Louisiana Medicaid | Provider UPDATE

Volume 40, Issue 3 | February 2024

## Welcome

Welcome to the March issue of the **Louisiana Medicaid Provider Update** newsletter. This month holds the first day of spring and Daylight Savings Time. Although there is a change of season and a spring forward in time, one thing that remains consistent is the strength and resiliency of healthcare professionals like you.

As a valued provider, we appreciate your continued commitment to providing the highest quality care to the Louisiana's Medicaid population.

## Meet Undersecretary Michael Harrington

**Michael Harrington,** LDH's new undersecretary, is a former chief executive officer/chief operating officer of adult/pediatric tertiary and community health services including post-acute services.

With more than 25 years of service in for-profit and nonprofit health systems, his passion is developing reliable processes that engages people, process, technology and culture to improve patient and staff safety while balancing efficiency and effectiveness.

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## FDA Drug Safety Alert: FDA Adds *Boxed Warning* for Increased Risk of Severe Hypocalcemia in Patients with Advanced Chronic Kidney Disease Taking Osteoporosis Medicine Prolia (Denosumab)

*Compiled by:*
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In November of 2022, the U.S. Food and Drug Administration (FDA) announced that they were investigating the risk of severe hypocalcemia with serious outcomes, including hospitalization and death, in patients with advanced kidney disease on dialysis treated with the osteoporosis medicine Prolia (denosumab). When the FDA first approved Prolia, they required the manufacturer, Amgen, to conduct a long-term safety study in women with postmenopausal osteoporosis and men with osteoporosis. As of November 2022, the FDA review of interim results from the ongoing safety study of Prolia suggested an increased risk of hypocalcemia, or low calcium levels in the

blood, in patients with advanced kidney disease. Preliminary results from a separate internal FDA study further investigating the risk of hypocalcemia in dialysis patients treated with Prolia suggested that these patients are at substantial risk for severe and symptomatic hypocalcemia, including hospitalization and death.

**On January 19, 2024, the FDA issued an FDA Drug Safety Communication stating that they added a *Boxed Warning*, the FDA's most prominent warning, to the Prolia prescribing information about the significant risk of developing severe hypocalcemia in patients with advanced chronic kidney disease (CKD).**

Based on a completed FDA review of available information, the FDA has concluded that the osteoporosis medicine Prolia (denosumab) increases the risk of severe hypocalcemia in patients with advanced CKD, particularly patients on dialysis. Severe hypocalcemia appears to be more common in patients with CKD who also have a condition known as mineral and bone disorder (CKD-MBD). In patients with advanced CKD taking Prolia, severe hypocalcemia resulted in serious harm, including hospitalization, life-threatening events, and death. As a result, the FDA revised the Prolia prescribing information to include a new *Boxed Warning* **(**also known as a Black Box Warning**)** communicating this increased risk.

The FDA completed an evaluation to assess the risk of developing severe hypocalcemia with Prolia in patients with advanced CKD, including patients on dialysis. The evaluation primarily consisted of studies from the Centers for Medicare & Medicaid Services (CMS). The results showed a significant increase in the risk of developing severe hypocalcemia with Prolia treatment compared to another class of osteoporosis medicines called bisphosphonates. The FDA analysis found that most of the severe hypocalcemia events occur 2 to 10 weeks following each Prolia injection, with the greatest risk for hypocalcemia occurring during Weeks 2 to 5. Severe hypocalcemia can be asymptomatic or may present with symptoms that include confusion, seizures, irregular heart rhythm, fainting, face twitching, uncontrolled muscle spasms, or weakness, tingling, or numbness in parts of the body.

The FDA also reviewed 25 cases submitted to the FDA through the FDA Adverse Event Report System (FAERS) database from July 2010 through May 2021, describing patients with CKD, some of whom were on dialysis, who experienced complications of severe hypocalcemia after starting Prolia treatment including arrhythmias and other signs or symptoms associated with severe hypocalcemia such as confusion, seizures, face twitching, and muscle spasms or weakness.

The FDA added a *Boxed Warning* to the Prolia prescribing information about the significant risk of developing severe hypocalcemia in patients with advanced CKD. This warning and new labeling contains information to help reduce this risk, including appropriate patient selection for Prolia treatment, increased monitoring of blood calcium levels, and other strategies. The FDA also added this updated information to the patient *Medication Guide* and the Prolia Risk Evaluation and Mitigation Strategy (REMS), a drug safety program required by FDA to help ensure that Prolia's benefits outweigh its risks.

