



COLORADO

**Department of Health Care
Policy & Financing**

Colorado Drug Utilization Review Board Policy and Procedures

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Drug Utilization Review Policies and Procedures

Mission

To serve as an advisory board to the Colorado Department of Health Care Policy and Financing (HCPF, hereby referred to as “Department”) Health First Colorado (Colorado’s Medicaid Program) and is responsible for making recommendations in four areas: application of standards (as described in Section 8.800.9); retrospective drug utilization review (DUR); ongoing intervention with pharmacists and physicians concerning therapy problems identified 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

- 1)** The DUR Board shall, among other things:
 - a) Review and make recommendations on predetermined standards, retrospective DUR criteria, and prospective DUR criteria (prior authorization criteria) submitted to the DUR Board by the Department or the Department’s DUR vendor;
 - b) Evaluate the use of the predetermined standards, retrospective DUR criteria, and prospective DUR criteria. This should include, but not be limited to assessing the operational effect of the predetermined standards and criteria in use and making recommendations to the Department or the Department 's DUR vendor concerning modification or elimination of existing predetermined standards or the addition of new ones;
 - c) The DUR Board shall approve retrospective DUR criteria for the purposes of conducting further analyses and retrospective DUR provider outreach;
 - d) The DUR Board provides recommendations to the Department regarding prospective DUR criteria;

- e) Recommend guidelines governing written predetermined standards for prospective DUR that pharmacies not using approved software must use in conducting prospective DUR;
- f) Establish and provide input on maintaining an educational program under the direction of the Department. The Department may contract with accredited health care educational institutions (e.g. pharmacy or medical schools, retrospective DUR vendor, pharmacy associations, medical societies) for educating practitioners about common therapy problems to improve prescribing and dispensing practices;
- g) As requested; 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;
- h) Engaging in any other activities as designated by the Department.

Membership

- 1)** 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.
- 2)** The voting members of the DUR Board shall have recognized knowledge and expertise in one or more of the following:
 - a)** The clinically appropriate prescribing of covered outpatient drugs;
 - b)** The clinically appropriate dispensing of covered outpatient drugs;
 - c)** Drug use review, evaluation, and intervention;
 - d)** Medical quality assurance.
- 3)** Ex officio members of the DUR Board shall consist of the Department's DUR vendor liaison and the Account Manager from the DUR vendor.

Conflicts of Interest & Mandatory Disclosures

All DUR Board members must disclose, prior to being offered a seat on the board, annually, and during DUR Board meetings, any relationship, affiliation, or employment, that creates potential

or actual conflicts of interest that would make it difficult to fulfill DUR Board duties in an objective manner.

If a conflict of interest exists, members must recuse themselves from the applicable vote or discuss with the board during the meeting whether the situation rises to the level of an actual conflict. If a board member recuses themselves, they should not participate in the discussion of the agenda item or any vote regarding it.

A Conflict of interest means a board member has actual competing professional or personal obligations, prior relationships, or financial interests that would make it difficult to fulfill DUR Board duties in an objective manner.

Board Appointments and Terms

- 1)**The DUR Board members are appointed by the Executive Director of the Department.
- 2)**The retrospective DUR vendor and relevant professional organizations make recommendations regarding the nominees for the DUR Board to the Department DUR contract manager, who then makes recommendations to the Executive Director.
- 3)**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.
- 4)**The non-voting representative from the pharmaceutical industry shall serve a one-year term and may not be re-appointed.
- 5)**Board members may be replaced at the discretion of the Executive Director.
- 6)**The Board members may vote to remove any member who does not attend at least fifty percent of the meetings each year during their term.
- 7)**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

- 1)**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.

- 2)**The Chair presides over the meetings of the DUR Board and shall be elected by the DUR Board.
- 3)**The Vice-Chair presides over meetings of the DUR Board in the Chair's absence and shall be elected by the DUR Board.
- 4)**The Secretary shall be a representative from the DUR vendor or a DUR Board member if 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

- 1)** 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.
- 2)** Unless otherwise notified, meetings will be held at Skaggs School of Pharmacy and Pharmaceutical Sciences (12850 Montview Blvd, Aurora, CO 80045) as indicated in the DUR Board Meeting agenda.
- 3)** 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.
- 4)** Affirmative vote requires the majority of eligible voting members.
- 5)** If a conflict of interest exists, members must recuse themselves from discussion of that topic and the applicable vote.
- 6)** 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.
- 7)** There will be a Regular (public) session and may be an Executive session (as needed) 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).

