

Title 23: Medicaid

Part 200: General Provider Information

Part 200 Chapter 4: Provider Enrollment

Rule 4.10: 340B Providers

- A. The Division of Medicaid defines a 340B provider as a nonprofit healthcare organization that meets the requirements of, and is considered to be, a covered entity under Section 340B of the Public Health Service Act which has elected to enroll in the 340B program.
- B. The Division of Medicaid reimburses enrolled 340B covered entities for drugs purchased and dispensed/administered under the rules of the 340B program at the estimated acquisition cost (EAC) or the 340B actual acquisition cost (ACC). In the pharmacy point-of-sale venue, a reasonable dispensing fee will be paid.
 1. The Division of Medicaid defines the EAC or 340B actual acquisition cost as the price at which the covered entity has paid the wholesaler or manufacturer for the outpatient drug.
 2. Enrolled covered entities must maintain detailed and auditable records regarding the compliance with all 340B program requirements and policies.
- C. Covered 340B drugs, as found in section 1927 (k)(2) of the Social Security Act, include the following outpatient drugs:
 1. FDA-approved prescription drugs,
 2. Over-the-counter (OTC) drugs written on a prescription,
 3. Biological products that can be dispensed only by a prescription (other than vaccines), and
 4. FDA-approved insulin.
- D. Covered entities eligible to participate in the 340B program include, but are not limited to:
 1. Health Centers, such as:
 - a) Federally Qualified Health Centers,
 - b) Federally Qualified Health Center Look-Alikes, and
 - c) Tribal/Urban Indian Health Centers.
 2. Hospitals, such as:

- a) Children's Hospitals,
- b) Critical Access Hospitals,
- c) Disproportionate Share Hospitals,
- d) Free Standing Cancer Hospitals,
- e) Rural Referral Centers, and
- f) Sole Community Hospitals.

3. Specialized Clinics, such as:

- a) Black Lung Clinics,
- b) Comprehensive Hemophilia Diagnostic Treatment Centers,
- c) Title X Family Planning Clinics,
- d) Sexually Transmitted Disease Clinics, and
- e) Tuberculosis Clinics.

E. Covered entities must notify the Division of Medicaid of their election to opt-in or opt-out of the 340B program.

1. The Division of Medicaid defines opt-in as the election by a covered entity to purchase and dispense/administer covered 340B drugs to Medicaid beneficiaries. These covered entities must:

- a) Register, enroll and receive an identification number from the Health Resources and Services Administration (HRSA).
- b) Complete, sign and submit the Medicaid 340B Covered Entity Attestation and Election Form to the Division of Medicaid indicating enrollment status in the 340B program by July 1st of each year.
- c) Recertify with HRSA annually and notify the Division of Medicaid in writing of recertification.
- d) Dispense/administer covered 340B drugs purchased under the 340B program only to eligible beneficiaries who:

- 1) Receive health care services, other than drugs, from the 340B provider, or

- 2) Are part of a state operated or state funded AIDS drug purchasing assistance program.
 - e) Specify drugs purchased under the 340B program on all claims submitted to the Division of Medicaid.
 - f) Bill the Division of Medicaid the EAC or the 340B ACC for covered 340B drugs purchased through the 340B program.
 - g) Provide invoices upon request by the Division of Medicaid.
2. The Division of Medicaid defines opt-out as the election by a covered entity not to purchase and dispense/administer covered 340B drugs to Medicaid beneficiaries. These covered entities must:
- a) Complete, sign and submit the Medicaid 340B Covered Entity Attestation and Election Form to the Division of Medicaid indicating non-enrollment in the 340B program by July 1st of each year, and annually thereafter.
 - b) Bill the Division of Medicaid the covered entity's AAC for all covered drugs dispensed/administered.
- F. Covered entities may change their opt-in or opt-out election by completing, signing and submitting the Medicaid 340B Covered Entity Attestation and Election Form to the Division of Medicaid. The change is effective thirty (30) days following the Division of Medicaid's receipt of the form. Covered entities changing their enrollment status must meet the requirements in Rule 4.10.E.1) or 4.10.E.2).
- G. Covered entities who opt-in the 340B program are prohibited from:
- 1. Reselling or otherwise transferring discounted outpatient drugs to anyone other than a beneficiary of the covered entity, and
 - 2. Receiving duplicate discounts or rebates.
- H. A contract pharmacy, defined by the Division of Medicaid as an agent of a 340B covered entity and ineligible to be a freestanding 340B covered entity, cannot dispense and bill the Division of Medicaid for 340B outpatient drugs for Medicaid beneficiaries.
- I. A covered entity found in violation of Miss. Admin. Code Part 200, Rule 4.10.G is liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug provided under the agreement between the entity and the manufacturer.
- J. Covered entities who do not notify the Division of Medicaid of their 340B election according

