CHAPTER VII

DRUG UTILIZATION REVIEW PROGRAM

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PURPOSE AND SCOPE OF THE DUR PROGRAM

State and federal legislation created the directive for the Virginia Medicaid Drug Utilization Review (DUR) Program. The purpose of the DMAS Omnibus Budget Reconciliation Act of 1990 (OBRA '90) DUR Program is to ensure that prescriptions for outpatient drugs are appropriate, medically necessary, and are not likely to cause adverse medical conditions. OBRA '90 further requires that the DUR Program educate physicians and pharmacists to reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care. DMAS established a DUR Board to:

1. review and approve drug use criteria and standards for both retrospective and prospective DUR;
2. apply these criteria and standards in the performance of DUR activities;
3. review and report the results of DURs; and
4. recommend and evaluate educational intervention programs.

Retrospective DUR (RetroDUR) is required only for outpatients by OBRA '90. However, because of a previous state legislative mandate for nursing facility retrospective DUR, nursing facility patients are also included in the retrospective component of the DUR Program. Certain criteria used for the nursing facility population are tailored to the needs of the elderly; the data for the outpatient and nursing facility populations are analyzed and reported separately.

Prospective DUR (ProDUR), which includes prospective review, patient counseling, and patient profiling, is required only for outpatients. Patient counseling is not required for inpatients of a hospital or institution where a nurse or other caregiver authorized by the state is administering medications.

The impact of the DUR Program on Medicaid providers varies. The retrospective component primarily focuses on prescribing patterns and is likely to have more of an effect on physicians and other prescribing providers. The pharmacist is responsible for performing the activities required for the prospective component. As a result, ProDUR will affect pharmacy providers to a greater degree than prescribing providers.

RETROSPECTIVE DUR COMPONENT OVERVIEW

The retrospective component of the DUR Program consists of two parts:

- Retrospective claim review
- Provider education

<u>Retrospective DUR Computerized Claims Analysis</u>

OBRA '90 mandates that the following problems be addressed in the retrospective component of the DUR Program:

- Therapeutic appropriateness;

- Overutilization and underutilization;
- Appropriate use of generic products;
- Therapeutic duplication;
- Drug-disease contraindications;
- Drug-drug interactions;
- Incorrect drug dosage or duration of drug treatment; and
- Clinical abuse/misuse.

The DUR Board uses selected RetroDUR criteria that are representative of clinically important issues. The focus of these criteria is on high-risk, high-volume, and high-cost drugs. In addition, certain criteria have been tailored to specific populations; different criteria are used for ambulatory outpatient members than for elderly nursing facility members. The criteria are updated periodically to include new products and reflect changing needs as well as patterns identified through the DUR analyses and follow-up.

RetroDUR is performed at the direction of DMAS through the computer applications available from the DMAS retrospective DUR computer analysis contractor. The provider education functions are also the responsibility of DMAS, with input and guidance from the DUR Board. After the claims data are analyzed and reviewed, the DUR Board determines whether to send an intervention letter to the providers.

Retrospective DUR Criteria - General Outpatient Members

The criteria for the RetroDUR analysis of pharmacy claims data for general outpatient members are based on the criteria developed by the DMAS retrospective DUR computer analysis contractor. The DMAS DUR Board has selected general classes of retrospective DUR criteria that are representative of clinically important issues; the focus of these criteria is on high-risk, high-volume, and high-cost drugs.

Educational Program

Several educational approaches are used in RetroDUR, including letters to individual providers outlining specific or potential therapeutic problems. The purpose of these general communications is to provide information on the findings and to solicit feedback on the issues and outcomes related to the DUR Program.

Letters to individual providers outlining specific or potential therapeutic problems determined through the application of the DUR criteria are also used. In those cases where a patient's drug therapy falls outside of the criteria approved by the DUR Board, a letter citing authority for the generally accepted therapeutic recommendations is sent to the prescribing provider. The providers may also be requested to provide clarifying information and justification. While it is hoped that these efforts promote judicious and cost-conscious use of drugs, the thrust of the DUR Program interventions is educational and informative, not punitive. Finally, DMAS works with the various state pharmacy and medical associations to provide suggestions, and, when requested,

expertise for DUR-related seminar topics for continuing education purposes.

