Administrative Procedures Final Proposed Filing - Coversheet

FINAL PROPOSED RULE # 23-132

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:

Prosthetic and Orthotic Devices

/s/ Todd W. Daloz , on 2/8/23 (signature) (date)

Printed Name and Title:

Todd W. Daloz, Deputy Secretary, Agency of Human Services

RECEIVED 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

Revised November 1, 2021

Administrative Procedures Final Proposed Filing – Coversheet

1. TITLE OF RULE FILING: **Prosthetic and Orthotic Devices**

- 2. PROPOSED NUMBER ASSIGNED BY THE SECRETARY OF STATE 22P 032
- 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: Ashley.berliner@vermont.gov

Web URL (WHERE THE RULE WILL BE POSTED): https://humanservices.vermont.gov/rules-

policies/health-care-rules/health-care-

administrative-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: Susan Coburn

Agency: Department of Vermont Health Access

Mailing Address: 280 State Drive, Waterbury, VT 05671-1000 Telephone: (802) 578-9412 Fax: (802) 241-0450

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E-Mail: Susan.Coburn@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:

Revised November 1, 2021

(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 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 NOT RAISED FOR OR AGAINST THE ORIGINAL PROPOSAL.
- 12. THE AGENCY HAS NOT INCLUDED COPIES OF ALL WRITTEN SUBMISSIONS AND SYNOPSES OF ORAL COMMENTS RECEIVED.
- 13. THE AGENCY HAS NOT 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 Medicaid coverage of and reimbursement for prosthetic and orthotic devices under Vermont's Medicaid program. It is 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. Amendments include defining orthotic devices, removing lists of specific preapproved items, and clarifying coverage requirements. There are no additional costs associated with this rule because the amendments reflect existing practice and coverage policies for Medicaid in Vermont.

15. EXPLANATION OF WHY THE RULE IS NECESSARY:

The rule is necessary to define the criteria and coverage for prosthetic and orthotic devices. The rule aligns with federal and state guidance and law, improves clarity, and outlines coverage criteria.

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 in fiscal year 2022. The changes and amendments conform the rule with current practice and changes to federal and state 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: 12/14/2022

Time: 11:00 AM

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; Conference ID: 244318529#

Teams link made available through the Public Notice in the Global Commitment Register on the AHS website. 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):

12/21/2022

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

Medicaid

Prosthetic Devices

Orthotic Devices

Durable Medical Equipment

Health Care Administrative Rules

HCAR



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

Jenney Samuelson, Secretary

[phone] 802-241-0440 [fax] 802-241-0450

MEMORANDUM

То:	Sarah Copeland Hanzas, Secretary of State, Vermont Secretary of State Office Representative Trevor Squirrell, Chair, Legislative Committee on Administrative Rules (LCAR)
From:	Ashley Berliner, Director of Health Care Policy and Planning, Department of Vermont Health Access
Cc:	Charlene Dindo, Committee Assistant, LCAR Monica Hutt, Assistant Director of Policy and Communications, Agency of Administration Jenney Samuelson, Secretary, Agency of Human Services
Date:	February 16, 2023
Re:	Health Care Administrative Rules

Please find enclosed the final proposed rule filing from the Agency of Human Services for the following rules:

Amended:

- 22P031 Telehealth
- 22P032 Prosthetic and Orthotic Devices
- 22P033 Podiatry Services
- 22P034 Transplantation Services

A public hearing was held on December 14, 2022, and the public comment period ended December 21, 2022. No comments were received. No changes have been made since the filing of the proposed rules.

If you have any questions regarding these rules, please contact Susan Coburn, Health Care Policy Analyst, at 802-578-9412.



Administrative Procedures Adopting Page

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: Prosthetic and Orthotic Devices

- 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*):

The last amendment was 10/01/2008 by SOS# 08-040 entitled: Rules Renumbering, Renaming, and Reorganizing; and the last substantive amendment was 4/1/1999 by SOS # 99-016 entitled: Medicaid Policy Revisions Related to Purpose, Prior Authorization, Provider Responsibility and Selected Covered Services.



State of Vermont Agency of Administration 109 State Street Montpelier, VT 05609-0201 www.aoa.vermont.gov [phone] 802-828-3322 [fax] 802-828-2428 Kristin L. Clouser, Secretary

INTERAGENCY COMMITTEE ON ADMINISTRATIVE RULES (ICAR) MINUTES

Meeting Date/Location:October 10, 2022, virtually via Microsoft TeamsMembers Present:Chair Douglas Farnham, Brendan Atwood, Diane Bothfeld, Jared Adler, Jennifer
Mojo, John Kessler, Diane Sherman, Michael Obuchowski and Donna Russo-
SavageMinutes By:Melissa Mazza-Paquette

- 2:01 p.m. meeting called to order, welcome and introductions.
- Review and approval of minutes from the September 12, 2022 meeting.
- No additions/deletions to agenda. Agenda approved as drafted.
- No public comments made.
- The following emergency rules were supported by ICAR Chair Farnham (note the summaries may be found on the agenda):
 - Transitional Housing Program Emergency Rules, Agency of Human Services, Department for Children and Families, on 09/22/22
 - The Board of Medical Practice Emergency Rule, Agency of Human Services, Department of Health, on 09/30/22
 - PUC Emergency Rule 2.500 COVID-19 Emergency Procedures, Public Utility Commission, on 09/30/22
- Presentation of Proposed Rules on pages 3-9 to follow.
 - 1. Licensing Regulations for Foster Homes in Vermont, Agency of Human Services, Department for Children and Family Services, page 3
 - 2. Telehealth, Agency of Human Services, page 4
 - 3. Prosthetic and Orthotic Devices, Agency of Human Services, page 5
 - 4. Podiatry Services, Agency of Human Services, page 6
 - 5. Transplantation Services, Agency of Human Services, page 7
 - 6. Vermont Commercial Building Energy Standards, Department of Public Service, page 8
 - 7. Vermont Residential Building Energy Standards Amendments, Department of Public Service, page 9
- No other business.
- Next scheduled meeting is November 14, 2022 at 2:00 p.m.
- 3:47 p.m. meeting adjourned.



Proposed Rule: Prosthetic and Orthotic Devices, Agency of Human Services **Presented By:**

Motion made to accept the rule by John Kessler, seconded by Diane Bothfeld, and passed unanimously except for Brendan Atwood who abstained, with the following recommendations:

- 1. Be consistent throughout the rule with 'telehealth' whether it's capitalized or not.
- 2. Proposed Filing Coversheet, #8: As this summary is visible to the public, incorporate the changes, including the information from #9 of the Economic Impact Analysis.
- 3. Proposed Filing Coversheet, #15: Update the date.



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:

Prosthetic and Orthotic Devices

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:

There are no additional costs associated with this rule because the amendments reflect the 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: 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 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.

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:

Prosthetic and Orthotic Devices

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: 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:

Prosthetic and Orthotic Devices

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 stakeholders including Vermont Legal Aid, Bistate Primary Care Association, Vermont Association of Hospitals and Health Systems, Vermont Medical Society, VNAs of Vermont, and Vermont Care Partners on 5/3/2022. No comments were received.

AHS notified the Medicaid and Exchange Advisory Committee (MEAC) on 5/3/2022 including the estimated timeframe for filing and the proposed amendments to the rule. No comments were received.

The rule was posted on the AHS website for public comment and a public hearing was held on 12/14/2022. The public comment period closed 12/21/2022. No comments 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 Public Input

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 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;

Vermont Legal Aid;

Bi State Primary Care Association;

Vermont Association of Hospitals and Health Systems;

Vermont Medical Society;

VNAs of Vermont;

Vermont Care Partners; and

Medicaid and Exchange Advisory Committee.

nota Health Care Administrative Rule 4.212

Prosthetic and Orthotic Devices

4.212 Prosthetic and Orthotic Devices

4.212.1 Definitions

(a) <u>"Prosthetic devices" means replacement, corrective, or supportive devices to: artificially</u> replace a missing portion of the body, prevent or correct physical deformity or malfunction, or support a weak or deformed portion of the body.

This definition is in accordance with the federal definition found at 42 CFR §440.120(c).

(b) <u>"Orthotic devices</u>" means devices fashioned to support, correct, or improve the function of a body part.

4.212.2 Covered Services

- (a) <u>Prosthetic and orthotic devices are covered when medically necessary.</u>
- (b) <u>Vermont Medicaid publishes and maintains a list of pre-approved prosthetic and orthotic devices and any prior authorization requirements. This information is publicly available on the Department of Vermont Health Access website.</u>

4.212.3 Qualified Providers

(a) <u>Prosthetic and orthotic devices must be ordered by a physician or other licensed provider</u> working within the scope of their practice and enrolled with Vermont Medicaid.

4.212.4 Conditions for Coverage

- (a) <u>Prosthetic and orthotic devices must be necessary to address a beneficiary's medical condition</u> as ordered by a qualified provider.
- (b) <u>The face-to-face requirements in Health Care Administrative Rule 4.209 Durable Medical</u> <u>Equipment apply to prosthetic and orthotic devices that are also subject to the face-to-face</u> <u>requirement under Medicare.</u>
- (c) Coverage for Medicaid-approved shoes is limited to two pairs per adult beneficiary per calendar year unless additional pairs are medically necessary.
- (d) <u>Custom-made arch supports prescribed by a qualified provider are covered when they meet the definition of an orthotic.</u>
- (e) <u>Custom devices are covered only when prefabricated devices cannot meet the medical need.</u>
- (f) <u>These conditions for coverage do not apply to prosthetics and orthotics reimbursed as a component of an institutional payment.</u>

4.212.5 Non-Covered Services

(a) Orthotics or prosthetics that primarily serve to address social, recreational, or other factors and do not directly address a medical need.

