Maryland Pharmacy Program

Pharmacy News and Views

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New Primary Adult Care Program

Beginning JULY 1, 2006, the Maryland Department of Health and Mental Hygiene (DHMH) will offer a new Medical Assistance program, known as the Primary Adult Care Program (PAC). PAC will cover primary care benefits for low-income Maryland residents. DHMH combined two of its programs - the Maryland Pharmacy Assistance Program (MPP) and the Maryland Primary Care Program (MPC), to create PAC. The transition period will begin on July 1, 2006 and continue until September 1, 2006.

PAC will cover individuals age 19 and over who are not eligible for Medicare or full Medicaid benefits. Eligible individuals will also have to meet income and asset requirements. In addition to prescription drug coverage, PAC enrollees will receive primary care benefits, coverage for outpatient mental health services, and some additional services for individuals with diabetes. **PAC will not cover specialty care or inpatient and outpatient hospital care.**

Much like HealthChoice, DHMH is contracting with Managed Care Organizations (MCOs) to provide primary care services and pharmacy benefits to PAC members. PAC members must choose an MCO or they will be assigned to one. The MCOs will contract with primary care providers. Primary care providers wishing to participate in PAC must contract with one or more of the PAC MCOs. As in the HealthChoice MCO program, HIV medications and most mental health drugs are "carved out" from the PAC Program and will be covered by the fee-for-service Medicaid Pharmacy Program. PAC recipients will have a yellow and white Medical Care Program card for carved-out services. The Electronic Verification System (EVS) will include a message to identify PAC enrollees. Complete details on this new program will be provided shortly.

Part D Exception and Prior Authorization Request Form for Prescribing Physicians

The Centers for Medicare and Medicaid Services (CMS) has released a model Part D standardized exception and prior authorization request form ("Trigger Form") for prescribing physicians. It is titled *Medicare Part D Coverage Determination Request Form* and a copy is included on page 7 of this newsletter. The form was developed in conjunction with the American Medical Association and America's Health Insurance Plans to further the goal of simplifying procedures in the new Medicare drug benefit. This form allows for a simplified process for physicians to apply for coverage determinations on behalf of all of their Medicare beneficiaries enrolled in any Medicare drug plan. The form has been posted to the CMS.gov website, on the Provider Center page under "Part D Tools for Health Care Professions" at http://www.cms.hhs.gov/center/provider.asp.

Contents

Pharmacy News and Views is now on the Web

A copy of this newsletter and the previous editions of the ***Pharmacy News and Views*** newsletter can now be found on the HealthChoice Managed Care Organization website at www.mdmahealthchoicerx.com.

STATE OF MARYLAND
DHMH

Enrollment for Medicare Part D

The initial enrollment period for Medicare Part D drug plans ended on May 15, 2006. Individuals who are Medicare eligible and did not sign up for a plan prior to May 15, 2006 will not be able to enroll in a Part D drug plan until November 15, 2006. Medicare beneficiaries who do not need to enroll in a Part D drug plan include those who have existing qualified prescription drug coverage.

Qualified drug coverage includes prescription benefits that are at least as comprehensive as the Part D drug plans. Examples of qualified prescription drug coverage are those provided by employees retirement benefits, federal and state government retirement benefits and employee union benefits.

Individuals who do not join a Part D plan must pay a premium surcharge of 1% per month for every month beyond the deadline that they do not enroll. Beneficiaries will be required to pay this penalty surcharge each month in addition to their normal premium for as long as they have Medicare prescription drug coverage.

The next open enrollment period is November 15, 2006 to December 31, 2006. However, coverage for individuals who enroll during this period will not take effect until January 1, 2007. Individuals who turn 65 years old and become eligible for Medicare prior to November 15, 2006 will be able to select a Part D drug plan and begin receiving prescription benefits prior to the open enrollment period. To start the enrollment process or identify a recipient's plan, call 1-800-662-0210.

Medicare Part D Coverage of Prescription Niacin Products

The Centers for Medicare and Medicaid Services (CMS) has reversed an earlier decision to exclude prescription niacin products such as Niaspan® and Niacor® from coverage under Part D. These drugs are now included under Medicare Part D for use in treating lipid disorders. However, CMS has indicated that each Part D drug plan may choose to add these drugs to their formularies or continue to exclude them as long as adequate inclusion of other lipid lowering agents appear on the Plan's formulary. See page 3 for clarification of coverage of other drugs under Part D.

