DEPARTMENT OF INSURANCE
OFFICE OF THE COMMISSIONER
1400 Health Insurance Specific Provisions

1410 Reporting Medical Management Protocols for Insurance Coverage for Serious Mental Illness and Drug And Alcohol Dependency

1.0 Purpose

The purpose of this regulation is to set forth the format and submission requirements for the mental health parity report that is required to be submitted to the Delaware Health Information Network and the Department in accordance with 18 **Del.C.** §§3343 and 3571U.

2.0 Applicability

This regulation applies to every carrier as defined in Section 4.0 of this regulation who issues a health benefit plan as defined in Section 4.0 of this regulation.

3.0 Authority

The authority for this regulation is 18 **Del.C.** §§311, 3343 and 3571U and Del. S.B. 230/Del. S.A. 1, 149th Gen. Assem. §4 (2018), and promulgated in accordance with the Delaware Administrative Procedures Act, 29 **Del.C.** Chapter 101.

4.0 Definitions

The following words and terms, when used in this regulation, have the following meaning unless the context clearly indicates otherwise:

"**Carrier**" means any entity that provides health insurance in this State. For the purposes of this section, "carrier" includes an insurance company, health service corporation, health maintenance organization, managed care organization, and any other entity providing a plan of health insurance or health benefits subject to state insurance regulation. "Carrier" also includes any third-party administrator or other entity that adjusts, administers, or settles claims in connection with a health benefit plan. “Carrier” also includes any carrier who administers a health benefit plan under 31 **Del.C**. §505(3).

“**Commissioner**” means the Insurance Commissioner of the State of Delaware.

“**Department**” means the Delaware Department of Insurance.

“**FR**” means financial requirements, and includes but is not limited to deductibles, copayments, coinsurance, and out-of-pocket maximums.

“**Health benefit plan**" means any hospital or medical policy or certificate, major medical expense insurance, health service corporation subscriber contract, or health maintenance organization subscriber contract, as defined and qualified under 18 **Del.C.** §§3343 and 3578, and any assistance provided to an individual under 31 **Del.C.** §505(3).

“**Mental health parity report**” means the report that is to be submitted to the Department and to the Delaware Health Information Network pursuant to Section 5.0 of this regulation.

“**MHPAEA**” means the Mental Health Parity and Addiction Equity Act of 2008 (29 U.S.C. § 1185a) as amended and supplemented.

“**MH/SUD benefits**” means mental health and substance use disorder benefits.

“**M/S benefits**” means medical and surgical benefits.

“**NQTL**” means non-quantitative treatment limitation, and includes but is not limited to preauthorization requirements and first-fail requirements.

“**QTL**” means quantitative treatment limitation, and includes but is not limited to lifetime limits, episode limits, and day and visit limits.

5.0 Reporting Content and Format

5.1 Each carrier shall complete a mental health parity report, using forms provided by the Department, in which the carrier shall report on the following:

5.1.1 Whether the health insurance coverage is or is not exempt from MHPAEA. If the carrier reports that the health insurance coverage is exempt from MHPAEA, the carrier shall indicate the reason for the exemption, which may include, by way of example only, retiree-only plan, excepted benefits (45 CFR § 146.145(b)), short term limited duration insurance, small employer exemption (45 CFR § 146.136(f)), or increased cost exemption (45 CFR § 146.136(g));

5.1.2 If the health insurance coverage is not exempt from MHPAEA pursuant to subsection 5.1.1 of this regulation:

5.1.2.1 How the health insurance coverage provides MH and/or SUD benefits in addition to providing M/S benefits; and

5.1.2.2 Using the data collection tool incorporated as Appendix A of this regulation, how the insurance coverage provides MH/SUD benefits in each of the following six coverage classifications in which M/S benefits are provided:

5.1.2.2.1 Inpatient, in-network;

5.1.2.2.2 Inpatient, out-of-network;

5.1.2.2.3 Outpatient, in-network;

5.1.2.2.4 Outpatient, out-of-network;

5.1.2.2.5 Emergency care; and

5.1.2.2.6 Prescription drugs.

5.1.3 If the plan includes multiple tiers in its prescription drug formulary, whether the tier classifications are based on reasonable factors (such as cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up) determined in accordance with the rules for NQTLs at 45 CFR 146.136(c)(4)(i), and without regard to whether the drug is generally prescribed for MH/SUD or M/S benefits. To comply with this reporting requirement, a carrier shall explain how the plan's tiering factors for MH/SUD prescription drugs are comparable to and are applied no more stringently than the tiering factors for M/S prescription drugs.

