

**NEW YORK STATE DEPARTMENT OF HEALTH DIVISION OF  
HEALTH PLAN CONTRACTING AND OVERSIGHT  
ARTICLES 44 AND 49 STATEMENT OF DEFICIENCIES**

<b>NAME OF MANAGED CARE ORGANIZATION</b> Affinity Health Plan, Inc.	<b>TYPE OF SURVEY:</b> Focus Survey: MHPAEA Testing Phase I and Phase II Workbooks
<b>STREET ADDRESS, CITY, STATE, ZIP CODE</b> 1776 Eastchester Road Bronx, NY 10461	<b>SURVEY DATES:</b> August 22, 2018 – September 8, 2020

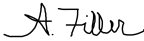
**NOTE:** The following list of deficiencies was identified by Health Department representatives during an Article 44 and/or Article 49 operational or focused survey of your Managed Care Organization (MCO). Correction of these deficiencies is required in order to bring your MCO into compliance with Article 44 and/or 49 of the New York State Public Health Law and the New York State Official Compilation of Codes, Rules, and Regulations (10NYCRR). In the column headed Provider Plan of Correction, describe the Plan of Corrective Action and anticipated date of corrections. The Plan of Correction should be returned within 15 business days.

Deficiencies	Plan of Correction with Timetable
<p><b>0 CRR-NY 98-1.16 Disclosure and filing.</b> <b>(h) In the event an MCO does not provide substantially complete reports or other information required under this Subpart by the due date, or provide requested information within 30 days of any written request for a specific analysis or report by the superintendent or commissioner, the superintendent or commissioner is authorized to levy a civil penalty, after notice and hearing, pursuant to section 12 of the Public Health Law or sections 307 and 308 of the Insurance Law.</b></p> <p><b><u>Deficiency:</u></b></p> <p>Based on the review of Affinity Health Plan, Inc.'s Phase I and Phase II nonquantitative treatment limitation (NQTL) workbook submissions, the MCO failed to provide all required information and comparative analyses demonstrating compliance with the Mental Health Parity and Addiction Equity Act of 2008, (P.L. 110-345; MHPAEA) for 5 of 9 NQTLs examined; prior authorization, concurrent review, formulary design, coding edits, out of network coverage standards, and reimbursement.</p>	<p><b><u>Description of Correction:</u></b></p> <p>Affinity will update and maintain the Phase I and Phase II workbooks and will perform substantive comparative analyses demonstrating compliance with the Mental Health Parity and Addiction Equity Act of 2008 (P.L. 110-345; MHPAEA). The comparative analyses will focus upon ensuring parity for prior authorization, concurrent review, formulary design, coding edits, out of network coverage standards, and reimbursement.</p> <p>The comparative analyses and workbook update will also reflect the guidance Affinity received from New York State/Milliman during its call on March 9, 2021.</p> <p><b><u>Education and Training</u></b></p> <p>Affinity will continue to provide training on the Parity requirements as part of its annual mandated employee Compliance training.</p> <p>If a policy or procedure is changed as a result of the activities specified in this plan of correction (POC) the employees whose assigned duties may be impacted will receive training in the revised policy or procedure. If a delegated vendor's activities are impacted as a result of this POC, the Plan shall ensure that the vendor's impacted employees receive any necessary training.</p> <p>Any employee involved in the activities specified in this POC will additional parity related training as required. For example, subject matter experts assigned to update each workbook area will be trained on both the Parity requirements and any policies and procedures updated as a result of the activities specified in this Plan of Correction (POC).</p>

MCO Representative's Signature <i>Lisa Mingione</i>	Date August 23, 2021
Title VP - Chief Compliance Officer	

9/20/2021 - 12:04pm: Call with Zhanna Kelley, Director of Compliance.

POC update/correction: Comparative analyses for prior authorization and concurrent review will follow the instructions listed for the applicable step(s) within the workbook and will not be limited to the percentage of denials.



Ashley Filler  
BHI Parity Analyst  
NYS OMH

For example, Subject Matter Experts assigned to update each workbook area will be trained on both the Parity requirements and any updated policies and procedures updated as a result of the remediation activities specified in this plan of correction.

### Monitoring and Auditing

In order to ensure parity between physical health and behavioral health services, Affinity shall perform a quarterly comparative analysis of the percentages of inpatient and outpatient prior authorization and concurrent review denials for physical and behavioral health services. If the percentage of inpatient and/or outpatient behavioral health prior authorization and concurrent review denials are higher than physical health denials, Affinity shall review a quarterly sample of at least 20 inpatient and/or outpatient behavioral health prior authorization/concurrent review denials (depending upon if one or both failed) to ensure that they were appropriate and will use such data to provide direction to its behavioral health vendor.

The comparison of physical and behavioral health prior authorization and concurrent review denials shall commence no later than September 7, 2021. The sampling and validation of behavioral health prior authorizations shall commence within 21 days of the identification of the need for such sampling and will continue until the level of outpatient behavioral health prior authorization/concurrent review denials is equal to or less than the level of outpatient physical health prior authorization/concurrent review denials for at least two consecutive quarters.

In order to ensure parity between prescription drug prior authorization/concurrent review decisions for physical health and behavioral health conditions, Affinity shall perform a quarterly comparative analysis of the percentages of outpatient prior authorization and concurrent review denials for prescription drug prior authorizations for physical and behavioral health conditions. If the percentage of prescription drug authorization/concurrent review denials is higher for behavioral health conditions than it is for physical health conditions, Affinity shall review a quarterly sample of at least 20 prescription drug prior authorization/concurrent review denials for behavioral health conditions to ensure that they were appropriate and will use such data to review its criteria for making prescription drug prior authorization/concurrent review prescription drug decisions related to behavioral health.

