FINAL PROPOSED RULE # 19-P77

Administrative Procedures – Final Proposed Rule Filing

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 requiring a signature shall be original signatures of the appropriate adopting authority or authorized person, and all filings are to 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:

Medical Necessity for Covered Services

_____, on 2-14-2020
(signature) (date)

Printed Name and Title:
Michael K. Smith, Secretary of the Agency of Human Services

RECEIVED BY: _____

RECEIVED
FEB 20 2020

BY: .....

- ☐ Coversheet
- ☐ Adopting Page
- ☐ Economic Impact Analysis
- ☐ Environmental Impact Analysis
- ☐ Strategy for Maximizing Public Input
- ☐ Scientific Information Statement (if applicable)
- ☐ Incorporated by Reference Statement (if applicable)
- ☐ Clean text of the rule (Amended text without annotation)
- ☐ Annotated text (Clearly marking changes from previous rule)
- ☐ ICAR Minutes
- ☐ Copy of Comments
- ☐ Responsiveness Summary

1. TITLE OF RULE FILING:
   Medical Necessity for Covered Services
2. PROPOSED NUMBER ASSIGNED BY THE SECRETARY OF STATE
   19P-077
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: Linda Narrow McLemore

   Agency: Agency of Human Services

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

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

   E-Mail: linda.mclemore@vermont.gov

   Web URL *(WHERE THE RULE WILL BE POSTED)*:
   http://humanservices.vermont.gov/on-line-rules
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: Jessica Ploesser

   Agency: Agency of Human Services

   Mailing Address: 280 State Drive Waterbury, NOB 1 South,
   VT 05671-1000

   Telephone: 802 241 - 0454 Fax: 802 241 - 0450

   E-Mail: jessica.ploesser@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:

   PLEASE SUMMARIZE THE REASON FOR THE EXEMPTION:
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)

8. EXPLANATION OF HOW THE RULE IS WITHIN THE AUTHORITY OF THE AGENCY:
AHS's authority to adopt rules is identified above. The 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.

9. THE FILING HAS CHANGED SINCE THE FILING OF THE PROPOSED RULE.

10. THE AGENCY HAS 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**):
The rule sets forth the medical necessity criteria for coverage of Medicaid services for adults and beneficiaries under 21 years old. When adopted it will replace current Medicaid Rule 7103 on medical necessity. This rule is being promulgated as part of the sequential adoption of Health Care Administrative Rules designed to improve public accessibility and comprehension of the numerous rules concerning the operation of Vermont's Medicaid program.

15. EXPLANATION OF WHY THE RULE IS NECESSARY:
The rule is necessary to set forth the medical necessity standard for coverage of Medicaid services including for persons under age 21. For Medicaid

beneficiaries under 21, services are covered if necessary to correct or ameliorate a diagnosis or medical condition. The rule also aligns with current practice that medical necessity is found when the requirements of clinical criteria and guidelines adopted by Medicaid have been met, when a service is the least costly, appropriate health service that is available, when a service is not solely for the convenience of the beneficiary's caregiver or a provider, and when a service is supported by documentation of medical evidence in the beneficiary's medical records.

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; Hospitals; Health law, policy, and related advocacy and community-based organizations and groups including the Office of Health Care Advocate; and health care providers.

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. The changes and amendments largely conform the rule with current practice and federal laws that have already been implemented.

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: 12/11/2019

Time: 02:00 PM

Street Address: Waterbury State Office Complex, Ash Conference Room- A213, 280 State Drive, Waterbury, VT

Zip Code: 05671

Date:

Time: AM

Street Address:

Zip Code:

Date:

Time: AM

Street Address:

Zip Code:

Date:

Time: AM

Street Address:

Zip Code:

21. DEADLINE FOR COMMENT (NO EARLIER THAN 7 DAYS FOLLOWING LAST HEARING):
12/18/19

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

Medical Necessity

Early Periodic Screening Diagnostic and Treatment

EPSDT

Medicaid

Health Care Administrative Rules

HCAR

State of Vermont
Agency of Human Services
280 State Drive
Waterbury, VT 05671-1000
www.humanservices.vermont.gov

Michael K. Smith, Secretary

Date: January 24, 2020

RE: Final Proposed Rule: List of Changes Made to Proposed Rule HCAR 4.101 on Medical Necessity of Covered Services

