PATIENT COUNSELING AND DRUG UTILIZATION REVIEW

Federal and state laws and regulations require that pharmacists provide the pharmaceutical care services described below. The intent of the laws and regulations is to improve the quality of pharmaceutical care by ensuring that medications are appropriate, medically necessary and not likely to have adverse medical results.

The Pharmacy Program utilizes several different Drug Utilization Review (DUR) applications in its program that are either federally and/or state mandated.

In 1990 the federal Omnibus Budget Reconciliation Act (OBRA) amended the Social Security Act to include the specific requirement that states must administer a DUR Program with a DUR Board. OBRA 90 states that a drug use review program assures that prescriptions are appropriate, are medically necessary and are not likely to result in adverse medical results. In accordance with the Act and federal regulations, states are mandated to have a Medicaid DUR program with the goal, "…to ensure appropriate drug therapy, while permitting sufficient professional prerogatives to allow for individual drug therapy." The federal DUR program's required components are:

1. Beneficiary counseling;
2. Prospective drug review;
3. Retrospective drug use review;
4. Educational program; and
5. State DUR Board.

Patient Counseling

Patient counseling must be offered and provided in accordance with the Louisiana Board of Pharmacy Regulations at LAC, 46:LIII, §517.

Components of Patient Counseling

In accordance with those regulations, the pharmacist, at a minimum, should be convinced that the beneficiary or caregiver is informed of the following:

1. Name and description of the medications;

2. Dosage form, dosage, route of administration and duration of therapy;

3. Special directions and precautions for preparation, administration and use by the beneficiary;

4. Common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance and the action required in the event of their occurrence;

5. Techniques for self-monitoring drug therapy;

6. Proper storage of the medication;

7. Prescription refill information, if any; and

8. The action to be taken in the event of a missed dose.

Exceptions to Counseling Requirement

Counseling is not required for inpatients of a hospital or institution where a nurse or other licensed health care professional is authorized to administer medications.

Waiver

According to the regulations, no pharmacist or pharmacy may solicit or encourage blanket waivers for patient counseling. However, the regulations do not prohibit the beneficiary or caregiver from declining patient counseling.

Prospective Utilization Review (UniDUR)

Prior to filling or refilling a prescription, the pharmacist must review the prescription and the patient record for therapeutic appropriateness.

If there is an indication of possible drug contraindications or abuse, the pharmacist must take appropriate action to resolve the issue(s).

UniDUR Features

UniDUR has the following features:

1. UniDUR provides real-time screening of all Point of Sale (POS) prescription drug claims against the Louisiana Medicaid clinical database;

2. UniDUR reports "clinical events" as defined by the Pharmacy Program. The events are based on extensive development research done by the program staff, contractors, fiscal intermediary (FI), University of Louisiana at Monroe (ULM) School of Pharmacy, and the Drug Utilization Review (DUR) Board; and

3. UniDUR provides an on-line response to a pharmacy within seconds of significant UniDUR events with the disposition of the claim.

How UniDUR Works

The UniDUR system accepts POS transactions from the Medicaid claims adjudication system and screens each prescription against a patient's prescription profile. The profile includes the beneficiary's active drug products, medical diagnosis profile, gender and age.

Screening occurs using one or more of the clinical screening modules that are based upon the clinical criteria defined by Pharmacy Program staff. The results of the screening are returned to the claims adjudication system in the form of clinical events. The system then completes the adjudication of the claim according to the program's established parameters and sends a response to the pharmacy.

Clinical Events

If a potential drug issue is identified, a clinical event is triggered, and the pharmacy will receive a UniDUR message. Prescriptions are screened for the following potential drug issues:

1. Compliance Monitoring – refills too early or too late;

2. Prescribing Limits – excessive or inadequate dosages, or duration of therapy;

3. Therapeutic Duplication – two or more prescriptions with duplicative actions, whether prescribed by the same or different prescribers;

4. Drug-Drug Interaction – drugs that should not be taken concurrently;

5. Drug-Disease Precaution – specific drugs that may cause harm in recipients with certain known medical conditions;

6. Disease-Drug Precaution – diseases where specified drugs are suggested for use to deter disease progression or complications; and

7. Pregnancy Precaution – drugs with high risk of fetal harm dispensed to childbearing women.

NOTE: Refer to "Prospective Drug Utilization Policies/Limits/Edits" in Section 37.1 Covered Services, Limitations, and Exclusions of this manual chapter for detailed policy information.

