

FDA Drug Safety Communication Regarding Side Effects with Fluoroquinolone Antibiotics

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On July 10, 2018, the Food and Drug Administration (FDA) released a drug safety communication regarding side effects of fluoroquinolone antibiotics. The FDA is strengthening the current warnings in the prescribing information that fluoroquinolone antibiotics may cause significant decreases in blood sugar and certain mental health side effects. The low blood sugar levels can result in serious problems, including coma, particularly in older people and patients with diabetes who are taking medicines to reduce blood sugar. These changes are being made because the FDA's recent review found reports of life-threatening low blood sugar side effects and reports of additional mental health side effects.

The FDA is requiring these updates in the drug labels and to the patient Medication Guides for the entire class of fluoroquinolones. This affects only the fluoroquinolone formulations taken by mouth or given by injection. Blood sugar disturbances, including high blood sugar and low blood sugar, are already included as a warning in most fluoroquinolone drug labels; however, the FDA is adding that low blood sugar levels, also called hypoglycemia, can lead to coma. Across the fluoroquinolone antibiotic class, a range of mental health side effects are already described under *Central Nervous System Effects* in the *Warnings and Precautions* section of the drug label, which differed by individual drug. The new label changes will make the mental health side effects more prominent and more consistent across the systemic fluoroquinolone drug class. The mental health side effects to be added to or updated across all the fluoroquinolones are disturbances in attention, disorientation, agitation, nervousness, memory impairment, and serious disturbances in mental abilities called delirium.

Healthcare professionals should be aware of the potential risk of hypoglycemia sometimes resulting in coma, occurring more frequently in the elderly and those with diabetes taking an oral hypoglycemic medicine or insulin. Alert patients of the symptoms of hypoglycemia and carefully monitor blood glucose levels in these patients, and discuss with them how to treat themselves if they have symptoms of hypoglycemia. Inform patients about the risk of psychiatric adverse reactions that can occur after just one dose. Stop fluoroquinolone treatment immediately if a patient reports any central nervous system side effects, including psychiatric adverse reactions, or blood glucose disturbances and switch to a non-fluoroquinolone antibiotic if possible. Stop fluoroquinolone treatment immediately if a patient reports serious side effects involving the tendons, muscles, joints, or nerves, and switch to a non-fluoroquinolone antibiotic to complete the patient's treatment course. Healthcare professionals should not prescribe fluoroquinolones to patients who have other treatment options for acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, and uncomplicated urinary tract infections because the risks outweigh the benefits in these patients.

The FDA continues to monitor and evaluate the safety and effectiveness of medicines after they are approved. In the case of fluoroquinolones, the FDA reviewed reports of submitted cases and the published medical literature of apparently

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healthy patients who experienced serious changes in mood, behavior, and blood sugar levels while being treated with systemic fluoroquinolones. The FDA is requiring several changes to the *Warnings and Precautions* section in the fluoroquinolones drug labels. Details will be added describing hypoglycemic coma, and the new subheading “Psychiatric Adverse Reactions” found under *Central Nervous System Effects* will help clarify and identify the mental health side effects.

Reference: <https://www.fda.gov/Drugs/DrugSafety/ucm611032.htm>

Pharmacy Facts

Program Updates from Louisiana Medicaid

Pharmacy facts, which includes program updates from Louisiana Medicaid, can also be found online at: <http://ldh.la.gov/index.cfm/page/3036>.

Single Preferred Drug List Update

Louisiana Medicaid recently started its rulemaking process for the transition to a Single Preferred Drug List (PDL) with publication of a notice of intent (NOI). The NOI is included in the August 20, 2018 edition of the Louisiana Register, found [here](#).

As part of the ongoing Single PDL development process, Medicaid has worked to ensure an open dialogue with pharmacists. The agency recently provided direct response to two written inquiries – one from the Louisiana Independent Pharmacies Association (LIPA) and another from a single, independent pharmacist. The original letter from LIPA can be found [here](#), and Medicaid’s response can be viewed [here](#). The Medicaid response to Hollier’s Family Pharmacy in Breaux Bridge can be viewed [here](#).

As stated in previous Pharmacy Facts editions, the agency is pursuing the Single PDL as a means of improving the experience of Medicaid recipients, pharmacists and prescribing providers who interact with the Medicaid pharmacy program. We appreciate your interest in this development and will continue to provide updates on it through *Pharmacy Facts*: www.ldh.la.gov/pharmacyfacts.