**What Should Health Care Professionals Do?**

It is important that the appropriateness of Prolia treatment in patients with advanced CKD be determined by a health care professional with expertise in the diagnosis and management of CKD-MBD including renal osteodystrophy, a complication that weakens bone. Treating bone disease in patients with advanced and dialysis-dependent CKD is challenging because of the difficulty in diagnosing and confirming the underlying altered bone metabolism responsible for the low bone mass and increased fracture risk, and the complex benefit-risk considerations of approved osteoporosis treatments in this population.

Prolia is a prescription medicine approved in June 2010 to treat postmenopausal women with osteoporosis at high risk for bone fracture. Prolia was later approved to treat men with osteoporosis, glucocorticoid induced osteoporosis, bone loss in men receiving androgen deprivation therapy for prostate cancer and in women receiving aromatase inhibitor therapy for breast cancer. Prolia works by blocking a protein called RANK (receptor activator of nuclear factor kappa beta) and helps prevent bone cells called osteoclasts from breaking down bone in the body. A health care professional administers Prolia by injection

Before prescribing Prolia, health care professionals should assess their patients' kidney function. For patients with advanced CKD, particularly those on dialysis, health care professionals should consider the risk of severe hypocalcemia with Prolia in the context of other available treatments for osteoporosis. If Prolia is still being considered for these patients, for initial or continued use, health care professionals should check their calcium blood levels and assess them for evidence of CKD-MBD.

Proper management of CKD-MBD, correction of hypocalcemia, and supplementation with calcium and activated vitamin D prior to Prolia treatment is expected to decrease the risk of developing severe hypocalcemia and any associated complications. Following Prolia administration, close monitoring of blood calcium levels and prompt management of hypocalcemia is essential to prevent complications such as seizures or arrhythmias. Prescribers should advise patients to promptly report symptoms that could be consistent with hypocalcemia, such as confusion, seizures, irregular heart rhythm, fainting, face twitching, uncontrolled muscle spasms, or weakness, tingling, or numbness in parts of the body.

**Steps to help reduce the risk of severe hypocalcemia include the following:**

- Involving a health care professional with expertise in the diagnosis and management of CKD-MBD, such as a nephrologist, when determining the appropriateness of initiating and continuing Prolia in patients with advanced CKD.
- Considering whether Prolia's benefits are expected to outweigh the risks in patients with advanced CKD based on patient selection and risk factors for hypocalcemia: assess kidney function, identify evidence of CKD-MBD, and check blood calcium levels.
- Managing CKD-MBD, correcting hypocalcemia, and supplementing with calcium and activated vitamin D prior to and during Prolia treatment may decrease the risk of severe hypocalcemia and any associated complications.
- Following Prolia administration, close monitoring of serum calcium levels and prompt management of severe hypocalcemia is critical to reduce the risk of complications such as seizures and arrhythmias.

**References**

FDA investigating risk of severe hypocalcemia in patients on dialysis receiving osteoporosis medicine Prolia (denosumab) | FDA 11/22/2022
FDA adds Boxed Warning for increased risk of severe hypocalcemia in patients with advanced chronic kidney disease taking osteoporosis medicine Prolia (denosumab) | FDA 1/19/2024

# Did You Know: Provider to Provider Consultation Line

PPCL

PROVIDER TO PROVIDER CONSULTATION LINE

Pediatric and Perinatal Mental Health Support

The Louisiana Provider-to-Provider Consultation Line (PPCL) is a no-cost provider-to-provider telephone consultation and education program to help pediatric and perinatal health care providers address their patients' behavioral and mental health needs.

**How Does PPCL Work?**

- Mental Health Consultants are available 8:00 am to 4:30 PM, Monday through Friday.
- Speak to a Resource Specialist for resource and referral information.
- For clinical questions, including questions regarding psychiatric medications, you will be connected with a psychiatrist
- Receive a written summary of your consultation
- We can also connect with you via telehealth, e-mail, or submitted requests by clicking here

**Call us at (833)721-2881** or email us at ppcl@la.gov.

**Stay connected!** It takes about 2 minutes to enroll in PPCL. Enrolling helps us contact you, ensures we have the data our funder (HRSA) needs, and gives us information about what our partners need.

**Missed our presentations?** Click on the links to view our Perinatal Mental Health webinars or the Pediatric Mental Health TeleECHO recordings.