- 8)** Members of the public, pharmaceutical industry representatives and stakeholders are welcome during the Regular session.
- 9)** The Executive session may 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.

Comments and Oral Presentations

- 1)** Manufacturer and public written comments to the DUR Board will be restricted to products that are being reviewed for prior authorization criteria;
- 2)** 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 vendor liaison or delegated representative, as identified on the DUR Board meeting agenda. Persons must sign up no later than 24 hours in advance with the DUR vendor liaison in order to have their materials considered for distribution to the DUR Board;
- 3)** All manufacturer and public written comments received and approved by the deadline will be accessible to DUR Board members;
- 4)** Oral presentations at the DUR Board meeting shall be restricted to products that are being reviewed for prior authorization criteria;
- 5)** Presentations from manufacturers and members of the public shall be limited to a maximum of three 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 vendor liaison in order to speak at the DUR Board meeting;
- 6)** Persons giving oral presentations must disclose all relationships to pharmaceutical manufacturers;
- 7)** Persons will be called to present in the order in which they signed in for each set of prior authorization criteria;
- 8)** Presentations must be limited to verbal comments. No visual aids, other than designated handouts, are permitted.

Public Communication

- 1)** The Department is responsible for public notification of DUR Board information;
- 2)** The proposed agenda for each DUR Board meeting shall be posted publicly at least thirty days before the meeting;
- 3)** The Regular session meeting minutes shall be posted publicly no later than thirty days after the DUR Board approves the minutes;
- 4)** 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 and Prospective Criteria Approval Processes

- 1)** The DUR Board shall review criteria and standards to be applied in retrospective DUR and prospective DUR. The following sections outline process of approving criteria:
 - a)** Source material used for these processes must be consistent with peer-reviewed medical literature and the following compendia:
 - i) American Hospital Formulary Service Drug Information;
 - ii) United States Pharmacopeia-Drug Information;
 - iii) American Medical Association Drug Evaluations.
 - b)** Interventions resulting from approved retrospective criteria include further analyses and policy recommendations to the Department and letters sent to providers informing them that members have met specified criteria;
 - c)** Interventions resulting from prospective criteria include prior authorization and medication use recommendations provided to the Department.
- 2)** Retrospective Criteria Approval Process
 - a)** The retrospective DUR vendor shall present new intervention criteria recommendations at least quarterly at the DUR Board meeting;
 - b)** The proposed retrospective criteria shall be grouped by drug class and each drug within a class shall be reviewed individually;

- c) The DUR Board may recommend changes to the proposed retrospective criteria;
- d) After a review of the proposed retrospective criteria, the DUR Board shall vote to approve, provisionally approve or deny the retrospective criteria;
- e) 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.

3) Prospective Criteria Approval Process

- a) The DUR vendor shall present draft version of prior authorization criteria at the DUR Board meeting;
- b) The DUR Board may make changes to the proposed criteria using above-described source material;
- c) After a review of the proposed retrospective criteria, the DUR Board shall vote to approve, provisionally approve or deny the prospective/prior authorization criteria.

Technical definitions:

- a) **Criteria** are predetermined standards against which aspects of good medical care are measured.
- b) **Standards** represent the range of acceptable variation of observed behavior from criteria or norms. The standards shall be based on the following:
- c) **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.
- d) **Adverse medical result** is a clinically significant undesirable effect experienced by a patient, due to a course of drug therapy.
- e) **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.

- f) **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.
- g) **Incorrect drug dosage** is a dosage that lies outside the daily dosage range specified in predetermined standards as necessary to achieve therapeutic benefit.
- h) **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.
- i) **Drug-allergy interactions** are the significant potential for, or the occurrence of, an allergic reaction, as a result of drug therapy.
- j) **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.

Applicable Standards:

1) Colorado:

a) [10 CCR 2505 – 10 8.800](#)

b) [C.R.S. Section 24-6-402](#)

2) Federal:

a) [42 CFR Subpart K](#)