

## FDA Drug Safety Communication: Opioid Labeling Changes

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On April 9, 2019, the U.S. Food and Drug Administration (FDA) issued a drug safety communication requiring labeling changes to the prescribing information for opioid pain medicines that are intended for use in the outpatient setting. These changes will provide expanded guidance to healthcare professionals on how to safely decrease the dose in patients who are dependent on opioid pain medicines when the dose is to be decreased or the medicine is to be discontinued. These changes will also include new prescribing information on side effects including central sleep apnea and drug interactions.

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### Consider tapering to a reduced opioid dosage or tapering and discontinuing opioid therapy when your patient...

- Does not have clinically meaningful improvement in pain and function (e.g. at least 30% improvement on the 3-item PEG scale, which is a screening tool used to assess pain intensity and interference).
- Is taking opioid dosages  $\geq 50$  MME (Morphine Milligram Equivalent) / day without evidence of benefit or opioids are combined with benzodiazepines.
- Requests dosage reduction.
- Experiences overdose or other serious adverse event.
- Shows early warning signs for overdose risk such as confusion, sedation, or slurred speech.
- Shows signs of substance use disorder (e.g., work or family problems related to opioid use, difficulty controlling use).

### Talk to Your Patients About Dose Tapering

- Provide the patient with an opportunity to discuss the opioid tapering plan prior to initiation and to discuss any concerns they may have.
- Validate and normalize concerns while explaining how the known risks of long-term opioid treatment outweigh the limited benefits. Emphasize how maintaining the current opioid dose, or increasing it, puts the patient at serious risk.
- Explain that dose increases will not necessarily reduce pain. A dose decrease, although counterintuitive, may decrease pain and lead to improvements overall by reducing negative effects of opioid therapy and alleviating opioid-induced hyperalgesia, or heightened pain sensitivity.
- Reassure patients that a careful dose-lowering plan can minimize withdrawal symptoms.
- Reinforce that you will not abandon the patient and that you will work with them to address pain control and withdrawal symptoms during the tapering process.

### How to taper

- When deciding how to discontinue or decrease opioid therapy, consider a variety of factors, including the dose of the opioid analgesic the patient has been taking, the duration of treatment, the type of pain being treated, and the physical and psychological attributes of the patient.
- Collaborate with the patient on a tapering plan. There are no standard opioid tapering schedules that are suitable for all patients. A patient-specific plan should be used to taper the dose of the opioid gradually. A reasonable starting regimen would be a reduction of 10% of the original dose/week or month. Some patients do better with slower tapers.
- Providers should discuss with patients undergoing tapering the increased risk for overdose on abrupt return to a previously prescribed higher dose.
- To ensure success, it is important to monitor depression, anxiety, and insomnia before and during the tapering process. If these are controlled, pain does not usually increase.
- Frequent follow-up with patients is important. Reassess the patient regularly to manage pain and withdrawal symptoms that emerge.
- When opioid analgesics are being discontinued due to a suspected substance use disorder, evaluate and treat the patient, which should include evidence-based approaches such as medication assisted treatment of opioid use disorder.

**Adjust**



Adjust the rate and duration of the taper according to the patient's response.

**Monitor**



Don't reverse the taper: however the rate may be slowed or paused while monitoring and managing withdrawal symptoms.

**Reduce**



Once the smallest available dose is reached, the interval between doses can be extended and opioids may be stopped when taken less than once a day.



Learn about the risks of prescription opioids  
[www.cdc.gov/drugoverdose](http://www.cdc.gov/drugoverdose)



References: [www.cdc.gov](http://www.cdc.gov)  
[www.fda.gov](http://www.fda.gov)

# PHARMACY FACTS

## Program Updates from Louisiana Medicaid

Pharmacy Facts can also be found online at: <http://ldh.la.gov/index.cfm/page/3036>.

April 16, 2019 Revised: 4.17.2019

### Medicaid single preferred drug list implementation on schedule for May 1, 2019

Work continues on the single preferred drug list (PDL) for all managed care organizations (MCO) and Medicaid fee-for-service (FFS). Medicaid is on schedule for a May 1, 2019 implementation date.

Staff continues to work on state rulemaking and amendments to the State Plan with the Centers for Medicare & Medicaid Services (CMS). **Proposed** changes include:

- An increase in the professional dispensing fee from \$10.41 to \$10.99 for FFS prescriptions, upon CMS approval.
- A change in the ingredient cost methodology from Average Acquisition Cost (AAC) to the National Average Drug Acquisition Cost (NADAC), upon CMS approval.

Although the dispensing fee and NADAC changes are only applicable to FFS Medicaid, MCOs are mandated through legislation to reimburse local pharmacies at the FFS rate.

