Issue: 340B Policy Clarification

SUMMARY

- The overlap of the 340B Drug Pricing Program and the Medicaid Drug Rebate program creates the possibility of duplicate discounts, which are prohibited under federal law.
- States are federally mandated to seek federal drug rebates on Managed Care Medicaid claims, meaning that the potential for duplicate discounts exists for managed care claims.
- Louisiana uses the Health Resources and Services Administration’s (HRSA) Medicaid Exclusion File for both Fee-for-Service (FFS) and Managed Care Medicaid claims in order to prevent duplicate discounts.
- Contract pharmacies are not permitted to bill Medicaid for drugs purchased at 340B pricing. This includes both FFS and Managed Care Medicaid.

340B & DRUG REBATE PROGRAM BACKGROUND

The national Medicaid Drug Rebate program was established in 1991 as a means to offset both state and federal Medicaid drug expenditures. When a drug manufacturer enters into a national rebate agreement, they are also required to enter into agreements with two other federal programs in order to have their drugs covered under Medicaid. One of these programs is the 340B Drug Pricing Program.

The 340B Drug Pricing Program was designed to enable participating providers, referred to as “covered entities,” to stretch scarce federal resources by obtaining covered outpatient drugs at significantly discounted prices. This program is administered by the Health Resources and Services Administration’s (HRSA) Office of Pharmacy Affairs (OPA).

When a covered entity bills Medicaid for a pharmacy or outpatient physician-administered drug claim, the possibility of duplicate discounts exists due to the overlap of the Medicaid Drug Rebate and 340B Drug Pricing Programs. Therefore, when a covered entity enrolls in the 340B program, it must choose whether it will “carve-in” or “carve-out” its Medicaid patients. Carve-in means that all drugs dispensed to Medicaid patients were purchased under the 340B Drug Pricing Program, while carve-out means that no drugs dispensed to Medicaid patients were purchased under the 340B Drug Pricing Program.

Additional information on the 340B Drug Pricing Program can be found at [http://www.hrsa.gov/opa](http://www.hrsa.gov/opa).
MEDICAID EXCLUSION FILE

HRSA communicates carve-in designations to states via the Medicaid Exclusion File (MEF) in order to alert states that Medicaid Drug Rebates should not be sought on MEF providers’ drug claims.

When a covered entity chooses to carve-in, it must provide HRSA with the National Provider Identification (NPI) and/or Medicaid provider number for each site that carves in for the purpose of inclusion in the MEF. An entry in the MEF indicates that a covered entity has chosen to carve-in for a single quarter.

A covered entity can change its carve-in or carve-out designation at any time; however, HRSA stipulates that the effective date of any such change will be the first day of a calendar quarter. Status changes for the next calendar quarter must be provided by the 15th day of the month preceding the quarter’s start (March 15, June 15, Sep. 15 and Dec. 15). Changes submitted after this date will not be effective until the start of the second quarter following the change. Because the MEF is produced on the 15th day of the month preceding a quarter’s start, this ensures that an entity’s carve-in or carve-out election is properly reflected on the applicable quarter’s MEF.

States can elect to identify 340B claims using methods other than the exclusion file (e.g. claim level indicators). **Louisiana currently uses the MEF as the sole means of identifying 340B drug claims.**

Additional information regarding the MEF can be found at [https://opanet.hrsa.gov/340B](https://opanet.hrsa.gov/340B).

MANAGED CARE MEDICAID

Section 2501(c) of the Patient Protection and Affordable Care Act (ACA) requires state Medicaid agencies to seek rebates on drugs dispensed by Medicaid Managed Care Organizations (MCOs). This means that the potential for duplicate discounts exists for both FFS and Managed Care Medicaid.

