Highly Confidential

Coalition Policy Principles

We support a comprehensive set of federal legislative changes to update the 340B program to ensure it benefits patients and true safety-net providers in the 340B program. These changes are designed to work together to realign the program and put it on a sustainable path for the future. This coalition supports an approach that includes all the policy areas outlined below, with statutory changes that include both contract pharmacy and several updates necessary to curb abuse and better target the program to safety-net providers.

Intent. The 340B program is intended to help support safety net providers' serving low-income and vulnerable patients. The 340B program should be structured to enable true safety-net providers to better reach communities that otherwise would not have access to affordable health care services and the medications they depend on.

Patient Definition. HRSA's 1996 patient definition is overly board and needs to be updated to safeguard the integrity of the program and serve vulnerable populations. New patient definition requirements should have strong safeguards, including the following:

- Whether a prescription qualifies for a 340B discount should be established on a prescription-by-prescription basis, and standards for evaluating whether a prescription qualifies for 340B should be objective and auditable.

- Only those prescriptions that are directly related to a medical condition for which an individual sought care from the covered entity (in accordance with the provisions set forth below, including with respect to permitted referrals for certain covered entities) should qualify as a prescription for a "patient," and thus a prescription that the covered entity may fill with a drug purchased under the 340B program.

- The covered entity must maintain a consistent responsibility for care of a patient in order for prescriptions for such a patient to qualify for a 340B discount.

- Except for the specific circumstances below, prescriptions should only qualify for a 340B discount if they are written by providers who are employed at or are independent contractors providing patient care services for 340B covered entities.

    - Prescriptions generated from referrals should only qualify for 340B discounts for patients of a: 1) Critical Access Hospital (CAH), 2) Sole Community Hospital (SCH), or 3) a grantee with a federal grant[1] that requires the recipient to contract

[1] A small share of grantees operate more like hospitals and should be treated as DSH hospitals for the purposes of the legislation. For purposes of this document, that includes but is not limited to (i) a federally qualified health center (FQHC) that has been designated by HRSA as a FQHC "look-alike" that submits an initial 340B program registration after [date in spring 2023] and (ii) A federal grantee described in section 340B(a)(4)(A) of the Public Health Service Act that is an affiliate of a hospital.

or refer for required services. In these cases, the covered entity shall be required to demonstrate overall responsibility for care coordination (i.e., beyond providing episodic care).

- An updated definition should not include the language in the 1996 patient definition allowing 340B to be used for prescriptions that are written by providers that are not employed or under contract with the covered entity and instead fall under "other arrangements."

- Telehealth prescriptions should only be eligible for 340B discounts for grantees when telehealth is included in the scope of their grant. Except for CAHs and SCHs, hospitals should not be able to claim 340B discounts for prescriptions written as part of a telehealth encounter. For grantees, CAHs and SCHs, prescriptions written as part of a telehealth encounter would be eligible for 340B discounts only if they satisfy the in-person visit requirements set forth in the Medicare mental health telehealth requirements.[2]

- The patient must receive a health care service that is consistent with the covered entity's scope of grant, project, or contract, as applicable. In addition to the criteria outlined above and other relevant considerations, an in-person visit is required every 12 months for hospitals and every 24 months for direct recipients of a federal grant for an individual to maintain his or her status as a "patient."

Contract Pharmacy. Contract pharmacy arrangements should be allowed only as part of these broader program changes and when the covered entities meet specified criteria to expand access to care for safety-net patients and to prevent fraud and program violations. In general:

- Covered entities are required to develop and maintain procedures to prevent diversion and duplicate discounts in accordance with federal and state laws and policies to prevent duplicate Medicaid/340B discounts (including duplicate 340B/Medicaid managed care discounts). Contract pharmacies that do not ensure any relevant requirements are met will be banned from participating in the program.

- Contract pharmacy arrangements should be limited to: 1) covered entities located in a medially undeserved area (MUA) or an area serving medically underserved population (MUP), or 2) qualified prescriptions provided within the scope of a Federal grant for covered entities that provide care to specific populations, such as HIV and chronic illness.

- Excluding specialty and mail order pharmacies, contract pharmacies should be located near the service are where the covered entity provides care or an identified service area.

[2] For purposes of this section, prescriptions written as part of a telehealth encounter would be eligible for 340B discounts it the covered entity claiming the prescription has: (i) conducted an in-person exam of the individual within the six months before the initial telehealth service and (ii) furnished at least one in-person service to the individual within 12 months of each subsequent telehealth service. *See, e.g.*, 42 CFR Section 410.87(b)(3)(xiv) (Medicare mental health telehealth requirements).

- Prescriptions filled at a specialty or mail order pharmacy can only qualify for 340B discounts in the following circumstances:

    - Patients of a direct recipient[3] of a federal grant living in a grantee's service area

    - Patients of a SCH or CAH who live in a county that the Office of Management and Budget (OMB) does not currently designate as a Metropolitan Statistical Area (MSA).

