



COMMONWEALTH of VIRGINIA

Department of Medical Assistance Services

DRUG UTILIZATION REVIEW PROGRAM

Virginia Medicaid Drug Utilization Review (DUR) Board
Thursday, September 14, 2023, 1:00pm
DMAS -- 600 East Broad Street

Agenda

1. **Call to Order and Introductions** – John Morgan, MD, Chief Clinical Innovation Officer, Chair
 2. **Minutes - Approval of Minutes from the June 8, 2023 meeting**
 3. **By-Laws Review**
 4. **New Drugs – Grid**
 - a) Cuvrior™ (trientine tetrahydrochloride)
 - b) Daybue™ (trofinetide)
 - c) Furoscix® (furosemide injection)
 - d) Skyclarys™ (omaveloxolone)
 - e) Veozah™ (fezolinetant)
 5. **MRx Pipeline/DUR Quarterly Newsletter – Available on WebPortal**
 6. **Topics for Discussion**
 - a) Antipsychotic Medications in Children
 - b) Antidepressant Medications in Children
 - c) Mood Stabilizer Medications in Children
 - d) Overlaps in Antipsychotics, Antidepressants and Mood Stabilizers in Children
 - e) Synagis
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- 7. Reports**
 - a) ProDUR
 - b) RetroDUR
 - i. Recent RetroDUR Activity
 - ii. RetroDUR Criteria Estimates
 - c) Utilization Analysis

- 8. Adjournment**

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES
DRUG UTILIZATION REVIEW BOARD BY-
LAWS

Mission Statement

Section 4401, 1927(g) of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) mandated that the Virginia Department of Medical Assistance Services (DMAS) develop and adopt regulations effective January 1, 1993, for a drug utilization review (DUR) program for covered outpatient drugs. The Bill established a Drug Utilization Review Board, which will review and approve drug use criteria and standards for both retrospective and prospective drug utilization reviews, apply these criteria and standards in the application of DUR activities, review and report the results of DURs and recommend and evaluate educational intervention programs.

ARTICLE 1

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DUR Board Structure

1.1 Name — This body shall be known as the DMAS Drug Utilization Review Board, hereinafter referred to as the DUR Board.

1.2 Composition — The DUR Board shall consist of thirteen members. At least one-third of the members shall be currently licensed pharmacists, and one-third but no more than 51 percent of the members shall be currently licensed physicians. There shall be at least one but no more than two nurse practitioner members on the DUR Board. The DUR Board shall include the DMAS Chief Medical Officer (CMO) or designee and the DMAS Clinical Pharmacist. The Director of DMAS shall appoint all DUR Board members. The director of DMAS shall fill any vacancy on the DUR Board, other than expiration of term, for the unexpired portion of the term. The Director of DMAS shall provide staff assistance to the DUR Board and its Officers in the routine conduct of business.

The Director of DMAS shall establish the DUR Board either directly or through a contract with an outside vendor. The DUR Board shall submit recommendations on prospective and retrospective drug use review to the director. The director reserves the right to reject such recommendations and shall so notify the board consistent with federal requirements. The DUR Board shall adhere to all the requirements of client confidentiality with respect to patient specific information.

The DUR Board shall consist of 13 members. At least one-third of the members shall be pharmacists. At least one-third but no more than 51% of the members shall be physicians. There shall be at least one but no more than two nurse members. All pharmacist, physician and nurse members shall be licensed by the Commonwealth with such licenses in good standing. The Director of DMAS shall invite submission of candidates from each of these groups. Other individuals and groups interested in submitting names of candidates for the DUR Board shall indicate their interest to the director in writing. The director shall appoint the physician members from candidates submitted by the Medical Society of Virginia, the Old Dominion Medical Society, and each of the medical schools in the Commonwealth. The director shall appoint the pharmacist members from candidates submitted by the Medical College of Virginia/Virginia Commonwealth University School of Pharmacy, the Virginia Pharmaceutical Association, Virginia Chain Drug Store Association, and the Virginia Society of Consultant Pharmacists. The director shall appoint the nurse member or members from candidates submitted by the Virginia Nurses Association.

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1.1. At least five of the physicians and pharmacists appointed to the DUR Board shall be licensed and actively practicing.

