

State of Vermont Department of Financial Regulation 89 Main Street Montpelier, VT 05620-3101

VIA ELECTRONIC MAIL

November 22, 2023

Rep. Lori Houghton, Chair House Committee on Health Care For consumer assistance: [Banking] 888-568-4547 [Insurance] 800-964-1784 [Securities] 877-550-3907 www.dfr.vermont.gov

Sen. Virginia Lyons, Chair Senate Committee on Health and Welfare

Dear Rep. Houghton and Senator Lyons,

The Department of Financial Regulation (Department) is writing to follow up on the report submitted under Act 183 of 2022 in collaboration with the Green Mountain Care Board (GMCB).¹ In that report, the Department and GMCB identified several measures for the Legislature's consideration to better satisfy the goals contemplated in Act 183.

By way of reminder, the Department and GMCB advised that the attestation requirement for insurers that require prior authorization (PA) under 18 V.S.A. § 9418b(h) would be strengthened. Under § 9418b(h), a health insurer is required to review "the list of medical procedures and medical tests for which it requires prior authorization at least annually and eliminate the prior authorization requirements for those procedures and tests for which such a requirement is no longer justified or for which requests are routinely approved with such frequency as to demonstrate that the prior authorization requirement does not promote health care quality or reduce health care spending to a degree sufficient to justify the administrative costs to the plan." Starting this year, the Department and GMCB required insurers attesting to § 9418b(h) compliance to submit the following:

- A general description of the standards used by insurers to evaluate PA requirements.
- A list of services for which PA requirements were eliminated or added during the preceding plan year and the rationale for changing those requirements.
- A list of the ten most requested PA and the PA approval rate for those PA; and
- The percentage of urgent and non-urgent PA requests granted because processing time exceeded the statutory timeframes established under 18 V.S.A. § 9418b(g)(4).

All insurers subject to the attestation requirement submitted their reports by September 15, 2023.

¹ Available online at: <u>https://legislature.vermont.gov/assets/Legislative-Reports/Act-183-Report.pdf</u>.



The Department and GMCB also advised the Legislature to further consider specific measures to reform the PA process in Vermont, including:

- amending 18 V.S.A. § 9418b(g)(4) to decrease the timeframe for health insurers to respond to completed PA requests.
- prohibiting insurers from requiring reauthorization during the current plan year when a PA has been granted for services.
- expanding provider gold-carding polit programs; and
- placing limits on step therapy.

At the urging of the House Committee on Health Care, the Department informally met with Jessa Barnard, Executive Director at Vermont Medical Society (VMS), Christine Cooney, Director of Government Relations for New England at Cigna, Jordan Etsey, Director of Government Relations at MVP Health Care (MVP), and Sara Teachout, Director of Government and Media Relations at Blue Cross Blue Shield of Vermont (BCBSVT) during the summer to discuss the measures outlined in the Act 183 report and explore avenues of broad consensus. Julia Boles, Health Policy Advisor at the GMCB, joined us for these meetings.

This memorandum will briefly summarize the § 9418b(h) attestation reports and feedback from stakeholders on the measures outlined in the Act 183 report.

1. Section 9418b(h) Attestation Reports.

The Department received § 9418b(h) attestation reports from Cigna, MVP, and BCBSVT.² The attestation reports are appended to this memorandum as Attachments A, B, and C.

All three insurers stated that they reviewed their PA requirements on at least a quarterly basis and made decisions on whether to add or eliminate a given PA requirement based on criteria such as: volume, PA approval percentage, medical literature, administrative burden on the insurer and the provider, potential cost-savings, and impact on health care quality.

The insurers also gave examples of services for which PA were added or eliminated. However, some insurers did not provide information about added PA requirements and only gave select examples of removed PA requirements. The Department will be following up with all three insurers in December to obtain more complete responses.

In general, the responses indicated that since 2022, the insurers have both added and removed PA requirements, including PA requirements for newly created CPT/HCPCS codes. The insurers removed PA requirements for services such as phototherapy (CPT E0691), dry needling (CPT 20560), respiratory assist devices (CPT E0470), C-Reactive Protein- High Sensitivity (CPT 86141), and in-state in-network mental health and substance use inpatient, residential, partial hospital and intensive outpatient treatment programs, mostly due to changes in medical science and low denial volumes. The insurers added PA requirements for services such as CGM

² The Department and GMCB also received a § 9418b(h) attestation report from Wellfleet Insurance Company ("Wellfleet"), which contracts with Cigna to perform prior authorization services. Therefore, for purposes of this reporting, information submitted by Cigna includes Wellfleet members.



supplies (CPT A4238), nerve grafting (CPT 64910), intracept systems (CPT 64628), durable medical equipment (DME), and prescription drugs, because they consider the services to be investigational or due to high cost.

The insurers submitted information about the most requested PAs for prescription drugs and medical services and the denial rates for those services. Denial rates for both service categories ranged from a low of 0.5% to a high of 100%. Since either extreme represents relatively low-volume services, we encourage review of the attached attestation reports.

Finally, the insurers submitted aggregated statistics about the percentage of PAs granted due to exceeding the statutory timeframe for review. Cigna reported that it did not grant any PA requests for this reason; MVP reported that 4.96% of its PA requests were granted for this reason; and BCBSVT reported that less than one percent of its were granted for this reason.

2. Act 183 Report Measures.

Between May and September 2023, the Department met with stakeholders to solicit feedback on the measures highlighted in the Act 183 report. The conversations focused on measures enacted in other states rather than any specific language drafted by the Department or GMCB. Both the Department and GMCB would like to acknowledge and thank the VMS, Cigna, MVP, and BCBSVT for taking the time to engage on this project over the summer. Written feedback from stakeholders on the proposals in the Act 183 report is appended to this memorandum.

a. Decreasing Timeframes to Respond to Completed PA Requests.

Under 18 V.S.A. § 9418b(g)(1)(4), insurers have 48 hours to respond to completed "urgent" PA requests and two business days to respond to non-urgent PA requests. For the purposes of reviewing PA requests, DFR Rule H-2009-03 § 3.2(B) classifies the following as urgent:

- requests related to mental health and substance abuse conditions, unless the member or treating provider informs the insurer that the request is not urgent.
- pharmacy benefit determinations, unless the member or treating provider informs the insurer that the request is not urgent.
- requests related to whether use of a prescription drug for the treatment of cancer is medically necessary or is an experimental or investigational use.
- all requests designated as urgent by a member's health care provider or by the member.

Insurers must also advise health care providers that they have received the PA request and identify any needed information to approve the request within 24 hours of receipt. The statute does not directly state how long insurers have to approve a PA request after receiving additional information from a provider. For this reason, decision times can be between three and five days from initial submission if the provider is required to submit missing information to complete the request—even for urgent PA requests. The insurers noted, however, that the primary source of delay in decision making is not receiving the records needed from the requesting provider.



To address this issue, the Department discussed with stakeholders the merits of a 24-hour response period similar to that in Ky. Rev. Stat. § 304.17A-607(1)(i).³. MVP advised that it could support a 24-hour response period but urged removal of the requirement to acknowledge receipt of the request in writing, arguing that it would be unnecessary when a decision is required within 24 hours of receiving a completed urgent PA request. BCBSVT, citing operational concerns, advised that responding to urgent PA requests within 24 hours would be "problematic" at present, but that it could meet that timeline with a sufficient implementation period. Cigna stated that a 24-hour response period would not be conducive to receiving information from providers and may increase PA denial rates. Cigna added that any timelines for responding to PA requests should be from the receipt of necessary clinical information and suggested that providers also be subject to deadlines to submit requested clinical information.

We also discussed clarifying the definition of "urgent" requests in the context of a 24-hour response period. According to BCBSVT, approximately 8% of PA requests are marked as urgent. Stakeholders had conflicting ideas about what constitutes an "urgent" service, and it is unlikely that any consensus could be reached about changing the definition in Rule H-2009-03.

Finally, the Department notes that § 9418b is ambiguous regarding the timeframe for insurers to decide a PA request after receiving missing information from a provider. Providing further clarification could help reduce the response time for PA requests.

b. Placing Limitations on Reauthorization.

Vermont law does not place any limitation on how frequently insurers can require reauthorization for services that require PA. For consumers who are stabilized on prescription drugs or other services subject to reauthorization, uncertainty about whether their care will be covered by insurance in the near-term is a continuing source of frustration. For providers who need to take time to get a previously submitted PA reapproved, reauthorization represents an additional, unnecessary administrative burden associated with PA. To address this issue, the Act 183 report suggested that the Legislature consider prohibiting insurers from requiring reauthorization during the current plan year when a PA has been approved for services deemed preventative by the IRS under 26 U.S.C. § 223(c)(2)(C), which includes prescription drugs for many chronic conditions.

Because IRS notice 2019-45 defines the scope of services and items that constitute preventive care under § 223,⁴ the Department assumed that it would provide a reasonable basis for limiting reauthorization. The insurers, however, expressed concern that using IRS guidance governing tax treatment of preventative services to limit reauthorization would be overly broad, and hinder their ability to reduce growth in medical spending. MVP separately expressed concern about the administrative burden associated with prohibiting reauthorization during the "plan year" since plan years vary by policy or account and may not align with the calendar year. Cigna, BCBSVT, and MVP also advised that legislating indefinite or "lifetime" PAs would be bad policy for reasons of patient safety and affordability.



³ Available online at: <u>https://apps.legislature.ky.gov/law/statutes/statute.aspx?id=53231</u>.

⁴ Available online at: <u>https://www.irs.gov/pub/irs-drop/n-19-45.pdf</u>.

As an example of related legislation that has been enacted in other states, Cigna identified Connecticut Public Act No. 23-204 § 221(b),⁵ which will go into effect January 1, 2025, prohibits insurers from requiring "prospective or concurrent review of a recurring prescription drug to directly treat any autoimmune disorder, multiple sclerosis or cancer after such health carrier has certified such prescription drug through utilization review." The Connecticut law does not require insurers to cover prescription drugs that are excluded from coverage under the terms of coverage, brand name drugs when a generic is available, or prescription drugs that were approved by a consumer's previous health insurer.

