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

NAME OF MANAGED CARE ORGANIZATION	TYPE OF SURVEY: Reissued
Highmark Western and Northeastern New York, Inc. (f/k/a HealthNow New York, Inc.)	Focus Survey: Mental Health Parity and Addiction Equity Act Testing of Phase III Workbooks
STREET ADDRESS, CITY, STATE, ZIP CODE 257 West Genesee Street Buffalo, NY 14202	**SURVEY DATES:** March 11, 2020- November 30, 2020 Survey ID#: -1302543068

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
10 CRR-NY 98-1.16 Disclosure and filing **(h) In the event an MCO does not provide substantial-ly 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 Highmark Western and Northeastern New York, Inc.'s (f/k/a HealthNow New York, Inc.) (Highmark) Phase III 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 (MHPAEA), P.L. 110-343, for 5 of 10 NQTLs examined; retrospective review, outlier review, experimental/investigational determinations, fail first, and provider credentialing. Specifically, Highmark failed to provide all information and substantive comparative analyses for retrospective review, experimental/investigational determinations, and provider credentialing in Steps 2 through 5 in the inpatient and outpatient benefit classifications. The MCO also failed to provide all information and substantive comparative analyses in Steps 2 through 5 for outlier review (excluding Step 2), experimental/investigational determinations, and fail first in the prescription drugs benefit classification and provider credentialing in the emergency care benefit	**Plan Response – Retrospective Reviews**: Retrospective reviews are requests for authorization by a provider after services have been delivered. Both Inpatient and Outpatient (IP and OP) requests for Behavioral Health (BH) services are accepted and reviewed by the plan. BH does not render any administrative denials for late notification. Medical/Surgical (M/S) do issue administrative denials for late notification for certain services. The plan runs authorization and denial reports on an ongoing basis and the BH team has not issued an administrative denial for any requests related to retrospective reviews. On receiving the request, a BH clinician reviews for medical necessity. Associates who review these requests and render a clinical decision are licensed clinicians within both the BH and Physical Health (PH) team. Both the BH and PH teams have to meet the same standards for notification. The BH retrospective review process for both IP and OP are not more stringent than the PH side. The BH and PH processes will be reviewed on a quarterly basis and workbook will be updated. Responsible party: Primary: [redacted] – BH Manager; Secondary – [redacted] – BH Program Manager Ongoing Monitoring: Compliance with state and federal requirements for provision of comparable coverage for benefits to treat mental health and substance use disorder is monitored via the Mental Health and Substance Use Disorder Parity Compliance Program. Written policies and procedures that describe how parity compliance is assessed, monitored, and managed were established effective on December 28, 2021, including the system for the ongoing assessment of parity compliance. By December 31,

classification.	2021 and annually thereafter, the plan will submit a written certification to the Commissioner that these requirements have been satisfactorily met. This certification will be in the form prescribed by the Commissioner and signed by the plan president or the Compliance Director. A copy will be provided to the NY Board of Managers. Status of parity findings will be reported in quarterly Behavioral Health Quality Management Committee meetings beginning August 31st, 2021. The Committee will also review any plan of action that needs to be submitted to ensure parity compliance, if the comparative analysis reveals that a BH process is more stringent than PH. Plan of Action will include the following: • Identify any processes that appear to be more stringent • Identify changes that need to be implemented to ensure parity • Identify specific due dates and business owners for tracking • Identify the methodology to complete a parity analysis once the changes are implemented to ensure parity compliance Updates and findings from the BHQMC will be reported to executive leadership at the Plan Compliance Committee which meets no less than four times per year. If any comparative analysis identifies an NQTL to be noncompliant, as performed per the plan of correction by Highmark, Highmark will conduct reeducation and training of all applicable associates and updates to associated resource documents to ensure compliance. Responsible Parties: Primary: [redacted], Director, Quality Management Secondary: [redacted] Program Manager **Plan Response: Outlier Review** Our process for IP has changed since our submission. The plan does not have an outlier management program in place currently. The plan has submitted a proposed program to the state and if approved, this will be implemented in 2022/2023. Once a process is approved and ready for implementation associates will be trained on the revised processes no later than 30 days of finalization. This training will be completed at weekly Huddle meetings held every Wednesday. Additionally, all teams within BH will again review their focused process at smaller team meetings & huddles.

	Documentation of training will be maintained and tracked for completion at least annually. Since we currently do not have an outlier program in place for BH IP or BH OP, assessing whether we are less stringent than PH or M/S is not applicable. The BH and PH processes will be reviewed on a quarterly basis and workbook will be updated. Responsible party: Primary: [redacted] – BH Manager; Secondary –Alison West, Program Manager Plan Response (Pharmacy): The workbook was reviewed and updated based on state feedback. All drugs are at parity with respect to the above policies referencing ProDUR and rDUR as outlined within the workbook responses. For future NQTL surveys, we will follow workbook reporting prompts to demonstrate that the processes, strategies, evidentiary standards, and other factors used in designing and operationalizing the NQTL for MH/SUD benefits are comparable to those for M/S benefits, by using side-by-side comparison of sample medications. The team will continue to monitor on a routine basis and assess for compliance with parity. Responsible Party: [redacted], WNY Pharmacy Program Manager Ongoing Monitoring: Compliance with state and federal requirements for provision of comparable coverage for benefits to treat mental health and substance use disorder is monitored via the Mental Health and Substance Use Disorder Parity Compliance Program. Written policies and procedures that describe how parity compliance is assessed, monitored, and managed were established effective on December 28, 2021, including the system for the ongoing assessment of parity compliance. By December 31, 2021 and annually thereafter, the plan will submit a written certification to the Commissioner that these requirements have been satisfactorily met. This certification will be in the form prescribed by the Commissioner and signed by the plan president or the Compliance Director. A copy will be provided to the NY Board of Managers. Status of parity findings will be reported in quarterly Behavioral Health Quality Management Committee meetings beginning August 31st, 2021. The Committee will also review any plan of action that needs to be submitted to ensure parity compliance, if the comparative analysis reveals that a BH process is more stringent than PH.

