DRUG USE REVIEW PROGRAM

Medicaid Program
State of Hawaii

Executive Summary

Section 1927(g) of the Social Security Act requires that a drug use review program be established for covered outpatient drugs to assure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical outcomes. The Drug Use Review (hereinafter "DUR") Program assesses data on drug use against predetermined standards which are consistent with widely recognized compendia and the peer reviewed medical literature. The DUR Program is comprised of four major components.

Prospective DUR

Prospective DUR involves screening for drug therapy problems before each prescription is filled or dispensed at the point of sale. As part of prospective DUR, based upon standards established by applicable State law and/or DUR Board, a pharmacist must offer to counsel Medicaid patients or caregivers concerning matters, which the pharmacist considers significant. In addition, the pharmacist must make reasonable efforts to maintain patient profiles.

Retrospective DUR

Retrospective DUR involves using existing Medicaid information systems or other systems to implement ongoing periodic assessments of drug claims data, based upon predetermined standards, to monitor for therapeutic appropriateness and specific problems specified in the statute.

Educational Program

A vital component of Retrospective DUR is the educational program conducted through DUR Board guidance. General information dissemination and interventions are intended to improve prescribing and dispensing practices, and educate practitioners on common and serious drug therapy problems.

DUR Board

An advisory board must be appointed whose members must have expertise as specified in the statute, and must include licensed actively practicing physicians and pharmacists. Activities of the DUR Board include retrospective DUR, application of standards, and ongoing education and interventions, as well as preparation of an annual report to the State.

GENERAL REQUIREMENTS

Effective Date

DUR Program requirements must be met no later than January 1, 1993.

Nursing Facility Residents

Drugs dispensed to nursing facilities residents are subject to all requirements of the DUR program except those relating to Patient Counseling.

Organized Health Care Setting Exemption

1. A hospital dispensing outpatient drugs is exempt from the DUR Program if it uses a drug formulary and bills Med-QUEST at no more than its purchasing costs.
2. Covered outpatient drugs dispensed by health maintenance organizations are not subject to the requirements of the DUR Program.

Predetermined Standards

The DUR Program assesses drug use against predetermined standards found in the three compendia specified below and the peer reviewed medical literature.

1. American Medical Association Drug Evaluations
2. United States Pharmacopeia Drug Information
3. American Hospital Formulary Service Drug Information

Compliance with this statutory requirement (see §1927(g)(1)(B) of the Act) is based on the considerations that follow.

1. **Definition:** Predetermined standards include:
   a. Criteria: These are predetermined elements of health care based upon professional expertise, prior experience, and the professional literature with which the quality, medical necessity, and appropriateness of health care services may be compared.

   b. Standards: These are professionally developed expressions of the range of acceptable variation from a criterion.

2. **Source of Standards**: Predetermined standards may be developed by the DUR Board *de novo*, may be acquired from vendors of prospective or retrospective DUR, and may also be obtained from academic researchers or other organizations.

3. **Approval of Standards**: Standards to be applied in the prospective and retrospective DUR sections must be approved by the DUR Board prior to implementation. This includes both the establishment of new and the revision of existing standards. This applies to clinical standards, which serve as the basis for prospective and retrospective DUR software but not to algorithms based upon those standards. DUR Board approval is also required for policy for establishing written criteria that must be used by pharmacies conducting prospective DUR without computers. The Board may also require that it approve specific written criteria used by such pharmacies.

4. **Standards Requirements**: Clinically acceptable predetermined standards must also meet the following requirements for DUR Board approval.

    a. Predetermined standards must be based upon the three specified compendia and the peer reviewed medical literature, which includes medical, pharmaceutical, or scientific publications where manuscripts are chosen for publication based upon critical review by unbiased independent experts.

    b. Differences between source materials must be resolved by the Board through a consensus process.

    c. Predetermined standards are nonproprietary and readily available to providers of service and the public.

    d. Predetermined standards must be clinically valid and scientifically based.

    e. Predetermined standards must be tested against claims data prior to implementation to assess the level of identifiable significant therapeutic problems.

    f. Predetermined standards applied in prospective and retrospective DUR must not be inconsistent.

    g. Predetermined standards must be subjected to ongoing evaluation, with inclusion of provider feedback and modification where necessary.

