HEALTH CARE
AUTHORITY

DRAFT

Bylaws of the Combined Pharmacy & Therapeutics and Drug Utilization Review Committees

New Mexico Health Care Authority/ Medical Assistance Division Fee for Service P&T/DUR

December 2025

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ARTICLE I – DEFINITIONS & ACRONYMS

CHP **Center for Health Policy at the University of New Mexico**

Resource for health care evaluation, advancing data-driven solutions to improve health care delivery, access, and quality for all New Mexicans through partnerships with health care, state, and academic leaders.

CMS **Centers for Medicare & Medicaid Services**

CMS is the federal agency that provides health coverage to more than 160 million through Medicare, Medicaid, and Children's Health Insurance Program, and the Health Insurance Marketplace. CMS works in partnership with the entire health care community to improve quality, equity and outcomes in the health care system.

COI **Conflict of Interest**

A conflict of interest is when personal interests or relationship cause bias in decision-making and affect performance.

DUR **Drug Utilization Review**

DUR is an authorized and systematic review of medication use, which includes assessing prescription patterns, identifying potential issues, and implementing interventions to optimize drug therapy. The primary goals of DUR are to promote patient safety, improve health outcomes, and enhance the quality of pharmaceutical care.

FDA **Food & Drug Administration**

The FDA is a federal agency that protects and promotes public health by ensuring the safety and effectiveness of various products, such as drugs, devices, food, cosmetics and tobacco.

FFS **Fee for Service**

A reimbursement model used by Medicaid for healthcare services. It allows healthcare providers to receive payment for services rendered, with specific regulations and guidelines in place to ensure quality and efficiency in service delivery.

HCA **Health Care Authority**

HCA is a state agency to ensures New Mexicans attain their highest level of health by providing whole-person, cost-effective, accessible, and high-quality health care

and safety-net services. The HCA leverages purchasing power, partnerships and data analytics to create innovative policies and models of comprehensive coverage for New Mexicans.

MAD **Medical Assistance Division**

MAD is the direct administrator for the Medicaid program in New Mexico. It oversees services for over 800,000 members.

MCO **Managed Care Organizations**

A healthcare delivery system that coordinates and manages healthcare services to control costs while maintaining quality care for its members. They negotiate contracts with a network of providers, including hospitals, physicians, and specialists, to offer services at reduced costs. The primary goal of MCOs is to improve the quality of care, reduce unnecessary treatments and manage healthcare expenses effectively. New Mexico's MCOs are: Presbyterian Health Plan, United Health Care, Molina Health Care, Blue Cross/Blue Shield.

NMAC **New Mexico Administrative Code**

State program rules and regulations administrated for New Mexico.

P&T **Pharmacy & Therapeutics**

P&T is a committee that decides which drugs will appear on a hospital or health insurance plan's drug formulary. The committee consists of healthcare provider involved in prescribing, dispensing, and administering medications, as well as administrators who evaluate medication use.

PDL **Preferred Drug List**

PDL is a standardized list of medications that the state recommends over others in the same therapeutic class based on clinical effectiveness and value. The PDL will align medication coverage across Medicaid health plans, known as Medicaid Managed Care Organizations (MCOs,) and the Fee-for-Service program

PRIME **PDL Support Vendor**

The vendor contracted with the Healthcare Authority to review, evaluate, develop and maintain the PDL for the New Mexico Healthcare Authority.

PRODUR Prospective Drug Utilization Review requires each state to develop a DUR program targeted, in part, at reducing clinical and abuse and misuse of outpatient prescription drugs covered under the State's Medicaid Program. Medicaid DUR is a structured, ongoing program that interprets patterns of drug use in Medicaid

programs and includes prospective drug review, retrospective drug use review, data assessment of drug use against predetermined standards, and ongoing educational outreach activities conducted by Medicaid state agencies, managed health care systems, pharmacy benefit managers (PBMs), academic institutions and/or other applicable stakeholders. The Medicaid DUR Program promotes patient safety through state-administered utilization management tools and systems that interface with the claims processing systems.

Vendor P&T approved vendor (Prime Therapeutics)

ARTICLE II - NAME

The name of the organization shall be the **New Mexico Health Care Authority/Medical Assistance Division Combined Pharmaceuticals & Therapeutics (P&T) and Drug Utilization Review (DUR) Committees (the Committee).**

ARTICLE III – PURPOSE

The Committee serves in an advisory capacity to the New Mexico Health Care Authority/Medical Assistance Division, to perform reviews and make recommendations which facilitate the development and maintenance of the New Mexico Preferred Drug List for the Combined Pharmaceutical and Therapeutics and the Drug Utilization Review. Including but not limited to recommending structured, ongoing review of practitioner prescribing, pharmacist dispensing, and patient use of medication. In addition to recommending agents to be added to the state unified PDL. Operate with transparency and provide clinical guidance for Medicaid formularies per the Center for Medicare & Medicaid Services (CMS) mandate.