	Plan of Action will include the following: • Identify any processes that appear to be more stringent • Identify changes that need to be implemented to ensure parity • Identify specific due dates and business owners for tracking • Identify the methodology to complete a parity analysis once the changes are implemented to ensure parity compliance Updates and findings from the BHQMC will be reported to executive leadership at the Plan Compliance Committee which meets no less than four times per year. If any comparative analysis identifies an NQTL to be noncompliant, as performed per the plan of correction by Highmark, Highmark will conduct reeducation and training of all applicable associates and updates to associated resource documents to ensure compliance. Responsible Parties: Primary: [redacted], Director, Quality Management Secondary: [redacted] Program Manager **Plan Response: Experimental/Investigational Determinations** These requests are reviewed by a Medical Director on the BH side and a Medical Director on the PH – M/S side. If the services are denied by the Medical Director, then both the BH and PH teams follow the same process for notification and members have the same appeal rights. If these services are appealed, both BH and PH follow the same appeal review process. When we reviewed our 2021 initial denial and final adverse determination data, we found that BH had issued 0 initial denials for this reason and 0 FADs for this reason and PH had issued approximately 3-5 per week initial denials for this reason and approximately 3- 5 per week FADs for this reason. The BH process is not more stringent than the PH M/S process. The BH and PH processes will be reviewed on a quarterly basis and workbook will be updated. In addition, we will review IAD (denials) and FAD (appeals) for this reason on a quarterly basis to ensure that the BH process is not more stringent than the PH process. Our organization has one policy and procedure governing experimental and investigational drug use

	for ALL drugs, and the policy is described below. In general, when drug criteria is being developed for a non-behavioral health medication (for example, Rituxan ({rituximab}, in additional to reviewing the FDA label for appropriate medically necessary indications/dosage/warning/contraindications, the clinical pharmacy team will also review the drug compendia listed below for any acceptable off-label uses. The team will then research and review any relevant society guidelines and other peer-reviewed medical literature for medically acceptable off-label uses and present their findings to the Pharmacy and Therapeutics committee for consideration and addition to the drug criteria. In creating drug criteria for behavioral health medications (for example, Invega Trinza) the clinical pharmacy will follow the same procedures outlined above in their process for developing clinical criteria. That is, a review of the FDA label, drug compendia, society guidelines, and any peer-reviewed medical literature would be conducted, and any acceptable off-label uses that meet our off-label policy would be presented to the Pharmacy and Therapeutics committee for consideration and addition to the drug criteria. All drug criteria (behavioral health and non-BH) are reviewed at least annually to ensure that new indications (labeled or off-label) are identified and researched accordingly, as well as any new associated guidelines and or peer-reviewed literature, so that considerations with regards to criteria updates, can be made and discussed with the Pharmacy and Therapeutics committee. The team will continue to monitor on a routine basis and asses for compliance with parity if these requirements change. In order for prescriptions for experimental/investigational products to be authorized for coverage, the company must ensure: A. Off Label Use: Off-label drug use is considered medically necessary when all of the following conditions are met: 1. The drug is approved by the FDA. AND 2. The drug is being prescribed to treat a medical condition not listed in the product label and for which medical treatment is medically necessary. AND 3. The prescribed drug use is supported in any one or more of the following: • American Hospital Formulary Service Drug Information® (AHFS®); or Thomson Reuters (Healthcare) Inc. DrugPoints® meeting each of the following: o Strength of Recommendation Class I or IIa; and o Strength of Evidence Category A or B; and o Efficacy Class I or IIa ; or

	• National Comprehensive Cancer Network (NCCN) Drug & Biologics Compendium ™ Category of Evidence and Consensus 1 or 2A; or • Two articles from major scientific or medical peer-reviewed journals (excluding case reports, letters, posters, and abstracts), or published studies having validated and uncontested data, which support the proposed use for the specific medical condition as safe and effective. o Examples of accepted journals include, but are not limited to, Journal of American Medical Association, New England Journal of Medicine, and Lancet. o Accepted study designs include, but are not limited to, randomized, double blind, placebo controlled clinical trials. If the off-label drug use is determined to be medically necessary, its use shall also be determined to be "non-investigational" for the purposes of benefit determination. B. Orphan Drug Use: Use of an orphan drug is considered medically necessary when it receives FDA Orphan Drug designation and approval for marketing ("Designated/Approved"). C. Investigational Drugs for Compassionate Use, Parallel Track or under a Treatment IND: These drugs have not received FDA new drug approval and therefore are not reimbursable under Medicaid. D. Emergency Use Authorizations: The company may consider emergency use of a drug as medically appropriate when the following criteria are met: 1. The FDA has issued an EUA. 2. Use must not be outside the scope of, or inconsistent with, the conditions of the EUA Responsible Party (Pharmacy)- [redacted], WNY Pharmacy Program Manager Responsible Party (HCM & BH): Primary – [redacted] – Manager BH, Secondary [redacted], Program Manager & [redacted], HCM Director Ongoing Monitoring: Compliance with state and federal requirements for provision of comparable coverage for benefits to treat mental health and substance use disorder is monitored via the Mental Health and Substance Use Disorder Parity Compliance Program. Written policies and procedures that describe how parity compliance is assessed, monitored, and managed were established effective on December 28, 2021, including the system for the ongoing assessment of parity compliance. By December 31, 2021 and annually thereafter, the plan will submit a written certification to the Commissioner that these requirements have been satisfactorily met. This