Due to this duplicate discount potential, **Louisiana requires that covered entities utilize the same carve-in or carve-out designation for Managed Care Medicaid patients as for FFS Medicaid patients.** If a covered entity appears on the MEF, Louisiana will exclude that provider’s FFS and MCO claims from rebate invoicing. Since claims for FFS Medicaid and Managed Care Medicaid recipients are treated identically in regards to exclusion from rebate invoicing, **any reference to “Medicaid recipients” in this document refers to both FFS and Managed Care Medicaid recipients.**

In order to allow covered entities to identify Managed Care Medicaid patients from an MCO’s private insurance patients, Louisiana requires its MCOs to utilize a unique Processor Control Number (PCN) or Group Number for Louisiana Medicaid (RFP17.8.2).

Louisiana Medicaid FFS & MCO BIN, PCN, and Group Numbers for pharmacy claims:

<table>
<thead>
<tr>
<th>Plan Name</th>
<th>PBM Name</th>
<th>BIN</th>
<th>PCN</th>
<th>Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>AETNA</td>
<td>CVS Health</td>
<td>610591</td>
<td>ADV</td>
<td>RX8834</td>
</tr>
<tr>
<td>AMERIGROUP</td>
<td>Express Scripts</td>
<td>003858</td>
<td>MA</td>
<td>WKLA</td>
</tr>
<tr>
<td>AMERIHEALTH CARITAS LA</td>
<td>PerformRx</td>
<td>600428</td>
<td>06030000</td>
<td>n/a</td>
</tr>
</tbody>
</table>
Plan Name | PBM Name | BIN | PCN | Group
---|---|---|---|---
LA HEALTHCARE CONNECTIONS | USScript | 008019 | n/a | n/a
UNITED HEALTHCARE | OptumRx | 610494 | 9999 | ACULA
FFS / LEGACY MEDICAID | n/a | 610514 | LOUIPROD | n/a

Payer ID can be utilized to identify Managed Care Medicaid recipients’ medical claims. Please refer to [www.makingmedicaidbetter.com](http://www.makingmedicaidbetter.com) for information regarding Electronic Data Interchange (EDI) claim submissions. A copy of this information has been attached for your convenience.

**CONTRACT PHARMACIES**

HRSA permits covered entities to contract with one or more pharmacies to provide services to the covered entity’s patients in order to increase patient access to 340B drugs.

HRSA expressly prohibits contract pharmacies from dispensing drugs purchased under the 340B Drug Pricing Program to Medicaid recipients unless the covered entity, the contract pharmacy, and the state Medicaid agency have established an arrangement to prevent duplicate discounts (75 FR 10272, March 5, 2010). **Louisiana** currently has no such agreements in place and **requires that all contract pharmacies carve-out Medicaid recipients for both FFS and MCO 340B drug claims.**

Covered entities are required to perform annual audits of their contract pharmacies and are responsible for ensuring that contract pharmacies have systems in place to prevent duplicate discounts. Per 72 FR 10272, March 5, 2010, “The covered entity remains responsible at all times for the disposition of covered outpatient drugs it purchases through a contract pharmacy.”

**CURRENT BILLING GUIDELINES**

These general guidelines apply to both the Fee-for-Service and Managed Care Medicaid programs. For full billing procedures, please refer to each plan’s provider manual.

**Carve-In**

**FFS Pharmacy**

Covered entities who carve-in Medicaid recipients should bill a drug’s actual acquisition cost in National Council for Prescription Drug Programs (NCPDP) field 409-D9 Ingredient Cost Submitted.

**MCO Pharmacy**

Covered entities who carve-in Medicaid recipients should bill according to the contract arrangements between the 340B covered entity and the MCO.

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1Full text from Federal Register (FR) available at [www.federalregister.gov](http://www.federalregister.gov)
Contract pharmacies are not permitted to carve-in FFS or MCO Medicaid for drugs purchased at 340B prices.

**FFS and MCO Physician Administered Drugs**

**Hospital Outpatient Claims**

Covered entities who carve in Medicaid recipients should bill at the drug’s actual acquisition cost. Dispensing fees, supply fees, admin fees, etc. should be billed using the appropriate revenue codes. Any discrepancies in pricing will be rectified in the annual cost settlement process.

