

5160-1-17.11

**Requirements for 340B covered entities.****(A) Definitions**

- (1) "340B drug pricing program" means the program enacted under the Veteran's Health Care Act of 1992, Public Law 102 - 585, codified as Section 340B of the Public Health Services Act, 42 U.S.C. 256b (April 1, 2016).
- (2) "340B covered entity" means an entity that is listed in 42 U.S.C. 256b(a)(4) that meets the requirements of 42 U.S.C. 256b(a)(5) (April 1, 2016) and is eligible to participate in the 340B drug pricing program.
- (B) No later than thirty days following the effective date of this rule, Ohio medicaid providers participating in the 340B drug pricing program as of the effective date of this rule shall notify the Ohio department of medicaid (ODM) of their 340B covered entity status by following the process prescribed on the ODM website, www.medicaid.ohio.gov. Thereafter, the provider shall notify ODM every year when it recertifies its eligibility for the 340B drug pricing program.
- (C) Applicants seeking a Medicaid provider agreement after the effective date of this rule shall follow the process prescribed on the ODM website, www.medicaid.ohio.gov, to notify ODM of their 340B covered entity status. Thereafter, if a provider agreement is entered into with ODM, the provider shall notify ODM every year when it recertifies its eligibility for the 340B drug pricing program.
- (D) When a 340B covered entity with an Ohio medicaid provider agreement uses drugs acquired through the 340B drug pricing program for a medicaid recipient, the 340B covered entity shall file claims in accordance with ODM's 340B drug claims filing requirements.
- (E) When a 340B covered entity with an Ohio medicaid provider agreement uses a drug that is not acquired through the 340B drug pricing program for a medicaid recipient, the 340B covered entity shall file claims in accordance with ODM's non-340B drug claims filing requirements.
- (F) Drugs acquired through the 340B drug pricing program and dispensed by an entity under contract with the 340B covered entity are not covered by medicaid fee-for-service or managed care and no claim shall be submitted for medicaid reimbursement. It is the responsibility of the 340B covered entity to assure compliance by its contractors.

Effective:

Five Year Review (FYR) Dates:

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Certification

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Date

Promulgated Under: 119.03  
Statutory Authority: 5162.03, 5164.02  
Rule Amplifies: 5164.02