VERMONT

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

For consumer assistance:
[Banking] 888-568-4547
[Insurance] 800-964- 1784
[Securities] 877-550-3907
www.dfr.vermont.gov

Insurance Bulletin No. 234

Act 111 of 2024 Implementation Frequently Asked Questions

December 19, 2024

The purpose of this bulletin is to clarify the application of Act 111 of 2024 to health insurers, health care providers, and consumers.

Part 1: Prior Authorization (Effective January 1, 2025).

A: What health plans does Act 111's prior authorization provisions apply to?

Under 18 V.S.A. § 9418(a)(8), health plan is defined broadly as "a health insurer, disability insurer, health maintenance organization, medical or hospital service corporation, and, to the extent permitted under federal law, any administrator of an insured or self-insured plan." The term "health plan" also includes plans that require their medical groups, independent practice associations, or other independent contractors to pay claims for health care services.

Act 111 also applies to non-ERISA health plans in accordance with federal law (29 U.S.C. § 1002). Those plan types include health plans established and funded by employees, state and local government health plans, publicly financed hospitals and educational institution plans, and church plans. Examples include the Vermont State Employees Health Plan and Vermont Education Health Initiative.

Act 111 does not apply to self-funded health plans established and maintained by private employers, over which state regulation is preempted under the federal Employee Retirement Income Security Act of 1974 (ERISA). ERISA health plans may, however, choose to voluntarily comply with Act 111.

Act 111 does not apply to Medicare or Vermont Medicaid.

B: How is prior authorization defined under Vermont law?

Under 18 V.S.A. § 9418(a)(15), prior authorization is defined broadly as "the process used by a health plan to determine the medical necessity, medical appropriateness, or both, of otherwise covered drugs, medical procedures, medical tests, and health care services." Prior authorization also includes preadmission review, pretreatment review, and utilization review.

C: How does Act 111 affect health plan prior authorization practices?

Act 111 adds a new subsection to Vermont's prior authorization statute (18 V.S.A. § 9418b), prohibiting health plans from imposing "any prior authorization requirement for any admission, item, service, treatment, or procedure ordered by a primary care provider."

This prohibition does not apply to prior authorization requirements for prescription drugs or for an admission, item, service, treatment, or procedure that is provided out-of-network.

D: Who qualifies as a "primary care provider" for purposes of Act 111?

Act 111 provides that (18 V.S.A. § 9418b(c)(1)(B)(2)), "primary care provider" has the same meaning as is used by the Vermont Blueprint for Health (Blueprint).

Under 18 V.S.A. § 706(c)(1), the Blueprint makes payments to "medical home practices" for attributed patients and to contribute to shared costs of community health teams. Blueprint payments are made in addition to normal fee-for-service reimbursement or other payments.

Section 4.5.1 of the Blueprint Manual defines "Patient-Centered Medical Homes" which receive Blueprint payments as "primary care practice[s] that [have] completed the program eligibility requirements outlined in this document including achieving official recognition based on National Committee for Quality Assurance – Patient-Centered Medical Home (NCQA PCMH) standards."[1]

Appendix 3 of the Blueprint Manual, which establishes the common attribution algorithm for commercial insurers, Medicaid, and Medicare, identifies Blueprint medical home practices by the National Provider Identifiers (NPIs) of the individual providers associated with them. The Blueprint maintains a roster of individual Blueprint providers by NPI, which is updated monthly and provided to payers for purposes of facilitating Blueprint payments.

To align with the Blueprint and provide certainty as to the scope of Act 111, the Department interprets "primary care provider" to correspond with the individual provider NPIs on the Blueprint roster.

The Department anticipates that the Legislature will amend Act 111 during the 2025 legislative session and encourages health plans to begin working to extend Act 111's prior authorization exemptions to all providers who contract and enroll as a primary care provider with the plan.

E: How will providers know if Act 111 applies to a patient's health plan?

The Department expects health plans to advise providers whether a patient has a health plan to which Act 111 applies through Eligibility Benefit Inquiry and Response (270/271) transactions, or other means readily accessible to providers.

The Department encourages health plans to begin providing an indicator on member identification cards that signifies whether the plan requires compliance with Act 111, in addition to other state laws and rules.