	certification will be in the form prescribed by the Commissioner and signed by the plan president or the Compliance Director. A copy will be provided to the NY Board of Managers. Status of parity findings will be reported in quarterly Behavioral Health Quality Management Committee meetings beginning August 31st, 2021. The Committee will also review any plan of action that needs to be submitted to ensure parity compliance, if the comparative analysis reveals that a BH process is more stringent than PH. Plan of Action will include the following: • Identify any processes that appear to be more stringent • Identify changes that need to be implemented to ensure parity • Identify specific due dates and business owners for tracking • Identify the methodology to complete a parity analysis once the changes are implemented to ensure parity compliance Updates and findings from the BHQMC will be reported to executive leadership at the Plan Compliance Committee which meets no less than four times per year. If any comparative analysis identifies an NQTL to be noncompliant, as performed per the plan of correction by Highmark, Highmark will conduct reeducation and training of all applicable associates and updates to associated resource documents to ensure compliance. Responsible Parties:Primary: [redacted], Director, Quality Management Secondary: [redacted]t, Program Manager **Plan Response (Fail First IP/OP BH):** The plan does not have any requirements or processes in place that a member has to have tried a lower level of care within BH and failed at this level to access a higher level of care. Neither the BH benefits nor the BH Medical Necessity Criteria has any requirement to this effect. As this does not apply to BH assessing whether we are less stringent than PH or M/S is not applicable. The BH and PH processes will be reviewed on a quarterly basis and workbook will be updated. Plan Response (Pharmacy): Fail First; Pharmacy: Highmark's PBM has a Pharmacy & Therapeutics

	Committee (P&T) which reviews the clinical benefits of a medication and a Value Added Committee (VAC) which reviews the pharmaco-economic values of medications. If it is deemed via the P&T committee that the clinical applicability of a set of drugs is equivalent, the VAC may elect to employ step therapy based on pharmacoeconomic factors. Clinical review of medications is done using grading studies with the Delfini method and evidence-based medicine. All medications are reviewed consistent with our P&T charter processes. As an example, the P&T committee may approve a step therapy criteria for a non-behavioral health drug/class of drugs, such as topical NSAIDs, because these drugs are deemed to all be clinically equivalent (i.e., Pennsaid, Voltaren gel, Flector Patch) for the majority of indications. The P&T committee may also approve any applicable step therapy overrides in cases where one of these drugs may have a unique use that the others do not have. After which, the VAC committee may select one of these topical NSAIDs (for example, Voltaren gel) to be the preferred agent in the class. However, the clinical override would also be implemented to ensure any unique uses/circumstances are accounted for. An override may also exist for individuals that are stable on their current therapy. From there, at the point-of-sale, if an individual is requesting Pennsaid (diclofenac topical solution) for an indication that Voltaren gel also covers, the individual would be required to try and fail or have an intolerance/contraindication to Voltaren gel first (unless they are already stabilized on Pennsaid). If the individual is requesting Pennsaid for an indication not covered by Voltaren gel, then the request for Pennsaid would be approved based on the override criteria. The same procedure outlined above for non-BH drugs/classes of drugs would also be followed for behavioral health drugs. For example, the P&T committee may approve a step therapy criteria for SSRIs because they deem them to be clinically equivalent for the majority of indications. The committee may also approve any applicable step therapy overrides in cases where one of these drugs may have a unique use that the others do not have. After which, the VAC committee may select one of these SSRIs (for example, sertraline) to be the preferred agent in the class. Any clinical overrides would also be implemented in the process. At the point-of-sale, if an individual is requesting Viibryd for an indication that sertraline also covers, they would then be required to try and fail or have an intolerance/contraindication to sertraline first (unless they are already stabilized on Viibryd). If the individual is requesting Viibryd for an indication not covered by sertraline, then the request for Viibryd would be approved based on the override criteria. The team will

