

SPRING 2023

Montana Healthcare

Pharmacy Programs Link (Current Montana Healthcare Programs Preferred Drug List, Provider Notices, DUR Board/ Meeting Information, Resources) http://medicaidprovider.mt.gov/19

For current drug prior authorization criteria: <u>https://www.mpqhf.org/</u> <u>corporate/montanans-withmedicaid/pharmacy/</u>

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 1-800-395-7961

Mountain-Pacific Quality Health

X-DEA Waiver Requirement Removed to Improve Access to Treatment

On December 29, 2022, the U.S. Congress signed into effect a year-end omnibus legislative package, <u>the Consolidated Appropriations Act, 2023</u> (CAA 2023). The bipartisan Mainstreaming Addiction Treatment Act included in the omnibus package eliminated the DATA-Waiver Program under the <u>Drug Addiction Treatment Act</u> (DATA 2000). DATA 2000 required health care providers to possess an X-Waiver to prescribe buprenorphine, a Schedule III drug, for outpatient use for the treatment of opioid use disorder (OUD).

For a provider to prescribe buprenorphine for OUD, DATA 2000 required practitioners to submit a notification of intent to the Substance Abuse and Mental Health Services Administration (SAMHSA), hold an active state medical license, have a current U.S. Drug Enforcement Administration (DEA) registration number and obtain an additional certification in addiction through an approved, eight-hour training course, among other requirements. The DEA would then issue the provider an X-Waiver, named after the additional DEA number, which begins with the letter "X" and is given to providers who obtain the waiver. The number of patients a provider could treat under an X-Waiver was strictly capped.

On January 12, 2023, the DEA released a letter to registrants, announcing their support of Congress' removal of the requirement that health care providers possess a DATA-Waiver, commonly referred to as an X-Waiver, to prescribe buprenorphine to treat OUD. The DEA included the following information:

All DEA registrants should be aware of the following:

- A DATA-Waiver registration is no longer required to treat patients with buprenorphine for OUD.
- Going forward, all prescriptions for buprenorphine only require a standard DEA registration number. The previously used DATA-Waiver registration numbers are no longer needed for any prescription.
- There are no longer any limits or patient caps on the number of patients a prescriber may treat for OUD with buprenorphine.
- The Act does not impact existing state laws or regulations that may be applicable.

CAA 2023 included legislated changes to DEA licensing, which include all prescribers licensed to dispense controlled substances (except veterinarians).

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X-DEA Waiver Requirement Removed (cont.)

Prescribers will be required to complete a one-time, eight-hour course on the treatment and management of patients with opioid or other substance use disorders and the safe pharmacological management of pain.

This new requirement is scheduled to go into effect June 21, 2023, and DEA licensees will need to comply as their licenses expire.

Specifics of this program are in the process of being determined by the Substance Abuse and Mental Health Services Administration (SAMHSA) and the DEA, who plan to publish further details.

For more information:

SAMHSA - Removal of DATA Waiver (X-Waiver) Requirement <u>https://www.samhsa.gov/medications-substance-use-disorders/removal-data-waiver-requirement</u>

Policy & Medicine - MATE Act Becomes Law: DEA Healthcare Provider License Holders Required to Complete 8 Hours of Education on Opioid Treatment

https://www.policymed.com/2023/01/mate-act-becomes-law-dea-prescriber-license-holders-required-tocomplete-8-hours-of-education-on-opioid-treatment.html



Where Do I Find ...?

