NEW YORKSTATEDEPARTMENTOF HEALTH DIVISIONOF HEALTHPLANCONTRACTINGANDOVERSIGHT ARTICLES 44 AND 49 STATEMENTOF DEFICIENCIES

NAME OF MANAGED CARE ORGANIZATION	TYPE OF SURVEY:
Affinity Health Plan, Inc.	Focus Survey: MHPAEA Testing Phase I and Phase II Workbooks
STREET ADDRESS, CITY, STATE, ZIP CODE	**SURVEY DATES:**
1776 Eastchester Road Bronx, NY 10461	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 within15 business days.

Deficiencies	Plan of Correction with Timetable
0 CRR-NY 98-1.16 Disclosure and filing. **(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.** **Deficiency:** 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.	**Description of Correction:** 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. 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. **Education and Training** Affinity will continue to provide training on the Parity requirements as part of its annual mandated employee Compliance training. 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. 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).

MCO Representative's Signature	Date
[redacted]	August 23, 2021
Title VP - Chief Compliance Officer	

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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 Heath 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.

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Prior authorization • 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. • 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.	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. 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&T) committee policies and procedures and review it's PBM's P&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&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. 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. 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. 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.

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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** [redacted], Director Corporate Compliance, and [redacted], Director Behavioral Health shall be responsible for overseeing this corrective action. [redacted], 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 [redacted]	Date August 23, 2021
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Statement of Findings

Affinity Health Plan, Inc.

MHPAEA Testing Phase I and Phase II Workbooks

August 22, 2018- September 8, 2020

Parity Compliance

35.1 Contractor and SDOH Compliance With Applicable Laws

Notwithstanding any inconsistent provisions in this Agreement, the Contractor and SDOH shall comply with all applicable requirements of the State Public Health Law; the State Social Services Law; the State Finance Law; the State Mental Hygiene Law; the State Insurance Law; Title XIX of the Social Security Act; Title VI of the Civil Rights Act of 1964 and 45 CFR Part 80, as amended; Title IX of the Education Amendments of 1972; Section 504 of the Rehabilitation Act of 1973 and 45 CFR Part 84, as amended; the Age Discrimination Act of 1975 and 45 CFR Part 91, as amended; the ADA; Title XIII of the Federal Public Health Services Act, 42 U.S.C § 300e et seq., regulations promulgated thereunder; the Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191) and related regulations; the Federal False Claims Act, 31 U.S.C. § 3729 et seq.; MentalHealth Parity and Addiction Equity Act of 2008, (P.L. 110-345); for Contractors operating in NewYork City, the New York City Health Code; and all other applicable legal and regulatoryrequirements in effect at the time that this Agreement is signed and as adopted or amended duringthe term of this Agreement. The parties agree that this Agreement shall be interpreted according tothe laws of the State of New York.

(42 CFR 438.910(d) *Nonquantitative treatment limitations.)*

(42 CFR 438.920(b) *State Responsibilities*.)

Finding:

Based on the review of Affinity Health Plan, Inc.'s Phase I and Phase II nonquantitative treatment limitation (NQTL) workbook submissions, the Managed Care Organization (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.

•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 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.

•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.

It is Affinity's understanding that because of the Pharmacy carve out project, scheduled for April 1, 2021, MCO's are not required to address pharmacy related parity phase one or two findings. The following plan of correction addresses non-pharmacy related finding related items. The Plan has requested a meeting with Milliman/OMH for clarification of the finding. Email requesting such a meeting was sent to the OMH Parity mailbox on 12/02, 12/03 and 12/07; the scheduling of the meeting is pending. The Plan's Technical questions include the following:

1. Please explain what would constitute an acceptable comparative analysis demonstrating compliance for prior authorization, concurrent review, formulary design, coding edits, out of network coverage standards, and reimbursement.

2. The finding indicates that a comparative analysis is needed for 5 of 9 NQTLS examined but appears to list 6 items (see #1 above); please clarify.

3. Please explain what is meant by "factors in (Step 3) evidentiary standards comparability and equivalent stringency for outpatient and prescription drug prior authorization and concurrent review."
4. Please confirm that due to the impending pharmacy carve-out effective April 1, 2021, plans do not need to address pharmacy related findings. Depending upon the responses to these questions, Affinity reserves the right to ask additional follow up questions. Following the receipt of these clarifications from Milliman/OMH, the Plan shall address the following items listed in the finding.

a. For Phase I, the Plan shall define factors in (Step 3) evidentiary standards comparability and equivalent stringency for outpatient concurrent review.

b. For Phase I, the Plan shall provide substantive comparative analyses for (Step 5) in operation comparability and equivalent stringency for inpatient and outpatient authorization and concurrent review.

c. For Phase II the Plan shall define factors in (Step 3) evidentiary standards comparability and equivalent stringency and provide substantive comparative analyses for (Step 3) evidentiary standards for inpatient and outpatient out of network coverage standards and reimbursement comparability and equivalent stringency.

d. For Phase II the Plan shall provide substantive comparative analyses for (Step 4) comparability and equivalent stringency for inpatient and outpatient out of network coverage standards and reimbursement.

e. For Phase II the Plan shall provide substantive comparative analyses for (Step 5) in operation comparability and equivalent stringency for inpatient and outpatient out of network coverage standards and reimbursement. The timeline for completing these tasks is dependent upon the receipt of the clarifying information cited above. The tasks shall be completed no more than 90 days from the receipt of complete clarifying information by the Plan from Milliman/OMH.

Plan of Correction

Description of Correction:

Affinity 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. In addition, Affinity will update & maintain the Parity Phase I and Phase II workbooks with the required information,

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.

Education and Training

Affinity will continue to provide training on the Parity requirements as part of its annual mandated employee Compliance training.

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.

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).

In addition, 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 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 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 Heath Plan shall 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. 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.

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 review its PBM's pharmacy and therapeutics (P&T) committee policies and procedures and review it's PBM's P&T meeting minutes. In addition, the Plan shall perform a comparative analysis of decisions made through utilization management rules for behavioral health and non-behavioral conditions/medication treatment developed through the P&T committee to ensure there is equivalency 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.

In order to ensure both Inpatient and Outpatient Out of Network (OON) parity, Affinity shall 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.

This 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.

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 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. This 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.

Affinity will 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. This 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.

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

[redacted] Director Corporate Compliance, and [redacted], Director Behavioral Health shall be responsible for overseeing this corrective action.

[redacted], 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.

[redacted]
VP – Chief Compliance Officer

[redacted]

09/17/2021

[redacted]

[redacted]
BH Parity Analyst
NYS OMH