	continue to monitor on a routine basis and assess for compliance with parity if these requirements change. Based on FDA labeled administration, drug compendia, and/or peer-reviewed medical literature, drug criteria for certain medications, such as Invega Hafyera, may require that the individual have completed a prior course of treatment or initiated a specific course of treatment due to clinical/safety concerns prior to coverage of Invega Hafyera. For example, the FDA label for Invega Hafyera requires that individuals be adequately treated with either Invega Sustenna for a least 4 months, or Invega Trinza for at least one-month cycle, prior to being treated with Invega Hafyera. This information is presented for discussion to the Pharmacy and Therapeutics committee for consideration and addition to the criteria. During the prior authorization process, an individual is requesting Invega Hafyera (and treatment naïve to Invega Hafyera) would be required to have an adequate trial of Invega Trinza or Invega Sustenna (as detailed per label) before Invega Hafyera could be approved. The process for the development of drug criteria for non-behavorial health medications as it relates to prior courses of treatment is exactly the same. For example, if an individual is requesting Rituxan Hycela (and treatment naïve), they would be required to have at least 1 infusion of Rituxan IV before Rituxan Hycela (SC) could be approved. This criteria would have been presented to the Pharmacy and Therapeutics committee for consideration and addition to the criteria per FDA label due to clinical/safety concerns. The team will continue to monitor on a routine basis and assess for compliance with parity if these requirements change. Responsible Party: [redacted], WNY Pharmacy Program Manager Ongoing Monitoring: Compliance with state and federal requirements for provision of comparable coverage for benefits to treat mental health and substance use disorder is monitored via the Mental Health and Substance Use Disorder Parity Compliance Program. Written policies and procedures that describe how parity compliance is assessed, monitored, and managed were established effective on December 28, 2021, including the system for the ongoing assessment of parity compliance. By December 31, 2021 and annually thereafter, the plan will submit a written certification to the Commissioner that these requirements have been satisfactorily met. This certification will be in the form prescribed by the Commissioner and signed by the plan president or the

	Compliance Director. A copy will be provided to the NY Board of Managers. Status of parity findings will be reported in quarterly Behavioral Health Quality Management Committee meetings beginning August 31st, 2021. The Committee will also review any plan of action that needs to be submitted to ensure parity compliance, if the comparative analysis reveals that a BH process is more stringent than PH. Plan of Action will include the following: • Identify any processes that appear to be more stringent • Identify changes that need to be implemented to ensure parity • Identify specific due dates and business owners for tracking • Identify the methodology to complete a parity analysis once the changes are implemented to ensure parity compliance Updates and findings from the BHQMC will be reported to executive leadership at the Plan Compliance Committee which meets no less than four times per year. If any comparative analysis identifies an NQTL to be noncompliant, as performed per the plan of correction by Highmark, Highmark will conduct reeducation and training of all applicable associates and updates to associated resource documents to ensure compliance. Responsible Parties: Primary: [redacted], Director, Quality Management Secondary: [redacted], Program Manager **Plan Response: Provider Credentialing** The Plan's Credentialing Program and Criteria is applied across all provider types without regard to whether or not a practitioner is a BH or a PH M/S provider. All practitioners (both BH and PH M/S) must meet the same criteria and undergo the same credentialing process based on professional competency and criteria which includes, but is not limited to, a review of state licensure, education, training, board certification and a review of adverse events such as state licensure or federal sanctions. The Plan builds its program under the guidelines of the National Committee of Quality Assurance (NCQA), CMS regulations and state regulations, in this case, NY DOH Article 44.

	Determinations as to which practitioners require additional individual review by the Credentials Committee are made according to predetermined criteria related to professional conduct and competence. Credentials Committee decisions are based on issues of professional conduct and competence as reported and verified through the credentialing process. In addition, annually the Plan will audit credentialing files to identify discriminatory practices. Should discriminatory practices be identified through audit or through other means, the Plan will take appropriate action(s) to track and eliminate those practices. Results from the most recent discrimination audit indicated no concerns with adherence to the Plan's Non-Discrimination Policy requirements. Responsible Party: Primary: [redacted], CPCS, Credentialing Manager II -Secondary: [redacted], WNY Provider Relations Director Ongoing Monitoring: Compliance with state and federal requirements for provision of comparable coverage for benefits to treat mental health and substance use disorder is monitored via the Mental Health and Substance Use Disorder Parity Compliance Program. Written policies and procedures that describe how parity compliance is assessed, monitored, and managed were established effective on December 28, 2021, including the system for the ongoing assessment of parity compliance. By December 31, 2021 and annually thereafter, the plan will submit a written certification to the Commissioner that these requirements have been satisfactorily met. This certification will be in the form prescribed by the Commissioner and signed by the plan president or the Compliance Director. A copy will be provided to the NY Board of Managers. Status of parity findings will be reported in quarterly Behavioral Health Quality Management Committee meetings beginning August 31st, 2021. The Committee will also review any plan of action that needs to be submitted to ensure parity compliance, if the comparative analysis reveals that a BH process is more stringent than PH. Plan of Action will include the following: • Identify any processes that appear to be more stringent

	• Identify changes that need to be implemented to ensure parity • Identify specific due dates and business owners for tracking • Identify the methodology to complete a parity analysis once the changes are implemented to ensure parity compliance Updates and findings from the BHQMC will be reported to executive leadership at the Plan Compliance Committee which meets no less than four times per year. If any comparative analysis identifies an NQTL to be noncompliant, as performed per the plan of correction by Highmark, Highmark will conduct reeducation and training of all applicable associates and updates to associated resource documents to ensure compliance. Responsible Parties: Primary: [redacted], Director, Quality Management Secondary: [redacted] Program Manager

MCO Representative's Signature 	Date January 11, 2022
Title RVP & President, Medicaid Health Plan	

MCO Representative's Signature	Date
Title	

Statement of Findings: Reissued
Highmark Western and Northeastern New York, Inc.
(f/k/a HealthNow New York, Inc.)
Mental Health Parity and Addiction Equity Act Testing of Phase III Workbooks
March 11, 2020 - November 30, 2020
Survey ID#: -1302543068

Parity Compliance

10.2 Compliance with State Medicaid Plan, Applicable Laws and Regulations
h.) Mental Health and Substance Use Disorder Benefits Parity Requirements
ii.) The Contractor shall comply with mental health and substance use disorder benefits parity requirements for financial requirements and treatment limitations specified in 42 CFR 438.910.