Cigna suggested that any similar proposal in Vermont should allow exclusions for covering a brand name drug when an equivalent brand name drug is available or covering a reference product when a biosimilar drug is available. Cigna added that nothing should prohibit a carrier from conducting a prior authorization review of a dosage change of a prescription drug, and that insurers should not be prohibited from conducting PA reviews for controlled substances when permitted under Vermont law.⁶

MVP pointed to legislation under consideration in Massachusetts, H.1143,⁷ that requires approved PAs to be valid for "the duration of a prescribed or ordered course of treatment, or at least 1 year." The Massachusetts legislation also requires insurers to maintain coverage for insureds who are stable on treatments, services, or courses of medication for at least 90 days upon enrollment.

Although the VMS and the broader provider coalition would welcome any "guardrails" on reauthorization, the Department notes that the Massachusetts legislation would be the simplest to implement and enforce since it would not involve making determinations about whether the service or prescription drug at issue meets the criteria to be exempted from reauthorization.

c. Expanding Gold Carding Pilots.

In the context of PA, "gold carding" refers to programs that exempt providers who have a high PA approval rate from PA requirements. As noted in the Act 183 report, Vermont implemented narrow gold carding pilots under Act 140 of 2020. Those pilots, however, were either so narrowly crafted that no providers qualified, or exempted a wide swath of procedures, medications, or providers—making it difficult for a provider to determine whether they even qualified for the gold carding pilots.

The Department and GMCB thus invited the Legislature to consider expanding on the gold carding pilot programs instituted under Act 140 of 2020, which required insurers to implement mechanisms to exempt providers from PA requirements if they met certain criteria. As a model for how such an expansion could work we looked to H.B 3459 in Texas,⁸ enacted in 2021, which

⁸ Available online at: <u>https://capitol.texas.gov/BillLookup/History.aspx?LegSess=87R&Bill=HB3459</u>



⁵ Available online at: <u>https://cga.ct.gov/2023/act/pa/pdf/2023PA-00204-R00HB-06941-PA.pdf</u>.

⁶ Under 18 V.S.A. § 4754(a), insurers cannot require PA for medication-assisted substance use disorder treatment (MAT) if the dosage prescribed is within the U.S. Food and Drug Administration's dosing recommendations.

⁷ Available online at: <u>https://malegislature.gov/Bills/193/H1143</u>.

requires health plans to provide exemptions from PA requirements for individual CPT/HCPCS codes for which providers have an approval rate of at least 90%.

Through the National Association of Insurance Commissioners (NAIC), the Department received a detailed presentation from the Texas Department of Insurance (TDI) on the mechanics of H.B 3459, which is appended to this memorandum. The TDI found that after a lengthy rulemaking and implementation process to outline the terms under which providers could be exempted from PA, the impact was "smaller than expected," with only 3% of providers receiving an exception for one or more services. The TDI identified several changes to the law that could increase its effectiveness, including reducing the granularity of health care services for purposes of qualifying for exemptions and requiring insurers to combine data for providers across all affiliated entities, including those not subject to the law, such as self-insured and Medicare Advantage plans.

When we discussed the merits of adopting a Texas-style gold carding law in Vermont, it became clear that there was no consensus among the stakeholders. All insurers oppose expanding the gold carding pilots to a greater or lesser extent. MVP, for instance, commented that additional gold carding requirements "create administrative complexity, add costs, and increase—rather than reduce—plan-provider-member abrasion." MVP added that if the Legislature were inclined to expand gold carding in Vermont, despite the lack of stakeholder consensus, PA exceptions should be made by service, like the PA exception for medication-assisted substance use disorder treatment, rather than by provider group. VMS, on the other hand, strongly supported expanding gold carding programs in an effort to meaningfully reduce the day-to-day administrative demand on providers. VMS also acknowledged the shortcomings of the Texas gold carding law and indicated that it would support providing the Department with rulemaking authority to implement an expanded gold-carding program that exempts categories of services from PA for plans that are subject to the Department's jurisdiction.

The Department is also concerned about the administrative complexity necessary to effectuate a measure like the Texas gold-carding law. In addition to applying gold carding on an individual CPT/HCPCS code level, the Texas law required a lengthy rulemaking process covering everything from determining what constitutes an "eligible preauthorization request" to written notice requirements, and the TDI oversees an ongoing appeals process for cases in which an insurer revokes a provider's gold card. A similar gold carding expansion in Vermont would require additional funding for administration and enforcement.

d. Step Therapy Reform.

Step therapy is a subset of PA "that specifies the sequence in which different prescription drugs are to be tried for treating a specified medical condition."⁹ Because step therapy protocols often do not consider a patient's individual clinical circumstances, they can be highly disruptive—especially in cases where a patient has already stabilized on a drug that is higher on the protocol. Under current law in Vermont, the only recourse that patients with commercial



⁹ DFR Rule H-2009-03 § 1.4(EEE).

insurance have when a prescribed or ordered drug is denied under a step therapy protocol is to take an external appeal through the Department.

In the Act 183 report, the Department and GMCB suggested that the Legislature consider step therapy reform as a step towards broader PA reform. Although many states have enacted some form of step therapy reform, the Department's conversations with stakeholders focused on reforms enacted in Massachusetts and New York.

In Massachusetts, M.G.L. c 118e, § 51A,¹⁰ enacted in 2023, requires insurers to provide an exception process to their step therapy protocols that is granted when any of the following four conditions apply:

- when the protocol "is contraindicated or will likely cause an adverse reaction in or physical or mental harm."
- when the prescription drug required under the protocol "is expected to be ineffective based on the known clinical characteristics of the enrollee and the known characteristics of the prescription drug regimen."
- the patient has already tried the prescription drug required under the step therapy protocol, or "another prescription drug in the same pharmacologic class or with the same mechanism of action."
- the patient is stable on a prescription drug and switching drugs would result in an adverse reaction in or physical or mental harm to the patient.

Massachusetts requires insurers to respond to requests for a step therapy exception within 3 business days (or 24 hours in emergencies). If the insurer does not respond the exception is deemed granted.

In New York, Insurance Law § 4903(c-1) and Public Health Law § 4903(3-a) requires insurers to accept "step therapy protocol override requests" that are treated as the equivalent of PA requests. To support these requests, providers must show documentation indicating that:

- the protocol is contraindicated or will likely cause an adverse reaction or physical or mental harm to the insured.
- the protocol is expected to be ineffective based on the insured's known clinical history, condition, and prescription drug regimen.
- the patient has already tried prescription drugs on the protocol, which have been discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.
- the patient is stable on prescription drugs prescribed by their provider as long as the insurer is not prevented from requiring the patient to try an AB-rated generic equivalent; or

¹⁰ Available online at: <u>https://www.mass.gov/info-details/mass-general-laws-c118e-ss-51a</u>.



• the protocol is not in the patient's best interest because it will: 1) pose a barrier to adherence; 2) will likely worsen a comorbid condition; or 3) will likely decrease the insured's ability to achieve or maintain reasonable functional ability.

New York requires insurers to respond to an override request within 72 hours (24 hours in an emergency), and if the insurer does not respond, the step therapy protocol override is granted in favor of the patient.

In both New York and Massachusetts, the crux of step therapy reform is implementation of a clear exception process to step therapy protocols. In concept, both the insurers and providers support this idea. MVP wrote that "Ensuring that Vermonters have access to a clear and understandable exceptions process is the best public policy approach to step therapy." Cigna and other health plans operating in Massachusetts wrote with respect to the Commonwealth's step therapy reform legislation that "health plan members should not be required to repeat a medication that is unsafe or ineffective if they change health plans." When it came to the particulars of the legislation in both states, however, stakeholders expressed misgivings to the Department.

MVP's primary concern was that Vermont would regulate step therapy differently than other forms of PA, noting that members seeking a prescription drug exception receive decisions within 24 hours, regardless of whether the exception is for PA or a step therapy requirement. Cigna reiterated concerns that the Massachusetts Association of Health Plans (MAHP) raised with the Massachusetts legislation, in that the required exceptions to step therapy protocols were too broad. MAHP urged the General Court to consider: 1) striking the exemption for patients who had already tried a drug in the same pharmacological class; 2) excluding preferred drug lists; and 3) requiring insurers to cover a short-term supply of a covered prescription drug in an emergency, instead of responding within 24 hours. Cigna also suggested that "equivalent biosimilars" should be excluded from step therapy reform efforts, since those medications drive affordability gains and are considered clinically equivalent to the biologic drugs they substitute for. VMS expressed concern about a step therapy exception process that places the burden on providers rather than insurers to show that a patient meets the requirements for an exception.

Nevertheless, based on discussions with stakeholders, a compromise position on step therapy reform may be achievable if limited to setting out a uniform standard for seeking exceptions from step therapy protocols that is otherwise consistent with the timeframes and processes for requesting a PA.



Please let me know if you have any additional questions. The Department would also be pleased to schedule a meeting to discuss any of the issues raised in this memorandum or appended materials.

Thank you,

<u>/s/ E. Sebastian Arduengo</u>

E. Sebastian Arduengo (he/him/his) Assistant General Counsel Director of External Appeals

cc: Jennifer Carbee, Legislative Counsel Susan Barrett, GMCB Jessa Barnard, Vermont Medical Society Sara Teachout, BCBSVT Jordan Estey, MVP Christine Cooney, Cigna Michael Fisher, Office of the Health Care Advocate



Prior Authorization Attestation Form (2023)

Under <u>18 V.S.A.</u> § <u>9418b(h)</u>, a health plan shall review prior authorizations (PA) at least annually and eliminate PA requirements for those procedures and tests for which such a requirement is no longer justified or for which requests are routinely approved with such frequency as to demonstrate that the prior authorization requirement does not promote health care quality or reduce health care spending to a degree sufficient to justify the administrative costs to the plan. A health plan shall attest to the Department of Financial Regulation (DFR) and the Green Mountain Care Board (GMCB) annually on or before September 15 that it has completed the review and appropriate elimination of PA requirements.