1. HCAR 4.101.1(c) Definition of medically necessary
   - **Proposed Rule:** "**Medically necessary**" means health care services, including diagnostic testing, preventive services, and aftercare, that are appropriate, in terms of type, amount, frequency, level, setting, and duration to the beneficiary's diagnosis or health condition, and that:

     ***

     (5) are supported by documentation of medical evidence in the beneficiary's medical records.
   - **Final Proposed Rule:** "**Medically necessary**" means health care services, including diagnostic testing, preventive services, and aftercare, that are appropriate, in terms of type, amount, frequency, level, setting, and duration to the beneficiary's diagnosis or health condition, and that:

     ***

     (5) are supported by documentation in the beneficiary's medical records.

2. HCAR 4.101.2(b) Conditions for coverage
   - **Proposed Rule:** For EPSDT eligible beneficiaries (see Rule 4.106), a determination of medical necessity also includes a case by case determination that a service is needed to correct or ameliorate a diagnosis or health condition.
   - **Final Proposed Rule:** For EPSDT eligible beneficiaries (see Rule 4.106), a determination of medical necessity also includes a case by case determination that a service is needed to correct or ameliorate a diagnosis or health condition or achieve proper growth and development or prevent the onset or worsening of a health condition.

Administrative Procedures – 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:
   Medical Necessity for Covered Services
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 as long as 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*):

   Renumbering and Restructuring of Vermont Rules includes 7103 Medical Necessity (last effective April 1, 1999), SOS Log #08-040, October 1, 2008

State of Vermont
Agency of Administration
109 State Street
Montpelier, VT 05609-0201
www.aoa.vermont.gov

[phone] 802-828-3322
[fax] 802-828-3320

Office of the Secretary

INTERAGENCY COMMITTEE ON ADMINISTRATIVE RULES (ICAR) MINUTES

Meeting Date/Location: October 14, 2019, Pavilion Building, 5th floor conference room, 109 State Street, Montpelier, VT 05609
Members Present: Chair Brad Ferland, Dirk Anderson, Diane Bothfeld, John Kessler, Matt Langham, Steve Knudson, Clare O'Shaughnessy and (via phone) Jennifer Mojo
Members Absent: Ashley Berliner
Minutes By: Melissa Mazza-Paquette

- 2:00 p.m. meeting called to order.
- Review and approval of minutes from the September 9, 2019 meeting.
- Added notes:
  - Louise Corliss in the Secretary of State's office will be out of the office from October 17-22 and on the 28th, therefore there will be limited coverage during that time. Please plan accordingly and contact Louise with any concerns.
  - Shayla Livingston from the Agency of Human Services will be serving as an active committee member in Ashley Berliner's absence from November through February.
- Agenda approved as drafted.
- No public comments made.
- Presentation of Proposed Rules on pages 2-6 to follow.
  1. Chemicals of High Concern in Children's Products Rule, Agency of Human Services, Department of Health, page 2
  2. Medical Necessity for Covered Services, Agency of Human Services, page 3
  3. Early and Periodic Screening, Diagnostic and Treatment (EPSDT), Agency of Human Services, page 4
  4. Non-Emergency Medical Transportation, Agency of Human Services, page 5
  5. Ambulance Services, Agency of Human Services, page 6
- Next scheduled meeting is Wednesday, November 13, 2019 at 2:00 p.m.
- 2:40 p.m. meeting adjourned.

Proposed Rule: Medical Necessity for Covered Services, Agency of Human Services
Presented by Linda McLemore

Motion made to accept the rule by Dirk Anderson, seconded by Diane Bothfeld, and passed unanimously with the following recommendations:

1. Proposed Rule Coversheet, page 4, #12: Remove 'in fiscal year 2019'.
2. Proposed Rule Coversheet, page 4, #14: Clarify room location by including the word 'conference room' and be consistent with all proposed rules submitted at this hearing.
3. Public Input, page 1, #3: Update.

Administrative Procedures – 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.

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:

   Medical Necessity for Covered Services

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 under age 21; Agency of Human Services including its Departments; health care providers including hospitals; Health law, policy, and related advocacy and community based organizations and groups including the Office of Health Care Advocate.

