Louisiana Department of Health
Informational Bulletin 16-9
Revised September 1, 2017

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 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 HRSA's Office of Pharmacy Affairs (OPA).

When a covered entity bills Medicaid for a pharmacy or outpatient physician-administered drug, 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.

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.

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.

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

Plan Name	PBM Name	BIN	PCN	Group
AETNA	CVS Health	610591	ADV	RX8834
HEALTHY BLUE	Express Scripts	003858	MA	WKLA
AMERIHEALTH CARITAS LA	PerformRx	600428	06030000	n/a
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 the Provider & Plan Resources page 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)[1]. **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.**

Effective Sept. 12, 2017, pharmacy claims should deny at Point of Sale (POS) if 340B indicators are on the claim but the pharmacy is not listed in the MEF. These claims should be filled with regular pharmacy stock, not 340B stock, and billed accordingly.

CURRENT BILLING GUIDELINES

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.

Contract pharmacies are not permitted to carve-in FFS or MCO Medicaid for drugs purchased at 340B prices.

Carve-Out and Contract Pharmacies

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

Aetna	http://www.aetnabetterhealth.com/louisiana/providers/manual
Healthy Blue	https://providers.healthyblue.la.com

[1]Full text from Federal Register (FR) available at www.federalregister.gov

AmeriHealth Caritas	http://amerihealthcaritasla.com/provider/index.aspx
Louisiana Healthcare Connections	http://www.louisianahealthconnect.com/for-providers/provider-resources/
United Healthcare	http://www.uhccommunityplan.com/health-professionals/la.html
Fee-for-Service	http://www.lamedicaid.com/provweb1/Providermanuals/Intro_Page.aspx

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. FQHC and RHC claims for physician administered drugs will be included in the all-inclusive T1015 encounter rate as they are currently.

Providers can also contact the appropriate department listed below for further information:

FFS Program	Reimbursement Questions Contact	Phone
Pharmacy	Pharmacy Help Desk	1-800-437-9101
All Others (Hospital, Professional Services, etc.)	Molina Provider Relations	1-800-473-2783

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:

Plan Name	Provider Relations
Aetna	1-855-242-0802
Healthy Blue	1-844-521-6942
AmeriHealth Caritas	1-888-922-0007

Louisiana Healthcare Connections	1-866-595-8133
United Healthcare	1-866-675-1607

POLICY COMPLIANCE

If the policies described herein have not yet been adopted by your facility, please contact Dana Drelick, Drug Rebate Supervisor, via email at Dana.Drelick@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.

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.

Beginning with date of service Sept. 12, 2017, providers shall submit both FFS and managed care claims with the following claim-level indicators below.

Pharmacy Claims

340B Pharmacy claims shall contain BOTH indicators below:

NCPDP Field	NCPDP Field Name	NCPDP Values
420-DK	Submission Clarification Code	20 = 340B
423-DN	Basis of Cost Determination	08 = 340B Disproportionate Share Pricing

Physician-Administered Drug Claims

Providers shall submit the UD modifier to identify 340B drugs on outpatient physician-administered drug claims. This includes outpatient professional service 340B drug claims. Due to the cost to charge methodology, outpatient hospital claims are excluded from the claim level indicator requirement.

- CMS 1450/UB04: Enter UD Modifier immediately following drug HCPCS/CPT code in field 44. For example, HCPCS J1111 billed as J1111UD.
- CMS 1500: Enter HCPCS code in field 24C followed by the UD Modifier.
- 837I: Loop 2400 SV2 can send up to four modifiers SV202-3, SV202-4, SV202-5, and SV202-6.
- 837P: Loop 2400 SV1 can send up to four modifiers in SV101-3, SV101-4, SV101-5, and SV101-6.

QUESTIONS

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

Contact Name	Email	Phone
Dana Drelick, **Drug Rebate Supervisor**	Dana.Drelick@la.gov	225-342-9045
Dara Horcasitas, **Drug Rebate Director**	Dara.Horcasitas@la.gov	225-342-9289
Medicaid Pharmacy Help Desk	Medicaid.Pharmacy@la.gov Attn: Drug Rebate Dept.	1-800-437-9101

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Managed Care Organizations (MCOs) EDI Submissions

AmeriHealth Caritas
Payer ID 273575066

Trading Partner
EMDEON

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

Louisiana Healthcare Connections
Payer ID 68069

Trading Partners:

Emdeon/Change Healthcare	MedAvant/Capario/Emdeon	Availity
Gateway EDI/TriZetto	Smart Data Solutions	Infinedi
Experian	Encoda	ClaimRemedi
Allscripts/PayerPath	ViaTrack	GHN-Online/Greenway Eligibility
MD On-line/Ability	Relay Health/McKesson	Practice Insight
SSI	ZirMed	InMediata

For support: 1-800-225-2573 Ext. 6075525 or via email at EDIBA@centene.com

Healthy Blue

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 – Claim Payer ID 81237

A provider may contact the Healthy Blue EDI Hotline at 1-800-470-9630 to start the electronic claims submission process, or with any questions.

UnitedHealthcare
Payer ID 87726

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
OptumInsight	Practice Insight	RealMed
RelayHealth	SSI	ZirMed

Aetna Better Health of Louisiana

Payer ID 128LA

Emdeon www.emdeon.com 1-877-469-3263

Emdeon is the EDI vendor we use. Providers need to contract the software vendor directly for further questions about their electronic billing. All electronic submissions shall be submitted in compliance with applicable law including HIPAA regulations and Aetna Better Health of Louisiana policies and procedures. If you use a clearinghouse 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. For pharmacy resources, visit https://www.caremark.com/wps/portal and click on Pharmacists & Medical Professionals.