to the Miss. Admin. Code Part 200, Rule 4.10.E annually by July 1st, will be considered as opting-out of the 340B program and the Division of Medicaid will collect rebates on drugs billed by these covered entities opting-out.

- K. A covered entity who knowingly or willfully makes, or causes to be made, a false statement, attestation or representation of a material fact in any application and/or form for Medicaid benefits or Medicaid payments may be prosecuted under federal and state criminal laws pursuant to Miss. Admin. Code Part 200, Rule 1.3.

Source: Sec. 340B of the Public Health Service Act (Pub. L. 102-585), as amended by the Patient Protection and Affordable Care Act (Pub. L. 111-148), Health Care and Education Reconciliation Act (Pub. L. 111-152) and Medicare and Medicaid Extenders Act of 2010 (Pub. L. 111-309); 42 C.F.R. § 447.512; Miss. Code Ann §§ 43-13-117, 121.

History: New Rule to correspond with SPA 14-001 eff. 07/01/2014.

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- c) Recertify with HRSA annually and notify the Division of Medicaid in writing of recertification.
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 - 1) Receive health care services, other than drugs, from the 340B provider, or

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 - e) Specify drugs purchased under the 340B program on all claims submitted to the Division of Medicaid.
 - f) Bill the Division of Medicaid the EAC or the 340B ~~actual acquisition cost~~ ACC for covered 340B drugs purchased through the ~~3040B~~ program.
 - g) ~~Submit~~ Provide invoices upon request ~~as required~~ by the Division of Medicaid.
2. The Division of Medicaid defines opt-out as ~~the a covered entity election~~ g by a covered entity not to purchase and dispense/administer covered 340B drugs to Medicaid beneficiaries. These covered entities must:
- a) Complete, sign and submit the Medicaid 340B Covered Entity Attestation and Election and Attestation Form to the Division of Medicaid indicating non-enrollment in the 340B program by July 1st of each year, 2014, and annually thereafter, by July 1.
 - b) Bill the Division of Medicaid the covered entity's ~~actual acquisition cost~~ AAC for all covered drugs dispensed/administered.
- F. Covered entities may change their opt-in or opt-out election by completing, signing and submitting the Medicaid 340B Covered Entity Attestation and Election Form with a thirty (30) day notification to the Division of Medicaid. The change is effective thirty (30) days following the Division of Medicaid's receipt of the form. of the election change meeting Covered entities changing their enrollment status must meet the requirements in Rule 4.10.ED.1) or 4.10.ED.2).
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- ~~H.I.~~ A covered entity found in violation of Miss. Admin. Code Part 200, Rule 4.10.G. is liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug provided under the agreement between the entity and the manufacturer.

~~I.J.~~ Covered entities who do not notify the Division of Medicaid of their 340B election according to the Miss. Admin. Code Part 200, Rule 4.10.E annually by July 1st, will be considered as opting-out of the 340B program and the Division of Medicaid will collect rebates on drugs billed by these covered entities opting-out.

~~J.K.~~ ~~Under Miss. Admin. Code Part 200, Rule 1.3, a~~ provider covered entity who knowingly or willfully makes, or causes to be made, a false statement, attestation or representation of a material fact in any application and/or form for Medicaid benefits or Medicaid payments may be prosecuted under federal and state criminal laws pursuant to Miss. Admin. Code Part 200, Rule 1.3.

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