REPORT ON

MHPAEA TARGET MARKET CONDUCT EXAMINATION

OF

CIGNA HEALTH AND LIFE INSURANCE COMPANY

AS OF JANUARY 1, 2022

Conducted from October 12, 2022

Through

February 12, 2024

By

Health Market Conduct Section

Life and Health Market Regulation Division

BUREAU OF INSURANCE

STATE CORPORATION COMMISSION

COMMONWEALTH OF VIRGINIA

FEIN: 59-1031071
NAIC: 67369

COMMONWEALTH OF VIRGINIA

SCOTT A. WHITE
COMMISSIONER OF INSURANCE
STATE CORPORATION COMMISSION
BUREAU OF INSURANCE

P.O. BOX 1157
RICHMOND, VIRGINIA 23218

1300 E. MAIN STREET
RICHMOND, VIRGINIA 23219

TELEPHONE: (804) 371-9741
scc.virginia.gov

STATE CORPORATION COMMISSION

BUREAU OF INSURANCE

I, Brant Lyons, Principal Insurance Market Examiner of the Bureau of Insurance (Bureau), do hereby certify that the attached copy of the Target Market Conduct Examination Report of Cigna Health and Life Insurance Company as of January 1, 2022, conducted at the State Corporation Commission in Richmond, VA is a true copy of the original Report on file with the Bureau and also includes a true copy of the Company's responses to the findings set forth therein, and of the Bureau's review letters and the State Corporation Commission's Order in Case No. INS-2024-00135 finalizing the Report.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the official seal of the Bureau at the City of Richmond, Virginia, this 29th day of January 2025.

Brant Lyons

Examiner in Charge

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I. BACKGROUND OF MHPAEA & NQTL REQUIREMENTS

The Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 were published on November 13, 2013 and apply to health insurance carriers for plan years beginning on or after July 1, 2014.

As part of these regulations, 45 CFR 146.136(a) defines treatment limitations as limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations ("QTLs"), which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations ("NQTLs"), which otherwise limit the scope or duration of benefits for treatment under a plan or coverage. 45 CFR 146.136(c)(4)(ii) provides an illustrative list of examples of NQTLs, such as "medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative."

45 CFR 146.136(c)(4)(i) states that a health plan (or health insurance coverage) may not impose an NQTL with respect to mental health or substance use disorder benefits in any classification[1] unless, under the terms of the plan (or health insurance coverage) as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the NQTL to mental health or substance use disorder 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 medical/surgical benefits in the classification. The Mental Health Parity and Addiction Equity Act ("MHPAEA") is incorporated into § 38.2-3412.1 B of the Code of Virginia ("the Code"), which allows the Bureau of Insurance ("BOI") to enforce this requirement for Virginia fully-insured plans.

The Consolidated Appropriations Act, 2021 ("CAA"), which was effective in December of 2020, implemented specific documentation requirements for demonstrating compliance with 45 CFR 146.136(c)(4)(i). These requirements were codified in 42 USC 300gg-26(a)(8)(A), which sets forth that health carriers shall perform and document comparative analyses of the design and application of NQTLs and, beginning February 10, 2021, make available to the applicable State authority, upon request, the comparative analyses. These comparative analyses must include the following information:

(i) The specific plan or coverage terms or other relevant terms regarding the NQTLs and a description of all mental health or substance use disorder

[1] The six classifications of MHPAEA are "Outpatient, In-Network," "Outpatient, Out-of-Network," "Inpatient, In-Network," "Inpatient, Out-of-Network," "Emergency Care," and "Prescription Drugs."

and medical or surgical benefits to which each such term applies in each respective benefits classification.

(ii) The factors used to determine that the NQTLs will apply to mental health or substance use disorder benefits and medical or surgical benefits.

(iii) The evidentiary standards used for the factors identified in clause (ii), when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTLs to mental health or substance use disorder benefits and medical or surgical benefits.

(iv) The comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in the benefits classification.

(v) The specific findings and conclusions reached by the group health plan or health insurance issuer with respect to the health insurance coverage, including any results of the analyses described in this subparagraph that indicate that the plan or coverage is or is not in compliance with this section.