18.5 Reporting Requirements
a) The Contractor shall submit the following reports to SDOH (unless otherwise specified). The Contractor will certify the data submitted pursuant to this section as required by SDOH. The certification shall be in the manner and format established by SDOH and must attest, based on best knowledge, information, and belief to the accuracy, completeness and truthfulness of the data being submitted.
xxii) Mental Health and Substance Use Disorder Parity Reporting Requirements
Upon request by the SDOH, OMH or OASAS the Contractor shall prepare and submit documentation and reports, in a form and format specified by SDOH, OMH or OASAS, necessary for the SDOH, OMH or OASAS to establish and demonstrate compliance with 42 CFR 438 Subpart K, and applicable State statute, rules and guidance.

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.; Mental Health Parity and Addiction Equity Act of 2008, (P.L. 110-345); for Contractors operating in New York City, the New York City Health Code; and all other applicable legal and regulatory requirements in effect at the time that this Agreement is signed and as adopted or amended during the term of this Agreement. The parties agree that this Agreement shall be interpreted according to the laws of the State of New York.

Finding:

Statement of Findings: Reissued
Highmark Western and Northeastern New York, Inc.
(f/k/a HealthNow New York, Inc.l
Mental Health Parity and Addiction Equity Act Testing of Phase III Workbooks
March 11, 2020 - November 30, 2020
Survey ID #: **-1302543068**

Based on the review of Highmark Western and Northeastern New York, Inc.'s (f/k/a Highmark New York, Inc.) (Highmark) Phase III 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, (MHPAEA), P.L. 110-343, for 5 of 10 NQTLs examined; retrospective review, outlier review, experimental/investigational determinations, fail first and provider credentialing.

Specifically, Highmark failed to provide all information and substantive comparative analyses for retrospective review, experimental/investigational determinations, and provider credentialing in Steps 2 through 5 in the inpatient and outpatient benefit classifications. The MCO also failed to provide all information and substantive comparative analyses in Steps 2 through 5 for outlier review (excluding Step 2), experimental/investigational determinations, and fail first in the prescription drugs benefit classification and provider credentialing in the emergency care benefit classification.

Plan Response – Retrospective Reviews:
Retrospective reviews are requests for authorization by a provider after services have been delivered. Both Inpatient and Outpatient (IP and OP) requests for Behavioral Health (BH) services are accepted and reviewed by the plan. BH does not render any administrative denials for late notification. Medical/Surgical (M/S) do issue administrative denials for late notification for certain services. The plan runs authorization and denial reports on an ongoing basis and the BH team has not issued an administrative denial for any requests related to retrospective reviews. On receiving the request, a BH clinician reviews for medical necessity. Associates who review these requests and render a clinical decision are licensed clinicians within both the BH and Physical Health (PH) team. Both the BH and PH teams have to meet the same standards for notification. The BH retrospective review process for both IP and OP are not more stringent than the PH side. The BH and PH processes will be reviewed on a quarterly basis and workbook will be updated.

Responsible party: Primary: [redacted] – BH Manager; Secondary – [redacted] – BH Program Manager

Ongoing Monitoring: Compliance with state and federal requirements for provision of comparable coverage for benefits to treat mental health and substance use disorder is monitored via the Mental Health and Substance Use Disorder Parity Compliance Program.

Written policies and procedures that describe how parity compliance is assessed, monitored, and managed were established effective on December 28, 2021, including the system for the ongoing assessment of parity compliance. By December 31, 2021 and annually thereafter, the plan will submit a written certification to the Commissioner that these requirements have been satisfactorily met. This certification will be in the form prescribed by the Commissioner and signed by the plan president or the Compliance Director. A copy will be provided to the NY Board

of Managers.

Status of parity findings will be reported in quarterly Behavioral Health Quality Management Committee meetings beginning August 31st, 2021. The Committee will also review any plan of action that needs to be submitted to ensure parity compliance, if the comparative analysis reveals that a BH process is more stringent than PH.

Plan of Action will include the following:

- Identify any processes that appear to be more stringent
- Identify changes that need to be implemented to ensure parity
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- Identify the methodology to complete a parity analysis once the changes are implemented to ensure parity compliance

Updates and findings from the BHQMC will be reported to executive leadership at the Plan Compliance Committee which meets no less than four times per year.

If any comparative analysis identifies an NQTL to be noncompliant, as performed per the plan of correction by Highmark, Highmark will conduct reeducation and training of all applicable associates and updates to associated resource documents to ensure compliance.

Responsible Parties: Primary: [redacted], Director, Quality Management Secondary: [redacted] Program Manager

Plan Response: Outlier Review

Our process for IP has changed since our submission. The plan does not have an outlier management program in place currently. The plan has submitted a proposed program to the state and if approved, this will be implemented in 2022/2023. Once a process is approved and ready for implementation associates will be trained on the revised processes no later than 30 days of finalization. This training will be completed at weekly Huddle meetings held every Wednesday. Additionally, all teams within BH will again review their focused process at smaller team meetings & huddles. Documentation of training will be maintained and tracked for completion at least annually. Since we currently do not have an outlier program in place for BH IP or BH OP, assessing whether we are less stringent than PH or M/S is not applicable. The BH and PH processes will be reviewed on a quarterly basis and workbook will be updated.

