Final Proposed Filing - Coversheet

Instructions:

In accordance with Title 3 Chapter 25 of the Vermont Statutes Annotated and the "Rule on Rulemaking" adopted by the Office of the Secretary of State, this filing will be considered complete upon filing and acceptance of these forms with the Office of the Secretary of State, and the Legislative Committee on Administrative Rules.

All forms shall be submitted at the Office of the Secretary of State, no later than 3:30 pm on the last scheduled day of the work week.

The data provided in text areas of these forms will be used to generate a notice of rulemaking in the portal of "Proposed Rule Postings" online, and the newspapers of record if the rule is marked for publication. Publication of notices will be charged back to the promulgating agency.

PLEASE REMOVE ANY COVERSHEET OR FORM NOT REQUIRED WITH THE CURRENT FILING BEFORE DELIVERY!

Certification Statement: As the adopting Authority of this rule (see 3 V.S.A. § 801 (b) (11) for a definition), I approve the contents of this filing entitled:

Prior Authorizat	tion							
/s/ Kristin L. McClure				, on	5/5/25			
			(date)					
Printed Name and Title: Kristin McClure, Services		Secretary,	Agency o	f Human				
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☐ Responsiveness Summary

1. TITLE OF RULE FILING:

Prior Authorization

2. PROPOSED NUMBER ASSIGNED BY THE SECRETARY OF STATE 24P030

3. ADOPTING AGENCY:

Agency of Human Services (AHS)

4. PRIMARY CONTACT PERSON:

(A PERSON WHO IS ABLE TO ANSWER QUESTIONS ABOUT THE CONTENT OF THE RULE).

Name: Ashley Berliner

Agency: Agency of Human Services

Mailing Address: 280 State Drive, Waterbury, VT 05671-1000

Telephone: 802-578-9305 Fax: 802-241-0450 E-Mail: AHS.MedicaidPolicy@vermont.gov

Web URL (WHERE THE RULE WILL BE POSTED):

https://humanservices.vermont.gov/rulespolicies/health-care-rules/health-careadministrative-rules-hcar

5. SECONDARY CONTACT PERSON:

(A SPECIFIC PERSON FROM WHOM COPIES OF FILINGS MAY BE REQUESTED OR WHO MAY ANSWER QUESTIONS ABOUT FORMS SUBMITTED FOR FILING IF DIFFERENT FROM THE PRIMARY CONTACT PERSON).

Name: Linda Narrow McLemore

Agency: Agency of Human Services

Mailing Address: 280 State Drive, Waterbury, VT 05671-1000

Telephone: 802-779-3258 Fax: 802-241-0450

E-Mail: Linda.McLemore@Vermont.gov

6. RECORDS EXEMPTION INCLUDED WITHIN RULE:

(DOES THE RULE CONTAIN ANY PROVISION DESIGNATING INFORMATION AS CONFIDENTIAL; LIMITING ITS PUBLIC RELEASE; OR OTHERWISE, EXEMPTING IT FROM INSPECTION AND COPYING?) No

IF YES, CITE THE STATUTORY AUTHORITY FOR THE EXEMPTION:

N/A

PLEASE SUMMARIZE THE REASON FOR THE EXEMPTION:

N/A

7. LEGAL AUTHORITY / ENABLING LEGISLATION:

(The specific statutory or legal citation from session law indicating who the adopting Entity is and thus who the signatory should be. THIS SHOULD BE A SPECIFIC CITATION NOT A CHAPTER CITATION).

3 V.S.A. § 801(b)(11); 33 V.S.A. § 1901(a)(1)

EXPLANATION OF HOW THE RULE IS WITHIN THE AUTHORITY OF THE AGENCY:

AHS's authority to adopt rules is identified above. These statutes authorize AHS as the adopting authority for administrative procedures and afford rulemaking authority for the administration of Vermont's medical assistance programs under Title XIX (Medicaid) of the Social Security Act.

8.

- 9. THE FILING HAS NOT CHANGED SINCE THE FILING OF THE PROPOSED RULE.
- 10. THE AGENCY HAS NOT INCLUDED WITH THIS FILING A LETTER EXPLAINING IN DETAIL WHAT CHANGES WERE MADE, CITING CHAPTER AND SECTION WHERE APPLICABLE.
- 11. SUBSTANTIAL ARGUMENTS AND CONSIDERATIONS WERE RAISED FOR OR AGAINST THE ORIGINAL PROPOSAL.
- 12. THE AGENCY HAS INCLUDED COPIES OF ALL WRITTEN SUBMISSIONS AND SYNOPSES OF ORAL COMMENTS RECEIVED.
- 13. THE AGENCY HAS INCLUDED A LETTER EXPLAINING IN DETAIL THE REASONS FOR THE AGENCY'S DECISION TO REJECT OR ADOPT THEM.
- 14. CONCISE SUMMARY (150 WORDS OR LESS):

This rule sets forth the criteria for Vermont Medicaid's prior authorization process. It amends current prior authorization Rule 7102 titled "Prior Authorization." Revisions include: (1) align the rule with 42 CFR 438.210(d)(2) that requires that expedited prior authorizations be decided within 72 hours of request, (2) provide that standard prior authorizations must be decided within seven days of request, (3) add clarity regarding the prior authorization process for pharmacy requests, and (4) add prior authorization requirements for the routine patient costs of a beneficiary when they are related to a clinical trial.

15. EXPLANATION OF WHY THE RULE IS NECESSARY:

The rule is necessary to define the criteria for prior authorization. This amendment aligns rule with federal and state guidance and law, improves clarity, and makes technical corrections.

16. EXPLANATION OF HOW THE RULE IS NOT ARBITRARY:

The rule is required to implement state and federal health care guidance and laws. Additionally, the rule is within the authority of the Secretary, is within the expertise of AHS, and is based on relevant factors including consideration of how the rule affects the people and entities listed below.

17. LIST OF PEOPLE, ENTERPRISES AND GOVERNMENT ENTITIES AFFECTED BY THIS RULE:

Medicaid beneficiaries; Agency of Human Services including its Departments; health care providers; and health law, policy and related advocacy and community-based organizations and groups including the Office of Health Care Advocate.

18. BRIEF SUMMARY OF ECONOMIC IMPACT (150 WORDS OR LESS):

The rule does not increase or lessen an economic burden on any person or entity including no impact on the State's gross annualized budget in fiscal years 2024, 2025, and 2026. The changes and amendments to prior authorization criteria conform the rule with current practice.

19. A HEARING WAS HELD.

20. HEARING INFORMATION

(THE FIRST HEARING SHALL BE NO SOONER THAN 30 DAYS FOLLOWING THE POSTING OF NOTICES ONLINE).

IF THIS FORM IS INSUFFICIENT TO LIST THE INFORMATION FOR EACH HEARING, PLEASE ATTACH A SEPARATE SHEET TO COMPLETE THE HEARING INFORMATION.

Date: 9/11/2024 Time: 02:00 PM

Street Address: Cherry A Conference Room Waterbury State Office Complex, 280 State Drive, Waterbury, VT

OR

Virtual Hearing - Phone or Microsoft Teams call in (802)552-8456, 75316921#; Teams link - URL is below and

also will be available through the Public Notice in the Global Commitment Register on the AHS website.

Zip Code: 05671

URL for Virtual: https://teams.microsoft.com/l/meetupjoin/19%3ameeting ZjA4ZDlkNjAtNTRhZC00YTYzLWJkNWUtMDM3Y 2RmNmVkYmIz%40thread.v2/0?context=%7b%22Tid%22%3a%2220b 4933b-baad-433c-9c02-

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21. DEADLINE FOR COMMENT (NO EARLIER THAN 7 DAYS FOLLOWING LAST HEARING):

9/18/2024

KEYWORDS (PLEASE PROVIDE AT LEAST 3 KEYWORDS OR PHRASES TO AID IN THE SEARCHABILITY OF THE RULE NOTICE ONLINE).

Prior authorization

Prior approval

Medicaid

Administrative Procedures Final Proposed Filing – Coversheet

Health Care Administrative Rules HCAR

Adopting Page

Instructions:

This form must accompany each filing made during the rulemaking process:

Note: To satisfy the requirement for an annotated text, an agency must submit the entire rule in annotated form with proposed and final proposed filings. Filing an annotated paragraph or page of a larger rule is not sufficient. Annotation must clearly show the changes to the rule.

When possible, the agency shall file the annotated text, using the appropriate page or pages from the Code of Vermont Rules as a basis for the annotated version. New rules need not be accompanied by an annotated text.

- 1. TITLE OF RULE FILING:
 Prior Authorization
- 2. ADOPTING AGENCY:
 Agency of Human Services (AHS)
- 3. TYPE OF FILING (*Please choose the type of filing from the dropdown menu based on the definitions provided below*):
 - **AMENDMENT** Any change to an already existing rule, even if it is a complete rewrite of the rule, it is considered an amendment if the rule is replaced with other text.
 - **NEW RULE** A rule that did not previously exist even under a different name.
 - **REPEAL** The removal of a rule in its entirety, without replacing it with other text.

