DRUG USE REVIEW PROGRAM

Medicaid Program
State of Hawaii

PROSPECTIVE DUR

CLINICAL SCREENING

Prospective review of drug therapy is required for each prescription submitted by a Medicaid recipient before the prescription is filled or delivered at the point of sale or distribution. This review requires screening, based upon predetermined standards, for the following potential drug therapy problems:

- **Therapeutic duplication**: the prescribing and dispensing of two or more drugs from the same therapeutic class such that the combined daily dose puts the recipient at risk of an adverse medical result or incurs additional program costs without additional therapeutic benefit.

- **Drug disease contraindications**: the potential for, or the occurrence of, an undesirable alteration of the therapeutic effect of a given drug because of the presence, in the patient for whom it is prescribed, of a disease condition or the potential for, or the occurrence of, an adverse effect of the drug on the patient's disease condition.

- **Drug-drug interactions**: the potential for, or occurrence of, a clinically significant adverse medical effect as a result of the recipient using two or more drugs together.

- **Incorrect drug dosage or duration**: the dosage lies outside the daily dosage specified in predetermined standards as necessary to achieve therapeutic benefit. Dosage is the strength multiplied by the quantity dispensed divided by day's supply. Incorrect duration is when the number of days of prescribed therapy exceeds or falls short of the recommendations contained in the predetermined standards.

- **Drug allergy interactions**: the significant potential for, or the occurrence of, an allergic reaction as a result of drug therapy.

- **Clinical abuse/misuse**: the occurrence of situations referred to in the definitions of abuse, gross overuse, over-utilization, and under-utilization, as defined below, and incorrect dosage and duration, as defined previously.

a. **Abuse**: provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program. (42 CFR 455.2)

b. **Gross overuse**: repetitive over-utilization without therapeutic benefit.

c. **Over-utilization**: use of a drug in a quantity, strength, or duration that is greater than necessary to achieve a desired therapeutic goal or that puts the recipient at risk of a clinically significant undesirable effect, or both.

d. **Under-utilization**: use of a drug in insufficient quantity, strength, or duration to achieve a desired therapeutic goal or that puts the recipient at risk of a clinically significant undesired effect, or both.

All definitions in this section are found in 42 CFR (Code of Federal Regulations) §456 unless specified otherwise.

1. **On Site Pharmacy Screening**: It is the sole responsibility of individual pharmacies participating in the Medicaid Program to undertake on site prospective DUR screening. Pharmacies may use prospective DUR software databases that are able to screen for the therapeutic problems listed above and do so on explicit standards. It is not expected that these databases will contain patient-specific diagnosis or allergy information. When, in the pharmacist's professional judgement, obtaining such information is essential, he/she should consult the patient or the patient's health care provider.

   Pharmacies without computers, or those which choose not to use prospective DUR database packages, must apply prospective DUR drug therapy screening that is consistent with the criteria included in references such as the American Hospital Formulary Service Drug Information (AHFS DI), the American Medical Association Drug Evaluations, the United States Pharmacopoeia Drug Information (USP DI), or peer reviewed medical or pharmaceutical literature.

2. **Electronic Claims Management (ECM) Based Screening**: It is anticipated that prospective DUR screening as a component of an approved ECM system (sometimes referred to as "point of sale") will eventually become the standard. At a minimum, an ECM system must screen for the problems specified above against drug claims history recorded in the Medicaid Management Information System (MMIS) or other drug claims processing system. Electronic alerts concerning potential therapeutic problems will be transmitted to the pharmacy where they serve as an aid to the pharmacist in the exercise of his or her professional judgement in filling the prescription.

PATIENT COUNSELING

Standards for counseling by pharmacists must be established under applicable State law. Applicable State law is defined as the State Pharmacy Practice Act or State Board of Pharmacy policy incorporated into State law by reference. There are no such precedents in the State of Hawaii, so patient-counseling standards will be established by the DUR Board.