Responsible party: Primary: [redacted] – BH Manager; Secondary – [redacted], Program Manager

Plan Response (Pharmacy): The workbook was reviewed and updated based on state feedback. All drugs are at parity with respect to the above policies referencing ProDUR and rDUR as outlined within the workbook responses. For future NQTL surveys, we will follow workbook reporting prompts to demonstrate that the processes, strategies, evidentiary standards, and other factors used in designing and operationalizing the NQTL for MH/SUD benefits are comparable to those for M/S benefits, by using side-by-side comparison of sample medications. The team will continue to monitor on a routine basis and assess for compliance with parity.

Responsible Party: [redacted], WNY Pharmacy Program Manager

Ongoing Monitoring: Compliance with state and federal requirements for provision of comparable coverage for benefits to treat mental health and substance use disorder is monitored via the Mental Health and Substance Use Disorder Parity Compliance Program.

Written policies and procedures that describe how parity compliance is assessed, monitored, and managed were established effective on December 28, 2021, including the system for the ongoing assessment of parity compliance. By December 31, 2021 and annually thereafter, the plan will submit a written certification to the Commissioner that these requirements have been satisfactorily met. This certification will be in the form prescribed by the Commissioner and signed by the plan president or the Compliance Director. A copy will be provided to the NY Board of Managers.

Status of parity findings will be reported in quarterly Behavioral Health Quality Management Committee meetings beginning August 31st, 2021. The Committee will also review any plan of action that needs to be submitted to ensure parity compliance, if the comparative analysis reveals that a BH process is more stringent than PH.

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Updates and findings from the BHQMC will be reported to executive leadership at the Plan Compliance Committee which meets no less than four times per year.

If any comparative analysis identifies an NQTL to be noncompliant, as performed per the plan of correction by Highmark, Highmark will conduct reeducation and training of all applicable associates and updates to associated resource documents to ensure compliance.

Responsible Parties: Primary: [redacted] Director, Quality Management Secondary: [redacted], Program Manager

Plan Response: Experimental/Investigational Determinations

These requests are reviewed by a Medical Director on the BH side and a Medical Director on the PH – M/S side. If the services are denied by the Medical Director, then both the BH and PH teams follow the same process for notification and members have the same appeal rights. If these services are appealed, both BH and PH follow the same appeal review process. When we reviewed our 2021 initial denial and final adverse determination data, we found that BH had issued 0 initial denials for this reason and 0 FADs for this reason and PH had issued approximately 3-5 per week initial denials for this reason and approximately 3- 5 per week FADs for this reason. The BH process is not more stringent than the PH M/S process.

The BH and PH processes will be reviewed on a quarterly basis and workbook will be updated. In addition, we will review IAD (denials) and FAD (appeals) for this reason on a quarterly basis to ensure that the BH process is not more stringent than the PH process.

Our organization has one policy and procedure governing experimental and investigational drug use for ALL drugs, and the policy is described below. In general, when drug criteria is being developed for a non-behavioral health medication (for example, Rituxan ({rituximab}, in additional to reviewing the FDA label for appropriate medically necessary indications/dosage/warning/contraindications, the clinical pharmacy team will also review the

drug compendia listed below for any acceptable off-label uses. The team will then research and review any relevant society guidelines and other peer-reviewed medical literature for medically acceptable off-label uses and present their findings to the Pharmacy and Therapeutics committee for consideration and addition to the drug criteria. In creating drug criteria for behavioral health medications (for example, Invega Trinza) the clinical pharmacy will follow the same procedures outlined above in their process for developing clinical criteria. That is, a review of the FDA label, drug compendia, society guidelines, and any peer-reviewed medical literature would be conducted, and any acceptable off-label uses that meet our off-label policy would be presented to the Pharmacy and Therapeutics committee for consideration and addition to the drug criteria.

All drug criteria (behavioral health and non-BH) are reviewed at least annually to ensure that new indications (labeled or off-label) are identified and researched accordingly, as well as any new associated guidelines and or peer-reviewed literature, so that considerations with regards to criteria updates, can be made and discussed with the Pharmacy and Therapeutics committee.

The team will continue to monitor on a routine basis and asses for compliance with parity if these requirements change.
In order for prescriptions for experimental/investigational products to be authorized for coverage, the company must ensure:

A. Off Label Use: Off-label drug use is considered medically necessary when all of the following conditions are met:

1. The drug is approved by the FDA. AND
2. The drug is being prescribed to treat a medical condition not listed in the product label and for which medical treatment is medically necessary. AND
3. The prescribed drug use is supported in any one or more of the following: • American Hospital Formulary Service Drug Information® (AHFS®); or Thomson Reuters (Healthcare) Inc. DrugPoints® meeting each of the following:
    - o Strength of Recommendation Class I or IIa; and
    - o Strength of Evidence Category A or B; and
    - o Efficacy Class I or IIa ; or
        - • National Comprehensive Cancer Network (NCCN) Drug & Biologics Compendium ™ Category of Evidence and Consensus 1 or 2A; or
        - • Two articles from major scientific or medical peer-reviewed journals (excluding case reports, letters, posters, and abstracts), or published studies having validated and uncontested data, which support the proposed use for the specific medical condition as safe and effective.
    - o Examples of accepted journals include, but are not limited to, Journal of American Medical Association, New England Journal of Medicine, and Lancet.
    - o Accepted study designs include, but are not limited to, randomized, double blind, placebo controlled clinical trials.

    If the off-label drug use is determined to be medically necessary, its use shall also be determined to be "non-investigational" for the purposes of benefit determination.

