Summary of Express Terms

This rule establishes mental health and substance use disorder parity compliance program requirements to ensure that managed care organizations (MCOs) are providing coverage for benefits for the treatment of mental health and substance use disorder that is comparable to other health benefits provided by the MCO, as required under both state and federal law. The rule requires that such programs establish corporate governance for parity compliance, identify discrepancies in coverage of services for the treatment of mental health conditions and substance use disorder, provide mental health and substance use disorder training and education for employees and agents, and ensure appropriate identification and remediation of improper practices. Pursuant to the rule, MCOs are required to provide written notification to affected enrollees and the Commissioner regarding any identified improper practice. Failure to remediate improper practices under the rule may result in a civil penalty that would be deposited in a fund established pursuant to section 99-hh of the State Finance Law.

Pursuant to the authority vested in the Commissioner of Health by section 4403 of the Public Health Law, Part 98 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended by adding a new Subpart 98-4, to be effective 90 days after publication of the Notice of Adoption in the State Register, to read as follows:

A new Subpart 98-4 is added:

98-4.1 Purpose

The purpose of this Subpart is to establish mental health and substance use disorder parity compliance program requirements to ensure that managed care organizations (MCOs) are providing coverage for benefits for the treatment of mental health and substance use disorder that is comparable to other health benefits provided by the MCO, as required under both state and federal law. This Subpart requires that such compliance programs establish corporate governance for parity compliance, identify discrepancies in coverage of services for the treatment of mental health conditions and substance use disorder, and ensure appropriate identification and remediation of improper practices.

98-4.2 Applicability

This Subpart shall apply to all MCOs offering coverage that are subject to the mental health and substance use disorder requirements under Insurance Law § 4303 and Public Health Law § 4406.

98-4.3 Definitions**.** For the purposes of this Subpart, the following definitions shall apply:

(a) *Benefit classification* means the following classifications of medical and surgical benefits and mental health and substance use disorder benefits for purposes of complying with the MHPAEA: inpatient in-network, inpatient out-of-network, outpatient in-network, outpatient out-of-network, emergency care and prescription drugs. The outpatient classification includes any subclassification of office visits.

(b) *Comparative analysis* means an analysis of the nonquantitative treatment limitations imposed on mental health or substance use disorder benefits to determine if such limitations are comparable to and applied no more stringently, both as written and in operation, than nonquantitative treatment limitations imposed on medical or surgical benefits within the same benefit classification. Comparative analysis includes the documented identification and assessment of the factors, processes, strategies, and evidentiary standards the MCO relied upon to determine the applicability and design of a nonquantitative treatment limitation and the processes and strategies the MCO used in operationalizing a nonquantitative treatment limitation to illustrate MCO compliance with MHPAEA.

(c) *Compliance program* means a mental health and substance use disorder parity compliance program.

(d) *Financial requirements* means deductibles, copayments, coinsurance, and out-of-pocket maximums.

(e) *Latency period* means the period of time that must elapse between the time at which a dose of drug is applied to a biologic system and the time at which a specified pharmacologic effect is produced.

(f) *MHPAEA* means the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, codified at 29 U.S.C. section 1185a, and its implementing regulations and sub-regulatory guidance.

(g) *Nonquantitative treatment limitation* means a qualitative limit affecting the scope or duration of benefits such as medical management standards limiting or excluding benefits based on medical necessity, or based on whether the treatment is experimental or investigational; formulary design for prescription drugs; network tier design; standards for provider admission to participate in a network, including reimbursement rates; methods for determining usual, customary, and reasonable charges; fail-first or step therapy protocols; exclusions based on failure to complete a course of treatment; and restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits.

(h) *Provider* means a physician, health care professional, or facility licensed, registered, certified, or otherwise authorized or accredited as required by state law.

(i) *Quantitative treatment limitation* means a numerical limit affecting the scope or duration of benefits.

98-4.4. Mental health and substance use disorder parity compliance program.