This filing is AN AMENDMENT OF AN EXISTING RULE

4. LAST ADOPTED (PLEASE PROVIDE THE SOS LOG#, TITLE AND EFFECTIVE DATE OF THE LAST ADOPTION FOR THE EXISTING RULE):

SOS Rule Log # 08-040 (10/1/08) (rules amended, renumbered, and reorganized); Requesting Coverage Exceptions, effective 4/1/1999

Economic Impact Analysis

Instructions:

In completing the economic impact analysis, an agency analyzes and evaluates the anticipated costs and benefits to be expected from adoption of the rule; estimates the costs and benefits for each category of people enterprises and government entities affected by the rule; compares alternatives to adopting the rule; and explains their analysis concluding that rulemaking is the most appropriate method of achieving the regulatory purpose. If no impacts are anticipated, please specify "No impact anticipated" in the field.

Rules affecting or regulating schools or school districts must include cost implications to local school districts and taxpayers in the impact statement, a clear statement of associated costs, and consideration of alternatives to the rule to reduce or ameliorate costs to local school districts while still achieving the objectives of the rule (see 3 V.S.A. § 832b for details).

Rules affecting small businesses (excluding impacts incidental to the purchase and payment of goods and services by the State or an agency thereof), must include ways that a business can reduce the cost or burden of compliance or an explanation of why the agency determines that such evaluation isn't appropriate, and an evaluation of creative, innovative or flexible methods of compliance that would not significantly impair the effectiveness of the rule or increase the risk to the health, safety, or welfare of the public or those affected by the rule.

1. TITLE OF RULE FILING:

Prior Authorization

2. ADOPTING AGENCY:

Agency of Human Services (AHS)

3. CATEGORY OF AFFECTED PARTIES:

LIST CATEGORIES OF PEOPLE, ENTERPRISES, AND GOVERNMENTAL ENTITIES POTENTIALLY AFFECTED BY THE ADOPTION OF THIS RULE AND THE ESTIMATED COSTS AND BENEFITS ANTICIPATED:

Medicaid beneficiaries; Agency of Human Services including its Departments; health care providers; and health law, policy and related advocacy and community-based organizations and groups including the Office of Health Care Advocate.

The rule does not increase or lessen an economic burden on any person or entity including no impact on the

State's gross annualized budget in fiscal years 2024, 2025, and 2026. The changes and amendments to prior authorization criteria conform the rule with current practice.

4. IMPACT ON SCHOOLS:

INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON PUBLIC EDUCATION, PUBLIC SCHOOLS, LOCAL SCHOOL DISTRICTS AND/OR TAXPAYERS CLEARLY STATING ANY ASSOCIATED COSTS:

No impact

5. ALTERNATIVES: Consideration of Alternatives to the Rule to Reduce or Ameliorate Costs to Local School districts while still achieving the objective of the Rule.

Not applicable

6. IMPACT ON SMALL BUSINESSES:

INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON SMALL BUSINESSES (EXCLUDING IMPACTS INCIDENTAL TO THE PURCHASE AND PAYMENT OF GOODS AND SERVICES BY THE STATE OR AN AGENCY THEREOF):

No impact

7. SMALL BUSINESS COMPLIANCE: EXPLAIN WAYS A BUSINESS CAN REDUCE THE COST/BURDEN OF COMPLIANCE OR AN EXPLANATION OF WHY THE AGENCY DETERMINES THAT SUCH EVALUATION ISN'T APPROPRIATE.

Not applicable

8. COMPARISON:

COMPARE THE IMPACT OF THE RULE WITH THE ECONOMIC IMPACT OF OTHER ALTERNATIVES TO THE RULE, INCLUDING NO RULE ON THE SUBJECT OR A RULE HAVING SEPARATE REQUIREMENTS FOR SMALL BUSINESS:

There is no economic impact for there to be a comparison.

9. SUFFICIENCY: Describe How the Analysis was conducted, identifying relevant internal and/or external sources of information used. There are no additional costs associated with this rule because the amendments reflect existing practice and coverage policies for Vermont Medicaid. There are no alternatives to the adoption of the rule; it is necessary to ensure continued alignment with federal and state guidance and law for covered services and benefits within Vermont Medicaid.

Environmental Impact Analysis

Instructions:

In completing the environmental impact analysis, an agency analyzes and evaluates the anticipated environmental impacts (positive or negative) to be expected from adoption of the rule; compares alternatives to adopting the rule; explains the sufficiency of the environmental impact analysis. If no impacts are anticipated, please specify "No impact anticipated" in the field.

Examples of Environmental Impacts include but are not limited to:

- Impacts on the emission of greenhouse gases
- Impacts on the discharge of pollutants to water
- Impacts on the arability of land
- Impacts on the climate
- Impacts on the flow of water
- Impacts on recreation
- Or other environmental impacts

1. TITLE OF RULE FILING:

Prior Authorization

2. ADOPTING AGENCY:

Agency of Human Services (AHS)

- 3. GREENHOUSE GAS: EXPLAIN HOW THE RULE IMPACTS THE EMISSION OF GREENHOUSE GASES (E.G. TRANSPORTATION OF PEOPLE OR GOODS; BUILDING INFRASTRUCTURE; LAND USE AND DEVELOPMENT, WASTE GENERATION, ETC.):

 No impact
- 4. WATER: EXPLAIN HOW THE RULE IMPACTS WATER (E.G. DISCHARGE / ELIMINATION OF POLLUTION INTO VERMONT WATERS, THE FLOW OF WATER IN THE STATE, WATER QUALITY ETC.):

No impact

5. LAND: EXPLAIN HOW THE RULE IMPACTS LAND (E.G. IMPACTS ON FORESTRY, AGRICULTURE ETC.):

No impact

6. RECREATION: EXPLAIN HOW THE RULE IMPACTS RECREATION IN THE STATE: No impact

- 7. CLIMATE: EXPLAIN HOW THE RULE IMPACTS THE CLIMATE IN THE STATE: No impact
- 8. OTHER: EXPLAIN HOW THE RULE IMPACT OTHER ASPECTS OF VERMONT'S ENVIRONMENT:
 No impact
- 9. SUFFICIENCY: DESCRIBE HOW THE ANALYSIS WAS CONDUCTED, IDENTIFYING RELEVANT INTERNAL AND/OR EXTERNAL SOURCES OF INFORMATION USED. This rule has no impact on the environment.

Public Input Maximization Plan

Instructions:

Agencies are encouraged to hold hearings as part of their strategy to maximize the involvement of the public in the development of rules. Please complete the form below by describing the agency's strategy for maximizing public input (what it did do, or will do to maximize the involvement of the public).

This form must accompany each filing made during the rulemaking process:

1. TITLE OF RULE FILING:

Prior Authorization

2. ADOPTING AGENCY:

Agency of Human Services (AHS)

3. PLEASE DESCRIBE THE AGENCY'S STRATEGY TO MAXIMIZE PUBLIC INVOLVEMENT IN THE DEVELOPMENT OF THE PROPOSED RULE, LISTING THE STEPS THAT HAVE BEEN OR WILL BE TAKEN TO COMPLY WITH THAT STRATEGY:

AHS shared the proposed rule with the Medicaid and Exchange Advisory Committee (MEAC), Vermont Legal Aid (VLA), Vermont Medical Society (VMS), Vermont Association of Hospitals and Health Systems (VAHHS), Vermont Care Partners (VCP), Bi-State Primary Care Association, and the VNAs of Vermont on 3/1/24, and made changes based upon comments that were received.

When a rule is filed with the Office of the Secretary of State, AHS provides notice and access to the rule through the Global Commitment Register (GCR). The GCR provides notification of policy changes and clarifications of existing Medicaid policy, including rulemaking, under Vermont's 1115 Global Commitment to Health waiver. Anyone can subscribe to the GCR. Proposed, final proposed, and adopted rules, including all public comments and responses to rulemaking, are posted to the GCR. Subscribers receive email notifications of rule filings including hyperlinks to

Public Input

posted documents and an explanation of how to provide comment and be involved in the rulemaking.

4. BEYOND GENERAL ADVERTISEMENTS, PLEASE LIST THE PEOPLE AND ORGANIZATIONS THAT HAVE BEEN OR WILL BE INVOLVED IN THE DEVELOPMENT OF THE PROPOSED RULE:

Agency of Human Services, and the Department of Vermont Health Access;

Health Care Advocate, Vermont Legal Aid Society;

Medicaid and Exchange Advisory Committee;

Vermont Medical Society;

Vermont Association of Hospitals and Health Systems;

Vermont Care Partners; and

Bi-State Primary Care Association

VNA.