The Offer to Counsel

1. The *offer* to counsel shall be made by the pharmacist in a face-to-face communication with each Medicaid patient or caregiver who presents a new or refill prescription, unless the offer is refused, matters which, in the pharmacist's professional judgement, are deemed significant.

2. The *offer to counsel* may be delegated to ancillary personnel.

3. In certain non-routine instances, it would be permissible for the *offer to counsel* to be made in a written communication, by telephone, or in a manner determined by the pharmacist as appropriate and reasonable, such as:

    a. in cases of language barriers or hearing impairments.

    b. in the case of mail order delivery, home health care delivery, or other instances where direct contact with the patient is not available, a toll-free number should be provided for counseling by a pharmacist. The patient should be informed of the availability of counseling and provided with the telephone number. A toll-free number is not necessary if most patients can access the pharmacy by a local or toll-free exchange or if most prescriptions are distributed in the pharmacy.

4. A refusal to accept an offer of counseling must be documented.

5. In no circumstances should the burden to receive counseling be shifted to the patient.

The Conduct of Counseling

The pharmacist must personally perform counseling with the patient or caregiver. This responsibility cannot be delegated to ancillary personnel. The content of counseling is governed solely by the professional judgement of the pharmacist. Topics for discussion may include:

1. Name and description of the medication;

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

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

4. Common and severe side effects, adverse effects or interactions, and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

5. Techniques for self-monitoring drug therapy;

6. Proper storage;

7. Prescription refill information; and

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

The counseling list is NOT to be interpreted as a checklist of information to be provided with each prescription. The pharmacist should use professional judgement to determine which information is most necessary in each case.

The pharmacist may supplement oral information with written information but may not use written information alone to fulfill the counseling requirement.

Patient Profiles

The pharmacist shall make reasonable efforts to obtain, record, and maintain information on Medicaid patients receiving prescriptions except when the pharmacist has reasonable belief that the patient will not continue to obtain prescription medications from that pharmacy. The collection, recording and maintenance of patient profiles may be delegated to ancillary personnel; however, the pharmacist is directly responsible for reviewing and interpreting patient profiles, and seeking clarification where confusing or conflicting information is present. It is expected that the pharmacist will be guided by professional judgement as to whether and when individual history information should be sought from the physician or other health care providers. Such profiles are to include at least the following information:

1. Patient name, address and phone number;

2. Date of birth (or age) and gender;

3. Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices currently in use by the patient;

4. Pharmacist comments relevant to the individual's drug therapy.

The patient profiles shall be maintained for at least three years from the date when the last prescription was filled.

Compliance Monitoring

Compliance with the requirements for prospective screening, counseling and maintenance of patient profiles will be monitored with the following techniques.

1. The *DUR Bulletin* will notify pharmacies of prospective DUR statutory and regulatory requirements.

2. Professional association communications such as the *Hawaii Medical Journal* and newsletters of the Hawaii Pharmaceutical Association will be used periodically to inform providers of prospective DUR standards, processes and results.

3. As part of the routine quarterly retrospective DUR profile screening, pharmacies showing high incidence of therapeutic problems detectable by prospective DUR screening will be identified.

4. Once a year, all Medicaid recipients will be informed of their rights to receive counseling through a Board mailing, and request feedback as to whether counseling was offered and received.

5. Pharmacy site inspections by the Compliance Section to review records documenting interventions as a result of prospective DUR screening and to review documentation on counseling and the maintenance of patient profiles will be performed yearly on a sample of no less than 2% of pharmacies, or upon specific recommendations of the DUR Board.

RETROSPECTIVE DUR

Pattern Analysis

There is an ongoing periodic screening of claims data, no less frequently than quarterly, to identify patterns of fraud, abuse, gross overuse, and inappropriate or medically unnecessary care. It is not necessary to screen against all predetermined standards as part of each periodic screening.