(a) Every MCO shall adopt and implement a compliance program that shall include at a minimum:

(1) designation of an appropriately experienced individual who shall:

(i) be responsible for assessing, monitoring, and managing parity compliance;

(ii) report directly to the MCO's chief executive officer or other senior manager; and

(iii) report no less than annually to the MCO's board of directors or other governing body, or the appropriate committee thereof, on the activities of the compliance program;

(2) written policies and procedures that implement the compliance program, and that describe how the MCO's parity compliance is assessed, monitored, and managed, including:

(i) a system for assigning each benefit to the defined benefit classifications as required by MHPAEA;

(ii) methodologies for the identification and testing of all financial requirements and quantitative treatment limitations; and

(iii) methodologies for the identification and testing, including a comparative analysis, of all non-quantitative treatment limitations that are imposed on mental health or substance use disorder benefits;

(3) methodologies for the identification and remediation of improper practices, as described in paragraph (1) of subdivision (b) of this section;

(4) a system for the ongoing assessment of parity compliance, which shall include:

(i) review of a statistically valid sample of preauthorization, concurrent, and retrospective review denials for mental health and substance use disorder benefits to ensure such determinations were consistent with the clinical review criteria approved by the commissioner of mental health or designated by the commissioner of addiction services and supports, in consultation with the superintendent of financial services and the commissioner, and that such criteria have been applied comparably to and no more stringently than criteria applied to medical or surgical benefits;

(ii) review of the comparability of coverage within each benefit classification for mental health and substance use disorder benefits to ensure that coverage for a comparable continuum of services is available for mental health and substance use disorder benefits as is available for medical or surgical benefits, including residential and outpatient rehabilitation services;

(iii) review of the percentage of services provided by out-of-network providers for mental health and substance use disorder benefits where no in-network provider

was available, compared to the percentage of services provided by out-of-network providers for medical and surgical benefits where no in-network provider was available, to ensure that the processes and strategies for the recruitment and retention of mental health and substance use disorder providers are effective in reducing disparities in out-of-network use and to ensure that there is an adequate network of mental health and substance use disorder providers to provide services on an in-network basis;

(iv) review of provider credentialing policies and procedures to ensure that the documentation and qualifications required for credentialing mental health and substance use disorder providers are comparable to and applied no more stringently than the documentation and qualifications required for credentialing medical or surgical providers and to ensure that there is an adequate network of mental health and substance use disorder providers to provide services on an in-network basis;

(v) review of the average length of time to negotiate provider agreements and negotiated reimbursement rates with network providers and methods for the determination of usual, customary and reasonable charges, to ensure that reimbursement rates for mental health and substance use disorder benefits are established using standards that are comparable to and applied no more stringently than the standards used for medical or surgical benefits and to ensure that there is an adequate network of mental health and substance use disorder providers to provide services on an in-network basis;

(vi) review of MCO policies for the automatic or systematic non-payment or down-coding of Current Procedural Terminology codes used for mental health and substance use disorder benefits to ensure that they are comparable to and applied no more than stringently than MCO policies for the automatic or systematic non-payment or down-coding of Current Procedural Terminology codes used for medical or surgical benefits;

(vii) review of all mental health and substance use disorder medications subject to nonquantitative treatment limitations, including step-therapy protocols or other preauthorization requirements, to ensure that the factors such as cost and latency periods, processes, strategies, and evidentiary standards the insurer relied upon to determine whether to apply the nonquantitative treatment limitation were comparable to and applied no more stringently than the factors, processes, strategies, and evidentiary standards the insurer relied upon to determine whether to apply nonquantitative treatment limitations, including step therapy or other preauthorization requirements, to medications to treat medical or surgical conditions;

(viii) review of any fail-first requirements applicable to mental health or substance use disorder benefits to ensure that they are comparable to and applied no more stringently than any fail-first requirements applicable to medical or surgical benefits; and

(ix) review of any restrictions based on geographic location, facility type, provider specialty, or other criteria applicable to mental health or substance use disorder

benefits to ensure that any such restriction is comparable to, and applied no more stringently than, any restriction applicable to medical or surgical benefits;

(5) a process for the actuarial certification in compliance with actuarial standards of practice, of the data used for, and the outcome of, the analyses of the financial requirements and quantitative treatment limitations applicable to mental health and substance use disorder benefits to ensure that they are no more restrictive than the predominant financial requirements and quantitative treatment limitations applied to substantially all the medical and surgical benefits;

(6) training and education for all employees, directors, or other governing body members, agents, and other representatives engaged in functions that are subject to federal or state mental health and substance use disorder parity requirements or involved in analysis as a part of the compliance program; provided that such training shall occur at least annually and shall be made a part of the orientation for such new employees, directors, or other governing body members, agents, and other representatives;

(7) the methods by which employees, directors or other governing body members, agents, and other representatives may report parity compliance issues to the individual responsible for compliance, as described in subdivision (a) of this section; provided that such methods shall include a method for anonymous and confidential reporting of potential compliance issues as they are identified; and

(8) a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including reporting and investigating potential issues and reporting to appropriate officials as provided in Labor Law §§ 740 and 741.

