



Dear Provider:

Per the Miss. Administrative Code, Title 23, Part 200, Rule 4.10, all covered entities, as defined in Section 340B of the Public Health Service Act, are required to notify the Division of Medicaid as of July 1<sup>st</sup> of each year of their election to opt-in or opt-out of the 340B program by completing the 340B Covered Entity Attestation and Election Form.

Covered entities electing to opt-in the 340B program are also required to enroll and re-certify annually on the Health Resources and Services Administration (HRSA) website. Covered entities electing to change their 340B enrollment status or billing of 340B or non-340B drugs must immediately notify the Division of Medicaid by completing the appropriate Sections on the 340B Covered Entity Attestation and Election Form. The change is effective thirty (30) days from the Division of Medicaid's receipt of notice.

**Instructions for completing the 340B Covered Entity Attestation and Election Form:**

- Section I: Each covered entity must complete
- Section II: Only covered entities electing to opt-in the 340B program must complete
- Section III: Only covered entities electing to opt-out of the 340B program must complete

**Covered entities include, but are not limited to, the following:**

- Health Centers, such as Federally Qualified Health Centers, Federally Qualified Health Center Look-Alikes, and Tribal/Urban Indian Health Centers.
- Hospitals, such as Children's Hospitals, Critical Access Hospitals, Disproportionate Share Hospitals, Free Standing Cancer Hospitals, Rural Referral Centers, and Sole Community Hospitals.
- Specialized Clinics, such as Black Lung Clinics, Comprehensive Hemophilia Diagnostic Treatment Centers, Title X Family Planning Clinics, Sexually Transmitted Disease Clinics, and Tuberculosis Clinics.
- Pharmacies

**Completed forms must be submitted to Xerox Provider Enrollment by July 1<sup>st</sup> via:**

- **E-mail:** [msinquiries@xerox.com](mailto:msinquiries@xerox.com).
- **Fax:** (888) 495-8169, or
- **Mail:** P. O. Box 23078  
Jackson, MS 39225

Covered entities who fail to notify the Division of Medicaid of their 340B election according to the Mississippi Administrative Code Part 200, Rule 4.10.E, annually by July 1<sup>st</sup>, will be classified as opting-out of the 340B program and the Division of Medicaid will collect rebates on drugs billed by these covered entities.

For questions or additional assistance, please contact Xerox at (800) 884-3222.

Sincerely,

Provider Enrollment



### 340B Covered Entity Attestation and Election Form

Per Miss. Admin. Code, Title 23, Part 200, Rule 4.10 all covered entities, as defined in Section 340B of the Public Health Service Act, are required to notify the Division of Medicaid as of July 1<sup>st</sup> of each year of their election to opt-in or opt-out of the 340B program by completing Section I and either Section II or III, as applicable. Covered entities electing to opt-in are also required to enroll and re-certify annually on the Health Resources and Services Administration (HRSA) website. Covered entities electing to change their 340B enrollment status or billing of 340B or non-340B drugs must immediately notify the Division of Medicaid by completing the appropriate Sections below. The change is effective thirty (30) days following the Division of Medicaid's receipt of notice.

**This form must be signed and returned to Xerox Provider Enrollment via e-mail to msinquiries@xerox.com, fax to 888-495-8169, or mail to P. O. Box 23078, Jackson, MS 39225.**

#### SECTION I: Provider Identification

Attesting Provider Name: \_\_\_\_\_  
Medicaid ID #: \_\_\_\_\_ NPI #: \_\_\_\_\_  
Name of person with Signature Authority: \_\_\_\_\_  
(Please Print)  
Phone Number: \_\_\_\_\_ Fax Number: \_\_\_\_\_  
Email Address: \_\_\_\_\_

#### SECTION II: Election to Opt-In

The above named provider is a covered entity, enrolled with HRSA and has elected to opt-in under the 340B program and will bill Medicaid the estimated acquisition cost or the 340B actual acquisition cost of any drug purchased at the 340B price.

HRSA 340B ID #: \_\_\_\_\_

- Initial Opt-In Election  
Date of most recent HRSA Certification: \_\_\_\_\_
- Annual Attestation  
Date of most recent HRSA Certification: \_\_\_\_\_

This provider will bill Medicaid for (check one):

- Only 340B drugs beginning \_\_\_\_\_, or
- Both 340B and non-340 drugs beginning \_\_\_\_\_.

#### SECTION III: Election to Opt-Out

The above named provider is a covered entity and has elected to opt-out of the 340B program and will bill Medicaid their usual and customary charge.

- Opt-out of the 340B, beginning \_\_\_\_\_.
- If applicable, dis-enrolled with HRSA on \_\_\_\_\_ and will bill Medicaid the actual acquisition cost of all drugs beginning \_\_\_\_\_.

