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August 13, 2021

Ms. Lisa Larson
Director of Regulatory Affairs
Maryland Insurance Administration
200 St. Paul Place, Suite 2700
Baltimore, Maryland 21202

*Sent via email:* InsuranceRegReview.mia@maryland.gov

**RE: Comments on Draft Proposed Regulations-COMAR 31.10.51 *Mental Health Benefits and Substance Use Disorder Benefits – Reports on Nonquantitative Treatment Limitations and Data***

Dear Ms. Larson:

CareFirst appreciates the opportunity to comment on the MIA's draft proposed Mental Health Parity and Addiction Equity Act (MHPAEA) regulations. We are also reviewing the proposed templates for the reports referenced in these regulations and will be providing further comment for your consideration by September 7, as requested.

Below we offer comments on draft proposed Regulations .03, .04 and .07.

Most of our comments focus on Regulation .03 Definitions, and fall into the following categories:

(1) Defined terms that need not be defined because they are understood by their plain meaning, including defined terms that are already used in the Insurance Article and have never been defined;
(2) Defined terms that are already defined differently in State or corresponding Federal laws and regulations; or
(3) Defined terms that are never used in this regulation.

We flag each of these terms below and offer cross-references to other existing sources or suggested definitions where applicable. To the extent these definitions are inconsistent with existing law or otherwise unnecessary, we recommend modification or deletion in these regulations. For defined terms that are not used in these regulations, we note that the MIA can clarify terms in the instructions that accompany the report templates on its website to the extent necessary. Regulations .04C and .05C provide that carriers shall follow the instructions posted on the Administration's website to complete the analysis and data reports. To that end, we offer substantive recommendations for some of these terms.

**Regulation .03 Definitions**

**(1) Defined terms that need not be defined because they are understood by their plain meaning, including defined terms that are already used in the Insurance Article and have never been defined.**

**B(7) "Evidentiary Standards"**
This term is not defined in the federal MHPAEA laws and regulations, FAQs or the DOL Compliance Tool. We do not recommend defining the term here, as it is understood by its plain meaning. Further, the term may be defined in forthcoming federal regulations in a way that is inconsistent with this proposed definition.

**B(8) "Factors"**
We believe that this term does not need to be defined, as its plain meaning tracks the proposed definition.

**B(24) "Provider Credentialing and Contracting"**
"Provider Credentialing" and "Contracting" are discussed elsewhere in the Insurance, Health Occupations and Health-General Articles with no definitions. We suggest that this definition is not needed and that the plain meaning of these terms is sufficient.

**(2) Defined terms that are already defined differently in the Code or elsewhere.**

**B(13) "Medical Necessity"**
As defined elsewhere in COMAR 10.67.01.01, "medical necessity" means "what is medically necessary." Further, this definition is not accurate. "Medical necessity" itself does not consist of the "definition, criteria, or guideline" used to determine what is medically appropriate. We recommend tracking the existing COMAR definition.

**B(23) "Provider"**
This term deviates from other definitions of "provider" in the Insurance Article. We suggest that this definition mirror or cross-reference one of the existing definitions-for example:

**(i) "Provider"** means a person or entity licensed, certified, or otherwise authorized under the Health Occupations Article or the Health - General Article to provide health care services.
**(ii)** "Provider" includes:
**1.** a health care facility;
**2.** a pharmacy;
**3.** a professional services corporation;
**4.** a partnership;
**5.** a limited liability company;
**6.** a professional office; and
**7.** any other entity licensed or authorized by law to provide or deliver professional health care services through or on behalf of a provider.
Md. INSURANCE Code Ann. § 15-123

### (3) Defined terms that are never used in this regulation.

The following terms are defined but never used in this Chapter, thus these definitions should all be stricken from the regulations. If the MIA deems it necessary to define or clarify these terms in corresponding report templates, we offer comments below for your consideration.

**B(6) "Emergency Services"**
Insofar as the MIA incorporates a definition of this term into the corresponding report templates, we recommend that the definition track existing law at Md. HEALTH-GENERAL Code Ann. § 19-701:

> **(e) Emergency services. --** "**Emergency services**" means those health care services that are provided in a hospital emergency facility after the sudden onset of a medical condition that manifests itself by symptoms of sufficient severity, including severe pain, that the absence of immediate medical attention could reasonably be expected by a prudent layperson, who possesses an average knowledge of health and medicine, to result in:
>
> **(1)** Placing the patient's health in serious jeopardy;
> **(2)** Serious impairment to bodily functions; or
> **(3)** Serious dysfunction of any bodily organ or part.

**B(11) "Measures"**
We do not believe that this term needs to be defined anywhere, as its plain meaning tracks the proposed definition**.**

**B(18) "Plan Documents"**
Insofar as the MIA incorporates a definition of this term into the corresponding report templates, we recommend that the definition track federal guidance on what constitutes "plan documents." Specifically, FAQ 39[1] states:

> ERISA's general disclosure obligation in section 104(b) and the accompanying disclosure regulation at 29 CFR 2520.104b-1 provide that, for plans subject to ERISA, instruments under which the plan is established or operated must generally be furnished to plan participants within 30 days of request. A document that specifies procedures, formulas, methodologies, or schedules that are applied in determining or calculating a participant's benefit under the plan constitutes an instrument under which the plan is established or operated. Instruments under which the plan is established or operated include documents with information on medical necessity criteria for both medical/surgical benefits and MH/SUD benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply an NQTL with respect to medical/surgical benefits and MH/SUD benefits under the plan.

We suggest the following language based upon the above guidance:

> "Plan Documents means instruments under which the plan is established or operated."

