DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Consumer Information and Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201

September 1, 2022

Blue Cross Blue Shield of Texas – Texas – HIOS # 33602

Tiffany Lee, Senior Auditor
Tiffany_A_Lee@bcbstx.com

Re: Final Determination Letter - Finding of Non-Compliance - Mental Health Parity and Addiction Equity Act (MHPAEA) Non-Quantitative Treatment Limitation (NQTL) Comparative Analysis Review – Prior authorization treatment limitations for outpatient, out-of-network services

Dear Ms. Lee:

This notice is being sent to inform you that a review of the Corrective Action Plan (CAP) and additional comparative analysis submitted to address the instances of non-compliance noted in the MHPAEA NQTL Analysis Review (Review) is complete. This letter also identifies, as applicable, additional remediation and corrective action CMS identified as necessary to fully address the instances of non-compliance.

The purpose of the Review was to assess Blue Cross Blue Shield of Texas' (Issuer) compliance with the following requirements under Title XXVII of the Public Health Service Act (PHS Act) and its implementing regulations for the specific NQTL comparative analysis reviewed:

> 42 U.S.C. § 300gg-26, 45 C.F.R. §§ 146.136 and 147.160 - Parity In Mental Health And Substance Use Disorder Benefits.

The Review covered prior authorization review treatment limitations for outpatient, out-of-network services for the 2021 plan year.

CMS conducted this Review pursuant to PHS Act § 2726(a)(8)(A) and (B), as added by Section 203 of Title II of Division BB of the Consolidated Appropriations Act, 2021.[1] CMS contracted with Examination Resources, LLC to assist CMS with conducting this Review.

On October 25, 2021, CMS sent an initial determination letter of non-compliance to the Issuer and requested a CAP and additional comparative analysis to demonstrate compliance. After

[1] Pub. L. 116-260 (Dec. 27, 2020).

reviewing the CAP and additional comparative analysis, CMS is finalizing the determination of non-compliance with MHPAEA in the following areas:

I. Failures to Provide Sufficient Information

PHS Act § 2726(a)(8)(A) requires that the Issuer "make available […] upon request, the comparative analyses and the following information: […] (iii) The **evidentiary standards** used for the factors identified in clause (ii) […] provided that every **factor shall be defined**, and **any other source or evidence relied upon** to design and apply the NQTLs to mental health or substance use disorder benefits and medical or surgical benefits. (iv) The comparative analyses **demonstrating** that the **processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation**, are comparable to, and are applied no more stringently than, the **processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits** in the benefits classification" (emphasis added). CMS has identified violations of this provision in the following instances:

1. The Issuer did not Provide Sufficient Information Regarding how Each Factor Utilized in the Design and Application of the Prior Authorization Treatment Limitations for Outpatient, Out-of-Network Services NQTL is Applied and Could Result in a Prior Authorization Requirement.

The Issuer provided insufficient information regarding how the factors utilized in the design and application of the NQTL would prompt the prior authorization (PA) requirement, referenced in their CAP response document (*CMS_BCBSTX_0000739_TX LG PA Source & Criteria Mapping, Tab 2 "Definitions"*)The Issuer provided a list of seven factors used in the design and application of the NQTL: 1) level of care (LOC) or treatment requested is high intensity and/or high complexity and for which LOC guidelines are broadly recognized and accepted; 2) treatment is at increased risk of misuse, overutilization and/or fraud and abuse; 3) to verify that treatment requested is provided at least restrictive and most appropriate level of care; 4) treatment requested is only appropriate for specific clinical diagnosis, conditions, and stages of care; 5) diagnostic testing requested applies only to specific diagnosis and conditions; 6) treatment requested is provided for or administered to vulnerable populations; and 7) treatment is indicated for treatment resistant conditions, and is therefore not considered a first line treatment for a condition (*CMS_BCBSTX_0000739_TX LG PA Source & Criteria Mapping, Tab 2 "Definitions"*).