Administrative coordination of the Committee is performed by HCA/MAD administration in conjunction with MAD's pharmacy benefit vendors Conduent and Prime Therapeutics.

ARTICLE IV– ROLES AND RESPONSIBILITIES

A. The Committee shall, among other things:

1. Review and make recommendations on predetermined standards, retrospective DUR criteria, and prospective P&T criteria (prior authorization criteria) submitted to the Committee by the HCA/MAD or the HCA/MAD's DUR/P&T vendor.
2. Evaluate the use of the predetermined standards, retrospective DUR criteria, and prospective P&T 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 HCA/MAD or HCA/MAD 's DUR/P&T vendor concerning modification or elimination of existing predetermined standards or the addition of new ones.
3. The Committee shall approve retrospective DUR criteria for the purposes of conducting further analyses and retrospective DUR provider outreach
    a. Review, update, and approve policies and procedures governing provisions of the NM Medicaid pharmacy benefit as related to the medication use process.
    b. Review, update and recommend guidelines and other utilization management tools for the use of limited access drugs and non-preferred therapies.
    c. Establish and provide input on maintaining an educational program under the direction of HCA/MAD. The HCA/MAD 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.
4. Review newly FDA-approved drugs and related-products within 90-days and make recommendations for each newly FDA-approved drug with respect to the PDL within 180-days of market availability.
    a. Objectively appraise, evaluate, and select pharmaceuticals and related products (to be referred to as "drugs" or "medications" for the remainder of this document) for recommendation for coverage on the PDL.
    b. The Committee provides recommendations to HCA/MAD regarding prospective P&T criteria.
5. All classes covered under the PDL should be reviewed annually to place within the PDL
    a. The P&T committee and/or HCA can request a class be reviewed more than once a year as needed to accommodate new clinical and economic information
    b. Many drug classes are managed through the PDL but there are many other drugs that are covered by Medicaid that aren't managed through the PDL. Pursuant to the rules, the Pharmacy Office has the option to add new PDL drug classes to the PDL as determined appropriate
    c. Prior to each P and T review, the PDL classes are categorized into two groups: "Less active" classes and "more active" classes.

d. Classes with any of the following attributes may be considered as a "less active" class:
    i. the majority, if not all preferred products are now generic;
    ii. no utilization by members exists;
    iii. there are no stakeholder comments (from the public or industry);
    iv. no anticipated change in previous years' motions set forward for consideration by the Agency
e. The rest of the PDL drug classes that are not considered "less active" are given the status of "more active." All "less active" classes will be grouped together for a mass review for a more streamlined review during the meeting for the P and T committee's purpose. We continue to review all "more active" classes using the same process as previously used for all PDL classes. We will list all "less active" classes at the end of the agenda under a mass review section for discussion, if needed.

6. Prepare an annual report along with the DUR/P&T vendor describing the nature and scope of the DUR/P&T program, summarizing educational strategies used, and estimating the cost savings generated.
7. Engage in any other activities as designated by HCA/MAD.

ARTICLE V– RETROSPECTIVE AND PROSPECTIVE CRITERIA APPROVAL PROCESS

A. The Committee shall review criteria and standards to be applied in retrospective DUR and prospective P&T. The following sections outline process of approving criteria:
B. Source material used for these processes must be consistent with peer-reviewed medical literature Interventions resulting from approved retrospective criteria include further analyses and policy recommendations to HCA/MAD 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 HCA/MAD.

D. Retrospective Criteria Approval Process

1. The retrospective DUR vendor shall present new intervention criteria recommendations at least quarterly at the Committee meeting.
2. The proposed retrospective criteria shall be grouped by drug class and each drug within a class shall be reviewed individually.
3. The Committee may recommend changes to the proposed retrospective criteria.
4. After a review of the proposed retrospective criteria, the Committee shall vote to approve, provisionally approve or deny the retrospective criteria.
5. If criteria are provisionally approved, any Committee members' questions or concerns with the proposed criteria shall be researched by the retrospective DUR vendor and the answers shall be reported to the Committee at the next meeting. The Committee may then approve, make additional changes, or deny the provisional criteria.

E. Prospective Criteria Approval Process

1. The P&T vendor shall present a draft version of prior authorization criteria at the Committee meeting.
2. The Committee may make changes to the proposed criteria using the above-described source material.
3. After a review of the proposed retrospective criteria, the Committee shall vote to approve, provisionally approve or deny the prospective/prior authorization criteria.