(b) <u>Duplicate items are not covered.</u>

7508 Prosthetics Devices (04/01/1999, 98-11F)

A prosthetic device is a replacement, corrective or supportive device to: 1) artificially replace a missing portion of the body; 2) prevent or correct physical deformity or malfunction; or 3) support a weak or deformed portion of the body. Prosthetics include orthotics. This definition is taken from the federal definition found at 42 CFR §440.120(c).

7508.1 Eligibility for Care (04/01/1999, 98-11F)

Coverage of a prosthetic device is available for beneficiaries of any age.

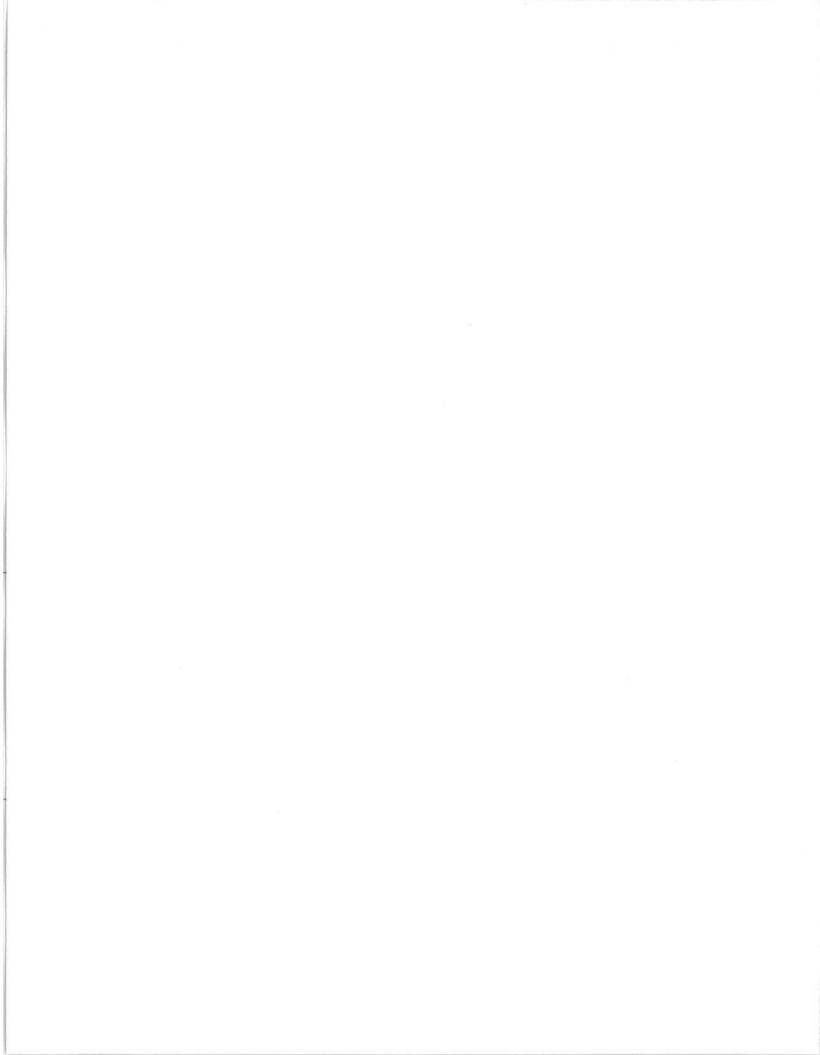
7508.2 Covered Services (04/01/1999, 98-11F)

Items and services that have been pre-approved for coverage are limited to:

- artificial limbs;
- artificial larynx;
- breast forms;
- prosthetic shoes;
- ostomy products;
- parenteral and enteral nutrition services;
- prosthetic eyes;
- braces and trusses for the purpose of supporting a weak or malformed body member;
- orthotic shoes as an integral part of a leg brace or affixed to an integral part of a leg brace;
- aircast splints;
- foot abduction rotation bars;
- shoe lifts, elevation heels, wedges; and
- molded orthopedic shoes when prescribed for diabetes, severe rheumatoid arthritis, ischemic, intractable ulcerations, congenital defects, and deformities due to injuries.

The complete policy regarding hearing, vision, vocal, and dental prostheses is contained in rules 7315, 7316, 7507 and 7312-7314.6, respectively.

7508.3 <u>Conditions for Coverage</u> (04/01/1999, 98-11F)



Prosthetic devices must be prescribed by a physician or podiatrist who is enrolled with Vermont Medicaid.