The Issuer stated that "Each service recommended for PA is discussed individually and in consideration of the impact of the seven bulleted factors on the Prior Authorization – Outpatient, Out-of-Network NQTL" (*CMS_BCBSTX_0000737 CMS MHPAEA NQTL 2021_HCSC Index to Request No 2 Documentation, "Item 3" Tab, cell C23*). The Issuer also stated that "meeting one or more of the factors listed above may be determinative" of whether the outpatient mental health and substance use disorder (MH/SUD) or medical/surgical (M/S) service is subject to prior authorization (*CMS_BCBSTX_0000001_TX HMO PA NQTL 2021 and CMS_BCBSTX_0000011_TX PPO PA NQTL 2021, pg. 4*), and that "[n]o such threshholds [sic] (number of factors, weight of any single factor, etc) are used" to make this determination

(*CMS_BCBSTX_0000737 CMS MHPAEA NQTL 2021_HCSC Index to Request No 2 Documentation, "Item 3" Tab, cell C23*). The initial determination letter of non-compliance identified the Issuer had not provided sufficient sources, evidentiary standards, or guidelines utilized in the application of any of the factors used in the design and application of the NQTL. In its CAP response, the Issuer provided a mapping document to demonstrate which "Category of Factors" were attributed to each service resulting in a prior authorization requirement. However, the mapping combined the seven factors into three broader "Categor[ies] of Factors" which are Appropriateness of Care, High Complexity, and Risk of Overutilization, stating "Please note that in the interest of simplification, the seven factors utilized in the Company's determination of prior authorization were condensed into three broader Categories of Prior Authorization Factors for the purpose of consolidating factors that are similar in nature" (*CMS_BCBSTX_0000739_TX LG PA Source & Criteria Mapping, Tab 2 "Definitions"*). Excluding one of the three broader factors, "Risk of Overutilization," which is one of the seven original factors, the remaining six factors are split between "Appropriateness of Care," which includes factors 3), 5), and 7) from the above list, and "High Complexity," which includes factors 1), 4), and 6) from the above list. It is unspecified which of the original six factors prompted either "Appropriateness of Care" and "High Complexity" to be considered for a prior authorization service or which of the six factors, respective to their broader factor, are weighed more than the others within the "Appropriateness of Care" and "High Complexity" categories. The Issuer did not provide additional documentation to demonstrate how each of the seven factors were applied to the MH/SUD and M/S benefits, resulting in a prior authorization requirement. Therefore, the Issuer did not provide sufficient sources, guidelines, or evidentiary standards for how the seven factors are utilized to prompt a prior authorization requirement nor provided information for how these factors are weighed in the design and application of the Prior authorization treatment limitations for outpatient, out-of-network services NQTL for MH/SUD and M/S benefits. Without this information, CMS is unable to determine how each factor is utilized in the design and application of the NQTL or validate the relative comparability and stringency of each factor as applied to M/S and MH/SUD benefits.

Without this information, CMS is unable to validate whether the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits are comparable to and no more stringently applied than those applied to M/S benefits, as written or in operation. As such, the following corrective action is required:

i. Provide a revised mapping document to demonstrate which of the seven identified factors are attributed to each service resulting in a prior authorization requirement, including information for how these factors are weighed in the design and application of the NQTL for MH/SUD and M/S benefits by September 21, 2022.

2. The Issuer did not Provide Sufficient Information Regarding the Extent to which the Issuer Defines and Measures one of its Factors or Evidentiary Standards in a Quantitative Manner in the Design and Application of the Prior Authorization Treatment Limitations for Outpatient, Out-of-Network Services NQTL.