Patient Affordability. All covered entities should meet basic standards to ensure 340B discounts help make prescriptions more affordable for needy patients. In general:

- Grantees should provide support to ensure low-income patients they serve can afford their medicines. This support should be consistent with the scope of their grant and at least as generous as any sliding fee scale requirements for other medical care.

- 340B hospitals should have a sliding fee scale for medicines that, at a minimum, applies to uninsured patients and patients under 200% of the federal poverty level with private insurance. This program should have auditable records, policies, and procedures.

- Covered entities must offer prescription discount programs through contract pharmacy arrangements. HRSA shall develop best practices to ensure that qualifying patients benefit from these programs at the point of sale, with contract pharmacies responsible for compliance with relevant best practices.

- The US Department of Health and Human Services Office of Inspector General (OIG) shall annually conduct random reviews of contract pharmacy policies and practices to evaluate whether patients are receiving discounts on 340B prescriptions at the point of sale, and OIG shall publish an annual report of its findings.

Covered Entity Eligibility. Flawed hospital eligibility rules that have enabled abuse should be updated to help put the program on a more sustainable path and to help vulnerable populations afford their medicines. In general:

- New hospital eligibility standards for disproportionate share hospitals (DSH) should be added to existing criteria to ensure the program is supporting true safety-net hospitals. These hospitals should be limited to no more than five retail (not specialty or mail order) contract pharmacies, assuming they meet other criteria listed in this document.

[3] Exceptions to the requirement in this section to be a direct recipient of a federal grant should be made with respect to the three following entity types: 1) any FQHC that is not affiliated with a hospital, that has been designated by HRSA as a FQHC "look-alike," and that submits an initial 340B program registration on or before [date in spring 2023], 2) any Ryan White HIV/AIDS program sub-grantee that is not an affiliate of a hospital, 3) any STD subgrantee that also receives a separate direct federal grant.

- Additional eligibility standards should include quantitative metrics that appropriately identify hospitals treating a disproportionately large share of low-income patients on an outpatient basis.

    - To the extent that new measures may need to be developed, charity care as a percent of operating costs should be used as an interim eligibility requirement. Under this interim requirement, a threshold would be set for charity care that accomplishes the above goal.[4]

- Hospitals that engage in aggressive debt collection or that do not act in a way that is consistent with safety net mission should not be able to participate in 340B.

- Additional criteria for nongovernmental hospitals should be added, and existing criteria strengthened and updated to address concerns from the Government Accountability Office.

- RRCs, which currently do not have to treat any rural patients in order to obtain a RRC designation, should be required to qualify as DSH under 42 USC Section 256b(a)(4)(L), unless an RRC demonstrates that it treats a reasonable share of rural patients using revised eligibility criteria.

- Rural Emergency Hospitals should be eligible for the 340B program if they meet the same 340B standards as a CAH.

Child Sites and Subgrantee Eligibility. "Child sites" are not mentioned anywhere in the 340B statute and were created by HRSA in non-binding guidance. Lax child site standards have permitted health systems to exploit safety-net hospitals to tap into discounted medicines for their health system's sites of service, which are often located in more affluent areas, regardless of the communities or patients they serve. In general:

- Child sites should be an integral part of the 340B hospital and provide a meaningful range of clinically relevant services beyond dispensing, infusing, or otherwise furnishing prescriptions. Each child site must demonstrate that it is an "integral part" of the hospital by meeting the Medicare provider-based standards under 42 CFR section 413.65, being wholly-owned by the hospital, and being listed as reimbursable on the hospital's most recently field Medicare cost report and with such report demonstrating that the services provided at the site have associated costs and charges for hospital outpatient services under Medicare.

- Individual child sites must meet the same or analogous[5] eligibility requirements as compared to their parent hospital, including any new charity care requirements and any new requirements related to the share of low-income patients seen on an outpatient basis,

[4] Charity care should be calculated as ([Charity Care Charges and Uninsured Discounts (determined in accordance with hospital's charity care criteria/policy or financial assistance policy)] * [Cost-to-Charge Ratio]) – [Payments].
[5] "Analogous" in this context means that the same requirements described in this section that are applicable to the parent hospital are applied to the child site with respect to its outpatient population.

have the same charity care policies and sliding fee scale, and devote at least as large a share of total revenue towards safety-net care as their parent hospital.

- The current 340B eligibility standards for subgrantees are overly broad and vulnerable to abuse. These eligibility criteria should be revisited to ensure they are accomplishing their intended purpose and support the aims of the overarching grant funding.

Insurers and For-Profit Stakeholders' Involvement in 340B. The savings generated from the 340B program are intended to support safety-net providers and vulnerable patients and should not be diverted for private benefit or other purposes not closely tied to a covered entity's safety-net mission. In general:

- Pharmacy benefit managers (PBMs) and insurers should not siphon 340B savings by lowering reimbursement for prescriptions with 340B discounts.