C/O LEGISLATIVE OPERATIONS 115 STATE STREET MONTPELIER, VT 05633-5301

SEN. SETH BONGARTZ, VICE CHAIR

SEN. SCOTT BECK SEN. ROBERT PLUNKETT SEN. DAVID WEEKS



REP. TREVOR SQUIRRELL, CHAIR REP. MARK HIGLEY REP. CAROL ODE REP. LARRY SATCOWITZ

TEL: (802) 828-2231

STATE OF VERMONT

Legislative Committee on Administrative Rules (LCAR)

April 16, 2025

Louise Corliss, APA Clerk Vermont State Archives & Records Administration 1078 U.S. Route 2, Middlesex Montpelier, VT 05633-7701

Dear Ms. Corliss:

The Legislative Committee on Administrative Rules considered a request to extend the adoption deadline from the Agency of Human Services relating to 24-P30 Health Care Administrative Rule on Prior Authorization for Medicaid Services at its meeting on March 13, 2025. Pursuant to 3 V.S.A § 843(c), the Committee voted to extend the deadline for adoption and the Agency of Human Services has until June 15, 2025 to complete the adoption process by filing with the Secretary of State and the Legislative Committee on Administrative Rules.

The Committee deferred action on the content of the rule until a meeting date to be determined.

Sincerely,

Emery Mattheis, Committee Assistant

cc: Linda McLemore, Agency of Human Services



OFFICE OF THE SECRETARY TEL: (802) 241-0440 FAX: (802) 241-0450

> JENNEY SAMUELSON SECRETARY

KRISTIN MCCLURE DEPUTY SECRETARY

STATE OF VERMONT AGENCY OF HUMAN SERVICES

MEMORANDUM

TO: Sarah Copeland Hanzas, Secretary of State

FROM: Jenney Samuelson, Secretary, Agency of Human Services (

DATE: November 21, 2024

SUBJECT: Signatory Authority for Purposes of Authorizing Administrative Rules

I hereby designate Kristin McClure, Deputy Secretary, Agency of Human Services as signatory to fulfill the duties of the Secretary of the Agency of Human Services as the adopting authority for administrative rules as required by Vermont's Administrative Procedures Act, 3. V.S.A § 801 et seq.

CC: KristinMcClure@vermont.gov

State of Vermont Agency of Administration 109 State Street Montpelier, VT 05609-0201 www.aoa.vermont.gov [phone] 802-828-3322

INTERAGENCY COMMITTEE ON ADMINISTRATIVE RULES (ICAR) MINUTES

Meeting Date/Location: July 8, 2024, virtually via Microsoft Teams

Members Present: Chair Sean Brown, Jared Adler, Jennifer Mojo, Michael Obuchowski, and Nicole

Dubuque

Members Absent: John Kessler and Diane Sherman

Minutes By: Melissa Mazza-Paquette

- 2:00 p.m. meeting called to order, welcome and introductions.
- Review and approval of minutes from the May 13, 2024 meeting.
- No additions/deletions to agenda. Agenda approved as drafted.
- Note: An emergency rule titled 'General Assistance Emergency Housing Assistance Emergency Rules', provided by the Agency of Human Services, Department for Children and Families, was supported by ICAR Chair Brown on June 25, 2024.
- No public comments made.
- Presentation of Proposed Rules on pages 2-6 to follow.
 - 1. Marriage Ceremony For Incarcerated Individuals, Department of Corrections, page 2
 - 2. Best Management Practices Rule, Agency of Agriculture, Food and Markets, page 3
 - 3. Technical Service Provider Certification Rule, Agency of Agriculture, Food and Markets, page 4
 - 4. Prior Authorization, Agency of Human Services, page 5
 - 5. Vermont Saves Program Rule, Office of the State Treasurer, page 6
- No other business.
- Next scheduled meeting is August 12, 2024 at 2:00 p.m.
- 2:47 p.m. meeting adjourned.



Proposed Rule: Marriage Ceremony For Incarcerated Individuals, Department of Corrections

Presented By: Margaret "MJ" Faller and David Turner

Motion made to accept to accept the rule as presented by Sean Brown, seconded by Mike Obuchowski, and passed unanimously except for Natalie Weill who abstained, with no recommendations.

Proposed Rule: Best Management Practices Rule, Agency of Agriculture, Food and Markets

Presented By: Laura DiPietro and Nina Gage

Motion made to accept the rule as presented by Sean Brown, seconded by Jared Adler, and passed unanimously except for Nicole Dubuque who abstained, with no recommendations.

Proposed Rule: Technical Service Provider Certification Rule, Agency of Agriculture, Food and Markets

Presented By: Laura DiPietro and Nina Gage

Motion made to accept the rule as presented by Sean Brown, seconded by Mike Obuchowski, and passed unanimously except for Nicole Dubuque who abstained, with no recommendations.



Proposed Rule: Prior Authorization, Agency of Human Services

Presented By: Linda McLemore

Motion made to accept the rule as presented by Sean Brown, seconded by Nicole Dubuque, and passed unanimously except for Natalie Weill who abstained, with no recommendations.

Proposed Rule: Vermont Saves Program Rule, Office of the State Treasurer

Presented By: Becky Wasserman

Motion made to accept the rule as presented by Sean Brown, seconded by Mike Obuchowski, and passed unanimously except for Natalie Weill who abstained, with no recommendations.



7102 4.103 Prior Authorization (04/01/1999, 98 11F)

4.103.1 Definitions

Prior authorization is a process used by the department to assure the appropriate use of health care services. The goal of prior authorization is to assure that the proposed health service is medically needed; that all appropriate, less expensive alternatives have been given consideration; and that the proposed service conforms to generally accepted practice parameters recognized by health care providers in the same or similar general specialty who typically treat or manage the diagnosis or condition. It involves a request for approval of each health service that is designated as requiring prior approval before the service is rendered. The department shall notify each patient and provider of its decision, which is arrived at by applying the criteria set forth in rule 7102.2.

For purposes of this rule, the following definitions apply:

- (a) "**Prior authorization**" is a process through which a request for coverage of a service is submitted to Vermont Medicaid for review and approval before the service is provided in order for the service to be covered.
- (b) "Pharmacy benefit" means the covered Vermont Medicaid services described in HCAR 4.207, titled "Prescribed Drugs."

71024.103.1—2 Criteria for Utilizing Prior Authorization (04/01/1999, 98 11F)

- (a) Vermont Medicaid requires prior authorization for any service that has an imminent harm code.

 The list of imminent harm codes can be found on the Department of Vermont Health Access (DHVA) website.
- (b) The department Vermont Medicaid may require prior authorization of payment for a service if it determines that when one or more of the following criteria are met:

A. ____(1) The health-service is of questionable medical necessity as determined by the department Vermont Medicaid. B. ____

(2) The department Vermont Medicaid determines that use of the health service needs requires monitoring to manage the

expenditure of Medicaid program funds.

C. (3) Less expensive <u>medically</u> appropriate alternatives to the <u>health</u> service are generally available. D.

(4) The health-service is investigational or experimental.

- (5) The service is not already determined to be covered for beneficiaries who are under the age of 21 pursuant to the requirement of HCAR 4.106, titled, "Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Services."
- (6) The request is for coverage of routine patient costs for services furnished in connection with participation in a qualifying clinical trial pursuant to 42 USC

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1396(a)(30)(hereinafter referred to as "routine patient costs related to a qualifying clinical trial").

E.(7) -The —The health service is newly developed or modified.

F.(8) —The department Vermont Medicaid determines that monitoring a health service of a continuing nature is necessary to prevent the continuation of the service when it ceases to be beneficial.

The complete and current list of all services and items including procedure codes that require prior authorization is set out in the <u>Provider Manual</u>. The list is updated periodically. Additions and deletions to the list are also published in advance in the provider advisory newsletter and other communications to providers.

4.103.3, List of Services Requiring Prior Authorization

- (a) Prior authorization is required for some services. A list of services that require prior authorization can be found on the DVHA website.
 - (1) Services, other than the pharmacy benefit, that require prior authorization are identified in the Fee Schedule in the Vermont Medicaid Portal, which is available on the DVHA website.
 - (2) Pharmacy benefits that require prior authorization are identified in the Preferred Drug List, which is available on the DVHA website. Some preferred and all non-preferred drugs are subject to prior authorization as described in the Preferred Drug List.

7102.24.103.4 Prior Authorization Determinations (04/01/1999, 98 11F)

(a) <u>Vermont Medicaid will approve a A-request for prior authorization of a covered health-service will</u> if it determines that the service meets the following criteria;

<u>be approved if the health service: A. is (1) Mmedically necessary necessity for covered services</u> criteria as set forth in HCAR 4.101, titled "Medical Necessity for Covered Services,"(see rule 7103);

B.(2) –<u>I</u>is appropriate and effective to the medical needs of the beneficiary;

C.—(3) Is timely, considering the nature and present state of the beneficiary's medical condition; D.

(4) is Is the least expensive, appropriate health service available;

(7)

E.(5) — is Is FDA-approved or authorized, if it the service is FDA regulated;

<u>F.(6)</u> — <u>I</u>is subject to a manufacturer's rebate agreement and meets applicable criteria in the <u>Preferred</u> Drug list, if the service is a <u>prescribed</u> drug;

G. <u>I</u>is not a preliminary procedure or treatment leading to a service that is not covered by Vermont Medicaid;

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(8) Is not the repair of an item that is not covered by Vermont

Medicaid, INTERPRETIVE MEMO

[X] Medicaid Covered Services Rule

Interpretation

[] Medicaid Covered Services ProcedureInterpretation

This interpretive memo remains effective statewide until it is specifically supersededed either by a subsequent interpretive memo or by a contradictory rule with a later date.