Maryland Medicaid Drug Utilization Review Board

The Maryland Medicaid Drug Utilization Review Board (DUR Board) advises the Maryland Medicaid Pharmacy Program with respect to medication use within the fee-for-service population and utilization of mental health drugs for the HealthChoice population.

The DUR Board meets quarterly and advises Maryland Medicaid regarding the following:

- Review of prospective and retrospective DUR criteria, prior authorization criteria and quantity or dosage form limitations developed by the Division of Clinical Pharmacy Services or by contracted vendors.
- Evaluate the use of criteria and interventions, including assessing the operational effect of the criteria and interventions, in order to identify areas of prescribing and dispensing of specific drugs that may result in adverse patient outcomes.
- Evaluate patient drug utilization that may represent potential fraud and abuse and make disposition recommendations.
- Identify educational needs and develop educational plans to improve prescribing or dispensing practices, and evaluate the effect of these educational interventions.
- Review and approve the annual CMS DUR report describing the nature and scope of the DUR program, summarizing education/intervention strategies used, and estimating the cost savings generated.

Recently the DUR Board policies and procedures were updated to allow for an expanded DUR Board membership. The DUR Board now includes ten members with the ability to expand to up to twelve members if deemed appropriate by the Maryland Medicaid Pharmacy Program. Currently four physicians and six pharmacists serve on the DUR Board.

All physicians and pharmacists serving on the DUR Board are licensed in the State of Maryland and are actively practicing. DUR Board pharmacist members have extensive experience in all practice settings of community pharmacy and long term care consulting pharmacy. Physician DUR Board members have expertise in psychiatry, internal medicine, family practice and infectious diseases.

If you have an interest in serving on the DUR Board when vacancies become available in the future and you would like additional information or an application please contact the DUR Board administrator at 1-800-260-2555.

Preferred Drug List (PDL)

The Pharmacy and Therapeutics (P&T) Committee makes recommendations to the Department regarding PDL drug status. The P&T Committee is now meeting twice a year to review drug classes for consideration on the PDL. The next P&T Committee meeting is scheduled for August 17, 2006.

The Maryland Medicaid Pharmacy Program is currently reviewing the list of drug classes that will be reviewed by the P&T Committee at the August meeting. Changes to the PDL as a result of the August P&T Committee meeting go into effect October 3, 2006.

Medicare Part D Drugs / Part D Excluded Drugs

This table provides Part D coverage clarifications for specific products / drugs / drug categories in accordance with statutory and regulatory requirements for Part D drugs. This is not an exhaustive list but only addresses those products / drugs / drug categories that have been the subject of frequently asked questions. Specific products not identified in this table should always be evaluated against the statutory and regulatory definition of a "Part D drug" before drawing conclusions from this table. This table does not address Part B versus Part D coverage questions. The following table was derived from a recently published list available on the Medicare website at http://www.pharmacistelink.com/Medicarerx/Community_Care_RX/pdf/20060419PartDExclDrugs.pdf.

Product / Drug / Drug Category *(Listing is NOT all-inclusive)*	**May be covered under basic Part D benefit** *(when used for "medically accepted indication"[1])*	**Comments**
Advicor®	Yes	See Commercially Available Combination Product Policy
Agents when used for anorexia, weight loss	No	
Agents when used for cosmetic purposes or hair growth	No	Treatments indicated for psoriasis, acne, rosacea, or vitiligo are NOT considered cosmetic
Agents when used for symptomatic relief of cough and colds	No	All agents when used for symptomatic relief of cough, cold, or cough and cold are excluded from Part D
Antihistamine / Decongestant Combinations (Rx)	Yes, except when being used for symptomatic relief of cough and cold	
Barbiturates	No	
Benzodiazepines	No	
Blood glucose testing strips	No	NOT directly associated with injection of insulin
Commercially available combination prescription products	Yes, if it contains at least one Part D drug component and the product as a whole is not excluded from Part D for another reasion (e.g. used for cough and cold, less-than-effective DESI drug)	Commercially available combination prescription drug products that contain at least one Part D drug component are Part D drugs when used for a "medically accepted" indication, unless CMS makes a determination that such product, as a whole, belongs in one of the categories of drugs excluded from coverage under Part D. If CMS has not provided guidance to exclude a specific combination product, such combination product containing at least one Part D drug component should be considered a Part D drug unless it is excluded from coverage under Part D for another reason.
Electrolytes / Replenishers: *Potassium, Sodium, Calcium, Magnesium	Yes	*Potassium Iodide products are excluded from Part D as Iodine products (minerals) becuase they are not used for potassium supplementation
Fioricet® (Bultalbital, APAP, Caffeine)	No	See Commercially Available Combination Product Policy
Fioricet® with Codeine	Yes	See Commercially Available Combination Product Policy
Fiorinal® (Butalbital, ASA, Caffeine)	No	See Commercially Available Combination Product Policy
Fiorinal® with Codeine	Yes	
Fosamax plus D	Yes	
Guaifenesin (Rx)	Yes	
Insulin	Yes	
Insulin syringes	Yes	Syringes are NOT covered for injection of other drugs

[1] Medically Accepted Indication for purposes of Part D is an FDA labeled indication or an indication supported by citation in either the American Hospital formulary system (AHFS), USP-DI, or Drugdex.

