

COMMISSION ON STEP THERAPY PROTOCOLS

Minutes of Virtual Meeting Held April 17, 2025

Call to Order

Kevin Beagan, Deputy Commissioner of the Health Care Access Bureau, presided over the Organizational Meeting of the Commission on Step Therapy Protocols (Commission) held virtually on April 17, 2025, beginning at 10:00 AM EST. Kevin introduced Rita Gallo, Health Analyst at the Bureau of Managed Care, who will take the minutes of each meeting, and provided the following agenda items:

Agenda

1. Introductions
2. Open Meeting Law
3. Step Therapy Data Collection Tool
4. Future Meetings

1. Introductions – Commission Members

Commission Members	Member Information
Nancy Ryan	Designee of Executive Director David Seltz of the Health Policy Commission (OPP)
Kimberly Lenz	Designee of Assistant Secretary for MassHealth Michael Levine
Caitlin Sullivan	Designee of Executive Director Lauren Peters of the Center for Health Information and Analysis
Cheryl Bartlett	A representative of the Massachusetts Public Health Association
Paul Jones	A representative of Blue Cross and Blue Shield of Massachusetts, Inc.
Sarah Chiaramida	A representative of the Massachusetts Association of Health Plans, Inc.
Marc Hymovitz	A representative of a patient advocacy organization (ACSCan)
Clinton Pong	A licensed physician in the Commonwealth (PCP, Family Practice)
Darlene Sawicki, CNP	A licensed clinician, other than a physician who has prescribing authority under the scope of her license (MGH)

Commission Members Not in Attendance	Member Information
Eileen McAnneny	A representative of an employer organization

Guests	Guest Information
Rebecca Butler	Counsel to the Commissioner, Division of Insurance
Niels Puetthoff	Director, Bureau of Managed Care, Division of Insurance
Marie Exantus	Senior Health Analyst, Bureau of Managed Care, Division of Insurance
Rita Gallo	Health Analyst, Bureau of Managed Care, Division of Insurance

2. Open Meeting Law

Kevin reviewed the contents of the Open Meeting Notice for the Organizational Meeting of the Commission on Step Therapy Protocols, distributed to Commission members via email dated April 14, 2025 (Open Meeting Notice). The Open Meeting Notice, including the following attachments, is incorporated herein by reference:

- Email to Commission members dated April 12, 2025, which provided Commission members with a copy of the relevant legislation at <https://malegislature.gov/Laws/SessionLaws/Acts/2022/Chapter254> and the following purposes of the Commission:

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- (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; and
- (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; and
- (iii) produce a report to submit to the secretary of health and human services and the joint committee on health care financing by October 1 in even-numbered years.
- Open Meeting Law Guide;
- Certificate of Receipt of Open Meeting Law Materials, the form of which was prepared by the Attorney General and is available on the Office of the Attorney General's website;
- Certification on Form O, which must be completed by Commission members who were appointed to the Commission by the Governor after they have been sworn in;
- Presentation from the State Ethics Commission about the Conflict of Interest Law – M.G.L. c. 268A, and the state conflict of interest training required for Commission members appointed to the Commission by the Governor at: [Massachusetts Conflict of Interest Law Training \(skillburst.com\)](https://www.skillburst.com/training/massachusetts-conflict-of-interest-law-training);
- Proposed Agenda for the Organizational Meeting to be held on April 17, 2025; and
- Data collection tool proposed by the Division in connection with preparation of an aggregate report of carriers' step therapy experiences, together with draft guidelines intended to assist carriers in completing the data collection tool.

Kevin indicated that pursuant the Open Meeting Law, the Division serves as meeting coordinator and is responsible for taking notes, which will become the official minutes of each meeting. Kevin introduced Rebecca Butler, Counsel to the Insurance Commissioner, to explain the Open Meeting Law in greater detail.

