Colorado
Drug Utilization Review Board
Policy and Procedures

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Drug Utilization Review Board
Policies and Procedures

Mission

To serve as an advisory board to the Colorado Department of Health Care Policy and Financing (Department) Medical Assistance Program and is responsible for making recommendations in four areas: application of standards (as described in Section 8.838); retrospective drug utilization review (DUR); ongoing intervention with pharmacists and physicians concerning therapy problems indentified in the course of the DUR program; and recommendations regarding prior authorization criteria.

Administration

Administrative coordination of the DUR Board is performed by the retrospective DUR vendor or other party as designated by the Department.

Duties

The DUR Board shall, among other things:

1. Review and make recommendations on predetermined standards and criteria submitted to the DUR Board by the Department or the Department's contractor;

2. Evaluate the use of the predetermined standards and criteria including assessing the operational effect of the predetermined standards and criteria in use and making recommendations to the Department or Department's contractor concerning modification or elimination of existing predetermined standards or the addition of new ones;

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

4. Establish an educational program under the direction of the Department or the Department may contract with accredited health care educational institutions (e.g. pharmacy or medical schools, retrospective DUR contractor, pharmacy associations, medical societies) for the purpose of educating practitioners with regard to common therapy problems to improve prescribing and dispensing practices.

5. Prepare an annual report along with the DUR vendor describing the nature and scope of the DUR program, summarizing educational strategies used, and estimating the cost savings generated.

6. Review prior authorization criteria presented by the Department and make recommendations regarding those criteria.

Membership

A. The DUR Board shall consist of nine members. Membership on the DUR Board shall consist of four physicians, four pharmacists who are licensed and actively practicing in the State of Colorado and one non-voting representative from the pharmaceutical industry.

B. The members of the DUR Board shall have recognized knowledge and expertise in one or more of the following:

1. The clinically appropriate prescribing of covered outpatient drugs;
2. The clinically appropriate dispensing of covered outpatient drugs;
3. Drug use review, evaluation, and intervention;
4. Medical quality assurance.

C. Ex officio members of the DUR Board shall consist of the Department's DUR liaison and the Account Manager from the DUR vendor. The DUR Account Manager may serve as the Secretary of the Board.

D. The DUR Board members must disclose, at the beginning of any DUR Board meeting, any conflicts of interest that would make it difficult to fulfill DUR Board duties in an objective manner.

Board Appointments and Terms

A. The DUR Board members are appointed by the Executive Director of the Department.

B. The retrospective DUR vendor and relevant professional organizations make recommendations regarding the nominees for the DUR Board to the DUR liaison, who then makes recommendations to the Executive Director.

C. The physician and pharmacist Board members shall serve two-year terms and such terms shall be staggered, so that new Board members are appointed each year. DUR Board members may be re-appointed to two-year terms.

D. The non-voting representative from the pharmaceutical industry shall serve a one-year term and may not be re-appointed.

E. Board members may be replaced at the discretion of the Executive Director.

F. The Board members may vote to remove any member who does not attend at least fifty percent of the meetings each year.

G. The Executive Director shall fill a vacancy occurring in the membership of the DUR Board for the remainder of the unexpired term. Such replacement shall meet all applicable requirements as set forth above.

Chair, Vice-Chair and Secretary Responsibilities

A. The Chair and Vice-Chair shall consist of one physician and one pharmacist. The officer positions shall alternate between a pharmacist and physician annually unless otherwise determined by the DUR Board members.

B. The Chair presides over the meetings of the DUR Board and shall be elected by the DUR Board.

C. The Vice-Chair presides over meetings of the DUR Board in the Chair's absence and shall be elected by the DUR Board.

D. The Secretary shall be a representative from the DUR vendor or a DUR Board member elected by the DUR Board. The Secretary shall record the minutes of the DUR Board meetings and shall present the minutes to the DUR Board for approval.

Meetings

A. Meetings are held at least quarterly at a time and place agreed upon by the DUR Board and specified by the retrospective DUR vendor in collaboration with the Department.

B. Unless otherwise notified, meetings will be held in Denver, CO.

C. Meetings will be held when a quorum of at least five voting members are present. If a quorum is not present, the DUR Board may hold discussions on agenda items, but may not vote.

D. Affirmative vote requires the majority of eligible voting members.

E. If a conflict of interest exists, members must recuse themselves from the applicable vote.

F. An agenda and any necessary supplementary materials will be prepared and distributed to the Board members at least two weeks in advance of the meetings to allow sufficient review time.