Reference 7102.4 Date of this Memo 05/01/2008 Page 1 of 1
This Memo: [X] is New [] Replaces one dated _____

QUESTION: Is there a change in the timeframe for processing prior authorization requests?

ANSWER: Yes. The timeframes now correspond to 42 CFR §438.210. OVHA will continue to issue a notice of decision within three days of receipt of all the necessary information. However, the longest time to wait for a decision is now 28 days, not 30. A request must be decided within 14 days of receipt of the request, but that time frame may be extended up to another 14 days if the beneficiary or provider request the extension.

or if the extension is needed to obtain additional information and an extension is in the beneficiary's intere Also, when a provider indicates, or OVHA determines, that following this timeframe could seriously jeopardize the beneficiary's life, health, or ability to attain, maintain, or regain maximum function, OVHA must make an expedited decision and provide notice as expeditiously as the beneficiary's health condition requires and no later than three working days after receipt of the request. This may be extended up to 14 days if the beneficiary so requests, or if the extension is needed to obtain additional information and an extension is in the beneficiary's interest.

H. is not the repair of an item uncovered by Medicaid; I. (9) I is not experimental or investigational. <u>L(10)</u> —<u>Iis furnished by a provider working within their scope of practice, and</u>

(11) Is not solely for the convenience of the beneficiary or the beneficiary's caretaker or provider with appropriate credentials.

(a)(b) Prior authorization is determined on a case-by-case basis.

(b)(c) The department Vermont Medicaid is responsible for determining questions of coverage and medical necessity under the Vermont Medicaid program. The department Vermont Medicaid may contract with external organizations to help-assist with prior authorization make these determinations; but Vermont Medicaid however, is the final authority for these decisions, rests with the department.

A prior authorization request must include a Supporting information for a prior authorization request must include a completed elaim-prior authorization form that has been submitted by a Vermont Medicaid-enrolled provider. and a completed medical necessity form. Additional information necessary to show that the service meets the relevant criteria that may be required, includesing the following items:

- (1) the The patients beneficiary's relevant complete medical records;
- •—(2) Tthe patients beneficiary's plan of care;
- •—(3) Aa statement of long-term and short-term treatment goals;
- —(4) a-A response to clinical questions posed by the department Vermont Medicaid;
- (5) a-A second opinion or an evaluation by another practitioner provider, at Medicaid Vermont Medicaid's expense;
- •—(6) Tthe practitioners provider's detailed and reasoned opinion in support of medical necessity;
- -(7) a-A statement of the alternatives considered and the provider's reasons for rejecting them; and,
- (8) a A statement of the practitioner's provider's evaluation of alternatives suggested by the department Vermont Medicaid and the provider's reasons for rejecting them.

If any of this additional information is required, the department will notify the provider promptly. Once the necessary information has been received, the beneficiary will be sent a notice of decision that may be appealed. See rule 4151.

71024103.3—5 Waiver Prior Authorization Requirements and Waiver of Prior Authorization (04/01/1999, 98-11F)

(a) When a service is subject to prior authorization, Vermont Medicaid will not pay for the service unless approval is given in advance of receipt of the service except if Vermont Medicaid determines the service meets the standards for waiver set forth at HCAR 4.103.5(b).

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(a) For covered services designated as needing prior authorization, The department Vermont Medicaid shall-will waive the requirement that a covered service receive prior authorization if, in the department's judgement, it determines that the service that was provided without prior authorization is a covered service and meets one or both of the following eircumstances: criteria:

(b),

- (1) The service was required to treat an emergency medical condition, or
- <u>(2)</u> The service was provided:
 - (A) prior to the determination of before the individual's Vermont Medicaid eligibility was determined, and

(A)(B) within the retroactive coverage period.

7102.44.103.6- Prior Authorization Process (04/01/1999, 98-11F)

(a) Specific and general prior authorization forms can be found on the DVHA website.

(a)(b) The Pprior authorization process commences begins when Vermont Medicaid with the receipt of areceives a written prior authorization request from a Vermont Medicaid-enrolled provider. The department will issue a notice of decision within three working days of receiving all necessary information.

- (c) The department Vermont Medicaid will act in good faith to obtain the any additional necessary information promptly so that it can determine, within 30 days the relevant timeframes described at HCAR 4.103,6(e), (f), and (g), whether the request may will be approved or denied. The department will issue a notice of decision within 30 days of receiving the initial prior authorization request, even if all necessary information has not been received.
- (d) Any decision to deny a prior authorization request or to authorize a service in an amount, duration, or scope that is less than requested, will be made by an individual who has appropriate expertise in addressing the enrollee's medical, behavioral health, or long-term services and supports needs.
- (e) Time requirements for prior authorization determinations on services other than covered outpatient drugs that are part of the pharmacy benefit and described at Section 1927 of the Social Security Act (hereinafter referred to as "covered outpatient drugs") and routine patient costs related to a qualifying clinical trial, as described at HCAR 4.103,2(b)(5)::
 - (1) Standard Time. Vermont Medicaid will make a prior authorization determination and provide notice, compliant with HCAR 8.100.3(a)-(b), titled "Internal Appeals, Grievances, Notices, and State Fair Hearings on Medicaid Services," as expeditiously as the beneficiary's condition requires, but not more than seven days from Vermont Medicaid's receipt of the request for prior authorization.
 - (1) Expedited Time. When a provider indicates, or Vermont Medicaid determines, that the standard time for a prior authorization determination could seriously jeopardize the beneficiary's life or

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4.103#

Prior Authorization

health or ability to attain, maintain, or regain maximum function, Vermont Medicaid will make an expedited decision and provide notice, compliant with HCAR 8.100.3(a)-(b), titled "Internal Appeals, Grievances, Notices, and State Fair Hearings on Medicaid Services," as expeditiously as the beneficiary's health condition requires and no later than 72 hours after receipt of the request for the service.

(2).

- (3) Extensions of Time.
 - (A) The standard and expedited timeframes for a prior authorization determination on services other than covered outpatient drugs, as described at HCAR 4.103.6(e), may be extended up to 14 days if:
 - (i) The beneficiary or provider requests the extension, or
 - (ii) Vermont Medicaid justifies a need for additional information and shows that the extension is in the beneficiary's best interest (e.g., more medical documentation is required and without it, the request would be denied).
 - (B) If Vermont Medicaid meets the criteria for extending the time for standard and expedited prior authorization determinations, it will:
 - (i) Give notice to the beneficiary of the reason to extend the timeframe and inform
 the beneficiary of the right to file a grievance if they disagree with the decision to
 extend the timeframe, and
 - (ii) Issue and carry out its decision as expeditiously as the beneficiary's health condition requires and not later than the date the extension expires,
- (4) Maximum Time for Prior Authorization Determinations on services other than covered outpatient drugs, as described at 4.103.6(e), and routine patient costs related to a clinical trial, as described at HCAR 4.103.2(b)(5). The maximum time, including any extensions, for Vermont Medicaid to decide to approve or deny a prior authorization request is:
 - (A)21 days from receipt of a request for a standard prior authorization determination (seven days plus 14 day extension), or
 - (B) 17 days from receipt of a request for an expedited prior authorization determination (72 hours plus 14 day extension).
- (f) Prior authorization requirements, including time requirements, for covered outpatient drugs, as described at HCAR 4.103.6(e).
 - (1) Vermont Medicaid will:
 - (A) Provide a response by telephone or telecommunication device within 24 hours of a request for prior authorization, and
 - (B) Except with respect to excluded drugs listed in Section 1927(d)(2) of the Social Security Act, provide for the dispensing of at least a 72-hour supply of a covered outpatient drug, as described at 4.103.6(e), when prior authorization has not been secured and the need to fill the prescription is determined to be a medical emergency. Prior authorization will still be needed for further dispensing.

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(g) Prior authorization requirements, including time requirements, for routine patient costs of a beneficiary when related to a clinical trial, as described at HCAR 4.103,2(b)(5). Vermont Medicaid will provide a response within 72 hours of a request for prior authorization without regard to the geographic location or network affiliation of the health care provider treating the beneficiary or the principal investigator of the qualifying clinical trial. Extensions of time are permitted pursuant to HCAR 4.103,6(e)(3).

(h) Notice requirements. Vermont Medicaid will notify the requesting provider and give the beneficiary written notice of any decision to deny a prior authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. Such notice will be consistent with HCAR 8.100.3, titled "Internal Appeals, Grievances, Notices, and State Fair Hearings on Medicaid Services," or, if the service is a covered outpatient drug, as described at HCAR 4.103,6(e), then consistent with Section 1927(d)(5)(A) of the Social Security Act. 1927(d)(5)(A).