The Issuer defines "Factor 2" as "Treatment is at increased risk of misuse, overutilization and/or fraud and abuse" (*BCBSTX Corrective Action Plan 12_9_21, pg. 2*). There are several MH/SUD and M/S services where this factor was determined to be applicable, impacting the Issuer's

determination to impose a prior authorization requirement for that service (*CMS_BCBSTX_0000739_TX LG PA Source & Criteria Mapping, Tab 1, "Mapping Document").* In the Issuer's revised comparative analysis submitted on December 9, 2021, the Issuer defined overutilization to include "reviews [of] utilization data based on claims to identify statistical outliers that are at the extreme high end for number of visits, services, or days. High outliers can be indicative of fraud and abuse or use that goes beyond what is reasonably expected to be efficacious and therefore raises questions of whether the care is effective. In some cases, BCBSTX does not rely on specific utilization data, but rather makes determinations based on the professional judgment and expertise of clinical staff" (*CMS_BCBSTX_0000755_TX HMO PA NQTL 2021_v4, pg. 9 and CMS_BCBSTX_0000743_TX PPO PA NQTL 2021_v4, pg. 9*). The Issuer specifically states that the sources, evidentiary standards, or guidelines considered for this factor include "Fraud reporting and alerts (CMS, HHS OIG, HHS, DOJ)" and the use of their own internal "Special Investigations Department (SID) [which] has an embedded Data Intelligence Unit (DIU)." Per the Issuer, SAS and Dataiku DSS programs are utilized to "identify potential outliers (when compared to normal utilization) across all providers, members, procedure codes and provider types." The Issuer states that "SID does not use any quantitative measures to determine whether to make a Prior Authorization or other recommendation" (*BCBSTX Corrective Action Plan 12_9_21, pg. 2-3*).

Although the Issuer stated no quantitative measures were used in making a prior authorization recommendation, the Issuer's response indicates utilization data is analyzed for potential statistical outliers as a source or evidentiary standard for the "Treatment is at increased risk of misuse, overutilization and/or fraud and abuse" factor. If there are certain thresholds for flagging a potential outlier or determining data as a statistical outlier resulting in this factor being applicable to a service (and therefore resulting in a prior authorization requirement), this is a quantitative measure utilized in the design and application of the NQTL. However, no information was provided regarding any threshold utilized in order to flag or determine data to be a "statistical outlier." Therefore, the Issuer did not provide sufficient information, including precise definitions and supporting sources, describing the extent to which the "Risk of Overutilization" factor, as well as the supporting evidentiary standards utilized to assess this factor, is defined in a quantitative manner.

Given the information provided in the CAP response documents for this factor, it appears there are quantitative measures utilized in the design and application of the NQTL that prompts a prior authorization requirement for both MH/SUD and M/S services, as described in above paragraph. However, without precise definitions and supporting sources describing the extent to which the "Risk of Overutilization" factor, as well as the supporting evidentiary standards utilized to assess this factor, is defined in a quantitative manner, CMS is unable to determine how this factor is utilized in the design and application of the NQTL, or validate the relative comparability and stringency of the factor relating to M/S and MH/SUD benefits.

Without this information, CMS is unable to validate whether the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits, are comparable to and no more stringently applied than those applied to M/S benefits, as written or in operation. As such, the following corrective action is required:

i. Provide precise definitions and supporting sources describing the extent to which the "Risk of Overutilization" factor, as well as the supporting evidentiary standards utilized to assess this factor, is defined in a quantitative manner. This includes any quantitative measures utilized to measure "statistical outliers" (including "potential" statistical outliers) when analyzing utilization data as a source/evidentiary standard for the "Treatment is at increased risk of misuse, overutilization and/or fraud and abuse factor" by September 21, 2022.

3. The Issuer did not Provide Sufficient Information Regarding Sources, Evidentiary Standards, or Guidelines Considered for its Additional Factors, Such as Market Conditions or Populations, Utilized in the Design or Application of the Prior Authorization Treatment Limitations for Outpatient, Out-of-Network Services NQTL.

