



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. For providers who bill on a CMS 1500 Health Insurance Claim Form or Uniform Billing (UB-04) Form and elect to opt-in, effective November 1, 2018, 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). A "TB" modifier is required on Medicare primary crossover claims to identify a 340B-purchased drug in addition to the corresponding Healthcare Common Procedure Coding System (HCPCS) and National Drug Code (NDC).

For pharmacy providers, 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. Claims billed electronically in the D.0 format, the AAC must be submitted in field #409-D9, field name "INGREDIENT COST SUBMITTED". The professional dispensing fee must be submitted in field # 412-DC, field name "DISPENSING FEE SUBMITTED". 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, if there is a change of address with a particular site, or if the covered entity has added or terminated a child site to the 340B program. Any provider changing their 340B status including but not limited to address changes, addition of child site, and termination of a parent or child site, 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 for the state to validate a covered entity's participation in the 340B program.

What is the correct contact information to whom a provider should submit either a new or updated 340B covered entity attestation and enrollment form?

A Mississippi Medicaid provider who is currently registered with HRSA as a 340B covered entity may submit the attestation form to Gainwell Technologies via one of the methods:

- a. E-mail to ms_drugrebate@gainwelltechnologies.com
- b. Fax to 866-644-6148, or
- c. Mail to Gainwell Technologies, PO Box 6014, Ridgeland, MS 39158-6014

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 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 November 1, 2018, 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). If the claim is billed as Medicare primary, then a "TB" modifier must be billed.

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://opanet.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 with corresponding NPI(s) and associated Medicaid provider number(s) will help the state identify and validate providers which may share the same billing NPI. Both NPI and linked Medicaid provider number(s) should be reported to HRSA.

If a covered entity has terminated or added a child site, or if there has been an address change with one of the corresponding sites, does a provider need to communicate any changes or updates to the Division of Medicaid?

Yes. Any HRSA-enrolled Mississippi Medicaid provider that has a change of address with either the parent site or child site should communicate this change immediately with HRSA. After HRSA has been notified of any change, the provider should complete a new attestation form located on DOM’s website indicating the provider’s name, address, 340B ID, provider NPI, provider’s corresponding Medicaid provider number, etc. as required on the form. The provider shall indicate which Medicaid provider ID(s) corresponds to the specific NPI number. If an NPI has multiple Medicaid provider ID numbers, then the provider should indicate this on the form.

DOM requires that a new attestation form shall be completed by the provider and submitted to Gainwell, the Fiscal agent for the Mississippi Division of Medicaid, if a child site has been added to or terminated from the 340B program.

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

No. Drugs acquired through the federal 340B drug pricing program and dispensed by 340B contract pharmacies as defined by HRSA are not covered by DOM. Therefore, a 340B contract pharmacy must carve out DOM Fee for Service and MSCAN from its 340B operation. DOM will not reimburse contract pharmacies for 340B drugs billed to DOM.

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 (and, if billed as a Medicaid primary crossover claim, the “TB” 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.

I am a hospital provider. It is our responsibility to purchase drugs which are cost effective considering so many patients are receiving Medicaid. Is the questionnaire intended for hospitals or for just those practicing retail pharmacies?

The 340B Attestation Form is for both pharmacy and outpatient medical providers that purchase and dispense 340B drugs to qualified Medicaid beneficiaries. Providers must maintain their registration with HRSA in addition to registering with the State of Mississippi as a 340B Covered Entity. The appropriate modifiers should be utilized when billing 340B medications. For more information, please visit the Division of Medicaid’s 340B webpage located at <https://medicaid.ms.gov/providers/pharmacy/340b-program/>.

Does the requirement for modifier include managed care plans such as Magnolia and United Health, or does it apply to fee for service only?

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

Does the requirement for the UD modifier apply to claims billed to Medicaid when Medicaid is the secondary payer?

Yes. Providers must include the “UD” modifier for 340B purchased and administered drugs billed secondary to Medicaid on CMS 1500 and outpatient UB-04 claims. The “TB” modifier is required if the claim is Medicare primary.

Is the UD modifier needed for all 340B drugs on outpatient claims as of November 1? If a drug is not paid separately (paid as part of the APC bundle), is the UD modifier required on those drugs not paid separately by Medicaid?

For providers who bill on a CMS 1500 Health Insurance Claim Form or Uniform Billing (UB-04) Form and elect to opt-in, effective November 1, 2018, 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) on outpatient billed claims. The “TB” modifier is required if the claim is billed as Medicare primary. Bundled drugs that are not paid separately are not included with this requirement.