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4.103 <u>Prior Authorization</u>

4.103.1 Definitions

For purposes of this rule, the following definitions apply:

- (a) "**Prior authorization**" is a process through which a request for coverage of a service is submitted to Vermont Medicaid for review and approval before the service is provided in order for the service to be covered.
- (b) "**Pharmacy benefit**" means the covered Vermont Medicaid services described in HCAR 4.207, titled "Prescribed Drugs."

4.103.2 Criteria for Utilizing Prior Authorization

- (a) Vermont Medicaid requires prior authorization for any service that has an imminent harm code. The list of imminent harm codes can be found on the Department of Vermont Health Access (DHVA) website.
- (b) Vermont Medicaid may require prior authorization if it determines that one or more of the following criteria are met:
 - (1) The service is of questionable medical necessity as determined by Vermont Medicaid.
 - (2) Vermont Medicaid determines that use of the service requires monitoring to manage the expenditure of Medicaid program funds.
 - (3) Less expensive medically appropriate alternatives to the service are generally available.
 - (4) The service is investigational or experimental.
 - (5) The service is not already determined to be covered for beneficiaries who are under the age of 21 pursuant to the requirement of HCAR 4.106, titled, "Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Services."
 - (6) The request is for coverage of routine patient costs for services furnished in connection with participation in a qualifying clinical trial pursuant to 42 USC 1396(a)(30)(hereinafter referred to as "routine patient costs related to a qualifying clinical trial").
 - (7) The service is newly developed or modified.
 - (8) Vermont Medicaid determines that monitoring a service of a continuing nature is necessary to prevent the continuation of the service when it ceases to be beneficial.

4.103.3 List of Services Requiring Prior Authorization

- (a) Prior authorization is required for some services. A list of services that require prior authorization can be found on the DVHA website.
 - (1) Services, other than the pharmacy benefit, that require prior authorization are identified in the Fee Schedule in the Vermont Medicaid Portal, which is available on the DVHA website.
 - (2) Pharmacy benefits that require prior authorization are identified in the Preferred Drug List, which is available on the DVHA website. Some preferred and all non-preferred drugs are subject to prior authorization as described in the Preferred Drug List.

4.103.4 Prior Authorization Determinations

- (a) Vermont Medicaid will approve a request for prior authorization of a covered service if it determines that the service meets the following criteria:
 - (1) Medical necessity for covered services criteria as set forth in HCAR 4.101, titled "Medical Necessity for Covered Services,"
 - (2) Is appropriate and effective to the medical needs of the beneficiary,
 - (3) Is timely, considering the nature and present state of the beneficiary's medical condition,
 - (4) Is the least expensive, appropriate service available,
 - (5) Is FDA-approved or authorized, if the service is FDA regulated,
 - (6) Is subject to a manufacturer's rebate agreement and meets applicable criteria in the Preferred Drug list, if the service is a prescribed drug,
 - (7) Is not a preliminary procedure or treatment leading to a service that is not covered by Vermont Medicaid,
 - (8) Is not the repair of an item that is not covered by Vermont Medicaid,
 - (9) Is not experimental or investigational,
 - (10) Is furnished by a provider working within their scope of practice, and
 - (11) Is not solely for the convenience of the beneficiary or the beneficiary's caretaker or provider.
- (b) Prior authorization is determined on a case-by-case basis.
- (c) Vermont Medicaid is responsible for determining questions of coverage and medical necessity. Vermont Medicaid may contract with external organizations to assist with prior authorization determinations but Vermont Medicaid is the final authority for these decisions.
- (d) A prior authorization request must include a completed prior authorization form that has been submitted by a Vermont Medicaid-enrolled provider. Additional information necessary to show that the service meets the relevant criteria may be required, including the following items:
 - (1) The beneficiary's relevant medical records,
 - (2) The beneficiary's plan of care,
 - (3) A statement of long-term and short-term treatment goals,
 - (4) A response to clinical questions posed by Vermont Medicaid,

- (5) A second opinion or an evaluation by another provider, at Vermont Medicaid's expense,
- (6) The provider's detailed and reasoned opinion in support of medical necessity,
- (7) A statement of the alternatives considered and the provider's reasons for rejecting them, and
- (8) A statement of the provider's evaluation of alternatives suggested by Vermont Medicaid and the provider's reasons for rejecting them.

4103.5 Prior Authorization Requirements and Waiver

- (a) When a service is subject to prior authorization, Vermont Medicaid will not pay for the service unless approval is given in advance of receipt of the service except if Vermont Medicaid determines the service meets the standards for waiver set forth at HCAR 4.103.5(b).
- (b) For covered services designated as needing prior authorization, Vermont Medicaid will waive the requirement if it determines that the service that was provided without prior authorization is a covered service and meets one of the following criteria:
 - (1) The service was required to treat an emergency medical condition, or
 - (2) The service was provided:
 - (A) before the individual's Vermont Medicaid eligibility was determined, and
 - (B) within the retroactive coverage period.

4.103.6 Prior Authorization Process

- (a) Specific and general prior authorization forms can be found on the DVHA website.
- (b) The prior authorization process begins when Vermont Medicaid receives a written prior authorization request from a Vermont Medicaid-enrolled provider.
- (c) Vermont Medicaid will act in good faith to obtain any additional necessary information promptly so that it can determine, within the relevant timeframes described at HCAR 4.103.6(e), (f), and (g), whether the request will be approved or denied.
- (d) Any decision to deny a prior authorization request or to authorize a service in an amount, duration, or scope that is less than requested, will be made by an individual who has appropriate expertise in addressing the enrollee's medical, behavioral health, or long-term services and supports needs.
- (e) Time requirements for prior authorization determinations on services other than covered outpatient drugs that are part of the pharmacy benefit and described at Section 1927 of the Social Security Act (hereinafter referred to as "covered outpatient drugs") and routine patient costs related to a qualifying clinical trial, as described at HCAR 4.103.2(b)(5):
 - (1) <u>Standard Time</u>. Vermont Medicaid will make a prior authorization determination and provide notice, compliant with HCAR 8.100.3(a)-(b), titled "Internal Appeals, Grievances, Notices, and

- State Fair Hearings on Medicaid Services," as expeditiously as the beneficiary's condition requires, but not more than seven days from Vermont Medicaid's receipt of the request for prior authorization.
- (2) Expedited Time. When a provider indicates, or Vermont Medicaid determines, that the standard time for a prior authorization determination could seriously jeopardize the beneficiary's life or health or ability to attain, maintain, or regain maximum function, Vermont Medicaid will make an expedited decision and provide notice, compliant with HCAR 8.100.3(a)-(b), titled "Internal Appeals, Grievances, Notices, and State Fair Hearings on Medicaid Services," as expeditiously as the beneficiary's health condition requires and no later than 72 hours after receipt of the request for the service.
- (3) Extensions of Time.
 - (A) The standard and expedited timeframes for a prior authorization determination on services other than covered outpatient drugs, as described at HCAR 4.103.6(e), may be extended up to 14 days if:
 - (i) The beneficiary or provider requests the extension, or
 - (ii) Vermont Medicaid justifies a need for additional information and shows that the extension is in the beneficiary's best interest (e.g., more medical documentation is required and without it, the request would be denied).
 - (B) If Vermont Medicaid meets the criteria for extending the time for standard and expedited prior authorization determinations, it will:
 - (i) Give notice to the beneficiary of the reason to extend the timeframe and inform the beneficiary of the right to file a grievance if they disagree with the decision to extend the timeframe, and
 - (ii) Issue and carry out its decision as expeditiously as the beneficiary's health condition requires and not later than the date the extension expires.
- (4) <u>Maximum Time for Prior Authorization Determinations on services other than covered outpatient drugs, as described at 4.103.6(e), and routine patient costs related to a clinical trial, as described at HCAR 4.103.2(b)(5). The maximum time, including any extensions, for Vermont Medicaid to decide to approve or deny a prior authorization request is:</u>
 - (A)21 days from receipt of a request for a standard prior authorization determination (seven days plus 14 day extension), or
 - (B) 17 days from receipt of a request for an expedited prior authorization determination (72 hours plus 14 day extension).
- (f) <u>Prior authorization requirements, including time requirements, for covered outpatient drugs, as</u> described at HCAR 4.103.6(e).
 - (1) Vermont Medicaid will:
 - (A) Provide a response by telephone or telecommunication device within 24 hours of a request for prior authorization, and
 - (B) Except with respect to excluded drugs listed in Section 1927(d)(2) of the Social Security Act, provide for the dispensing of at least a 72-hour supply of a covered outpatient drug, as

described at 4.103.6(e), when prior authorization has not been secured and the need to fill the prescription is determined to be a medical emergency. Prior authorization will still be needed for further dispensing.