Cost of Dispensing (COD) Survey Update

There is a minor delay in the release of results from the Cost of Dispensing (COD) Survey. As reported in the [June 21 edition of Pharmacy Facts](#), Medicaid had hoped to share results in August. Mercer, the contractor that both conducted the survey and is compiling the report, has identified issues with some of the submissions, which necessitated corrections. Medicaid anticipates the draft results will be available in September. Please watch for future Pharmacy Facts to announce the report’s release.



Implementation of New Medicaid Eligibility System Delayed

The implementation of LaMEDS, the state’s new Medicaid eligibility and enrollment system, is being delayed with a tentative target date of November. LaMEDS includes a Provider Portal, which replaces the current Facility Notification System (FNS) and allows provider representatives, hospital representatives, and Support Coordination Agency (SCA) reps to submit forms for Medicaid to process. All current representatives authorized to submit forms in FNS will be required to reregister in the new system. Announcements will be posted on the current FNS site in advance of Go Live. Please send all questions to MSMcomm@la.gov

Healthy Louisiana Open Enrollment Closed

The Healthy Louisiana open enrollment period closed July 31. Confirmation letters have been mailed to members with changes effective on Sept. 1.

The managed care organization (MCO) Continuity of Care provisions remain applicable, and the MCO shall provide continuation of such services for up to 90 calendar days or until the member is reasonably transferred without interruption of care, whichever is less, including specialized behavioral health.

As a reminder, all health care providers delivering services to Louisiana Medicaid and LaCHIP recipients enrolled in MCOs are welcome to inform their patients of the plans they have chosen to participate with, but Louisiana Medicaid has strict prohibitions against patient steering.

The requirements below must be strictly observed by all Medicaid managed care providers:

- Providers may inform their patients of all MCO networks in which they participate, and can inform patients of the benefits, services and specialty care services offered through the MCOs in which they participate.
- Providers are not allowed to disclose only some of the MCOs in which they participate. Disclosure of MCO participation must be all or nothing.
- Providers can display signage, provided by the MCO, at their location indicating which MCOs are accepted there, but must include all MCOs in which they participate in this signage.

Providers MAY NOT RECOMMEND one MCO over another MCO and MAY NOT OFFER patients incentives for selecting one MCO over another. Providers may allow use of office equipment (phones, computers, etc.) for member-directed enrollment or disenrollment purposes.

- Patients who need assistance with their MCO services should call the Member Services Hotline for the MCO in which they are enrolled, and those who wish to learn more about the different MCOs should contact the Healthy Louisiana Enrollment Broker at 1-855-229-6848 to receive assistance in making an MCO decision.
- Under NO CIRCUMSTANCES is a provider allowed to change a member's MCO or request an MCO reassignment on a member's behalf. Disenrollment requests must be initiated and approved by the member. These prohibitions against patient steering apply to participation in the Medicaid managed care and the legacy Medicaid programs.

For pharmacies enrolled as Louisiana Medicaid providers, or contracted with any MCO's pharmacy benefit manager, the same steering prohibitions stated above apply to communications with Medicaid/Medicaid managed care patients.

If a provider or MCO is found to have engaged in patient steering, they may be subject to sanctions such as, but not limited to, monetary penalties, loss of linked patients and/or excluded from enrollment in Medicaid/Medicaid managed care network opportunities.

Refer to [Informational Bulletin 12-31](#) for more information.



Home Health Program: Federal and State Changes

Louisiana Medicaid is updating the Home Health Services program requirements in accordance with federal regulations that are found at 42 CFR 440.70. Although the changes mandated by the Centers for Medicare and Medicaid Services (CMS) apply to all Medicaid managed care organizations (MCOs), changes to MCO systems and claims processing requirements for Home Health Services are MCO-specific. For questions regarding MCO updates, please contact the appropriate MCO.