Affinity Health Plan shall on an ongoing basis ensure that its Pharmacy Benefit Manager, CVS Caremark, applies evidentiary standards when deciding which drugs should be included on the plan's formulary and that there is evidentiary equivalency between drugs used for behavioral health and non-behavioral health conditions.

MCO Representative's Signature



Title

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August 23, 2021

<p>Prior authorization</p> <ul style="list-style-type: none"> <li>Specifically, in Phase I, Affinity Health Plan, Inc. failed to define factors in (Step 3) evidentiary standards comparability and equivalent stringency for outpatient and prescription drug prior authorization and concurrent review. The MCO failed to provide substantive comparative analyses for (Step 5) in operation comparability and equivalent stringency for inpatient, outpatient, and prescription drug prior authorization and concurrent review. Affinity also failed to no physical health provide a substantive (Step 4) as written comparability and equivalent stringency comparative analysis for prescription drug concurrent review. For prescription drugs formulary design, the MCO failed to provide substantive comparative analyses for (Step 3) evidentiary standards comparability and equivalent stringency, (Step 4) as written comparability and equivalent stringency, (Step 5) in operation comparability and equivalent stringency.</li> <li>Specifically, in Phase II, Affinity Health Plan, Inc. failed to define factors in (Step 3) evidentiary standards comparability and equivalent stringency and provide substantive comparative analyses for (Step 3) evidentiary standards comparability and equivalent stringency, (Step 4) as written comparability and equivalent stringency, (Step 5) in operation comparability and equivalent stringency for inpatient and outpatient out of network coverage standards and reimbursement.</li> </ul>	<p>These standards shall include factors such as drug indications, clinical evidence (scientific evidence, standards of practice, peer-reviewed medical literature, accepted clinical practice guidelines), adverse event profile, available dosage forms, dosing frequency, generic competition, and adherence factors.</p> <p>The Plan shall also ensure there are no differences in formulary development for behavioral health related and other types of conditions. In this regard Affinity Health Plan shall on an ongoing basis review its PBM's pharmacy and therapeutics (P&amp;T) committee policies and procedures and review it's PBM's P&amp;T meeting minutes. In addition, the Plan shall perform a quarterly comparative analysis of decisions made through utilization management rules for behavioral health and non-behavioral conditions/medication treatment developed through the P&amp;T committee to ensure there is equivalence on such decisions between drugs used to treat behavioral health and non-behavioral conditions on the Plan's formulary. This analysis shall be completed as soon as possible but no later than October 31, 2021. Results from the analysis shall be used to provide feedback to Affinity's PBM and, if necessary, to request changes to the PBM's policies and procedures.</p> <p>In order to ensure both Inpatient and Outpatient Out of Network (OON) parity, Affinity shall annually perform a study of the factors which are used to approve OON requests for both Inpatient and Outpatient services for behavioral health and physical health conditions. We will ensure that no factor used for approving an OON behavioral health service is more stringent than that used for physical health services.</p> <p>The initial OON study shall be completed no later than October 31, 2021. Any required changes shall be implemented as soon as possible but no more than 60 days from the completion of the aforementioned study.</p> <p>In general Affinity Health Plan utilizes the Medicaid fee schedule when negotiating provider reimbursement levels. In order to ensure parity in reimbursement levels, we shall annually perform a study of the factors which are used to negotiate fees that are higher than the Medicaid fee schedule for both physical health and behavioral health services to ensure they are consistent and will address any situation where a factor used for behavioral health services is more stringent than that used for physical health services or where a factor used for physical health services is not being used for behavioral health services. The initial study shall be completed no later than October 31, 2021 and corrective action where necessary shall be completed as soon as possible but no more than 60 days from the completion of the aforementioned study.</p>
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Affinity will. Annually identify and compare the coding edits used for behavioral health and physical health to ensure that no behavioral health coding edit is more stringent or fundamentally different than those used for physical health. The initial comparison shall be completed as soon as possible, but no later than October 31, 2021. Corrective actions, where necessary, shall be completed within 60 days of the completion of this comparison.

In addition, the process for approving changes to medical review and coverage policies shall be updated to ensure any changes to such policies are reviewed to ensure there is parity between behavioral health and physical health policies.

As stated earlier Phase I and Phase II workbooks will be updated and maintained on an ongoing basis with the required information and substantive comparative analyses demonstrating compliance with the Mental Health Parity and Addiction Equity Act of 2008 (P.L. 110-345; MHPAEA)

A subject matter expert (SME) will be assigned to each workbook area, i.e., prior authorization, concurrent review, formulary, etc. The SME will be responsible for completing their assigned section. The SME will complete the testing workbook included in the guidance to review the required steps of the NQTL spreadsheets for Phase 1 and Phase 2 and will create a Policy and Procedure specifying workbook completion requirements.

A quality assurance process will be developed to ensure that each section of the workbook is completed correctly, in a timely manner, and in compliance with the Mental Health and Addiction Equality Act: New York Medicaid Managed Care, Alternative Benefit Plan and Children's. If as a result of the completion and or update of the aforementioned workbooks and comparative analysis it is determined that a behavioral health policy or procedure needs to be revised, Affinity shall revise and promulgate the policy and procedure.

**Persons Responsible**

Zhanna Kelley, Director Corporate Compliance, and Larry Klein, Director Behavioral Health shall be responsible for overseeing this corrective action.

Rudy Andrew, Vice President, Pharmacy Management shall be responsible for overseeing corrective actions related to Pharmacy.

**Date Certain for Completion**

The Plan of Correction shall be completed no later than October 31, 2021, except where further action is required as a result of the comparative analyses outlined in this POC.

MCO Representative's Signature

*Lisa Mingione*

Title

VP - Chief Compliance Officer

Date

August 23, 2021