

# Ohio Department of Medicaid

## Pharmacy & Therapeutics Committee By-Laws

### **Article I – PURPOSE**

#### Section I – Duties

The Pharmacy and Therapeutics Committee (Committee) has been established pursuant to Ohio Revised Code §5164.7510 to assist the Ohio Department of Medicaid (ODM) and its Medicaid Director with developing and maintaining a Preferred Drug List (PDL) for the Medicaid program.

#### Section II – Process

The Committee serves in an advisory role to ODM. Committee members shall review and recommend to the Medicaid Director drugs that should be included on the PDL. The Committee's recommendations shall be made based on the evaluation of competent evidence regarding the relative safety, efficacy, and effectiveness of prescribed drugs within a class or classes of prescribed drugs. A vote by a majority of a quorum is necessary to make recommendations to the Director. In the case of a tie, the Chairperson shall decide the outcome.

### **Article II – MEMBERSHIP**

#### Section I – Appointment

1) The Committee shall consist of ten members and the members shall be appointed by the Medicaid Director. The Director shall seek recommendations for membership from relevant professional organizations. A candidate for membership recommended by a professional organization shall have professional experience working with Medicaid recipients. Committee members shall possess 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 and monitoring of covered outpatient drugs;
- c. Drug use review, evaluation and intervention; or
- d. Medical quality assurance.

2) The ten members shall include: three pharmacists licensed under Chapter 4729 of the Revised Code; two doctors of medicine and two doctors of osteopathy who hold certificates to practice issued under Chapter 4731 of the Revised Code, and one of whom is a family practice physician; a registered nurse licensed under Chapter 4723 of the Revised Code; a pharmacologist who has a doctoral degree; and a psychiatrist who holds a certificate to practice issued under Chapter 4731 of the Revised Code.

#### Section II – Term

Each Committee member shall be appointed to a two-year term after which each member will come up for review by the ODM Director and new members may be considered. Members may be appointed by the ODM Director to an unlimited number of terms.

### Section III – Officers

There shall be a Chairperson and a Vice-Chairperson who shall be nominated and elected by a majority of the Committee. Other officers as deemed necessary and appropriate by the Committee may be nominated and elected by a majority vote. The Vice-Chairperson will take the place of the Chairperson upon his or her absence or request.

### Section IV – Responsibilities

Committee members shall:

- 1) Review and recommend to the Medicaid Director the drugs that should be included on the PDL. Their recommendations shall be made based on the evaluation of competent, peer reviewed medical literature, professional guidelines and evidence regarding the relative safety, efficacy, and effectiveness of prescribed drugs within a class or classes of prescribed drugs.
- 2) Apply their knowledge of current clinical practice during discussions and the making of recommendations.
- 3) Attend and participate in all Committee meetings, unless they are excused for good cause shown or otherwise excused by the Chairperson. In the event the Chairperson is unable to attend, the Chairperson shall provide advance written notice for the absence to the ODM clinical vendor, who shall note the reasons for the absence in the meeting minutes.

### Section V – Removal and Resignation

A Committee member may resign or may be removed at any time by the Medicaid Director, with or without cause.

## **Article III – MEETINGS**

### Section I – Frequency

The Committee will meet up to four times a year as scheduled by ODM and at special meetings as determined by the Committee. One or more of the following topics may be discussed at the meetings:

- New brand drug or generic drugs on the market
- Changes to be made to the PDL based on any local or national issues (including contract issues)
- Feedback from drug manufacturers and the public through a Public Comment session

### Section II – Procedure

1) The tentative meeting agenda, draft PDL, any therapeutic class reviews (TCRs) and new drug reviews (NDRs), and any other pertinent information will be made available electronically by the ODM clinical vendor to the Committee members no less than fourteen days in advance of the meeting.

- 2) For any meeting where the majority or all of the PDL is on the agenda, the meeting agenda, draft PDL and drug reviews/therapeutic class reviews, and any other pertinent information will be sent electronically by the clinical vendor to the Committee members no less than thirty days in advance of the meeting.
- 3) A detailed committee agenda shall be posted on ODM's website not later than fourteen days prior to the date of a regularly scheduled meeting, and not later than seventy-two hours prior to the date of a special meeting called by the Committee. For meetings where a majority or all of the PDL is on the agenda, a draft PDL shall be posted on ODM's website.
- 4) During the Committee meetings, non-extracted PDL categories will be voted on by a consent agenda. Extracted categories will be reviewed and voted on individually. The Clinical vendor, ODM representatives and Committee members are able to request extraction of any or all categories for any reason.
- 5) The Committee may establish one or more subcommittees to investigate and analyze issues consistent with the duties of the Committee under Ohio Revised Code §5164.7510. The subcommittee(s) may submit proposals to the Committee regarding the issues and the Committee may adopt, reject or modify the proposals.
- 6) The Committee shall post its recommendations on the website not later than seven days after the meeting at which the recommendation was approved.
- 7) The ODM clinical vendor shall take meeting minutes.
- 8) The Committee shall conduct its meeting according to parliamentary procedures outlined in *Robert's Rules of Order*.