---

[1] *Available at:* https://blueprintforhealth.vermont.gov/sites/bfh/files/doc_library/Blueprint%20Manual%20July%202022_Updated.pdf.

F: What does it mean to "order" an admission, item, service, treatment, or procedure?

Act 111 does not define the term "order." The Department interprets this term consistent with Centers for Medicare and Medicare Services (CMS) guidance,[2] limiting applicability to admissions and non-physician, items, services, treatments, or procedures within the ordering provider's scope of practice and licensure under state law, such as Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), Clinical Laboratory Services, Imaging Services, and Home Health Services.

Providers who have questions about whether an admission, item, service, treatment, or procedure qualifies for Act 111's prior authorization exemption should contact the health plan's customer service or provider relations department.

G: How should billing providers bill claims exempt from prior authorization under Act 111?

Billing providers should enter the ordering provider's NPI on the following claim lines to indicate to health plans that a claim is exempt from prior authorization under Act 111:

- Electronic Facility Claims (CMS UB-04): Line 78-79, or 80.
- Electronic Claims (ASC X12N 837 format): Fields corresponding to CMS UB-04 Lines 78-79, or 80.
- Professional Services Claims (CMS 1500): Line 17.
- Professional Electronic Claims (ASC X12N 837 format): Fields corresponding to CMS 1500 Lines 17 and/or 17b. Please refer to health plan for specific details.

Please refer to health plan for specific details.

Part 2: Payment Policies and Manuals (Effective January 1, 2025).

A: What is the health plan notice requirement to providers for existing payment policies, manuals, or changes to existing payment policies and manuals under Act 111?

Act 111 adds new subparagraph 18 V.S.A. § 9418c(a)(5), which requires health plans to give contracted providers notice at least 60 days in advance of any "new policy or manual, or any change to an existing policy or manual" if the plan uses those polices or manuals to augment its contract with a provider.

Act 111 requires the notice to be conspicuously titled "Notice of Policy Change" and it must include the following provisions:

- A summary of the new policy, manual, or change;
- An explanation of the policy, manual, or change;
- The effective date of the policy, manual, or change; and

[2] *Available at*: https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/chain-ownership-system-pecos/ordering-certifying.

- Notice of the right to object in writing to the policy, manual, or change, including:
    - The timeframe for submitting objections; and
    - Information on where and how to send the objection.

Providers have 60 days after receiving the notice to object in writing. If a provider objects, health plans have 30 days to respond. In the event of a dispute, Act 111 requires health plans to work with the provider to achieve a "reasonable resolution" to the objection.

If the provider is unsatisfied with the proposed resolution, Act 111 reserves to the provider any remedy available under the provider's health plan contract or applicable law.

B: Are health plans required to give providers 60-days' notice for coding updates required by federal law?

Under the Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. § 1320d–2(c), and its supporting regulations (45 C.F.R. § 162, Subpart J), CMS and the American Medical Association (AMA) release quarterly updates for new, updated, or terminated Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) billing codes. Federal law requires health plans to make these changes effective on the first month of the next calendar year quarter. CMS and the AMA also release new International Classification of Diseases (ICD-10) on an annual basis, which are included in this process.

To the extent that federal law requires health plans to make coding or payment updates, Act 111 does not require 60-day advance notice to providers. The Department encourages health plans to notice providers about coding or payment updates as soon as practicable.

Part 3: Claims Editing (Effective January 1, 2026).

A: What is claims editing? How does Act 111 impact health plan claims editing practices?

In general, "claims editing" refers to the process that health plans use to review submitted claims for consistency with CMS and AMA medical coding guidelines.

Under 18 V.S.A. § 9418(a)(6), "editing" is defined as:

> a practice or procedure pursuant to which one or more adjustments are made to Current Procedural Terminology (CPT) codes, American Society of Anesthesiologists' (ASA) current procedural terminology, the American Dental Association's (ADA) current dental terminology, or Healthcare Common Procedure Coding System (HCPCS) Level II codes included in a claim that result in:
>
> (A) payment being made based on some, but not all, of the codes originally billed by a participating health care provider;
>
> (B) payment being made based on different codes from those originally billed by a participating health care provider;

(C) payment for one or more of the codes included in the claim originally billed by a participating health care provider being reduced by application of payer's editing software, such as multiple procedure logic software;

(D) payment for one or more of the codes being denied;

(E) a reduced payment as a result of services provided to an insured that are claimed under more than one procedure code on the same service date; or

(F) any combination of the [above].