Attorney Butler provided the following information regarding the Commission and the Open Meeting Law:

- Commission members may access a general description of the Commission, the Open Meeting Law Guide and determinations on the AGO website.
- All communications within public meetings of the Commission are subject to the Public Records Law; therefore, Commission members should not engage in communications, including emails, to a quorum of Commission members outside of Commission meetings, as these communications are also subject to the Public Records Law. Commission members should contact either Kevin Beagan (kevin.beagan@mass.gov) or Rebecca Butler(rebecca.butler@mass.gov) to introduce topics for consideration by the Commission in an appropriate meeting.
- Commission meetings will be held virtually; therefore, all voting will be conducted by roll call voting, a record of which will be recorded in the meeting minutes and will become part of the public record.
- Each Commission member must submit a signed Certificate of Receipt of Open Meeting Law Materials and complete the swearing-in process, as outlined on the Open Meeting Notice.

Kevin requested that:

- All Commission members return their signed Certificates of Receipt of Open Meeting Law Materials to Kevin, Attorney Butler or Rita Gallo (rita.gallo@mass.gov) within two (2) weeks of their receipt of the forms (i.e., by April 28, 2025); and
- Commission members appointed by the Governor also complete the swearing-in process.

Motion Introduced: Motion to Agree to Hold this Meeting Virtually and to Hold All Subsequent Meetings Virtually Unless Designated Otherwise

- Moved by Cheryl; seconded by Darlene; no discussion requested

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- Motion passed unanimously by all Commission members in attendance:

Voting Member Name	Yes	No	Other
Kevin Beagan	X		
Nancy Ryan	X		
Kimberly Lenz	X		
Caitlin Sullivan	X		
Cheryl Bartlett	X		
Paul Jones	X		
Sarah Chiaramida	X		
Marc Hymovitz	X		
Eileen McAnneny			Not in Attendance
Clinton Pong	X		
Darlene Sawicki, CNP	X		

Kevin solicited additional agenda items, and hearing none, proceeded with the Agenda.

3. Step Therapy Data Collection Tool

Kevin introduced the draft Step Therapy Data Collection Tool (Tool) and carrier guide to Commission members for comment and proposed changes. The Division will require carriers to submit an initial data report using the Tool for a retrospective reporting period and annual reports subsequently. Open discussion:

- Sarah expressed concerns regarding:
 - Delineating between Med/Surgical and BH/SUD to collect meaningful data in a clear concise way;
 - The time, effort and resources required for any associated systems updates; and
 - Duplication of prior authorization data, which forms were modified relatively recently to collect much of the same information, e.g., prescriber, provider type – it may be necessary to clarify the Division's expectations.
- Kevin asked whether reporting should be based on provider classification or drug classification.
- Kim indicated that some of the information requested on the Tool may be baked into the prior authorization process, e.g., adverse reactions, allergies to medication; therefore, these items may be under-reported as part of the step therapy protocol.
- Sarah concurred with Kim and expressed concerns that carrier reporting might be subjective and, therefore, inconsistent.
- Clinton indicated that, as a physician, he is approaching the requirements from the perspective of what patients care most about:
 - Drug shortages, supply chain issues, availability of preferred drug, with which patients struggle most in the step therapy process;
 - Delays between delivery of a prescribed drug to the pharmacy and point of resolution at which the patient receives the drug (i.e., delays in advising patients that the drug is available at the pharmacy);
 - Clinton prefers data reporting by provider type.
- Darlene requested clarification regarding the definition of “adverse effects” for reporting. How will this be determined? Severe and life threatening? Reintroduce at milder level?
- Kevin indicated that carriers would report based on provider coding.
- Paul indicated that the standard form has a place [for providers] to indicate which exception is being requested.