5.1.4 If the plan includes multiple network tiers of in-network providers, whether the tiering is based on reasonable factors (such as quality, performance, and market standards) determined in accordance with the rules for NQTLs at 45 CFR 146.136(c)(4)(i), and without regard to whether a provider provides services with respect to MH/SUD benefits or M/S benefits. To comply with this reporting requirement a carrier shall explain how the plan's tiering factors for MH/SUD network tiers are comparable to and are applied no more stringently than the tiering factors for M/S network tiers.

5.1.5 Whether the plan complies with the parity requirements for aggregate lifetime and annual dollar limits, including the prohibition on lifetime dollar limits or annual dollar limits for MH/SUD benefits that are lower than the lifetime or annual dollar limits imposed on M/S benefits. To comply with this reporting requirement, a carrier shall list the services subject to lifetime or annual limits, separated into MH/SUD and M/S benefits.

5.1.6 Whether the plan imposes any FR or QTLs on MH/SUD benefits in any classification that is more restrictive than the predominant FR or QTL of that type that applies to substantially all M/S benefits in the same classification. To comply with this reporting requirement a carrier shall demonstrate compliance with this standard by completing the data collection tool incorporated as Appendix A of this regulation by reference;

5.1.7 Whether the plan applies any cumulative financial requirements or cumulative QTL for MH/SUD benefits in a classification that accumulates separately from any cumulative financial requirement or QTL established for M/S benefits in the same classification. To demonstrate compliance with this standard, the carrier shall complete the data collection tool incorporated as Appendix A to this regulation;

5.1.8 Whether the plan imposes NQTLs on MH/SUD benefits in any classification. If so, the carrier shall demonstrate compliance with parity requirements by completing the data collection tool incorporated as Appendix A of this regulation. For purposes of this subsection 5.1.8, examples of NQTLs include but are not limited to:

- Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;
- Prior authorization and ongoing authorization requirements;
- Concurrent review standards;
- Formulary design for prescription drugs;
- For plans with multiple network tiers (such as preferred providers and participating providers), network tier design;

- Standards for provider admission to participate in a network, including reimbursement rates;
- Plan or insurer's methods for determining usual, customary and reasonable charges;
- Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as "fail-first" policies or "step therapy" protocols);
- Restrictions on applicable provider billing codes;
- Standards for providing access to out-of-network providers;
- Exclusions based on failure to complete a course of treatment;
- Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan; and
- Any other non-numerical limitation on MH/SUD benefits; and

5.1.9 Whether the carrier complies with MHPAEA disclosure requirements including:

5.1.9.1 Criteria for medical necessity determinations for MH/SUD benefits; and

5.1.9.2 The reasons for any denial of benefits of any kind.

5.2 Nothing in this Section shall supersede any federal or State law governing the privacy of health information.

6.0 Report submission deadlines and deadline extension request requirements

6.1 Each carrier who is required to submit a mental health parity report pursuant to this regulation shall submit its initial report on or before July 1, 2019.

6.2 Each carrier who is required to submit a mental health parity report pursuant to this regulation shall submit an amended report 30 calendar days after the close of any year during which the carrier made significant changes to how it designs and applies its medical management protocols.

6.3 One copy of each report required to be prepared in accordance with this Regulation shall be submitted to each of the following addresses:

Delaware Health Information Network
Attn.: Mental Health Parity Report
107 Wolf Creek Blvd. #2
Dover, DE 19901

Delaware Department of Insurance
Attn: Mental Health Parity Report
1351 West North Street Suite 101
Dover, DE 19904

6.4 A carrier may request from the Commissioner an extension of the deadline for submission of the initial report to be submitted pursuant to subsection 6.1 of this regulation, and any subsequent reports to be submitted pursuant to subsection 6.2 of this regulation for due cause. To request an extension pursuant to this subparagraph, the carrier shall, no later than 30 days prior to the reporting deadline, petition the Commissioner for a reporting deadline extension, with a copy of the request to the Delaware Health Information Network, stating the reasons for the extension request.