By signing this document, I certify that the information provided herein is true, accurate and complete to the best of my knowledge. I understand that any falsification, omission or concealment of any material fact may subject me to civil monetary penalties, fines, criminal prosecution, or disqualification from the Medicaid program. A covered entity who knowingly or willfully makes, or causes to be made, a false statement, attestation or representation of any 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 Title 23, Part 200, Rule 1.3. A false attestation can result in civil and monetary penalties as well as fines, and may automatically disqualify the provider as a provider of Medicaid services.

Signature: \_\_\_\_\_ Title: \_\_\_\_\_

Date: \_\_\_\_\_

# 340B FAQs

(Updated as of June 20, 2014)

## 1. What is the 340B Program?

The 340B program is a Drug Pricing Program which resulted from enactment of the Veterans Health Care Act of 1992, which is Section 340B of the Public Health Service Act. Section 340B of the Public Health Service Act 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 make them ineligible for the Medicaid drug rebate. State Medicaid programs are mandated to ensure that rebates are not claimed on these drugs.

The 340B Drug Pricing Program requires drug manufacturers to provide outpatient drugs to eligible health care organizations/covered entities at significantly reduced prices. The 340B Program enables covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. Eligible health care organizations/covered entities are defined in statute and include HRSA-supported health centers and look-alikes, Ryan White clinics and State AIDS Drug Assistance programs, Medicare/Medicaid Disproportionate Share Hospitals, children's hospitals, and other safety net providers.

To participate in the 340B Program, eligible organizations/covered entities must register and be enrolled with the 340B program and comply with all 340B Program requirements. Once enrolled, covered entities are assigned a 340B identification number that vendors verify before allowing an organization to purchase 340B discounted drugs.

To See the full list of eligible organizations/covered entities and for additional information, Providers may access the Health Resources and Services Administration (HRSA) website: (<http://www.hrsa.gov/opa/index.html>).

## 2. Which organizations are eligible for the 340B program?

According to the HRSA website, "Only nonprofit health care organizations that have certain Federal designations or receive funding from specific Federal programs are eligible organizations (covered entities) that can register, be enrolled and purchase discounted drugs through the 340B Program. These include Federally Qualified Health Centers, Ryan White HIV/AIDS Program grantees, and certain types of hospitals and specialized clinics."

## 3. Which Mississippi Medicaid Providers should fill out the attestation form?

Any Mississippi Division of Medicaid (DOM) provider that is eligible for the 340B program and will NOT be seeking reimbursement from MS DOM as a participating 340B provider should complete the form to OPT OUT.

Any MS DOM provider that is eligible for the 340B program and will be seeking reimbursement from MS DOM as a participating 340B provider should complete the form to OPT IN.

## 4. Our facility is a participant in the 340B program. Does the facility have to file the form only or the individual providers?

This form is for facilities only. Non-340B entities, like prescribers can discard the letter.

**5. Are MSCAN (aka Coordinated/Managed Care) claims included?**

Yes, MSCAN or Coordinated/Managed Care claims are included in the 340B billing process.

**6. 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 CMS and OIG recommendations for Medicaid agencies. It is Medicaid's intent that all 340B providers will complete the form and submit to Medicaid. If a 340B provider does not submit said attestation form, then the provider will be considered by Medicaid as a non-340B entity and this fact may trigger audits from 340B regulatory bodies and drug manufacturers.

**7. I am a prescriber and I don't know why I received the 340B letter/attestation. What am I to do with this?**

All Medicaid providers received this letter in order for MS Medicaid to have comprehensive documentation of current 340B provider status. Non-340B entities, like prescribers can discard the letter.

**8. The only drugs that we purchase through 340B are injectibles. 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.**

DOM would prefer that facility complete section III of the attestation form and submit to Medicaid. MS Medicaid will have documentation that your facility is recognized as a 340B entity and not billing Medicaid for 340B drugs. Having such documentation on file will assist the agency with drug manufacturer's rebate disputes in the future.

**9. Retail Pharmacies or anyone using POS who Opt-in must bill at the 340B AAC. If they Opt-out, they can bill at the usual and customary price.**

A Traditional Retail Pharmacy is ineligible to purchase 340B drugs. Pharmacies which are eligible (enrolled with HRSA and affiliated with 340B entity) and purchase 340B drugs must Opt-in or Opt-out regarding Medicaid.

MS Medicaid does not allow contract Pharmacies to dispense 340B drugs.

**10. Institutions, Clinics, etc., must bill at the 340B EAC or the 340B AAC if they Opt-in to use 340B priced drugs on qualified Medicaid Outpatients.**

Information regarding billing directions for 340B medical and pharmacy claims is located in the June 2014 MS Medicaid Provider Bulletin, at:

<https://www.ms-medicaid.com/msenvision/providerBulletins.do>.

Pharmacy specific 340B billing information is located on the Pharmacy page of DOM's website at <https://www.medicaid.ms.gov/providers/pharmacy/>; under 'Latest Pharmacy News and Notices'.

