Mountain-Pacific Quality Health

DUR PROGRAM NEWS

SUMMER 2022

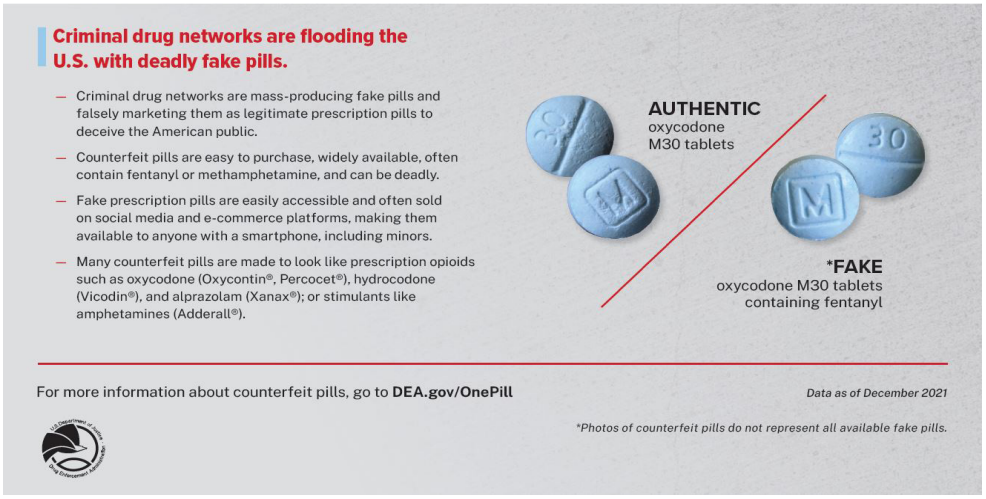
Fentanyl Poisoning and Death on the Rise in Montana

Several Montana counties have seen a dramatic increase in the number of overdose deaths due to opioids. Beyond deaths, fentanyl poisoning is becoming a common occurrence in emergency departments across the state.

Per the Montana Department of Public Health and Human Services (DPHHS), the number of seizures of fentanyl by law enforcement has skyrocketed in Montana this year. During the first three months of 2022, more fentanyl was seized than in the last four years combined.[1]

Alarmingly, the newest trend in fentanyl abuse is the shift from injection to smoking. A recent study published in *The Journal of Drug and Alcohol Dependence* states people who previously injected black tar heroin are making the shift to smoking fentanyl.[2] They mainly cited a lack of remaining viable veins as the impetus for the switch. Additionally, after making the switch from injection to smoking, many users reported a feeling of improved health, fewer financial problems and reduced stigma, including first-time users hoping to avoid needle track marks.

A large contributor to this problem is counterfeit medications. See below for a fact sheet from the U.S. Drug Enforcement Administration (DEA) on the realities of fake opioids.



[1]Nerison, K. (2022, April 7). Montana Highway Patrol fentanyl seizures in 2022 already surpass 2021 total. Montana Department of Justice. Retrieved from https://dojmt.gov/montana-highway-patrol-fentanyl-seizures-in-2022-already-surpass-2021-total/

[2]Alex H. Kral, Barrot H. Lambdin, Erica N. Browne, Lynn D. Wenger, Ricky N. Bluthenthal, Jon E. Zibbell, Peter J. Davidson,. Transition from injecting opioids to smoking fentanyl in San Francisco, California. Drug and Alcohol Dependence, Volume 227, 2021. https://doi.org/10.1016/j.drugalcdep.2021.109003.

Montana Healthcare Pharmacy Programs Links
(Current Preferred Drug List, provider notices, DUR Board/ meeting information, resources)
http://medicaidprovider.mt.gov/19

For current drug prior authorization criteria:
https://www.mpqhf.org/corporate/montanans-with-medicaid/pharmacy/

The Drug Utilization Review (DUR) Program, administered by Mountain-Pacific through a contract with the Allied Health Services Bureau of the Montana Department of Public Health and Human Services, is the quality assurance body seeking to assure the quality of pharmaceutical care and to help provide rational, cost-effective medication therapy for Montana Healthcare Programs members.

