Louisiana Medicaid | Provider UPDATE

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Updated Medication Safety Labeling Related to Pregnancy and Lactation

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Medication use during pregnancy has increased profoundly over the years. In fact, over 90% of women use at least one medication during pregnancy, and about 70% use at least one prescription medication. A 2011 study utilizing data from a 30-year period, from 1976 to 2008, concluded that, during this time, medication use during the first trimester of pregnancy increased by more than 60%. Although use of medication during pregnancy appears to be common, even today, little is known about the effects of taking medications during pregnancy. Less than 10% of medications approved by the U.S. Food and Drug Administration (FDA) since 1980 have enough information to determine their risk for birth defects.

Many women take medication during pregnancy for chronic health reasons, such as asthma, diabetes, depression, or seizures. In situations such as these, the provider must assess the medication's benefits to the mother versus the risks to the unborn child. The benefits of deciding to continue therapy for chronic conditions will sometimes outweigh the risks. Accidental exposure to medications may also occur when a woman takes medications without knowing she is pregnant. In a self-reported first-trimester medication-use study, 5,381 mothers identified 54 different medications taken during the first trimester. Of these, 31 were prescription medications and 23 were over-the-counter medications. Only two of the 54 most commonly used medications had 'Good to Excellent' data available to assess teratogenic risk in humans, based on information found in the Teratogen Information System (TERIS) Database. Some of the most commonly reported prescription medications used during pregnancy included progestins from oral contraceptives, amoxicillin, progesterone, albuterol, promethazine, and estrogenic compounds. The most commonly used over-the-counter medications included acetaminophen, ibuprofen, docusate, pseudoephedrine, aspirin, and naproxen.

In response to the increased usage of medications during pregnancy, the Food and Drug Administration (FDA), along with the Centers for Disease Control and Prevention (CDC), has taken measures to highlight the need for safer use of medications during pregnancy. In June 2015, after determining that the pregnancy category system utilizing A, B, C, D, and X was inconsistent with the need to accurately and consistently communicate differences in degrees of fetal risk, the FDA shifted to a new system for all drugs which enter the market after that time. The FDA also requires the removal of the old categorization from all drug product labeling for drugs already on the market. The new labeling requirements contain summaries of the risks of a drug during pregnancy and discussions of the data supporting these summaries. These requirements provide more meaningful information for healthcare providers which can be used to make better informed prescribing decisions for their pregnant patients and facilitate more effective counseling regarding medication use during pregnancy.

The revised pregnancy subsection of drug prescribing information is presented under the following headings: pregnancy, lactation, and females and males of reproductive potential. See Table 1 for more information regarding these headings and subheadings.

Table 1. Revised Pregnancy and Lactation Labeling

Subsection	Subheadings	Description
8.1 Pregnancy	Pregnancy Exposure Registry (if applicable)	Provides information regarding the availability of a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to the medication during pregnancy. Contact information for the registry is also included.
	Risk Summary	Includes statement that the drug is contraindicated during pregnancy (if applicable) and risk statements based on human data, animal data, and pharmacology. Information about background risk of birth defects and miscarriage rates are also included.
	Clinical Considerations (if applicable)	Includes information regarding disease-associated maternal and/or embryo/fetal risk, dose adjustments during pregnancy and the postpartum period, maternal and fetal/neonatal adverse reactions, and labor or delivery considerations.
	Data (if applicable)	Describes the data that provide the scientific basis for the information presented in the Risk Summary and Clinical Consideration Sections.
8.2 Lactation Risk Summary	Risk Summary	Discusses presence of drug in human milk and the effects of the drug on the breastfed child and on milk production.
	Clinical Considerations (if applicable)	Discusses minimizing exposure to the breastfed infant and monitoring the breastfed infant for adverse reactions.
	Data (if applicable)	Describes the data that provide the scientific basis for the information presented in the Risk Summary and Clinical Consideration Sections.
8.3 Females and Males of Reproductive Potential (omit if none of the subheadings are applicable)	Pregnancy Testing (if applicable)	Provides recommendations or requirements for pregnancy testing before, during, or after drug therapy.
	Contraception (if applicable)	Provides recommendations or requirements for contraception use before, during, or after drug therapy.
	Infertility (if applicable)	Includes information on human and/or animal data suggesting drug-associated effects on fertility.

Reference: www.fda.gov

Birth defects and prematurity account for $29 billion in costs annually in the United States.