Devices must be appropriate for beneficiary's age, gross and fine motor skills, developmental status, mental functioning, and physical condition.

Duplicate items are not covered (e.g., two pairs of customized orthotics).

Coverage for Medicaid approved shoes is limited to two pairs per adult beneficiary per calendar year unless a prior authorization review finds special circumstances that warrant additional pairs.

Custom made arch supports prescribed by a physician or podiatrist are covered when they meet the definition of an orthotic (i.e., are used as a brace, truss or other similar device for the purpose of supporting a weak or deformed body member).

7508.4 Prior Authorization Requirements (04/01/1999, 98-11F)

Many items of prosthetic/orthotic equipment are subject to prior authorization review but they are not specified here because they are unusually numerous and they change frequently due to product change, new product availability, and the department's need for utilization management. The <u>Provider Manual</u> contains a detailed list of prosthetic/orthotic equipment, their codes, and fee schedule. It also indicates which prosthetic/orthotic equipment codes require prior authorization.

7508.5 Non-Covered Services (04/01/1999, 98-11F)

Unless authorized for coverage via rule 7104, items that are not covered include:

- orthopedic shoes when prescribed for flat feet; and
- orthotics/prosthetics that primarily serve to address social, recreational, or other factors and do not directly address a medical need.

7508.6 Qualified Providers (04/01/1999, 98-11F)

Providers of prosthetic and orthotic devices must be licensed, registered and/or certified by the state (where required) and be enrolled with Vermont Medicaid.

7508.7 Reimbursement (04/01/1999, 98-11F)

Reimbursement for prosthetic and orthotic devices is described in the Provider Manual.

Prosthetic/orthotic suppliers may not bill Medicaid for items furnished by hospitals their inor out-patients. Hospitals cannot bill separately for prosthetic or orthotic supplies.

The cost of modifications made within 60 days of purchase is included in the initial reimbursement of the orthotic or prosthetic.

Prosthetic and Orthotic Devices

4.212 Prosthetic and Orthotic Devices

4.212.1 Definitions

(a) **"Prosthetic devices**" means replacement, corrective, or supportive devices to: artificially replace a missing portion of the body, prevent or correct physical deformity or malfunction, or support a weak or deformed portion of the body.

This definition is in accordance with the federal definition found at 42 CFR §440.120(c).

(b) **"Orthotic devices"** means devices fashioned to support, correct, or improve the function of a body part.

4.212.2 Covered Services

- (a) Prosthetic and orthotic devices are covered when medically necessary.
- (b) Vermont Medicaid publishes and maintains a list of pre-approved prosthetic and orthotic devices and any prior authorization requirements. This information is publicly available on the Department of Vermont Health Access website.

4.212.3 Qualified Providers

(a) Prosthetic and orthotic devices must be ordered by a physician or other licensed provider working within the scope of their practice and enrolled with Vermont Medicaid.

4.212.4 Conditions for Coverage

- (a) Prosthetic and orthotic devices must be necessary to address a beneficiary's medical condition as ordered by a qualified provider.
- (b) The face-to-face requirements in Health Care Administrative Rule 4.209 Durable Medical Equipment apply to prosthetic and orthotic devices that are also subject to the face-to-face requirement under Medicare.
- (c) Coverage for Medicaid-approved shoes is limited to two pairs per adult beneficiary per calendar year unless additional pairs are medically necessary.
- (d) Custom-made arch supports prescribed by a qualified provider are covered when they meet the definition of an orthotic.
- (e) Custom devices are covered only when prefabricated devices cannot meet the medical need.
- (f) These conditions for coverage do not apply to prosthetics and orthotics reimbursed as a component of an institutional payment.

4.212.5 Non-Covered Services

(a) Orthotics or prosthetics that primarily serve to address social, recreational, or other factors and do not directly address a medical need.

Prosthetic and Orthotic Devices

(b) Duplicate items are not covered.

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 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.