The Departments of Labor ("DOL"), Health and Human Services ("HHS"), and the Treasury (collectively, "the Departments") issued FAQS ABOUT MENTAL HEALTH AND SUBSTANCE USE DISORDER PARITY IMPLEMENTATION AND THE CONSOLIDATED APPROPRIATIONS ACT, 2021 PART 45 ("FAQ 45") on April 2, 2021. This guidance further reiterated health carriers' responsibility to demonstrate compliance and the required five-step process. The requirements are summarized by these statements in FAQ 45, Q2:

> …Plans and issuers should ensure that comparative analyses are sufficiently specific, detailed, and reasoned to demonstrate whether the processes, strategies, evidentiary standards, or other factors used in developing and applying an NQTL are comparable and applied no more stringently to MH/SUD benefits than to medical/surgical benefits, as described further below. To that end, a general statement of compliance, coupled with a conclusory reference to broadly stated processes, strategies, evidentiary standards, or other factors is insufficient to meet this statutory requirement….

FAQ 45, Q2 also includes specific examples of minimum information that needs to be discussed in a comparative analysis for it to be deemed sufficient (see page 4 of FAQ

45). FAQ 45, Q3 includes specific examples of why comparative analyses would be deemed insufficient (see page 5 of FAQ 45).

Additional guidance regarding MHPAEA is provided in various FAQs published by the Departments and in the Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA) ("Self-Compliance Tool") published by the DOL.

Throughout this Report, the examiners refer to mental health or substance use disorder ("MH/SUD") benefits and medical or surgical ("M/S") benefits.

II. PURPOSE & SCOPE OF EXAMINATION

This is a report of the Target Market Conduct Examination of Cigna Health and Life Insurance Company ("Cigna" or "the Company"), which was conducted under the authority of § 38.2-1317.1 of the Code. The purpose of this examination was to determine compliance with the NQTL requirements of MHPAEA, 42 USC 300gg-26(a)(8)(A), § 38.2-3412.1 B of the Code, and other Virginia insurance statutes and regulations, and, therefore, that the Company's operations were consistent with public interest.

Two target examinations were conducted that included reviews for compliance with the requirements of MHPAEA. The first target examination focused on various areas of review for the period beginning July 1, 2018, through June 30, 2019, including financial requirements and QTLs of MHPAEA. Findings from the first examination are included in a separate report that was finalized on August 21, 2024 under Case No. INS-2024-00064. While the BOI also initially requested documentation of comparative analyses to determine compliance regarding NQTLs, the CAA implemented more stringent requirements for the documentation of comparative analyses effective in 2021, subsequent to the time frame of the first examination. The second examination was initiated to request and review updated comparative analyses under the requirements of the CAA. This Report focuses on the second examination.

This examination included a detailed review of Cigna's comparative analyses for fully-insured individual and large group comprehensive major medical insurance coverage issued or in force on January 1, 2022.

The examiners followed internal procedures that are based on the NAIC Market Regulation Handbook to perform this examination. The examiners may not have discovered every unacceptable or non-compliant activity in which the Company is engaged. Failure to identify, comment on, or criticize specific Company practices in Virginia or in other jurisdictions does not constitute acceptance of such practices.

All instances of non-compliance identified during this examination are noted in this Report. Examples referred to in this Report are keyed to the numbers of the examiners'

Review Sheets furnished to Cigna during the examination. Cigna was given the opportunity to respond to each finding in this Report.

The Report includes Corrective Action Items and Recommendations for the Company to address. The Company is required to take Corrective Action when restitution is owed to Virginia consumers or providers, a general business practice is established, or a violation or issue was identified where additional controls must be put in place to ensure compliance going forward. The examiners may decide to make a Recommendation instead of a Corrective Action when a violation was not found but the Company should review its current processes, procedures, and operations to ensure compliance in the future.

III. EXECUTIVE SUMMARY

This examination was initiated as a result of market analysis and was conducted to determine compliance with the NQTL requirements of MHPAEA, 42 USC 300gg-26(a)(8)(A), § 38.2 3412.1 B of the Code, and other Virginia insurance statutes and regulations.