(b) Improper practices prohibited.

(1) The following shall be considered improper practices related to mental health and substance use disorder benefits:

(i) implementing a utilization review policy that uses different standards to determine the level of documentation required for utilization review of mental health or substance use disorder benefits, as compared to the level of documentation required for the utilization review of medical or surgical benefits, including the submission of medical records, treatment plans, or evidence of patient involvement or motivation in care or patient response to treatment;

(ii) requiring preauthorization, concurrent, or retrospective utilization review for a higher percentage of mental health or substance use disorder benefits in the absence of defined clinical or quality triggers, as compared to medical or surgical benefits;

(iii) implementing a methodology for developing and applying provider reimbursement rates for mental health or substance use disorder benefits that is not comparable to or is applied more stringently than the methodology for developing and applying provider reimbursement rates for medical or surgical benefits; and

(iv) implementing claim edits or system configurations that provide for higher rates of approval through auto-adjudication for claims for inpatient medical or surgical benefits than for inpatient mental health or substance use disorder benefits.

(2) An MCO shall monitor for and detect improper practices as described in paragraph one of this subdivision and remediate or develop a plan to remediate any improper practices as soon as practicable, but in no event later than 60 days after discovery.

(3) An MCO shall provide written notification to affected enrollees and the Commissioner and conspicuously post on the MCO's website a notice regarding any identified improper practice described in paragraph (1) of this subdivision, including a description of the MCO's efforts to remediate the improper practice or its plan for remediation, within 60 days of discovery of the improper practice.

(c) An MCO shall be responsible for and coordinate parity compliance monitoring activities with any agents and other representatives providing benefit management services or performing utilization review activities on behalf of the MCO.

(d) Annual certification.

(1) By December 31, 2021 and annually thereafter, each MCO shall electronically submit a written certification to the commissioner that the MCO satisfactorily meets the requirements of this subpart.

(2) Such certification shall be in a form prescribed by the Commissioner and signed by the MCO's chief executive officer or the individual responsible for assessing, monitoring, and managing the compliance program, attesting to the best of such individual's knowledge and belief that the information contained therein is true and that a copy of the certification has been provided to the MCO's board of directors or other governing body, or the appropriate committee thereof.

(e) Exemptions from electronic filing and submission requirements.

(1) An MCO required to make an electronic filing or a submission pursuant to this subpart may apply to the Commissioner for an exemption from the requirement that the filing or submission be electronic by submitting a written request to the Commissioner for approval at least 30 days before the MCO is required to submit to the Commissioner the particular filing or submission that is the subject of the request.

(2) The request for an exemption shall:

(i) set forth the MCO's NAIC number, if applicable;

(ii) identify the specific filing or submission for which the MCO is applying for the exemption;

(iii) specify whether the MCO is making the request for an exemption based upon undue hardship, impracticability, or good cause, and set forth a detailed explanation as to the reason that the Commissioner should approve the request; and

(iv) specify whether the request for an exemption extends to future filings or submissions, in addition to the specific filing or submission identified in paragraph (2) of this subdivision.

(3) The MCO requesting an exemption shall submit, upon the Commissioner's request, any additional information necessary for the Commissioner to evaluate the MCO's request for an exemption.

(4) The MCO shall be exempt from the electronic filing or submission requirement upon the Commissioner's written determination so exempting the MCO, where the determination specifies the basis upon which the Commissioner is granting or denying the request and to which filings or submissions the exemption applies.

(5) If the Commissioner approves an MCO's request for an exemption from the electronic filing or submission requirement, then the MCO shall make a physical filing in a form acceptable to the Commissioner.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Public Health Law (PHL) section 4403(2) states the Commissioner may adopt and amend rules and regulations to effectuate the purposes and provisions of Article 44, which governs the certification and operational requirements of managed care organizations (MCOs).