Effective September 1, 2018, the following requirements apply to services provided to all Medicaid recipients, whether enrolled in an MCO or receiving services through Legacy Medicaid:

- Recipients ages 21 and older are no longer restricted to an annual limit of 50 visits.
- A face-to-face visit between the patient and the physician or an allowed Non-Physician Provider (NPP) must occur no more than 90 days prior to admission to the home health agency.
- The orders for home health services must be written by the recipient's physician.
- Medicaid recipients do not have to be homebound in order to receive home health services, in accordance with 440.70(c)(1). Such services can be provided in a recipient's residential setting, which is defined as any non-institutional setting in which normal life activities take place.
 - Services cannot be provided in a hospital, nursing facility, or ICF for individuals with intellectual disabilities, except as allowed in 42 CFR 440.70(c).
- Medical supplies, equipment and appliances suitable for use in any setting in which normal life activities take place are provided in accordance with physician review and other requirements as specified in 42 CFR 440.70(b)(3).

Specific information on the face-to-face requirement from CMS can be found in the final rule [here](#).

Effective September 1, 2018, the following processes must be followed by providers rendering services to Legacy Medicaid recipients:

- All home health skilled nursing and nursing aide services for Legacy Medicaid recipients ages 21 and older will require prior authorization by Molina before services can begin.
 - All Initial and Reconsideration requests for prior authorization must be submitted using the Electronic-PA (e-PA) process. The e-PA is a web application that provides a secure, web-based tool for providers to submit prior authorization requests and to view the status of previously submitted requests. The PA type for "Home Health Skilled Nursing and Home Health Aide Services for Ages 21 or Older" is PA type 18 (PA-18).
 - For more information regarding e-PA, visit www.lamedicaid.com or call the Molina Prior Authorization Home Health Unit at 1-800-807-1320, then press Option 1.
- The Face-to-Face Encounter (F2F) form must be submitted with the prior authorization request for Legacy Medicaid adult home health recipients.
 - A face-to-face encounter must be documented in the beneficiary's file for recipients aged 0-20 years.
- The Home Health Policy/Guidelines for Skilled Nursing and Nursing Aide Services for Over 21 Years of Age and the prior authorization process is located [here](#).
- The Face-to-Face (F2F) Encounter form is located [here](#).

Physical, Occupational and Speech Therapy, including audiology services, continue to be covered services in the home health program.

For questions regarding these changes and/or Legacy Medicaid home health prior authorizations, please contact Michelle Renée at (225) 342-6888.

Online Medicaid Provider Manual Chapter Revisions as of August 1, 2018

Manual Chapter	Section(s)	Date of Revision(s)
Federally Qualified Health Centers	Table of Contents 22.4 Reimbursement Appendix A Contact Information Appendix E FQHC Services Facility Survey	08/21/18
Hospital Services	Table of Contents 25.0 Overview 25.1 Provider Requirements 25.2 Inpatient Service 25.3 Outpatient Services 25.5 Reserved 25.6 Prior Authorization 25.7 Reimbursement 25.8 Claims Related Information Appendix A Forms and Links Appendix B Contact/Referral Information	08/23/18

Archived Online Medicaid Provider Manual Chapter Revisions as of August 1, 2018

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Remittance Advice Corner

Attention Providers of Home Health Services:

Louisiana Medicaid is updating the Home Health Services program requirements for Medicaid beneficiaries, in accordance with 42 CFR 440.70. This remittance advice specifically address fee-for-service Medicaid beneficiaries who receive home health services. Updates to Medicaid managed care organization (MCO) related systems and claims processing changes are plan specific and are the responsibility of each MCO. For questions regarding MCO updates, please contact the appropriate MCO.

Effective September 1, 2018 the following requirements must be followed:

- All home health skilled nursing and nursing aide services for Legacy Medicaid beneficiaries ages 21 and older will require prior authorization before services can begin.
- A face-to-face visit between the patient and the physician or an allowed Non-Physician Provider (NPP) must occur no more than 90 days prior to admission to the home health agency.
- The face-to-face encounter form must be submitted with the prior authorization request for adult home health beneficiaries.
- A face-to-face encounter must be documented in the beneficiary's file for recipients aged 0-20 years.
- The orders for home health services must be written by the recipient's physician.
- Medicaid recipients do not have to be homebound in order to receive home health services, in accordance with 440.70(c)(1). Such services can be provided in a recipient's residential setting, which is defined as any non-institutional setting in which normal life activities take place.
 - Services cannot be provided in a hospital, nursing facility, or ICF for individuals with intellectual disabilities, except as allowed in 42 CFR 440.70(c).
- Medical supplies, equipment and appliances suitable for use in any setting in which normal life activities take place are provided in accordance with physician review and other requirements as specified in 42 CFR 440.70(b)(3).