Health plan payment policies and manuals do not constitute edits or claims editing under Vermont law.

Act 111 (18 V.S.A. § 9418a(b)) requires health plans to limit claims editing to the following standards, processes, and guidelines.

- The CMS National Correct Coding Initiative (NCCI) as in effect for Medicare for claims for outpatient and professional services.
- The CMS Medicare Code Editor as in effect for Medicare for facility claims.
- Appropriate nationally recognized edit standards, guidelines, or conventions for pharmacy claims.
- Other appropriate nationally recognized edit standards, guidelines, or conventions approved by the Department for any other claim.

B: What if Medicare changes an applicable edit standard, process, or guideline?

Health plans are required to apply the relevant edit standards, processes, and guidelines from NCCI or Medicare Code Editor in effect on the date the claim is submitted.

However, if Medicare changes an applicable edit standard, process, or guideline within 90 days prior to the date the claim is submitted, Act 111 (18 V.S.A. § 9418a(b)(2)) allows health plan to use the prior version of the edit standard, process, or guideline if it has not yet updated its claims processing system.

C: Can health plans use other claims editing standards?

Act 111 (18 V.S.A. § 9418a(c)), allows health plans to use other claims editing standards in certain situations:

- When use of other claims editing standards is necessary to comply with State or federal laws, rules, regulations, or coverage mandates.
- When use of other claims editing standards is more favorable to providers than the NCCI or Medicare Code Editor.
- To address new codes that are not yet incorporated into a health plan's claims processing system.

In each case, the applicable edit standards must be:

- Developed with input from the provider community.

- Clearly supported by nationally recognized standards, guidelines, or conventions approved by the Department.
- Made available to providers on the health plan's website and electronic communications.

D: When can health plans release new edits?

Not more than quarterly, to take effect on January 1, April 1, July 1, or October 1.

New edits must be filed with the Department prior to implementation. Health plans must also give providers at least 30 days' advance notice prior to implementation.

If Medicare changes an edit standard, process, or guideline, health plans must incorporate those modifications into their next quarterly release of edits.

E: Can health plans review submitted claims for correct coding prior to adjudication?

Under Act 111 (18 V.S.A. § 9418a(e)), health plans may not require providers to submit medical record documentation to adjudicate a claim as part of a prepayment coding validation edit review, unless it is targeted to a specific provider or provider group for the purposes of:

- Evaluating "high-dollar" claims (The Department interprets "high-dollar claims" to mean payable claims over $100,000—corresponding to the upper limit of Medicare's claims processing system).
- Verifying complex financial arrangements.
- Investigating member questions.
- Conducting post-audit monitoring.
- Addressing a reasonable belief of fraud, waste, or abuse.
- Other circumstances determined by the Department.

F: Does Act 111 prohibit health plans from denying claims during adjudication?

Act 111 does not prohibit health plans from denying a claim during adjudication if the health plan determines that a billed item, service, treatment, or procedure is not medically necessary, experimental or investigational, or otherwise excluded from coverage under the terms of its subscriber contract with its member.

G: Does Act 111 prohibit health plans from auditing paid claims?

Act 111 does not prohibit health plans from auditing paid claims after adjudication.

H: Do Act 111's limitations on claims editing and provider notice requirements apply to providers outside of Vermont?

Act 111's limitations on claims editing and provider notice requirements apply to "health care providers" or "providers," defined under 18 V.S.A. § 9418(a)(9) as "a person, partnership, or corporation licensed, certified, or otherwise authorized by law to provide professional health care services in this State…"

Therefore, Act 111's limitations do not apply to providers that are not licensed, certified, or otherwise authorized by law to provide health care services in Vermont.

Part 4: Step Therapy (Effective January 1, 2025).

A: What is step therapy? How does Act 111 impact health plan step therapy practices?