- (g) <u>Prior authorization requirements, including time requirements, for routine patient costs of a beneficiary when related to a clinical trial, as described at HCAR 4.103.2(b)(5).</u> Vermont Medicaid will provide a response within 72 hours of a request for prior authorization without regard to the geographic location or network affiliation of the health care provider treating the beneficiary or the principal investigator of the qualifying clinical trial. Extensions of time are permitted pursuant to HCAR 4.103.6(e)(3).
- (h) Notice requirements. Vermont Medicaid will notify the requesting provider and give the beneficiary written notice of any decision to deny a prior authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. Such notice will be consistent with HCAR 8.100.3, titled "Internal Appeals, Grievances, Notices, and State Fair Hearings on Medicaid Services," or, if the service is a covered outpatient drug, as described at HCAR 4.103.6(e), then consistent with Section 1927(d)(5)(A) of the Social Security Act.

RESPONSIVENESS SUMMARY

Vermont Medical Society (VMS) made the following points in its comments:

- Opposes change from "shall" to "may" at HCAR 4.103.5 and 4.103.5.
- Opposes removal of text at current Medicaid Rule 7102.2 that requires the agency to notify the provider promptly if additional information is needed.
- Supports further shortening the time frame for standard prior authorization decisions and shortening the time frame for deciding expedited requests from those described at proposed HCAR 4.103.6(e).
- Recommends that additional requirements be specified at proposed HCAR 4.103.6(d) regarding the individual who determines if a prior authorization request is approved or denied.

Response:

AHS agrees with VMS that if the criteria described at proposed HCAR 4.103.4 is met then Vermont Medicaid must approve the prior authorization request. AHS made this revision, as recommended by VMS, prior to filing the proposed rule.

AHS will not be revising the rule to include the recommended additional text referenced at bullet 2 above because it is not necessary, given other requirements and options available to providers.

- Proposed HCAR 4.103.6(c), like current Medicaid Services Rule 7103.2, requires
 Vermont Medicaid "to act in good faith to obtain any additional necessary
 information promptly so that it can determine, within relevant timeframes described
 at HCAR 4.103.6(e), (f), and (g), whether the request will be approved or denied."
 Vermont Medicaid staff may seek additional information from the provider by phone
 call, fax, or through the Medicaid Management Information System (MMIS).
- Additionally, when this proposed rule would take effect, January 1, 2026, Vermont
 Medicaid is scheduled to have implemented a new programming interface, as
 required by federal law, that will dramatically improve the prior authorization
 process for providers. The system is designed to reduce burdens for providers by
 allowing streamlined data exchanges and faster prior authorization decisions. The
 system will give providers electronic access to the status of a prior authorization in
 "real time," once it is reviewed, including if additional information is necessary.
- Finally, when there is an adverse decision on the prior authorization request due to missing information, this will be explained in the notice of decision sent to the provider.

AHS does not support shortening the maximum time frames for standard and expedited prior authorization requests any further at this time; therefore, AHS will not be revising the timelines set forth at proposed HCAR 4.103.6(e).

- This rulemaking, if finalized, will change Vermont Medicaid's timeline for deciding standard prior authorization requests from 14 days to seven days, as of January 1, 2026.
- This revision will align the rule with 42 CFR 438.210(d)(1)(i)(B) that requires state Medicaid agencies to determine standard prior authorizations within seven days by January 1, 2026.
- The expedited request time frame will remain at 72 hours, as required by federal law at 42 CFR 438.210(d)(2)(i). This time frame is the same as exists in current rule.
- These timelines represent the maximum time that Vermont Medicaid may take to determine prior authorization; however, these proposed rules mandate that Vermont Medicaid determine prior authorization "as expeditiously as the beneficiary's health condition requires." HCAR 4.103.6(e)

AHS will not be revising proposed HCAR 4.103.6(d) as suggested by the commenter (i.e., that rule require that person determining whether to approve a prior authorization request be a clinician that has a current, valid non-restricted license to practice in the State of Vermont and that it is the same type of license and specialty as the provider requesting the service).

• The proposed rule repeats, verbatim, the requirement at 42 CFR 438.210(b)(3), i.e., that any decision to deny a request or to authorize an amount, duration, or scope that is less than requested, will be made by an individual who has appropriate expertise in addressing the enrollee's medical, behavioral health, or long-term services and supports.

Laboratory Corporation of America Holdings (LabCorp) made the following points in its comments:

- Recommends eliminating the requirement of prior authorization and instead authorizing the use of retrospective authorization for laboratory services and recommends excepting laboratory providers from certain additional information requirements.
- Recommends limiting Artificial Intelligence (AI) systems to support roles, not a final decision making role.
- Recommends revising the rule to provide that medical necessity determinations made at prior authorization be based on current need without consideration of future treatments that are not covered by Vermont Medicaid.

Response:

AHS will not except laboratory services from the requirements at HCAR 4.103.5(a) or 4.103.4(d) as recommended by the commenter at bullet one.

Responsiveness Summary Final Proposed Rule HCAR 4.103

- These requirements, that authorization be made prior to the delivery of the service and that requests are supported by sufficient medical documentation, are two important ways that Vermont Medicaid ensures its coverage only extends to medically necessary services that are the most cost effective appropriate treatment that is available.
- Prior authorization is used to limit access to unnecessary care while preserving beneficiary access to appropriate medical care.
- During the last several years and ongoing, Vermont Medicaid has undertaken a
 systemic review and removed prior authorization requirements for services for
 which the requirement is no longer justified or the requirements are routinely
 approved with a frequency that demonstrates that the prior authorization
 requirement is not necessary.

Artificial intelligence is never a decision maker on prior authorization requests made to Vermont Medicaid. AHS will not be revising its rule because it is not necessary as the proposed rule, as required by federal law, already requires that the decision on prior authorization be made by a person. See proposed HCAR 4.103.6(d) and 42 CFR 438.210(b)(3).

AHS will not be revising proposed HCAR 4.103.4(a)(9) that prohibits coverage of a procedure that is considered preliminary to a service that is not covered by Vermont Medicaid.

- LabCorp identifies concerns regarding the coverage of certain diagnostic testing (e.g., Non-Invasive Prenatal Testing or NIPT).
- It is a long standing requirement in Vermont Medicaid rules (since at least 1999) and good policy that the agency not cover procedures that are preliminary to a non-covered service. Medicaid Services Rule 71.02.2(G)
- It is expected that by July 1, 2025, Vermont Medicaid will release guidance (available on the agency website) to implement its decision to remove prior authorization for approximately 40 diagnostic tests.



To: Medicaid Policy Unit, <u>AHS.MedicaidPolicy@Vermont.gov</u> From: Jessa Barnard, Vermont Medical Society, <u>jbarnard@vtmd.org</u>

Date: September 13, 2024

RE: Global Commitment Register (GCR) proposed policy 24-105: Health Care

Administrative Rule Update – Prior Authorization

The Vermont Medical Society submits these comments on behalf of our physician and physician assistant members in response to the GCR Proposed Policy 24-105: Health Care Administrative Rule Update – Prior Authorization.

VMS thanks DVHA for the opportunity comment on the proposed changes pre-rulemaking and appreciates that DVHA incorporated VMS comments from March 2024 to make granting prior authorization approval at sections 4.103.4 and 4.103.5 mandatory, rather than optional, if criteria are met and to correct cross references in 4.103.6(c).

VMS reiterates the following comments also submitted in March:

- 1. VMS opposes the removal of the requirement to inform the provider promptly if more information is needed to complete the PA request at 4.103.4 (d). VMS believes it adds clarity to keep this requirement at 4.103.4 (d) while also addressing obtaining additional information at 4.103.6(c). VMS also requests more specificity regarding "prompt" notification in the form of a requirement to notify a provider within 24 hours.
- 2. VMS urges DVHA to reduce the timeframes for approving PA requests. In 4.103.6(e) they are 7 days for standard requests and 72 hours for expedited requests. However, with the enactment this year of Act 111, the legislature will require as of January 1, 2025 that commercial carriers make a decision on prior authorization requests within 24 hours for urgent requests and 2 business days for standard requests. VMS urges DVHA to adopt these same timeframes.

VMS also requests that DVHA add specificity at 4.103.6 (d) that a decision to deny a prior authorization request be made not only by "an individual who has appropriate expertise in addressing the enrollee's medical, behavioral health, or long-term services and supports needs" but also by a clinician who possess a current and valid non-restricted license to practice in Vermont; and is of the same license type and specialty as the provider who is requesting the service.

Thank you for your consideration and please reach out for additional information.