(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

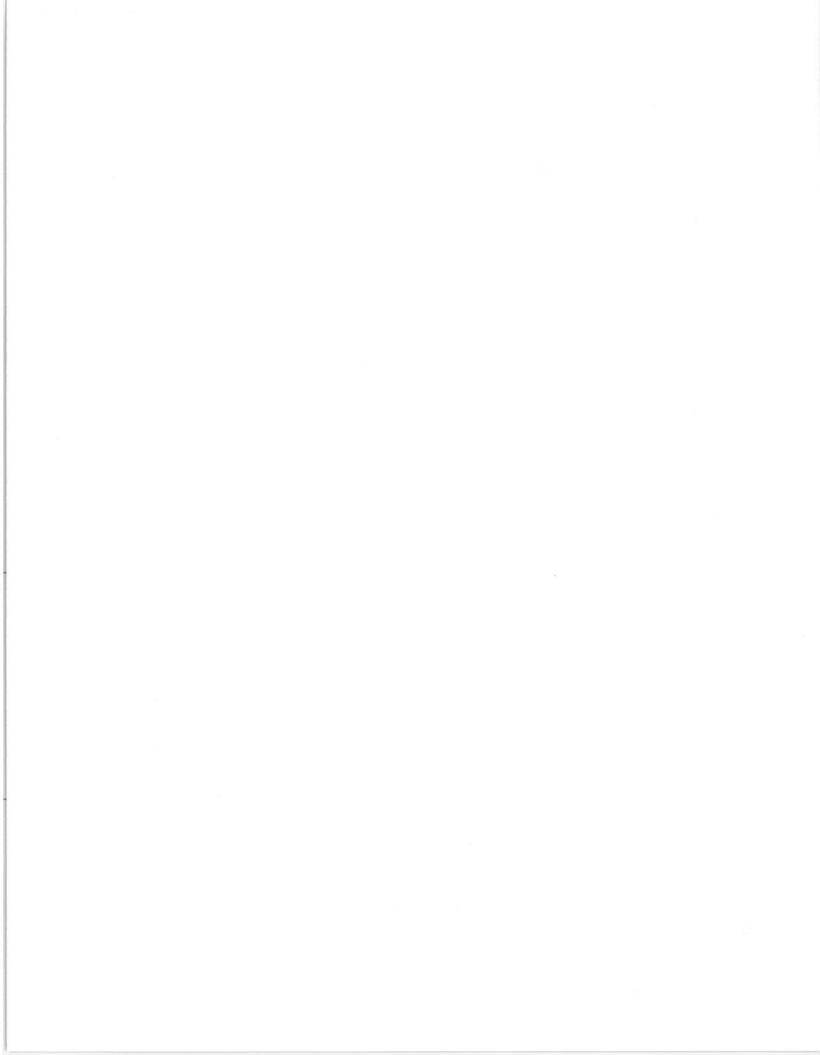
(F) a statement that establishes criteria or guidelines to be used by the staff of an agency in performing audits, investigations, or inspections, in settling commercial disputes or negotiating commercial arrangements, or in the defense, prosecution, or settlement of cases, if disclosure of the criteria 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 , 2006 VT 65, and , 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.) VERMONT GENERAL ASSEMBLY

The Vermont Statutes Online

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 Care 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.)



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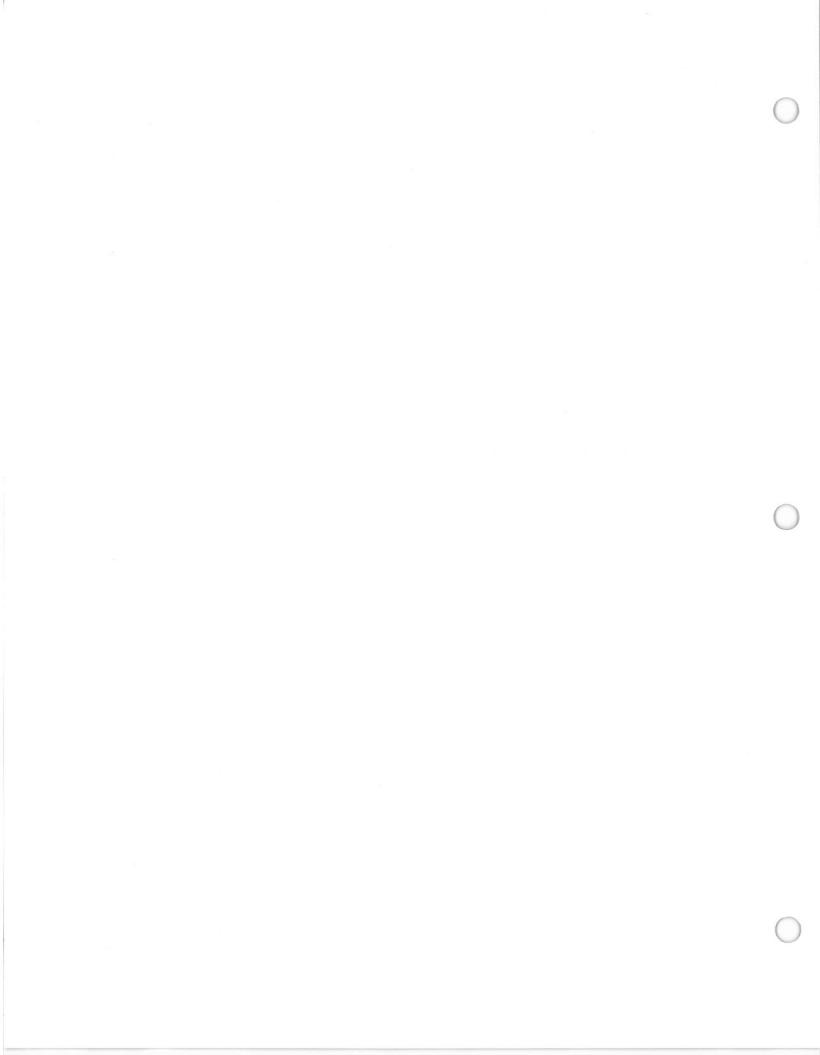
Deadline For Public Comment

Deadline: Dec 21, 2022

Please submit comments to the agency or primary contact person listed below, before the deadline.