**The provider fee requirement will remain unchanged. The provider fee (\$0.10) will continue to be reimbursed separately from the professional dispensing fee, per legislative mandate, in NCPDP field 558-AW (flat sales tax paid). Pharmacy providers should continue to submit the provider fee (\$0.10) in NCPDP field 481-HA (flat sales tax submitted) on all pharmacy claims.**

The single PDL that will become effective on May 1, 2019 will be posted through a static link on April 29, 2019 on the [Louisiana Medicaid](#) and [Louisiana Department of Health](#) websites. The current FFS PDL is the same PDL that will become effective on May 1, 2019. Links to criteria are embedded in the current posted FFS PDL, and some criteria will be updated to become effective on May 1, 2019.

Additional clarifications are forthcoming and will be shared in future editions of Pharmacy Facts. More background on the single PDL can be found in previous editions of [Pharmacy Facts](#).

### Billing changes with MCOs

Healthy Blue is changing its pharmacy benefit manager (PBM) from Express Scripts to IngenioRx. The **BIN, PCN and Group** will change effective May 1, 2019. See below:

- RXBIN: 020107
- RXPCN: FG
- RXGRP: WKLA

AmeriHealth Caritas Louisiana will change its **BIN ONLY** effective May 1, 2019. See below:

- RXBIN: 019595

April 29, 2019

### **Medicaid single preferred drug list effective May 1, 2019**

Effective May 1, 2019, the Preferred Drug List (PDL) that has been in place for fee-for-service (FFS) Medicaid since January will expand to include managed care organizations (MCO).

Drugs on the PDL will not be subject to prior authorization. The other drugs in the process (non-preferred) will require prior authorization. The list of drugs will be the same for FFS and all five MCOs. Each of the five MCOs will establish a permanent link to the Single PDL on their existing provider web pages. Medicaid will also post the link on their provider pages, including that program's [fiscal intermediary website](#) and the pharmacy portal on the [Provider & Plan Resources page](#).

Members of the newly created Pharmacy Advisory Committee have made recommendations to LDH to further streamline the prior authorization process and drug selection.

More background on the single PDL can be found in previous editions of Pharmacy Facts.

### **Pharmacy and Therapeutics Committee**

The Pharmacy and Therapeutics Committee met on Friday, April 26. Topics included:

- The preferred or non-preferred status of drugs in 59 therapeutic drug classes.
- Clinical and financial considerations of the therapeutic classes.

Upon approval of Louisiana Department of Health Secretary Dr. Rebekah Gee, the recommendations will be implemented with an effective date of July 1, 2019.

Pharmacy claims for FFS members and MCO members will all follow the Single PDL status.

### **Reimbursement Changes**

Also on May 1, reimbursement methodology will change for FFS recipient pharmacy claims and for MCO enrollees who fill prescriptions at local pharmacies.

Ingredient cost will change from average acquisition cost (AAC) to national average drug acquisition cost (NADAC). The professional dispensing fee will increase from \$10.41 to \$10.99 on the identified claims.

## **Eligibility and Enrollment System Provider Bulletins**

Louisiana Medicaid is publishing bi-weekly provider bulletins to address provider questions and concerns around the new eligibility and enrollment system. The information in these bulletins covers a wide range of provider issues and provider types. This and other news can be found on the web site dedicated to the new system, found here:

<http://ldh.la.gov/index.cfm/page/3497>.

If there are topics you feel need to be covered in these public communications, please let us know by sending an email to [Healthy@la.gov](mailto:Healthy@la.gov).



## Online Medicaid Provider Manual Chapter Revisions as of April 2019

Manual Chapter	Section(s)	Date of Revision(s)
Durable Medical Equipment	Table of Contents	04/25/19

## Archived Online Medicaid Provider Manual Chapter Archived as of April 2019

Manual Chapter	Section(s)	Date of Omission(s)
Durable Medical Equipment	Table of Contents	04/25/19

## Remittance Advice Corner

### Attention Ordering Providers and Providers of Laboratory Services

Effective for dates of service on or after July 1, 2019, Louisiana Medicaid has adopted the following changes to the coverage of Urine Drug Testing:

- Presumptive drug testing is limited to 24 total tests per member per calendar year. Providers are to consider the methodology used when selecting the appropriate procedure code for the presumptive testing.
- Definitive drug testing is limited to 18 total tests per member per calendar year. CPT codes 80320-80377 for individual substance(s) or metabolites will no longer be covered. Providers should instead use HCPCS codes G0480 (Drug tests, definitive...per day, 1-7 drug class(es), including metabolite(s) if performed) or G0481 (Drug tests, definitive...per day, 8-14 drug class(es), including metabolite(s) if performed) or their successors.

Testing more than fourteen definitive drug classes per day is not reimbursable.

No more than one presumptive and one definitive test will be reimbursed per day per recipient, from the same or different provider.