Medicare Part D Drugs / Part D Excluded Drugs

(continued)

Product / Drug / Drug Category *(Listing is NOT all-inclusive)*	**May be covered under basic Part D benefit** *(when used for "medically accepted indication"[1])*	**Comments**
Klonopin® (Clonazepam)	No	
Lancets	No	
Less-than-effective DESI Drugs (and those drugs identical, related or similar)	No	
Leucovorin Calcium	Yes	
Librax®	No	Less-than-effective DESI drug
Limbitrol® (Amitriptyline / chlordiazeposide)	Yes	See Commercially Available Combination Product Policy
Megestrol Acetate and Growth Hormone when used for AIDS wasting and cachexia	Yes	Prescription drug products that otherwise satisfy the definition of Part D drug are Part D drugs when used for AIDS wasting and cachexia if these conditions are "medically accepted" indications, as defined by section 1927(k)(6) of the Social Security Act (SSA), for the particular Part D drug.
Primidone (Mysoline®)	Yes	NOT considered a barbiturate
Nonprescription / Over-the-counter (OTC) drugs[2]	No, except Insulin and supplies associated with the injection of insulin	Supplies associated with the injection of insulin include syringes, alcohol wipes, insulin pens and pen needles, gauze, and alcohol
Omacor®	Yes	
Phenobarbital	No	Barbiturate
Polysaccharide Iron Complex	No	Prescription vitamin / mineral product
Prescription niacin products	Yes	Prescription niacin products are approved by the Food and Drug Administration as safe and effective drugs, are used therapeutically for the treatment of dyslipidemia, and do not serve as nutritional supplements or address a vitamin deficiency. These products are used at dosages much higher than appropriate for nutritional supplementation. For these reasons, CMS has concluded that these products should not be considered prescription vitamins for purposes of Part D coverage, and therefore, are not universally excluded from coverage under the Medicare prescription drug program.
Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations	No	
Smoking cessation drugs (OTC)	No	
Smoking cessation drugs (Rx)	Yes	
Suboxone®, Subutex®	Yes	
Vitamin D Analogs (Calcitriol, doxercalciferol, paricalcitol, and dihydrotachsterol)	Yes	

[2] Part D plans may include OTC drugs in step therapy protocols as part of their cost effective drug utilization management program. However, OTC drugs included in these step therapy protocols are considered administrative costs, not Part D drugs.

Program Integrity Administration

The Program Integrity Administration is part of a Department of Health and Mental Hygiene (DHMH) and was established in July, 2004. It is part of an ongoing initiative to reduce costs associated with the Maryland Medicaid Program by identifying and eliminating Medicaid fraud, waste, and abuse without reducing recipient eligibility and benefits.

In 2005, Maryland Medicaid covered approximately 616,000 Maryland residents at a cost of approximately 5 billion dollars. According to the Government Accountability Office (GAO), as much as10% of all health care spending nationally, may be lost to fraud, waste or abuse.

Due to the rising cost of health care and diminishing government resources, the Maryland Medicaid Program has initiated new quality control measures designed to increase cost savings while ensuring program integrity through the elimination of recipient and provider fraud and abuse.

The goals of the Program are to:

- Identify ways to reduce the cost of the Medicaid Program without reducing services or number of beneficiaries served.
- Review each Program for compliance with policies and regulations
- Correct compliance issues within the Program through communication with agencies
- Propose enhancements to improve compliance and consistency
- Provide training to staff to eliminate or reduce Medicaid errors
- Increase referrals to Medicaid Fraud Control Unit
- Provide follow-up reviews of legislative and federal governmental audits

Preventing Medication Errors

There has been growing attention focused on medical errors, which have been identified as the eighth leading cause of death in the U.S. There are estimates that between 48,000 to 98,000 deaths are related to medical errors per year. Of these, it is estimated that as many as 7,000 deaths may be the result of medication errors.