5. **Review Requirements**: The review based on clinical criteria uses predetermined standards to determine the population at risk of a clinically significant adverse medical result and applies standards, appropriate to this population, across providers and patients to determine the provider outliners whose prescribing, dispensing, or consumption practices may not conform to accepted standards of care. Various statistical measures may be applied to the data. Standards may be considered in deciding if an in-depth review is needed to determine whether to intervene once the potential therapeutic problems have been identified through the use of clinical criteria.

State Plan Assurance

Assurance that predetermined standards that meet all requirements have been approved by the DUR Board must be based on written documentation (e.g., Board minutes, memorandum).

Confidentiality

The DUR Program will ensure the confidentiality of patient related data consistent with Federal confidentiality requirements (see 42 CFR 431, Subpart F).

DRUG USE REVIEW (DUR) BOARD

General Requirements

See DUR Board Constitution and Bylaws (Appendix I).

Membership Requirements

DUR Board Members include health professionals with knowledge and expertise in one or more of the following areas:

1. Clinically appropriate prescribing of covered outpatient drugs;

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

3. Drug utilization review, evaluation, and intervention;

4. Medical quality assurance.

See also the DUR Board Bylaws, Section II (Appendix I).

Medicaid Program/DUR Board Relationship

The DUR Board is an advisory body to the Hawaii Medicaid Program. The Medicaid Program has the authority to reject recommendations or decisions of the DUR Board. In the event of such rejections, the Medicaid Program will notify the DUR Board, in writing, of the reasons for such action and allow the DUR Board to reconsider its recommendation or decision.

DUR Board Activities

In addition to the broad purpose of the DUR Board stated in the Constitution, Article III (Appendix I), Section 1927 (g)(3)(c) of the Social Security Act assigns three specific activities to the Board. These activities are the application of standards, retrospective DUR, and ongoing interventions with pharmacists and physicians concerning therapy problems identified in the course of retrospective DUR.

1. **Application of Standards**

   a. **Retrospective DUR:** The DUR Board approves predetermined standards (criteria and standards) presented to it and those that the DUR Board develops. Board approval is required both for the implementation of new standards and for revision or elimination of existing standards.

      The Medicaid Program will generate reports on the application of standards to claims adjudicated through the State MMIS. Such reports provide he basis both for evaluation of standards by the DUR Board and for selection of interventions to be carried out by the DUR Board. Such reports will be generated no less frequently than quarterly and must indicate the number of claims run for each criterion, the incidence of screen failures for each criterion and for each provider, and the reasons for the failure. Reports will also aggregate failures, grouped by criterion for each provider and for each Medicaid recipient.
      The DUR Board, based upon review of the reports, evaluates experience with the use of predetermined standards and makes recommendations concerning modification or elimination of existing standards.

   b. **Prospective DUR:** The DUR Board reviews DUR databases to determine if they are based on accepted standards and contain the required screens. This does not mean that the Board must review and approve each database used by individual pharmacies. The responsibility of the DUR Board is limited to becoming familiar with DUR software, and approving the criteria for the DUR standards, which make up that software. It is the responsibility of the pharmacies to ensure that the databases they are using meet the DUR Board approved criteria.

The DUR Board review process is limited to the review of prospective DUR software databases known to the DUR Board and to evaluations requested by commercial vendors. The Board also develops policy guidelines for the use of written predetermined standards by pharmacies not using prospective DUR database software to conduct prospective DUR.