The examiners requested comparative analyses, and related documentation, for seven NQTLs from the list of Cigna's NQTLs associated with two individual and two large group fully insured comprehensive major medical policies selected from the largest plans by enrollment for Cigna's policies issued and in force on January 1, 2022. When accounting for the number of policies and applicable classifications, the BOI's review accounts for 160 comparative analyses. However, comparative analyses are commonly performed in the aggregate and may address the protocols applied to a carrier's entire Virginia book of business rather than just the selected policies. Although the NQTLs reviewed during this examination were related to medical management techniques and blanket policy exclusions, the examiners note that they may request any NQTLs, including these, to review during future examinations or inquiries.

This Report contains violations due to insufficient comparative analyses and disparities in design or application regarding the following NQTLs:

- Prior Authorization
- Concurrent Review
- Retrospective Review
- Post-Payment Retrospective Review
- Medical Necessity

- Experimental/Investigational/Unproven (“EIU”)

This Report also contains violations due to more specific concerns identified as part of reviewing comparative analyses for the above-mentioned NQTLs, including the following:

- Restrictive medical necessity criteria regarding autism spectrum disorders (“ASD”) assessment and treatment, as well as applied behavior analysis (“ABA”)
- Restrictive medical necessity criteria regarding gender reassignment surgery for gender dysphoria
- Impermissible methodology for calculating factors to determine which benefits are subject to prior authorization, concurrent review, and retrospective review
- More lenient prior authorization, concurrent review, and retrospective review requirements imposed on outpatient physical therapy, occupational therapy, and chiropractic medical or surgical benefits as compared to requirements imposed on outpatient mental health or substance use disorder benefits
- Impermissible methodology for sub-classification of outpatient benefits

A Corrective Action Plan (“CAP”) that must be implemented by Cigna was established to address these issues and others discussed in the Report. Cigna will document completion of each CAP Item to the examiners. If Cigna does not complete the required Corrective actions by December 31, 2024, with the exception of CAP Item Number 8, which will be completed on or before March 31, 2025, Cigna will be required to remove the associated NQTLs from all MH/SUD benefits in the classifications or sub-classifications reviewed as part of this examination, until Cigna can provide sufficient comparative analyses demonstrating compliance with MHPAEA to justify the application of the NQTLs to MH/SUD benefits.

In its response to the draft version of this Report, Cigna agreed to complete the majority of the specified CAP Items and has begun taking action to address the findings. The Company expressed continued disagreement regarding its gender dysphoria medical necessity criteria and its methodology for sub-classifications. However, the BOI did not find Cigna’s arguments persuasive and maintained that the Company must complete all the required Corrective Actions.

IV. COMPANY PROFILE

Cigna Health and Life Insurance Company is a wholly-owned subsidiary of Connecticut General Life Insurance Company and is an indirect subsidiary of CIGNA Corporation.

The Company was originally incorporated in Florida in 1963. Cigna was authorized to transact the business of accident and sickness insurance in Virginia in 1980.

The table below shows the Company's premium volume and approximate market share in Virginia during 2022 for the lines of insurance included in this examination.*

YEAR AND LINE	PREMIUM VOLUME	MARKET SHARE
2022 Individual Accident & Health	$285,047,808	6.05%
2022 Group Accident & Health	$801,114,210	8.66%

* Source: The 2022 Annual Statements on file with the National Association of Insurance Commissioners.

V. REVIEW PROCESS

The BOI began its examination by requesting that Cigna identify the largest plans by enrollment for Cigna's policies issued and in force on January 1, 2022 and provide a list of NQTLs that Cigna applied under those policies. Based on this information, the examiners requested comparative analyses for five NQTLs associated with two individual and two large group comprehensive major medical policies. Upon the identification of additional concerns, the examiners reviewed comparative analyses for two additional NQTLs and other more specific documentation.