To comply with the attestation requirements outlined in 18 V.S.A. § 9418b(h), health plans shall complete the below form and submit it to DFR and GMCB on or before September 15, 2023.

To the extent that a health plan believes that materials requested herein are exempt from public disclosure as a "trade secret" under 1 V.S.A. § 317(c)(9), the plan must request confidentiality prior to submission. Submitted materials will not be exempt from public disclosure unless DFR and GMCB advise in writing that the materials meet the requirements for a trade secret.

Contact information:

- Sebastian Arduengo—Department of Financial Regulation (Sebastian.Arduengo@vermont.gov);
- Julia Boles—Green Mountain Care Board (Julia.Boles@vermont.gov).

Questions:

The below questions apply to health plans as defined in 18 V.S.A. 9418(a)(8) (including third party administrators, to the extent permitted under federal law):

- 1. Has the health plan reviewed the list of medical procedures and medical tests for which it requires prior authorization (PA) at least once during the proceeding plan year and eliminated the PA requirements for procedures and tests for which such a requirement is no longer justified or for which requests are routinely approved with such frequency as to demonstrate that the PA requirement does not promote health care quality or reduce health care spending to a degree sufficient to justify the administrative costs to the plan? Yes, the list of services subject to prior authorization ("Prior Authorization List" or "PreCert List") and concurrent review is reviewed no less frequently than annually to determine if any services, whether Mental Health(MH)/Substance Use Disorder(SUD) or Medical(M)/Surgical(S), should be removed or added to the list.
 - a. What is the health plan's timeline for reviewing and eliminating prior authorization requirements? In answering this question, please provide the dates for the two most recent review cycles. The Plan reviews the PreCert List not less than annually. High-cost/high-frequency services on the PreCert List are subject to ongoing review as new data and research are received. Last reviewed April 2023 and May 2023.
 - b. Does the health plan ever add/eliminate PA requirements during a plan year (as opposed to between plan years)? Please explain. Yes. New codes are added as they are released from the AMA or CMS (January, April, July, and October). Existing codes are added or removed as they are reviewed. The last review conducted which resulted in the removal of codes was May 2023. Cigna removed the codes as of August 2023.
 - c. What are the standards used by the health plan to evaluate PA requirements as outlined in 18 V.S.A. § 9418b(h) (including the thresholds the health plan considers in looking for routinely approved Pas, how the health plan determines whether Pas are promoting health care quality or reducing health care spending to a degree sufficient to justify the administrative costs to the plan)? To determine

whether a service may be subject to prior authorization, one or more of the following variables must be met *first*, then a Return on Investment ("ROI") threshold must be established for the service to be subject to prior authorization review:

- i. qualitative variable of whether the service is determined to be experimental, investigational or unproven according to clinical evidence;
- ii. qualitative variable of whether the service may present a serious customer safety risk;
- iii. quantitative variable of whether the treatment type is a driver of high-cost growth;
- iv. quantitative variable of the variability in cost, quality and utilization based upon diagnosis, treatment, provider type and/or geographic region; and
- v. quantitative variable of treatment type subject to a higher potential for fraud, waste and/or abuse must be met *first*, then a Return on Investment ("ROI") threshold must be established for the service to be subject to prior authorization review.

For the review period in question, the factors used to determine the application of Prior Authorization to MH/SUD and/or M/S services is the presence of at least one of the non-quantitative variables set forth above, plus the projected return on investment (ROI) to review the service must generally exceed a ratio of 3.0. Services/procedures must meet one of the first five factors (i-v above) before the ROI calculation is applied to determine if the service will be placed on PreCert List. There are instances where certain services may require Prior Authorization that do not meet the ROI of 3.0. These include services cosmetic in nature, services that are determined to be Experimental, Investigational and/or Unproven ("EIU"), services that have not been assigned a CPT/HCPC code, services that may be subject to fraud, waste, and abuse, and certain services that identify customers who may be appropriate for a case management program.

As of August 2023, the ROI threshold for M/S services was raised to 7.5 resulting in the removal of 634 codes, some of which are associated with inappropriate or over utilization. Evernorth is currently evaluating the ROI thresholds for MH/SUD services to determine whether a similar adjustment must be made.

- d. Does the health plan take into account the administrative burden of PAs on health care providers and patients and whether the administrative barriers to submit PAs may inhibit access to medically necessary care? Please explain. Yes. We frequently receive input from providers and review codes based on the input in addition to our standard reviews.
- 2. What medical procedures and tests had PA requirements eliminated or added during the preceding plan year and what was the rationale for changing those requirements?



3. What are the ten most requested PAs for **both** medical PAs and prescription drug PAs (20 total) during the preceding plan year? For each of the 20 PAs, please provide the number of PAs requested and approval rate for each PA (PAs in this list may overlap with eliminated PAs identified in question 2).



4. What percentage of urgent and non-urgent PA requests are granted because processing time exceeded the statutory timeframes established under <u>18 V.S.A. § 9418b(g)(4)</u>? Cigna did not have any prior authorization requests (whether urgent or non-urgent) that were granted because processing time exceeded the statutory timeframes.

Peggy Rupp

State Regulatory Manager 9/14/2023



September 14, 2023

CERTIFICATION OF COMPLIANCE WITH VERMONT 18 V.S.A. § 9418b(h)

Health Plans written and administered by Wellfleet Insurance Company ("Wellfleet") and issued in the state of Vermont utilize Cigna Health and Life Insurance Company ("Cigna") to perform precertification services for medical procedures and medical tests.

Cigna was provided validation to Wellfleet that the list of medical procedures and medical tests for which prior authorization is required are reviewed at least annually and prior authorization requirements for those procedures and tests for which a prior authorization is no longer justified or for which requests are routinely approved with such frequency as to demonstrate that the prior authorization requirement does not promote health care quality or reduce health care spending to a degree sufficient to justify the administrative costs to the plan are eliminated.

As such, I, Dr. Barrie Baker, Chief Medical Officer of Wellfleet, attest to the Commissioner of Financial Regulation and Chair of the Green Mountain Care Board that Cigna Health and Life Insurance Company, Inc. is in compliance with 18 V.S.A. § 9418b(h).

2023 11.11 EDT

Signature

<u>Chief Medical Officer</u> Title

09/14/2023

Date

Attachment C.1 - MVP Public Disclosure Response

Arduengo, Sebastian

| From: | Alfred, Craig <calfred@mvphealthcare.com></calfred@mvphealthcare.com> |
|----------|---|
| Sent: | Friday, September 29, 2023 2:56 PM |
| То: | Arduengo, Sebastian; Estey, Jordan; Boles, Julia; Barber, Michael |
| Cc: | Hopsicker, Jim; Boody, Elizabeth |
| Subject: | RE: MVP Health Care - Annual Prior Authorization Attestation and Report |

EXTERNAL SENDER: Do not open attachments or click on links unless you recognize and trust the sender. Sebastian,

After further internal discussion, we no longer believe the data contained in the report fits within the exemption from disclosure offered by § 317(c)(9). Thank you for your patience.

Does DFR have any plans to publicize these reports, or would that only happen in response to a records request?

Regards, Craig

From: Arduengo, Sebastian <Sebastian.Arduengo@vermont.gov>

Sent: Friday, September 29, 2023 11:06 AM

To: Estey, Jordan <JEstey@mvphealthcare.com>; Boles, Julia <Julia.Boles@vermont.gov>; Barber, Michael <Michael.Barber@vermont.gov>

Cc: Hopsicker, Jim <JHopsicker@mvphealthcare.com>; Alfred, Craig <CAlfred@mvphealthcare.com>; Boody, Elizabeth <EBoody@mvphealthcare.com>

Subject: Re: MVP Health Care - Annual Prior Authorization Attestation and Report

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If you were not expecting this email or are unsure if enclosed links or attachments are safe, click the **"Phish Alert" button** in the Outlook ribbon above. Someone from Cybersecurity will review this email and will let you know if it's safe to proceed, or if this was a phishing attempt.

Questions:

The below questions apply to health plans as defined in 18 V.S.A. 9418(a)(8) (including third party administrators, to the extent permitted under federal law):

- 1. Has the health plan reviewed the list of medical procedures and medical tests for which it requires prior authorization (PA) at least once during the proceeding plan year and eliminated the PA requirements for procedures and tests for which such a requirement is no longer justified or for which requests are routinely approved with such frequency as to demonstrate that the PA requirement does not promote health care quality or reduce health care spending to a degree sufficient to justify the administrative costs to the plan?
 - a. What is the health plan's timeline for reviewing and eliminating prior authorization requirements? In answering this question, please provide the dates for the two most recent review cycles.

MVP Response: MVP continuously brings our clinical policies and data through our independent, physician run committee process. Below is a list of meeting dates, by MVP committee, where relevant PA policies and criteria were reviewed.

| | 2023 | |
|---------------------------------|--------------------------------------|----------------------------------|
| Medical Management Committee | Pharmacy & Therapeutics Committee | Clinical Operations Committee |
| 2/16/2023 | 1/19/2023 | Q1: 1/3/2023 |
| 3/16/2023 | 2/16/2023 | Q2: 4/10/2023 |
| 7/20/2023 | 3/16/2023 | Q3: 7/10/2023 |
| 8/17/2023 | 4/20/2023 | |
| | 5/18/2023 | |
| | 6/15/2023 | |
| | 7/20/2023 | |
| | 2022 | |
| Medical Management Committee | Pharmacy & Therapeutics Committee | Clinical Operations Committee |
| 1/20/2022 | 1/20/2022 | Q1: 2/7/2022 |
| 2/17/2022 | 2/17/2022 | Q2: 4/25/2022 |
| 3/17/2022 | 3/17/2022 | Q3: 8/1/2022 |
| 4/21/2022 | 4/21/2022 | Q4: 10/31/2022 |
| 5/19/2022 | 5/19/2022 | |
| 6/16/2022 | 6/16/2022 | |
| 7/21/2022 | 7/21/2022 | |
| 8/18/2022 | 8/18/2022 | |
| 9/15/2022 | 9/15/2022 | |
| 10/20/2022 | 10/20/2022 | |
| 11/17/2022 | 11/17/2022 | |
| 12/15/2022 | 12/15/2022 | |

Additionally, MVP performed annual reviews of its PA criteria on the following dates:

- 9/2/2021
- 9/6/2022
- b. Does the health plan ever add/eliminate PA requirements during a plan year (as opposed to between plan years)? Please explain.