The Hawaii Medicaid Program submits information on prospective DUR database software to the DUR Board for evaluation. Upon notification of the results of this evaluation (unless an ECM system is established for prospective DUR), the Medicaid Program will provide information through provider bulletins to participating pharmacies concerning the acceptability of commercial prospective DUR database packages. As part of the compliance monitoring function, the DUR Program will ensure that participating pharmacies use acceptable prospective DUR database software or comply with guidelines on written criteria.

2. **Retrospective DUR**

The DUR Board approves predetermined standards and reviews reports on the results of the application of standards to develop recommendations concerning the modification or elimination of existing standards and the need for new ones.

Reports on the application of specific standards are generated which identify patterns of inappropriate and medically unnecessary care in terms of screen failures associated with specific physicians, pharmacists, and Medicaid recipients. These reports provide the basis for standards modifications and for education and intervention activities.

3. **Education and Intervention Program**

The Medicaid Program, through the DUR Board, educates practitioners with regard to common therapy problems to improve prescribing and dispensing practices. Intervention activities will include, but not be limited to:

a. Information dissemination;

b. Written, oral or electronic reminders;

c. Face-to-face discussions, and

d. Intensified review or monitoring.

Based upon in-depth reviews of the reports on the application of standards, the DUR Board engages in the following activities.

a. Recommend general education topics and develop educational materials matched to the drug therapy problems identified;

b. Share education topics with other entities involved in continuing education of pharmacists and physicians;

c. Recommend the mix of each type of provider specific intervention method (e.g., written, oral, electronic reminders, face-to-face discussion, increased review/monitoring), that would most effectively lead to improvement in the quality of drug therapy;

d. Make recommendations as to which mix of the interventions would most effectively lead to improvement in the quality of drug therapy;

e. Re-evaluate no less often than semiannually the appropriateness of existing intervention methods and make changes as appropriate.

The only direct role that the Hawaii Medicaid Program has in conducting education and interventions is to provide application of standards reports to the DUR Board.

Annual Report Requirement

The DUR Board prepares an annual report to the Hawaii Medicaid Program, which in turn is required to submit an annual report for the overall DUR Program to the Secretary of the Health Care Financing Administration (HCFA) no later than March 31st of each calendar year. The report provides the basis for evaluating the effectiveness of Hawaii's DUR Program.

DUR Board Annual Report Content

1. The report includes a description of the nature and scope of the retrospective DUR Program. It identifies the frequency of claims data screening, and the criteria and standards used. Copies of clinical criteria are enclosed with the report. Each succeeding year, only new or revised criteria and deleted criteria are required.

2. A summary is presented of non-patient/provider specific educational activities, e.g., continuing education meetings held and examples of written materials used. It includes information on the use of each type of intervention. It also assesses the effectiveness of each type of intervention on changes in prescribing/dispensing practices.

3. An evaluation of the adequacy of prospective DUR database software and details on policy guidelines adopted by the DUR Board pertaining to written criteria that pharmacies not using computer prospective DUR database may use is required.

STATE ANNUAL DUR PROGRAM REPORT

This report includes the DUR Board annual report and adds the following information:

1. A description of the prospective DUR Program, which indicates whether, prospective DUR is performed at the pharmacy site or is included in the ECM system. Included are details concerning State standards for counseling, requirements on maintenance of profiles, and, when applicable, documentation of DUR and counseling activities.

2. Cost savings estimates accrued to the DUR program. This includes a detailed specification of the methodology used to prepare the cost estimates. The cost estimates will distinguish between drug product cost savings and total Medicaid savings. Total Medicaid savings include estimation of savings resulting from reduced physician visits and hospital admissions related to the problems associated with the use of prescription drugs. Cost savings will also distinguish between savings attributable to prospective and retrospective DUR. Reports will focus on aggregate savings, not on changes associated with particular interventions or changes involving particular drugs or therapeutic classes of drugs, and will be adjusted for the impact of price increases, drug product rebates, and enrollee profiles.