Montana Healthcare Programs
Drug Prior Authorization Unit
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FDA Issues Authorization of COVID-19 Vaccines for Children
(6 Months - 5 Years Old)

The U.S. Food and Drug Administration (FDA) authorized emergency use of the Moderna COVID-19 vaccine and the Pfizer-BioNTech COVID-19 vaccine for the prevention of COVID-19 to include use in children down to six months of age.

For the Moderna COVID-19 Vaccine, the FDA amended the emergency use authorization (EUA) to include use of the vaccine in individuals six months through 17 years of age. The vaccine had been authorized for use in adults 18 years of age and older.

For the Pfizer-BioNTech COVID-19 vaccine, the FDA amended the EUA to include use of the vaccine in individuals six months through four years of age. The vaccine had been authorized for use in individuals five years of age and older.

Key points:

- The FDA's evaluation and analysis of the safety, effectiveness and manufacturing data of these vaccines was rigorous and comprehensive, supporting the EUAs.
- The agency determined the known and potential benefits of the Moderna and Pfizer-BioNTech COVID-19 vaccines outweigh the known and potential risks in the pediatric populations authorized for use for each vaccine.
- Prior to making the decision to authorize these vaccines for the respective pediatric populations, the FDA's independent Vaccines and Related Biological Products Advisory Committee was consulted and voted in support of the authorizations.

Evaluation of Pfizer-BioNTech COVID-19 Vaccine for Children Six Months through Four Years of Age

The effectiveness and safety data evaluated and analyzed by the FDA for the Pfizer-BioNTech COVID-19 vaccine were generated in an ongoing, randomized, blinded, placebo-controlled clinical trial in the United States and internationally, which enrolled infants and children.

Effectiveness

The effectiveness data to support the EUA in children six months through four years of age is based on a comparison of immune responses following three doses of the Pfizer-BioNTech COVID-19 vaccine in a subset of children in this age group to the immune responses among adults 16 through 25 years of age who received two higher doses of the Pfizer-BioNTech COVID-19 vaccine in a previous study. The previous study determined the vaccine to be effective in preventing COVID-19.

The study was conducted in two age subgroups. The immune response to the vaccine of approximately 80 children, six through 23 months of age, and approximately 140 children, two through four years of age, were compared to the immune response of approximately 170 of the older participants. In these FDA analyses, the immune response to the vaccine for both age groups of children was comparable to the immune response of the older participants. An additional analysis pertaining to the occurrence of COVID-19 cases was determined not to be reliable due to the low number of COVID-19 cases that occurred in study participants.

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COVID-19 Vaccines for Children (cont.)

Safety
The available safety data to support the EUA in children six through 23 months of age include approximately 1,170 who received the vaccine and approximately 600 who received placebo. Approximately 400 vaccine recipients were followed for safety for at least two months following the third dose. For the participants two through four years of age, approximately 1,800 received the vaccine, and approximately 900 received placebo. Approximately 600 vaccine recipients were followed for safety for at least two months following the third dose.

The most commonly reported side effects in clinical trial participants six through 23 months of age who received the vaccine were irritability, decreased appetite, fever and pain, tenderness, redness and swelling at the injection site. These side effects were also reported for the vaccine recipients two through four years age, in addition to fever, headache and chills.

Risks of Myocarditis and Pericarditis
The FDA and the Centers for Disease Control and Prevention (CDC) safety surveillance systems have previously identified increased risks of myocarditis and pericarditis following vaccination with the Moderna COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 vaccine, particularly following the second dose. The observed risk is highest in males 18 through 24 years of age for the Moderna COVID-19 vaccine and in males 12 through 17 years of age for the Pfizer-BioNTech COVID-19 vaccine.

FDA and CDC analyses of available safety surveillance data from the U.S. and other countries on myocarditis outcomes continue to strengthen the evidence that most cases of myocarditis associated with the Moderna and Pfizer-BioNTech COVID-19 vaccines are characterized by rapid resolution of symptoms following conservative management, with no impact on quality of life reported by most patients who were contacted for follow-up at 90 days or more after reporting myocarditis. The risks of myocarditis and pericarditis are described in the fact sheets for each of these vaccines.