Does the requirement to bill at Actual Acquisition Cost (AAC) apply to physician administered drugs provided to a Medicaid patient in an Outpatient setting in a hospital, and does the requirement to bill at AAC apply only to Fee for Service Medicaid patients, or does it also apply to patients with United and Magnolia Managed Medicaid plans?

The Actual Acquisition Cost (AAC) billing requirement applies to point-of-sale (POS) pharmacies in fee-for-service (FFS) and coordinated care organizations (CCOs) electing to dispense and/or administer drugs which have been purchased under the rules of the 340B program. The AAC billing requirement does not currently apply to physician administered drugs billed on a CMS 1500 Health Insurance Claim Form or Uniform Billing Form (UB-04).

What process are hospital outpatient departments considering for drugs that are purchased in a unit/quantity different from the CPT unit/quantity?

Medical providers purchasing and dispensing 340B medications as part of a physician administered drug claim should bill the drug according to the HCPCS amount prescribed.

For example, a 1-gram bottle of ceftriaxone is purchased. The provider dispenses only 500mg of the drug. HCPCS code J0696 (250mg per billed unit) would be billed for two units equaling 500mg of product.

Will DOM continue to use HRSA’s Medicaid Exclusion File? If so, please describe how DOM will use the file and what is expected of entities in regards to maintaining the file. Since DOM is moving to a UD modifier model, entities may need to show HRSA auditors what the file expectations are for participating Mississippi covered entities.

HRSA currently requires that covered entities recertify their eligibility annually to maintain their status in the 340B drug program. Providers are expected to follow HRSA guidelines for program adherence.

When recertifying, it is important to provide HRSA both the provider’s NPI number and all associated eight-digit Mississippi Medicaid Provider ID numbers. This information, in addition to the 340B Attestation Form, is used to validate a covered entity’s eligibility when billing Medicaid for drugs purchased and dispensed through the 340B program. Once the provider’s information has been validated by crosschecking the HRSA website information with the Attestation Form, the provider’s eligibility is then updated in the state’s Medicaid MMIS system.

Claims that are billed for 340B drugs must have the appropriate modifier attached at the billed line level for proper adjudication. If the covered entity is not registered with the state, the claim will deny at the line level where the appropriate modifier was utilized.

Due to the complexities involved in determining 340B claim eligibility, covered entities may use a 3rd party vendor to qualify claims retrospectively and not at the time of dispensation. These pharmacies will need to have a process in place that allows for the reprocessing of claims with the updated removal or addition of 340B pricing in the submission fields. What is the allowable timeframe in which the pharmacy can reprocess a claim without adversely affecting the DOM rebate invoicing process?

Mississippi Medicaid allows providers to file claims initially within one year from the date of service. Claims filed within twelve (12) months from the initial date of service, but denied, can be resubmitted with the transaction control number (TCN) from the original denied claim. Corrected claims must be submitted no later than two years from the initial date of service. Medicare crossover claims timely filing limit is 180 days from the Medicare pay date. Providers are encouraged to submit their claims as soon as possible after the dates of service. Please refer to Section 1.12 of the Billing Handbook located at <http://medicaid.ms.gov> for further information.

“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.” Does this requirement still apply?

Pursuant to policy, 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 (the “TB” modifier is required if the claim is billed as Medicare primary), 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. Also, claims billed electronically in the D.0 format, the AAC must be submitted in field #409-D9, field name “INGREDIENT COST SUBMITTED”. The professional dispensing fee must be submitted in field # 412-DC, field name “DISPENSING FEE SUBMITTED”.

Many 340B entities serving both inpatients and outpatients use a virtual inventory since maintaining two separate inventories may be considered cost prohibitive. For hospitals who must abide by the GPO Prohibition, drugs are purchased at WAC and are only repurchased on GPO or 340B after a sufficient number of qualified claims have accrued. In most cases, it is impossible to know whether the actual drug administered to a patient was purchased on 340B. The rule should instead say “a UD modifier is required to identify a 340B qualified claim”. Hospitals should be able to identify and place a UD modifier on all appropriate qualified claims. 340B qualifications are based on the patient encounter and not the drug’s purchase history.

The 340B Drug Pricing Program allows covered entities to purchase discounted drugs for qualifying patients. The state recognizes that medical claims are billed after initial services are provided such as in physician clinics, outpatient clinics, etc. and after the provider has properly determined the patient’s 340B eligibility based on HRSA-defined criteria.

Once submitted to the state, claims are adjudicated at the line level in which individual services were rendered including potentially purchased and dispensed 340B drugs. Rebates are invoiced to drug manufacturers based on the line level at which Medicaid made a payment since a single claim may contain several drugs by different manufacturers billed on separate lines.

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