There are no additional costs associated with this rule because the amendments largely reflect existing practice and coverage policies for Medicaid in Vermont.

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: *EXPLAIN THE SUFFICIENCY OF THIS ECONOMIC IMPACT ANALYSIS.*
There are no additional costs associated with this rule because the amendments generally reflect existing practice and coverage policies for Medicaid in Vermont. 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's Medicaid program.

Administrative Procedures – 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.

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:

   Medical Necessity for Covered Services

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 IMPACT 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: *EXPLAIN THE SUFFICIENCY OF THIS ENVIRONMENTAL IMPACT ANALYSIS.*
   This rule has no impact on the environment.

Administrative Procedures – Public Input

Instructions:

In completing the public input statement, an agency describes the strategy prescribed by ICAR to maximize public input, what it did do, or will do to comply with that plan to maximize the involvement of the public in the development of the rule.

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

1. TITLE OF RULE FILING:

   Medical Necessity for Covered Services

2. ADOPTING AGENCY:

   Agency of Human Services (AHS)

3. PLEASE DESCRIBE THE STRATEGY PRESCRIBED BY ICAR TO MAXIMIZE PUBLIC INVOLVEMENT IN THE DEVELOPMENT OF THE PROPOSED RULE:

   ICAR agreed with the steps for public input that are outlined in question 4, below.

4. PLEASE LIST THE STEPS THAT HAVE BEEN OR WILL BE TAKEN TO COMPLY WITH THAT STRATEGY:

   The Agency of Human Services (AHS) shared the proposed rule with Vermont Legal Aid, the Vermont Medical Society, and the Medicaid Exchange and Advisory Board on August 14, 2019. Comments were received and considered in drafting this proposed rule.

   A public hearing was held on December 11, 2019 and the public comment period closed on December 18, 2019. There were no attendees to the public hearing. AHS received public comments from Vermont Legal Aid and Vermont Medical Society.

   AHS provides notice and access to the rule through the Global Commitment Register when the rule is filed with the Office of the Secretary of State. The Global Commitment Register 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 Global Commitment Register. The proposed, final proposed, and adopted rules and all public comments and responses to this rulemaking will be posted on the Register on the Agency of Human Services website.

Subscribers receive email notification of rule filings including hyperlinks to posted documents and an explanation of how to provide comment and be involved in the rulemaking.

5. 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;

Vermont Legal Aid;

Vermont Medical Society;

Medicaid and Exchange Advisory Board;

Bi-State Primary Care;

Vermont Association of Hospitals and Health Systems; and

Vermont Family Network.

Responsiveness Summary – Medical Necessity for Covered Services

Comment on HCAR 4.101.1(b): To make clear that "generally accepted medical practice standards" may be based on any of the three listed bases (credible scientific evidence, physician specialty society recommendations, and prevailing opinion of providers practicing in the relevant clinical area), the word "or" should be inserted between sub (1) and sub (2).

Response: The use of "or" at the end of the text at HCAR 4.101.1(b)(2) clearly indicates that "generally accepted medical practice standards" may be based on any of the three listed bases. The use of "or" in this list is consistent with its use in other lists in HCAR (e.g., HCAR 4.104), and we believe that changing its use here would only add confusion to the rule due to the inconsistency it would inject into the rule. The rule is not being revised.

Comment on HCAR 4.101.1(c)(1) and (2): Insert the words "will or are reasonably expected to" at the beginning of these paragraphs. When particular treatments or services are recommended, they are done so in the hopes that the treatment or service will help restore or maintain a beneficiary's health, or prevent deterioration or palliate the beneficiary's condition. There is no guarantee that a recommended treatment or service will absolutely achieve the desired effect.

Response: Neither the proposed rule nor the rule that is currently in effect, which is worded similarly to the proposed rule in regard to this comment, require that a treatment be "guaranteed" to "absolutely achieve a desired effect," in order to be considered medically necessary. DVHA clinical staff who determine medical necessity do not require that a prescribed treatment be guaranteed to achieve a particular result. It is understood that it is not possible for a provider to guarantee that a particular outcome can be reached based upon a treatment as responses to treatment are so individualized. We are not aware of any situation in which the Medicaid Agency has denied services based upon an interpretation of medical necessity that requires that the success of a service be guaranteed. The rule is not being revised.

