Mountain Pacific DUR PROGRAM NEWS

FALL 2025

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:
https://mpqhf.org/resources/pharmacy-resources/#drug-prior-authorization

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 (DPHHS), 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.

Clinic to Community:
Practicing Antimicrobial Stewardship Across All Settings

As we settle into the autumn season, with winter fast approaching, now is the time to recall the importance of practicing antimicrobial stewardship. Generally, antimicrobial stewardship aims to provide education to health care practitioners on the 4Ds; right drug, right dose, right delivery and right duration.[1] In aligning with the primary aims of antimicrobial stewardship, we attempt to maintain an effort to prevent the development of antibiotic-resistant bacteria, improve patient outcomes and reduce health care-related expenses. The latest Centers for Disease Control and Prevention (CDC) report on antimicrobial resistance estimates that around 2.8 million antimicrobial-resistant infections occur each year and around 35,000 of them are fatal.[2] Additionally, the CDC and the Veteran's Administration estimate that the hospital cost of treating infections caused by just six of the most prominent drug-resistant microbes in the United States exceed $4.6 billion annually.[2] While prudence and diligence are necessary when it comes to appropriate prescribing, if we are to genuinely improve patient outcomes and decrease health care expenses, we must also advocate for rapid and accurate diagnostic tools, novel treatment approaches and improved public health education on infection prevention.

While it is true bacteria have a myriad of ancient molecular pathways for developing resistance mechanisms, the misuse and overuse of antibiotic therapy unnecessarily exacerbates a growing threat to public health. Antibiotics are capable of instigating resistance through a variety of ways, including

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Montana Healthcare Programs
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Antimicrobial Stewardship (cont.)

through selective pressure, promotion of genetic alterations and enabling the exchange of resistance mechanisms among and between bacterial species.[3, 4] These unique mechanisms in response to antibiotics further highlight why it is critically important to rule out a viral infection during the winter months and to additionally have a definitive and rapid diagnosis of a bacterial infection with susceptibilities when possible.

There is some dismissal regarding the overall efficacy of reserving broad-spectrum antibiotics and the magnitude of impact this strategy may have on reducing antimicrobial resistance. Increased and widespread antibiotic use over the last several decades has been a potent driver of antimicrobial resistance.[5] Furthermore, antimicrobial stewardship is not just about the appropriate use of antibiotics. It is also about enhancing diagnostic techniques, infection prevention, public health education and cost-effective practices to name a few.[3] Diagnostic delays, treating viral illnesses with antibiotics and selecting the wrong antibiotic all contribute to increased health care costs, which places a financial burden on individuals, communities and health care facilities.[6] Good antimicrobial stewardship is an amalgamation of a multi-pronged approach to ultimately improve patient outcomes and benefit public health.

A significant contributor to the decline in new antibiotic development over recent years is the high cost of drug discovery coupled with the rapid evolution of antimicrobial resistance. Fortunately, the medical industry has begun to evolve and is actively modifying its approach to antimicrobial resistance beyond traditional antibiotics. Future advancements include the development of monoclonal antibodies for specific bacteria, vaccine technologies aimed at preventing resistance potential and stem cell antimicrobial peptide therapies targeted to inhibit bacterial growth.[4] While the new research and development in this area are exciting and promising, it remains imperative that we all continue to do our part to combat the growing problem of antimicrobial resistance with good antimicrobial stewardship practices.

As technology rapidly advances and provides us with greater insight into medicinal practices, the single best thing we can do is to remain educated about new developments and breakthroughs. When it comes to antimicrobial stewardship, a litany of resources are at our disposal, including continuing education (CE) modules, workshops and webinars.

Undoubtedly, there is still a vast amount of knowledge left to be understood about antimicrobial resistance patterns. However, by limiting misuse and overuse of antibiotics, establishing rapid and accurate diagnoses, educating our patients on infection prevention and educating ourselves on best practices, we can limit unnecessary exacerbation of antibiotic resistance development.

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Antimicrobial Stewardship (cont.)