B. Orphan Drug Use: Use of an orphan drug is considered medically necessary when it receives FDA Orphan Drug designation and approval for marketing ("Designated/Approved").
C. Investigational Drugs for Compassionate Use, Parallel Track or under a Treatment IND: These drugs have not received FDA new drug approval and therefore are not reimbursable under Medicaid.
D. Emergency Use Authorizations: The company may consider emergency use of a drug as medically appropriate when the following criteria are met:

1. The FDA has issued an EUA.
2. Use must not be outside the scope of, or inconsistent with, the conditions of the EUA

Responsible Party (Pharmacy)- [redacted], WNY Pharmacy Program Manager

Responsible Party (HCM & BH): Primary – [redacted] – Manager BH, Secondary [redacted], Program Manager & [redacted], HCM Director

Ongoing Monitoring: Compliance with state and federal requirements for provision of comparable coverage for benefits to treat mental health and substance use disorder is monitored via the Mental Health and Substance Use Disorder Parity Compliance Program.

Written policies and procedures that describe how parity compliance is assessed, monitored, and managed were established effective on December 28, 2021, including the system for the ongoing assessment of parity compliance. By December 31, 2021 and annually thereafter, the plan will submit a written certification to the Commissioner that these requirements have been satisfactorily met. This certification will be in the form prescribed by the Commissioner and signed by the plan president or the Compliance Director. A copy will be provided to the NY Board of Managers.

Status of parity findings will be reported in quarterly Behavioral Health Quality Management Committee meetings beginning August 31st, 2021. The Committee will also review any plan of action that needs to be submitted to ensure parity compliance, if the comparative analysis reveals that a BH process is more stringent than PH.

Plan of Action will include the following:

- Identify any processes that appear to be more stringent
- Identify changes that need to be implemented to ensure parity
- Identify specific due dates and business owners for tracking
- Identify the methodology to complete a parity analysis once the changes are implemented to ensure parity compliance

Updates and findings from the BHQMC will be reported to executive leadership at the Plan Compliance Committee which meets no less than four times per year.

If any comparative analysis identifies an NQTL to be noncompliant, as performed per the plan of correction by Highmark, Highmark will conduct reeducation and training of all applicable associates and updates to associated resource documents to ensure compliance.

Responsible Parties: Primary: [redacted], Director, Quality Management Secondary: [redacted], Program Manager

Plan Response (Fail First IP/OP BH):
The plan does not have any requirements or processes in place that a member has to have tried a lower level of care within BH and failed at this level to access a higher level of care. Neither the BH benefits nor the BH Medical Necessity Criteria has any requirement to this effect. As this does not apply to BH assessing whether we are less stringent than PH or M/S is not applicable. The BH and PH processes will be reviewed on a quarterly basis and workbook will be updated.

Plan Response (Pharmacy): Fail First; Pharmacy:

Highmark's PBM has a Pharmacy & Therapeutics Committee (P&T) which reviews the clinical benefits of a medication and a Value Added Committee (VAC) which reviews the pharmaco-economic values of medications. If it is deemed via the P&T committee that the clinical applicability of a set of drugs is equivalent, the VAC may elect to employ step therapy based on pharmacoeconomic factors. Clinical review of medications is done using grading studies with the Delfini method and evidence-based medicine. All medications are reviewed consistent with our P&T charter processes. As an example, the P&T committee may approve a step therapy criteria for a non-behavioral health drug/class of drugs, such as topical NSAIDs, because these drugs are deemed to all be clinically equivalent (i.e., Pennsaid, Voltaren gel, Flector Patch) for the majority of indications. The P&T committee may also approve any applicable step therapy overrides in cases where one of these drugs may have a unique use that the others do not have. After which, the VAC committee may select one of these topical NSAIDs (for example, Voltaren gel) to be the preferred agent in the class. However, the clinical override would also be implemented to ensure any unique uses/circumstances are accounted for. An override may also exist for individuals that are stable on their current therapy. From there, at the point-of-sale, if an individual is requesting Pennsaid (diclofenac topical solution) for an indication that Voltaren gel also covers, the individual would be required to try and fail or have an intolerance/contraindication to Voltaren gel first (unless they are already stabilized on Pennsaid). If the individual is requesting Pennsaid for an indication not covered by Voltaren gel, then the request for Pennsaid would be approved based on the override criteria. The same procedure outlined above for non-BH drugs/classes of drugs would also be followed for behavioral health drugs. For example, the P&T committee may approve a step therapy criteria for SSRIs because they deem them to be clinically equivalent for the majority of indications. The committee may also approve any applicable step therapy overrides in cases where one of these drugs may have a unique use that the others do not have. After which, the VAC committee may select one of these SSRIs (for example, sertraline) to be the preferred agent in the class. Any clinical overrides would also be implemented in the process. At the point-of-sale, if an individual is requesting Viibryd for an indication that sertraline also covers, they would then be required to try and fail or have an intolerance/contraindication to sertraline first (unless they are already stabilized on Viibryd). If the individual is requesting Viibryd for an indication not covered by sertraline, then the request for Viibryd would be approved based on the override criteria. The team will continue to monitor on a routine basis and assess for compliance with parity if these requirements change.

