



**Division of Medicaid (DOM)
340B Frequently Asked Questions**

What is the 340B Program?

The 340B program is a Drug Pricing Program established by the Veterans Health Care Act of 1992, which is Section 340B of the Public Health Service Act (PHSA). Section 340B limits the cost of covered outpatient drugs to certain federal grantees, federally-qualified health center look-alikes, and qualified hospitals. These providers purchase, dispense and/or administer pharmaceuticals at significantly discounted prices. The significant discount applied to the cost of these drugs makes these drugs ineligible for the Medicaid drug rebate. State Medicaid programs are mandated to ensure that rebates are not claimed on these drugs thereby preventing duplicate discounts for these drugs.

Health Resources and Services Administration (HRSA) is specifically responsible for the enforcement of covered entity compliance with the duplicate discount prohibition. More information regarding eligibility and program logistics can be found on HRSA's website at www.hrsa.gov/opa.

Section 340B and rebate collection

In order to comply with Federal law, claims must be completed and submitted correctly as mandated by Section 340B(a)(5)(A)(i) prohibiting duplicate discounts. This occurs when the manufacturer gives the provider discounted 340B pricing and also pays DOM a rebate for the same drug. Manufacturers are not required to pay rebates on a 340B drug if the manufacturer has already provided a discounted price to the provider.

Providers must bill the appropriate code(s) on a claim billed with a 340B purchased drug. A "UD" modifier is required for physician administered drug claims, while pharmacy claims require the inclusion of both "08" in field 423-DN, the Basis of Cost Determination field, and "20" in field 420-DK, the Submission Clarification Code. The state will then extract appropriate claims from rebate invoicing and collection.

Our facility is a participant in the 340B program. Does the facility only have to file the attestation form, or do individual providers also need to complete the attestation form?

This form is only for facilities, i.e., billing providers. Non-340B entities, such as prescribers, may discard the initial attestation form. Registration should reflect the same information as provided to HRSA regarding program enrollment. As such, the 340B attestation form has been submitted to each provider issued a unique HRSA 340B identification number.

Does our facility need to fill out this form annually or on another specified frequency?

DOM requires that 340B providers with a unique 340B identification number complete this form only once unless the provider changes its opt-in (carve-in) or opt-out (carve-out) status with HRSA. Any provider changing their 340B status will be required to notify DOM via submission of an updated attestation form.

Are MSCAN (aka coordinated/managed care) claims included?

MSCAN claims are included in the 340B program attestation process. Providers only need to fill out the Division of Medicaid attestation form. DOM will share this information with the Coordinated Care Organizations.

Does the 340B billing requirement apply to Coordinated Care Organizations ?

Yes. Coordinated Care Organizations must adopt the same 340B billing policies as DOM.

What will happen if a 340B entity does not complete and return the attestation form to Medicaid?

The new policy, including attestation form, is in alignment with Centers for Medicare and Medicaid and Office of the Inspector General recommendations for Medicaid agencies. It is the intent of the Mississippi Division of Medicaid that all 340B providers will complete the form and submit it to DOM. If a 340B provider does not submit the attestation form, that provider will be considered by Medicaid as a non-340B entity (an opt-out provider that purchases drugs at 340B pricing but will never bill the Division of Medicaid for 340B purchased drugs). That fact may trigger audits from 340B regulatory bodies and drug manufacturers. Registration by a 340B covered entity is required on the www.hrsa.gov/opa website in order for the state to validate a covered entity's participation in the 340B program.

I am a prescriber and I do not know why I received the 340B attestation letter. What am I to do with this?

Identified Mississippi Medicaid providers received this letter in order for DOM to have comprehensive documentation of current 340B provider registration status. This entity received a letter because this provider was previously identified by HRSA and registered as a 340B covered entity. Refer to <https://www.hrsa.gov/opa> regarding the definition of 340B covered entity and general policy guidelines for entities. Non-340B entities may discard the letter.

The only drugs that we purchase through 340B are injectables. Since these are only administered in conjunction with an office visit and therefore covered under our rate, I am not sure how this is to be handled.

The facility is required to complete the attestation form and submit to Medicaid. DOM will have documentation that your facility is recognized as a 340B entity (opt-in) and will bill Medicaid for 340B drugs. Having such documentation on file will assist the agency with drug manufacturer's rebate disputes in the future.

For providers who bill on a CMS 1500 Health Insurance Claim Form or Uniform Billing (UB-04) Form and elect to opt-in, effective April 1, 2017, a UD modifier is required to identify a 340B purchased drug in addition to the corresponding Healthcare Common Procedure Coding System (HCPCS) and National Drug Code (NDC).

How do covered entities check to see if a facility has already been registered with HRSA?

Providers and pharmaceutical manufacturers may check HRSA's 340B Medicaid Exclusion File located at <https://opanel.hrsa.gov/opa/CEMedicaidExtract>. Validation of 340B status will help providers, drug manufacturers, and the state avoid the duplicate discount prohibition set by Federal law.

The facility has multiple locations with more than one HRSA-issued 340B identification number. Do we have to provide all 340B issued IDs with the attestation form?

Yes. DOM requires that all providers carving in 340B medications provide all HRSA-issued 340B identification numbers with their attestation form. DOM has submitted letters to each HRSA-registered provider that has been issued a unique, individual 340B ID.

Since the possibility exists of participating Mississippi Medicaid providers having a "one to many" NPI number, for example, when several Mississippi Medicaid Provider ID numbers associated with a single NPI number, DOM must validate the individual 340B ID numbers as either electing to opt-in or opt-out of billing 340B-purchased drugs to DOM. Providing each 340B ID will help the state identify and validate providers which may share the same billing NPI.

Are contract pharmacies allowed to bill Medicaid for 340B drugs?

No, DOM will not reimburse contract pharmacies for 340B drugs billed to DOM. Therefore, a 340B contract pharmacy must carve out DOM Fee for Services and MSCAN from its 340B operation.

What if our facility is registered as a "carve-in / opt-in" covered entity and bills for a drug that is deemed not eligible through the 340B drug pricing program?

If the drug is not eligible for 340B pricing, the provider will bill the drug at the usual and customary charge for the drug and should not include the UD modifier for physician administered drug claims or both the "20" and "08" in fields 420-DN and 423-DN, respectively, for pharmacy claims.

How does a provider carve-out Medicaid?

A covered entity will choose to forego the 340B discount drugs for all Medicaid beneficiaries. If the provider chooses to carve-out, according to HRSA and the 340B Prime Vendor Program (PVP), the 340B drug is dispensed and administered to non-Medicaid patients.

Why has our facility received several letters for the same billing ID number?

When several Mississippi Medicaid Provider ID numbers are associated with a single NPI number, DOM must validate the individual 340B ID numbers as either electing to opt-in or opt-out of billing 340B-purchased drugs.

Additional information regarding 340B program eligibility, rules, regulations, and logistics may be found on the HRSA website at www.hrsa.gov/opa.