- Pharmacies and other for-profit third parties should have limits placed on the fees they can charge for 340B-related services to ensure covered entities and the patients they serve receive most of the savings associated with the program.

- PBMs and insurers should not be permitted to ban covered entities or their contract pharmacies from providing 340B claims data to third parties (including to manufacturers or a clearinghouse).

- PBMs and insurers should not be permitted to ban covered entities or their contact pharmacies from reducing copays for low-income insured patients who receive 340B drugs.

Claims Data / Clearinghouse. Manufacturers should have access to the data needed to properly administer the program and prevent abuse. In general:

- An independent clearinghouse should facilitate claims verification for purposes of 340B-eligiblity and share that data with manufacturers.

- There should be a clear hierarchy so that only one covered entity claims the 340B discount for eligible prescriptions. The clearinghouse will work to operationalize this requirement.

- Covered entities should submit all relevant data[6] to the clearinghouse within a reasonable timeframe after a prescription is dispensed or administered. Such data should be provided for claims regardless of payer.

- Safeguards should be put in place to ensure all data is deidentified, HIPAA-compliant, and not used for any unauthorized purpose, including marketing, reimbursement, or coverage determinations.

[6] See Appendix 1

- Grantees should submit to the clearinghouse information regarding the scope of their federal grant(s), which should be made available to manufacturers upon request.

Transparency. Public reporting of basic information is critical to maintain the long-term integrity of the program and facilitate appropriate oversight. In general:

- All covered entities should be required to report to HHS basic information about their involvement in the 340B program, including the total acquisition cost and reimbursement for 340B discounted medicines, payer mix, and the total amount spent subsidizing out-of-pocket costs for patients receiving 340B discounted medicines.

- Hospitals should report this information separately for each child site.

- The state or local government contracts that are in the basis for certain private non-profit hospital eligibility in the program should be publicly available.

Governance. Agency rulemaking authority if and to the extent needed to implement specific legislative provisions. Additional and improved program integrity measures to help enforce these changes should also be included.

- HRSA should conduct rulemaking jointly with CMS, as appropriate, to ensure that any new rulemaking (if needed) complements CMS's efforts to operationalize the Inflation Reduction Act and the Medicaid duplicate discount prohibition in the 340B statute, the Medicaid drug rebate statute (42 CFR section 1396r-8(i)(1), and the Medicaid statute (42 USC Section 1396b(m)(2)(A)(xiii)(III).

- The 340B program is a federal program governed exclusively by federal law. The provisions of the 340B statute and the regulations issued thereunder, shall supersede any state or local law, regulation, or other provision (other than state licensing laws relating to pharmacies) relating to or that could otherwise affect the 340B program. No state or local law, regulation or other provision shall grant additional rights or impose additional obligations related to the 340B program.

Appendix 1

340B Claims Level Data/Clearinghouse and Claims Modifier Requirements

WHAT: Provision of claims level data to manufacturers on 340B drugs via a clearinghouse and claims modifier requirement for all 340B scripts

WHY: Strengthen 340B program integrity to guard against diversion and duplicate discounts

DETAILS:

- Covered entities required to submit claims level data (CLD) and claims modifiers associated with 340B drugs to clearinghouse; any conflicting state law requirements are preempted.
    - Covered entities can rely on a third-party administrator or other vendor to provide data on their behalf.
    - Data must be submitted within a reasonable period of time after the prescription is filled.
- The clearinghouse shall make CLD available to each manufacturer on an individual 340B script basis.
- The Secretary of HHS shall select the clearinghouse in consultation with CMS, OIG, and HRSA and through an open bidding process.

- Necessary Data Elements: CLD (in machine-readable form) related to the prescription, to be shared with the clearinghouse shall include, at a minimum and as applicable:
    - Prescription number
    - Prescribed date
    - Prescription fill date
    - National Drug Code (NDC) of the drug
    - Quantity dispensed or administered
    - BIN/PCN/Group Number of the patient
    - National Provider Identification (NPI) of the prescriber
    - NPI of the dispensing pharmacy
    - 340B ID of the covered entity dispensing or administering the drug
    - 340B claims modifier ('JG', 'TB', or any successor modifier) or the Submission Clarification Code of '20' or any successor modifier developed by the National Council for Prescription Drug Programs (NCPDP) to identify claims for 340B-purchased drugs)
    - Wholesaler invoice number

- Data sharing safeguards:
    - Data requirements to be structured to minimize administrative burdens on covered entities.

- The de-identified data elements being shared via the clearinghouse will be done in a manner that is compliant with HIPAA requirements, and in a safe and secure manner that protects patient privacy.
- The information provided is not to be used outside of the stated purpose and is not be shared beyond the parties mentioned.
- The data shared is not be:
    - Sold or given to competitors
    - Used by third party payors for reimbursement or coverage determination
    - Used for any marketing purposes, clinical or other initiatives