6.4.1 No reporting deadline shall be extended for a period longer than 60 days.

6.4.2 If the Commissioner fails to affirmatively approve or disapprove an extension request within 30 days of receipt of the request, the request shall be deemed approved.

6.4.3 The Commissioner may extend the 30-day review period for not more than 30 additional days by providing the carrier with written notice of the extension before the expiration of the initial 30-day review period.

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7.0 Enforcement Authority

7.1 To ensure compliance with the provisions of this regulation and to protect Delaware health care consumers, the Commissioner may, in his or her discretion, examine the business and financial affairs of a carrier doing business in this state by utilizing the powers granted by 18 **Del.C.** §§320, 3343(g)(5), 3571U(a)(5), and other provisions of Title 18 as may be applicable.

7.2 Any person or entity who violates any provision of this regulation shall be subject to the penalties provided in 18 **Del.C.** Chapter 3, and such other provisions of Title 18 as may be applicable.

8.0 Severability

If any provision of this regulation, or the application thereof to any person or circumstance, is held invalid, such invalidity shall not affect other provisions or applications of this regulation which can be given effect without the invalid provision or application, and to that end the provisions of this regulation are severable.

9.0 Effective Date

This regulation shall be effective on June 11, 2019.

APPENDIX A
DATA COLLECTION TOOL FOR MENTAL HEALTH PARITY ANALYSIS

Most parity analysis examines benefits by comparing MH/SUD to M/S within a classification. 45 CFR 146.136(c)(2)(i). The exception is aggregate lifetime or annual dollar limits (to the extent the plan is not prohibited from imposing such limits under Federal or State law), which are examined for the plan as a whole. See 45 CFR 146.136(b). The following is intended to simplify data collection for parity analysis at the classification level.

A-1 GUIDANCE FOR PLACING BENEFITS INTO CLASSIFICATIONS:

MH/SUD and M/S benefits must be mapped to one of six classifications of benefits: (1) inpatient in-network, (2) inpatient out-of-network, (3) outpatient in-network, (4) outpatient out-of-network, (5) prescription drugs, and (6) emergency care (see subsection 5.1.3 of this regulation and 45 CFR 146.136(c)(2)(ii)):

- The "inpatient" classification typically refers to services or items provided to a beneficiary when a physician has written an order for admission to a facility, while the "outpatient" classification refers to services or items provided in a setting that does not require a physician's order for admission and does not meet the definition of emergency care.
- "Office visits" are a permissible sub-classification separate from other outpatient services.
- The term "emergency care" typically refers to services or items delivered in an emergency department setting or to stabilize an emergency or crisis, other than in an inpatient setting. *See* 18 **Del.C.** Chapters 33 and 35 concerning emergency care standards.
- Some benefits, for example lab and radiology, may fit into multiple classifications depending on whether they are provided during an inpatient stay, on an outpatient basis, or in the emergency department.
- Insurers should use the same decision-making standards to classify all benefits, so that the same standard applies to M/S and MH/SUD benefits. For example, if a plan classifies care in skilled nursing facilities and rehabilitation hospitals for M/S benefits as inpatient benefits, it must classify covered care in residential treatment facilities for MH/SUD benefits as inpatient benefits.

A-2 FINANCIAL REQUIREMENTS AND QUANTITATIVE TREATMENT LIMITATIONS:

Types of FRs include deductibles, copayments, coinsurance, and out-of-pocket maximums. See 45 CFR 146.136(c)(1)(ii). Types of QTLs include annual, episode, and lifetime day and visit limits, for example number of treatments, visits, or days of coverage. See 45 CFR 146.136(c)(1)(ii). A two-part analysis applies to FRs and QTLs. In general, MHPAEA regulations require that any FR or QTL imposed on MH/SUD benefits not be more restrictive than the predominant level of financial requirement or treatment limitation of that type that applies to substantially all medical/surgical benefits in a classification.

