



October 10, 2018

Attention Medicaid Provider:

Background:

The Centers of Medicare and Medicaid Services (CMS) requires the Mississippi Division of Medicaid (DOM) to define its policies and oversight activities related to 340B purchased drugs as outlined in CMS state release No. 161, dated October 26, 2012. Additionally, CMS mandates that states be in compliance with the new reimbursement requirements in the Covered Outpatient Drug Final Rule, pursuant to 42 C.F.R. Part 447, by no later than April 1, 2017.

Pursuant to the Veterans Health Care Act of 1992, which is Section 340B of the Public Health Service Act (PHSA), 340B covered entities are allowed to purchase and dispense/administer pharmaceuticals at significantly discounted prices. DOM is prohibited from collecting drug rebates on these outpatient drugs which have been purchased at significant discounts preventing duplicate discounts.

If you meet the definition of a 340B covered entity according to the Health Resources and Services Administration (HRSA) and intend on both purchasing and administering 340B drugs to qualified Medicaid beneficiaries, you are required to complete the enclosed form entitled **340B Covered Entity Attestation & Provider Enrollment Form** and submit the completed form to Gainwell, DOM's fiscal agent, with your registration packet. For more information regarding the 340B program and eligibility, please refer to HRSA's website located at www.hrsa.gov/opa.

Participating 340B providers have one of two options to complete on the Attestation Form:

Section I: Provider Identification + **Section II:** Election to Opt-in = Enrollment complete!

OR

Section I: Provider Identification + **Section III:** Election to Opt-out = Enrollment complete!

DOM requires completion of this form only once, unless you change your opt-in/opt-out status with HRSA. Any anticipated change must be submitted to DOM thirty (30) days before the actual effective date of the 340B status change. DOM will provide United Healthcare Community Plan and Magnolia Health with a list of providers and their opt-in/opt-out status. No additional forms need to be completed for the coordinated care organizations.

Completing Section II Election to Opt-In (Billing DOM for 340B Drugs):

Opt-in is defined as a provider electing to dispense and/or administer drugs, which have been purchased under the rules of the 340B program and billing DOM for Medicaid beneficiaries enrolled in either fee-for-service (FFS) or in a coordinated care organization (CCO) but not enrolled in the Children's Health Insurance Program (CHIP).

- For point-of-sale (POS) pharmacies who elect to opt-in, effective November 1, 2018, ingredient costs must be billed to DOM at the actual acquisition cost (AAC). This AAC is defined as the price at which you have paid the wholesaler or manufacturer for the 340B drug with no mark-up.
 - 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”. Also, providers must enter a “08” in field 423-DN, the Basis of Cost Determination field, and “20” in field 420-DK, the Submission Clarification Code.
 - For further billing instructions please refer to DOM’s website located at <https://medicaid.ms.gov/providers/pharmacy/>.
- 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).

Completing Section III Election to Opt-Out (Not Billing DOM for 340B Drugs):

Opt-out is defined as a provider electing *never* to dispense, administer, and bill 340B drugs which have been purchased under the rules of the 340B program for any Medicaid beneficiary. If selecting this option, your provider number/NPI should not be listed on the HRSA Medicaid Exclusion File. Opting-out does not preclude you from dispensing and/or administering and billing **non**-340B purchased drugs for any Medicaid beneficiary.

Changes in 340B Enrollment Status Notification:

If you elect to change your 340B enrollment status you must immediately notify DOM by completing the appropriate Sections on the **340B Covered Entity Attestation & Provider Enrollment Form** located on the DOM website at medicaid.ms.gov. You must notify DOM no later than thirty (30) days before the actual effective date of the 340B status change.

For questions or additional assistance, please contact our fiscal agent, Gainwell Technologies, toll-free at (800) 884-3222.



340B Covered Entity Attestation & Provider Enrollment Form

1. Complete and sign this form for each of your 340B ID numbers assigned by HRSA,
2. Locate your 340B "Covered Entity Information" sheet at HRSA's website located at <https://340bopais.hrsa.gov/coveredentitysearch> and print so that DOM may validate your 340B election and update your Mississippi Medicaid eligibility file, and
3. Submit both documents to Gainwell's Provider Enrollment:
 - a. E-mail to ms_drugrebate@gainwelltechnologies.com
 - b. Fax to 1-866-644-6148
 - c. Mail to Gainwell Technologies, P. O. Box 6014, Ridgeland, MS 39158-6014

SECTION I: 340B Covered Entity Information as listed on the [HRSA website](#):

Attesting Covered Entity Name: _____

Covered Entity Address: _____

Medicaid Provider #: _____ Billing NPI #: _____

(Printed Name of Authorized Official as indicated on HRSA enrollment)

Phone Number: _____ Fax Number: _____

Email Address: _____

SECTION II: Election to Opt-In

The above named provider is a covered entity, enrolled with HRSA, has elected to opt-in under the 340B program, and will bill the Division of Medicaid in accordance with applicable policies.

Opt-In Election
340B ID: _____

Participating Start Date: _____ Date of most recent HRSA Recertification: _____

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 never bill DOM for any drugs purchased under the 340B program. This entity's provider number/NPI should not be listed on the HRSA Medicaid Exclusion File.

Opt-out of the 340B, beginning _____ 340B ID: _____

If applicable, dis-enrolled with HRSA on _____ and will never bill DOM for any drugs purchased under the 340B program 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. Under Miss. Admin. Code. Title 23, Part 200, Rule 1.3, a provider who knowingly or willfully makes, or causes to be made, false statement or representation of any material fact in any application for Medicaid benefits or Medicaid payments may be prosecuted under federal and state criminal laws. 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.

Authorized Official Name (please print): _____

Signature of Authorized Official: _____ Position: _____

Date: _____