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2. All individuals appointed to the DUR Board shall demonstrate knowledge and expertise in one or more of the following areas:

- a. The clinically appropriate prescribing of covered outpatient drugs;
- b. The clinically appropriate dispensing and monitoring of outpatient drugs;
- c. Drug use review, evaluation, and intervention; and
- d. Medical quality assurance.

C. Consistent with its by-laws, the DUR Board members shall serve at the pleasure of the director, for terms established by the director. Vacancies shall be filled in the same manner as the original appointment.

1.3 Term of Office — Consistent with its by-laws, the DUR Board members shall serve at the pleasure of the director, for terms established by the director. Vacancies shall be filled in the same manner as the original appointment.

Each DUR Board member shall be appointed for a two-year term, commencing on July 1 of the year of the appointment. Members' terms shall continue until a replacement member has been appointed. Should any DUR Board member be unable to fulfill his/her term on the DUR Board, that member shall provide written notice to the Chairperson of the DUR Board at least 30 days prior to resignation and shall also provide written notice to the Director of DMAS.

There is an expectation that a member of the DUR Board attends at least 50% percent of the meetings yearly. The DUR Board shall elect from among its members a chairperson and a vice-chairperson. Officers may be elected to successive terms.

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ARTICLE 11

DUR Board Meetings

2.1 Regular Meetings — The DUR Board shall hold meetings no less than quarterly, and upon call by the Director or as needed in the City of Richmond.

2.2 Special Meetings — The DUR Board may meet at such other times and places as the Director of DMAS determines to be necessary and appropriate. Reasonable effort must be made by or on behalf of the Chairperson to notify each DUR Board member of the meeting.

2.3 Meeting Notice — Each DUR Board member shall file with the Director of DMAS the e-mail address, mailing address and telephone number to which meeting notices and other information are to be directed. Where available, facsimile number and electronic mail address should also be provided. Notice of all regular meetings shall be given to the DUR Board members at least thirty days (30) in advance of the time and place meeting. Notice of all regular meetings shall also be announced at least three working days in advance of the meeting by publication in the Virginia Register or the Virginia Regulatory Town Hall.

2.4 Quorum — Seven (7) members of the DUR Board shall constitute a quorum.

2.5 Executive Session/Closed Meetings — Prior to meeting in an executive session closed meeting, the DUR Board must vote affirmatively to do so and must announce the purpose of the session meeting. This purpose shall consist of one or more of the purposes for which executive or closed meetings are permitted in accordance with Section 2-1-344§ 2.2-3711 of the Code of Virginia, the pertinent portion of the Virginia Freedom of Information Act.

Discussion in the ~~executive~~closed session must be limited to the subject or subjects stated in the motion. No final action may be taken in ~~executive~~the closed session. Upon return to open session, any action taken or motion adopted must be restated, voted upon, and placed in the minutes in order to become effective.

2.6 Conduct of Business — The rules contained in the most recently published edition of Roberts Rules of Order Newly Revised shall govern the DUR Board in all cases to which they are applicable, to the extent that they are not inconsistent with the laws of Virginia, these By-Laws, or any special rule which the DUR Board may adopt.

2.7 The DUR Board shall be assisted in carrying out its administrative duties, including the maintenance of minutes and records, by staff provided by the director of DMAS.

2.8 Electronic Participation in Meetings Excluding During Declared States of Emergency – An individual member may participate in a meeting of the DUR Board or a public meeting of any committee established by the DUR Board through electronic communication from a remote location for the following reasons:

1. A temporary or permanent disability or other medical condition prevents the member's physical attendance;
2. A family member's medical condition that requires the member to provide care for such family member, thereby preventing the member's physical attendance;
3. A member's principal residence is more than 60 miles from the meeting location; or
4. A personal matter prevents the member's physical attendance and identifies with specificity the nature of the personal matter.