Rule Details

Rule Number:	22P032
Title:	Prosthetic and Orthotic Devices.
Туре:	Standard
Status:	Proposed
Agency:	Agency of Human Services
Legal Authority:	3 V.S.A. § 801(b)(11); 33 V.S.A. § 1901(a)(1)
Summary:	This rule sets forth the criteria for Medicaid coverage of and reimbursement for prosthetic and orthotic devices under Vermont's Medicaid program. It is 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. Amendments include defining orthotic devices, removing lists of specific preapproved items, and clarifying coverage requirements.
Persons Affected:	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.
Economic Impact:	The rule does not increase of lessen an economic burden on any person or entity including no impact on the State's gross annualized budget in fiscal year 2022. The changes and amendments conform the rule with current practice and changes to federal and state laws that have already been implemented.



Posting date:

Nov 02,2022

Hearing Information

Information for Hearing #1 Hearing 12-14-2022 11:00 AM (ADD TO YOUR CALENDAR) date: Location: Waterbury State Office Complex, Cherry A Conference Room Address: 280 State Drive City: Waterbury VT State: 05671 Zip: Virtual Hearing via MS Teams: call in (audio only) +1 802-552-8456,,244318529# United States, Montpelier Phone Conference ID: 244 318 529# or https://teams.microsoft.com/l/meetup-Hearing join/193ameeting MmZkZjVhY2YtYThkZS00NmY1LTgxZGQtZTc2NjAyNjA5NzQy40thread.v2 Notes: /0?context7b22Tid223a2220b4933b-baad-433c-9c02-70edcc7559c6222c22Oid223a22f3f538c6b253-4e92-a6c6-6ec68fa6b8a5227d

Contact Information

Information for Primary Contact

PRIMARY CONTACT PERSON - A PERSON WHO IS ABLE TO ANSWER QUESTIONS ABOUT THE CONTENT OF THE RULE.

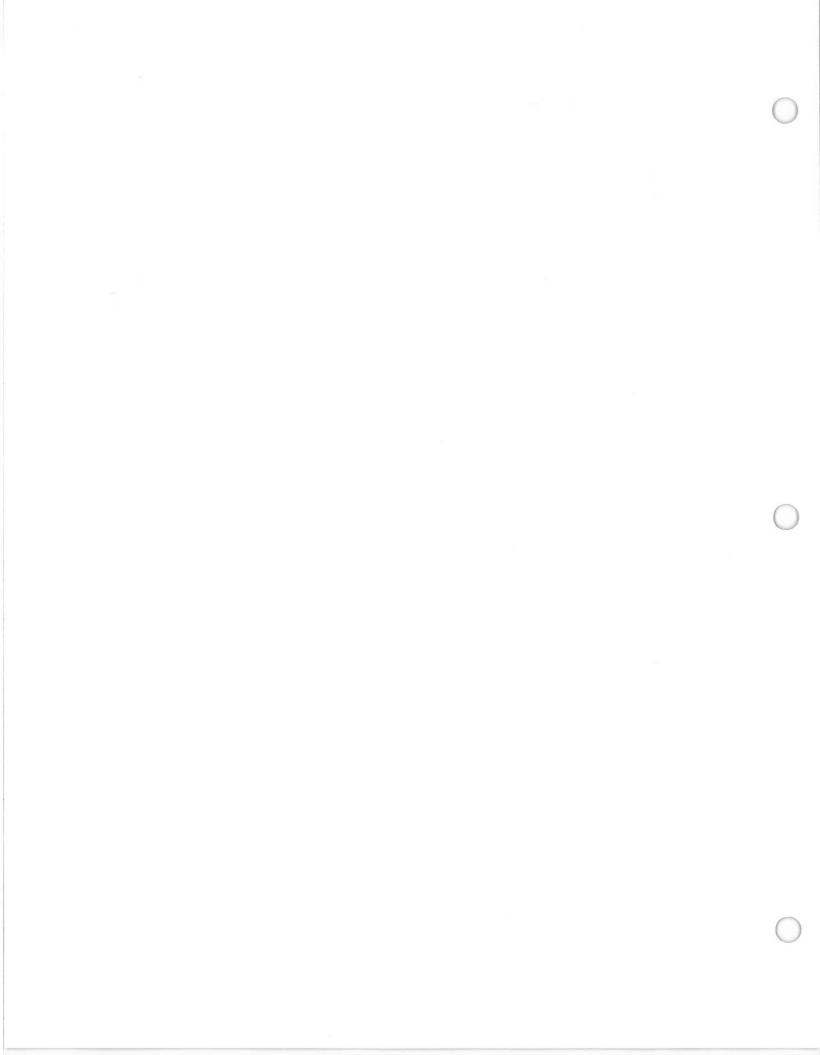
Level:	Primary
Name:	Ashley Berliner
Agency:	Agency of Human Services
Address:	Waterbury State Office Complex, 280 State Drive
City:	Waterbury
State:	VT
Zip:	05671-1000
Telephone:	802-578-9305
Fax:	802-241-0450
Email:	ashley.berliner@vermont.gov