**Professional Services Claims**

Covered entities who carve in Medicaid recipients should bill at the drug’s actual acquisition cost. Dispensing fees, supply fees, admin fees, etc. should be billed using the appropriate revenue codes.

**Carve-Out**

Covered entities who carve-out Medicaid recipients should bill according to normal guidelines provided in each plan’s provider manual for non-340B drug claims. Links have been provided below:

- **Aetna**

- **Amerigroup**
  [https://providers.amerigroup.com/pages/la.aspx](https://providers.amerigroup.com/pages/la.aspx)

- **AmeriHealth Caritas**

- **Louisiana Healthcare Connections**
  [http://www.louisianahealthconnect.com/for-providers/provider-resources/](http://www.louisianahealthconnect.com/for-providers/provider-resources/)

- **United Healthcare**

- **Fee-for-Service**

**REIMBURSEMENT**

**Fee for Service (FFS)**

As of May 1, 2017, FFS Pharmacy Outpatient claims for drugs purchased at 340B rates will be reimbursed at Actual Acquisition Cost plus a professional dispensing fee or Usual and Customary, whichever is less. Reimbursement methodologies for physician administered drugs will not change. Outpatient Hospital claims for physician administered drugs will continue to be paid using a cost to charge methodology on the interim and are settled at cost during final settlement. FQHCs and RHCs claims for physician administered drugs will be included in the all-inclusive T1015 encounter rate as they are currently. Current reimbursement methodologies for covered entities who carve in Medicaid do not differ from each program’s standard reimbursement methodology.
Information regarding reimbursement methodologies can be found in each program’s provider manual (links above). Providers can also contact the appropriate department listed below for further information:

<table>
<thead>
<tr>
<th>FFS Program</th>
<th>Reimbursement Questions</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy</td>
<td>Contact Pharmacy Help Desk</td>
<td>1-800-437-9101</td>
</tr>
<tr>
<td>All Others</td>
<td>Molina Provider Relations</td>
<td>1-800-473-2783</td>
</tr>
<tr>
<td>(Hospital, Professional Services, etc.)</td>
<td></td>
<td></td>
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</tbody>
</table>

**Managed Care**

Managed care reimbursements are made in accordance with contractual arrangements between the covered entity and MCO.

For questions about reimbursement, please contact the provider relations department of the appropriate plan:

<table>
<thead>
<tr>
<th>Plan Name</th>
<th>Provider Relations</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aetna</td>
<td></td>
<td>1-855-242-0802</td>
</tr>
<tr>
<td>Amerigroup</td>
<td></td>
<td>1-800-454-3730</td>
</tr>
<tr>
<td>AmeriHealth Caritas</td>
<td></td>
<td>1-888-922-0007</td>
</tr>
<tr>
<td>Louisiana Healthcare Connections</td>
<td></td>
<td>1-866-595-8133</td>
</tr>
<tr>
<td>United Healthcare</td>
<td></td>
<td>1-866-675-1607</td>
</tr>
</tbody>
</table>

**POLICY COMPLIANCE**

If the policies described herein have not yet been adopted by your facility, please contact Dara Horcasitas, Drug Rebate Supervisor, via email at Dara.Horcasitas@LA.GOV so that claims can be assessed for possible exclusion from drug rebate invoices.

Future noncompliance may result in recoupments, sanctions and/or other disciplinary action taken against the provider.
TRANSITION TO CLAIM-LEVEL INDICATORS

A covered entity’s Medicaid claims may not be exclusively 340B because of orphan drug regulations, 340B drug stock shortages, and other billing issues. 340B claim-level indicators shall be entered to identify drug claims that should be excluded from the rebate invoicing process.

Providers shall submit both FFS and managed care claims with the following claim-level indicators below. However, they are not being used to exclude claims from drug rebate invoicing at this time. We discourage providers to begin testing the use of these indicators.