Based on FDA labeled administration, drug compendia, and/or peer-reviewed medical literature, drug criteria for certain medications, such as Invega Hafyera, may require that the individual have completed a prior course of treatment or initiated a specific course of treatment due to clinical/safety concerns prior to coverage of Invega Hafyera. For example, the FDA label for Invega Hafyera requires that individuals be adequately treated with either Invega Sustenna for a least 4 months, or Invega Trinza for at least one-month cycle, prior to being treated with Invega Hafyera. This information is presented for discussion to the Pharmacy and Therapeutics committee for consideration and addition to the criteria. During the prior authorization process, an individual is requesting Invega Hafyera (and treatment naïve to Invega Hafyera) would be required to have an adequate trial of Invega Trinza or Invega Sustenna (as detailed per label) before Invega Hafyera could be approved. The process for the development of drug criteria for non-behavorial health medications as it relates to prior courses of treatment is exactly the same. For example, if an individual is requesting Rituxan Hycela (and treatment naïve), they would be required to have at least 1 infusion of Rituxan IV before Rituxan Hycela (SC) could be approved. This criteria would have been presented to the Pharmacy and Therapeutics committee for consideration and addition to the criteria per FDA label due to clinical/safety concerns. The team will continue to monitor on a routine basis and assess for compliance with parity if these requirements change.

Responsible Party: [redacted], WNY Pharmacy Program Manager

Ongoing Monitoring: Compliance with state and federal requirements for provision of comparable coverage for benefits to treat mental health and substance use disorder is monitored via the Mental Health and Substance Use Disorder Parity Compliance Program.

Written policies and procedures that describe how parity compliance is assessed, monitored, and managed were established effective on December 28, 2021, including the system for the ongoing assessment of parity compliance. By December 31, 2021 and annually thereafter, the plan will submit a written certification to the Commissioner that these requirements have been satisfactorily met. This certification will be in the form prescribed by the Commissioner and signed by the plan president or the Compliance Director. A copy will be provided to the NY Board of Managers.

Status of parity findings will be reported in quarterly Behavioral Health Quality Management Committee meetings beginning August 31st, 2021. The Committee will also review any plan of action that needs to be submitted to ensure parity compliance, if the comparative analysis reveals that a BH process is more stringent than PH.

Plan of Action will include the following:

- Identify any processes that appear to be more stringent
- Identify changes that need to be implemented to ensure parity
- Identify specific due dates and business owners for tracking
- Identify the methodology to complete a parity analysis once the changes are implemented to ensure parity compliance

Updates and findings from the BHQMC will be reported to executive leadership at the Plan Compliance Committee which meets no less than four times per year.

If any comparative analysis identifies an NQTL to be noncompliant, as performed per the plan of correction by Highmark, Highmark will conduct reeducation and training of all applicable associates and updates to associated resource documents to ensure compliance.

Responsible Parties: Primary: [redacted] Director, Quality Management Secondary: [redacted] Program Manager

Plan Response: Provider Credentialing

The Plan's Credentialing Program and Criteria is applied across all provider types without regard to whether or not a practitioner is a BH or a PH M/S provider. All practitioners (both BH and PH M/S) must meet the same criteria and undergo the same credentialing process based on professional competency and criteria which includes, but is not limited to, a review of state licensure, education, training, board certification and a review of adverse events such as state licensure or federal sanctions. The Plan builds its program under the guidelines of the National Committee of Quality Assurance (NCQA), CMS regulations and state regulations, in this case, NY DOH Article 44.

Determinations as to which practitioners require additional individual review by the Credentials Committee are made according to predetermined criteria related to professional conduct and competence. Credentials Committee decisions are based on issues of professional conduct and competence as reported and verified through the credentialing process.

In addition, annually the Plan will audit credentialing files to identify discriminatory practices. Should discriminatory practices be identified through audit or through other means, the Plan will take appropriate action(s) to track and eliminate those practices. Results from the most recent discrimination audit indicated no concerns with adherence to the Plan's Non-Discrimination Policy requirements.
Responsible Party: Primary: [redacted], CPCS, Credentialing Manager II -Secondary: [redacted], WNY Provider Relations Director
Ongoing Monitoring: Compliance with state and federal requirements for provision of comparable coverage for benefits to treat mental health and substance use disorder is monitored via the Mental Health and Substance Use Disorder Parity Compliance Program.

Written policies and procedures that describe how parity compliance is assessed, monitored, and managed were established effective on December 28, 2021, including the system for the ongoing assessment of parity compliance. By December 31, 2021 and annually thereafter, the plan will submit a written certification to the Commissioner that these requirements have been satisfactorily met. This certification will be in the form prescribed by the Commissioner and signed by the plan president or the Compliance Director. A copy will be provided to the NY Board of Managers.

Status of parity findings will be reported in quarterly Behavioral Health Quality Management Committee meetings beginning August 31st, 2021. The Committee will also review any plan of action that needs to be submitted to ensure parity compliance, if the comparative analysis reveals that a BH process is more stringent than PH.

Plan of Action will include the following:

- Identify any processes that appear to be more stringent
- Identify changes that need to be implemented to ensure parity
- Identify specific due dates and business owners for tracking
- Identify the methodology to complete a parity analysis once the changes are implemented to ensure parity compliance

Updates and findings from the BHQMC will be reported to executive leadership at the Plan Compliance Committee which meets no less than four times per year.

If any comparative analysis identifies an NQTL to be noncompliant, as performed per the plan of correction by Highmark, Highmark will conduct reeducation and training of all applicable associates and updates to associated resource documents to ensure compliance.

Responsible Parties: Primary: [redacted] Director, Quality Management Secondary: [redacted], Program Manager