The objective of screening is to identify patterns of behavior involving physicians, pharmacists, and individual Medicaid recipients, or patterns associated with specific drugs or groups of drugs. Analysis of patterns involves identification of the incidence of screen failure associated with a particular provider or a particular drug, and may also involve analysis of individual screen failure associated with a specific recipient and one or more providers.

Screening Requirements

Screens used in conducting pattern analyses are based on explicit predetermined standards and involve monitoring at least the following:

- Therapeutic appropriateness
- Over and underutilization
- Appropriate use of generic products
- Therapeutic duplication
- Drug disease contraindications
- Drug interactions
- Incorrect dosage or duration of therapy
- Clinical abuse/misuse

In applying the predetermined standards to monitor for the problems listed above, therapeutic criteria determine the population at risk. Normative standards are used to statistically determine outliners where prescribing or dispensing practices may not conform to acceptable standards of care.

As a result of the application of standards, remedial strategies may be introduced (when appropriate) to improve the quality of care and conserve personal or program funds. These strategies may include additional educational programs, intensified monitoring, changes in predetermined standards, or other actions that the DUR Board deems appropriate.

Education and Intervention

The DUR Board will maintain an active ongoing education and intervention program that addresses drug therapy problems using data obtained through the retrospective DUR process. The purpose of the program is to educate practitioners on significant drug therapy problems to improve prescribing and dispensing practices.

The education and intervention program includes but it is not limited to:

1. **General Information Dissemination**: Information about the DUR Board, specific standards, common therapeutic problems associated with specific drugs or drug classes, and other matters concerning the operation of the DUR Program that the Board considers appropriate is disseminated. This non-provider and non-patient specific information can be disseminated by means of provider bulletins, seminars, videos, continuing education or other appropriate media and occurs at intervals satisfactory to the DUR Board. Information dissemination should be consistent with State continuing education requirements for physicians and pharmacists.

2. **Provider/Patient Specific Information Dissemination**: When circumstances dictate, the DUR Board directs provider or patient specific interventions. These communications may be through written, oral, or electronic reminders, as well as face-to-face discussions between health professionals concerning therapeutic problems and changes needed to achieve optimal prescribing, dispensing and pharmaceutical care.

3. **Intensified Review or Monitoring**: This involves monitoring specific drug prescribers or dispensers of drugs. The DUR Board establishes selection criteria for intensified review and monitoring of providers.

WORKING RELATIONSHIPS

1. **Surveillance and Utilization Review System (SURS):** SURS is the responsibility of the Compliance Section of the Med-QUEST Division. Screeners review claims data quarterly for inappropriate utilization based on recipient-driven, provider-driven and treatment analysis (diagnosis)-driven reports produced by the Medicaid Management Information System (MMIS). Follow-up and intervention are performed when detailed review warrants, and compliance checks performed when indicated.

   In respect to drug therapy, Compliance screeners should bring significant problems to the attention of the DUR Program so they may be considered for retrospective review by the DUR Board. Conversely, when the DUR Board independently establishes criteria and standards for retrospective review, the Compliance Branch will be consulted to determine if there are possibilities to adopt existing SURS methodology and share resources.

2. **Medicaid Investigation Division:** When it is suspected, during the course of drug use review, that an intentional deception or misrepresentation has been made by a person, a recommendation can be made to the Branch] Compliance Section to conduct a preliminary investigation. If the investigation confirms the suspicion, the Compliance Section can make a

referral to the Medicaid Investigations Division of the Department of the Attorney General.

3. **Medicine and Pharmacy Professional Associations:** The Hawaii Medical Association (HMA) and the Hawaii Pharmaceutical Association (HPhA) and the Hawaii Society of Hospital Pharmacists (HSHP) will be the principal professional liaisons to physician and pharmacist providers. They will be consulted for DUR Board nominees and serve as sounding boards for obtaining feedback on criteria and standards ratification.