

# VERMONT MEDICAL SOCIETY

August 7, 2017

Ashley Berliner  
Director of Healthcare Policy and Planning  
Agency of Human Services  
208 Hurricane Lane  
Williston, VT 05495

Via email to: [Ashley.Berliner@vermont.gov](mailto:Ashley.Berliner@vermont.gov)

Re: Comments on Proposed Rule 4.104.3, Experimental and Investigational Services

Dear Ms. Berliner:

Thank you for accepting comments from members of the Medicaid and Exchange Advisory Group prior to the publication of Rule 4.104.3 regarding Experimental and Investigational Services. The Vermont Medical Society is submitting these comments on behalf of our 2000 physician and physician assistant members. With the short time for review, these comments are likely not comprehensive but represent the feedback we have been able to solicit to date and we may have further comments in the rulemaking process.

## Definition of "Experimental and Investigational"

The Vermont Medical Society seconds Vermont Legal Aid's concern that it is unclear 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. Further, our members are concerned with the lack of clarity related to how the rule will be implemented. Is the processes for challenging whether a treatment is experimental or investigational the same as that outlined under 7104 for Coverage Exceptions? If so, that section states that services that are "experimental and investigational" will not be covered, creating an apparent loop between the two definitions. Our members request additional clarity regarding how to appeal or challenge a determination of whether a service is "experimental and investigational."

## Criteria for Evaluation

Our members commented that it should be clarified in Section 4.104.3(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.

Our members also commented that in order to ensure that treatments for rare diseases are covered, 4.104.3(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.*

Finally, our members commented that 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.

Thank you for considering the Vermont Medical Society's comments and we look forward to working with you as this rule proceeds.

Sincerely,

A handwritten signature in black ink that reads "Jessa Barnard". The signature is written in a cursive, flowing style.

Jessa Barnard, Esq.  
General Counsel and Vice President for Policy