Comments on HCAR 4.101.1(c)(3)

This paragraph is new and constitutes an additional restriction on access to services. As such it should be deleted in its entirety.

VMS has concerns with the addition to the definition of "medically necessary" that the service be "the least costly, appropriate health care service that is available." The definition of "medically necessary" already incorporates that the service be "appropriate in terms of type, amount, frequency, level, setting and duration." Beyond those factors, the service should be clinically appropriate as further defined by items (C) (1), (2), (4) and (5). Adding cost to the list

of defining characteristics of the service complicates interpretation of this section as the list now blends cost and clinical factors and because it is unclear if the service has met all of the other criteria but may be more expensive (for example, because the location of the service provider is closer to the location where the patient lives) does this make the service no longer "medically necessary?"

Further, the prior authorization process anticipates separate consideration of medical necessity and cost (prior authorization can weigh whether " the proposed health service is medically needed [and] that all appropriate, less-expensive alternatives have been given consideration..." (Previously Rule 7102). It makes interpretation difficult to incorporate both of these elements within the one definition and analysis of medically necessary.

Response: Most State Medicaid Agencies consider cost in deciding whether to cover a requested service and many consider cost as a factor in determining medical necessity (e.g., Connecticut, Massachusetts, New Hampshire, Oregon, Rhode Island, Colorado, Iowa, Maryland, Ohio, Tennessee, Washington).

Vermont Medicaid has always considered cost in determining whether a service will be covered. Cost is a longstanding required consideration whenever the Agency is requested to prior authorize any service (DVHA Covered Services Rule 7102.2 states that a "request for prior authorization of a covered health service will be approved if the health services is.... the least expensive, appropriate health service available.)

In response to a commenter's question, a service that meets the criteria at proposed rule 4.101.1(c)(1), (2), (4), and (5) may be determined not medically necessary if there is another service that also meets these criteria and is also less costly, appropriate, and available. For example, Vermont Medicaid generally does not cover a name brand prescription medicine when a less costly generic is appropriate and available.

Vermont Medicaid is in the process of removing prior authorization requirements from many of its services. Accordingly, it is critical that cost be considered in determining whether medical necessity is met since many services will no longer undergo the prior authorization process.

The rule is not being revised.

Comment on HCAR 4.101.1(c)(4): This paragraph is new and constitutes an additional restriction on access to services. As such it should be deleted in its entirety.

Response: The commenter's characterization of the proposed revision is not accurate. This rule change simply codifies Vermont Medicaid current practice of not covering services that are needed **solely** for the convenience of a provider or a beneficiary's caregiver.

Many other Medicaid Agencies consider convenience when determining medical necessity (e.g., Connecticut, New Hampshire, Rhode Island, Colorado, Florida, Iowa, Maryland, Oregon, Tennessee). The majority of these states determine that a service is not medically necessary if it is "primarily" for the convenience of a caregiver, provider, or the beneficiary. By contrast, Vermont Medicaid proposes to align its approach with the approach taken by Oregon and Rhode Island, which require that a beneficiary's request for services be denied for medical necessity only if the **sole** reason for the service is for the convenience of a provider or caregiver.

The rule is not being revised.

Comment on HCAR 4.101.1(c)(5): This paragraph is confusing. What is meant by "documentation of medical evidence?"

Response: We have revised the rule to eliminate the confusion suggested by the commenter.

Comment: The proposed rule omits from the definition of medically necessary, health services that "prevent the reasonably likely onset of a health problem or detect an incipient problem. This language is in the current definition of medically necessary health services at Rule 7102(C). As preventive care is a critical aspect of containing health care costs, this language should be retained in the proposed rule.

Response: The referenced language was removed as unnecessarily repetitive of the criteria at HCAR 4.101.1(c)(1), "help restore or **maintain the beneficiary's health**," criteria that is intended to provide for the coverage of preventive care services. The text is being removed solely because it is repetitive. The rule is not being revised.

Comments on HCAR 4.101.2(b):

[F]ails to include the full scope of EPSDT medically necessity as set forth in proposed 4.106 to include services that are "needed to achieve proper growth and development or prevent the onset or worsening of a health condition."

