

CHAPTER 510D

340B PROGRAM — COVERED ENTITIES AND CONTRACT PHARMACIES

Referred to in §87.4, 296.7, 331.301, 364.4, 505.28, 505.29, 507B.4, 669.14, 670.7

510D.1	Definitions.	510D.3	Enforcement.
510D.2	340B drug program — contract pharmacies and covered entities.	510D.4	Rules.
		510D.5	Conflict of laws.
		510D.6	Applicability.

510D.1 Definitions.

As used in [this chapter](#), unless the context otherwise requires:

1. “340B program” means the program created pursuant to the Veterans Health Care Act of 1992, Pub. L. No. 102-585, §602, and codified as section 340B of the federal Public Health Services Act.
2. “Commissioner” means the commissioner of insurance.
3. “Contract pharmacy” means a pharmacy that has executed a contract with a covered entity to dispense covered outpatient drugs, purchased by the covered entity through the 340B program, to eligible patients of the covered entity.
4. “Covered entity” means the same as defined in 42 U.S.C. §256b(a)(4).
5. “Group health plan” means the same as defined in [section 513B.2](#).
6. “Medicaid managed care organization” means an entity acting pursuant to a contract with the department of health and human services to administer the medical assistance program under [chapter 249A](#), and that meets the definition of “health maintenance organization” under [section 514B.1](#).
7. “Pharmacy benefits manager” means the same as defined in [section 510B.1](#).
8. “Similarly situated entity or pharmacy” means an entity or pharmacy located in Iowa that is of a generally comparable size, and that operates in a market with similar demographic characteristics, including population size, density, distribution, and vital statistics, and reasonably similar economic and geographic conditions.
9. “Third-party administrator” means the same as defined in [section 510.11](#).
[2023 Acts, ch 43, §2](#)
NEW section

510D.2 340B drug program — contract pharmacies and covered entities.

1. Group health plans, health carriers that offer group or individual health insurance coverage, third-party administrators, and pharmacy benefits managers shall not discriminate against a covered entity or a contract pharmacy by reimbursing the covered entity or the contract pharmacy for a prescription drug or a dispensing fee in an amount less than the group health plan, health carrier, third-party administrator, or pharmacy benefits manager reimburses a similarly situated entity or pharmacy that is not a covered entity or a contract pharmacy.

2. a. Group health plans, health carriers that offer group or individual health insurance coverage, third-party administrators, and pharmacy benefits managers shall not, on the basis that an entity is a covered entity or that a pharmacy is a contract pharmacy, or that a covered entity or contract pharmacy participate in the 340B program, impose any of the following contractual terms and conditions on the covered entity or the contract pharmacy that differ from those imposed on a similarly situated entity or pharmacy that is not a covered entity or a contract pharmacy:

- (1) Fees or other assessments that are not required by state law or the Iowa administrative code.
- (2) Chargebacks, clawbacks, or other reimbursement adjustments that are not required by state law or the Iowa administrative code.
- (3) Professional dispensing fees that are not required by state law or the Iowa administrative code.
- (4) Restrictions or requirements related to participation in standard or preferred pharmacy networks.

(5) Requirements related to the frequency or scope of audits.

(6) Requirements related to inventory management systems that utilize generally accepted accounting principles.

(7) Requirements related to mandatory disclosure either directly or through a third party, except disclosures required by federal law, of prescription orders that are filled with covered outpatient drugs obtained through the 340B program.

b. Paragraph “a”, subparagraphs (1) and (2), shall not be construed to prohibit adjustments for overpayments or other errors associated with an adjudicated claim.

c. Paragraph “a”, subparagraph (7), shall not be construed to prohibit modifiers or other identifiers on claims to identify whether a drug was purchased through the 340B program or to prevent duplication of rebates.

3. Group health plans, health carriers that offer group or individual health insurance coverage, third-party administrators, and pharmacy benefits managers shall not do any of the following on the basis that an entity is a covered entity or that a pharmacy is a contract pharmacy, or that a covered entity or a contract pharmacy participates in the 340B program:

a. Place any restrictions or impose any requirements on an individual that chooses to obtain a covered outpatient drug from a covered entity or a contract pharmacy, whether in person, via courier or the United States post office, or any other form of delivery.

b. Refuse to contract with a covered entity or a contract pharmacy based on any criteria that is not applied equally to a contract with a similarly situated entity or pharmacy that does not participate in the 340B drug program.

c. Impose any restriction or condition on a covered entity that interferes with the covered entity’s ability to maximize the value of the discounts obtained by the covered entity through the covered entity’s participation in the 340B drug program.

[2023 Acts, ch 43, §3](#)

NEW section

510D.3 Enforcement.

1. The commissioner may take any enforcement action under the commissioner’s authority to enforce compliance with [this chapter](#).

2. After notice and hearing, the commissioner may issue any order or impose any penalty pursuant to [section 507B.7](#) upon a finding that a group health plan, a health carrier that offers group or individual health insurance coverage, a third-party administrator, or a pharmacy benefits manager violated [this chapter](#).

3. A violation of [this chapter](#) shall be an unfair or deceptive act or practice in the business of insurance pursuant to [section 507B.4, subsection 3](#).

[2023 Acts, ch 43, §4](#)

NEW section

510D.4 Rules.

The commissioner of insurance may adopt rules as necessary to implement the chapter.

[2023 Acts, ch 43, §5](#)

NEW section

510D.5 Conflict of laws.

If any provision of [this chapter](#) is inconsistent or in conflict with applicable state or federal law or rule, or the state Medicaid plan, the applicable state or federal law or rule, or the state Medicaid plan, shall prevail to the extent necessary to eliminate the inconsistency or conflict.

[2023 Acts, ch 43, §6](#)

NEW section

510D.6 Applicability.

[This chapter](#) shall apply to covered entities, contract pharmacies, group health plans, health carriers that offer group or individual health insurance coverage, third-party administrators, and pharmacy benefits managers, but shall not apply to their operations under a contract with the state Medicaid agency or a Medicaid managed care organization, regardless of whether

the covered entity or contract pharmacy is eligible to retain the 340B discounts generated by the covered entities and contract pharmacies.

[2023 Acts, ch 43, §7](#)

NEW section