Procedure for Approval:

1. Notification: The member requesting to participate through electronic communication from a remote location must notify the DUR Board or committee chair on or before the day of the meeting.
2. Quorum: A quorum of the DUR Board, or a simple majority of the committee, must be physically assembled at the primary or central meeting location identified in the public notice required for the meeting.
3. Technological Arrangements: Arrangements must be made for the voice of the remote participant to be heard by all persons at the primary or central meeting location.
4. Documentation: The specific reason the member is unable to attend the meeting, and the remote location from which the member participates, shall be recorded in the meeting minutes; notwithstanding this disclosure requirement, the specific medical condition(s) or related clinical information affecting the member requesting virtual participation shall not be publicly disclosed but will instead be treated as consistent with Protected Health Information. The nature of the personal matter shall also be included in the minutes. The remote location from which the member participates need not be open to the public and may be identified in the minutes by general description.
5. Limitation: Members may only participate through electronic communication due to personal matters for no more than two meetings of the DUR Board or committee vote to disapprove the member's electronic participation from a remote location, such disapproval shall be recorded in the minutes.

2.9 Electronic Participation in Meetings During Declared States of Emergency – The DUR Board may meet by electronic communication means without a quorum of the public body physically assembled at one location when the Governor has declared a state of emergency in accordance with Virginia Code § 44-146.17 or the locality in which the public body is located has declared a local state of emergency pursuant to Virginia Code § 44-146.21, provided that (i) the catastrophic nature of the declared emergency makes it impracticable or unsafe to assemble a

quorum in a single location and (ii) the purpose of the meeting is to provide for the continuity of operations of the DUR Board or the discharge of its lawful purposes, duties, and responsibilities. The DUR Board shall:

1. Give public notice using the best available method given the nature of the emergency, which notice shall be given contemporaneously with the notice provided to members of the DUR Board;
2. Arrange for public access to such meeting through electronic communication means, including videoconferencing if already used by the DUR Board;
3. Provide the public with the opportunity to comment at DUR Board meeting when public comment is customarily received.

The nature of the emergency, the fact that the meeting was held by electronic communication means, and the type of electronic communication means by which the meeting was held shall be stated in the minutes.

ARTICLE 111

DUR Board Authority

3.1 Powers and Duties — The DUR Board shall review and approve the retrospective drug utilization review criteria and standards. A listing of approved criteria and standards for use in prospective drug utilization reviews shall also be established. The approved criteria and standards may include commercial software packages, drug interaction handbooks, and other published and/or written criteria. The DUR Board shall recommend educational intervention programs and shall evaluate the success of educational interventions and make recommendations for modifications to the educational intervention program.

3.2 The DUR Board shall submit a report at least semi-annually evaluating the success of interventions and making recommendations for modifications to the educational program, if appropriate. The DUR Board shall evaluate the educational program developed by DMAS or DMAS' vendor pursuant to the requirements of these regulations and make recommendations concerning the appropriate mix of intervention approaches.

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3.23 The DUR Board shall submit a report on an annual basis to the Director of DMAS for submission to the Virginia Secretary of Health and Human Services. The report shall include a description of the activities of the DUR Board, including the nature and scope of the prospective and retrospective DUR programs, a summary of the interventions used an assessment of the impact of the educational interventions on quality of care, and an estimate of the cost savings generated as a result of the program and other information specified by the Director. DMAS shall prepare and submit, on an annual basis, a report to the U.S. Secretary of Health and Human Services that incorporates the DUR Board's report and conforms to the requirements set forth in 42 CFR § 456.712.

3.3 The activities of the DUR Board and the Medicaid fraud programs are and shall be maintained as separate. The DUR Board shall cause referral of suspected cases of fraud and abuse to the appropriate fraud and abuse control unit with the Medicaid agency.

ARTICLE IV

DUR Board Officers

4.1 — Type of Officer — The DMAS CMO or designee shall serve as the Chairperson.

4.3 — Duties of Chair

~~4.3.1 The Chairperson of the DUR Board shall preside, when present, at all meetings of the DUR Board; appoint members to committees; vote as any other member of the DUR Board on any issue; and perform other duties which may be delegated by the DUR Board.
The Chairperson shall work closely with the Director of DMAS or his/her designee in determining the type of involvement that will enable DUR Board members to carry out their responsibilities.~~

ARTICLE IV

DUR Board Officers

~~4.1 Term of Office At the first meeting of the DUR Board after July 1 of each year, the DUR Board shall elect officers from its membership for the coming DMAS fiscal year. Those elected shall assume their offices immediately following their election and shall serve until their successors are elected. The Director of DMAS shall fill any vacancy on the DUR Board, other than by expiration of term, for the unexpired portion of the term.~~