[1] FAQs about Mental Health and Substance Use Disorder Parity Implementation and the 21st Century Cures Act Part 39 (Sept. 5, 2019), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-39-final.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-andFAQs/Downloads/FAQs-Part-39.pdf.

**B(19) "Prescription Drug Formulary Design"**

We believe this definition is not necessary. This term is understood by its plain meaning and other existing definitions in the Insurance Article. "Prescription Drug" is used throughout the Insurance Article and COMAR without definition. "Formulary" is defined in the Insurance Article (Md. INSURANCE Code Ann. § 15-1601). "Design" is understood through its ordinary meaning. The term "continually updated" in this proposed definition creates an ambiguity as to what constitutes a formulary design (i.e., how often is "continually"?). For these reasons, this definition is not needed.

**B(20) "Prior Authorization"**

Insofar as the MIA incorporates a definition of this term into the corresponding report templates, we recommend that the definition track what already appears in the Insurance Code:

> **(10)** "**Prior authorization**" means a utilization management technique that:
>
> **(i)** is used by carriers and managed care organizations;
>
> **(ii)** requires prior approval for a procedure, treatment, medication, or service before an enrollee is eligible for full payment of the benefit; and
>
> **(iii)** is used to determine whether the procedure, treatment, medication, or service is medically necessary.
>
> Md. INSURANCE Code Ann. § 15-140

If the MIA feels that a different definition for "prior authorization" is needed, we suggest the following clarifying modification to the proposed definition (bold, underlined):

> *(a) "Prior authorization" means the process that a carrier or any entity delegated by the carrier to manage mental health, substance use disorder, or medical/surgical benefits on behalf of the carrier requires a member or provider to follow prior to the rendering of services to determine if coverage will be provided based on considerations such as medical necessity, level of care, appropriateness of health care services, provider type, geographic location, or diagnosis exclusions. Prior authorization includes, but is not limited to, preauthorization, precertification, prospective review, preadmission review, pretreatment review, utilization review, and any requirement that a member or provider notify the carrier or organization prior to receiving or delivering a health care service. Prior authorization includes reauthorization of services or benefits that had received preauthorization, but for which the approval period has lapsed* ***at the time the request is submitted****. A request for prior authorization is one received during the reporting period, regardless of whether or when services are delivered or whether or when a claim is submitted.*

**B(22) "Process for Assessment of New Technology"**

We do not believe that this term needs to be defined anywhere, as its plain meaning tracks the proposed definition**.**

**B(27) "Restrictions for Provider Specialty"**

We believe that the restrictions outlined in this definition cannot exist under Maryland law, which requires reimbursement of providers for providing covered services within the scope of their license/certificate (Md. Ins. Art. § 15-701). A carrier cannot impose restrictions that prevent the reimbursement of a provider when providing a covered service within the scope of their license. Therefore, this definition is not needed.

**B(28) "Restrictions that Limit Duration or Scope of Benefits for Services"**
Insofar as the MIA incorporates a definition of this term into the corresponding report templates, we note that this concept is referenced in federal regulations at 45 C.F.R. § 146.136(c)(4)(ii)(H), which states that NQTLs include "Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan or coverage." We recommend that to the extent a definition is needed, that the MIA cross-reference the federal regulation or track this language exactly.

We have no substantive concerns with the following definitions as proposed, should the MIA incorporate them into the report templates:
**B(3) "Case Management"**
**B(9) "Failure to Complete a Course of Treatment"**
**B(17) "Pharmacy Services"**
**B(26) "Reimbursement Rates"**
**B(29) "Retrospective Review"**

**Regulation .04 Filing of Nonquantitative Treatment Limitation Analysis Report**

**G(1):**
This regulation states:

> *(2) The analysis required by Insurance Article, § 15-144(d), Annotated Code of Maryland shall have been performed for* ***processes*** *in place during the calendar year preceding the analysis report.*

Emphasis added.

We believe the word "processes" should be "nonquantitative treatment limitations."

**G(3):**
This regulation is redundant to the requirements outlined in Regulation .04B. One of these two sections should be stricken.

**G(4)(h):**
This draft language does not track the statute. We suggest the following language consistent with Ins. § 15-144(e)(3) and (4), which specifies that "the results of audits, reviews and analyses" should be reported, should replace the proposed text as follows:

> *Results of* ***audits, reviews and analyses*** *to check sample claims or other administrative data to assess how each NQTL operates in practice, and whether written processes are correctly carried out, performed on the NQTLs identified in Insurance Article, § 15-144 (c)(2)(ii), Annotated Code of Maryland to conduct the comparative analysisrequired under Insurance Article, § 15-144 (d)(2), Annotated Code of Maryland as written, and in operation;*

**G(4)(j):**
We suggest the following language, consistent with the Federal DOL Tool's Compliance Tip[2], should replace the proposed text:

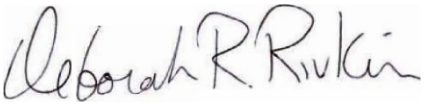
*A description of the consequences or penalties that apply when the NQTL requirement is not met.*

**Regulation .07 Compliance Plan**

**Regulation .07C(1)** provides that a compliance plan "shall include an **acknowledgement** of the Commissioner's finding of noncompliance." We suggest that the term "acknowledgement" be changed to "statement." An "acknowledgement" is not required by statute, and the term "statement" puts the compliance plan in context without implying a carrier's concession that there was a violation.

We want to thank you for this opportunity to provide our comments, and we look forward to continuing this important conversation.

Sincerely,



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[2] See: 2020 MHPAEA Self-Compliance Tool at p. 26, available at https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf.