covered entity shall permit the Secretary (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits, which shall be no more frequent than once every three years, and with a lookback period no longer than one year) to audit at the Secretary's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A), (B) (C) and (D).
(ii) To the extent practicable, audits conducted under this subsection should be conducted in accordance with existing audit protocols of covered entities.
(iii) Audits shall also include review of the health center's use of 340B savings as compared to its community benefit report on IRS form 990.

(F) REPORTING—

(i) Covered entities must include the use of 340B savings as part of its community benefit report in IRS form 990.

(ii) Covered entities must submit annual reports to HRSA that include:

(a) Community benefit provided as reported on the health center's IRS form 990.

(b) Tangible evidence of the benefit to patients.

(iii) HRSA shall publish annual aggregate reports of such information submitted by covered entities.

(c) All health centers must have a summary of the use of 340B funds available upon request.

(E) ADDITIONAL SANCTION FOR NONCOMPLIANCE.—If the Secretary finds, after audit as described in subparagraph (D) and after notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs (A) or (B), the covered entity shall be required to develop a corrective action plan that is approved by the Secretary and which must be completed within two years. Failure to adhere to the plan and restore compliance will result in removal from the program for a determined period of time.

(5) CERTIFICATION OF CERTAIN COVERED ENTITIES

Covered entities described in this section are subject to the certification and recertification processes as defined in Section 340B.

(6) ACCESS TO PRIME VENDOR PROGRAM

Covered entities described in this section are eligible to enter into contracts with prime vendors for the distribution of covered outpatient drugs. If a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution.

(7) NOTICE TO MANUFACTURERS.

The Secretary shall notify manufacturers of covered outpatient drugs and single State agencies under section 1902(a)(5) of the Social Security Act of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of paragraph (5) or that are no longer certified pursuant to paragraph (7).

(8) NO PROHIBITION ON LARGER DISCOUNT.

Nothing in this subsection shall prohibit a manufacturer from charging a price for a drug that is lower than the maximum price that may be charged under paragraph (1).

(9) DRUGS PROVIDED UNDER STATE MEDICAID PLANS.

For drugs purchased by the covered entity for which payment is made, either directly or indirectly, by the State under the State plan for medical assistance under title XIX of the Social Security Act, such payment shall be no less than the cost as defined in Section 1847A(c)(6)(B) of the Social Security Act, in addition to an adequate and reasonable dispensing fee.

(10) PROHIBITION ON DISCRIMINATION.

(a) In General. A group health plan, a health insurance issuer offering group or individual health insurance coverage, or a pharmacy benefit manager may not discriminate against a covered entity or its contracted pharmacy defined in this section by:

(1) imposing requirements, exclusions, reimbursement terms, or other conditions on such entity or pharmacy that differ from those applied to entities or pharmacies that are not covered entities or specified pharmacies on the basis that the entity or pharmacy is a covered entity or specified pharmacy or that the entity or pharmacy dispenses 340B or 340C drugs, including by taking any action prohibited under subsection (b).

(2) imposing requirements, exclusions, copayments or other conditions on drugs that are purchased under this section that differ from those applied to the same drugs when purchased outside of this program.

(b) Specified Prohibited Actions.—A group health plan, a health insurance issuer offering group or individual health insurance coverage, or a pharmacy benefit manager may not discriminate against a covered entity or a specified pharmacy by doing any of the following:

(1) Reimbursing a covered entity or specified pharmacy for a quantity of a 340B drug (as defined in subsection (d)) in an amount less than such plan, issuer, or manager (as applicable) would pay to any other similarly situated (as specified by the Secretary) entity or pharmacy that is not a covered entity or a specified pharmacy for such quantity of such drug on the basis that the entity or pharmacy is a covered entity or specified pharmacy or that the entity or pharmacy dispenses 340B drugs.

(2) Imposing any terms or conditions on covered entities or specified pharmacies with respect to any of the following that differ from such terms or conditions applied to other similarly situated entities or pharmacies that are not covered entities or specified pharmacies on the basis that the entity or pharmacy is a covered entity or specified pharmacy or that the entity or pharmacy dispenses 340B drugs:

(A) Fees, chargebacks, clawbacks, adjustments, or other assessments.

(B) Professional dispensing fees.

(C) Restrictions or requirements regarding participation in standard or preferred pharmacy networks.

(D) Requirements relating to the frequency or scope of audits or to inventory management systems using generally accepted accounting principles.

(E) Any other restrictions, conditions, practices, or policies that, as specified by the Administrator of the Health Resources and Services Administration, interfere with the ability of a covered entity to maximize the value of discounts provided under section 340B.

(3) Interfering with an individual's choice to receive a 340B drug from a covered entity or specified pharmacy, whether in person or via direct delivery, mail, or other form of shipment.

(4) Requiring a covered entity or specified pharmacy to identify, either directly or through a third party, 340B or 340C drugs.

(5) Refusing to contract with a covered entity or specified pharmacy for reasons other than those that apply equally to entities or pharmacies that are not covered entities or specified pharmacies, or on the basis that—

(A) the entity or pharmacy is a covered entity or a specified pharmacy; or

(B) the entity or pharmacy is described in any of subparagraphs (A) through (O) of section 340B(a)(4).

(6) Refusing to provide coverage for a drug that was purchased under this section if it provides coverage for the same drug when it is purchased outside this section.

(c) Enforcement Mechanism For Pharmacy Benefit Managers.—The Secretary shall impose a civil monetary penalty on any pharmacy benefit manager that violates the requirements of this section. Such penalty shall not exceed $5,000 per violation per day. The Secretary shall issue proposed regulations to implement this subsection not later than 60 days after the date of the enactment of this subsection and shall finalize such regulations not later than 180 days after such date of enactment.

(11) REGULATORY AUTHORITY- The Secretary may issue regulations as necessary to implement this section.

(b) OTHER DEFINITIONS.

(1) IN GENERAL.—In this section, the terms ‘‘average manufacturer price’’, ‘‘covered outpatient drug’’, and ‘‘manufacturer’’ have the meaning given such terms in section 1927(k) of the Social Security Act.

(2) COVERED DRUG.—In this section, the term ‘covered drug’—

(A) means a covered outpatient drug (as defined in section 1927(k)(2) of the Social Security Act); and

(B) includes, notwithstanding paragraph (3)(A) of section 1927(k) of such Act, a drug used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section.

(c) AUTHORIZATION OF APPROPRIATIONS.

There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for fiscal year 2022 and each succeeding fiscal year.