Laboratory Corporation of America® Holdings

531 South Spring Street Burlington, North Carolina 27215

Daton A. Lynch

Director, State Government Relations & Public Policy

Telephone: (571) 308-5287 Email: lyncd10@labcorp.com

September 18, 2024

Via e-mail: <u>AHS.MedicaidPolicy@vermont.gov</u>

Vermont Agency of Human Services Medicaid Policy Unit 280 State Drive, Center Building Waterbury, VT 05671-1000

Re: HCAR - Proposed Rule Updates - Prior Authorization (GCR 24-105)

Dear Agency of Human Services:

Labcorp is a leading global life sciences company dedicated to advancing health and improving the lives of Vermont's residents. With our longstanding commitment to providing high-quality diagnostic testing, Labcorp plays a vital role in supporting the state's healthcare system. In light of this commitment, Labcorp respectfully submits the following comments and recommendations regarding the proposed rule updates to HCAR § 4.103 concerning prior authorization of Vermont Medicaid services. Labcorp appreciates AHS efforts to align agency regulations with federal standards, and believes the proposed rule can be further enhanced with the implementation of the following key recommendations:

Recommendation 1: Update the Rule to Authorize Retrospective Authorization for Laboratory Services (Section 4.103.5(a))

As drafted, Section 4.103.5(a) indicates that prior authorization may only be obtained before the service is provided. While this policy seeks to ensure that cost control and coverage decisions are made proactively for services that can be postponed, it presents a significant challenge for laboratory services. The date of service for a laboratory test is the date of specimen collection, which is often performed by the ordering provider; as a result, it is often literally impossible for a laboratory to obtain "prior" authorization for a test. Laboratories are often unaware of the need for prior authorization until after the "service" has already been performed and an order has been received at the lab with a specimen, at which point the laboratory is obligated to perform the test and report the results promptly in the interest of patient care. Further, delaying the testing process to secure prior authorization can result in delayed diagnoses, which may negatively affect patient outcomes. Laboratory services, which often face unique challenges due to the delayed receipt of specimens and absence of direct patient interaction, would benefit from a dedicated retrospective authorization window for services that are not precluded from prior authorization (PA) requirements.

Recommendation: Labcorp recommends that retrospective authorization for laboratory services be explicitly authorized under the proposed rule. AHS is encouraged to establish a 30-day retrospective authorization window specifically for laboratory services. A retrospective window will provide laboratories with the necessary time to receive specimens, complete processing, and submit the required documentation after the service has been provided.

Recommendation 2: Exception for Laboratory Providers from Additional Information Requirements (Section 4.103.4(d))

Section 4.103.4(d) outlines the extensive documentation that may be required to accompany prior authorization requests, including treatment plans, opinions on alternatives, and detailed responses to Vermont Medicaid's inquiries. While appropriate documentation is important, laboratories do not have access to the comprehensive medical records of patients when submitting prior authorization requests. Consequently, the submission of the detailed documentation that may be required under Section 4.103.4(d) is notably impractical for laboratory providers.

Recommendation: Labcorp recommends including a regulatory exception to Section 4.103.4(d) specifying that the additional information items that may be required under Section 4.103.4(d), shall not be required of a laboratory provider. The requested Section 4.103.4(d) exception acknowledges the limited access laboratory providers have to patient records; prevents unnecessary administrative burdens on these providers; and safeguards the efficiency of Vermont Medicaid's prior authorization process without delaying patient care due to patient information that laboratories can neither access nor provide.

Recommendation 3: Limit AI Systems to Supportive Roles, Not Final Decision-Making (Section 4.103.4(c))

Section 4.103.4(c) authorizes Vermont Medicaid to contract with external organizations to assist with prior authorization determinations. In the absence of additional regulatory limitations or clarifying language, as drafted Section 4.103.4 permits AHS to contract with vendors providing Artificial Intelligence (AI) systems to assist with prior authorizations. While Labcorp acknowledges that the State of Vermont intends to use AI systems to improve the quality of government services provided to residents, it is critical that healthcare determinations related to prior authorizations remain centered on the individual needs of each patient. Reliance on AI in these important decisions could result in impersonal or inaccurate outcomes, particularly in cases where human judgment and individualized assessments are essential element for quality health care.

Recommendation: Labcorp encourages AHS to preserve the essential human element in healthcare decisions, and necessarily recommends that the proposed rule be updated to explicitly limit the use of artificial intelligence systems for prior authorizations to data aggregation and support functions only. AI should not be used to make final determinations in prior authorization decisions. These determinations should remain the responsibility of qualified professionals who can fully assess each patient's unique

circumstances and context of each request—this recommended approach aligns with the Vermont's AI policy vision to use AI "in a human-centered way that recognizes the dignity and value of all persons."

Recommendation 4: Clarify Treatment of Services That May Lead to Non-Covered <u>Procedures (Section 4.103.4(a)(9))</u>

Section 4.103.4(a)(7) currently states that prior authorization will not be granted for a procedure if it is considered preliminary to a service that is not covered by Vermont Medicaid. This language raises concerns that necessary diagnostic services, such as Non-Invasive Prenatal Testing (NIPT), could be denied simply because they may lead to a non-covered procedure. NIPT results can and often do inform decisions not to perform a non-covered procedure that might otherwise have been performed. The broad application of this provision could result in unjustified denials of essential diagnostic services, even when those services are medically necessary.

Recommendation: Labcorp recommends updating the proposed rule to clarify that services like NIPT will not be denied solely because they may lead to a non-covered procedure. To affirm that patients will receive necessary diagnostic services without unnecessary delays or denials, the rule should explicitly state that prior authorization determinations are based on the medical necessity of the service at the time of the request, without consideration of speculative future treatments.

Recommended Action

Labcorp appreciates Vermont's commitment to improving healthcare access and ensuring that Medicaid services are administered appropriately. To further improve healthcare delivery and streamline administrative processes, we respectfully urge AHS to: (1) allow retroactive prior authorization for laboratory services; (2) exempt laboratory providers from the extensive *additional information* requirements listed under Section 4.103.4(d); (3) limit the role of AI systems to supportive functions without permitting them to make final prior authorization determinations; and (4) affirm that prior authorization decisions are based on the medical necessity of the service at the time of the request without prospective consideration of any potential future treatments. By adopting these recommendations, we believe the prior authorization process will better balance administrative efficiency with the provision of timely, high-quality care for Vermont residents.

Respectfully submitted,

Daton A. Lynch

Director, State Government Relations & Public Policy Laboratory Corporation of America® Holdings

¹ https://digitalservices.vermont.gov/ai

The Vermont Statutes Online

The Statutes below include the actions of the 2024 session of the General Assembly.

NOTE: The Vermont Statutes Online is an unofficial copy of the Vermont Statutes Annotated that is provided as a convenience.

Title 3: Executive

Chapter 025: Administrative Procedure

Subchapter 001: GENERAL PROVISIONS

(Cite as: 3 V.S.A. § 801)

§ 801. Short title and definitions

- (a) This chapter may be cited as the "Vermont Administrative Procedure Act."
- (b) As used in this chapter:
- (1) "Agency" means a State board, commission, department, agency, or other entity or officer of State government, other than the Legislature, the courts, the Commander in Chief, and the Military Department, authorized by law to make rules or to determine contested cases.
- (2) "Contested case" means a proceeding, including but not restricted to ratemaking and licensing, in which the legal rights, duties, or privileges of a party are required by law to be determined by an agency after an opportunity for hearing.
- (3) "License" includes the whole or part of any agency permit, certificate, approval, registration, charter, or similar form of permission required by law.
- (4) "Licensing" includes the agency process respecting the grant, denial, renewal, revocation, suspension, annulment, withdrawal, or amendment of a license.
- (5) "Party" means each person or agency named or admitted as a party, or properly seeking and entitled as of right to be admitted as a party.
- (6) "Person" means any individual, partnership, corporation, association, governmental subdivision, or public or private organization of any character other than an agency.
- (7) "Practice" means a substantive or procedural requirement of an agency, affecting one or more persons who are not employees of the agency, that is used by the agency in the discharge of its powers and duties. The term includes all such requirements, regardless of whether they are stated in writing.

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- (8) "Procedure" means a practice that has been adopted in writing, either at the election of the agency or as the result of a request under subsection 831(b) of this title. The term includes any practice of any agency that has been adopted in writing, whether or not labeled as a procedure, except for each of the following:
 - (A) a rule adopted under sections 836-844 of this title;
- (B) a written document issued in a contested case that imposes substantive or procedural requirements on the parties to the case;
 - (C) a statement that concerns only:
- (i) the internal management of an agency and does not affect private rights or procedures available to the public;
- (ii) the internal management of facilities that are secured for the safety of the public and the individuals residing within them; or
- (iii) guidance regarding the safety or security of the staff of an agency or its designated service providers or of individuals being provided services by the agency or such a provider;
- (D) an intergovernmental or interagency memorandum, directive, or communication that does not affect private rights or procedures available to the public;
 - (E) an opinion of the Attorney General; or
- (F) a statement that establishes criteria or guidelines to be used by the staff of an agency in performing audits, investigations, or inspections, in settling commercial disputes or negotiating commercial arrangements, or in the defense, prosecution, or settlement of cases, if disclosure of the criteria or guidelines would compromise an investigation or the health and safety of an employee or member of the public, enable law violators to avoid detection, facilitate disregard of requirements imposed by law, or give a clearly improper advantage to persons that are in an adverse position to the State.
- (9) "Rule" means each agency statement of general applicability that implements, interprets, or prescribes law or policy and that has been adopted in the manner provided by sections 836-844 of this title.
- (10) "Incorporation by reference" means the use of language in the text of a regulation that expressly refers to a document other than the regulation itself.
- (11) "Adopting authority" means, for agencies that are attached to the Agencies of Administration, of Commerce and Community Development, of Natural Resources, of Human Services, and of Transportation, or any of their components, the secretaries of those agencies; for agencies attached to other departments or any of their components, the commissioners of those departments; and for other agencies, the chief officer of the agency. However, for the procedural rules of boards with quasi-judicial powers, for the Transportation Board, for the Vermont Veterans' Memorial Cemetery Advisory Board,

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and for the Fish and Wildlife Board, the chair or executive secretary of the board shall be the adopting authority. The Secretary of State shall be the adopting authority for the Office of Professional Regulation.