Information regarding this policy is forthcoming and will be found on [www.lamedicaid.com](http://www.lamedicaid.com) under the Provider Manuals link, within the *Professional Services* and *Independent Laboratory Services* manuals. Fee schedules will be updated accordingly and can be found at the appropriate link on [www.lamedicaid.com](http://www.lamedicaid.com).

Questions regarding this message and fee for service claims should be directed to DXC Technology Provider Relations at (800) 473-2783 or (225) 924-5040. Questions regarding managed care claims should be directed to the appropriate Managed Care Organization.



### Attention Providers of Laboratory Services

Effective for dates of service on or after August 1, 2019, Louisiana Medicaid will require all providers to include a valid Clinical Laboratory Improvement Amendments (CLIA) number on all claims submitted for laboratory services. Claims submitted with an absent, incorrect or invalid CLIA number will deny.

For claims submitted using the CMS-1500 form, the CLIA number will be required in block 23. Providers should refer to the *CMS 1500 Billing Instructions* under the *Billing Information* link at [www.lamedicaid.com](http://www.lamedicaid.com), where complete instructions will be provided.

Information regarding this policy change is forthcoming and will be found on [www.lamedicaid.com](http://www.lamedicaid.com) under the Provider Manuals link, within the *Professional Services* and *Independent Laboratory* manuals.

Questions regarding this message and fee for service claims should be directed to DXC Technology Provider Relations at (800) 473-2783 or (225) 924-5040. Questions regarding managed care claims should be directed to the appropriate Managed Care Organization.



**Attention Federally Qualified Health Centers (FQHC) and Rural Health Clinic (RHC) Providers**

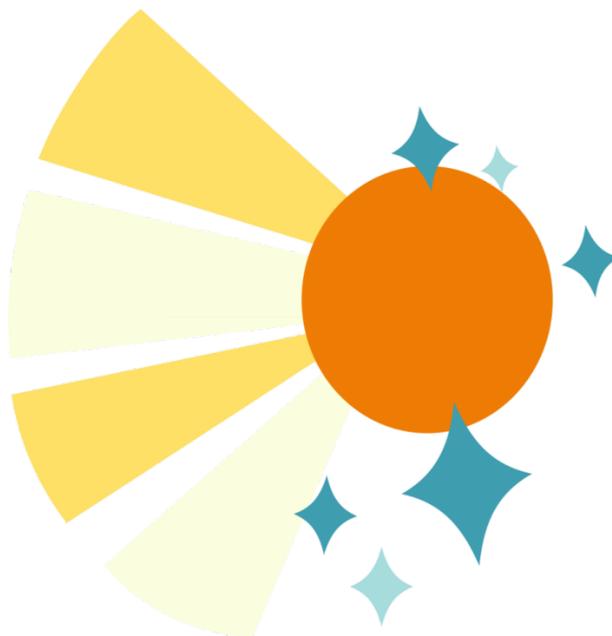
Effective April 1, 2019, and with dates of service forward, Louisiana Medicaid has established an alternative payment methodology (APM) for behavioral health services provided in FQHC and RHC facilities. All FQHC and RHC providers should review the Informational Bulletin at <http://www.ldh.la.gov/index.cfm/page/1198> for additional information regarding this change.

LDH is requesting that RHC and FQHC providers hold all behavioral health claim submissions, with dates of service beginning April 1, 2019, until further notification from LDH. This will allow DXC Technology time to prepare their systems for processing these claims. Claims submitted prior to system updates may result in denial or incorrect payment requiring submission of claim adjustments.

LDH will notify RHC and FQHC providers once the system can accept these claims.

Information regarding this change is forthcoming and will be located on [www.lamedicaid.com](http://www.lamedicaid.com) under the Provider Manuals link, within the FQHC and RHC Provider manual. An update the FQHC and RHC fee schedules is also forthcoming.

Questions regarding this notice and fee for service claims should be directed to DXC Technology Provider Relations at (800) 473-2783 or (225) 924-5040.



## For Information or Assistance, Call Us!

Provider Enrollment	(225)216-6370	General Medicaid Eligibility Hotline	1-888-342-6207
<b>Prior Authorization:</b>		MMIS Claims Processing Resolution Unit	(225) 342-3855
Home Health/EPSDT – PCS	1-800-807-1320		
Dental	1-866-263-6534 1-504-941-8206		
DME & All Other	1-800-488-6334 (225) 928-5263	MMIS/Recipient Retroactive Reimbursement	(225) 342-1739 1-866-640-3905
Hospital Pre-Certification	1-800-877-0666		
Provider Relations	1-800-473-2783 (225) 924-5040	Medicare Savings Program and Medicaid Purchase Hotline	1-888-544-7996
REVS Line	1-800-776-6323 (225) 216-(REVS)7387		
Point of Sale Help Desk	1-800-648-0790 (225) 216-6381	For Hearing Impaired  Pharmacy Hotline  Medicaid Fraud Hotline	1-877-544-9544  1-800-437-9101  1-800-488-2917