VMS is concerned with the removal of weighing whether a service will help "achieve proper growth and development" from the definition of medical necessity for EPSDT services in 4.101.2 (b). The current rule for EPSDT services (7410) and proposed in 4.106.5 (b)(3) contain this phrase and VMS believes this is an important element of the EPSDT program. This phrase should be maintained in 4.101.2 (b).

Response: The text at issue - "needed to achieve proper growth and development or prevent the onset or worsening of a health condition-" is already set forth at HCAR 4.106.5(b)(3); however, we have moved this text from HCAR 4.106.5(b)(3) to the medical necessity rule in response to commenters' recommendations.

VERMONT MEDICAL SOCIETY

TO: Ashley Berliner, Director of Medicaid Policy, AHS.MedicaidPolicy@vermont.gov

FROM: Jill Sudhoff-Guerin, Policy and Communications Manager, Vermont Medical Society

DATE: December 16, 2019

Re: Comments on Draft HCAR Rule 4.101 (Medical Necessity), Rule 4.106 (EPSDT) and Rule 4.225 (Non-Emergency Medical Transportation)

Thank you for accepting comments from the Vermont Medical Society regarding proposed HCAR Rules 4.101 (Medical Necessity), 4.106 (EPSDT) and 4.225 (Non-Emergency Medical Transportation). The Vermont Medical Society is submitting these comments on behalf of our 2000 physician and physician assistant members largely to reiterate what we submitted in August, as we did not see any changes made to the final proposed rule.

VMS has identified three areas of concern with the proposals:

1. **HCAR Rule 4.101, Medical Necessity, Cost**

VMS has concerns with the addition to the definition of "medically necessary" that the service be "the least costly, appropriate health care service that is available." The definition of "medically necessary" already incorporates that the service be "appropriate in terms of type, amount, frequency, level, setting and duration." Beyond those factors, the service should be clinically appropriate as further defined by items (C) (1), (2), (4) and (5). Adding cost to the list of defining characteristics of the service complicates interpretation of this section as the list now blends cost and clinical factors and because it is unclear if the service has met all of the other criteria but may be more expensive (for example, because the location of the service provider is closer to the location where the patient lives) does this make the service no longer "medically necessary?"

Further, the prior authorization process anticipates separate consideration of medical necessity and cost (prior authorization can weigh whether " the proposed health service is medically needed [and] that all appropriate, less-expensive alternatives have been given consideration..." (Previously Rule 7102). It makes interpretation difficult to incorporate both of these elements within the one definition and analysis of medically necessary.

2. **HCAR Rule 4.106, Medical Necessity, EPSDT Services**

VMS is concerned with the removal of weighing whether a service will help "achieve proper growth and development" from the definition of medical necessity for EPSDT services in 4.101.2 (b). The current rule for EPSDT services (7410) and proposed in 4.106.5 (b)(3) contain this phrase and VMS believes this is an important element of the EPSDT program. This phrase should be maintained in 4.101.2 (b).

3. **HCAR Rule 4.225, Non-Emergency Medical Transportation**

VMS is concerned that requiring prior authorization for all transportation coverage and deleting all exceptions of prior authorization in 4.225.5 (7408) will result in the ambulance being the only mode of Medicaid covered transportation, which is likely the most-costly alternative. VMS believes that by eliminating exceptions to prior authorizations for transportation, beneficiaries will be discouraged from

accessing less expensive transportation options, which runs counter to DVHA's goals of reducing health care costs. Also, what happens to a beneficiary if their prior authorization for transportation is denied? Can they appeal?

Thank you for considering our comments and we look forward to the further development of these rules.

VERMONT LEGAL AID, INC.

DISABILITY LAW PROJECT
57 NORTH MAIN STREET SUITE 2
RUTLAND, VERMONT 05701
(802) 775-0021 (VOICE AND TTY)
FAX (802) 775-0022
(800) 769-7459

OFFICES:
BURLINGTON
RUTLAND
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By email to: AHS.MedicaidPolicy@vermont.gov

December 18, 2019

Ashley Berliner, Director of Healthcare Policy and Planning
Agency of Human Services
280 State Drive, Center Building
Waterbury, VT
05671-1000

Re: Comments on HCAR 4.101, Medical Necessity for Covered Services; 4.106 Early and Periodic Screening, Diagnosis and Treatment; and 4.225, Non-Emergency Medical Transportation.