Website Address: https://humanservices.vermont.gov/rules-policies/health-care-rules

Information for Secondary Contact

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.

Level:	Secondary
Name:	Hillary Hill
Agency:	Agency of Human Services
Address:	Waterbury State Office Complex, 280 State Drive
City:	Waterbury
State:	VT
Zip:	05671
Telephone:	802-989-4245
Fax:	802-241-0450



Vermont Secretary of State Rules Service

Email:

hillary.hill@vermont.gov

Keyword Information

Keywords:

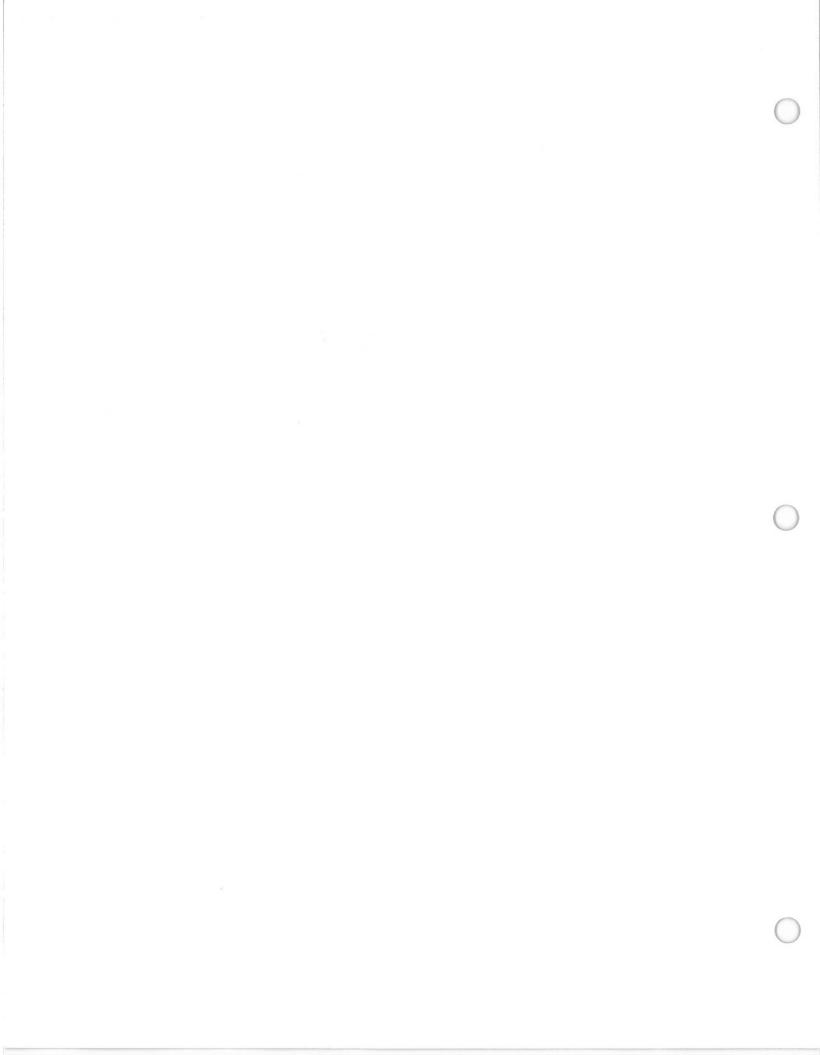
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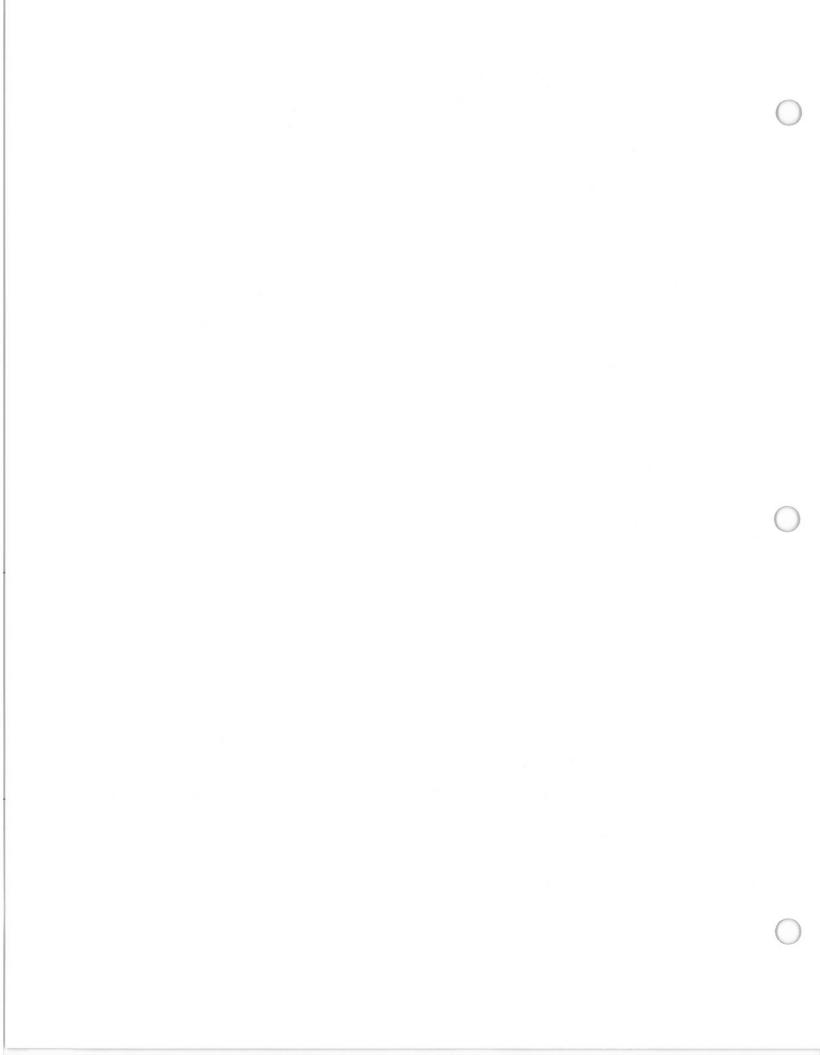
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If you have questions, or if the printing schedule of your paper is disrupted by holiday etc. please contact VSARA at 802-828-3700, or E-Mail <u>sos.statutoryfilings@vermont.gov</u>, Thanks.