The following NQTLs were reviewed:

- Prior Authorization
- Concurrent Review
- Retrospective Review
- Post-Payment Retrospective Review
- Medical Necessity
- Experimental/Investigational/Unproven ("EIU")
- Blanket Policy Exclusions

The NQTLs were requested and reviewed in the following classifications:

- Inpatient, In-Network
- Inpatient, Out-of-Network
- Outpatient, In-Network (and applicable sub-classifications)

- Outpatient, Out-of-Network (and applicable sub-classifications)
- Emergency Care

The Company was also asked to confirm the classifications where certain NQTLs may not apply. For example, prior authorization is generally not applied to emergency care, so in that case, no comparative analysis is required for prior authorization in this classification. When accounting for the number of policies and applicable classifications, the BOI's review accounts for 160 comparative analyses. However, it is also important to note that comparative analyses are commonly performed in the aggregate and may address the protocols applied to a carrier's entire Virginia book of business rather than just the selected policies.

Cigna was provided the reporting template developed by the examiners to ensure the correct format was followed in presenting the required information under the five-step process. For the majority of NQTLs, Cigna was provided specific instructions developed by the examiners for minimum content that was required to be included for the comparative analyses to be sufficient. For example, as part of the prior authorization comparative analyses, Cigna was instructed to include a discussion of elements such as first-level review, physician review, and peer-to-peer review, along with an explanation of how these processes are comparable between MH/SUD benefits and M/S benefits.

The examiners reviewed the provided comparative analyses and supporting documentation, including provider manuals, policy documents, utilization management procedures, medical necessity criteria, and others. The review also involved requesting and reviewing supporting documentation of calculations for certain quantitative factors.

For comparative analyses that were initially deemed insufficient, the examiners provided Cigna with Review Sheets specifically explaining the additional information that was needed to make the comparative analyses sufficient, and Cigna was given a reasonable amount of time to provide additional comparative analyses to reflect compliance. Cigna provided additional comparative analyses and supplemental responses to the examiners' initial observations. Upon review of the additional comparative analyses and Cigna's supplemental responses, the BOI made determinations of whether or not Cigna was in compliance with MHPAEA. Those determinations and detailed rationales for the decisions were communicated to Cigna and are reflected in this Report.

VI. COMPARATIVE ANALYSES

MHPAEA requires that processes, strategies, evidentiary standards, and other factors be comparable between MH/SUD benefits and M/S benefits as written and in operation. The as-written component of MHPAEA requires carriers to demonstrate comparability

regarding utilization management manuals, policy documents, provider contracts, provider manuals, design of factors, medical necessity criteria, and any other company procedures or protocols that address the terms of the NQTL (i.e., the content of the company's written procedures and the design of the NQTL). The in-operation component of MHPAEA requires carriers to demonstrate comparability regarding the real-time application of the NQTL, including examination of how processes are carried out, evaluation of internal audit results and other quality assurance oversight measures, documentation of outcomes data, and analysis of other elements.

The examiners reviewed each NQTL comparative analysis, along with supporting documentation, to determine compliance with various requirements, including but not limited to the following:

- § 38.2-3412.1 B of the Code
- 45 CFR 146.136(c)(4)(i)
- 42 USC 300gg-26(a)(8)(A)

The BOI notes that reviews of comparative analyses and supporting documentation are time-consuming and complex and that these reviews commonly involve a high volume of information. While this Report includes examples of the deficiencies identified, it does not provide an exhaustive list of all of the deficiencies for each comparative analysis.

This Report refers to the "initial" and "additional" comparative analyses. The comparative analyses originally provided by Cigna are identified as "initial comparative analyses." Where Cigna's initial comparative analyses were deemed to be insufficient by the examiners, Cigna was given a second opportunity to provide comparative analyses to reflect compliance. Cigna's second attempts at providing sufficient documentation and explanations are identified as "additional comparative analyses."

Cigna also provided point-by-point responses, as well as supporting documentation, regarding each of the examiners' specific Review Sheet observations to elaborate on information provided in the additional comparative analyses, to highlight where revisions were made to the initial comparative analyses, and to explain areas of disagreement with the examiners. Cigna's point-by-point responses are identified in this Report as "supplemental responses."