ARTICLE V – PROSPECTIVE DRUG REVIEW FUNCTIONS:

A. The Board is responsible for evaluating the use and effectiveness of the ProDUR system, recommending to HCA/MAD or HCA/MAD's contractor any additions, deletions or modifications of the standards used for development of the ProDUR alerts and edits.

ARTICLE VI – RETROSPECTIVE DRUG REVIEW FUNCTION:

A. Ongoing periodic examination (no less frequently than quarterly) of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and Medicaid recipients, or associated with specific drugs or groups of drugs. Retrospective DUR includes, but is not limited to, using predetermined standards to monitor for the following:

1. Therapeutic appropriateness
2. Over-utilization and underutilization
3. Appropriate use of generic products
4. Therapeutic duplication
5. Drug-disease contraindication
6. Drug-drug interaction
7. Incorrect drug dosage
8. Incorrect DUR of drug treatment
9. Clinical abuse or misuse

ARTICLE VII – EDUCATIONAL PROGRAM

A. An ongoing educational outreach program using Committee data to educate practitioners on common drug therapy problems, with the aim of improving prescribing and dispensing practices. The program may utilize a variety of educational tools including the “reminders” listed in the preceding paragraph and a newsletter sent to all providers and included in the Pharmacy Section of the New Mexico Medicaid website.

ARTICLE VIII – MEMBERSHIP REQUIREMENTS/STRUCTURE

A. The Code of Federal Regulations has specific requirements for membership of the Committee. At least one-third, but not more than 51 percent of the Committee members must be prescribers (physicians, nurse practitioners, physician assistants), and at least one-third of the Committee members must be pharmacists. These physicians and pharmacists must be licensed and actively practicing in New Mexico. Each nominee must have recognized knowledge and expertise in one or more of the following:

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

B. In addition to membership described above, the Committee shall have one patient representative. The patient representative will:

   1. Represent the patient perspective as a member of the P&T committee.

   2. Have relevant experience or participation in patient or community-based organizations.

   3. Be able to demonstrate the ability to integrate data interpretations with practical patient considerations.

   4. Have a broad understanding of one or more condition or diseases, associated treatment options, and research.

C. All Committee members will be required to complete and sign a Non-Disclosure and Confidentiality Agreement and a Conflict-of-Interest Policy. If a conflict of interest exists, members must recuse themselves from discussion of that topic and the applicable vote. Mileage reimbursement for members traveling to meetings from outside Albuquerque will be provided in compliance with the per diem and milage act. The MAD pharmacy staff and Vendors will prepare meeting agendas/minutes, and work closely with the Board, but will not serve as voting members. A voting member may send a substitute to a meeting if the member is unable to attend.

D. Nominations can come from active board members, MCO partners, HCA/MAD staff, or public stakeholders. An email should be sent to the HCA/MAD Director of Pharmacy or pharmacy representative and should include the nominee's resume/CV and a letter of recommendation. Nominations can be approved by the Committee or HCA/MAD Chief Medical Officer and then formally appointed by the Medicaid Director.

E. The Committee will consist of 9-11 members, and a quorum is defined as greater than 50% of voting members present (e.g. 6 of 11).

F. The Committee members will serve an initial three-year term and will be eligible to serve one additional three-year term. Members must maintain active New Mexico licensing and registration and licenses must remain in good standing.

G. The HCA/MAD Medical Director may terminate the appointment of any Committee member for Good Cause.

H. The HCA/MAD Medical Director shall fill a vacancy occurring in membership of the Committee for the remainder of the unexpired term.

I. A Committee member will be considered inactive after no attendance or communication with HCA/MAD for 6 months. If a newly appointed board member does not attend the first meeting after their appointment and does not communicate with HCA/MAD staff, they will not be considered appointed, and the board has the right to appoint a new member earlier than 6 months.

ARTICLE IX – OFFICERS

A. The P&T committee will be led by the Chairperson and Vice-Chairperson

B. The chairperson will be elected by the membership of the committee. Term will be one year in length.
   a) The duties of the Chairperson is to preside over the P&T committee meeting

C. The vice-Chairperson will be elected by the membership of the committee. Term for the vice-chairperson will be one year in length
   a) The duties of the vice-chair are to assist the Charier person and preside over meeting in the chairperson's absence
D. In cases of officer resignation, a replacement will be elected at next meeting.