~~4.2 Type of Officers The DUR Board shall have a Chairperson and a Vice Chairperson.~~

~~4.3 Duties of Officers~~

~~4.3.1 The Chairperson of the DUR Board shall preside, when present, at all meetings of the DUR Board; appoint members to committees; vote as any other member of the DUR Board on any issue; perform other duties which may be delegated by the DUR Board; and delegate to the Vice Chairperson such duties as may be appropriate.
The Chairperson shall work closely with the Director of DMAS or his/her designee in determining the type of involvement that will enable DUR Board members to carry out their responsibilities.~~

~~4.3.2 The Vice Chairperson shall assume all the powers and duties of the Chairperson in the absence of the Chairperson at any meeting or in the event that the Chairperson is disabled or the office is vacant. The Vice Chairperson shall also perform such other duties as requested by the DUR Board or by the Chairperson.~~

ARTICLE V

Committees

5.1 Committees - Committees may be constituted at any time by action of the full DUR Board or the Chairperson. Such committees shall be formed when necessary for the efficient functioning of the DUR Board. Members of a committee and its chairperson shall be appointed by the Chairperson from among the membership of the DUR Board. At the time a committee is created, its mission shall be specifically established by action of the DUR Board or by the Chairperson. In creating such committees, the Chairperson shall specify the time within which the committee is to make its report(s) to the DUR Board.

5.2 Activities - The DUR Committee's activities include, but are not limited to, the review of patient, pharmacist, and physician exceptional drug utilization profiles generated from retrospective reviews applying knowledge and experience as a professional and the retrospective criteria and standards approved by the DUR Board.

Develop and recommend modifications to the prospective and retrospective standards based on clinical experience, new literature findings, and communications from practitioners pursuant to the educational program.

Make referrals in a manner consistent with the rules adopted by the DUR Board to the appropriate intra agency division in instances where an exceptional drug use pattern is suggestive of fraud or abuse.

Provide technical expertise to assist DMAS staff in the compilation of reports and recommendations to be presented to the DUR Board and the director.

ARTICLE VI

DUR Board Documents

6.1 Official Papers All official records of the DUR Board shall be kept on file at DMAS and shall be open to inspection. All files shall be maintained for five years. Minutes of the DUR Board shall be permanently retained.

ARTICLE Vu

Public Participation

7.1 Public Participation — Citizens may attend all DUR Board meetings, except ~~executive~~closed sessions as defined by the Freedom of Information Act, and may record the proceedings in writing or ~~be~~ using a recording device. The DUR Board may make and enforce reasonable rules regarding the conduct of persons attending its meeting.

7.2 Presentations to the DUR Board - Opportunities shall be provided for individuals or citizens representing a group or groups to appear on the agenda of a regular meeting of the DUR Board. Requests to appear before the Board should be made in writing and received thirty (30) days before a scheduled meeting, including subject matter and speaker name in order that they may be included on the agenda. Please send information to the DUR Board Coordinator, Rachel.cain@dmass.virginia.gov. The Chairperson may waive the 30-day requirement. The Chairperson will designate which presentations will be heard, In honoring such requests, the DUR Board will limit presentations to five (5) minutes, unless the Chairperson grants an extension.

ARTICLE VIII

Revisions and Compliance

8.1 Amendments — The By-Laws of the DUR Board may be amended at any regular meeting of the DUR Board by a majority vote, provided that the proposed action was submitted in writing at the previous regular meeting of the DUR Board and is included in the notice of the meeting at which a vote is to be taken.

8.2 Review — The By-Laws shall be reviewed in total at least every two years, with a limited annual review for compliance with the Code of Virginia and Section 4401, 1927(g) of the Omnibus Budget Reconciliation Act of 1990. Revisions shall be made as necessary and after approval by the Director of DMAS, the By-Laws signed and dated to indicate the time of last review.

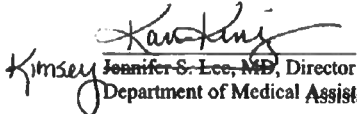
8.3 Effective Date— the foregoing By-Laws shall go into effect on the 13th day of December 2018.

Approved:



Bill Rock, PharmD
Chair, DUR Board

Bill Rock, PharmD


Jennifer S. Lee, MD, Director
Department of Medical Assistance Services

Date of last review: December 13, 2018