#### **Article IV - QUORUM**

A quorum of five members of the Committee is required to conduct business. A majority will determine the Committee's election of officers, committee appointments, and recommendations.

No business can be transacted without a quorum except to adjourn the meeting. If a question is raised, debate is allowed but no vote can be taken.

To be considered present, to vote, and to be included in determining whether a quorum is present at a meeting, a member must be present in person unless permitted by ODM to attend virtually pursuant to the Americans with Disabilities Act or any other state or federal law. A request to attend virtually must be submitted to ODM at least one week prior to a scheduled meeting.

#### **Article V - PUBLIC PARTICIPATION**

An interested party shall be permitted to make a presentation or submit written material to the Committee during a committee meeting. The presentation or other material shall be relevant to an issue under consideration by the Committee and any written material, including a transcript of testimony to be given on the day of the meeting, may be submitted to the Committee in advance of the meeting.

Drug manufacturers whose products are under review may make a presentation or submit written material to the Committee. Drug manufacturers should focus on the relative clinical merits of their drug versus comparable products, and not discuss price with the Committee. Drug manufacturers shall not discuss Committee business, by any means, including oral or written communication, with individual Committee members outside the public meeting setting.

#### Guidelines for Presenters:

1) Interested parties may request to present and provide written materials to the Committee by contacting the clinical vendor before the meeting. Interested parties may also request to present and provide written materials during the meeting. If the request to present is submitted before the scheduled meeting, the presenter must provide both an explanation of the topic and, if the interested party presenter is not a drug manufacturer, a signed conflict of interest statement. The conflict of interest statement must include the interested party's affiliation (employer, client, advocacy group, etc...), relationships with any pharmaceutical manufacturers, and any other relevant relationships, which may impact the speaker's statements.

The clinical vendor contact information is available on the Department's website at: <http://pharmacy.medicaid.ohio.gov>.

2) The clinical vendor will confirm presentations with the interested party before the meeting. To be confirmed as a presenter at the meeting, requests to present must be received by 5:00pm on the Friday before the scheduled meeting.

- a. Presentations by Interested Parties will be limited to a maximum of three minutes, with the Committee chair having the option to extend or further limit the speaker's time depending on the situation. The Committee chair will not unreasonably deny requests for additional presentation time.
- b. Presentations by Interested Parties who are Drug Manufacturers will be limited to a maximum of three minutes, with the Committee chair having the option to extend or further limit the speaker's time depending on the situation.
- c. Presenters should email an electronic copy of the presentation to the ODM clinical vendor for distribution to the Committee.
- d. Unscheduled presenters should check-in with the clinical vendor before the start of the meeting and provide a description of the topic to be discussed and a signed conflict of interest statement. Unscheduled presenters will not be permitted to present at the meeting before providing the above.

3) Written materials should be submitted to the ODM clinical vendor in electronic form at least two business days prior to the scheduled meeting to give the Committee time to review the materials before matters are voted upon. Because of time limitations, written materials submitted after this deadline may not be reviewed by the Committee before matters are voted upon.

#### **Article VI - DISCLOSURE OF INTEREST**

Members of the Committee will be required to submit, on an annual basis, a signed "Pharmacy and Therapeutics Committee Conflict of Interest Policy" form. Committee members have an ongoing duty to disclose to the Committee any conflicts or potential conflicts of interests.

If a member has an interest that may affect or be perceived to affect the member's independence of judgment, the member must recuse himself/herself from the voting process for the drug class concerned. This recusal includes but is not limited to refraining from deliberation or debate, making recommendations, volunteering advice, and participating in the decision-making process in any way.

The Chairperson will review the criteria that members should use to determine whether to recuse themselves from the voting process at the beginning of each meeting and ask whether any members need to recuse themselves from consideration of a particular drug or class of drugs.

## **Article VII - AMENDMENT OF BY-LAWS**

Amendments to the By-Laws may be decided by majority vote at any Committee meeting. Any proposed amendments must be submitted prior to the meeting and be included in the agenda of the meeting during which the vote will be taken.

### **Document History**

Date	Action
10/1/2015	Draft
12/22/2015	Draft v2
1/13/2016	Approved by P&T Committee
1/10/2018	Review of bylaws; Updates to public participation suggested
10/2/2018	Draft v3 for review by P&T Committee
10/3/2018	Approved by P&T Committee
7/7/2020	Draft v4 for review by P&T Committee
7/8/2020	Approved by P&T Committee
1/12/2022	Approved by P&T Committee