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**Date:** December 27, 2017

**RE:** Responses to Public Comments for the following Health Care Administrative Rules:

- 4.104 Medicaid Non-Covered Services
- 4.223 Abortion
- 9.103 Supervised Billing

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A summary of comments received and the Agency of Human Services' responses to these comments is included below.

### **HCAR 4.104, Medicaid Non-Covered Services**

Comments were received from Vermont Legal Aid, Inc. and the Vermont Medical Society on behalf of their members.

#### **1) Definition of Experimental and Investigational**

**Comment:** Commenters asked how the new definition of “experimental and investigational” relates to those terms as used in other places in the Medicaid coverage rules. For example, how does the term relate to “investigational” services referenced under rule 7102 for prior authorization?

**Response:** The non-covered services rule at 4.104.2 applies to all references to “experimental” or “investigational” in Vermont Medicaid’s medical services rules, including DVHA Rule 7102 on prior authorization.

The clarity of the wording of DVHA Rule 7102 on prior authorizations will be addressed when that rule is incorporated into HCAR. Current DVHA Rule 7102.2(I) accurately reflects long standing DVHA policy and practice that a prior authorization will be approved if the health service is *not* [emphasis added] experimental or investigational.

**Comment:** It is unclear to what extent the terms “experimental” and “investigational” are to be used synonymously under the rules. Rule 4.104.2 makes no special mention as to whether the terms “experimental” and “investigational” are meant to hold the same meaning in all cases, or if there are situations in which they should be taken to mean different things.

**Response:** HCAR Rule 4.104.2 applies to all medical service rules where the terms “experimental” or “investigational” are used. Rule 4.104.2 provides that the words “experimental” and “investigational” have the same meaning. As the two terms are not

always co-located in other rules, the proposed rule was amended to replace “experimental and investigational” with “experimental or investigational” for clarity.

**Comment:** The definition of “service” in proposed rule 4.104.2 appears, by its terms, to apply to some Medicaid covered items that should not be evaluated for effectiveness of medical care. Medicaid covers some services that are not considered “medical care.” For example, long-term Medicaid covered services including assistance with activities of daily living (ADL’s) such as eating, bathing, dressing and toileting. Providers or facilities that provide such necessary supports may be excluded from reimbursement because their services are not considered “medical care” nor proven to be safe and effective. Suggest that AHS add the term “medical” to §§ 4.104.2(a) and 4.104.2(b) to not improperly restrict payment for non-medical covered items.

**Response:** The term “medical” has been added to Rules 4.104.2(a) and 4.104.2(b). Medical services that DVHA routinely covers, under the Medicaid State Plan and Global Commitment to Health Waiver, including those solely for the provision of ADLs, are not considered experimental or investigational. Payment will not be restricted for such services due to this rule.

**Comment:** The proposed definition may pose obstacles to treatment for patients with rare diseases.

**Response:** The rule reflects the criteria used to evaluate medical and scientific evidence. The list at 4.104.2(c) is not exhaustive. It does not preclude review of other sources of current credible evidence for patients with rare diseases.

## 2) Appeal or Challenge a Determination:

**Comment:** Is the processes for challenging whether a treatment is experimental or investigational the same as that outlined under 7104 for Coverage Exceptions? Additional clarity is requested regarding how to appeal or challenge a determination of whether a service is “experimental and investigational.”

**Response:** The coverage exception process is used to request that the Department of Vermont Health Access cover a service that is not already included on a list of covered services. Requests are considered on a case by case basis according to the unique needs of a beneficiary. The internal grievance and appeals process found at Rule 7110 Global Commitment Appeals and Grievances may be used to challenge a decision by Vermont Medicaid.

## 3) Use of Criteria:

**Comment:** It should be clarified in Section 4.104.2(c) that any one of the listed criteria (1) through (4) can serve to demonstrate that a service is not experimental or investigational, rather than suggesting a service might need to meet all four criteria. This could be clarified by listing “or” between the four criteria.