Dear Ashley:

Thank you for the opportunity to comment on AHS's proposed rules on "Medical Necessity for Covered Services," "Early and Periodic Screening, Diagnosis and Treatment," and "Non-Emergency Medical Transportation." Vermont Legal Aid submits the following comments and suggestions.

Medical Necessity for Covered Services

4.101.1(b) Generally accepted practice standards

- To make clear that "generally accepted practice standards" may be based on any of the three listed bases, (credible scientific evidence, physician specialty society recommendations, and prevailing opinions of providers practicing in the relevant clinical area), the word "or" should be inserted between sub (1) and sub (2).

4.101.1(c) Medically necessary

- 4.101.1(c)(1) and (2) Insert the words *"will or are reasonably expected to"* at the beginning of these paragraphs. When particular treatments or services are recommended they are done so in the hopes that the treatment or service will help restore or maintain a beneficiary's health, or prevent deterioration or palliate the beneficiary's condition. There is no guarantee that a recommended treatment or service will absolutely achieve the desired effect. Therefore, we suggest the addition of this language.

- 4.101.1(c)(3) This paragraph is new and constitutes an additional restriction on access to services. As such it should be deleted in its entirety.

- 4.101.1(c)(4) This paragraph is new and constitutes an additional restriction on access to services. As such it should be deleted in its entirety.

- 4.101.1(c)(5) This paragraph is confusing. What is meant by "documentation of medical evidence?"

- The proposed rule omits from the definition of medically necessary, health services that "prevent the reasonably likely onset of a health problem or detect an incipient problem." This language is in the current definition of medically necessary health services at Rule 7103(C). As preventive care is a critical aspect of containing health care costs, this language should be retained in the proposed rule.

4.101.2 Conditions for Coverage

- 4.101.2(b) fails to include the full scope of EPSDT medical necessity as set forth in proposed HCAR 4.106 to include services that are "needed to achieve proper growth and development or prevent the onset or worsening of a health condition." We suggest that this section be amended to read:

  (b) For EPSDT eligible beneficiaries (see HCAR 4.106), a determination of medical necessity also includes a case by case determination that a services is needed to correct or ameliorate a diagnosis or health condition, to achieve proper growth and development, or prevent the onset or worsening of a health condition.

Early and Periodic Screening, Diagnostic and Treatment (EPSDT)

4.106.5 Diagnostic and Treatment Services

- 4.106.5(c). Cost effectiveness should not be achieved by placing additional burdens on beneficiaries and their families. This section should be amended to assure that beneficiaries will not be required to accept purportedly equally effective and available cost effective alternatives, where those alternatives will be more burdensome than the requested service. We suggest this paragraph be amended to read:

  (c)Vermont Medicaid may approve a cost effective alternative to the requested EPSDT service provided the alternative is equally effective and available, and does not impose burdens on the beneficiary or beneficiary's family that are not present with the requested EPSDT service.

Non-Emergency Medical Transportation

4.225.4 Conditions for Coverage

- 4.225.4(a) Add "reasonably" to this clause. "Transportation is not otherwise *reasonably* available to the Medicaid beneficiary." Also the rule should define what constitutes "reasonably available"

- 4.225.4(c)
  - The 30 mile radius should be changed to 75 miles. For some parts of Vermont there are very few providers and a 30 mile radius does not give beneficiaries an adequate choice of providers. What is the Agency's factual and legal basis for setting the limit at 30 miles? We object to the 30 mile radius limit and believe it arbitrarily denies needed Medicaid transportation to beneficiaries living in Vermont's many rural communities. In addition, the distance requirement for out of area transports discussed on p. 22 of NEMT manual should also be increased from 60 miles to 75 miles.

  - "nearest available qualified provider" should be revised to "*nearest medically appropriate provider who is accepting patients and where the beneficiary can get an appointment within a reasonable time period*" Many providers, both specialists and PCPs, have significant wait times both for accepting new patients and scheduling appointments. It is critical that beneficiaries are actually able to access providers in a timely manner.

  - Add a clause establishing an exception process for the radius requirement. "Beneficiaries shall be able to apply for an exception to the mileage requirement if they can show that they cannot find a medically appropriate provider within the radius, with appointments available in a reasonable time period."