Medicaid Responses to a Clinical Event

Depending on the severity of the clinical event, Medicaid may:

1. Suppress the response to the pharmacy, but report it in aggregate to Medicaid staff;

2. Return the response to the pharmacy for informational purposes, not require any action and pay the claim as submitted; or

3. Return the response to the pharmacy, require the pharmacist to take appropriate action and report that action in the form of a claim override. Medicaid will deny payment if the pharmacist does not correctly override the claim.

Required Action

When a UniDUR response is received, the pharmacist must verify the information against the beneficiary's drug profile and current prescription, evaluate the conflict and decide whether or not to dispense the drug. Actions can range from conferring with the beneficiary and checking the beneficiary's profile to consulting with the prescriber.

If the message is "early refill" or "therapeutic duplication", the pharmacist must determine whether the prescription should be filled, refused or changed.

If the pharmacist or beneficiary is unaware of any conflicting prescriptions, the pharmacist may call the POS Help Desk for additional information on the UniDUR message. (See Section 37.5.4 for POS Help Desk contact number).

NOTE: Refer to Section 37.5.1 to access the POS User Guide and Section 37.1 Covered Services, Limitations, and Exclusions of this manual chapter for detailed information and instructions on the Prospective Drug Utilization Review (UniDUR) feature of the LMPBM System.

Retrospective Drug Utilization Review

The federal retrospective DUR requirements recognize the functions of Medicaid Management Information Systems (MMIS) and Surveillance and Utilization Review (SUR) subsystems which were in effect prior to OBRA 1990. The regulations, therefore, permit states to *limit retrospective DUR review activities to those that focus on appropriate and medically necessary care to avoid duplication of activities relating to fraud and abuse under the SUR program.*

LaDUR

The retrospective drug utilization review program in Louisiana is called LaDUR. The Pharmacy Program, through a contract with the FI, Gainwell Technologies, administers LaDUR as a component of its DUR system.

The LaDUR program includes four regional committees, each comprised of three pharmacist providers and one physician provider located throughout the state, who conduct monthly reviews of Medicaid beneficiary's prescription profiles. (These reviews assess the possibility of underutilization, over-utilization or contra-indications of prescription therapy by querying a beneficiary's disease history and drug utilization). The committees correspond with beneficiary's prescribers and pharmacists regarding their observations in an effort to identify prescription therapies and utilization patterns that correspond to specified therapeutic criteria.

LaDUR's Enhanced Focus

LaDUR has been enhanced in recent years by shifting its focus from a fundamental review of therapeutic drug criteria based on a beneficiary's prescription utilization to the examination of a beneficiary's disease states.

Extensive technical programming enhancements have allowed identification of prescription use or absence within a disease state. This shifts the program's focus from issues of over-utilization and drug duplication to a disease management focus. For example, clinical practice guidelines from

the American Diabetes Association were reviewed by the DUR Board to develop standards for LaDUR.

Drug Utilization Review Board

The federal OBRA '90 statute requires each state to establish a DUR Board. The Louisiana Department of Health (LDH), Bureau of Health Services Financing (BHSF) has established a Drug Utilization Review Board to assist the agency in assessing its DUR Program.

DUR Board Functions

The Board should:

1. Make recommendations and approve predetermined criteria established in retrospective DUR and prospective DUR;

2. Evaluate the use of predetermined criteria and standards in use and make recommendations to the BHSF concerning modification or elimination of existing predetermined criteria and standards or the adoption of new ones;

3. Recommend guidelines governing written predetermined criteria and standards that pharmacies not using approved software must use in performing prospective DUR;

4. Identify educational topics to improve prescribing and dispensing practices;

5. Make recommendations regarding interventions to improve quality of drug therapy;

6. Periodically re-evaluate educational interventions;

7. Be a knowledgeable group, dedicated to assisting the agency in the administration of its DUR Program in an advisory capacity; and

8. Prepare an annual report.

LaDUR Board Membership

Federal statute specifies the general board membership.

The membership of the DUR Board shall consist of at least one-third, but not more than 51 percent, licensed and actively practicing physicians, and at least one third licensed and actively practicing pharmacists.

The committee shall be composed of at least eight members (or approved designees) appointed by the secretary of LDH.

The committee shall consist of healthcare professionals who have recognized knowledge in:

1. Clinically appropriate prescribing of covered outpatient drugs;

2. Clinically appropriate dispensing and monitoring of covered outpatient drugs;

3. Drug use review, evaluation, and intervention; and

4. Medical quality assurance.