Under 8 V.S.A. § 4089i(i)(5), step therapy is defined as "protocols that establish the specific sequence in which prescription drugs for a specific medical condition are to be prescribed." These practices do not need to be labeled as step therapy to be considered step therapy under the statute.

Act 111 (8 V.S.A. § 4089i(e)(1)(B)), requires health plans to grant an exception to step therapy protocols upon request if any of the following conditions apply:

- The prescription drug required under the step-therapy protocol is contraindicated or will likely cause an adverse reaction or physical or mental harm to the insured.
- The prescription drug required under the step-therapy protocol is expected to be ineffective based on the insured's known clinical history, condition, and prescription drug regimen.
- The insured has already tried the prescription drugs on the protocol, or other prescription drugs in the same pharmacologic class or with the same mechanism of action, which have been discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, regardless of whether the insured was covered at the time by a plan offered by the current insurer or its pharmacy benefit manager.
- The insured is stable on a prescription drug selected by the insured's treating health care professional for the medical condition under consideration. Or
- The step-therapy protocol or a prescription drug required under the protocol is not in the patient's best interests because it will:
    - Pose a barrier to adherence.
    - Likely worsen a comorbid condition.
    - Likely decrease the insured's ability to achieve or maintain reasonable functional ability.

B: Which health plans does Act 111's step therapy protocol override provisions apply to?

Under Act 111 (8 V.S.A. § 4089i), the step therapy protocol override provisions apply to health insurers as that term is defined in 18 V.S.A. § 9402:

> any health insurance company, nonprofit hospital and medical service corporation, managed care organizations, and, to the extent permitted under federal law, any administrator of an insured, self-insured, or publicly funded health care benefit plan offered by public and private entities.

C: How should health plans process step therapy protocol override determination requests for covered prescription drugs)?

Act 111 (8 V.S.A. § 4089i(e)(1)(B)) requires health plans to process step therapy protocol override requests using the same procedure as prior authorization requests under 18 V.S.A. § 9418b.

D: If a health plan determines the insured's diagnosis does not warrant treatment with any prescription drug, do Act 111 step therapy protocol override requirements apply?

No, instead, Rule H-2009-03's utilization review requirements will apply.

To the extent that a health plan determines that treatment with a prescription drug is experimental or investigational, that determination may be externally appealed under 8 V.S.A. § 4089f.

E: If the health plan only reviews a prescription drug for medical necessity, do Act 111's step therapy protocol override requirements apply?

No, instead, Rule H-2009-03's utilization review requirements will apply.

To the extent that a health plan determines that treatment with a prescription drug is not medically necessary that determination may be externally appealed under 8 V.S.A. § 4089f.

F: What is the timeframe for health plans to make a step therapy protocol override determination under Act 111?

Act 111 (8 V.S.A. § 4089i(e)(1)(B)) requires health plans to make step therapy protocol override determinations in the same timeframe as prior authorization determinations under 18 V.S.A. § 9418b(g)(4).

Under 18 V.S.A. § 9418b(g)(4), failure to render a determination with the required timeframe will result in a deemed override.

G: How should a health plan determine whether a request for a prescription drug is urgent?

Under Rule H-2009-03, Section 3.2(B), the following requests are considered urgent:

- Requests related to mental health and substance abuse conditions, unless the member or treating provider informs the managed care organization that the request is not urgent.
- Pharmacy benefit determinations, unless the member or treating provider informs the managed care organization 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.
- Requests designated as urgent by a member's health care provider or by the member.

H: What supporting rationale and documentation must a provider submit for a step therapy protocol override determination?

To support a step therapy protocol override determination, providers should submit supporting rationale and documentation, such as clinical notes or laboratory results, which demonstrates one of the following:

- The required prescription drug(s) is contraindicated or will likely cause an adverse reaction or physical or mental harm to the insured.
- The required prescription drug(s) is expected to be ineffective based on the insured's known clinical history, condition, and prescription drug regimen.
- The insured has tried the required prescription drug(s) under his or her current or previous health insurance coverage, or another prescription drug in the same pharmacologic class or with the same mechanism of action, and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.
- The insured is stable on a prescription drug(s) selected by his or her health care professional for his or her medical condition. Or
- The required prescription drug(s) is not in the insured's best interest because it will likely cause a significant barrier to the insured's adherence to or compliance with the insured's plan of care, will likely worsen a comorbid condition, or will likely decrease the insured's ability to achieve or maintain reasonable functional ability in performing daily activities.

