COMMISSION ON STEP THERAPY PROTOCOLS

Minutes of Virtual Meeting Held June 11, 2026 - DRAFT

1. Call to Order

Kevin Beagan, Deputy Commissioner of the Health Care Access Bureau, presided over the Sixth Meeting of the Commission on Step Therapy Protocols (Commission) held virtually on June 11, 2026, beginning at 9:00 AM EST. Kevin called the meeting to order and introduced the following agenda items:

Agenda:

- Welcome
- Approval of Minutes
- Schedule for Future Meetings
- Review Draft – Exception Requests for Prescription Drugs
- Continuity of Coverage Plans
- Turnaround Times
- DOI Pharmacy Benefit Manager Regulation
- Dr. Clinton Pong: Inviting Patient Advocates to Future Meeting(s)
- Other Matters
- Adjournment

2. Welcome - Attendees

Commission Members in Attendance:
Nancy Ryan, Health Policy Commission (OPP)
Caitlin Sullivan, Center for Health Information and Analysis
Cheryl Bartlett, Massachusetts Public Health Association
Paul Jones, Blue Cross and Blue Shield of Massachusetts, Inc.
Sarah Chiaramida, Massachusetts Association of Health Plans, Inc.
Kimberly Lenz, MassHealth
Clinton Pong, MD (PCP, Family Practice), representing Massachusetts licensed physicians
Eileen McAnneny, representing Massachusetts employer organizations
Darlene Sawicki, CNP, representing MGH as a non-physician licensed Massachusetts prescribers

Commission Members Not in Attendance:
Marc Hymovitz, representing ACSCan, a patient advocacy organization

DRAFT

Guests:
Rebecca Butler, Counsel to the Massachusetts Insurance Commissioner, DOI
Sarah ShoemakerHunt, Office of Pharmaceutical Policy Analysis (OPPA), Health Policy Commission
Brandon Karaffa, Director of Pharmacy Benefit Oversight Management, DOI
Nicholas Aresenault, Pharmacy Benefit Research Analyst, DOI
Brianna Callahan, Counsel to the Massachusetts Insurance Commissioner, DOI
Colleen Marticio, Counsel to the Massachusetts Insurance Commissioner, DOI
Lauren Freeman, Health Care Access Bureau Intern, DOI
Rita Gallo, Health Analyst, Bureau of Managed Care, DOI

3. Approval of Minutes

Motion to Approve the Minutes of the Fifth Meeting of the Commission, Held March 12, 2025

- Introduced by Darlene; seconded by Sarah C.; no discussion requested
- Motion passed unanimously by all Commission members in attendance:

Member Voting:
Kevin Beagan, Yes
Nancy Ryan, Yes
Caitlin Sullivan, Yes
Cheryl Bartlett, Yes
Paul Jones, Yes
Sarah Chiaramida, Yes
Kimberly Lenz, Yes
Clinton Pong, Yes
Eileen McAnneny, Yes
Darlene Sawicki, CNP, Yes

Upon approval of the Minutes, Kevin proceeded with the agenda.

4. Schedule for Future Meetings

Kevin reminded Commission members that future meetings are currently scheduled for September 10, 2026, and December 10, 2026, at the revised start time of 9:00 AM.

DRAFT

5. Review Draft – Exception Requests for Prescription Drugs

Kevin presented the Draft 2025 Report of Exception Requests for Prescription Drugs that had been circulated to Commission members with the Meeting Notice, highlighting the following sections and inviting comment from members:

- Summary Page – Kevin noted significant variations in the numbers reported by carriers
- Section F – Provides several options for providers to select in support of the step therapy exception request; the selection of multiple options per form might have resulted in overreporting by carriers

Comments from Commission members:

