

FDA Drug Safety Communications

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FDA Drug Safety Communication Regarding Boxed Warning Update to Improve Safe Use of Benzodiazepines

On September 23, 2020, the U.S. Food and Drug Administration (FDA) released an FDA Drug Safety Communication stating that they are requiring an update to the Boxed Warning, FDA's most prominent safety warning, and requiring the addition of other information to the prescribing information for all benzodiazepine medicines. This information will describe the risks of abuse, misuse, addiction, physical dependence, and withdrawal reactions consistently across all the medicines in the class. The FDA is also requiring updates to the existing patient *Medication Guides* to help educate patients and caregivers about these risks. Other changes are also being required to several sections of the prescribing information, including to the *Warnings and Precautions*, *Drug Abuse and Dependence*, and *Patient Counseling Information* sections.

When deciding whether the benefits of prescribing a benzodiazepine outweigh the risks, healthcare professionals should consider the patient's condition and the other medicines being taken, and assess the risk of abuse, misuse, and addiction. Particular caution should be taken when prescribing benzodiazepines with opioids and other medicines that depress the central nervous system (CNS), which has resulted in serious side effects, including severe respiratory depression and death. Advise patients to seek immediate medical attention if they experience symptoms, such as difficulty breathing.

Limit the dosage and duration of each medicine to the minimum needed to achieve the desired clinical effect when prescribing benzodiazepines, alone or in combination with other medicines. Throughout therapy, monitor the patient for signs and symptoms of abuse, misuse, or addiction. If a substance use disorder is suspected, evaluate the patient and institute, or refer them for, early substance abuse treatment, as appropriate.

To reduce the risk of acute withdrawal reactions, use a gradual taper to reduce the dosage or to discontinue benzodiazepines. No standard benzodiazepine tapering schedule is suitable for all patients; therefore, create a patient-specific plan to gradually reduce the dosage, and ensure ongoing monitoring and support as needed to avoid serious withdrawal symptoms or worsening of the patient's medical condition.

Take precautions when benzodiazepines are used in combination with opioid addiction medications. Careful medication management by healthcare professionals can reduce the increased risk of serious side effects.

Healthcare professionals and patients should report side effects involving benzodiazepines to the [FDA MedWatch](#) program.

Reference: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-requiring-boxed-warning-updated-improve-safe-use-benzodiazepine-drug-class>

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FDA Drug Safety Communication Regarding Serious Problems with High Doses of the Allergy Medicine Diphenhydramine (Benadryl®)

On September 24, 2020, the U.S. Food and Drug Administration (FDA) released an FDA Drug Safety Communication warning that taking higher than recommended doses of the common over-the-counter (OTC) allergy medicine diphenhydramine (Benadryl®) can lead to serious heart problems, seizures, coma, or even death. The FDA is aware of news reports of teenagers ending up in emergency rooms or dying after participating in the “Benadryl Challenge” encouraged in videos posted on the social media application TikTok.

The FDA is investigating these reports and conducting a review to determine if additional cases have been reported. The FDA will update the public once the review is complete or if there is more information to share. The FDA also contacted TikTok and strongly urged them to remove the videos from their platform and to be vigilant to remove additional videos that may be posted.

Consumers, parents, and caregivers should store diphenhydramine and all other OTC and prescription medicines up and away and out of children’s reach and sight. FDA recommends you lock up medicines to prevent accidental poisonings by children and misuse by teens, especially when they are home more often due to the COVID-19 pandemic and may be more likely to experiment.

Healthcare professionals should be aware that the “Benadryl Challenge” is occurring among teens and alert their caregivers about it. Encourage teens and caregivers to read and follow the Drug Facts label. In the event of an overdose, healthcare professionals should attempt to determine whether a patient with a suspected overdose took diphenhydramine.

Healthcare professionals and patients are urged to report side effects involving diphenhydramine and other medicines to the [FDA MedWatch](#) program.

Reference: <https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-serious-problems-high-doses-allergy-medicine-diphenhydramine-benadryl>

New Medicaid Eligibility Group Covers COVID-19 Testing for Uninsured Patients

Per the Families First Coronavirus Response Act and the Coronavirus Aid, Relief, and Economic Security Act, Louisiana Medicaid has expanded coverage to include COVID-19 testing for uninsured individuals for the duration of the federally declared public health emergency. Coverage is limited to COVID-19 testing and related office visits for uninsured Louisiana residents. No treatment costs are covered under this program.