- 1. Current Montana Medicaid Preferred Drug List: <u>https://medicaidprovider.mt.gov/19</u>
- Prior authorization criteria for prescription drugs for the Montana Healthcare Programs: <u>https://www.mpqhf.org/corporate/montanans-with-</u><u>medicaid/pharmacy/</u> (under Drug Prior Authorization)
- Phone number to call for a prescription prior authorization: Drug Prior Authorization Unit: (800) 395-7961
- 4. Phone number to report suspicious or fraudulent behavior to Montana Healthcare Programs: Montana Healthcare Programs Fraud Hotline: (800) 376-1115
- 5. Physician-Administered Drug criteria: <u>https://www.mpqhf.org/corporate/montanans-with-medicaid/pharmacy/</u> (under Physician-Administered Drugs [PAD])
- 6. Phone number for help with the PAD billing portal: Call center: (800) 219-7035
- Agendas, meeting minutes and link to Drug Use Review (DUR) Board and Formulary Committee meetings: <u>https://medicaidprovider.mt.gov/19dur</u>



Ending the Public Health Emergency

On January 31, 2020, the Secretary of U.S. Health and Human Services (HHS) announced the determination of a public health emergency (PHE) due to the 2019 novel coronavirus. On February 9, 2023, HHS announced the federal PHE for COVID-19 will expire May 11, 2023.

The declaration of the PHE allowed access to additional resources by the federal government through various programs as well as additional funding from legislation, which provided additional monies to individual states to manage COVID-19 and its fallout. Through June of 2020, Montana received more than two million dollars in funding.

The COVID-19 policies implemented by federal and, subsequently, state governments had a dramatic impact on health care. Now as the PHE ends, the process of what HHS calls "unwinding" begins.

On February 9, HHS released <u>Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap</u>, which outlines some important parts of their plan. The state programs will have decisions in many of these areas as there are individual state regulations that were suspended by the PHE. The HHS notice outlines the areas that will and will not be affected at the federal level.

What will not be affected:

- Access to COVID-19 vaccinations and certain treatments, such as Paxlovid® and Lagevrio®
- The U.S. Food and Drug Administration (FDA)'s Emergency Use Authorizations (EUAs) for COVID-19 products (including tests, vaccines and treatments)
- Major Medicare telehealth flexibilities
- Medicaid telehealth flexibilities
- The process for states to begin eligibility redeterminations for Medicaid
- Access to buprenorphine for opioid use disorder treatment in opioid treatment programs (OTPs)
- Access to expanded methadone take-home doses for opioid use disorder treatment

What will be affected:

- Certain Medicare and Medicaid waivers and broad flexibilities for health care providers are no longer necessary and will end.
- Coverage for COVID-19 testing for Americans will change.
- Reporting of COVID-19 laboratory results and immunization data to the Centers for Disease Control and Prevention (CDC) will change.
- Certain FDA COVID-19-related guidance documents for industry that affect clinical practice and supply chains will end or be temporarily extended.
- FDA's ability to detect early shortages of critical devices related to COVID-19 will be more limited.
- Public Readiness and Emergency Preparedness (PREP) Act liability protections may be impacted.
- Health care providers' ability to safely dispense controlled substances via telemedicine without an in-person interaction is affected. However, there will be rulemaking that will propose to extend these flexibilities.

<u>A more complete description of the plan</u> is available on the HHS website. The Montana Department of Public Health and Human Services (DPHHS) published <u>a provider notice on March 17</u> about how the end of the PHE effects pharmacy coverage and <u>another notice on March 10</u> to all providers to assist with the unwinding process. These offer additional, Montana-specific information. More information about the effect of the end of the PHE on Medicaid and Healthy Montana Kids can be found at <u>https://dphhs.mt.gov/hcsd/medicaidupdates/</u>.



Dangers Associated with Albuterol Overutilization in Asthma

Over the last three years, albuterol has moved from the fourth to the first most dispensed medication in the Montana Medicaid population. According to the Centers for Disease Control and Prevention (CDC)'s most recent national asthma data, 7.8% of the population of the U.S. has asthma. For Montana, the incidence is higher at 10.6%.