**Pharmacy Claims**

<table>
<thead>
<tr>
<th>NCPDP Field</th>
<th>NCPDP Field Name</th>
<th>NCPDP Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>420-DK</td>
<td>Submission Clarification Code</td>
<td>20 = 340B</td>
</tr>
<tr>
<td>423-DN</td>
<td>Basis of Cost Determination</td>
<td>08 = 340B Disproportionate Share Pricing</td>
</tr>
</tbody>
</table>

**Physician-Administered Drug Claims**

Providers shall submit the UD modifier to identify 340B drugs on outpatient physician-administered drug claims. This includes outpatient hospital and outpatient professional service 340B drug claims.

- CMS 1450/UB04: Enter UD Modifier immediately following drug HCPCS/CPT code in field 44.
- CMS 1500: Enter HCPCS code in Loop 2400 SV101-2 followed by the modifier UD. Example: J1111 billed as J1111UD.

Further information will be provided prior to implementation.

**QUESTIONS**

If you have questions about the contents of this memo, you may contact:

<table>
<thead>
<tr>
<th>Contact Name</th>
<th>Email</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dara Horcasitas,</td>
<td><a href="mailto:Dara.Horcasitas@LA.GOV">Dara.Horcasitas@LA.GOV</a></td>
<td>225-342-9289</td>
</tr>
<tr>
<td>Drug Rebate Supervisor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicaid Pharmacy Help Desk</td>
<td><a href="mailto:Medicaid.Pharmacy@LA.GOV">Medicaid.Pharmacy@LA.GOV</a></td>
<td>1-800-437-9101</td>
</tr>
</tbody>
</table>
Informational Bulletin 16-9
Attachment: EDI Submission Information for Managed Care Plans

Managed Care Organizations (MCOs) EDI Submissions

AmeriHealth Caritas
Payer ID 273575066
Trading Partner
EMDEON

For EDI questions:
Email - edi.amerihethcaritasla.com
Phone – 1-866-428-7419
Emdeon Phone – 1-800-845-6592

Louisiana Healthcare Connections
Payer ID: 68069

Trading Partners:
Emdeon ENCODA GHA Online RelayHealth/McKessonGateway
EDI/TriZetto ClaimRemedi MDONLINE Medavant/Capario
Availity PayerPath Practice Insight SSI
Smart Data Solutions ViaTrack Medassets/Xactmed Zirmed
INFINEDI

For Support: 1-800-225-2573 Ext. 6075525 or via e-mail at EDIBA@centene.com

AmeriGroup
Trading Partners
Emdeon (formerly WebMD) – Claim Payer ID 27514
Capario (formerly MedAvant) – Claim Payer ID 28804
Availity (formerly THIN) – Claim Payer ID 26375
Smart Data Solutions – Claims Payer ID 81237
A provider may contact the AmeriGroup EDI Hotline at 1-800-390-5745 to start the electronic claims submission process, or with any questions.
UnitedHealthcare

Payer ID: 8772
For EDI questions or list of clearinghouses:
Phone – 1-800-842-1109 or 1-800-210-8315
Email – ac edi_ops@uhc.com

Current Trading Partners include (but not limited to):

- Allscripts
- Availity
- Capario
- Emdeon
- Gateway EDI/TriZetto
- MD Online
- MedAssets
- Navicure
- Office Ally
- OptumInsightTM
- Practice Insight
- RealMed
- RelayHealth
- SSI
- ZirMed

Aetna Better Health of Louisiana

Payer ID 128LA


Emdeon is the EDI vendor we use. Providers need to contact the software vendor directly for further questions about their electronic billing. All electronic submission shall be submitted in compliance with applicable law including HIPAA regulations and Aetna Better Health of Louisiana policies and procedures. If you use a clearing house other than Emdeon, please have them call Emdeon at the following number in order to establish connectivity: 1-800-845-6592 (Please run a test claim prior to submitting batches) Please use the Payer ID above when submitting claims to Aetna Better Health of Louisiana.