

Title 23: Division of 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 defines 340B purchased drugs as those:
 - 1. Produced by any manufacturer which has entered into and complies with an agreement under Section 1927 (a) of the Act which are prescribed for a medically acceptable indication,
 - 2. Purchased and administered or dispensed by 340B covered entities under the rules of the 340B program, and
 - 3. Dispensed and administered to a 340B eligible beneficiary as defined in Miss. Admin. Code Part 200, Rule 4.10.C.
- C. The Division of Medicaid defines an individual as a 340B eligible beneficiary if:
 - 1. The individual has established a relationship with the covered entity, such that the covered entity maintains records of the individual's healthcare,
 - 2. The individual received healthcare services from a healthcare professional who is either employed by the covered entity or provides healthcare under contractual or other arrangements such that responsibility for the care provided remains with the covered entity, and
 - 3. The individual receives a healthcare service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or federally qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.
- D. Covered entities:
 - 1. Eligibility to participate in the 340B program includes, but is not limited to:
 - a) Health Centers including, but not limited to:
 - 1) Federally Qualified Health Centers,

- 2) Federally Qualified Health Center Look-Alikes, and
 - 3) Tribal/Urban Indian Health Centers.
- b) Hospitals including, but not limited to:
- 1) Children's Hospitals,
 - 2) Critical Access Hospitals,
 - 3) Disproportionate Share Hospitals,
 - 4) Free Standing Cancer Hospitals,
 - 5) Rural Referral Centers, and
 - 6) Sole Community Hospitals.
- c) Specialized Clinics including, but not limited to:
- 1) Black Lung Clinics,
 - 2) Comprehensive Hemophilia Diagnostic Treatment Centers,
 - 3) Title X Family Planning Clinics,
 - 4) Sexually Transmitted Disease Clinics, and
 - 5) Tuberculosis Clinics.
2. Must comply with all Health Resources and Service Administration's (HRSA's) regulations and requirements.
 3. Must maintain detailed and auditable records regarding the compliance with all the Division of Medicaid's 340B program requirements and policies.
- E. Covered entities:
1. Must notify the Division of Medicaid of their election to participate in or to terminate from the federal 340B program.
 2. Who participate in the federal 340B drug program must notify the Division of Medicaid of their election to opt-in or opt-out of billing the Division of Medicaid for 340B purchased drugs and must comply with the following.

- a) The Division of Medicaid defines opt-in as a provider electing to dispense and/or administer drugs which have been purchased under the rules of the 340B federal program, and billing the Division of Medicaid for eligible Medicaid beneficiaries enrolled in either fee-for-service (FFS) or in a coordinated care organization (CCO). These covered entities must:
 - 1) Register, enroll and receive an identification number from HRSA.
 - 2) Complete, sign and submit the Division of Medicaid's 340B Covered Entity Attestation & Provider Enrollment Form to the Division of Medicaid indicating enrollment in the 340B program.
 - 3) Recertify with HRSA annually and notify the Division of Medicaid in writing by submitting the 340B Covered Entity Attestation & Provider Enrollment Form of any changes in 340B election status.
 - 4) Dispense/administer covered 340B drugs purchased under the 340B program only to eligible beneficiaries.
 - 5) Bill the Division of Medicaid according to Miss. Admin. Code Part 200, Rule 4.10.F.
 - 6) Submit drug invoices as required by the Division of Medicaid for auditing purposes.
 - b) The Division of Medicaid defines opt-out as a covered entity electing never to bill the Division of Medicaid for 340B purchased drugs. These covered entities must complete, sign and submit to the Division of Medicaid the 340B Covered Entity Attestation & Provider Enrollment Form indicating election to opt-out.
 - c) Covered entities must notify the Division of Medicaid immediately of any change in election in billing the Division of Medicaid for 340B purchased drugs.
- F. 340B covered entities who have elected to opt-in must bill the Division of Medicaid for dispensed/administered 340B purchased drugs as follows:
1. For point-of-sale (POS) claims, pharmacy providers must bill the ingredient cost at the actual acquisition cost (AAC) defined as the price the pharmacy paid the wholesaler or manufacturer for the 340B purchased drug with no mark-up plus the applicable professional dispensing fee. Providers must identify 340B purchased drugs dispensed or administered with the appropriate National Council for Prescription Drug Programs' (NCPDP) field values as defined by the Division of Medicaid.
 2. For medical claims, providers must bill 340B purchased Physician Administered Drugs (PAD) with the appropriate modifier to identify the 340B purchased drug and the corresponding Healthcare Common Procedure Coding System (HCPCS) and National

Drug Code (NDC).

- G. Under Miss. Admin. Code Part 200, Rule 1.3, a provider who knowingly or willfully makes, or causes to be made, false statement or representation of a material fact in any application for Medicaid benefits or Medicaid payments may be prosecuted under Federal and State criminal laws.
- 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.D.2. and D.3. 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.

Source: 42 U.S.C. § 256b; 42 C.F.R Part 10; 42 C.F.R. § 447.512; Miss. Code Ann §§ 43-13-117, 43-13-121; SPA 17-0002.

History: Revised eff. 04/01/2019; Eff. 11/01/2018. Removed Miss. Admin. Code Part 200, Chapter 4, Rule 4.10, B, E, F, and J to correspond with the withdrawal of SPA 14-015 eff. 11/01/2014; New Rule eff. 07/01/2014 to correspond with SPA 14-015 (eff. 07/01/2014).