ARTICLE X – MEETINGS

A. The Committee shall meet quarterly. Meeting location, date, time and a draft agenda will be prepared by the HCA/MAD Pharmacy staff will be posted at least 7 days prior to the meetings on the HCA/MAD website, with a final agenda posted at least 72 hours prior to the meeting.
B. All meetings will be held on a virtual platform which will allow for telephonic participation by members when it is otherwise difficult or impossible for members to access the virtual platform. The agenda will include specific items of business to be discussed or transacted at the meeting and may include new drug updates, presentations for new additions, and class review. Matters not listed as a specific item of business on the agenda may be discussed, but no action will be taken. Items not listed on the agenda for a meeting must be taken at a subsequent or special or regular meeting.
   a. The P&T committee will be open to the public except for the executive portion in which proprietary of identifiable health information will be discussed.
C. PDL meetings will be open to the public and Committee members may not discuss committee business with each other outside of the public meeting.
D. The Committee shall keep written minutes of all its meetings. The minutes shall include at a minimum, the date, time and place of the meeting, the names of members in attendance and those absent, the substance of the proposals considered and a record of any decisions and votes taken that show how each member voted. Draft minutes shall be prepared within 10 working days after the meeting and shall be approved, amended, or disapproved at the next meeting where a quorum is present. Minutes shall not become official until approved by the Committee. Minutes from previous meetings should be approved at the next meeting of the public body prior to moving forward with the agenda.
E. The Committee shall discuss and vote on each agenda item presented unless a two-thirds vote of appointed members agrees to table the matter. Tabled agenda items will be brought before the Committee at the next quarterly meeting.

F. When a quorum cannot be met in person, email approval of voting items shall be acceptable and reportable in meeting minutes. Alternatively, HCA/MAD Chief Medical Officer may independently approve minutes, targeted interventions, and mailings.

G. Meeting minutes will be distributed to the members after the approval of the Chairperson.

H. All meetings of the New Mexico Medicaid Committee or any subcommittee of the Committee shall be open meetings, unless a specific beneficiary or provider is being discussed. Should specific persons be under discussion, the Committee shall enter closed session. Information collected in the P&T/DUR program that identifies individuals is confidential and may not be disclosed by the HCA/MAD Committee to any persons other than those identified as the MAP eligible service providers or governmental entities legally authorized to receive such information as NMAC 8.324.4.15.

I. Executive sessions will be held for the purpose of reviewing proprietary information from the manufacturers and will not be open to the public.

J. The Committee Chairperson is responsible for initiating the Executive sessions, which are limited to Committee members and the New Mexico supplemental rebate vendor staff.

K If requests for information are made, the HCA/MAD shall review and determine if the request shall be granted. If the PDL support vendor receives the request, the PDL support vendor shall forward the request to the HCA/MAD for review and determination. If the request is approved, the HCA/MAD will send the material, or give the PDL support vendor permission to provide the material.

L. Remote participation is allowed if audible to all attendees.

ARTICLE XI – VOTING PROCEDURES

A. Each Committee member constituting a quorum shall vote to approve or disapprove of each action item on the agenda.

B. Electronic voting via email is allowed within seven days if quorum is not present. Alternatively, a P&T committee member can proxy their vote to another member of the committee for to vote in their stead. The member must notify the Committee chair and HCA pharmacy staff in writing prior to the scheduled P&T committee

ARTICLE XII - STAKEHOLDER COMMENT AND ORAL PRESENTATION

A. Stakeholders have the opportunity to present comments to the Committee through written comments directed to the designated HCA representative.
B. Stakeholder comments will be restricted to agenda items. Stakeholder comments should be clearly labeled as such and should indicate the agenda item the comments represent
C. All stakeholder comments received by the deadline found on the meeting agenda, which will be at least 1 business days prior to the meeting (by 5pm MST) will be accessible to Committee members.
D. All stakeholders (including manufacturers) submitting comments shall be limited to two minutes of comment. The summary must be limited to clinical information only and will:

    a) Exclude any reference to cost.
    b) Exclude anecdotal content.

ARTICLE XIII– PREFERRED DRUG LIST DEVELOPMENT

Recommendations based on clinical efficacy, safety, and cost-effectiveness.

Evidence sources include FDA labeling, peer-reviewed studies, and clinical guidelines.

ARTICLE XIV – RESTRICTION OF MEDICATIONS

Committee may recommend criteria or authorization or special restrictions.

ARTICLE XV – AMENDMENT OF BYLAWS

1. Proposed amendments to these Bylaws must be submitted, in writing, to the Committee 15 days in advance of a scheduled meeting in order to be acted upon.
1. Proposed amendments should be sent to the Committee via email.
2. Approval by the Committee shall be required to adopt a proposed amendment, and such amendments must be approved by the Medical Director to become effective.

3. The Bylaws become effective as of the date they are approved by the Medical Director. The Committee will make note of the date of the adoption of bylaws in the meeting minutes.