**Website and Resources:**
Check out our Web site here and share with colleagues. We look forward to hearing from you soon!

# Practical Communication Tool: Building Bridging Statements

PUBLIC HEALTH COMMUNICATIONS COLLABORATIVE

## Building Bridging Statements

A Practical Communications Tool for Acknowledging Tough Public Health Questions and Building Trust

Public health communicators play a vital role in saving lives and keeping people healthy by focusing on the most important, timely, and credible information available. Bridging statements are an effective communication tool to stay grounded in core messages and build trust with fact-based communications.

### Bridging Statements: Getting Back to the Core Message

Bridging is a tool that can help you answer questions in a way that conveys your most important fact-based messaging and corrects misinformation. Bridging statements are phrases that help you acknowledge the question, briefly respond, and then convey what you want people to know. Here are some examples of bridging statements:

*This is an evolving issue, but what is clear right now is...*

*I'm hearing that question a lot, and what I want people to take away is...*

*I understand your concern, but what we know is...*

*I know that this has been challenging, but the bottom line is...*

### Examples of Bridging Statements to Answer Tough Public Health Questions:

**Why aren't public health officials doing more to stop new variants from spreading?**

**A:** ***This is an evolving issue, but what is clear right now is*** as long as COVID-19 spreads, new variants are expected. Variants emerge through naturally occurring mutations in viruses. For example, the flu virus mutates often, which is why doctors recommend an updated flu vaccine each year. Getting an updated COVID-19 vaccine decreases the likelihood you will get sick from emerging variants and makes it less likely you will need hospitalization or die if you get infected.

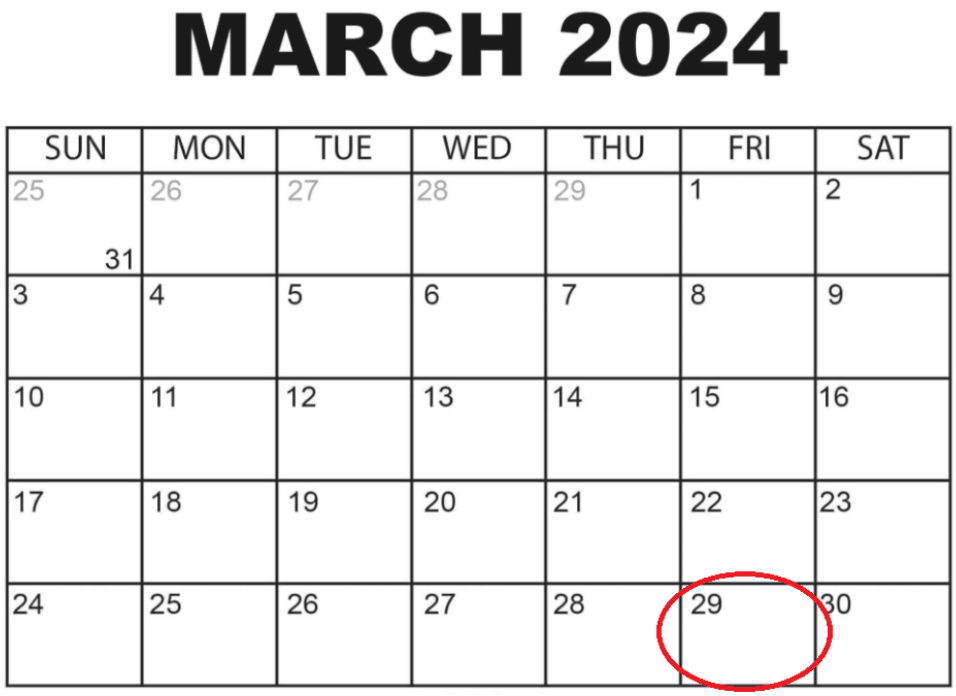
**I'm trying to get pregnant and I've seen social media videos claiming that vaccines could cause permanent health issues. Is this true?**

**A:** ***I understand your concern, but what we know is*** there is no evidence that fertility, pregnancy, or development is impacted by vaccines. It's also inaccurate to claim that vaccines increase the likelihood of pregnancy risks or complications. Vaccination is recommended for anyone who is pregnant, breastfeeding, or trying to get pregnant. Vaccines provide protective antibodies to both the pregnant person and the baby. While severe vaccination reactions are extremely rare, they can cause long-term health issues.