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FDA Notice of Impending Removal of Animal-Derived Thyroid

On August 6, 2025, the U.S. Food and Drug Administration (FDA) sent letters to manufacturers, importers and distributors of marketed, unapproved, animal-derived thyroid (ADT) medications, also known as desiccated thyroid extract (DTE). The letters notified the manufacturers of the agency's intent to take regulatory action against these unapproved medications. The FDA does not plan this action to begin immediately, so prescribers have time to move patients to an FDA-approved synthetic thyroid.[1]

Animal-derived thyroid products can trace their history back to England in the late 1800s. In the early 1900s the Armour Meat Packing company, one of the largest slaughterhouses in the U.S., started selling the thyroid glands of slaughtered pigs to pharmacies for compounding of thyroid replacement medication through an arduous manual process. Eventually, mechanization of this process led the Armour Company to form a drug division and begin to mass produce their own DTE with by-products from their slaughterhouses. The problem with this process became apparent when Armour was unable to consistently produce a standard dose because each pig's thyroid tissue did not contain equal amounts of thyroid hormone. Therefore, thyrotoxic effects of DTE were not uncommon.[2] To address some of the concerns with the naturally derived, inconsistent products, a synthetic thyroid hormone L-thyroxine (T_4) was developed and brought to market in 1958.

Jump forward in time to the 1970s when the development of major advancements occurred with radioimmunoassay-based thyroid function tests, which measured serum thyroid stimulating hormone (TSH) and, soon after, serum T_3 and T_4 levels. This allowed confirmation testing of blood levels to evaluate patient dose. The impact of these tests was reduction in thyrotoxicosis from excessively high doses. Gradually the shift in professional guideline recommendations and prescribing moved from naturally derived thyroid to synthetic L-thyroxine. However, for some prescribers and patients, their choice remained the natural product.

So, how does a product commonly used for more than 100 years end up on the FDA chopping block? The answer was spelled out in an email, return request required, sent to the "Manufacturers, Importers and Distributors of Animal-Derived Thyroid Products" on August 6, 2025. The complete explanation of the

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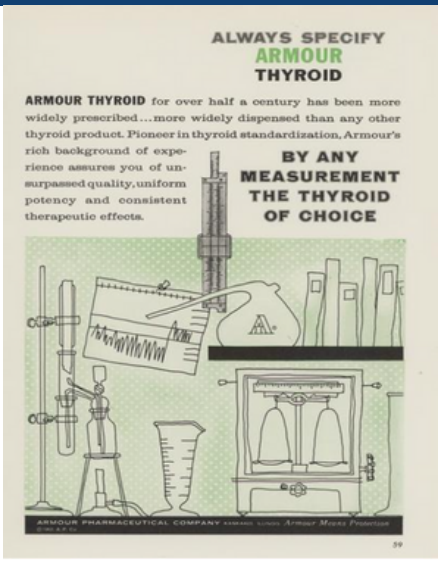
FDA Notice of Impending Removal (cont.)

basis in law and reason for this action is included in this email starting with the Biologics Price Competition and Innovation Act of 2009 and ending with the FDA statement that, from 1968 through February 2025, the FDA is aware of more than 500 adverse event reports associated with ADT products. This notice also included that compounding of DTE is not eligible for exemptions and is also considered an unapproved biological product. The FDA noted it is aware of the time required to transition patients to FDA-approved thyroid hormone replacement products, and that adequate time will be allowed for this transition, specifying "up to 12 months."[3]

This is going to be a big project. According to ClinCalc DrugStats Database, in 2023 ADT products came in as the 141st most dispensed drug in the U.S.,[4] impacting more than a million patients, according to FDA estimates.[3] It is time to let prescribers and patients know they need to get started.



1960-1963 Armour Thyroid advertisement https://digital.library.wisc.edu/1711.dl/MHCHRTVUC2EPM8D

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Gabapentin to Become a Controlled Substance in Montana

Effective October 1, 2025, gabapentin will be designated in Montana as a Schedule V controlled substance. The Montana Legislature passed House Bill 41 in February of 2025, aligning Montana with seven other states that have already taken this step.[1] The goal of this change is to increase patient safety and limit diversion and misuse of this medication. Prescriptions written for gabapentin will now be reported to the Montana Prescription Drug Registry, enabling prescribers to know more about their patients' medication profiles. Controlled substance designation will also implement criminal penalties for illegal possession and diversion. There are no such penalties for non-controlled substances. Additionally, gabapentin prescriptions will now require a provider with an active Drug Enforcement Administration (DEA) license. They will be valid for six months and may not be refilled more than five times without renewal. Limits on the number of refills and their allotted timeframe helps to prevent stockpiling, which in turn reduces the risk of diversion from unused medication and encourages patients to maintain regular

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follow-up with their health care providers. In practice, this means more opportunities for prescribers to reassess the appropriateness of therapy and address safety concerns.