- (12) "Small business" means a business employing no more than 20 full-time employees.
- (13)(A) "Arbitrary," when applied to an agency rule or action, means that one or more of the following apply:
 - (i) There is no factual basis for the decision made by the agency.
- (ii) The decision made by the agency is not rationally connected to the factual basis asserted for the decision.
- (iii) The decision made by the agency would not make sense to a reasonable person.
- (B) The General Assembly intends that this definition be applied in accordance with the Vermont Supreme Court's application of "arbitrary" in Beyers v. Water Resources Board, 2006 VT 65, and In re Town of Sherburne, 154 Vt. 596 (1990).
- (14) "Guidance document" means a written record that has not been adopted in accordance with sections 836-844 of this title and that is issued by an agency to assist the public by providing an agency's current approach to or interpretation of law or describing how and when an agency will exercise discretionary functions. The term does not include the documents described in subdivisions (8)(A) through (F) of this section.
- (15) "Index" means a searchable list of entries that contains subjects and titles with page numbers, hyperlinks, or other connections that link each entry to the text or document to which it refers. (Added 1967, No. 360 (Adj. Sess.), § 1, eff. July 1, 1969; amended 1981, No. 82, § 1; 1983, No. 158 (Adj. Sess.), eff. April 13, 1984; 1985, No. 56, § 1; 1985, No. 269 (Adj. Sess.), § 4; 1987, No. 76, § 18; 1989, No. 69, § 2, eff. May 27, 1989; 1989, No. 250 (Adj. Sess.), § 88; 2001, No. 149 (Adj. Sess.), § 46, eff. June 27, 2002; 2017, No. 113 (Adj. Sess.), § 3; 2017, No. 156 (Adj. Sess.), § 2.)

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Title 33: Human Services

Chapter 019: Medical Assistance

Subchapter 001 : MEDICAID

(Cite as: 33 V.S.A. § 1901)

§ 1901. Administration of program

- (a)(1) The Secretary of Human Services or designee shall take appropriate action, including making of rules, required to administer a medical assistance program under Title XIX (Medicaid) and Title XXI (SCHIP) of the Social Security Act.
- (2) The Secretary or designee shall seek approval from the General Assembly prior to applying for and implementing a waiver of Title XIX or Title XXI of the Social Security Act, an amendment to an existing waiver, or a new state option that would restrict eligibility or benefits pursuant to the Deficit Reduction Act of 2005. Approval by the General Assembly under this subdivision constitutes approval only for the changes that are scheduled for implementation.
 - (3) [Repealed.]
- (4) A manufacturer of pharmaceuticals purchased by individuals receiving State pharmaceutical assistance in programs administered under this chapter shall pay to the Department of Vermont Health Access, as the Secretary's designee, a rebate on all pharmaceutical claims for which State-only funds are expended in an amount that is in proportion to the State share of the total cost of the claim, as calculated annually on an aggregate basis, and based on the full Medicaid rebate amount as provided for in Section 1927(a) through (c) of the federal Social Security Act, 42 U.S.C. § 1396r-8.
 - (b) [Repealed.]
- (c) The Secretary may charge a monthly premium, in amounts set by the General Assembly, per family for pregnant women and children eligible for medical assistance under Sections 1902(a)(10)(A)(i)(III), (IV), (VI), and (VII) of Title XIX of the Social Security Act, whose family income exceeds 195 percent of the federal poverty level, as permitted under section 1902(r)(2) of that act. Fees collected under this subsection shall be credited to the State Health Care Resources Fund established in section 1901d of this title and shall be available to the Agency to offset the costs of providing Medicaid services. Any co-payments, coinsurance, or other cost sharing to be charged shall also be authorized and set by the General Assembly.
- (d)(1) To enable the State to manage public resources effectively while preserving and enhancing access to health care services in the State, the Department of Vermont Health Access is authorized to serve as a publicly operated managed care organization (MCO).
- (2) To the extent permitted under federal law, the Department of Vermont Health Access shall be exempt from any health maintenance organization (HMO) or MCO statutes in Vermont law and shall not be considered to be an HMO or MCO for purposes of State regulatory and reporting requirements. The MCO shall comply with the federal rules governing managed care organizations in 42 C.F.R. Part 438. The Vermont rules on the primary care case management in the Medicaid program shall be amended to apply to the MCO except to the extent that the rules conflict with the federal rules.
 - (3) The Agency of Human Services and Department of Vermont Health Access shall report to the Health

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Reform Oversight Committee about implementation of Global Commitment in a manner and at a frequency to be determined by the Committee. Reporting shall, at a minimum, enable the tracking of expenditures by eligibility category, the type of care received, and to the extent possible allow historical comparison with expenditures under the previous Medicaid appropriation model (by department and program) and, if appropriate, with the amounts transferred by another department to the Department of Vermont Health Access. Reporting shall include spending in comparison to any applicable budget neutrality standards.

- (e) [Repealed.]
- (f) The Secretary shall not impose a prescription co-payment for individuals under age 21 enrolled in Medicaid or Dr. Dynasaur.
- (g) The Department of Vermont Health Access shall post prominently on its website the total per-member per-month cost for each of its Medicaid and Medicaid waiver programs and the amount of the State's share and the beneficiary's share of such cost.
- (h) To the extent required to avoid federal antitrust violations, the Department of Vermont Health Access shall facilitate and supervise the participation of health care professionals and health care facilities in the planning and implementation of payment reform in the Medicaid and SCHIP programs. The Department shall ensure that the process and implementation include sufficient State supervision over these entities to comply with federal antitrust provisions and shall refer to the Attorney General for appropriate action the activities of any individual or entity that the Department determines, after notice and an opportunity to be heard, violate State or federal antitrust laws without a countervailing benefit of improving patient care, improving access to health care, increasing efficiency, or reducing costs by modifying payment methods. (Added 1967, No. 147, § 6; amended 1997, No. 155 (Adj. Sess.), § 21; 2005, No. 159 (Adj. Sess.), § 2; 2005, No. 215 (Adj. Sess.), § 308, eff. May 31, 2006; 2007, No. 74, § 3, eff. June 6, 2007; 2009, No. 156 (Adj. Sess.), § E.309.15, eff. June 3, 2010; 2009, No. 156 (Adj. Sess.), § 1.43; 2011, No. 48, § 16a, eff. Jan. 1, 2012; 2011, No. 139 (Adj. Sess.), § 51, eff. May 14, 2012; 2011, No. 162 (Adj. Sess.), § E.307.6; 2011, No. 171 (Adj. Sess.), § 41c; 2013, No. 79, § 23, eff. Jan. 1, 2014; 2013, No. 79, § 46; 2013, No. 131 (Adj. Sess.), § 39, eff. May 20, 2014; 2013, No. 142 (Adj. Sess.), § 98; 2017, No. 210 (Adj. Sess.), § 3, eff. June 1, 2018; 2023, No. 85 (Adj. Sess.), § 471, eff. July 1, 2024.)

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MEMORANDUM

OFFICE OF THE SECRETARY OF STATE

Primary Contact: Ashley Berliner, Agency of Human Services, 280 State

Drive, Waterbury, VT 05671-1000

Tel: 802-578-9305 Fax: 802-241-0450 E-Mail:

AHS.MedicaidPolicy@vermont.gov

Secondary Contact: Linda Narrow McLemore, Agency of Human Services, 280

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3258 Fax: 802-241-0450

E-Mail: Linda.McLemore@Vermont.gov.

URL: https://humanservices.vermont.gov/rules-policies/health-care-rules/health-care-administrative-rules-hcar

From: APA Coordinator, VSARA

RE: Prior Authorization.

Date 05/06/2025

We received Proposed Rule on 08/01/2024

Final Proposed Rule on 05/06/2025

Adopted Rule on

We have assigned the following rule number(s):

Proposed Rule Number: 24P030

Adopted Rule Number:

(Final Proposals are not assigned a new number; they retain the Proposed Rule Number.)

The following problems were taken care of by phone/should be

taken care of immediately: LCAR extended adoption deadline to June 15,

2025. Final Proposed Filing: An annotated

text was not received, one has been

requested. The annotation was supplied by

email no further action required.

We cannot accept this filing until the following problems are taken care of:

The notice for this proposed rule appeared/will appear

online on: 8/7/2024 and in the newspapers of record on 8/15/2024.

This rule takes effect on

Adoption Deadline: 06/15/2025

Please note:

If you have any questions, please call me at 828-2863. OR

E-Mail me at: sos.statutoryfilings@vermont.gov

cc: Emery Mattheis