MVP Response: MVP may add or eliminate PA requirements during a plan year. As previously stated, MVP does not just review the PA data once a year, so if a trend is identified, removal of PA requirements may occur at any time during the year.

c. What are the standards used by the health plan to evaluate PA requirements as outlined in 18 V.S.A. § 9418b(h) (including the thresholds the health plan considers in looking for routinely approved PAs, how the health plan determines whether PAs are promoting health care quality or reducing health care spending to a degree sufficient to justify the administrative costs to the plan)?

MVP Response: MVP considers multiple factors:

- Volume (those test & procedures with sufficient volume to reliably assess PA value)
- Prior authorization approval percentage (at least a 90% approval rate)
- Updates to standard of care and current literature supporting PA or removal
- Appeal and overturn rates
- Regulatory Requirements, drug safety, and quality of care are also weighed for removal of utilization management
- Delineation of impact of PA on health care spend to a degree sufficient to justify administrative costs to the plan (quantitative plan ROI including review cost / excluding alternative care costs)
- d. Does the health plan take into account the administrative burden of PAs on health care providers and patients and whether the administrative barriers to submit PAs may inhibit access to medically necessary care? Please explain.

MVP Response: MVP does evaluate the PA volume by provider and reviews utilization trends for certain services to ensure medically necessary care is being provided. MVP also does receive feedback from our participating providers and has modified and/or removed PA on specific services based upon their feedback.

2. What medical procedures and tests had PA requirements eliminated or added during the preceding plan year and what was the rationale for changing those requirements?

MVP Response: Removed Musculoskeletal service PAs including surgical procedures of spine, hip, knee, shoulder, and interventional pain management as of 7/1/2023. Additionally, the chart below outlines all PA changes made since February 2022.

| CPT Code | Service (Procedure) | Change | Prior Auth | Reason | Effec. Date | LOB |
|----------|------------------------|--------|------------|------------------|-------------|---------------------------|
| 53854 | Rezume BPH Tx | Remove | N/A | Moved to covered | 2/1/22 | All |
| 0089U | Pigmented Lesion Assay | Add | N/A | Investigational | 2/1/22 | Commercial, ASO, Medicaid |
| 0090U | myPath Melanoma | Add | N/A | Investigational | 2/1/22 | Commercial, ASO, Medicaid |

| E0691 | Phototherapy | Remove | Prior Auth | Moved to covered | 2/1/22 | All |
|-------|--|--------|------------|---------------------|---------|-----------|
| E0692 | Phototherapy | Remove | Prior Auth | Moved to covered | 2/1/22 | All |
| E0693 | Phototherapy | Remove | Prior Auth | Moved to covered | 2/1/22 | All |
| E0694 | Phototherapy | Remove | Prior Auth | Moved to covered | 2/1/22 | All |
| Q4249 | Skin substitutes | Add | N/A | Investigational | 2/1/22 | All |
| Q4250 | Skin substitutes | Add | N/A | Investigational | 2/1/22 | All |
| Q4251 | Skin substitutes | Add | N/A | Investigational | 2/1/22 | All |
| Q4252 | Skin substitutes | Add | N/A | Investigational | 2/1/22 | All |
| Q4253 | Skin substitutes | Add | N/A | Investigational | 2/1/22 | All |
| Q4254 | Skin substitutes | Add | N/A | Investigational | 2/1/22 | All |
| Q4255 | Skin substitutes | Add | N/A | Investigational | 2/1/22 | All |
| 43497 | POEM | Add | Prior Auth | High cost | 4/1/22 | All |
| 43180 | Linx | Add | N/A | Investigational | 4/1/22 | All |
| 43257 | EsophyX | Add | N/A | Investigational | 4/1/22 | All |
| H0019 | Residential Tx | Add | Prior Auth | Inpatient cost | 4/1/22 | All |
| J7402 | Sinuva | Add | Prior Auth | High cost | 4/1/22 | All |
| S1091 | Propel | Add | Prior Auth | High cost | 4/1/22 | All |
| A4238 | CGM supplies | Add | Prior Auth | High cost | 4/1/22 | All |
| E2102 | CGM supplies | Add | Prior Auth | High cost | 4/1/22 | All |
| | Zoladex | Add | Prior Auth | NYS DOH requirement | 5/14/22 | Medicaid |
| 81420 | cfDNA | Remove | N/A | Regulatory | 7/1/22 | Medicaid |
| 81507 | cfDNA | Remove | N/A | Regulatory | 7/1/22 | Medicaid |
| 77089 | Trabecular Bone Score | Remove | N/A | High volume | 7/1/22 | All |
| | Ondansetron | Remove | PA | Approval rate | 7/1/22 | Medicare |
| S0515 | Scleral lens | Remove | Prior Auth | Low denial volume | 8/1/22 | All |
| 93356 | myocardial strain imaging | Remove | N/A | Moved to covered | 8/1/22 | All |
| 64628 | Intracept System | Add | N/A | Investigational | 8/1/22 | All |
| 64629 | Intracept System | Add | N/A | Investigational | 8/1/22 | All |
| 0037U | pharmacogenomic testing | Add | N/A | Investigational | 8/1/22 | All |
| 20560 | dry needling | Remove | N/A | Moved to covered | 8/1/22 | All |
| 20561 | dry needling | Remove | N/A | Moved to covered | 8/1/22 | All |
| 0253T | iStent | Remove | N/A | Moved to covered | 8/1/22 | All |
| 64910 | nerve grafting | Add | N/A | Investigational | 8/1/22 | All |
| 64911 | nerve grafting | Add | N/A | Investigational | 8/1/22 | All |
| | Ondansetron | Remove | QL | Approval rate | 8/1/22 | Non-MED D |
| E0470 | Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask | Remove | Prior Auth | Low denial volume | 9/1/22 | All |
| E0471 | Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask | Remove | Prior Auth | Low denial volume | 9/1/22 | All |

| E0472 | Respiratory assist device, bi-level pressure capability, with backup rate feature, used with invasive interface, e.g., | Remove | Prior Auth | Low denial volume | 9/1/22 | All |
|-------|--|--------|------------|-----------------------|---------|---------------------------|
| E0562 | tracheostomy tube Humidifier, heated, used with positive airway pressure device | Remove | Prior Auth | Low denial volume | 9/1/22 | All |
| E0601 | Continuous positive airway pressure (CPAP) device | Remove | Prior Auth | Low denial volume | 9/1/22 | All |
| 0446T | implanted CGM | Remove | N/A | Moved to covered | 10/1/22 | Commercial, ASO, Medicaid |
| 0447T | implanted CGM | Remove | N/A | Moved to covered | 10/1/22 | Commercial, ASO, Medicaid |
| 0448T | implanted CGM | Remove | N/A | Moved to covered | 10/1/22 | Commercial, ASO, Medicaid |
| 31647 | Valve Devices | Add | Prior Auth | High cost | 10/1/22 | All |
| 31648 | Valve Devices | Add | Prior Auth | High cost | 10/1/22 | All |
| 31649 | Valve Devices | Add | Prior Auth | High cost | 10/1/22 | All |
| 31651 | Valve Devices | Add | Prior Auth | High cost | 10/1/22 | All |
| 64640 | cryoneurolysis ablation | Add | N/A | High cost, low volume | 10/1/22 | Commercial, ASO, Medicaid |
| | Alvesco | Add | | Exchange benchmark | 1/1/23 | Exchange |
| | Metaxalone 800mg | Add | | Exchange benchmark | 1/1/23 | Exchange |
| | Chlorzoxazone | Add | | Exchange benchmark | 1/1/23 | Exchange |
| | ASA/Caffeine/orphenadrine | Add | | Exchange benchmark | 1/1/23 | Exchange |

3. What are the ten most requested PAs for **both** medical PAs and prescription drug PAs (20 total) during the preceding plan year? For each of the 20 PAs, please provide the number of PAs requested and approval rate for each PA (PAs in this list may overlap with eliminated PAs identified in question 2).

MVP Response:

The ten (10) most requested PAs for medical services are as follows:

| Procedure Code and Description | Approved | % Approved | Denied | % Denied | Total Auths |
|---------------------------------------|----------|------------|--------|----------|-------------|
| 95810: Overnight sleep study | 234 | 87.97% | 32 | 12.03% | 266 |
| E0562: Humidifier heated used w PAP | 209 | 95.87% | 9 | 4.13% | 218 |
| E0601: Cont airway pressure device | 195 | 96.53% | 7 | 3.47% | 202 |
| 95811: Overnight sleep study | 190 | 96.45% | 7 | 3.55% | 197 |
| 62323: Inject medication around spine | 177 | 90.77% | 18 | 9.23% | 195 |
| K0553: Ther cgm supply allowance | 102 | 73.91% | 36 | 26.09% | 138 |
| 81420: Genetic analysis | 5 | 3.94% | 122 | 96.06% | 127 |
| 93356: Image of heart tissue | 0 | 0.00% | 97 | 100.00% | 97 |
| 64493: Spine injection | 82 | 87.23% | 12 | 12.77% | 94 |
| 64483: Spinal injection for disc pain | 84 | 93.33% | 6 | 6.67% | 90 |

The ten (10) most requested PAs for pharmacy services are as follows:

| Product Name | Approved | % Approved | Denied | % Denied | Total Auths |
|--------------|----------|------------|--------|----------|--------------------|
| TADALAFIL | 11 | 20.37% | 43 | 79.63% | 54 |
| DUPIXENT | 35 | 89.74% | 4 | 10.26% | 39 |

| FLUTICASONE PROPIONATE | 0 | 0.00% | 39 | 100.00% | 39 |
|------------------------|----|---------|----|---------|----|
| SILDENAFIL CITRATE | 3 | 8.33% | 33 | 91.67% | 36 |
| AJOVY *** | 34 | 100.00% | | | 34 |
| HUMIRA PEN | 32 | 96.97% | 1 | 3.03% | 33 |
| ONDANSETRON ODT | 23 | 69.70% | 10 | 30.30% | 33 |
| EMGALITY *** | 32 | 100.00% | | | 32 |
| STELARA | 25 | 89.29% | 3 | 10.71% | 28 |
| XIFAXAN | 14 | 50.00% | 14 | 50.00% | 28 |

*** These were added to gold card pilot program for part of reporting period.

4. What percentage of urgent and non-urgent PA requests are granted because processing time exceeded the statutory timeframes established under <u>18 V.S.A. § 9418b(g)(4)</u>?