Even more troubling, there are no ready solutions to the complex issues that contribute to this significant patient safety problem. Patient safety should be a cornerstone of the care we provide as healthcare professionals.

Medication errors can occur at many points in a highly complex medication delivery process, involving many individuals and decision points, from prescribing and ordering through administration and monitoring. Medication errors may or may not cause an adverse event, resulting in injury to the patient.

What We Can Do

All healthcare professionals can and must embrace the priority of safety for the patient irrespective of the role or the practice setting. A series of action steps have been identified and can effectively reduce patient risk.

- Request and obtain patient-specific information (height, weight, age, allergies).
- Clarify with prescriber any unclear or ambiguous prescription order.
- Verify and include dose and amount of drug to be dispensed.
- Eliminate the use of abbreviations for drug names.
- Develop specific locations of medication stock and inventory methods, for example, separate ophthalmic products from otics and inhalers from injectables.
- Routine inspections for expiration dates on products.
- Use reminders and redundancy in the prescription checking and labeling process.
- Assure consistent method for final check of product; consider routine use of two-person check for any dispensed prescription. Final check process should include a comparison of prescription to product and label.
- Ensure patient receives counseling regarding the safe and effective use of each prescribed medication and include both oral and written information.
- Assess patient's level of understanding of medication information provided.

Look-Alike / Sound-Alike Medication Names

Prescribed Drug:	*Instead of:*
Atrovent	Alupent
Dicloxacillin	Doxycycline
Xanax	Zantac
Zostrix	Zovirax
Klonopin	Clonidine
Hydroxyzine	Hydralazine
Coumadin	Kemadrin
Cardene	Codeine
Lovastatin	Lisinopril
Flovent	Flonase

FDA Adopts Standardized Nomenclature for Drug Labeling

The U.S. Food and Drug Administration (FDA) is adopting the "Problem List" Subset of SNOMED (Systematized Nomenclature of Medicine), for use in the electronic labeling initiative for prescription drug products as the standard computerized medical vocabulary system to be used to code important terms in the "Highlights" section of prescription drug labeling.

SNOMED was developed by the College of American Pathologists (CAP), and is one of the terminologies chosen by the U. S. Government as part of the health information technology infrastructure for clinical language. The Problem List Subset was created through a health technology partnership between the Department of Veterans Affairs (VA) and Kaiser Permanente.

This use of SNOMED for medical product labeling will improve the domestic exchange of product information in FDA-approved package inserts.

This move by the FDA will also allow healthcare professionals nationwide to electronically access and share critical health and treatment information more easily and efficiently. Specifically, the Problem List Subset of SNOMED can electronically code certain terms in the "Highlights" data elements of the new format for prescription drug information. This format will be required beginning June 30, 2006, for recently approved (within the last 5 years) and newly approved drug products.

The SNOMED system has been developed to provide coding for clinical terminology to make it computer readable across systems. For example, what is commonly known as a heart attack can also be called a myocardial infarction, infarct, or an MI. SNOMED provides one code for all of these terms for use in product labeling, enabling the electronic exchange of important health information from system to system.

The use of SNOMED in the "Highlights" section of prescription drug labeling will enhance the interoperability of electronic systems exchanging FDA approved labeling information in the care of patients.

The new labeling format will be integrated into the FDA's other e-Health efforts through a variety of ongoing initiatives. As prescription information is updated in this new format it will be used to provide medication information for DailyMed - an interagency online health information clearinghouse, sponsored by the National Library of Medicine.

DailyMed is maintaining the most up-to-date medication information free to consumers, healthcare professionals, and healthcare information providers. The DailyMed is making up-to-date information about FDA-regulated products widely available on the Internet at no cost. The website is: http://dailymed.nlm.nih.gov

FDA Advisory Committee Discusses Potential Black Box Warning for ADHD Drugs

In February of this year, the Food and Drug Administration (FDA) Drug Safety & Risk Management Advisory Committee recommended that a black box warning outlining cardiovascular risks in adults be added to the labeling of all stimulants used to treat ADHD.

In March of this year the FDA's Pediatric Advisory Committee recommended that a black box warning was not required to warn against episodes of psychosis, aggression and cardiac events that may be associated with the use of stimulants in treating ADHD in children. The Pediatric Advisory Committee felt that the risks of cardiovascular events in children were not similar to those in adults, except in children with cardiovascular abnormalities. The committee also declined to endorse a black box warning for all ADHD drugs warning against the possibility of psychiatric events, including aggression, and suicide thoughts.