I: Can health plans request additional documentation to support a step therapy protocol override request?

Health plans may request additional documentation to support a step therapy protocol override within the timeframes provided under 18 V.S.A. § 9418b(g)(4).

J: What do health plans need to provide when a step therapy protocol override request is decided?

Health plans deciding a step therapy protocol override request should comply with the requirements for a Notice of Benefit Determination under Rule H-2009-03, Section 3.2(G).

K: Does Act 111 prohibit health plans from conducting medical necessity reviews if a prescription drug is recommended or prescribed by a provider?

Act 111 does not prohibit medical necessity reviews for prescription drugs recommended or prescribed by a provider.

L: How does Act 111 define the "same pharmacologic class or with the same mechanism of action"?

Act 111 does not define the term "same pharmacologic class or with the same mechanism of action." The Department interprets "same pharmacologic class" to refer to drug classes within nationally recognized drug classification systems such as the United States Pharmacopeia Drug Classification System (USP DC), American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification System, or Medi-Span Generic Product Identifier (GPI), and "mechanism of action" according to the manufacturer FDA-approved labeling.

M: If the insured does not comply with the plan of care for taking a prescription drug, is it considered a "lack of efficacy" under Act 111?

A lack of efficacy is when a drug is no longer able to achieve the desired clinical response or goal despite proper drug administration. Failure to take the prescription drug as directed does not constitute a lack of efficacy.

N: What criteria should health plans use to determine if an insured is "stable on a prescription drug selected by the insured's treating health care professional for the medical condition under consideration"?

The Department encourages health plans to develop reasonable and uniform written criteria based on sound clinical judgment (and evidence-based practice protocols, if available) for use in determining whether an insured is "stable" for purposes of Act 111. Criteria for determining the insured's stability on a requested prescription drug should take into consideration the following factors:

- The medical profile of the insured (e.g., age, condition severity, the presence of any comorbidities, any concurrent medications, any history of adverse reactions, any history of use of alternative drugs known to be clinically effective in treating the condition etc.);
- The state of the insured's condition under consideration, while on the requested prescription drug;
- The prescriber's rationale for deeming an insured stable on the requested prescription drug (i.e., how, why, and on what basis did the prescriber conclude that the insured is stable on the requested prescription drug) and how such rationale aligns with standard medical practice and/or evidence-based practice protocols for the treatment of the insured's condition.

O: What criteria should health plans use to determine if a prescription drug is likely to cause a significant barrier to the insured's adherence to or compliance with the plan of care, will likely worsen a comorbid condition of the insured, or will likely decrease the insured's ability to achieve or maintain reasonable functional ability in performing daily activities?

Health plans are encouraged to develop reasonable and uniform written criteria based on sound clinical judgment (and evidence-based practice protocols, if available) for use in determining whether a prescription drug is likely to cause a significant barrier to the insured's adherence to or compliance with the plan of care, will likely worsen a comorbid condition of the insured, or will likely decrease the insured's ability to achieve or maintain reasonable functional ability in performing daily activities as provided for in Act 111.

These criteria should consider the insured's physical condition, mental health condition, and intellectual ability in determining whether a drug is likely to cause a significant barrier to the insured's adherence to or compliance with the plan of care.

P: Do Act 111's step therapy requirements apply to a health plan's pharmacy and medical benefits?

Act 111's step therapy requirements apply to prescription drugs covered by a health plan regardless of whether the prescription drug is considered a pharmacy benefit or a medical benefit in the health insurance policy.

Inquiries about this Bulletin should be directed to Sebastian Arduengo, Director of Health Insurance Regulation (Sebastian.Arduengo@vermont.gov).

DocuSigned by:
Kevin Gaffney
2DF65CB250564C4...
Kevin Gaffney, Commissioner

12/20/2024
Date