**Response:** The conjunction “or” has been added as recommended by the commenter.

**Comment:** In order to ensure that treatments for rare diseases are covered, 4.104.2(c)(2) should be slightly expanded to include practices undertaken by academic centers of excellence or professional medical societies, but that may not yet meet the definition of a “practice guideline,” as follows: *Current practices established in academic centers of excellence, or professional practice guidelines and or recommendations of professional governing bodies in the medical specialty area, or areas in which the service is applicable or used.*

**Response:** The rule reflects the criteria used to evaluate medical and scientific evidence. The list at 4.104.2(c) is not exhaustive. It does not preclude review of other sources of current credible evidence.

**Comment:** DVHA may want to consider if the new criteria listed in (c) could be inconsistent with other coverage mandates, such as naturopathic services or certain chiropractic treatments that are covered by DVHA but may not meet the criteria listed.

**Response:** The criteria used is consistent with other coverage mandates. Vermont Medicaid covers services as determined to be medically necessary. Covered naturopathic and chiropractic services are those allowable under state and federal regulations that are deemed medically necessary. Those services would meet the criteria listed and would not be determined experimental or investigational.

**Comment:** Types of medical evidence in Section 4.104.3(c) considered should be non-exhaustive and include guidance in their use. Commenter disagrees with AHS designating the evidence as “criteria” because the use of that term could lead to certain types of evidence automatically being given greater weight than others, when in fact that may be inappropriate. The type(s) of evidence being considered should be chosen based on the circumstances. AHS should consider adding catch-all language at the end of 4.104.2(c), such as:

*(5) Any other evidence typically considered by members of the relevant professional medical community.*

**Response:** The rule reflects the criteria that is used to evaluate medical and scientific evidence. These criteria are applied to determine if an item or service is considered experimental or investigational and therefore not covered. The rule as written does not include an exhaustive list or imply that any one criteria has weight over another. Accordingly, adding catch-all language to the rule is not necessary.

#### 4) Other

**Comment:** Recommend that AHS consult with a variety of medical professionals (including Medicaid providers) to ensure that the definition does not inadvertently exclude items and services currently covered by Medicaid.

**Response:** Current services authorized for coverage would not be excluded as a result of this rule. This rule only prohibits coverage of medical services that are not accepted medical practice and for which there is not medical or scientific evidence to support its use as safe and effective.

### **Proposed Rule HCAR 4.223, Abortion**

**Comment:**

The Physician Assistant Academy of Vermont, Vermont Medical Society, University of Vermont Medical Center, and Vermont Association of Hospitals and Health Systems, commented that surgical and medical abortion care is within the legal scope of practice of physician assistants and should be included in the list of qualified providers who may bill for abortion services.

**Response:**

The list of qualified providers at 4.223.1 was revised to include physician assistants.

### **Proposed Rule 17P042/ HCAR Rule 9.103, Supervised Billing**

**1) Comment:**

Section 9.103.2 (a)(1) lists as a qualified licensed provider for the purposes of the rule “A physician or licensed osteopathic physician certified in psychiatry by the American Board of Medical Specialties.” However, there are psychiatrists currently practicing and providing supervision in Vermont who are not Board Certified in psychiatry by the American Board of Medical Specialties. VMS recommends this section instead read as follows, consistent with other definitions found in Vermont statute:

*(1) A person licensed to practice medicine pursuant to 26 V.S.A. chapter 23 or 33 who specializes in the practice of psychiatry.*

**Response:**

The Department of Vermont Health Access (DVHA) finds it is best clinical practice for Medicaid contracted providers providing supervision to be licensed physicians board certified in psychiatry by the American Board of Medical Specialties.

**2) Comment:**

Section 9.103.2 (b), defining qualified non-licensed providers, appears to exclude pre-degree candidates working towards a degree, for example someone pursuing a doctoral degree in psychology who has not yet finished his or her dissertation. Our members understand that such individuals are currently practicing in some settings in Vermont. VMS recommends DVHA review Section 9.103.2 (b) to ensure that no non-licensed providers are inadvertently left off of the list of qualified non-licensed providers.

**Response:**

The language at 9.103.2(b) was revised to include “a doctoral degree or” master’s degree level mental health practitioner.