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RE: Responses to Public Comments for Health Care Administrative Rules: 4.202 Dental Services for Beneficiaries Age 21 and Older, 4.203 Dental Services for Beneficiaries Under Age 21, And Pregnant and Postpartum Women, 4.205 Orthodontic Treatment, 4.211 Augmentative and Alternative Communication Devices/Systems, and 10.100 Pharmaceutical Manufacturer Fee.

The following comments were received from the Office of the Health Care Advocate on January 13, 2017.

4.202 - Dental Services for Beneficiaries Age 21 and Older

Comment:
4.202.4. The section on qualified providers requires that services be "provided by, or under the supervision of, a licensed dentist." The HCA wants to be sure that "under the supervision of" includes the concept of a dental therapist working under the "general supervision" of a dentist as defined and described in Act 161 of the 2016 session. The profession of dental therapist was created in part to improve access to dental services for Medicaid patients and it is important that dental therapists are able to practice outside of dentist offices.

Response:
4.202.4 The term "under the supervision of a licensed dentist" will allow dental therapists to work under the general supervision of a dentist as defined in Act 161 of the 2016 session. This rule allows dental therapists and dental hygienists to work within their scope of practice under the supervision of a dentist as defined by 26 VSA Chapter 12.

Comment:
4.202.6 (d). The section on billing beneficiaries for procedures after the dental cap has been reached does not follow the requirements for notifying beneficiaries prior to service when a service will not be covered by Medicaid. We are not sure what is meant by "these conditions do not apply to services that are not covered by Vermont Medicaid." Beneficiaries are entitled to notice prior to the service if the provider believes that the service is not covered either because it exceeds the benefit cap or because it is generally non-covered.

Response:
After consideration of this comment the rule has been amended such that 4.202.6(d)(3) was moved to clarify that billed amounts for procedures not covered by Vermont Medicaid may exceed the rate in the Dental Procedures fee schedule. The rule was also amended to clarify that providers must obtain written acknowledgement of financial liability from a beneficiary prior to performing a procedure.

Comment:
We are not sure why the list of included medically necessary services and the co-payment information have been stricken from existing language and believe these should be maintained in the new regulation.

Response:
The co-payment requirements for Medicaid services are listed in Rule 7101.2(c) Medicaid Benefit Delivery. A separate rule on cost sharing will be adopted as part of the Health Care Administrative Rules (HCAR) in the near future. Cost sharing requirements will not be repeated in all related rules within HCAR.

Coverage of dental services must meet medical necessity criteria as defined in Rule 7103. A complete list of covered services is included in the "Dental Procedures Fee Schedule" that can be found on the Department of Vermont Health Access website as described in 4.202.7 of the rule. The list of covered services that is in the current Rule 7314 includes general categories of dental services. It is not inclusive of all covered dental services and therefore misleading. The complete list of covered dental services is publicly available elsewhere. For these reasons the list of general categories was removed from the rule.

4.203 - Dental Services for Beneficiaries Under Age 21, And Pregnant and Postpartum Women

Comment:
4.203.4 describes qualified providers. We have the same question with respect to this section as we did for 4.202.4.

Response: See above response to the same comment received for Rule 4.202 Dental Services for Beneficiaries Age 21 and Older

4.205- Orthodontic Treatment

Comment:
4.205.5 Conditions for coverage removes existing language specifying that treatment will be covered "if otherwise necessary under EPSDT." We ask that this phrase be included in the new regulation. It is especially important to include coverage when a child/young adult has a medical condition and a malocclusion affects his/her health even if the malocclusion does not meet the ordinary criteria for "severe."

Response:
Health Care Administrative Rules Introduction 1.000(d), adopted December 16, 2016, includes that: "Vermont Medicaid pays for all medically necessary services for beneficiaries under the age of 21 without regard to service limitations otherwise specified in these Health Care Administrative Rules. Further, federal EPSDT requirements may require in individual cases exceptions to the general Medicaid program rules". The inclusion of this language in the HCAR Introduction Rule 1.000 clarifies that EPSDT is a federal requirement that applies to the entirety of Vermont's Health Care Administrative Rules. For this reason, the EPSDT requirement will not be restated in each rule.

Comment:

We are not sure why the existing language specifying that there be "one major or two minor malocclusions" has been omitted from the new regulation and replaced with "a severe malocclusion." This is potentially a decrease in coverage for orthodontia depending on the criteria that are adopted.

Response:
The rule was amended to clarify that comprehensive orthodontic treatments require the presence of one major or two minor malocclusions. The rule also clarifies that medically necessary orthodontic treatment is provided when a beneficiary has a functional impairment that is equal to or greater than the severity of a functional impairment resulting from meeting the diagnostic criteria.

4.211 Augmentative and Alternative Communication Devices/Systems

Comment:
The Disability Law Project of Vermont Legal Aid is filing separate comments on this proposed regulation. The HCA agrees with the issues they have identified.

In addition, the HCA is concerned because this proposed regulation was not presented to the Medicaid and Exchange Advisory Board (MEAB). The statute requires that the MEAB "shall have the opportunity to comment on proposed rules prior to commencement of the rulemaking process." 33 V.S.A. § 402(c)(1). We believe that issues with the regulations could have been addressed had this process been followed.

Response:
Due to the number of comments received in response to the proposed Rule 4.211 Augmentative and Alternative Communication Devices/Systems, the Agency of Human Services will conduct a second comment period and public hearing. This will allow the public an opportunity to review and respond to proposed revisions to this rule. Amendments to the rule and the response to comments will be shared with the Medicaid and Exchange Advisory Board (MEAB) at their February 2017 meeting. The MEAB was informed of the Agency's intent to pre-file this rule via e-mail on June 3, 2016.

The following comment with a question was received from Bula Law Firm on Friday, December 16, 2016:

Comment:
Would you please tell me how the agency defines "labeler"? I was unable to find a definition in the rules.

Response:
The State of Vermont aligns with the Food and Drug Administration (FDA) when it defines 'labeler'. The FDA advises that a labeler is any firm that manufactures (including repackers or relabelers), or distributes (under its own name) the drug. A manufacturer distributes drugs under its own name.