MVP Response: 4.96%

Attachment D - BCBSVT Attestation Form

BlueCross BlueShield of Vermont

BERLIN 445 INDUSTRIAL LANE BERLIN, VERMONT 05602

P.O. BOX 186 MONTPELIER VT 05601-0186

800 247 2583 800 922 8778 800 255 4550

September 11, 2023

Department of Financial Regulation Attn. E. Sebastian Arduengo 89 Main Street Montpelier, VT 05620-3101

Green Mountain Care Board Attn. Julia Boles 144 State Street Montpelier, VT 05602

Re: 18 V.S.A. § 9418b Prior Authorization Attestation

Dear Attorney Arduengo and Ms. Boles,

I am writing to provide Blue Cross and Blue Shield of Vermont's ("BCBSVT") annual attestation regarding prior authorizations as required by 18 V.S.A. § 9418b(h)(2).

Pursuant to that statutory authority, I hereby certify to the best of my knowledge, information, and belief, on behalf of BCBSVT, an Independent Licensee of the Blue Cross and Blue Shield Association, with its principal offices located at 445 Industrial Lane, Berlin, VT 05602, that the following answers to questions posed by the Department of Financial Regulation are true:

1. Has the health plan reviewed the list of medical procedures and medical tests for which it requires prior authorization (PA) at least once during the proceeding plan year and eliminated the PA requirements for procedures and tests for which such a requirement is no longer justified or for which requests are routinely approved with such frequency as to demonstrate that the PA requirement does not promote health care quality or reduce health care spending to a degree sufficient to justify the administrative costs to the plan?

BCBSVT has conducted its review of the list of medical procedures and medical tests for which it requires prior authorization and has eliminated any prior authorization requirements for those procedures and tests for which requests are routinely approved with such frequency as to demonstrate that the prior authorization requirement does not promote a health care quality or reduce health care spending to a degree sufficient to justify the administrative costs to the plan.

a. What is the health plan's timeline for reviewing and eliminating prior authorization requirements? In answering this question, please provide the dates for the two most recent review cycles.

BCBSVT reviews and eliminates prior authorizations, at least, quarterly. For the CY 2022, the most recent reviews were on October 1, 2022, and November 1, 2022.

b. Does the health plan ever add/eliminate PA requirements during a plan year (as opposed to between plan years)? Please explain. 20

Yes., depending on the service, the reasons and PA's potential impact, BCBSVT makes changes during the plan year.

c. What are the standards used by the health plan to evaluate PA requirements as outlined in 18 V.S.A. § 9418b(h) (including the thresholds the health plan considers in looking for routinely approved PAs, how the health plan determines whether PAs are promoting health care quality or reducing health care?

During the routine and the additional ad-hoc PA reviews, BCBSVT considers the medical literature (standard of care), administrative burden on both providers and BCBSVT, impact on health care quality and potential overall cost savings before deciding on instituting PA.

d. Does the health plan take into account the administrative burden of PAs on health care providers and patients and whether the administrative barriers to submit PAs may inhibit access to medically necessary care? Please explain.

Yes, all factors, including access to medically necessary care, are considered before implementing or eliminating PA requirements.

2. What medical procedures and tests had PA requirements eliminated or added during the preceding plan year and what was the rationale for changing those requirements?

The following are examples of eliminating the PA requirements in CY 2022:

- a) January 2023, we removed the prior authorizations for in-state in-network mental health and substance use inpatient, residential, partial hospital and intensive outpatient treatment programs. We assessed average lengths of stay compared to MCG criteria and denial rates, and determined that these PAs were no longer required.
- b) CPT 86141 C-Reactive Protein- High Sensitivity, was removed on October 1, 2022 because the test is now considered medically necessary and is the standard of care.
- c) CPT 81221 CFTR (Cystic Fibrosis Transmembrane Conductor Regulator), was removed on October 1, 2022 because the test is considered medically necessary and has become the standard of care.
- 3. What are the ten most requested PAs for both medical PAs and prescription drug PAs (20 total) during the preceding plan year? For each of the 20 PAs, please provide the number of PAs requested and approval rate for each PA (PAs in this list may overlap with eliminated PAs identified in question 2).

Please see below.

| Top 10 MEDICAL Auth requests 2022 | | | | | | | |
|-----------------------------------|----------|--------|---------|--------|--------|-------|-------------|
| | Approval | Denial | Partial | Suspen | Closed | Total | Denial Rate |
| OP Surgery | 4351 | 552 | 31 | 0 | 2097 | 7031 | 11.2% |
| DME | 4423 | 247 | 12 | 0 | 489 | 5171 | 5.3% |
| Medical Surgical IP | 4351 | 136 | 74 | 0 | 265 | 4826 | 3.0% |
| Laboratory | 1383 | 550 | 13 | 0 | 157 | 2103 | 28.3% |
| Genetic Testing | 1285 | 591 | 57 | 0 | 75 | 2008 | 30.6% |
| | | | | | | | |
| HH Skilled Nursing | 1305 | 23 | 11 | 0 | 62 | 1401 | 1.7% |
| Polysonography | 1025 | 406 | 28 | 0 | 92 | 1551 | 27.8% |
| Chiropractic | 936 | 84 | 2 | 0 | 52 | 1074 | 8.2% |
| Labor and Delivery | 1039 | 0 | 0 | 0 | 5 | 1044 | 0.00% |
| Mental Health IP | 757 | 4 | 11 | 0 | 20 | 792 | 0.5% |

Additional clarification on medical PA data:

- In January 2023, we removed the prior authorizations for in-state in-network mental health and substance use inpatient, residential, partial hospital, and intensive outpatient treatment programs.
- Our home health denial rate is low because we typically work with home health agencies to adjust the number of visits that are requested to match the actual need. We usually do not deny these nursing visits unless a member does not require skilled nursing and is determined to be at a custodial level of care.
- Our labor and delivery PA is related to payment, but we do not review for medical necessity.

| Top 10 Pharn | nacy Authorizations for CY 2022 | | | | | |
|--------------|---------------------------------|-------------------|-----------------|-------|---------------|-------------|
| CARRIERCODE | DRUGNAME | Resolved_Approved | Resolved_Denied | Total | Approval Rate | Denial Rate |
| BVTCOM | вотох | 486 | 49 | 535 | 90.84% | 9.16% |
| BVTCOM | OZEMPIC | 123 | 233 | 356 | 34.55% | 65.45% |
| BVTCOM | AMPHETAMINE/DEXTROAMPHETAMINE | 184 | 95 | 279 | 65.95% | 34.05% |
| BVTCOM | OMEPRAZOLE | 207 | 23 | 230 | 90.00% | 10.00% |
| BVTCOM | WEGOVY | 202 | 27 | 229 | 88.21% | 11.79% |
| BVTCOM | NURTEC | 168 | 58 | 226 | 74.34% | 25.66% |
| BVTCOM | ADDERALL XR | 196 | 28 | 224 | 87.50% | 12.50% |
| BVTCOM | EMGALITY | 148 | 71 | 219 | 67.58% | 32.42% |
| BVTCOM | TRETINOIN | 186 | 24 | 210 | 88.57% | 11.43% |
| BVTCOM | UBRELVY | 137 | 56 | 193 | 70.98% | 29.02% |

Additional clarification on pharmacy PA data:

- The following medications are showing up on this list because they hit a quantity limit (QL) and the provider requested a QL override.
 - Adderall XR is currently in the brand preferred program and does not require PA.
 - Amphetamine/dextroamphetamine IR tabs do not require PA.
 - Omeprazole capsules are covered and do not require PA.
- Omeprazole tablets and omeprazole magnesium capsules are considered an OTC product and are not covered as a plan exclusion.
- 4. What percentage of urgent and non-urgent PA requests are granted because processing time exceeded the statutory timeframes established under 18 V.S.A. § 9418b(g)(4)?

Medical PA Requests: Urgent 0.37% and Non-Urgent 0.88% Pharmacy PA Requests: Urgent 0% and Non-Urgent 0.02% Please direct any questions or concerns regarding this attestation to me.

Thank you, <u>Tom Weigel, MD</u> Tom Weigel, MD (Sep 12, 2023 15:06 EDT)

Tom Weigel, MD, MBA Vice President and Chief Medical Officer

Attachment E - MVP Written Comment



625 State Street Schenectady, NY 12305-2111 mvphealthcare.com

August 14, 2023

E. Sebastian Arduengo Assistant General Counsel Director of External Appeals Department of Financial Regulation 89 Main Street Montpelier, Vermont 05602 Julia Boles Health Policy Advisor Green Mountain Care Board 144 State Street Montpelier, Vermont 05602

Dear Sebastian and Julia:

I write in response to the Department of Financial Regulation (DFR) and Green Mountain Care Board (GMCB) inquiry concerning several recommendations contained within DFR's February 15 report to the legislature on "Prior Authorizations; Administrative Cost Reductions," in response to Section 36 of Act 183 of 2022. MVP appreciates the opportunity to inform the work of Vermont policymakers on these important issues. My responses to each question are listed below.

Recommendation #1: Amend 18 V.S.A. §9418b(g)(4) to decrease the timeline for urgent prior authorization requests

Current Vermont statute requires health plans to review and respond to urgent prior authorization (PA) requests within 48 hours, and non-urgent PA requests within two (2) business days. The statute requires health plans to notify a provider of receipt and any missing information needed within 24 hours of receipt. Failure to provide a written notification of response or rendering of a decision within the prescribed timeframes results in automatic approval of the prior authorization request.

