North Carolina Medicaid Preferred Drug List Review Panel Guidelines and Procedures

I. Policy

In 2009, the North Carolina Department of Health and Human Services (DHHS) established the NC Medicaid Preferred Drug List (PDL) to allow NC Medicaid to ensure access to cost efficient as well as medically appropriate drug therapies that maximize patient health outcomes for all NC Medicaid beneficiaries. The PDL Review Panel was established the following year to review the PDL recommendations received from DHHS, NC Medicaid and the Physician Advisory Group Pharmacy and Therapeutics (PAG P&T) Committee to classify prescription medications as Preferred or Non-Preferred on the PDL.[1] In 2023, the North Carolina General Assembly codified the PDL as G.S. 108A-68.1A [Session Law 2023-134, Sections 9E.17(a)-(d)]. Legislation establishes the composition of the Review Panel, the cadence of PDL Review Panel meetings [no less than once a quarter], a public comment period, and procedure for the Review Panel to make recommendations to the Secretary of DHHS. It also provides DHHS with authority to adopt and publish other necessary and appropriate policies relating to the PDL, which are set forth herein.

II. Public Comment Period

DHB shall post recommended changes to the PDL and accept written public comments before the Review Panel meets. The public comment period shall be 30 days.

III. Membership

The Review Panel shall consist of the Director of Pharmacy for the Division of Health Benefits (DHB - NC Medicaid) and the following individuals appointed by the DHHS Secretary: (1) A representative from the Physicians Advisory Group Pharmacy & Therapeutics Committee (2) A representative from the Old North State Medical Society (3) A representative from the North Carolina Association of Pharmacists (4) A representative from Community Care of North Carolina (5) A representative from the North Carolina Psychiatric Association (6) A representative from the North Carolina Pediatric Society (7) A representative from the North Carolina Academy of Family Physicians (8) A representative from the North Carolina Chapter of the American College of Physicians (9) A representative from a research-based pharmaceutical company (10) A representative from hospital-based pharmacy.

NC Medicaid searches for Panel members that are dedicated, goal driven, and focused on Medicaid and the culturally diverse population it serves. In order to provide beneficiaries with the best quality of life, we need members of various backgrounds, diverse points of views, and lived experiences to provide advice on Medicaid programs and services. Having a diverse, equitable, and inclusive perspective will allow ideas to flourish, providing NC Medicaid with the best resources for beneficiaries.

[1] See S.L.2009-451, s. 10.66.(a)-(d); S.L.2010-31,s.10.33.(a)-(c); and S.L. 2011-145, s. 10.31.(d)r.2 for the full, historical legislative authority for the PDL.

The DHB Director of Pharmacy shall serve as chairperson of the PDL Review Panel. Individuals appointed to the Panel, except for the DHB Director of Pharmacy, shall serve a two-year term.

IV. Conflicts of Interest for Panel Members

Review Panel members are expected to operate in their capacity as voting members of this body with the highest ethical and professional standards. If a Review Panel member or an immediate family member has a financial relationship, ownership or financial interest, or other direct financial interest in a product or manufacturer being discussed, the Panel member shall recuse themselves from deliberation and voting on that drug or product. Review Panel members will sign a Conflict-of-Interest Statement annually while serving on the Panel.

V. Meeting Guidelines

The presence of 50 percent or more of panel members will be considered a quorum.

The currently listed products on the PDL, will not change status (Preferred / Non-Preferred) between quarterly Panel meetings. All changes or proposed changes are to occur at the next scheduled Meeting, with the exception the following conditions:

- Significant financial implications to the State
- Patient safety is at risk
- Product shortages in the marketplace or other access issues

The agenda of drug classes to be reviewed will be posted on the DHB website at least 15 days prior to the meeting.

Activities of the PDL Review Panel include the following:

- Conduct an open meeting no less than once per quarter to review the recommended policies and procedures related to the Medicaid PDL.
- Review new to market medications within PDL categories. Most new to market medications default to Non-Preferred status until reviewed by the PDL Panel.
- Review all PDL categories at least once during a calendar year, whether or not there are proposed recommendations. The purpose of the annual review of all categories is to ensure all medications listed on the PDL continue to be placed appropriately, given new clinical information since initial assignment to Preferred or Non-Preferred status.
- Defer any change proposed to a category during the meeting, which was not identified prior to setting of the agenda, for consideration and vote at the next meeting.
- Review written public comments received during the public comment period.
- Provide an opportunity for public comment during the meeting.
- Provide recommendations that are presented to the DHHS Secretary for final approval.

Minutes from each quarterly PDL Panel Review meeting will be posted publicly on the DHB website within 30 days of the date of the meeting.

VI. Public Comments During the PDL Panel Meeting

Time will be provided during each PDL Panel meeting for speakers to present comments related to the drug classes being reviewed.

Public comments are only allowed for medications or products being recommended for Non-Preferred status by the State in PDL categories being discussed, as documented on the publicly posted proposed PDL document during the 30-day comment period.

Public comments relating to any commercially available product within a drug class being reviewed shall be limited to new information (within the past twelve months). Comments shall address only the superiority of the product in question, when compared to the recommended Preferred products. Supporting evidence must be provided.

Speaker Registration

Speakers are required to register to provide comments during the meeting.

- Online speaker registration will be available on the DHB website until one business day prior to the meeting.
- Speakers may also register the day of the meeting by communicating with State staff regarding their desire to speak.
- Speakers should be prepared to give the following information about themselves at the beginning of their public comment:
    - Name of presenter
    - Company / organization affiliation, if applicable
    - The speaker must state if they are being compensated in any way for speaking on behalf of the drug or product, including if the speaker receives compensation as a consultant, a member of that pharmaceutical company's speaker's bureau, or participates in other educational speaking assignments, or receives other funding directly or indirectly through their employer from the pharmaceutical company.
- Each speaker will be given a maximum of 3 minutes to speak on a given product and/or State recommendation. Depending on the number of registered speakers, this time allotment may be reduced.

VII. Conduct of Manufacturers Toward Panel Members and NC Medicaid Staff

NC Medicaid understands that manufacturers of products under consideration may wish to inform Panel members or NC Medicaid staff of the superiority or attributes of their product throughout the year. However, NC Medicaid asks manufacturers to refrain from contacting Review Panel members or Medicaid staff members regarding any product under PDL consideration at least 30 days prior to the quarterly Meeting. Neither Review Panel members nor state staff are prohibited from reaching out on their own to inquire about specific products.