**11. Institutions, Clinics, etc. can charge their usual and customary prices to Medicaid if they Opt-out and do not use 340B priced drugs for their qualified Medicaid outpatients. Some providers believe that MS Medicaid expects them to bill at their EAC regardless of whether or not they purchase the drug on 340B.**

See the excerpt below from the pharmacy provider notice regarding pharmacy reimbursement and posted on the Pharmacy webpage at: <http://www.medicaid.ms.gov/providers/pharmacy/>; look under Latest Pharmacy News and Notices.

State Medicaid agencies reimburse participating pharmacy providers for covered outpatient drugs that are prescribed and dispensed to Medicaid beneficiaries. The payment consists of two parts: 1) reimbursement for drug ingredient costs, and 2) reimbursement for the cost of dispensing. In general, federal regulations require that Medicaid programs reimburse for drug ingredient costs at no more than the agency's best estimate of the acquisition cost for a drug. As defined in federal regulations at §42 CFR 447.502, estimated acquisition cost (EAC) is the state's best estimate of the prices generally and currently paid by providers for a drug marketed or sold by manufacturers or labelers in the package size of the drug most frequently purchased by providers.

Mississippi Division of Medicaid (DOM) is implementing a new drug pricing methodology to reimburse pharmacies that dispense pharmaceutical products to Medicaid beneficiaries. Effective July 1, 2014, DOM will start reimbursing pharmacies using the average acquisition cost (ACC) of a given pharmaceutical product using National Average Drug Acquisition Cost (NADAC) files that gives state Medicaid agencies covered outpatient drug information regarding retail prices for prescription drugs. The NADAC, published by CMS and updated weekly, is a more accurate reflection of the ingredient cost of the medications covered by the DOM drug benefit program.

The purpose of the NADAC is to create a new national price benchmark that is more reflective of the prices that pharmacies pay to acquire prescription and over-the-counter drugs. To ensure that NADACs are accurate, timely, and robust, the NADACs will be reviewed and updated on a weekly basis. Instead of the Average Wholesale Price (AWP), DOM will reimburse pharmacy providers based on the NADAC for the ingredient cost and a professional dispensing fee more in line with the true cost of dispensing.

**12. As covered entities, should all FQHCs submit the 340B Attestation and Election Form and are their penalties for non-submission?**

The new policy, including attestation form, is in alignment with CMS and OIG recommendation for Medicaid agencies. It is Medicaid's intent that all 340B providers will complete the form and submit to Medicaid. If a 340B provider does not submit said attestation form, then this provider will be considered a non-340B entity. This fact may trigger audits from 340B regulatory bodies and pharmaceutical manufacturers.

**13. For 340B covered entities, what is required of the Providers for records purposes?**

Enrolled covered entities must maintain detailed and auditable records regarding the compliance with all 340B program requirements and policies. Under Mississippi Administrative 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.

**14. What is required of 340B covered entities that provide 340B drugs as a Medical Service benefit?**

Covered entities providing 340B drugs as a Medical Service benefit are required to notify DOM as of July 1<sup>st</sup> of each year of their election to opt-in or opt-out of the 340B program by completing the 340B Covered Entity Attestation and Election Form. Covered entities who do not notify the DOM of their 340B election annually will be considered as opting-out of the 340B program and DOM will collect rebates on drugs billed by these covered entities opting-out.

**15. How should Providers (referencing Medical Services benefits) bill their 340B claims?**

Effective October 1, 2014, providers must bill 340B drug claims as follows:

- The 340B drugs must only be provided to eligible beneficiaries and they must receive health care services other than the drug from the 340B provider.
- The charges billed should be at the 340B actual acquisition cost paid to the wholesaler or manufacturer for the drug.
- The provider must specify the drugs purchased under the 340B program by appending the 'UD' modifier with the applicable HCPCS code and NDC on the CMS-1500/837 Professional and the UB04/837 Institutional claims forms to properly identify the 340B outpatient drugs.

**16. If I opt out of 340B with MS Medicaid what exactly does that mean?**

DOM defines *opt-out* as the election by a covered entity not to purchase and dispense/administer covered 340B drugs to Medicaid beneficiaries. Opting out of billing Medicaid has no bearing on a facility's 340B status with HRSA.

**17. I am a 340B pharmacy associated with a 340B facility. I bill Medicaid for pharmacy claims in the pharmacy point of sale (POS) program. My usual and customary charge for some drugs is less than the \$11.20 dispensing fee. Can I still bill Medicaid at our cost plus the \$11.20 dispensing fee?**

No. If a pharmacy's usual and customary charge for their patient population is a flat rate (for example \$4), then Medicaid should be charged \$4.

**18. I am a 340B pharmacy associated with a 340B facility. I bill Medicaid for pharmacy claims in the pharmacy point of sale (POS) program. How do I bill for non-340B drugs?**

The non-340B drugs should continue to be billed using the 'Usual and Customary' charge.