

SUSTAIN 340B ACT DRAFT LEGISLATION

Bipartisan proposal based on stakeholder input
and over 250 responses to the June 2023 RFI.

TAM24101 KD2

Discussion draft

S.L.C.

118TH CONGRESS
2D SESSION

S. _____

To _____ .

IN THE SENATE OF THE UNITED STATES

Mr. THUNE (for himself, Ms. STABENOW, Mrs. CAPITO, Ms. BALDWIN, Mr. MORAN, and Mr. CARDIN) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To _____ .

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; TABLE OF CONTENTS.**

4 (a) **SHORT TITLE.**—This Act may be cited as the
5 “Supporting Underserved and Strengthening Trans-
6 parency, Accountability, and Integrity Now and for the
7 Future of 340B Act” or the “SUSTAIN 340B Act”.

8 (b) **TABLE OF CONTENTS.**—The table of contents for
9 this Act is as follows:

CONTRACT PHARMACY

- 340B pricing access at CRx protections
- Submit CRx agreements to HHS
- Solidifies contract pharmacy essential elements in statute
- Register CRx under both parent and child sites
- CRx must provide data to entity for clearinghouse submission
- 10-year auditable record retention

CHILD SITES

- Must be wholly-owned
- Must offer same financial assistance as other sites
- Must participate in Medicare and Medicaid programs
- Providers must have clinical responsibility for the services related to the 340B drug dispensed
- Must have integrated or readily accessible medical records with the entity
- HHS to issue final rule for child sites historically eligible but no longer eligible under new criteria

INTEGRITY

- Protocol for audits to be publicly available
- Audits will not be closed until corrective action plan has been fully implemented, if applicable
- HHS to issue final rule for auditing entity's 340B Program eligibility and establish that failure to meet Program eligibility requirements can not be corrected retroactively

DUPLICATE DISCOUNT PREVENTION

- HHS may issue rules for duplicate discount prevention and clearinghouse
- Clearinghouse to prevent duplicate discounts offered by independent entity without conflicts with any stakeholders
- Claims level rebate file data from State Medicaid agencies and claims level data from covered entities to be collected and used to identify any duplicate discounts
- Covered entity, Secretary, State Medicaid agency, and manufacturer notified of any violations

EQUITABLE TREATMENT

- Group health plan, health insurance issuer, or pharmacy benefit manager may not discriminate against a covered entity, a contract pharmacy, or a participant by imposing requirements, exclusions, reimbursement terms, or other conditions that differ from an entity or pharmacy that does not dispense 340B drugs

TRANSPARENCY

- Annually report number of patients receiving 340B drugs, number of prescriptions filled with 340B drugs (by payer type), cost of charity care by location, description of the entity's use of savings, financial demographics of patients of the entity, policies related to medication access, government contracts (if applicable), TPAs, contract pharmacies, estimated discount realized, number of patients receiving outpatient services at entity, and operational costs of 340B program operation
- Reports to be published on HHS public website, with proprietary information redacted from contracts
- HHS to submit an annual report to Congress on information collected

USER FEE PROGRAM

- Secretary to assess and collect fees annually from entities participating in the 340B Program
- Fees = 0.01% of the average difference (over the last 5 years) of WAC – 340B price paid by the entity for purchased covered outpatient drugs
- Fees collected will be used for enhancing 340B Program integrity and oversight, including fee collection web-based system, data clearinghouse, OPAIS maintenance, manufacturer compliance tools, and audits
- HHS may establish rules to carry out the user fee program
- Inspector General of DHHS will annually review the user fee program, for the first 5 years

STUDIES AND REPORTS

- Medicaid and CHIP Commission must submit a report to Congress on their efforts to prevent duplicate discounts, within 1 year
- HHS to conduct a study on dispensing fees and submit report to Congress within 2 years

PATIENT DEFINITION

- TBD - Pending feedback from second RFP



THE PREFERRED
RESOURCE FOR COMMUNITY
HEALTH CENTERS