If the plan applies a cumulative FR or QTL (a FR or QTL that determines whether or to what extent benefits are provided based on accumulated amounts), the FR or QTL must not accumulate separately from any established for M/S benefits in a classification.

FINANCIAL REQUIREMENTS

Benefit Plan Design(s) Identifier(s): Submit a separate form for each benefit plan design. Plan Name: Date: Contact Name: Telephone Number: Email: Line of Business (HMO, EPO, POS, PPO): Contract Type (large group, small group, individual): Benefit Plan Effective Date:						
	Inpatient In-Network (if network tiers, may separate into tiers in accordance with 45 CFR 146.136 (c)(3)(iii)(B)).	Inpatient Out-of- Network	Outpatient In-Network (Issuer may choose to have sub-classifications for Outpatient Office Visits, and Other Outpatient Services) (if network tiers, may separate into tiers in accordance with 45 CFR 146.136 (c)(3)(iii)(B))	Outpatient Out-of-Network (Issuer may choose to have sub-classifications for Outpatient Office Visits, and Other Outpatient Services)	Emergency Care	Prescription Drugs
Does the plan provide MH/ SUD benefits?						
Does the plan provide M/S benefits?						
Total dollar amount of ALL plan payments for M/S benefits expected to be paid for the relevant plan year						
List each financial requirement that applies to the classification for MH/SUD benefits.						

For each type of financial requirement that applies to MH/ SUD benefits, list the expected percentage of plan payments for M/S benefits in each classification that are subject to that same type of financial requirement.						
For each level of each type of financial requirement that applies to at least 2/3rds of all M/S/ benefits in the classification, list the expected percentage of plan payments for M/S benefits subject to that financial requirement, that are subject to that level.						
Does the plan impose a separate cumulative financial requirement or QTL for MH/ SUD benefits that accumulates separately from any cumulative financial requirement or QTL for M/S benefits?						

QUANTITATIVE TREATMENT LIMITATIONS

Benefit Plan Design(s) Identifier(s): Submit a separate form for each benefit plan design. Plan Name: Date: Contact Name: Telephone Number: Email: Line of Business (HMO, EPO, POS, PPO): Contract Type (large group, small group, individual): Benefit Plan Effective Date:						
	Inpatient In-Network (if network tiers, may separate into tiers in accordance with 45 CFR 146.136 (c)(3)(iii)(B)).	Inpatient Out-of- Network	Outpatient In-Network (Issuer may choose to have sub-classifications for Outpatient Office Visits, and Other Outpatient Services) (if network tiers, may separate into tiers in accordance with 45 CFR 146.136 (c)(3)(iii)(B))	Outpatient Out-of-Network (Issuer may choose to have sub-classifications for Outpatient Office Visits, and Other Outpatient Services)	Emergency Care	Prescription Drugs
List each QTL that applies to the classification for MH/SUD benefits.						
For each type of QTL that applies to MH/ SUD benefits, list the expected percentage of plan payments for M/S benefits in each classification that are subject to that same type of QTL.						

For each level of each type of QTL that applies to at least 2/3rds of all M/S benefits in the classification, list the expected percentage of plan payments for M/S benefits subject to that QTL, that are subject to that level.						

A-3 NON-QUANTITATIVE TREATMENT LIMITATIONS:

NQTLs include but are not limited to medical management techniques such as step therapy and pre-authorization requirements. Coverage cannot impose a NQTL with respect to MH/SUD benefits in any classification unless, under the terms of the plan as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the NQTL to MH/SUD benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation with respect to M/S benefits in the classification. Note that not every NQTL needs an evidentiary standard. There is flexibility under MHPAEA for plans to use NQTLs. The focus is on finding out what processes and standards the plan actually uses.

All plan standards that are not FRs or QTLs and that limit the scope or duration of benefits for services are subject to the NQTL parity requirements. This includes restrictions such as geographic limits, facility-type limits, and network adequacy.

The following data collection chart is modeled after a tool used in federal MHPAEA examinations. Insurers who have completed "Table 5" for NQTLs may substitute those documents for completion of this chart.