In recent years increased misuse and diversion has been well documented. In Montana, law enforcement has reported an increase in driving under the influence (DUI) cases where gabapentin has been involved, as well as toxicological findings of high levels of the drug in post-mortem cases.[2] Although gabapentin has a place in therapy for a number of conditions, it can produce sedative or euphoric effects at higher doses or when combined with other central nervous system (CNS) depressants like opioids. On December 19, 2019, the FDA sent out a drug safety alert titled "FDA warns about serious breathing problems with seizure and nerve pain medicines gabapentin and pregabalin." This alert notified the public that additional warnings were being added to the prescribing information for these drugs. This has not been enough. Gabapentin has continued to be detected in almost one in 10 overdose deaths in the U. S., with it being ruled as a cause of death in almost half of the cases.[3]

Patient safety remains at the center of these changes. When taken in combination with opioids, gabapentin significantly increases the risk of respiratory depression and overdose.[5] By requiring closer monitoring and reporting, Montana's new law reinforces the importance of prescribers recognizing this interaction and taking steps to protect patients. These measures can help reduce preventable overdoses while improving awareness of gabapentin risks among both providers and patients.[5]

Studies conducted in other states show that tighter regulations lead to measurable changes in prescribing trends. A nationwide Medicare study found that states moving gabapentin to Schedule V saw an average drop of eight fewer days per patient per year, compared to about one fewer day in states that only required a prescription drug monitoring program (PDMP). In West Virginia, where both scheduling and PDMP measures have been implemented, gabapentin dispensing fell from around 79 million prescriptions in 2019 to 73.8 million in 2021.[4] These outcomes highlight how scheduling can influence clinical practice and reduce unnecessary exposure to the drug.

Finally, experts emphasize that Schedule V classification does not mean patients will lose access to gabapentin.[6] Instead, it places the drug under a framework designed to balance access with safety. Patients who benefit from gabapentin will still be able to receive it, but the added safeguards are expected to discourage misuse and promote more responsible prescribing practices.

References:

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Important Notice About Xifaxan®

Xifaxan® will no longer be covered by Medicaid Programs.

Effective October 1, 2025, Bausch Health US, LLC, and its subsidiary Salix Pharmaceuticals have terminated their participation in the Medicaid Drug Rebate Program. State Medicaid Programs are prohibited from using federal funds to pay for medications manufactured by companies that do not participate in the Medicaid Drug Rebate Program.

While Xifaxan® is not the only prescription drug affected by this decision by the manufacturer, it is an important one, as the cost for a standard course exceeds $2,000 at most locations. No generic is currently available, and therapeutic alternatives are limited for some indications. These costs may be offset by the manufacturer assistance program and various coupons if patients are eligible.

For more information on the manufacturer patient assistance programs, go to https://www.bauschhealthpap.com/siteassets/pdf/docs/bh-pap-application-pap-medicaid.pdf, https://www.bauschhealthpap.com/faq/ or https://xifaxan.copaysavingsprogram.com/.

For more information on the federal rebate program, go to Medicaid.gov, specifically https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program.

For more information on terminated labelers, visit https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information.

Vaccine Billing Information

Adults and children covered under Montana's Children's Health Insurance Program (CHIP) are eligible to receive vaccinations through their local pharmacy. The pharmacy must submit vaccination claims through their point-of-sale processing system using the DUR codes of AD, MA and 1B.

Children 18 years of age and under not covered under CHIP qualify for free vaccines through the Vaccines for Children program and can access those at their primary care provider's office. Pharmacy-administered vaccines are not available for this group.

Scan the QR code to the left or use the link for the current Montana **DPHHS PDL**.

Scan the QR code to the right or use the link for Mountain Pacific **drug PA resources**.