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NATIONAL COUNCIL OF INSURANCE LEGISLATORS (NCOIL)

Strengthening Transparency in the 340B Drug Pricing Program Model Act

Sponsored by Rep. Tom Oliverson, M.D. (TX).
Co-sponsored by Sen. Paul Utke (MN) – NCOIL President and Rep. Brenda Carter (MI) – NCOIL Secretary

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Section 1. Title

This Act shall be known as the [State] Strengthening Transparency in the 340B Drug Pricing Program Act.

Section 2. Purpose

The purpose of this Act is to promote and strengthen transparency in the 340B Drug Pricing Program by way of implementing reporting requirements on covered entities.

Section 3. Definitions

(a) "340B covered entity" means an entity described in 42 U.S.C. 256b(a)(4)(L) through 42 U.S.C. 256b(a)(4)(O) that is authorized to participate in the federal 340B Drug Pricing Program under Section 340B of the federal Public Health Service Act (42 U.S.C. 256b(a)(4)), and has a service address in [State] as of January 1 of the reporting year. The

term includes any offsite outpatient facility affiliated under the 340B program with a covered entity.

(b) “340B program" refers to the federal 340B Drug Pricing Program established under 42 U.S.C. 256b.

(c) “State Department” refers to the [State] Department of Health.

Section 4. Reporting Requirements

(a) Before April 1 of each year, a 340B covered entity shall report the following information and transactions to the state department concerning the 340B covered entity's participation in or participation on behalf of the 340Bcovered entity in the federal 340B program for the previous calendar year:

(1) The 340B covered entity’s:

A. Name;

B. Service address;

C. 340B program identification number; and

D. Designation of entity type, as specified in 42 U.S.C. 256b(a)(4)

(2) A copy of the 340B covered entity’s most recently filed Internal Revenue Service Schedule H Form 990 detailing the entity’s community benefit and community building activities, bad debt and collections practices, and related policies.

(~~2~~ 3)The aggregate acquisition cost for all prescription drugs obtained under the 340B program and dispensed or administered to patients.

(~~3~~ 4)The aggregate payment amount received for all drugs obtained under the 340B program and dispensed or administered to patients.

(~~4~~ 5) The aggregate payment made to pharmacies under contract to dispense drugs obtained under the 340B program.

(~~5~~ 6) The number of claims for prescription drugs described in subdivision (~~3~~ 4).

(7) A description of any adverse 340B program audits within the preceding 12 months.

(~~7~~ 8) How the 340B covered entity uses any savings from participating in the 340B program, including ~~the amount of savings used for the provision of charity care, community benefits, or a similar program of providing unreimbursed or subsidized health~~

~~care.~~ how the covered entity utilizes savings to directly lower patient out of pocket costs. ~~increase access to care.~~

~~(8) The aggregate payments made to any other entity that is not a 340B covered entity and is not a contract pharmacy as described in subdivision (4) for managing any aspect of the 340B covered entity's 340B program.~~

(9) The aggregate payments made for any ~~other administering~~ administrative expense for the 340B program~~.~~, including the aggregate payments made to any other entity that is not a 340B covered entity and is not a contract pharmacy as described in subdivision (4) for managing any aspect of the 340B covered entity's 340B Program.

(10) The aggregate number of prescription drugs dispensed or administered to patients for which a payment was reported under subdivision (~~3~~ 4).

(11) The percentage of the 340B covered entity's claims that were for prescription drugs obtained under the 340B program.

~~(12) The number and percentage of low income patients of the 340B covered entity that were served by a sliding fee scale for a prescription drug dispensed or administered under the 340B program.~~

(~~13~~12) The 340B covered entity's total operating costs.

~~(14) The 340B covered entity's total costs for charity care.~~

~~(15) A copy of the 340B covered entity's financial assistance policy for the reporting year.~~

(b) The information required to be reported under subsection (a)(~~3~~ 4) through (a)(~~5~~ 6) must, to the extent feasible, be reported by payer type, including the following:

(1) Commercial.

(2) Medicaid.

(3) Medicare.

(4) Uninsured.

(c) The data submitted in the reports required under subsection (a) is confidential and is not available for public inspection.

(d) Before November 15 of each year, the state department shall prepare a report that aggregates the data submitted under subsection (a) and:

(1) submit the report to the [legislative council]; and

(2) post the report on the state department's website.

Drafting Note: This Model is intended to strengthen transparency requirements for covered entities authorized to participate in the 340B Drug Pricing Program. Some States have also set forth transparency requirements on pharmaceutical manufactures that participate in the Program; however, this Model is intentionally limited in scope to apply only to covered entities, the entities for which the Program was created. Also, NCOIL has an existing Healthcare Cost Transparency Model Law which sets forth reporting requirements for pharmaceutical manufactures. States that have not yet adopted that Model are encouraged to do so.

Section 5. Penalties

A 340B covered entity that fails to provide the information required under Section 4 of this Act by the date required shall pay to the state department a fine of [xxx] per day for which the information is past due.

Section 6. Rules

The Commissioner shall adopt rules to effectuate the provisions of this Act.

Section 7. Effective Date

This Act shall take effect xxxxxx.