MVP's internal utilization management (UM) policy in Vermont already requires a 24-hour decision turnaround time for any PA request—urgent or non-urgent. An MVP systems limitation issue was identified during implementation of the Vermont law. In short, it's administratively difficult and burdensome for MVP to provide a written notice of receipt within 24 hours, and then to render urgent or non-urgent decisions within 48 hours or 2 business days, respectively. Thus, to maintain compliance, MVP's policy requires a decision on any Vermont PA request within 24 hours.

Because of MVP's current Vermont UM policy, we can support a shortening of the statutory timeframe for decisions on urgent PA requests. In doing so, however, we urge Vermont policymakers to remove the statutory written acknowledgement requirement. This requirement creates an unnecessary and costly administrative burden that serves little practical purpose for the physician or member when a decision is also required within 48 hours or 2 business days, and even less so when a decision will be required within 24 hours.

MVP also offers an observation concerning the practical effect of shortened timeframes. While well intentioned, a shorter review window places more burden on plan and provider staff, and likely increases the volume of adverse determinations on PA requests that lack the information necessary for MVP to render approval. Providers and patients can, of course, avail themselves of the appeals process, but that does not decrease the overall administrative burden for patients and providers.

MVP also understands that DFR and the GMCB are considering a change to the definition of an "urgent" request. Currently, MVP defers to the provider's judgement on the urgency of a particular request, and as

previously stated, renders decisions on urgent and non-urgent requests within 24 hours. Vermont should craft a clear definition of what constitutes an "urgent" request, and MVP is happy to support that effort.

Recommendation #2: Prohibit reauthorization during the current plan year when a PA has been granted for services considered preventive by the IRS under 26 U.S.C. § 223(c)(2)(C).

Prohibiting reauthorization of any service during the current "plan year" would be administratively burdensome, and limit MVP's ability to manage its formulary on behalf of beneficiaries. For example, each health plan or plan-sponsored coverage is likely to have different prescription drug formularies. Plan years vary by policy or account and may also not align with the calendar year.

The federal law cited above, and related IRS guidance (e.g., Notice 2019-45), govern tax treatment of certain preventive services offered by qualified high deductible health plans (HDHPs). This IRS safe harbor has a very different purpose than the preventive services graded A or B by the U.S. Preventive Services Task Force (USPSTF) and covered without cost-share or UM by fully insured commercial health insurers under the Affordable Care Act (ACA). For example, the IRS guidance list of services eligible for pre-deductible coverage is broader in scope than USPSTF recommendations. USPSTF recommendations name very specific preventive screenings and treatments for specific populations and age groups based upon clinical data. In contrast, the IRS lists broad categories of preventive services and treatments because the guidance is intended to allow (not require) HDHPs to cover certain preventive services without a deductible.

The IRS safe harbor permits first-dollar coverage of certain preventive services for HDHP enrollees. The broad categories of preventive services subject to the safe harbor include maintenance medications for certain chronic conditions, such as insulin and other glucose lowering agents, retinopathy screening, glucometers, and Hemoglobin A1c testing for individuals diagnosed with diabetes. Health plans are not required to cover all these services or devices or offer them without a cost share or UM.

Requiring health plans to cover all preventive services listed in existing and future IRS notices would undermine health plans' ability to achieve lower prescription drug costs through preferred prescription drug and medical device strategies. For example, MVP does not cover every single service or device in each IRS preventive service category. MVP has preferred contraceptives, asthma drugs, epi pens, and Naloxone that are deemed preventive for purposes of the IRS safe harbor and are proven to have clinical utility. MVP also conducts UM on preferred drugs to ensure that they are effective and used appropriately. MVP's PAs for some of these drugs are only valid for three or six months, so prohibiting reauthorization within a plan year would also disrupt our preferred drug and device strategies.

MVP fully supports ensuring patients have access to necessary treatments. To this end, MVP maintains a robust exceptions process for providers and patients to ensure access to and continuity of effective services and appropriate treatments. Our exceptions process strikes a careful balance between access and appropriate plan management.

Policymakers should reject this proposal and retain plans' ability to reauthorize certain services during plan years as well as preserve vital plan formulary tools, both of which help to mitigate costs and manage care for our members.

Recommendation #3: Expand the current Gold Carding Program under Act 140 of 2020

MVP supports a reduction of unnecessary PAs by service rather than any overly complex administrative solution, such as gold carding programs that require health plans to exempt individual providers or even provider groups. To this end, MVP has removed roughly 50-60 percent of its authorizations since 2017-2018. MVP conducts annual reviews of its UM and PA policies with an eye toward balancing clinical and

cost effectiveness, provider abrasion, and return on investment (ROI). For example, if a certain medical management policy does not yield a minimum ROI of 5 to 1, MVP will review whether that policy should continue. These PA reviews are performed by service rather than by individual provider.

Consistent with requirements of 18 V.S.A. §9418b(h), MVP annually attests to Vermont regulators that we review and eliminate PA requirements "for those procedures and tests for which such a requirement is no longer justified or for which requests are routinely approved with such frequency as to demonstrate that the prior authorization requirement does not promote health care quality or reduce health care spending to a degree sufficient to justify the administrative costs to the plan." MVP urges DFR to expand this attestation requirement, as planned, rather than creating an overly prescriptive, burdensome process that would potentially force plans to abandon PA tools that allow us to manage and oversee care, protecting consumers' health as well as their wallets.

Should Vermont move to expand its gold carding program, any PA exemption requirement should be by service, rather than by provider or provider group as required under Texas law. Such an approach would be consistent with the current VT gold carding program.

We are also concerned that the Texas law PA exemptions apply to prescription drugs. If Vermont chooses to follow suit, the administrative burden of applying pharmacy gold carding exemptions, by individual provider, would likely outweigh the ROI. Under this scenario, MVP could be forced to eliminate various pharmacy PA programs—which would have a considerable effect on total health care costs and member premiums. Pharmacy aside, MVP doesn't require PAs for very many primary care providers; rather, most are for specialty providers.

Moreover, Texas law would only require a minimum of five and no more than 20 claims from an individual provider during a six-month period from which to calculate the 90 percent threshold for gold carding status. These parameters are overly prescriptive, limiting plans' flexibility to eliminate PA in any other way; for example, over a shorter or longer period or by using more than 20 claims. The higher the minimum threshold, the better. The minimum threshold should be high enough to be meaningful and statistically significant. There should be no ceiling on the claims.

Any additional gold carding requirements only create administrative complexity, add costs, and increase rather than reduce—plan-provider-member abrasion. This is especially true when the requirements only apply to the fully insured commercial markets, as per the Texas law. Providers, for example, are still subject to various PA requirements in Medicaid and non-state-regulated products. Vermont policymakers should instead seek to ensure that any UM or PA requirements improve the quality and efficacy of care a patient receives and have a material ROI that results in member value. MVP urges Vermont policymakers to utilize the annual attestation process toward this end, providing transparency around plan decisions and policies, while also ensuring accountability and commitment to removing unnecessary administrative burden for providers and patients.

Recommendation #4: Limit step therapy

As DFR and the GMCB are aware, prescription drugs are among the fastest rising components of overall health care spending. Step therapy protocols are a valuable tool in ensuring that members are utilizing known, safe, and—where appropriate—cost-effective drugs. Step therapy is also a public health tool necessary to maintain the efficacy of certain prescription drugs, such as new antibiotics that could otherwise be overused and rendered less effective.

This concern is especially important for enrollees in the individual and small group markets, who are uniquely burdened by ever-increasing prescription drug and health care costs. MVP's ability to manage

the prescription drug benefit for these members—who comprise most of our business in Vermont—is especially important to control premium costs and ensure safety.

A 2022 Massachusetts law concerning step therapy is very similar to the New York State law governing MVP's New York State business. Both laws emphasize transparency on the use of any step therapy protocols, such as the availability and accessibility of any clinical criteria utilized. More importantly, both states have clear processes for a member and/or their provider to seek an exception to a step therapy protocol. Ensuring that Vermonters have access to a clear and understandable exceptions process is the best public policy approach to step therapy. Members/patients should be able to access the right drug therapy, at the right place, and at the right time. Exceptions processes and pathways provide this access without undermining or obviating UM programs.

While Vermont does not have extensive statutory requirements on step therapy protocols, it does have very stringent requirements on the timeliness of PA exceptions requests, and MVP exceeds these timeliness requirements. For example, MVP members seeking a prescription drug exception receive decisions within 24 hours, whether the exception in question is for a PA or a step therapy requirement. Furthermore, in accordance with federal 45 CFR 156.122(c), MVP's non-grandfathered individual and small group policies provide a standard and expedited formulary exception process for a clinically appropriate prescription drug that is not on the formulary. Existing rules and requirements already provide the necessary pathways to ensure coverage, while maintaining our ability to proactively manage the drug benefit and formulary.

We urge Vermont policymakers to avoid any new requirements that regulate step therapy differently than any UM, PA, or formulary exceptions process. Much of MVP's step therapy processes, for example, are embedded in its PA requirements. Enacting new and robust rules around step therapy would only confuse providers and members. Further, any such considerations must be based on evidence that Vermonters are failing to access appropriate prescription drugs in a timely manner.

MVP is supportive of transparency around the development of its step therapy requirements, including the availability of clinical criteria. That said, policymakers must consider the unintended consequences of requiring any specific clinical review criteria as a pre-requisite for a step therapy protocol. For example, New York and Massachusetts laws require any step therapy protocol to be based on any available evidence-based and peer reviewed clinical review criteria that accounts for the needs of atypical patient populations and diagnoses. Both state laws recognize the reality that for many of the new biologic drugs—and/or drugs that target rare diseases or conditions—such scientifically vetted criteria may not exist. Plans should be permitted to manage their formulary and develop appropriate protocols based on a variety of sources and methods.