Ongoing Safety Monitoring
As part of their original EUA requests, both ModernaTX Inc. and Pfizer Inc. submitted plans to continue to monitor the safety of the vaccines as they are used under EUA. These plans for monitoring the overall safety of the vaccines and ensuring any safety concerns are identified and evaluated in a timely manner, and which include monitoring for myocarditis and pericarditis, have been updated to include the newly authorized populations. In addition, longer-term safety follow-up is ongoing for participants enrolled in the clinical trials for both vaccines. The FDA and the CDC have several systems in place to continually monitor COVID-19 vaccine safety and allow for the timely detection and investigation of potential safety concerns.

It is mandatory for both ModernaTX Inc. and Pfizer Inc., as well as vaccination providers, to report the following to the Vaccine Adverse Event Reporting System (VAERS) for these two COVID-19 vaccines: serious adverse events, cases of Multisystem Inflammatory Syndrome and cases of COVID-19 that result in hospitalization or death. It is also mandatory for vaccination providers to report all vaccine administration errors to VAERS of which they become aware and for vaccine manufacturers to include a summary and analysis of all identified vaccine administration errors in monthly safety reports submitted to the FDA.

Related Information
- Pfizer-BioNTech COVID-19 Vaccine
- Moderna COVID-19 Vaccine
- COVID-19 Vaccines
- Emergency Use Authorization for Vaccines Explained
- Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry
- Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry

Montana Prepares for End of COVID-19 Public Health Emergency

What Community Partners Need to Know about Upcoming Medicaid Changes Regarding the Public Health Emergency Unwind: For information on how community partners can help with the unwinding and returning to a regular operations process after the COVID-19 public health emergency (PHE), please visit: https://medicaidprovider.mt.gov/docs/providernotices/2022PN/HelpMembersReceiveImportantInfoFromMTMedicaid05162022.pdf.

FAQs about the Preferred Drug List

The Drug Prior Authorization Unit frequently fields questions about the Montana Healthcare Program Preferred Drug List (PDL). Here are some of those questions and their answers that should help clarify the rationale behind Montana utilizing a PDL.

Q: Are all medications covered by the Montana Healthcare Programs listed on the PDL?
A: No. The PDL is not an all-inclusive list of every therapeutic category or medication covered by the Montana Healthcare Programs. The PDL was implemented as a "starting point" in several therapeutic classes. It has grown over the years, and at the rate new drugs are entering the market, we can expect its growth to continue.

Q: If a drug is not on the PDL, do the Montana Healthcare Programs cover it?
A: Unless specifically prohibited by legislation, all other medications not found on this list are also covered. Some medications may be subject to prior authorization.

Q: Why are some drugs preferred, and others are not?
A: The PDL development process depends on review of clinical evidence by the Montana Medicaid Drug Utilization Review (DUR) Board. The board is comprised of 10 members who are actively practicing physicians and pharmacists in Montana, plus a consumer representative appointed by DPHHS. There are three PDL meetings held annually. During these meetings, the DUR board reviews the evidence-based information and makes formulary recommendations to DPHHS for all the categories and drugs on the PDL. These meetings are open to the public and allow time for public comment. Input from the Montana provider community is also considered. DPHHS uses these recommendations to make PDL changes that are clinically effective and cost-effective for the State of Montana.

Q: Why are some branded medications preferred over their generic counterpart?
A: Preferred drug lists allow state Medicaid programs to participate in multi-state pooling initiatives and receive supplemental rebates from drug manufacturers for preferred agents. Often, the net cost of the branded product is significantly lower than its generic counterpart due to significant rebates. Therefore, preferring the brand product ultimately produces significant cost savings to the State.

Q: What is the benefit of the PDL to the State of Montana?
A: Montana is part of a multi-state pooling initiative that returns 100% of the rebates to each corresponding state.

- In Fiscal Year 2021, this amounted to **$27,520,615** returned to the State of Montana.
- By comparison, in Fiscal Year 2014, this amounted to **$3,938,667**.

This is savings to the taxpayers of Montana.