Providers for Legacy Medicaid recipients must submit all Initial and Reconsideration requests for prior authorization using the Electronic-PA (e-PA) process. The e-PA is a web application that provides a secure, web-based tool for providers to submit prior authorization requests and to view the status of previously submitted requests. The PA type for "Home Health Skilled Nursing and Home Health Aide Services for Ages 21 or Older" is PA type 18 (PA-18). For more information regarding e-PA, visit www.lamedicaid.com or call the Molina Prior Authorization Home Health Unit at 1-800-807-1320, then press Option 1.

The Home Health Policy/Guidelines for Skilled Nursing and Nursing Aide Services for Over 21 Years of Age and the prior authorization process will be located at:

http://www.lamedicaid.com/provweb1/ProviderTraining/packets/2018ProviderTraining/2018PT_Index.htm.

The Face-to-Face (F2F) Encounter form will be located at:

<http://www.lamedicaid.com/provweb1/Forms/forms.htm>.

Physical, Occupational and Speech Therapy, including audiology services, continue to be covered services in the home health program.

Additionally, beneficiaries ages 21 and older (adults) are no longer restricted to an annual limit of 50 visits

Specific information on the face-to-face requirement from CMS can be found in their final rule at this link:

<https://www.federalregister.gov/documents/2016/02/02/2016-01585/medicaid-program-face-to-face-requirements-for-home-health-services-policy-changes>.

For questions regarding this message and/or fee for service prior authorizations, please contact the Molina Prior Authorization Home Health Unit at 1-800-807-1320, then press Option 1.



Attention Louisiana Medicaid Providers:

Effective September 4, 2018, the Louisiana Medicaid Fee for Service (FFS) Pharmacy Program and Medicaid Managed Care Organizations (Aetna, AmeriHealth Caritas, Healthy Blue, Louisiana Healthcare Connections, and United Healthcare) will implement new Point of Sale (POS) edits for opioids in addition to current opioid prescription policy. Please refer to www.lamedicaid.com for more information.



Attention Louisiana Medicaid Providers:

Effective September 4, 2018, the Louisiana Medicaid Fee for Service (FFS) Pharmacy Program and Medicaid Managed Care Organizations (Aetna, AmeriHealth Caritas, Healthy Blue, Louisiana Healthcare Connections, and United Healthcare) will implement therapeutic duplication (TD) edits at Point of Sale (POS) for Short-Acting and Long-Acting Attention Deficit Disorder (ADD) and Attention Deficit Hyperactivity Disorder (ADHD) medications. Please refer to www.lamedicaid.com for more information.



Attention Louisiana Medicaid Providers:

Effective September 4, 2018, the Louisiana Medicaid Fee for Service (FFS) Pharmacy Program will implement edits at Point of Sale (POS) for naltrexone injection (Vivitrol®). Please refer to www.lamedicaid.com for more information.



Attention Louisiana Medicaid Providers:

Effective September 18, 2018, Fee for Service (FFS) Medicaid and Managed Care Organizations (Aetna, AmeriHealth Caritas, Healthy Blue, Louisiana Healthcare Connections, and United Healthcare) will implement edits at Point of Sale (POS) for lurasidone (Latuda®). Please refer to www.lamedicaid.com for more information.



Attention Louisiana Medicaid Providers:

Effective September 4, 2018, Fee for Service (FFS) Medicaid and Managed Care Organizations (Aetna, AmeriHealth Caritas, Healthy Blue, Louisiana Healthcare Connections, and United Healthcare) will implement edits at Point of Sale (POS) for buprenorphine extended-release injection (Sublocade®). Please refer to www.lamedicaid.com for more information.



Attention Louisiana Medicaid Providers:

Effective August 28, 2018, the Louisiana Medicaid Fee for Service (FFS) Pharmacy Program will implement Point of Sale (POS) diagnosis code requirements for ocrelizumab (Ocrevus®). Please refer to www.lamedicaid.com for more information.



For Information or Assistance, Call Us!

Provider Enrollment	(225)216-6370	General Medicaid Eligibility Hotline	1-888-342-6207
Prior Authorization:		MMIS Claims Processing Resolution Unit	(225) 342-3855
Home Health/EPSTD – 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	1-877-544-9544
		Pharmacy Hotline	1-800-437-9101
		Medicaid Fraud Hotline	1-800-488-2917