  - Add a clause providing that if a Medicaid beneficiary has a long standing relationship with the a provider outside the radius requirement, Medicaid will provide transportation for 6 months while the beneficiary looks for a medically appropriate provider who is accepting patients, and further allowing for this period to be extended upon request where the beneficiary has shown reasonable but unsuccessful efforts to locate a medically appropriate provider accepting new patients.

Additional Suggestions:

- Add a clause making it clear that Medicaid beneficiaries are entitled to ask for a Reasonable Accommodation (RA) to any of the conditions set out in 4.225.4. Transportation brokers shall be responsible for giving beneficiaries written notice that that they can request an RA, and written notice on the decision regarding the RA and contact person in the event the RA is not being implemented. Brokers shall also be responsible for giving Medicaid beneficiaries information about any other transportation program for which they may be eligible.

- Add a clause establishing an exception process and stating that DVHA has the authority to grant exceptions to any of the conditions set out in 4.225.4 based on individual need.

- Add a clause indicating any denial or reduction of services is governed by the Medicaid notice and appeal rules set out in HCAR Rule 8.100. Also add a specific clause that internal coverage appeals will be conducted by DVHA.

Thank you for considering our comments.

Sincerely,

Nancy Breiden, Project Director, Disability Law Project
Marjorie Stinchcombe, Staff Attorney, the Office of the Health Care Advocate
Michael Benvenuto, Project Director, Elder Law Project

Annotated Text

Medical Necessity for Covered Services

~~7103 Medical Necessity (04/01/1999, 98-11F)~~

~~"Medically necessary" means health care services, including diagnostic testing, preventive services, and aftercare, that are appropriate, in terms of type, amount, frequency, level, setting, and duration to the beneficiary's diagnosis or condition. Medically necessary care must be consistent with generally accepted practice parameters as recognized by health care providers in the same or similar general specialty as typically treat or manage the diagnosis or condition, and~~

~~A. help restore or maintain the beneficiary's health; or~~
~~B. prevent deterioration or palliate the beneficiary's condition; or~~
~~C. prevent the reasonably likely onset of a health problem or detect an incipient problem.~~

~~Additionally, for EPSDT-eligible beneficiaries, medically necessary includes a determination that a service is needed to achieve proper growth and development or prevent the onset or worsening of a health condition.~~

4.101 Medical Necessity for Covered Services (03/10/2020, GCR 19-060)

4.101.1 Definitions

(a) "**Ameliorate**" means to improve or maintain a beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

(b) "**Generally accepted practice standards**" means standards that are based on:
(1) credible scientific evidence published in peer-reviewed literature,
(2) physician specialty society recommendations, or
(3) the prevailing opinion of licensed health care providers practicing in the relevant clinical area.

(c) "**Medically necessary**" means health care services, including diagnostic testing, preventive services, and aftercare, that are appropriate, in terms of type, amount, frequency, level, setting, and duration to the beneficiary's diagnosis or health condition, and that:
(1) help restore or maintain the beneficiary's health, or
(2) prevent deterioration or palliate the beneficiary's condition, and
(3) are the least costly, appropriate health service that is available, and
(4) are not solely for the convenience of the beneficiary's caregiver or a provider, and
(5) are supported by documentation ~~of medical evidence~~ in the beneficiary's medical records.

4.101.2 Conditions for Coverage

(a) A health care service that is otherwise covered by Vermont Medicaid is considered medically necessary when the requirements of clinical criteria or guidelines adopted by Vermont Medicaid are met.
(1) Clinical criteria and guidelines adopted by Vermont Medicaid are available on the websites of the departments that are part of the Agency of Human Services.

Medical Necessity for Covered Services

(2) When the Agency has not adopted clinical criteria or guidelines for a requested service, or the adopted clinical criteria or guidelines are not applicable to the beneficiary, then medical necessity is met if the service is consistent with generally accepted practice standards.

(b) For EPSDT eligible beneficiaries (see HCAR 4.106), a determination of medical necessity also includes a case by case determination that a service is needed to correct or ameliorate a diagnosis or health condition or achieve proper growth and development or prevent the onset or worsening of a health condition.

(c) The Agency is the final authority for determinations of medical necessity.

Medical Necessity for Covered Services

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Medical Necessity

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VERMONT **GENERAL ASSEMBLY**

The Vermont Statutes Online

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 rate-making 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.

(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, 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.)