G. There will be a Regular session and an Executive session conducted during each Board meeting. Board members will vote to begin the Executive session pursuant to C.R.S. Section 24-6-402(3)(a)(III).

H. Visitors are welcome during the Regular session.

I. The Executive session will consist of the discussion of recipient profiles in accordance with the Health Information Portability and Accountability Act (HIPAA) and will be closed except to voting officio and ex officio members of the DUR Board.

J. Physician and pharmacist members of the DUR Board will be required to review approximately 25 patient profiles each quarter, which will be discussed at each Executive session.

Comments and Oral Presentations

A. Manufacturer and public written comments to the DUR Board will be restricted to products that are being reviewed for prior authorization criteria.

B. Manufacturers and members of the public have the opportunity to present written comments to the DUR Board by directing those comments to the Department's DUR liaison or delegated representative, as identified on the DUR Board meeting notice.

C. All manufacturer and public written comments received and approved by the deadline will be accessible to DUR Board members.

D. Oral presentations at the DUR Board meeting shall be restricted to products that are being reviewed for prior authorization criteria.

E. Presentations from manufacturers and members of the public shall be limited to a maximum of five minutes per drug product. Only one presentation per product will be permitted for a manufacturer. Persons must sign up no later than 24 hours in advance with the DUR Account Manager in order to speak at the DUR Board meeting.

F. Persons giving oral presentations must disclose all relationships to pharmaceutical manufacturers.

G. Persons will be called to present in the order in which they signed in for each set of prior authorization criteria.

H. Presentations must be limited to verbal comments. No visual aids, other than designated handouts, are permitted.

Public Communication

A. The Department is responsible for public notification of DUR Board information.

B. The proposed agenda for each DUR Board meeting shall be posted publicly at least thirty days before the meeting.

C. The Regular session meeting minutes shall be posted publicly no later than 30 days after the DUR Board approves the minutes.

D. If requests for information are made, the retrospective DUR vendor shall forward the request to the Department for review and approval. If the request is approved, the Department shall either send the material, or shall give the retrospective DUR vendor permission to provide the material.

Retrospective Criteria Approval Process

The DUR Board shall approve criteria and standards to be applied in retrospective DUR. The following sections outline the technical definitions and process of approving criteria.

A. Technical definitions

1. **Criteria** are predetermined standards against which aspects of good medical care are measured.

2. **Standards** represent the range of acceptable variation of observed behavior from criteria or norms. The standards shall be based on the following:

    a. **Therapeutic duplication** is 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.

    b. **Adverse medical result** is a clinically significant undesirable effect experienced by a patient, due to a course of drug therapy.

    c. **Drug-disease contraindication** is the potential for, or the occurrence of, an undesirable alteration of the therapeutic effect of a given medication 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.

d. **Adverse drug-drug interaction** is the potential for, or occurrence of a clinically significant adverse medical effect as a result of the patient using two or more drugs together.

e. **Incorrect drug dosage** is a dosage that lies outside the daily dosage range specified in predetermined standards as necessary to achieve therapeutic benefit.

f. **Incorrect duration of drug dosage** is the number of days of prescribed therapy that exceeds, or falls short of, the recommendations contained in the predetermined standards.

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

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

(i) **Abuse** means provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in unnecessary cost to the Medical Assistance program, or in reimbursement for services that are not medically necessary, or that fail to meet professionally recognized standards for health care.

(ii) **Gross overuse** means repetitive overutilization without therapeutic benefit.

(iii) **Overutilization** means use of a drug in quantities, or for duration that puts the recipient at risk of an adverse medical result.

(iv) **Underutilization** means that the drug is used by a recipient in insufficient quantity or duration to achieve a desired therapeutic goal.

B. Retrospective criteria approval process

1. The retrospective DUR vendor shall present new intervention criteria recommendations at least quarterly at the DUR Board meeting.

2. The proposed retrospective criteria shall be grouped by drug class and each drug within a class shall be reviewed individually.

3. The DUR Board may make changes to the proposed retrospective criteria.

4. After a review of the proposed retrospective criteria, the DUR Board shall vote to approve, provisionally approve or deny the retrospective criteria.

5. If criteria are provisionally approved, any DUR Board members' questions or concerns with the proposed criteria shall be researched by the retrospective DUR vendor and the answers shall be reported to the DUR Board at the next meeting. The DUR Board may then approve, make additional changes or deny the provisional criteria.