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- Sarah shared a link to the standard form in the meeting chat:
(<https://mhdL.pharmacy.services.conduent.com/MHDL/pubdownloadpa.do?id=9424>)
 - Section V of the standard form lists acceptable “Exceptions to Step Therapy.”
- Darlene stated that adverse reaction could be subjective.
- Kevin indicated that it might be useful to suggest clarifying information to the providers completing the form, as carriers are using the completed forms to process the exception requests and document their decisions for future reporting to the Division.
- Clinton built on Darlene’s concern stating that adverse reactions and contraindications are currently processed as the same item and should probably be reported on separately for accuracy.
- Kevin indicated that the group may recommend amendments to the law, but that it might be helpful in the short term to suggest clarifications.
- Kim:
 - Proposed differentiating between information on the form and carrier determinations, evaluating true adverse effect vs. expected results;
 - Prefers categorizing the data by drug, rather than prescriber, as this is consistent with mental health parity reporting; and
 - As there is currently a shortage of prescribers, family doctors may be writing for items usually written by specialists, which may skew the data.
- Kevin proposed tabling a vote on categorizing data reported on the Tool either by prescriber or drug classification to a later meeting, seeking additional input.
- Sarah agreed with Kim’s comments from a mental health parity reporting perspective and indicated that she is a proponent of clarity in reporting, particularly by drug.
- Paul indicated that there is likely to be overlap no matter how data is categorized, either by mental health or medical/surgical, and stated that reporting by type of drug might be more reliable. Paul added that he would like to see more family care providers offering mental health support.
- Caitlin stated that, based on how CHIA does other reporting, she favors categorization by drug. Caitlin also proposed differentiating between mental health and substance use disorder vs. behavioral health and substance use disorder, as CHIA includes behavioral health with substance use disorder in its reporting and distinguishes mental health as a separate category.
- Sarah supported consistency with CHIA’s categorization and favored categorizing by drug.
- Kevin clarified that the law tracks medical and non-medical separately and expressed support for reporting exception requests separately for mental health and behavioral health/substance use disorder data, i.e., per CHIA reporting.
- Sarah agrees, as NIDA (*sp*) also uses these categories in its reporting.
- Kevin tabled the vote for additional consideration, as he favors collecting the right information based on what carriers can do and what is meaningful for the Commission. Kevin proposed that the Commission decide the following in its next meeting:
 - Whether data should be collected based on prescriber classification or drug classification;
 - Whether data should be reported separately for mental health vs. behavioral health/substance use disorder categories; and
 - Whether any clarification can be provided to carriers regarding data collection categories.
- Paul favors the cleanest method of reporting.
- Sarah indicated that it might be difficult to segregate these types of exception requests.
- Kevin reinforced that the Commission was formed to:
 - Develop reporting that is helpful to our goals; and
 - Analyze the impact of reporting.

Future Meetings

Kevin proposed that:

- The Commission’s next meeting be held in May to discuss and vote on the data collection issues above;

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- While the Commission might meet in June, if necessary, there should be no Commission meetings in July or August; and
- The Commission should establish a quarterly meeting cadence thereafter up to the statutory report deadline in October 2026.

There were no objections to the cadence proposed above.

Kevin proposed that the May virtual meeting be held on a Thursday, beginning at 10:00 AM EST. There were no objections from Commission members to this proposal, and Kevin indicated that he would issue a doodle poll with a proposed schedule of upcoming Commission meetings for input from Commission members.

Final Thoughts

Caitlin asked whether the Tool is the definitive reporting method for this data. Are there other opportunities to report different data sets?

Kevin responded that the Tool is intended to be the standard reporting mechanism for this data, which is the most pressing need for now. The Division is open to collecting new data, possibly as part of a special exam if confidentiality and data aggregation are required.

Motion Introduced: Motion to Adjourn Meeting

- Moved by Paul; seconded by Darlene; no discussion requested
- Motion passed unanimously by all Commission members in attendance:

Voting Member Name	Yes	No	Other
Kevin Beagan	X		
Nancy Ryan	X		
Kimberly Lenz	X		
Caitlin Sullivan	X		
Cheryl Bartlett	X		
Paul Jones	X		
Sarah Chiaramida	X		
Marc Hymovitz	X		
Eileen McAnney			Not in Attendance
Clinton Pong	X		
Darlene Sawicki, CNP	X		

Kevin closed the meeting at 10:58 AM EST.