For additional resources and fact-based messaging guidance, visit PublicHealthCollaborative.org.

## State Office Holiday Closure

The Louisiana Department of Health will be closed in observance of Good Friday on March 29, 2024.




## Remittance Advice Corner

**SFY23 Voids of NCCI MUE OPH and DME Claims in December 19, 2023 Claim Cycle**

Louisiana Medicaid has processed administrative voids in the December 19, 2023 payment cycle for fee-forservice outpatient hospital (OPH) and DME claims that originally paid from July 1, 2022 through March 31, 2023 because they were not edited with the National Correct Coding Initiative (NCCI) Medically Unlikely Edits (MUE).

The voided OPH and DME claims were included in the June 27, 2023 recycle where they were reprocessed with EOB 809 (CCI: Units of service exceeds medically unlikely edit). However, the recycle did not correctly offset the original payment.

Questions regarding this message and fee-for-service claims are to be directed to Gainwell Technologies Provider Relations at (800) 473-2783 or (225) 924-5040.

**1099 Notice**

Louisiana Medicaid 2023 1099's will be distributed by U.S. Mail on or before January 31, 2024. Electronic copies are now available for download by going to the Louisiana Medicaid website, www.lamedicaid.com, Secure Portal, application link, Online 1099. If replacement copies or additional copies are needed, providers must print them from the website. If you feel there is an error on your 1099, please contact Gainwell Provider Enrollment at 225-216-6370. Prior year 1099's will be stored in the archive on www.lamedicaid.com.

# Louisiana Medicaid Updates and Authorities


**Keep up to date with all provider news and updates on the Louisiana Department of Health website:**
**Health Plan Advisories | La Dept. of Health**
**Informational Bulletins | La Dept. of Health**

**Louisiana Medicaid State Plan amendments and Rules are available at**
**Medicaid Policy Gateway | La Dept. of Health**

# Manual Chapter Revision Log

A recent revision has been made to the following Medicaid Provider Manual chapters. Providers should review the revisions in their entirety at www.lamedicaid.com under the "Provider Manual" link:

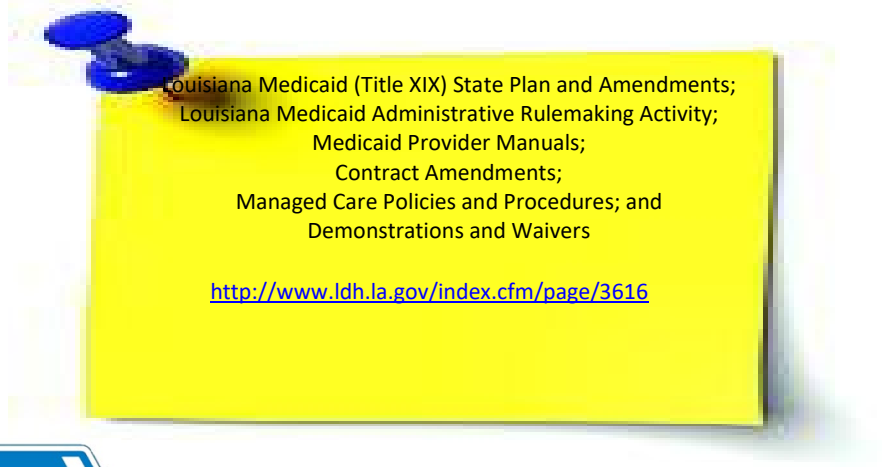
| Manual Chapter | Section(s) | Date of Revision(s) |
|---|---|---|
| Behavioral Health | • Section 2.2 – Bed Based Services – Crisis Stabilization for Adults<br>• Section 2.3 – Outpatient Services – Mental Health Rehabilitation (MHR) Services<br>• Appendix F – CSoC Wraparound | 02/05/24<br>02/26/24 |
| Community Choices Waiver (CCW) | • Section 7.2 – Self-Direction Option<br>• Section 7.3 – Beneficiary Requirements<br>• Section 7.4 – Beneficiary Rights and Responsibilities<br>• Section 7.11 – Support Coordination<br>• Section 7.12 – Organized Health Care Delivery System<br>Appendix E – Glossary | 02/06/24 |
| Adult Day Health Care (ADHC) | • Section 9.1 – Covered Services<br>• Section 9.2 – Beneficiary Requirements<br>• Section 9.3 – Beneficiary Rights and Responsibilities<br>• Section 9.4 – Service Access and Authorization<br>• Section 9.5 – Provider Requirements<br>• Section 9.6 – Record Keeping<br>• Section 9.9 – Incidents, Accidents, and Complaints<br>• Section 9.10 – Support Coordination<br>Appendix D – Glossary | 02/09/24 |
| Medical Transportation | • Section 10.3 – NEMT – Provider Requirements<br>Section 10.8 – Ambulance – Emergency Ambulance Transportation | 02/16/24 |
| Children's Choice (CC) Waiver | • Section 14.0 – Overview<br>• Section 14.1 – Covered Services<br>• Section 14.2 – Beneficiary Requirements<br>• Section 14.3 – Rights and Responsibilities<br>• Section 14.4 – Service Access and Authorization<br>• Section 14.5 – Provider Requirements<br>• Section 14.7 – Record Keeping<br>• Section 14.10 – Incidents, Accidents, and Complaints<br>• Section 14.11 – Support Coordination<br>• Section 14.12 – Self-Direction Option<br>Appendix B – Glossary | 02/23/24 |

