North Dakota Medicaid Pharmacy Program Quarterly News

Published Quarterly by Health Information Designs, Inc. Summer 2010

Welcome to the Summer 2010 edition of the "North Dakota Medicaid Pharmacy Program Quarterly News," a pharmacy newsletter presented by the North Dakota Department of Human Services and published by Health Information Designs, Inc. This newsletter is published as part of a continuing effort to keep the Medicaid provider community informed of important changes in the North Dakota Medicaid Pharmacy Program.

The North Dakota Department of Human Services has contracted with Health Information Designs, Inc. (HID) to review and process prior authorizations (PAs) for medications. For a current list of medications requiring a PA, as well as the necessary forms and criteria, visit www.hidndmedicaid.com, or call HID at (866) 773-0695 to have this information faxed. An important feature on this website is the NDC Drug Lookup. This allows you to determine if a specific NDC is covered (effective date), reimbursement amount, MAC pricing, copay information, and any limitations (prior authorization or quantity limits).

The Summer 2010 newsletter provides information regarding the Risk Evaluation and Mitigation Strategies (REMS) that the FDA has developed in response to safety concerns of drugs currently on the market. Also included in this newsletter are consumer guidelines for the proper disposal of medications.

The North Dakota Pharmacy Program team appreciates your comments and suggestions regarding this newsletter. To suggest topics for inclusion, or to make comments, please contact Health Information Designs, Inc. at (334) 502-3262, call toll free at 1-800-225-6998, or e-mail us at info@hidinc.com.

north dakota department of human services

Helpful Numbers

PA Help Desk	866-773-0695
To fax PAs	866-254-0761
To report adverse reactions	800-FDA-1088

Inside this issue:

Visit HID's North Dakota Department of Human Services Prior Authorization Webpage, *www.hidndmedicaid.com.*

Risk Evaluation and Mitigation Strategies

Rosiglitazone has been on the market for many years, but there is now evidence to suggest that it can increase the risk of heart problems. In September of 2010, the Food and Drug Administration (FDA) introduced restrictions for patients currently taking rosiglitazone. First, patients may continue taking rosiglitazone, but they must sign a consent that documents their understanding of the risks associated with continued therapy. Patients that are new to rosiglitazone must show that their diabetes has not been adequately controlled with other non-thiazolidinedione antidiabetic agents and that they are not candidates for pioglitazone therapy. This is just one example of the Risk Evaluation and Mitigation Strategies (REMS) that the FDA has developed in response to safety concerns regarding drugs that are currently on the market.

In September of 2007, the Food and Drug Administration Amendments Act (FDAAA) was signed into law. This bill amended the Food, Drug and Cosmetic Act, giving the FDA more resources and authority to safeguard public health.

In the legislation, the FDA is given the authority to:

- require post approval studies
- request that safety information be provided in labeling, or
- require that a drug manufacturer submit and execute a Risk Evaluation and Mitigation Strategy (REMS)

REMS are required if a drug has serious side effects, such as teratogenicity, cardiovascular side effects, liver damage, etc. This concept is not new to the FDA. Prior to the implementation of the FDAAA, there were certain drugs with special requirements, such as dispensing with a MedGuide or special registration conditions that had to be met prior to dispensing to the patient. The drugs that had requirements in place prior to 2007 were part of a program called risk minimization action plans, or RiskMAPs, so they are not technically REMS drugs. However, the FDA is currently in the process of converting RiskMAPs to REMS.

There are different things that REMS might require. For example:

- *Confirmation of patient age* – patients must be at least 18 years old to buy nicotine products.
- *MedGuides* – additional information must be dispensed with certain classes of drugs, including prescription NSAIDs and antidepressants.
- *Vaccine Information Statements (VIS)* – these statements provide patients or their guardians with information about the risks and benefits of the vaccine to be given.
- *Special training* – healthcare professionals might be required to have special training before they prescribe or dispense a certain drug. For example, physicians must have at least eight hours of special training before they can write prescriptions for Suboxone® or Subutex®.
- *Enrollment in special programs* – the patient, prescriber, and/or pharmacy might be required to enroll in a special program in order for a drug to be prescribed or dispensed. Those patients taking thalidomide for multiple myeloma, along with their doctor and pharmacy, must register with the System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.).
- *Registries* – patients taking clozapine must have their white blood cell count checked before they can have their prescription filled. This is for the patient's safety, but also allows the drug companies to analyze the data and determine how often this side effect occurs.
- *Dispensing from specialty pharmacies* – drugs for relatively rare diseases can be very expensive (such as bosentan) and are dispensed only from specialty pharmacies who have been certified.