Legislative Objectives:

Insurance Law section 4303 and Public Health Law § 4406 subject MCOs to certain mental health treatment and substance use disorder parity requirements, in accordance with the federal Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (29 U.S.C. section 1185a). Chapter 58 of the Laws of 2020 added Public Health Law section 4414(2) which provides that penalties collected from MCOs for violations of Insurance Law section 4303 shall be deposited in a fund established pursuant to State Finance Law section 99-hh.

This proposed rule accords with the public policy objectives that the Legislature sought to advance in Chapter 58 by establishing compliance program requirements to ensure that MCOs certified pursuant to Article 44 of the Public Health Law are providing comparable coverage for benefits to treat mental health and substance use disorder as required under both state and federal law. The proposed rule also requires that such compliance programs establish corporate governance for parity compliance, identify discrepancies in coverage of services for the treatment of mental health conditions and substance use disorder, and ensure appropriate identification and remediation of improper practices.

Needs and Benefits:

The Department finds that access to treatment for mental health and substance use disorder services is critical to abate the opioid and suicide epidemics affecting families throughout the state. Further, in accordance with state and federal law, MCOs are required to ensure they are offering comparable coverage and benefits for the treatment of mental health conditions and substance use disorder as they are for medical and surgical conditions. It is therefore in the public interest that MCOs implement compliance programs to effectuate and monitor parity compliance.

COSTS:

Costs to the Regulated Entities:

MCOs may incur additional costs to comply with the rule. The additional costs may include compliance costs associated with establishing and maintaining a compliance program. Specifically, MCOs will be responsible for creating written policies and procedures that implement the program and describe how the MCO's parity compliance is assessed, monitored and maintained, including methodologies for the identification and testing of all financial requirements and both quantitative and non-quantitative treatment limitations. Further the compliance program requires the identification and remediation of improper practices as well as training and education for all employees and other agents engaged in functions that are subject to state mental health and substance use disorder parity requirements. Any costs associated with the parity compliance program are expected to be minimal because prior to this proposed rule, MCOs were required to have undertaken significant measures to ensure compliance with state and federal mental health and substance use disorder parity requirements.

Costs to Local Governments:

The proposed changes are not expected to impose any costs upon local governments.

Costs to the Department of Health:

This proposed rule may impose compliance costs on the Department because the Department will be required to monitor whether MCOs are maintaining a compliance program that meets the requirements of this rule, identify improper MCO practices, and assess whether MCOs are remediating improper practice in a timely manner.

Local Government Mandates:

The proposed rule does not impose any program, service, duty or responsibility on any county, city, town, village, school district, fire district or other special district.

Paperwork:

Consistent with the statutory provisions, the proposed rule will require that MCOs establish corporate governance for parity compliance, identify discrepancies in coverage of services for the treatment of mental health conditions and substance use disorder, ensure appropriate identification and remediation of improper practices, and certify annually that the requirements of the regulations have been satisfactorily met. MCOs will incur additional paperwork to comply with this rule because they will need to provide written policies and procedures that implement the compliance program within their organization. MCOs will also be required to provide written notification to affected enrollees regarding identified improper practices.

Duplication:

This rule does not duplicate, overlap, or conflict with any existing state or federal rules or other legal requirements.

Alternatives:

There are no significant alternatives to consider except to not issue this rule. The establishment of a compliance program is necessary given the addition of Public Health Law section 4414(2) and State Finance Law section 99-hh, as created by Chapter 58 of the Laws of 2020. Section 4414(2) states that penalties collected for mental health and substance use disorder parity violations shall be deposited in the compliance fund, as created under 99-hh, but it fails to define what a compliance program is. The proposed rule provides detailed requirements and minimum standards for MCOs' mental health and substance use disorder parity compliance programs. Because of the importance of these provisions in helping ensure access to mental health and substance use disorder services, the alternative of not issuing this rule was rejected,

Federal Standards:

The rule does not exceed any minimum standards of the federal government for the same or similar subject areas.

Compliance Schedule:

The regulations will take effect 90 days after publication of the Notice of Adoption in the State Register.