Certain medications in pregnancy have been linked to the following:

- Birth defects
- Pregnancy loss
- Prematurity
- Infant death
- Developmental disabilities
- Unknown outcomes

The CDC initiative, *Treating for Two*, was created to improve the health of women and babies by working to identify the safest treatment options for the management of common conditions before and during pregnancy. The initiative aligns with three key drivers of safer medication use in pregnancy:

- Better research: Expansion and acceleration of research on medication use and pregnancy outcomes.
- Reliable guidance: Establishment of an ongoing process to evaluate current evidence and translate this evidence into summary clinical guidance.
- Informed decisions: Credible and reliable information to help prescribers, pharmacists, and consumers make treatment decisions.

In an effort to improve medication safety during pregnancy, healthcare providers should encourage their patients to ask questions, read medication labels, use caution when researching medications on the internet, and report any medication problems immediately. These small essential steps will lead to more informed decision making on behalf of the patient as well as the healthcare provider and will improve the health of women and babies.

References:

www.cdc.gov
www.fda.gov
www.federalregister.gov

ATTENTION PROVIDERS: PAYMENT ERROR RATE MEASUREMENT (PERM) FFY17 Currently Underway

Louisiana Medicaid is mandated to participate in the Centers for Medicare and Medicaid (CMS) **Payment Error Rate Measurement (PERM)** program which will assess our payment accuracy rate for the Medicaid and CHIP programs. If chosen in a random sample, your organization will soon receive a *Medical Records Request* from the CMS review contractor, CNI Advantage.

Please be advised that sampled providers who fail to cooperate with the CMS contractor by established deadlines may be subject to sanctioning by Louisiana Medicaid Program Integrity through the imposition of a payment recovery by means of a withholding of payment until the overpayment is satisfied, and/or a fine.

Please be reminded that providers who are no longer doing business with Louisiana Medicaid are obligated to retain recipient records for 5 years, under the terms of the Provider Enrollment Agreement.

For more information about PERM and your role as a provider, please visit the Provider link on the CMS PERM website: http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/PERM/Providers.html

If you have any questions, please call Catherine Altazan at 225-342-2612.

Remittance Advice Corner

Attention Outpatient Hospital Services Providers

During a recent claims processing system update, it was noted that the reimbursement for immunizations to outpatient hospital services providers was incorrect. The referenced processing error resulted in an overpayment to providers. This error has been corrected. Affected claims will be adjusted resulting in a recovery of the overpayments without any action on behalf of the provider. This adjustment will be included on the RA for Tuesday, August 22, 2017.

For questions regarding this message and/or fee for service claims, please contact Molina Provider Relations at (800) 473-2783 or (225) 924-5040.

Updates to Healthy Louisiana related systems and claims processing changes are plan specific and are the responsibility of each health plan. For questions regarding Healthy Louisiana updates, please contact the appropriate health plan.

Attention All Providers

On behalf of the Louisiana Department of Health (LDH), Health Management Systems (HMS) will hold a webinar for Institutional and Professional fee-for-service enrolled providers on August 30, 2017 at 2:00 p.m. CST. HMS will present an overview of their Provider Operations Department, Disallowance project processes, and Provider Portal benefits. The webinar offers a unique opportunity for providers to review current practices and participate in a question/answer forum. LDH encourages all Providers to enroll in this webinar by registering at https://hmsonline.webex.com/hmsonline/j.php?MTID=m13c54f99e66b1b2e411823d70bda2ea2
Please contact HMS's Provider Operations Department toll free at (888) 831-2738 for assistance in viewing on-line disallowances through Provider Portal."

Online Medicaid Provider Manual Chapter Revisions as of August, 2017

Manual Chapter	Section(s)	Date of Revision(s)
Behavioral Health Services	Table of Contents 2.1 Provider Requirements 2.3 Addiction Services Appendix B Glossary and Acronyms	08/30/17 08/30/17 08/30/17 08/30/17
Early and Periodic Screening, Diagnostics and Treatment (EPSDT) Health and Individuals with Disabilities Education Improvement Act (IDEA) – Related Services.	Title Page Table of Contents 20.1 Covered Services 20.2 Eligibility Criteria 20.4 Program Requirements 20.5 Record Keeping Appendix A Procedure Codes Appendix D Forms	08/18/17 08/18/17 08/18 and 08/23/17 08/18/17 08/18/17 08/18/17 08/18/17 08/18/17
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Home Health	Appendix C Procedure Codes and Rates	08/04/17
Hospital Services	25.7 Reimbursement	08/01/17
Pharmacy	37.5 Covered Services, Limitations and Exclusions Appendix C Medicaid Drug Federal Rebate Participation Pharmaceutical Companies	07/19/17 07/21/17

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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/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	1-877-544-9544
		Pharmacy Hotline	1-800-437-9101
		Medicaid Fraud Hotline	1-800-488-2917