The treatment of asthma has evolved over the years, with many advances. However, the concerns related to albuterol overutilization has remained a consistent concern. Too many people rely on their short-acting beta agonist (SABA) "rescue" inhaler. Sadly, over-reliance to the quick-acting bronchodilation of albuterol is



associated with an increase in mortality. We have all read the stories of a youth football player dying on the field from an asthma attack. Studies have proven the dangers associated with SABA monotherapy:

- SABA overuse (3 or more inhalers/year) is associated with an increased risk for exacerbations.
- Using a SABA for as little as 2 to 4 times per day for 1 to 2 weeks is associated with diminished bronchodilator effects and increased airway inflammation with hyperresponsiveness.
- Patient over-reliance on a SABA can increase the patient's belief that the SABA will work and minimize their perceived severity of the disease.
- In review of mortality data, 15 to 27% of patients who died from asthma had asthma symptoms less than weekly in the 3 months preceding their death.

Clinically, how can we make a change?

- Inhaled corticosteroids (ICS)-containing treatment is associated with a decrease in the frequency and severity of asthma symptoms and is associated with a decrease in mortality even in patients with mild asthma.
- Increasing the utilization of an ICS-containing maintenance inhaler is associated with reduced SABA use and improved asthma control, which improves mortality risk, even in mild asthma.

Guideline endorsement:

- The Global Initiative for Asthma (GINA) yearly publishes the Global Strategy for Asthma Management and Prevention report, with the most recent update in May 2022.
- The GINA guidelines address the Single Maintenance and Reliever Therapy (S.M.A.R.T.) approach, which recommends the combination budesonide/formoterol inhaler for use as both the rescue and maintenance inhaler. The guidelines recommend this approach for the treatment of persistent asthma in age 12 years and older in steps 3 through 5 of their treatment recommendations. They also recommend using budesonide/formoterol for as-needed use only (in place of a SABA) in ages 12 and older in steps 1 and 2 of their treatment recommendations. For additional information, including guideline direction for children younger than 12 years old, please refer to the complete GINA guidelines at https://ginasthma.org/gina-reports/.
- The U.S. National Asthma Education and Prevention Program (NAEPP) released guidelines for the management of asthma in 2020. Strong emphasis was placed on assessing the level of daily impairment a patient may be experiencing and the risk for exacerbations, medication side effects or loss of lung function and treating asthma in a stepwise approach.

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Dangers Associated with Albuterol Overutilization in Asthma

- While the NAEPP only recommends the complete S.M.A.R.T. approach in a subset of asthma patients, they do endorse an ICS-containing inhaler for maintenance in each step of their treatment recommendations for persistent asthma in all age groups.
- For additional information, including guideline direction for children younger than 12 years old, please refer to the complete NAEPP guidelines at <u>https://www.nhlbi.nih.gov/resources/2020-focused-updates-asthma-management-guidelines</u>.

References:

- National Asthma Education and Prevention Program: Expert panel report III: Guidelines for the diagnosis and management of asthma. Bethesda, MD: National Heart, Lung, and Blood Institute, 2007. (NIH publication no. 08-4051). <u>www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm</u> (Accessed on February 16, 2023).
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- 3. Suissa S., Ernst P., Benayoun S., Baltzan M., Cai B. Low-dose inhaled corticosteroids and the prevention of death from asthma. N. Engl. J. Med. 2000; 343:332–336
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- 5. Suissa S, Ernst P, Boivin JF, et al. A cohort analysis of excess mortality in asthma and the use of inhaled beta agonists. Am J Respir Crit Care Med 1994; 149: 604-610
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- 7. Cockcroft DW, McParland CP, Britto SA, et al. Regular inhaled salbutamol and airway responsiveness to allergen. Lancet 1993; 342: 833–837.
- 8. Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention. <u>https://ginasthma.org/gina-reports/</u>. Updated 2022. Accessed February 3, 2022.
- 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. J Allergy Clin Immunol. 2020 Dec;146(6):1217-1270.
- 10. Hancox RJ, Cowan JO, Flannery EM, et al. Bronchodilator tolerance and rebound bronchoconstriction during regular inhaled beta-agonist treatment. Respir Med 2000; 94: 767–771.
- 11. Centers for Disease Control and Prevention: 2020 Behavioral Risk Factor Surveillance System (BRFSS).