- Sarah C. indicated that reporting discrepancies might have resulted from providers' not having completed Section F or selecting multiple reasons on the same form, or carriers' over-reporting drugs not subject to step therapy
- Kim indicated that the normal drug approval process incorporates the same criteria as a step therapy exception request, and, as a result, step therapy exception requests were not called out for reporting
- Kevin reminded the group that Sarah C. was going to go back to carriers for suggestions on revising the reporting criteria and redesigning the exception request form with the goal of collecting more accurate data for the report to the legislature
- Sarah C. proposed the following suggestions from carriers:
    - Separating the step therapy exception request process from the prior authorization process for drugs;
    - Identifying a better distinction between medical/surgical providers and behavioral health/substance use disorder providers
    - Selecting only one criterion [for the step therapy exception request in Section F] ○ Simplifying instructions
- Paul indicated that Blue Cross limited its reporting only to step therapy exception requests and the information submitted by providers on the forms, and does not have the same concerns
- Kim suggested that discrepancies in reporting, possibly due to not calling out step therapy separately from the normal drug approval process, should not appear to point toward non-compliance with the requirements or failure of providers to submit the required exception requests
- Darlene added that it may be non-physicians, such as RNs or PAs, who are completing the forms and that they might require additional training to complete the forms correctly for reporting purposes
- Clinton added that it might also be an administrative staffer who is completing the forms or that approval request systems may be vary, especially if requests are collected electronically
- Kevin indicated that the Division welcomes suggestions for changing the processes for the collection and reporting of information to improve the accuracy of the annual report
- Kevin also requested that Sarah C. work with Kim and Paul to collect suggestions for consideration

DRAFT

6. Continuity of Coverage Plans

Building on the notes of the last meeting, Kevin reiterated that the Division's report should accurately reflect that the process as outlined in the law is being followed. Kevin confirmed with the group that no further discussion is required at this time.

7. Turnaround Times

Kevin confirmed with the group that no further discussion is required at this time.

8. DOI Pharmacy Benefit Manager Regulation

Kevin provided the group with an update on the Division's efforts to license Pharmacy Benefit Managers (PBMs) in Massachusetts and introduced the members of the new Pharmacy Benefit Management Team (PBM Team) within the Division, Brandon Karaffa and Nicholas Arsenault.

- Brandon shared that the PBM Team issued a Filing Guidance Notice on 5/15/2026 instructing PBMs to submit applications for the next 3-year licensing period to the Division by 7/1/2026. The PBM Team is working with PBMs to address their questions on the required materials and the review process and to date the Division has issued 42 PBM licenses for the 2026 calendar year. In addition to the current interim licensees, the Division anticipates that there may be as many as 10 additional applications, as it has received a number of requests for the application materials, as well as a check for the filing fee of $25,000 and the PBM Team believes this may be indicative of a trend in early applications
- Kevin added that the process to date has revealed that PBMs are not clear on how to be regulated. Even though the "top 3" PBMs are recognizable, other licensed PBMs might not have even Massachusetts business yet, but the Division aims to use the PBM licensing and oversight process to encourage PBMs to be good corporate citizens and to protect consumers

Kevin indicated that the Division is working with the Health Policy Commission (HPC) and CHIA to be sure that they can obtain good data and other necessary information from PBMs

- Caitlin provided an overview of CHIA's activities regarding PBMs:
    - CHIA has been collecting data from PBMs, starting 6/1/2026, and is currently performing QA and data validation, validating the data against other sources nationally, as available. ○ Of particular interest to CHIA are drug-level rebates from manufacturers or third parties or rebate aggregators, administrative fees that may be passed on to consumers, relationships between PBMs and related entities,

DRAFT

pricing information, and the development of drug formularies for Massachusetts residents.
    - CHIA is expecting to release a report in the October/November 2026 timeframe, presenting a profile of the data content and how it was validated, and eventually digging into the financial flow,

Input on PBMs from other Commission members:

- Clinton observed that pharmacy reps used to come into doctors' offices, but are now going to PBMs to influence formulary development and questioned whether this is a conflict of interest
- Kevin indicated that the Division is just beginning to understand PBM activities
- Darlene echoed Clinton's concerns and observed that pharmaceutical companies now refer to pharmacy reps as "educators," questioning the reason for the change in terminology
- Kim indicated that vertical integration presents a risk to accessibility, observing that contract costs have not decreased even though transparent pricing is replacing spread pricing
- Sarah Shoemaker-Hunt noted that the process Kim is describing is referred to as "profit tunneling" and indicated that the Office of Pharmaceutical Policy Analysis (OPPA) is analyzing these trends to understand drug pricing and affordability for its first annual report

Kevin reminded the group that the Division is currently working to implement the amendments to CMR 211 52.00 (Regulation 52) pertaining to prior authorization. The Division is conducting Q&A sessions with carriers on the new requirements with the goal of clearly defining the requirements. Subsequently, the Division will request implementation plans outlining the steps carriers will take to comply with the new requirements. These activities may intersect with the Step Therapy Commission concerning PACT Act drugs, vaccinations and drugs for persistent chronic illness and mental health conditions. Kevin indicated that the Division welcomes input from Commission members.