The new benefit is provided through Medicaid fee-for-service and not Healthy Louisiana through a managed care organization. Providers must be a Medicaid enrolled provider and must be enrolled before services are provided. Providers not enrolled as a Medicaid provider with DXC will need to complete a [temporary emergency application](#) with Medicaid’s fiscal intermediary, DXC, to be paid for testing and testing related services for the uninsured. Providers will be required to self-attest on the uninsured individual’s application to Medicaid that they are not also [billing the Department of Health and Human Services \(HHS\) or the Health Resources and Services Administration \(HRSA\)](#) for the same services. You also may not bill on any contract with the Louisiana Department of Health to provide COVID-19 testing for these patients. If Medicaid identifies other third party coverage is available (e.g., Medicare, private insurance), Medicaid will not cover the services.

For additional guidance, visit [Medicaid’s provider web page for COVID-19 testing coverage for uninsured individuals](#). The site contains billing information, a [detailed provider guide](#), frequently asked questions for providers, and the [simplified application](#) patients can fill out to determine if they are eligible for coverage.

Open Enrollment

Open Enrollment for Louisiana Medicaid enrollees is approaching. Between October 15, 2020 and November 30, 2020, enrollees can change their health plan without a qualifying reason, outside of their initial enrollment period. Please download the [Open Enrollment Informational Flyer](#) and display it in your office.

There are five health plans to choose from: Aetna, AmeriHealth Caritas, Healthy Blue, Louisiana Healthcare Connections and United Healthcare. In addition, for the first time, enrollees will have a choice between two dental plans. Previously, all Medicaid enrollees received dental coverage through one dental plan. There are two dental plans to choose from: DentaQuest and MCNA. Letters with information and instructions for choosing plans will be mailed in September to all enrollees that are included in this Open Enrollment period.

As a provider, it is important to let your patients know which plans you are accepting. **There are limitations on what you can tell an enrollee.** In general, you can inform enrollees which plans you accept, and the benefits, services and specialty care offered. However, you cannot:

- recommend one plan over another or incentivize a patient to select one plan over the other; or
- change an enrollee’s plan for him/her, or request a disenrollment on an enrollee’s behalf. These prohibitions against patient steering apply to participation in all Medicaid programs.

More details on Open Enrollment can be found on the [Informational Bulletins page](#).



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

September 4, 2020

Early Refills

During the recovery phase due to Hurricane Laura, pharmacists should use their professional judgement when determining if an early refill is appropriate. You can call the Managed Care Organizations (MCOs) and Fee-For-Service (FFS) help desks for assistance. Please see the numbers below:

Health Care Provider	Pharmacy Help Desk	Pharmacy Help Desk Phone Number
Aetna	CVS Health	(855) 364-2977
Amerihealth Caritas	PerformRx	(800) 684-5502
Fee-For-Service	DXC Technology	(800) 648-0790
Healthy Blue	CVS	(833) 236-6194
Louisiana Healthcare Connections	CVS Caremark	(800) 311-0543
UnitedHealthcare	Optum Rx	(866) 328-3108

The Louisiana State Board of Pharmacy (LABP) sent out guidance this week in reference to Hurricane Laura. Governor Edwards declared a State of Emergency for Hurricane Laura on August 21. This declaration will terminate on September 20 unless rescinded or extended. LABP developed a [resource page](#) for the Hurricane Laura emergency. [2020-0831](#) specifically gives guidance on dispensing emergency prescriptions, integrity of medication stock in

pharmacies directly impacted by hurricanes, reporting of theft or loss of controlled substances, and disposal of compromised medications in pharmacies affected by hurricanes.

The Louisiana Department of Health issued an [Informational Bulletin 20-17](#) that contains [Hurricane Laura Provider Assistance FAQs](#) and resources.



Remittance Advice Corner

Attention Louisiana Medicaid Providers:

Effective September 15, 2020, Fee-for-Service (FFS) Pharmacy Program and Managed Care Organizations (MCOs) will reimburse enrolled pharmacies for influenza vaccines and the administration of the vaccines by a pharmacist per program policy. In addition to influenza vaccines, select adult vaccines are covered as a pharmacy benefit. Please refer to lamedicaid.com for more information.

CHANGES TO DME, HOME HEALTH, PEDIATRIC DAY HEALTH CARE, REHABILITATION AND PERSONAL CARE SERVICES DUE TO HURRICANE LAURA - AUGUST 2020

Revised 09/01/2020

This policy change is effective August 25, 2020 and shall only be applicable for the following parishes: Allen, Beauregard, Calcasieu, Cameron, Grant, Jefferson Davis, Jackson, LaSalle, Lincoln, Natchitoches, Ouachita, Rapides, Sabine, Union, Vernon and Winn.