NON-QUANTITATIVE TREATMENT LIMITATIONS
Benefit Plan Design(s) Identifier(s): Submit a separate form for each benefit plan design. Plan Name: Date: Contact Name: Telephone Number: Email: Line of Business (HMO, EPO, POS, PPO): Contract Type (large group, small group, individual): Benefit Plan Effective Date:

Area	**Medical/Surgical Benefits** *Summarize the plan's applicable NQTLs, including any variations, by benefit.*	**Mental Health/Substance Use Disorder Benefits** *Summarize the plan's applicable NQTLs, including any variations, by benefit.*	**Explanation** *Describe the processes, strategies, evidentiary standards or other factors used to apply the NQTLs. Explain how the application of these factors is consistent with 45 CFR § 146.136(c)(4). Provide the relevant pages of the documents in which the NQTLs are described and list this documentation in the space provided below.*
A. Definition of Medical Necessity *What is the definition of medical necessity?*			
B. Prior-authorization Review Process *Include all services for which prior authorization is required. Describe any step therapy or "fail first" requirements and requirements for submission of treatment request forms or treatment plans.* Inpatient, In-Network:			
Outpatient, In-Network: Office Visits:			
Outpatient, In-Network: Other Outpatient Items and Services:			
Inpatient, Out-of-Network:			
Outpatient, Out-of-Network: Office Visits:			
Outpatient, Out-of-Network: Other Items and Services:			

C. Concurrent Review Process, including frequency and penalties for all services. *Describe any step therapy or "fail first" requirements and requirements for submission of treatment required forms or treatment plans.* Inpatient, In-Network:			
Outpatient, In-Network: Office Visits:			
Outpatient, In-Network: Other Outpatient Items and Services:			
Inpatient, Out-of-Network:			
Outpatient, Out-of-Network: Office Visits:			
Outpatient, Out-of-Network: Other Items and Services:			
D. Retrospective Review Process, including timeline and penalties. Inpatient, In-Network:			
Outpatient, In-Network: Office Visits:			
Outpatient, In-Network: Other Outpatient Items and Services:			
Inpatient, Out-of-Network:			
Outpatient, Out-of-Network: Office Visits:			
Outpatient, Out-of-Network: Other Items and Services:			
E. Emergency Services			
F. Pharmacy Services *Include all services for which prior authorization is required, any step therapy or "fail first" requirements, any other NQTLs.* Tier 1:			
Tier 2:			
Tier 3:			
Tier 4:			
G. Prescription Drug Formulary Design Describe how formulary are decisions made for the diagnosis and medically necessary treatment of medical, mental health and substance use disorder conditions.			

Describe the pertinent pharmacy management processes, including, but not limited to, cost-control measures, therapeutic substitution, and step therapy.			
What disciplines, such as primary care physicians (internists and pediatricians) and specialty physicians (including psychiatrists) and pharmacologists, are involved in development of the formulary for medications to treat medical, mental health and substance use disorder conditions?			
H. Case Management What case management services are available?			
What case management services are required?			
What are the eligibility criteria for case management services?			
I. Process for Assessment of New Technologies Definition of experimental/ investigational:			
Qualifications of individuals evaluating new technologies:			
Evidence consulted in evaluating new technologies:			
J. Standards for Provider Credentialing and Contracting Is the provider network open or closed?			
What are the credentialing standards for physicians?			
What are the credentialing standards for licensed non-physician providers? *Specify type of provider and standards; e.g., nurse practitioners, physician assistants, psychologists, clinical social workers?*			
What are the credentialing/ contracting standards for unlicensed personnel; e.g., home health aides, qualified autism service professionals and paraprofessionals?			

K. Exclusions for Failure to Complete a Course of Treatment Does the plan exclude benefits for failure to complete treatment?			
L. Restrictions that Limit Duration or Scope of Benefits for Services Does the plan restrict the geographic location in which services can be received; e.g., service area, within the state, within the United States?			
Does the plan restrict the type(s) of facilities in which enrollees can receive services?			
M. Restrictions for Provider Specialty Does the plan restrict the types of provider specialties that can provide certain M/S and/or MH/SUD benefits?			
List of Documents Referenced Above List each document referenced above, including reference to exhibit number, file name, or other identifying information for examiners.			

22 DE Reg. 1025 (06/01/19)

23 DE Reg. 316 (10/01/19)