A list of drugs with approved REMS, as well as those that require MedGuides, can be found on the FDA website, www.fda.gov.

References:

Guidance for Industry: Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications. U.S Department of Health and Human Services/Food and Drug Administration; September 2009.

Food and Drug Administration Amendments Act (FDAAA) of 2007. www.fda.gov. Accessed 11/2010.

Drugs with REMS and other special prescribing/dispensing requirements. Pharmacist's Letter/Prescriber's Letter 2010;26(11):261111.

Consumer Drug Disposal

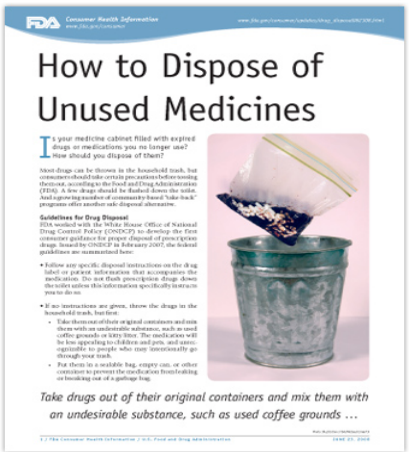
Most patients are unsure how to dispose of old or unused medications. How should pharmacists advise them? The Food and Drug Administration (FDA) worked with the White House Office of National Drug Control Policy (ONDCP) to develop consumer guidance for the proper disposal of medications. The federal guidelines state:

- Follow any specific disposal instructions that are included in the drug labeling. Medications should not be flushed unless the labeling recommends it.
- If no instructions are given, patients should be instructed to throw the drugs in the household trash, first taking them out of their original containers and mixing them with an undesirable substance (used coffee grounds or kitty litter). The medication should then be placed in a sealed bag or container to prevent it from leaking out of the garbage bag.
- Patients should be encouraged to participate in community drug take-back programs.
- Certain medications (such as the fentanyl patch or other potent narcotics) are recommended to be flushed. In these cases, the FDA has determined that this method is the most appropriate route of disposal because it presents the least risk to safety or accidental overdose. There are approximately 30 drugs on the 'Medicines Recommended for Disposal by Flushing' list and they can be accessed on the FDA website (www.fda.gov).

In spite of the safety reasons for flushing drugs, there are questions about how flushing affects the water supply. Trace levels of drug residues can be found in surface water (rivers and lakes) and in some community drinking water supplies. However, environmental experts have found that the majority of the residue is due to patients taking medications and passing them naturally. Still, the FDA does not want to introduce additional drug residue into the water supply, unnecessarily, therefore the agency requires all new drug applications to include an assessment of how the drug might affect the environment.

Another environmental concern lies with used inhalers. The inhalers that contained chlorofluorcarbons (CFCs) - a propellant which damages the ozone layer - have been phased out. Now there is concern about how to properly dispose of the used inhalers. Patients should be directed to their local trash and recycling facility for instructions, as some products can be disposed of in household trash or recyclables, while others may be considered hazardous waste and require special handling.

More information, and the handout shown below, can be found on the FDA website.



Reference: How to Dispose of Unused Medicines
www.fda.gov. Accessed Nov, 2010.

Health Information Designs, Inc. (HID) is the most experienced and qualified provider of drug utilization review and pharmacy support services in the country. We specialize in helping our clients promote clinically appropriate and cost-effective prescribing, dispensing, and utilization of prescription drugs.

For 33 years, HID has worked to improve the quality and cost effectiveness of health care through clinically rational use of prescription medication. Our clients include public and private healthcare plans throughout the U.S. with a combined total of over 14 million covered lives.

Health Information Designs, Inc. was founded in 1976 and is incorporated as a C Corporation in the State of Delaware. HID's initial mission was to market drug utilization review (DUR) services nationally and since its founding, has provided DUR services for clients in approximately two-thirds of the United States. HID is headquartered in Auburn, Alabama, with regional offices in Arkansas, Maryland, and Mississippi.

HEALTH
INFORMATION DESIGNS

391 Industry Drive
Auburn, AL 36832
Tel: 800-748-0130
Fax: 800-748-0116

PRST STD

U.S.
Postage