Further Discussion

MVP is happy to meet, at your convenience, to discuss these responses and answer any additional questions.

Sincerely,

Jordan F. Esty

Jordan T. Estey Senior Director, Government Affairs MVP Health Care

Attachment F - VMS Written Comment



- To: Sebastian Arduengo, Department of Financial Regulation
- From: Jessa Barnard, Vermont Medical Society Executive Director, jbarnard@vtmd.org
- Date: November 10, 2023
- RE: Support for Act 183 Report Recommendations and Prior Authorization Reform

Thank you for providing the Vermont Medical Society with the opportunity to comment on DFR's follow-up memorandum to the Act 183 Report. The Vermont Medical Society (VMS) represents 2900 physicians, physician assistants and PAs across Vermont. Perhaps no other issue garners as much attention and support from our membership as reducing the paperwork hassles that come between them and providing clinical patient care. In the face of overwhelming health care workforce shortages and clinician burnout, reducing prior authorization is one concrete step the legislature can take to help increase access to care.

The VMS strongly recommends that the legislature proceed with the four areas of reform discussed by DFR.

1. Decreasing Timeframes to Respond to Completed PA Requests.

VMS supports reducing the timeframe for insurers to respond to urgent PA requests to 24 hours.

2. Placing Limitations on Reauthorization.

VMS supports adopting in Vermont the proposals included in Massachusetts legislation $\underline{H. 1143}$ - also pointed to by MVP - that would:

- a. Prohibit PA for generic medications and medications and treatments that currently have low denial rates, low variation in utilization, or an evidence-base to treat chronic illness;
- b. Require a PA to be valid for the duration of treatment or at least 1 year; and
- c. Require insurers to honor the patient's PA from another insurer for at least 90 days.

3. Expanding Gold Carding Pilots.

VMS strongly supports reducing the number of procedures or clinicians subject to prior authorization until such reductions are meaningful enough to be felt in the day-to-day paperwork demanded of clinicians. VMS supports expanding Gold Card programs as proposed in <u>H. 220</u> and <u>S. 151</u>, modeled off of Texas, as a pathway to achieving this goal. VMS appreciates that Texas and DFR have identified some shortcomings of the Texas model noted since it was first adopted and VMS would support broader application, such as entire categories of services being exempt from PA. As further outlined below, one of the shortcomings of prior Gold Card pilots is their narrow application. VMS recommends that the legislature move forward with providing DFR with rulemaking authority to implement an expanded Gold Card program that exempts categories of services from prior authorization.



4. Step Therapy Reform.

VMS supports the adoption by Vermont of a clear step therapy override process following the New York or Massachusetts models. One of the most important elements is allowing an override of step therapy when a patient is stable on an existing prescription drug. VMS also supports the suggestion that an override process be consistent with Vermont's timeframes and processes for requesting a PA, as step therapy is only one form of PA. VMS also recommends that any limits on reauthorization discussed in (3) above – such as an approved request being valid for 1 year – also apply to step therapy.

VMS supports the reforms described above, and the urgent need for a reduction in prior authorization, for the following reasons:

- Vermont already is experiencing a health care professional workforce shortage. 16% of
 primary care physicians in Vermont are planning to retire or reduce hours within 12
 months.ⁱ We cannot afford to have one more primary care provider retire early or reduce
 their practice because of paperwork burdens.
- PA can decrease access to appropriate care and increase health care costs:
 - In a VMS member survey, 94% of respondents believed that the prior authorization process had a negative impact on their ability to treat patients, 81% reported that it is very or extremely difficult to determine when a PA will be required and 43% had made an emergency room or specialist referral to avoid having to go through the prior authorization process.
 - 64% of physicians in a national survey report that PA has led to ineffective initial treatments (i.e., step therapy); 62% of physicians report that PA has led to additional office visits and 46% of physicians report that PA has led to immediate care and/or ER visits. ⁱⁱ
- PA is taking clinicians away from patient care, exacerbating wait times:
 - A 2022 AMA survey reports that physicians complete, on average, 45 PAs per week and physicians or their staff spend almost two business days (14 hours) each week completing PAs.ⁱⁱⁱ
 - A recent time study revealed that during the office day, physicians spent 27.0% of their total time on direct clinical face time with patients and 49.2% of their time on EHR and desk work^{iv}



- Reducing prior authorization does not increase utilization. DVHA found that temporary waivers of high tech imaging prior authorization and prior authorization for DME, supplies, prosthetics, and orthotics during the COVID-19 public health emergency did not increase utilization of services and DVHA has extended these waivers.^v MVP's pilot gold card program found no additional expense or utilization.^{vi}
- Our current Vermont efforts to reduce prior authorization are fragmented and inconsistent: Prior authorization gold card pilots implemented by two Vermont payers in response to Act 140 were so narrowly crafted that no providers qualified; another program had low awareness and all programs exempted different types of procedures, medications or providers.^{vii} This fragmentation between payer programs can mean that it takes as much time and effort for a practitioner to determine if they are exempt from PA as to just go through the PA process.

It is time for meaningful action by every payer to reform prior authorization to an extent that the hours spent on administrative work are reduced and clinicians can spend more time in the exam room with patients.

ⁱ <u>https://www.healthvermont.gov/sites/default/files/document/HSI-stats-prov-phys20-detail.PDF</u>

ⁱⁱ https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

iii https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

iv https://pubmed.ncbi.nlm.nih.gov/27595430/

^v <u>https://legislature.vermont.gov/assets/Legislative-Reports/DVHA_Act-140-of-2020_Prior-Authorizations-Report_Final-with-Appendices.pdf</u>.

^{vi} <u>https://gmcboard.vermont.gov/sites/gmcb/files/documents/01-13-23-MVP-Health-Care-Act-140-2020-Gold-Carding-Pilot-Report.pdf</u>

https://legislature.vermont.gov/Documents/2024/WorkGroups/House%20Health%20Care/Prior%20Auth orizations/W~Julia%20Boles~Department%20of%20Financial%20Regulation%20(DFR)%20and%20Gre en%20Mountain%20Care%20Board%20(GMCB)%20Presentation%20-%20Act%20183%20(2022)%20Report%20-

^{%20}Prior%20Authorizations;%20Administrative%20Cost%20Reduction~4-26-2023.pdf - see slide 13)

Attachment G - TDI Goldcarding Presentaiton

Texas' "Goldcarding" law HB 3459 (2021)

Rachel Bowden, Texas Department of Insurance Health Innovations (B) Working Group NAIC Summer National Meeting, 2023

TDI | Agenda

- Texas "goldcarding" statute.
- Implementation process.
- Outcomes and challenges.
- Overview of law and rules.
- Questions.

TDI Statute enacted by HB 3459

- Bill: House Bill 3459 (87th Legislature), 2021.
- **Statute:** Texas Insurance Code (TIC) Chapter 4201, <u>Subchapter N</u>: Exemption from preauthorization requirements for physicians and providers providing certain health care services.
- **Applicability:** State-regulated health plans offered by HMOs, PPOs, and EPOs. Also applies to state employee and teacher plans. Doesn't apply to Medicaid or CHIP.
- **Requirement:** Health plans must provide exemptions from a preauthorization requirement for a particular health care service if the provider has a 90% approval rate for that service.

TDI Implementation process

Rules adopted in 2022:

- Title 28 of the Texas Administrative Code (TAC) 19.1730 19.733 Preauthorization Exemptions.
 - Adoption order
 - Administrative Code
- 28 TAC 12.601 Independent Review of Preauthorization Exemptions.
 - Adoption order
 - Administrative Code
- Form LHL011 Notice of Rescission of Preauthorization Exemption and Right to Request an Independent Review.

TDI Education

- TDI hosted a <u>webinar</u> in September 2022.
- Based on questions received during and after the webinar, TDI published Frequently Asked Questions.
- The biggest source of questions were from providers believing they should qualify but didn't receive a notice of exemption.
 - In most cases the threshold wasn't met based on preauthorization requests for TDI-regulated plans.
 - Providers had difficulty distinguishing between requests submitted to affiliated issuers for different plan types.

TDI Initial outcomes

- TDI conducted a survey in January 2023, following the initial round of exemptions due October 2022. On average:
 - Preauthorization was applied to 21% of claims and 85% of requests were approved, prior to implementation.
 - Preauthorization requirements applied to 3,000 distinct services.
 - Only 4% of providers met the threshold for evaluation for one or more services and only 3% received an exemption.
 - Exemptions were approved for 74% of providers who met the evaluation threshold.

TDI Policy considerations

- Impact was smaller than expected. Things that could increase the impact:
 - Lengthen evaluation period from six months to 12 months.
 - Reduce granularity of "particular health care service."
 - Reduce the threshold of five preauthorization requests.
 - Require issuers to combine data for providers across all affiliated entities, including those not subject to the law.
- Legislation was considered but not enacted (<u>HB 4343</u>).

TDI Overview of law and rules

- The following slides are an excerpt of the presentation shared with stakeholders in September 2022.
- View the <u>full presentation</u> for more detail.

TDI | Key definitions

For more, see <u>TAC 19.1730</u>.

- "Health care services," "physician" and "provider" are defined broadly: <u>TIC 843.002(13)</u>, (22), and (24).
- A "particular health care service" is one that is listed on an issuer's website as subject to preauthorization.
 - Listing was required by <u>SB 1742</u> (2019).
 - Rules: <u>TAC 19.1718(j)</u>.
- A "preauthorization exemption" is applicable to care rendered or ordered by a "treating physician or provider."

TDI | Eligibility for exemptions

- An exemption for a particular health care service is based on the physician's or provider's approval rate based on the outcomes of all "eligible preauthorization requests" for the service that:
 - Are submitted and finalized during the most recent six-month evaluation period (not pending appeal).
 - Result in the issuer either approving or issuing an adverse determination for the particular health care service.
- Modified requests are counted based on updated service requested.
- Outcomes for each separate service are counted individually.
- See <u>TAC 19.1730(3)</u>.