PROPOSED STATE RULES

By law, public notice of proposed rules must be given by publication in newspapers of record. The purpose of these notices is to give the public a chance to respond to the proposals. The public notices for administrative rules are now also available online at <u>https://secure.vermont.gov/SOS/rules/</u>. The law requires an agency to hold a public hearing on a proposed rule, if requested to do so in writing by 25 persons or an association having at least 25 members.

To make special arrangements for individuals with disabilities or special needs please call or write the contact person listed below as soon as possible.

To obtain further information concerning any scheduled hearing(s), obtain copies of proposed rule(s) or submit comments regarding proposed rule(s), please call or write the contact person listed below. You may also submit comments in writing to the Legislative Committee on Administrative Rules, State House, Montpelier, Vermont 05602 (802-828-2231).

Note: The four rules below have been promulgated by the Agency of Human Services who has requested the notices be combined to facilitate a savings for the agency. When contacting the agency about these rules please note the title and rule number of the rule(s) you are interested in.

- Telehealth Vermont Proposed Rule: 22P031
- Prosthetic and Orthotic Devices Vermont Proposed Rule: 22P032
- Podiatry Services Vermont Proposed Rule: 22P033
- Transplantation Services Vermont Proposed Rule:

AGENCY: Agency of Human Services

CONCISE SUMMARY: The proposed rules set forth criteria for coverage and service delivery for the Medicaid program. These rules are part of the sequential adoption of Health Care Administrative Rules (HCAR) designed to improve public accessibility and comprehension of the rules under Vermont's Medicaid Program. The amendments to each of the four rules align with relevant federal and state law and guidance. The amendment to telehealth adds audio-only services and outlines requirements for service delivery via audio-only as well as updates terminology and added clarity. The amendments to prosthetic and orthotic devices, podiatry services, and transplantation services were made to be consistent with HCAR language and formatting and to align with current practices.

FOR FURTHER INFORMATION, CONTACT: Hillary Hill, Agency of Human Services, 280 State Drive, Waterbury, VT 05671-1000; Tel: 802-989-4245; Fax: 802-241-0450; E-mail: <u>Hillary.hill@vermont.gov</u>; URL: <u>https://humanservices.vermont.gov/rules-policies/health-care-rules/health-care-administrative-rules-hcar</u>