PROSPECTIVE DUR COMPONENT

Overview

The prospective component of the DUR Program consists of three parts:

- ProDUR screening through DMAS' Medicaid Management Information System (MMIS) computer programming;
- Online, real-time notice to the pharmacist; and
- Patient counseling.

Since it is possible to perform the ProDUR screening function via a computer, DMAS has chosen to use this approach to facilitate the process. The pharmacist performs all ProDUR activities at the time a prescription is dispensed, applying the following general precepts:

- ProDUR screening shall be performed **before** all prescriptions for outpatient Virginia Medicaid members are filled; and
- The pharmacist may use his or her professional judgment as to the depth of counseling required for prescription refills.

Since pharmacy providers perform the ProDUR screenings, it is important that pharmacists discuss questions resulting from the prospective screening directly with the prescriber and/or member. Specific concerns may also be communicated to the DMAS DUR pharmacist at pharmacyteam@dmas.virginia.gov. Clarification on existing criteria and the need to develop new criteria or replace existing criteria are examples of such concerns.

Prospective DUR Screening Criteria

OBRA '90 requires that the following types of problems be addressed in the prospective component of the DUR Program:

- Therapeutic duplication;
- Drug-disease contraindications;
- Drug-drug interactions;
- Incorrect drug dosage or duration of drug treatment;
- Drug-allergy interactions; and
- Clinical abuse/misuse.

ProDUR activities are being carried out in Virginia's fee-for-service Medicaid Program as proposed by CMS. The approach used in the Virginia Medicaid DUR Program is to start with requirements that can be reasonably accomplished by the majority of pharmacy providers. With implementation of the mandated prospective component of the OBRA '90 DUR Program, the requirements for the DUR Program are likely to change over time.

While the following information on prospective screening is meant to serve as a guide for ProDUR activities for Virginia Medicaid providers, it should not be construed to be an all-encompassing document. Pharmacists, and other Medicaid providers, are expected to exert their clinical judgment in dealing with the types of problems outlined below.

Therapeutic Duplication

Therapeutic duplication is defined as the concomitant use of two or more drugs having the same or very similar pharmacologic properties. In some circumstances, therapeutic duplication may be appropriate (e.g., the use of more than one antihypertensive to treat difficult-to-control hypertension). However, in many situations, therapeutic duplication has the potential to cause the patient harm as a result of drug interactions, additive toxicity, and/or enhanced pharmacologic effects, and represents unnecessary health care expenditures.

Drug-Disease Contraindications

Drug-disease contraindications are identified by reference to medical claims data in the system. Alerts are sent when appropriate.

Drug-Drug Interactions

Drug-drug interactions may involve both prescription and non-prescription drugs.

Incorrect Drug Dosage or Duration of Drug Treatment

Incorrect drug dosage or duration of drug treatment is a problem that may be difficult to screen for because of lack of information about diagnoses, patient response to therapy, and hepatic and/or renal function. Where possible, the MMIS system identifies problems based on data submitted through the claims process.

Drug-Allergy Interactions

It is the responsibility of the dispensing pharmacist to detect drug-allergy interactions since Medicaid does not collect allergy data. It is important to remember that what may be called an allergy by a patient is often an adverse reaction or a side effect (e.g., most codeine/morphine allergies are really reports of adverse GI effects of the drug). When requesting allergy information, be sure to also ask, "what happened?" Reports of shortness of breath or skin rashes are usually indicative of true allergic reactions. Reports of GI upset (nausea, vomiting, diarrhea, etc.) and CNS disturbances (feeling "funny" or feeling sleepy) are generally the results of side effects. This does

not mean that side effects are to be trivialized and ignored. Rather, the patient should be educated as to the true nature of these undesirable results of drug therapy and encouraged to discuss them with the prescriber. More often than not, other therapeutic alternatives are available. Pharmacists should be vigilant for potential cross-sensitivity concerns when therapeutic alternatives are considered within classes of drugs (e.g., NSAIDs) and across classes of drugs (e.g., penicillins and cephalosporins).

