340B Drug Pricing Integrity and Affordability for Patients Act Discussion Draft

Section 1. Short Title; Table of Contents.

This section states the Act may be cited as, "The 340B Drug Pricing Integrity and Affordability for Patients Act," and establishes a table of contents.

Section 2. Rebate Conditions.

This section allows manufacturers to elect to offer upfront discounts, discounts after submissions of standardized claims data to a claims repository operated by the Secretary of Health and Human Services (HHS), or retroactive rebates within 10 days of submission of standardized claims data, to covered entities in order to reduce diversion or duplication of discounts. For a discount at the time of sale, the covered entity must keep separate inventory, establish procedures to identify eligible patients, and submit an annual attestation of compliance to the Secretary and manufacturer. If choosing to provide retroactive rebates, manufacturers must pay all rebates for undisputed claims within 10 days. Covered entities can obtain information about disputed claims and request adjudication by the Secretary.

This section also allows a covered entity to instead choose how to receive discounts or rebates, rather than being subject to the manufacturer's selection, provided that the covered entity passes along all discounts or rebates to the covered entity's 340B patients. In this circumstance, the covered entity may collect a nominal dispensing fee. This section defines standardized claims data in a manner that aligns with data already routinely collected by covered entities and requires any audits to be conducted at the Secretary or manufacturer's expense. It also creates enforcement penalties for fraudulent activity.

Section 3. Amendments to the Eligibility of Subgrantees.

This section requires covered entities who qualify for 340B due to their status as subgrantees of grants awarded under Title XXVI or Section 318 of the Public Health Service Act to submit information to the Secretary about, the grant, their public nonprofit status, certification that revenues from the 340B Program are consistent with the grant's scope, and verification that the covered entity's patient population is primarily low income or uninsured. An entity is prohibited from being an eligible covered entity if it only receives in-kind contributions from the primary grantee that were purchased with Title XXVI or Section 318 grant funds.

Section 4. Additional Definitions.

This section creates new definitions for the terms "patient," "outpatient health care service," "practitioner," and "specified nonhospital covered entity." Through these definitions, a covered entity may only claim a patient and generate revenue from the patient's 340B prescription if the patient has received outpatient care in the last two years, maintained a relationship with the covered entity, and the prescription is written by one of the covered entity's practitioners.

Section 5. Contract Pharmacies.

This section clarifies that manufacturers must ship drugs to a contract pharmacy and defines conditions for contract pharmacies to participate in the 340B Program. Covered entities that dispense 340B drugs through contract pharmacies must ensure that the drug purchases are within the scope of the covered entity's qualifying federal grant or statute, establish compliance procedures to prevent diversion or duplicate discounts, and register and annually recertify the contract pharmacy with HHS. This section also places limitations on contract pharmacy relationships for certain covered entities by requiring that the contract pharmacy be located in the service area of those covered entities and capping the number of pharmacies with which certain covered entities may contract. This section also allows the use of mail-order pharmacies for certain covered entities. This section requires covered entities to submit the written agreements with contract pharmacies to the Secretary, which must include provisions to ensure the contract pharmacy adheres to the covered entity's compliance procedures related to duplicate discounts and diversion. Penalties are established for contract pharmacies that violate the requirements of this section.

Section 6. Transparency.

This section requires certain hospital covered entities, and others specified by the Secretary, to annually report data such as the total number and types of individuals who received 340B drugs, total costs incurred, charity care, and margin generated from covered outpatient drugs. The Secretary is required to publicly publish data annually and conduct rulemaking within 180 days of the date of enactment.

Section 7. Ensuring Affordability.

This section requires certain hospital covered entities to establish a sliding fee scale to limit the maximum out-of-pocket obligations for low-income and uninsured patients. Such sliding fee scales must be certified by the Secretary and provided to patients. This section establishes a penalty for violations and requires the Secretary to conduct rulemaking.

Section 8. Hospital Child Sites.

This section allows hospital covered entities to register an off-campus outpatient facility as a "child site" to participate in the 340B Program if the facility meets certain criteria, such as being wholly owned by the covered entity, meeting Medicare provider-based standards, providing outpatient health care services other than drug dispensing or administration, being located in a shortage area, and meeting minimum charity care requirements. Facilities registered as "child sites" that no longer meet the requirements in this section must deregister and self-disclose any improper purchases.

Section 9. Contracting Reforms.

This section only allows third-party administrators (TPAs) to charge covered entities on a flat fee amount per unit of service consistent with fair market value of the service and applicable state and federal law. Contract pharmacy remuneration must also be a flat fee amount per each dispense and cannot exceed 125% of the average per-prescription dispensing fee paid to that pharmacy by all third-party payors in the most recent calendar year. TPAs or contract pharmacies that violate these requirements are subject to new enforcement requirements.

Section 10. Prime Vendor Program.

This section requires the Secretary to provide a choice to covered entities of at least two prime vendors, who are in turn required to be free of conflicts of interest, may not charge covered entities for educational services performed as part of the prime vendor contract, and must provide unlimited rights to HHS to data created or managed through the prime vendor contract. This section also prohibits prime vendors from negotiating procurement of non-340B related products on behalf of covered entities.

Section 11. Transfer of Civil Penalty Amounts Collected.

This section makes all civil monetary penalties collected for violations of section 340B available to HHS to cover the administrative costs of the 340B Program.

Section 12. Application; Regulations and Guidance.

This section provides the Secretary with the authority to promulgate regulations and guidance to implement 340B, as needed.