The Pediatric Advisory Committee recommended the risk of psychiatric events and aggression should be described in the warnings section of labeling of all ADHD drugs. Current labeling language for amphetamine drugs on cardio-vascular risks in patients with cardiac abnormalities should also be extended to all ADHD drugs.

Recommendations were also made to include a patient medication guide with all ADHD drugs dispensed which would describe the potential psychiatric, aggression, and cardiovascular risks associated with their use.

Plan Name _____
Phone # _____
Fax # _____

Medicare Part D Coverage Determination Request Form

This form cannot be used to request:

- Medicare non-covered drugs, including barbiturates, benzodiazepines, fertility drugs, drugs prescribed for weight loss, weight gain or hair growth, over-the-counter drugs, or prescription vitamins (except prenatal vitamins and fluoride preparations).
- **Biotech or other specialty drugs for which drug-specific forms are required. [See <Part D plan website.>] OR [See links to plan websites at http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/04_Formulary.asp]**

Patient Information		Prescriber Information		
Patient Name:		Prescriber Name:		
Member ID#:		NPI# (if available):		
Address:		Address:		
City:	State:	City:		State:
Home Phone:	Zip:	Office Phone #:	Office Fax #:	Zip:
Sex (circle): M F	DOB:	Contact Person:		

Diagnosis and Medical Information			
Medication:	Strength and Route of Administration:		Frequency:
☐ New Prescription OR Date Therapy Initiated:	Expected Length of Therapy:		Qty:
Height/Weight:	Drug Allergies:	Diagnosis:	
Prescriber's Signature:			Date:

Rationale for Exception Request or Prior Authorization
FORM CANNOT BE PROCESSED WITHOUT REQUIRED EXPLANATION

☐ Alternate drug(s) contraindicated or previously tried, but with adverse outcome (eg, toxicity, allergy, or therapeutic failure)

➔ Specify below: (1) Drug(s) contraindicated or tried; (2) adverse outcome for each; (3) if therapeutic failure, length of therapy on each drug(s);

☐ Complex patient with one or more chronic conditions (including, for example, psychiatric condition, diabetes) is stable on current drug(s); high risk of significant adverse clinical outcome with medication change

➔ Specify below: Anticipated significant adverse clinical outcome

☐ Medical need for different dosage form and/or higher dosage

➔ Specify below: (1) Dosage form(s) and/or dosage(s) tried; (2) explain medical reason

☐ Request for formulary tier exception

➔ Specify below: (1) Formulary or preferred drugs contraindicated or tried and failed, or tried and not as effective as requested drug; (2) if therapeutic failure, length of therapy on each drug and adverse outcome; (3) if not as effective, length of therapy on each drug and outcome

☐ Other:_____ ➔ Explain below

REQUIRED EXPLANATION:_____
_____
_____

Request for Expedited Review

☐ REQUEST FOR EXPEDITED REVIEW [24 HOURS]

➔ BY CHECKING THIS BOX AND SIGNING ABOVE, I CERTIFY THAT APPLYING THE 72 HOUR STANDARD REVIEW TIME FRAME MAY SERIOUSLY JEOPARDIZE THE LIFE OR HEALTH OF THE MEMBER OR THE MEMBER'S ABILITY TO REGAIN MAXIMUM FUNCTION

Information on this form is protected health information and subject to all privacy and security regulations under HIPAA.

Pharmacy News and Views
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Phone In Prescriptions for Maryland Medicaid

New legislation has passed the Maryland General Assembly which will allow phone in prescriptions for Maryland Medicaid.

Currently phone in prescriptions are not allowed under Maryland Medicaid regulations. The new legislation would conform Medicaid regulations with State regulations concerning phone in prescriptions.

The new regulations will take effect October 1, 2006.

Medication Therapy Management

Medication Therapy Management (MTM) is a requirement of all Medicare Part D Plans. Based on the current Medicare regulations, MTM services must be provided for recipients who have multiple chronic diseases and are expected to utilize over $4,000 of medications per year. The goals of MTM services are to optimize therapeutic outcomes for individual patients by improving medication use and reducing the risk of adverse events.

MTM services may include any of the following:

- Assessing patient's health status
- Formulating medication treatment plan
- Selecting, initiating, modifying, administering medications
- Monitoring and evaluating response to and safety of therapy
- Documenting care and communication with other primary care providers
- Providing verbal education and training to patient
- Providing information, support, resources to enhance compliance

Pharmacists should have many opportunities to participate in these services with Medicare Part D Drug Plans.

All Program information and updates featured in this issue of ***Pharmacy News and Views*** are the best information available at the time of printing. Any updates that became effective after the date of printing will be included in the next issue of our newsletter.