- Kim shared that her constituents have feedback on this issue and that two manufacturers have called to request that prior authorization requirements be removed from their drugs ASAP.

9. Dr. Pong's Request to Include Patient Advocates

Kevin asked that Clinton update the group on his request to invite patient advocates to future Commission meetings for discussion:

- Clinton indicated that when the bill was passed, it contained a provision for continuity of coverage for infusion access for multiple sclerosis (MS) patients
- Darlene indicated that she would be interested in following this topic for her practice
- Kevin indicated that patient advocates may be invited to participate in the September or December meeting; Kevin also indicated that the group previously discussed asking certain providers to share how they would complete a step therapy exception request, and MS was presented as an example in the last Commission meeting

DRAFT

- Nancy suggested including a case study in the final report to highlight the impact of the process on patients, showing the exception request from the patient's perspective and how the carrier would process the exception request
- Kevin indicated that the Commission does have time to capture this from carriers
- Paul added by way of background that, when this bill was introduced, there was a separate, stand-alone MS step therapy bill; those provisions were incorporated into the current step therapy bill to address advocates' concerns for MS patients without having a separate bill
- Kevin indicated that the Division is open to collecting input from Commission members by the end of June so that carriers can respond in the August/September timeframe with case study information for the annual report
- Sarah Shoemaker-Hunt proposed collecting all carriers' step therapy protocols for MS for illustration purposes
- Clinton will follow up with those who contacted him on participation and circle back to the Commission prior to the September meeting, and he will include Darlene in discussions regarding infusion processes

10. Other Matters

Kevin presented the relevant provisions of M.G.L. c. 176O § 12B (below) to emphasize the information the Commission is required to deliver in the annual report:

> (b) The commission shall study and assess the implementation of step therapy process reforms established in section 51A of chapter 118E and section 12A. The commission shall:
>
> (i) Analyze the impact of step therapy protocols on total medical expenses, health care quality outcomes, premium cost and out-of-pocket costs to the consumer and the health care cost benchmark.
>
> (ii) Assess the efficacy of the step therapy exception process in ensuring that consumers diagnosed with medical conditions that rely on stability or have achieved a positive clinical response on a medication are able to maintain that course of treatment including, but not limited to, a form of multiple sclerosis. The commission shall also examine any available empirical data on the impact of step therapy protocols on health disparities related to outcomes, access and medication adherence.

Kevin indicated that we do not appear to have enough information to satisfy the requirements of subparagraphs (i) and (ii), but that it may be sufficient to address the methodology for collecting and reporting the data with examples for this first report

- Sarah Shoemakeer-Hunt indicated that from OPPA's perspective, we would not be able to satisfy these requirements by September; APCD data is only current through 2024, and we are not there yet

DRAFT

- Caitlin from CHIA agrees, but indicated that it may be helpful to propose a plan to address these requirements in the future
- Kevin agreed and indicated that ideas for this approach would be welcome
- Clinton indicated that the infusion groups may be able to provide the examples needed for illustration in the report

There were no other matters proposed for discussion, and Kevin entertained a Motion to Adjourn the Meeting.

11. Motion to Adjourn Meeting

• Introduced by Paul; seconded by Caitlin; no discussion requested • Motion passed unanimously, and Kevin closed the meeting at 9:55 AM EST.

Member Voting:
Kevin Beagan, Yes
Nancy Ryan, Yes
Caitlin Sullivan, Yes
Cheryl Bartlett, Yes
Paul Jones, Yes
Sarah Chiaramida, Yes
Kimberly Lenz, Yes
Clinton Pong, Yes
Eileen McAnneny, Yes
Darlene Sawicki, CNP, No Vote Due to Early Departure

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