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

April 5, 2022

SHA, LLC DBA FirstCare Health Plans – Texas – HIOS #26539

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Re: Final Determination Letter - Finding of Non-Compliance - Mental Health Parity and Addiction Equity Act (MHPAEA) Non-Quantitative Treatment Limitation (NQTL) Comparative Analysis Review – Concurrent review for outpatient, in-network benefits

Dear Ms. Cornett and Ms. Portwood:

This notice is being sent to advise you that a review of the Corrective Action Plan (CAP) and additional comparative analysis submitted to address the instance 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 SHA, LLC DBA FirstCare Health Plans - Texas's (Issuer) compliance with the following requirements under Title XXVII of the Public Health Services 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 the 2021 plan year for concurrent review for outpatient, in-network mental health and substance use disorder (MH/SUD) benefits compared to outpatient, in-network medical/surgical (M/S) benefits. 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 conduct the Review in conjunction with CMS.

On September 3, 2021, CMS provided an initial determination letter of non-compliance to the Issuer and requested a CAP and revised comparative analysis to demonstrate compliance. Although the Issuer's prior submissions throughout the Review were specific to concurrent review for outpatient, in-network services, the CAP and the additional comparative analysis submitted in response to CMS' request stated that the Issuer does not perform concurrent review for outpatient, in-network services. The Issuer clarified that it performs a process similar to prior authorization, instead of concurrent review, for outpatient, in-network services. After reviewing the CAP and additional comparative analysis, CMS is finalizing the determination of non-compliance with MHPAEA in the following areas noted in the September 3, 2021 initial determination letter:

1. **The Issuer did not provide sufficient information regarding sources and/or evidentiary standards considered in the design or application of the NQTL.**
    a. PHS Act § 2726(a)(8)(A) requires that the Issuer "make available […] upon request, the comparative analyses and the following information: […] (ii) The **factors** used to determine that the NQTLs will apply to mental health or substance use disorder benefits and medical or surgical benefits. (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" (emphasis added).

    As described in the Initial Determination Letter, the Issuer's previous submissions did not provide sufficient information regarding how each of the six factors considered in its cost benefit analysis (MHPAEA NQTL Analysis on Concurrent Outpatient Review, page 4) are measured, including the parameters of any datasets, as well as sources used for decisions and copies of clinical guidelines utilized in the design and application of the NQTL. Furthermore, the Issuer's additional comparative analysis as part of the CAP submission identified 5 different factors considered in determining "whether to add or remove prior authorization for M/S and MH/SUD outpatient services" (MHPAEA NQTL Analysis of Prior Authorization_2.1.2022, pages 7 and 14). The Issuer's CAP response did not provide any sources used to measure the factors or copies of clinical guidelines utilized in the design and application of the NQTL for either the factors included in the Initial Determination Letter or the factors identified in the additional comparative analysis. The Issuer's remediation plan includes projects to (1) more clearly identify and define the factors used to decide whether to apply prior authorization to outpatient, in-network services, (2) build operations to measure data to monitor NQTLs in operation, and (3) develop a new enterprise MHPAEA compliance program to develop and ensure compliance with comprehensive policies for all operational functions subject to MHPAEA. These projects do not address the instance of non-compliance noted in the Initial

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

Determination Letter. Furthermore, while pages 6-7 of the "MHPAEA NQTL Analysis of Prior Authorization_2.1.2022" document and the "Clinical Criteria for UM Decisions P&P FCHP.HSD.354.P" document provided as part of the Issuer's CAP submission provide a listing of clinical criteria used in utilization management decisions, copies of those clinical criteria were not provided. The Issuer's remediation plan and additional comparative analysis did not identify or provide supporting documentation for the sources and/or evidentiary standards used to measure and apply its identified factors, nor did it provide copies of the policies and clinical guidelines referenced in the "NQTL Policy List" document. The submissions also did not include the clinical criteria utilized in making utilization management decisions. 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 Issuer's CAP submission did not adequately address the instance of non-compliance identified in the Initial Determination Letter and the following corrective action is required:

i. Provide the sources and/or evidentiary standards used to measure and determine applicability of the factors identified in the cost-benefit analysis relating to outpatient concurrent reviews (included in the Issuer's definition of prior authorization) as part of the design and application of the NQTL by July 7, 2022.
ii. Provide copies of clinical guidelines, sources and/or evidentiary standards used in the application of the NQTL to approve or deny a request for concurrent review (included in the Issuer's definition of prior authorization) pertaining to outpatient in-network services by July 7, 2022.

2. **The Issuer's comparative analysis did not adequately demonstrate how the issuer determined whether the processes, strategies, evidentiary standards, and other factors used to apply the NQTL are no more stringently applied in operation.**
   a. PHS Act § 2726(a)(8)(A) requires that the Issuer "make available […] upon request, the comparative analyses and the following information: […] (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).

   The Issuer's additional comparative analysis includes an analysis of Operations Measure Data as part of its comparability and stringency assessment (MHPAEA NQTL Analysis of Prior Authorization_2.1.2022, page 11-12). However, the data included as part of the comparability and stringency assessment includes data for all authorizations and is not specific to the NQTL under review, concurrent review for outpatient, in-network services. In an email dated February 1, 2022, the Issuer stated it is "unable to limit the data pull to reflect only those authorizations

that were extensions of previously approved care." Without a reasoned discussion of the findings or conclusions regarding the comparability and stringency of the NQTL under review and its associated processes, strategies, evidentiary standards, and other factors, CMS cannot assess whether the NQTL is no more stringently applied in operation. As such, the following corrective action is required:

i. Develop and analyze the PY2021 Operations Measure Data specific to authorizations for the extension of previously approved, ongoing services or care for outpatient, in-network services; and
ii. Include the results and analysis of the above-requested Operations Measure Data assessment in the reasoned discussion of the findings or conclusions regarding the comparability and stringency of the NQTL and its associated processes, strategies, evidentiary standards, and other factors by July 7, 2022.

3. **The Issuer did not provide all supporting documentation used in the design and application of the NQTL.**
   a. PHS Act § 2726(a)(8)(A) requires that the Issuer "make available […] upon request, the comparative analyses and the following information: […] (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). Page 3 of the "MHPAEA NQTL Analysis of Prior Authorization_2.1.2022" document states, "24 hours are allowed to render a decision" for both MH/SUD and M/S authorizations. On January 24, 2022, CMS requested supporting documentation of this policy. The supporting policy provided, "Notifications to Providers of Availability of Medical Directors for Peer-to-Peer Discussions," does not include specific timeframes for authorizations, nor did it address the 24-hour decision timeframe described in the comparative analysis. 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 supporting documentation demonstrating the timeframes for decisions involved in the design and application of the NQTL under review by July 7, 2022.

In addition, 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 the NQTLs in this review 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 April 13, 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 impose 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 does 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]

CMS's findings pertain only to the specific plan(s) to which the NQTL under review applies and is offered by the Issuer, and do not apply to any other plan or issuer, including other plans or coverage for which 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

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Date: 2024.06.05 08:10:30 -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.