TDI Treating providers

• Under <u>TAC 19.1731</u>:

- Exemptions are granted using the National Provider Identifier (NPI) under which preauthorization requests are made.
- Exemptions apply to care ordered, referred, or provided by the treating provider with the exemption.
- Nurses and PAs practicing under the supervision of a physician can rely on an exemption, as appropriate.
- A provider that performs care ordered or referred by a provider with an exemption must include the name and NPI of the ordering provider on the claim. 41

TDI Examples of eligible services

- A provider could qualify for an exemption for any type of service for which they commonly submit a preauthorization request – even if the service is ultimately provided by a different provider. For example:
 - Surgery.
 - Prescription drugs.
 - Imaging.
 - Physical therapy.

TDI Initial evaluation

- Initial "evaluation period" <u>TAC 19.1730(5)</u>: Jan. 1, 2022-June 30, 2022.
- Notice is due within five days of completing an evaluation.
 - Deadline for initial evaluation period: Oct. 1, 2022.
 - Deadline for subsequent evaluation periods: two months following the day after the end of the evaluation period.
- By rule, the evaluation to grant an exemption must be based on at least five eligible preauthorization requests; otherwise, no notice is required (TAC 19.1731(b) and TAC 19.1732(c)).
- The exemption must be in place for at least six months before it may be rescinded (TAC 19.1732(a)). 43

TDI Example: Initial evaluation is denied

Initial evaluation Jan. 1-June 30, 2022 Initial notice of denial issued by Oct. 1, 2022 Next evaluation period July 1-Dec. 31, 2022

Notice issued by March 1, 2023

TDI Example: Initial evaluation is granted

Initial evaluation Jan. 1-June 30, 2022

Initial notice of exemption issued by Oct. 1, 2022 Subject to rescission in June 2023, January 2024, or future

TDI Continued eligibility

- Issuers may continue exemptions without subsequent evaluations (<u>TIC</u> <u>4201.653(c)</u>).
- While an exemption is in effect, an issuer:
 - Can't deny payment based medical necessity, except for material misrepresentation or failure to perform the service.
 - May conduct retrospective reviews only to determine continued eligibility for an exemption (or investigate a basis for denial).
 - Refer to <u>TIC 4201.659</u>.
- An exemption must last at least six months before it may be rescinded.

TDI Rescissions

- By statute, issuers may rescind an exemption only after they:
 - Select a random sample of five-20 claims to retrospectively review.
 - Determine that less than 90% met the criteria (based on review by TX-licensed physician of the same/similar specialty, if applicable).
 - Provide a 30-day notice in January or June and an opportunity for an independent review.
- Refer to <u>TIC 4201.655(a) and (b)</u>.
- Issuers may determine the applicable six-month evaluation period for a notification of rescission but must provide a rescission notice within two months of the end of the evaluation period (TAC 19.1730(5)(C))?

TDI Example: Exemption is rescinded

Rescission notice

issued

June 1-30, 2023

Rescission evaluation Oct. 1, 2022-March 31, 2023 (or later)

Next evaluation period April 1-Sept. 30, 2023

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Notice issued by

Dec. 1, 2023

TDI LHL011

TDI's <u>LHL011</u> form illustrates requirements for issuers to provide rescission notices and IRO request forms.

TDI Texas Department of Insurance

LHL011 | 0722

Notice of Rescission of Preauthorization Exemption and Right to Request an Independent Review

Important information and instructions

Date of notice:

Unless you request an appeal to an independent review organization (IRO) as set forth below, the preauthorization exemption for ______ will be rescinded effective ______.

TDI Appeal of rescission

- An "adverse determination regarding a preauthorization exemption" (that one or more claims retrospectively reviewed as part of an evaluation did not meet the issuer's screening criteria and leads to a rescission) is subject to appeal to an independent review organization.
- A physician or provider may request an independent review by submitting the rescission notice form before the rescission effective date (TAC 19.1733(c)).
- If a rescission is based on failure to provide medical records, the records must be submitted with the request for independent review (TAC 19.1733(d)).

TDI Request for review by an IRO

- Issuers will submit IRO requests to TDI for exemptions using existing processes.
- See <u>TDI's website</u> and <u>Online IRO Request System</u>.

TDI Example: Rescission is appealed to an IRO

Rescission notice issued June 1, 2023, effective July 1, 2023 Provider may request appeal by June 30, 2023 (date requested starts 30-day IRO clock)

Issuer sends IRO request to TDI; TDI assigns to IRO (one working day each) IRO must complete review by 30th day; issuer must send decision to provider in five days

Visit: tdi.texas.gov/health/hb3459.html

Email: <u>Rachel.Bowden@tdi.texas.gov</u>

Attachment H - MAHP H.B.4929(MA) Letter



October 26, 2022

His Excellency Charles Baker Governor State House, Room 360 Boston, MA 02133

RE: House Bill 4929, An Act relative to step therapy and patient safety

Dear Governor Baker:

On behalf of the Massachusetts Association of Health Plans (MAHP) and our 16 member health plans and 2 behavioral health organizations, which provide health care coverage to nearly 3 million Massachusetts residents, we are writing to share our serious concerns with House Bill 4929, *An Act relative to step therapy and patient safety*, which is currently before you. The legislation as passed would jeopardize patient safety and affordability, as well as inhibit our efforts around health care cost containment, and we ask that you return the legislation with amendments to address these concerns.

Health care affordability remains a critical issue for the Commonwealth's employers and consumers and prescription drug spending continues to be one of the fastest growing categories of spending growth, with pharmacy costs continuing to outpace all other categories. As the Health Policy Commission (HPC) found in its most recent Health Care Cost Trends Report, drug spending grew by 8.6 percent in 2020 alone. Through its broad exemptions to health plan step therapy protocol, we estimate that House Bill 4929 could add an estimated 2-5 percent on top of that trend, significantly adding to the cost pressures borne by employers and consumers and jeopardizing the ability for the MassHealth program to continue to achieve savings through its pharmacy programs.

MAHP and our member plans agree that health plan members should not be required to repeat a medication that is unsafe or ineffective if they change health plans and have supported proposals to ensure continuity of care. However, House Bill 4929, which is heavily supported by drug manufacturers, goes well beyond mere continuity of care to include broad exceptions to step therapy protocols that are inconsistent with current clinical guidelines and impact the health plans' ability to lower prescription drug costs and ensure patient safety.

Our proposed amendments outlined below provide reasonable alternatives to address these issues, ensuring that members have access to the medications they need without jeopardizing the ability for health plans to effectively manage their pharmacy programs to control costs and ensure quality and safety. We urge you to return the bill with these amendments.

1. Strike the Reference to "Same Pharmacologic Class and Mechanism of Action"

- As drafted, the bill currently includes an exception that enables a member to receive an exception to step therapy if they have failed a drug in the same pharmacologic class or with the same mechanism of action (MOA).
- This is inconsistent with clinical guidelines for several disease categories. It is routine for therapy protocols to ask for a member to try more than one drug within a pharmacologic class or with the same mechanism of action, as set forth in established clinical guidelines.
- For example, for the treatment of high cholesterol, clinical guidelines recommend the pharmacologic class of statins, as the initial treatment. The class contains a range of generic and brand name drugs that differ in dosage, administration, and possible side effects. Just because one drug is ineffective, it does not mean that another drug in the same class will be ineffective. House Bill 4929 would enable the member to exclude the entire class of statins, costing as low as \$400 per year for a generic, and move to a more expensive drug, such as PCSK9 inhibitor Repatha, an injectable costing over \$12,000 per year.
- If a member has previously tried a brand name drug, the MOA exception requirement prevents plans from requiring the use of a generic since the generic and other brands in the class would have the same MOA despite the generic saving money for the member through a lower copayment, as well as being more fiscally responsible for the health plan and higher value for the employer or the government program.
- We urge you to amend the bill to insert language that would ensure that the exception allowing for members to move to a new pharmacologic class or drug with a different MOA is implemented in a manner consistent with established clinical guidelines.

2. <u>Exclude Preferred Drug Lists</u>

- As drafted, the bill currently extends the requirements to other pharmacy management programs, such as MassHealth and commercial health plan preferred drug lists (PDLs).
- Health plans and the MassHealth program utilize PDLs to achieve lower costs by directing members to lower cost and higher value prescription drugs.
- Health plans can achieve lower prices by higher volume, which is how MassHealth is able to achieve significant savings for its prescription drug program. Inclusion of preferred drug lists will frustrate the work MassHealth has done to date to establish a uniform preferred drug list and will eliminate any opportunities for MassHealth and the health plans to garner savings.
- We urge you to amend the bill to specifically exclude preferred drug lists from the requirements of House Bill 4929.

3. <u>Amend Requirements for Emergency Requests:</u>

- As drafted, the bill requires health plans and MassHealth to respond to emergency requests for step therapy exceptions within 24 hours.
- We urge you to amend the bill to instead direct health plans and MassHealth to cover a 7-day emergency supply of the requested medication, similar to policies in place for MassHealth today.
- This is a better deal for consumers, as it would give the health plans and MassHealth an opportunity to conduct a review of the request without resulting in any gaps in treatment for patients.

Health plans have limited tools to direct members to safe, effective, and lower cost drugs. The pharmaceutical industry is focused on removing these tools to drive members to new, high cost drugs, when in fact, there are lower cost drugs on the market today that may be equally as effective. For these reasons, we respectfully ask that you return the bill with these amendments.

Sincerely,

Michael D Openning NO, MBA

Michael Sherman, MD, MBA Chief Medical Officer Point32Health

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Kate McIntosh, MD Chief Medical Officer Health New England

Farah Shafi, MD, MBA Deputy Chief Medical Officer AllWays Health Partners

Jennefer Daley The

Jennifer Daley, MD, FACP New England Market Medical Executive Cigna

David Burnly, MO

David Brumley, MD Chief Medical Officer Fallon Health

Cltard A Port mo

Christopher Post, MD Chief Medical Officer Senior Whole Health

Jania Rubuskunno

Jessica Rubenstein, MD Acting Chief Medical Officer WellSense Health Plan

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Jan Cook, MD MPH Medical Director Massachusetts Association of Health Plans

(Signatures in process)