Medicaid beneficiaries who live in one of the parishes under mandatory evacuation, and who are in need of replacement equipment or supplies previously approved by Medicaid, may contact a Medicaid-enrolled durable medical equipment (DME) provider of their choice. Medicaid-enrolled providers must make a request to DXC Technology's Prior Authorization Unit; however, a new prescription and medical documentation are not required. The provider shall submit the required Prior Authorization Form (PA-01) along with a signed letter from the recipient, giving a current place of residence and stating that the original equipment or supplies were lost due to Hurricane Laura.

Beneficiaries who were approved to receive medical equipment, supplies, home health services, rehabilitation, pediatric day health care or personal care services from a provider in a parish with a mandatory evacuation that is no longer in business or unable to provide the approved equipment, supplies or services may obtain the approved items or services from a new provider of their choice. The provider must be enrolled in Medicaid. DXC Technology shall provide any guidance to the provider on the cancelation of the original authorization and issuance of a new authorization, if applicable.

All other prior authorization requests shall continue to be subject to the applicable requirements to establish medical necessity.

Questions concerning Healthy Louisiana managed care organization processes are to be directed to the appropriate MCO. Those questions related to Medicaid fee-for-service claims should be directed to DXC Technology Provider Relations at (800) 473-2783 or (225) 924-5040.

Medicaid Public Notice and Comment Procedure

As of Aug. 1, 2019, a public notice and comment period is required before certain policies and procedures are adopted. Drafts will be published on LDH's website to allow for public comment, as per HB 434 of the 2019 Regular Legislative Session. This requirement applies to managed care policies and procedures, systems guidance impacting edits and payment, and Medicaid provider manuals.

In compliance with R.S. 46:460.51(15), 460.53, and 460.54, this procedure provides for a defined term, a public notice requirement, implementation of a policy for the adoption of policies and procedures, and for related matters. Public Comments for the following policies and procedures can be left at the link below.

- Louisiana Medicaid (Title XIX) State Plan and Amendments;
- Louisiana Medicaid Administrative Rulemaking Activity;
- Medicaid Provider Manuals;
- Contract Amendments;
- Managed Care Policies & Procedures; and
- Demonstrations and Waivers.

<http://www.ldh.la.gov/index.cfm/page/3616>

Manual Chapter Revision Log

Manual Chapter	Section(s)	Date of Revision(s)
Behavioral Health Behavioral Health Services Manual Chapter	Appendix E-1 – Evidence Based Practices (EBPs) - Assertive Community Treatment	09/15/20
Professional Services Professional Services Manual Chapter	5.1 – Covered Services - Chiropractic 5.1 – Covered Services - Advance Practice Registered Nurses 5.1 – Covered Services - Hyperbaric Oxygen Therapy 5.1 – Covered Services - "Incident To" Services 5.1 – Covered Services – Podiatry	09/08/20
	5.1 – Telemedicine	09/09/20
	5.1 – Covered Services – Clinical Trials Table of Contents	09/22/20 09/23/20
	5.1 – Genetic Testing	09/29/20

For Information or Assistance, Call Us!

Provider Relations	1-800-473-2783 (225) 294-5040 Medicaid Provider Website	General Medicaid Eligibility Hotline	1-888-342-6207
Prior Authorization: Home Health/EPSDT – PCS	1-800-807-1320	MMIS Claims Processing	(225) 342-3855
Dental	1-855-702-6262 MCNA Provider Portal	Resolution Unit MMIS Claims Reimbursement	
DME & All Other	1-800-488-6334 (225) 928-5263	MMIS/Recipient Retroactive Reimbursement	(225) 342-1739 1-866-640-3905 MMIS Claims Reimbursement
Hospital Pre-Certification	1-800-877-0666		
REVS Line	1-800-776-6323 (225) 216-(REVS)7387 REVS Website	Medicare Savings	1-888-544-7996 Medicare Provider Website
Point of Sale Help Desk	1-800-648-0790 (225) 216-6381	For Hearing Impaired	1-877-544-9544
		Pharmacy Hotline	1-800-437-9101 Medicaid Pharmacy Benefits
		Medicaid Fraud Hotline	1-800-488-2917 Report Medicaid Fraud