Clinical Abuse/Misuse

Clinical abuse/misuse is the occurrence of any of the situations referred to in the definitions of abuse, gross overuse, overutilization, underutilization, and incorrect dosage or duration:

- **Abuse** means practices that are inconsistent with sound fiscal, business, or medical practices and result in unnecessary costs to the Virginia Medicaid Program or reimbursement for services that are not medically necessary or fail to meet professionally recognized standards for health care.
- **Gross overuse** means repetitive overutilization without therapeutic benefit.
- **Overutilization** means use of a drug in quantities or duration that puts the member at risk of an adverse medical condition.
- **Underutilization** means use of a drug by a member in insufficient quantity to achieve a desired therapeutic goal.
- **Incorrect drug dosage** means the dosage lies outside the daily dosage range (i.e., under dosage and excessive dosage) specified in predetermined standards (i.e., the manufacturer's dosage information) as necessary to achieve therapeutic benefit. Dosage range is the strength multiplied by the quantity dispensed divided by the number of days' supply.
- **Incorrect duration of drug treatment** means the number of days of prescribed therapy exceeds or falls short of the recommendations contained in the predetermined standards.

Summary of the Drugs and Drug Classes to be Covered by ProDUR

The criteria for the retrospective and prospective components of the DUR Program should be consistent if maximum benefit is to be derived from the Program. As previously noted, the RetroDUR criteria are representative of clinically important issues with a focus on high-risk, high-volume, and high-cost drugs. Thus, criteria very similar to those developed for RetroDUR will be used for ProDUR.

PATIENT COUNSELING ACTIVITIES

The state statute regarding patient counseling allows for a broader interpretation of what constitutes an "offer to counsel" than OBRA '90. The original intent of the OBRA '90 patient counseling mandate was for the pharmacist to make a verbal offer to discuss the medication to be dispensed with the Medicaid member or his or her agent.

Please note that:

- The pharmacist may delegate the responsibility of offering the counseling to a non-pharmacist; however, the actual responsibility for patient counseling may not be delegated to anyone except a pharmacy intern working under the supervision of a pharmacist.
- Printed materials may be used to **supplement** patient counseling, but **may not** be used **in place of** verbal counseling.

Both state statute and OBRA '90 also require that the information provided to members includes, but not be limited to, the following:

- Name and description of medication;
- Dosage form, dosage, route of administration, and duration of therapy;
- Special directions and precautions for preparation, administration, and use by the patient;
- Common adverse or severe side effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
- Techniques for self-monitoring drug therapy;
- Proper storage;
- Prescription refill information; and
- Action to be taken in the event of a missed dose.

The pharmacist should use his or her professional judgement as to the amount of information to provide in each area. The pharmacist must provide complete and thorough counseling before dispensing **all new** prescriptions. The degree of counseling to be provided before dispensing **refills** is subject to the pharmacist's discretion. The member or his or her agent may refuse counseling; however, the offer to counsel should not be presented in such a way as to encourage refusal of counseling. The acceptance or refusal of the offer to counsel should be documented, preferably in the patient's profile (see below).

PATIENT PROFILE ACTIVITIES

Both OBRA '90 and state ProDUR/patient counseling/patient profiling statutes require that the following information be included in the patient's profile:

- Patient's name, address, telephone number, date of birth (or current age), and gender;
- Medical history, including:
  - Disease state(s);
  - Known allergies and drug reactions; and

- A comprehensive list of medications and relevant devices;

- Pharmacist's comments relevant to the patient's drug use, including any failure to accept the pharmacist's offer to counsel.

PROVIDER PROFILING

Evaluation of claims-based data is also used to determine the presence of providers who receive a high number of alerts for unusual prescription use. Using the RetroDUR process, the system is programmed to collate the alerts generated for each prescriber or pharmacy. The DUR Board then determines which types of alerts are to be focused upon and sets the point for exceptions to trigger the system generation of a provider letter. Information conveyed to providers in this program reinforces the norms established for prescribing/dispensing of the classes or products in question.

Providers are asked to respond to a questionnaire regarding reasons for the documented pattern of care. Provider profiling is a useful tool in identifying prescribers and dispensers who may need educational intervention(s) related to potentially harmful therapeutic decisions.