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REGULATORY FLEXIBILITY ANALYSIS FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS

Effect of Rule:

This rule affects managed care organizations certified pursuant to Article 44 of the Public Health Law ("MCOs"). Chapter 58 of the Laws of 2020 added Public Health Law § 4414(2) which provides that penalties collected for violations of Insurance Law sections 4303 related to mental health and substance use disorder parity compliance shall be deposited in a fund established pursuant to State Finance Law § 99-hh. This rule establishes mental health and substance use disorder parity compliance program ("compliance program") requirements to ensure that MCOs are providing comparable coverage for benefits for the treatment of mental health and substance use disorder that is comparable to other health benefits provided by the MCO, as required under both state and federal law. This rule further requires that such compliance programs establish corporate governance for parity compliance, identify discrepancies in coverage of services for the treatment of mental health conditions and substance use disorder, and ensure appropriate identification and remediation of improper practices.

This rule does not affect local governments.

Compliance Requirements:

No local government will have to undertake any reporting, recordkeeping, or other affirmative acts to comply with this rule because the rule does not apply to any local government.

An MCO who is a small business will be subject to reporting, recordkeeping, or other compliance requirements as required by a compliance program. Any additional compliance requirements should be minimal because current state and federal law already requires MCOs who are small businesses to comply with mental health parity and substance use disorder requirements.

Professional Services:

No local government will need professional services to comply with this rule because the rule does not apply to any local government. No MCO that is a small business affected by this rule should need to retain professional services, such as lawyers or auditors, to comply with this rule.

Compliance Costs:

Costs to Regulated Parties:

MCOs who are small businesses may incur additional costs to comply with this rule. The additional costs may include costs associated with the training and education of employees, members of the board of directors, other governing body members, agents, and other contracted entities engaged in functions that are subject to state mental health and substance use disorder parity requirements. In addition, MCOs will be required to provide written notification to affected enrollees regarding identified improper practices, However, any additional costs should be minimal because state and federal law already require MCOs who are small businesses to comply with mental health parity and substance use disorder requirements.

Costs to State Government and Local Government:

State government will be responsible for enforcement. Any costs for enforcement will be managed within existing resources. There will be no costs to local governments.

Economic and Technological Feasibility:

The rule does not apply to any local government; therefore, no local government should experience any economic or technological impact as a result of the rule.

MCOs who are small businesses should not incur any economic or technological impact as a result of the rule.

Minimizing Adverse Impact:

There will not be an adverse impact on any local government because the rule does not apply to any local government. This rule should not have an adverse impact on an MCO who is a small business because it uniformly affects all MCOs who are subject to the rule.

Small Business and Local Government Participation:

The Department will comply with SAPA section 202-b(6) by providing MCO associations with a summary of the rule prior to the public comment period, publishing the proposed amendment in the State Register and posting the proposed amendment on its website.

RURAL AREA FLEXIBILITY ANALYSIS

Types and estimated numbers of rural areas:

Managed care organizations certified pursuant to Public Health Law article 44 ("MCOs") affected by this rule operate in every county in this state, including rural areas as defined by State Administrative Procedure Act section 102(10).

Reporting, recordkeeping and other compliance requirements; and professional services:

MCOs, including MCOs in rural areas, may be subject to additional reporting, recordkeeping, or other compliance requirements as the implementation of a mental health and substance use disorder parity compliance program ("compliance program") requires a record of ongoing assessment and monitoring of parity compliance including methodologies for the identification and testing of all financial requirements and both quantitative and non-quantitative treatment limitations. However, these additional compliance requirements are expected to be minimal because current state and federal law already requires MCOs to comply with mental health and substance use disorder parity requirements.

An MCO in a rural area should not need to retain professional services, such as lawyers or auditors, to comply with this rule.

Costs:

MCOs may incur additional costs to comply with the rule. The additional costs may include costs associated with the aforementioned reporting, recordkeeping, and other compliance costs. Further the program requires training and education for all employees, members of the

board of directors, other governing body members, agents, and other contracted entities engaged in functions that are subject to state mental health and substance use disorder parity requirements. Any costs associated with the compliance program should be minimal because prior to this proposed rule, MCOs would have undertaken significant measures to ensure compliance with state and federal mental health and substance use disorder parity requirements.

Minimizing adverse impact:

This rule uniformly affects MCOs that are located in both rural and non-rural areas of New York State. This rule should not have an adverse impact on rural areas.

Rural area participation:

MCOs, including MCOs in rural areas, will have an opportunity to participate in the rule-making process by submitting comments after the proposed rule is published in the State Register and on the Department of Health's website.

STATEMENT IN LIEU OF

JOB IMPACT STATEMENT

No Job Impact Statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. No adverse impact on jobs and/or employment opportunities is expected as a result of these proposed regulations.