| Manual Chapter | Section(s) | |
|---|---|---|
| Free-Standing End Stage Renal Disease (ESRD) | Section 17.1 – Covered Services | 02/23/24 |
| New Opportunities Waiver (NOW) | • Section 32.1 – Covered Services<br>Appendix E – Billing Codes | 02/06/24 |
| Residential Options Waiver (ROW) | • Table of Contents<br>• Section 38.0 – Overview<br>• Section 38.1 – Covered Services<br>• Section 38.2 – Self-Direction Option<br>• Section 38.6 – Provider Requirements<br>Appendix E – Billing Codes | 02/14/24 |

## 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 may be submitted at the link below.




### Useful Links

- Louisiana Medicaid Informational Bulletins – https://ldh.la.gov/page/1198
- Subscribe to Informational Bulletin Updates by Email - https://ldh.la.gov/index.cfm/communication/signup/3
- Pharmacy Facts Newsletter– https://ldh.la.gov/page/3036
- Louisiana Medicaid COVID-19 Provider Guidance - https://ldh.la.gov/page/3872

# Provider FAQs

1. ***Where is there a listing of Parish Office phone numbers?***
2. ***If a recipient comes back with a retroactive Medicaid card, is the provider required to accept the card?***
3. ***Does a recipient's 13-digit Medicaid number change if the CCN changes?***
4. ***Are State Medicaid cards interchangeable? If a recipient has a Louisiana Medicaid card, can it be used in other states?***
5. ***Can providers request a face-to-face visit when we have a problem?***
6. ***For recipients in Medicare HMOs that receive pharmacy services, can providers collect the Medicaid pharmacy co-payment?***
7. ***Do providers have to accept the Medicaid card for prior services if the recipient did not inform us of their Medicaid coverage at the time of services?***
8. ***Who should be contacted if a provider is retiring?***
9. ***If providers bill Medicaid for accident-related services, do they have to use the annotation stamp on our documentation?***
10. ***What if a Lock-In recipient tries to circumvent the program by going to the ER for services?***
11. ***Does the State print a complete list of error codes for provider use?***
12. ***If providers do not want to continue accepting Medicaid from an existing patient, can they stop seeing the patient?***

# For Information or Assistance, Call Us!


### General Medicaid Eligibility Hotline
1-888-342-6207

### Point of Sale Help Desk
1-800-648-0790
(225) 216-6381

### Provider Relations
1-800-473-2783
(225) 294-5040
Medicaid Provider Website

### MMIS Claims Processing Resolution Unit
(225) 342-3855
MMIS Claims Reimbursement

### Prior Authorization:

#### Home Health/EPSDT – PCS - Dental
1-800-807-1320
1-855-702-6262
MCNA Provider Portal

#### DME and All Other
1-800-488-6334
(225) 928-5263

### MMIS/Recipient Retroactive Reimbursement
(225) 342-1739
1-866-640-3905
MMIS Claims Reimbursement

### Medicare Savings
1-888-544-7996
Medicare Provider Website

### Hospital Pre-Certification
1-800-877-0666

### For Hearing Impaired
1-877-544-9544

### REVS Line
1-800-776-6323
(225) 216-(REVS)7387
REVS Website

### Pharmacy Hotline
1-800-437-9101
Medicaid Pharmacy Benefits

### Medicaid Fraud Hotline
1-800-488-2917
Report Medicaid Fraud