The Issuer provided insufficient information regarding the sources, evidentiary standards, or guidelines considered for the "additional factors, such as market conditions or populations," utilized in the design and application of the NQTL, referenced in the Issuer's initial submission (*CMS_BCBSTX_0000001_TX HMO PA NQTL2021.pdf and CMS_BCBSTX_0000011_TX PPO PA NQTL2021.pdf, pg. 5*) and its additional comparative analysis provided as part of the CAP submission (*CMS_BCBSTX_0000755_TX HMO PA NQTL 2021_v4 and CMS_BCBSTX_0000743_TX PPO PA NQTL 2021_v4, pg. 6*).

CMS requested further information regarding the sources, evidentiary standards, or guidelines considered with respect to these factors in the May 28, 2021 Insufficient Data Request. Item #3.I.ii requested "Regarding the statement "[Health Care Management] HCM considers additional factors, such as market conditions or populations, that may result in state or market variation in prior authorization requirements. Not all plans, states, or market segments must have the same list of services subject to prior authorization […] What is the source data used?" (*pg. 4*). CMS identified the sources, evidentiary standards, or guidelines for these "additional factors, such as market conditions or populations" as an area of insufficiency in the October 25, 2021 initial determination letter. The Issuer's December 9, 2021 CAP submission did not include the sources, evidentiary standards, or guidelines considered for the "market conditions or populations" factors that may be considered in determining whether prior authorization will be required for a service and sent an additional follow-up request for this information January 6, 2022. The Issuer's supplemental response on January 14, 2022, confirms the use of these additional factors in determining the list of services subject to a prior authorization requirement, stating that they are considered in the "development of the Prior Authorization list" (*BCBSTX Corrective Action Plan Suppl 1_14_22.pdf, pg. 1*). However, the sources, evidentiary standards, or guidelines considered with respect to these additional factors were not provided, despite multiple requests.

Without this information, CMS is unable to validate whether the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits, are comparable to and no more stringently applied than those applied to M/S benefits, as written or in operation. As such, the following corrective actions are required:

i. Provide the definition of the "market conditions or populations" factor(s) utilized in the development of the Prior Authorization list, including any associated hierarchical weight compared to any other factors utilized in the design of the of the NQTL; and
ii. Provide the sources, evidentiary standards, and/or guidelines considered with respect to the "market conditions or populations" factor(s), utilized in the development of the Prior Authorization list by September 21, 2022.

II. Next Steps

Pursuant to PHS Act § 2726(a)(8)(B)(iii)(I)(bb), the Issuer must, within seven calendar days of the date of this letter, notify all individuals enrolled under a plan subject to this NQTL that it is not compliant with the requirements under MHPAEA. Please provide a copy of the letter, with the date(s) the letter was sent, and a list of recipients by September 6, 2022.

If the Issuer fails to complete the identified corrective actions, provide appropriate notice to its enrollees, or provide documentation of these actions to CMS, CMS may pursue further enforcement action, including the potential imposition of civil money penalties pursuant to 45 C.F.R. § 150.301.

CMS's findings detailed in this letter pertain only to the NQTL under review and do not bind CMS in any subsequent or further review of other plan provisions or their application for compliance with governing law, including MHPAEA. If additional information is provided to CMS regarding this NQTL or plan, CMS reserves the right to conduct an additional review for compliance with MHPAEA or other applicable PHS Act requirements.[2] Importantly, CMS's findings pertain only to the specific plans to which the NQTL under review applies and are offered by the Issuer and do not apply to any other plan or issuer, including other plans or coverage for the Issuer acts as an Administrator.

CMS will include a summary of the comparative analysis results of this Review, determination of non-compliance, and the identity of the Issuer in its annual report to Congress pursuant to PHS Act § 2726(a)(8)(B)(iv).

Sincerely,
Mary M. Nugent -S
Digitally signed by Mary M. Nugent -S
Date: 2024.06.04 17:18:49 -04'00'
Mary Nugent
Director, Compliance and Enforcement Division
Oversight Group
Center for Consumer Information and Insurance Oversight
Centers for Medicare & Medicaid Services

cc: Texas Department of Insurance

[2] *See* PHS Act § 2726(a)(8)(B)(i). *See also* 45 C.F.R. § 150.303.