FINDINGS: PRIOR AUTHORIZATION

NQTL Description: Prior authorization is the requirement to obtain approval before a specific service is delivered to a patient in order to qualify for payment/coverage.

Finding: The Company's comparative analyses for prior authorization were insufficient and in violation of § 38.2-3412.1 B of the Code for the failure to comply with 45 CFR 146.136(c)(4)(i) and 42 USC 300gg-26(a)(8)(A).

Discussion: As discussed in Review Sheet MH02-HW, Cigna's comparative analyses in each applicable classification or sub-classification were insufficient to demonstrate compliance with MHPAEA and/or indicated that processes, strategies, evidentiary standards, or other factors were not comparable between MH/SUD benefits and M/S benefits. Examples of deficiencies are discussed below.

Failure to Account for All Forms of Prior Authorization

There are multiple forms of prior authorization utilized by carriers, which may include clinical review at the nurse or physician level (i.e., medical necessity review by the carrier's clinical staff is required to obtain an authorization); approval of services requiring only notification from the provider to the carrier (e.g., a patient is admitted to an inpatient stay from the emergency department of the hospital, and notification is required in lieu of a clinical review to obtain an authorization); and non-clinical review (i.e., authorization can be approved by the carrier's non-clinical staff based on predetermined criteria, which is a function commonly referred to by multiple carriers as "fast certification"). Each form of prior authorization utilized by the carrier must be accounted for throughout the five steps of a comparative analysis, and the processes, strategies, evidentiary standards, or other factors may vary among these different forms. The comparative analysis must explain why some services are subject to notification or non-clinical review/fast certification rather than clinical review and how this determination is comparable between MH/SUD benefits and M/S benefits. Cigna's initial comparative analyses accounted for the clinical review form of prior authorization but failed to account for the notification and non-clinical review/fast certification forms of prior authorization altogether. Cigna was given a second attempt to account for all forms of the NQTL.

Cigna's additional comparative analyses included brief descriptions regarding non-clinical review/fast certification as part of step one, but the Company failed to include the complete information needed in step one through step five, such as the factors, definitions, and evidentiary standards that determine which MH/SUD benefits and M/S benefits are subject to this form of prior authorization. Cigna's additional prior authorization comparative analyses continued to fail to account for the notification form of prior authorization altogether, even though information in Cigna's provider manuals and explanations provided by Cigna regarding other NQTLs indicated that Cigna utilizes this form of prior authorization.

BOI Determination

Based on Cigna's failure to account for all forms of prior authorization, Cigna's comparative analyses were insufficient to demonstrate compliance with MHPAEA.

Peer-to-Peer Review Variation

For M/S benefits, Cigna's clinical review process begins with a nurse reviewing the submitted prior authorization (commonly called a "first-level review"). The nurse can approve the request as submitted if it meets the medical necessity criteria. The nurse cannot deny care, and they must refer the request to a physician reviewer (commonly called "second-level review," "physician review," or "medical director review") if the submission does not meet the medical necessity criteria and is a potential denial. The physician reviewer can approve the submission or deny the submission as not medically necessary. If this review results in a determination that the requested service is not medically necessary, the treating provider (on behalf of the patient) has the option to either file an appeal or request a peer-to-peer review, which is a phone discussion between Cigna's physician reviewer and the treating provider where additional context can be provided in support of medical necessity. If the peer-to-peer review results in the medical necessity denial being upheld, the treating provider has the option to submit an appeal. This results in a two-step clinical review process consisting of review by a nurse followed by review by a physician, with the ability of the treating provider to request a third step (i.e., peer-to-peer review) prior to the option of an appeal.

For MH/SUD benefits, Cigna initially follows a similar clinical review process that begins with a care manager (an MH/SUD clinical reviewer with qualifications comparable to those of a nurse) reviewing the submitted prior authorization and having the ability to approve the request as submitted or refer the request to a physician reviewer in the event of a potential medical necessity denial. However, at this point there is a major difference for MH/SUD benefits in that Cigna automatically solicits a peer-to-peer review with the treating provider in lieu of a physician review, which is a process referred to by Cigna as a "proactive peer-to-peer review." The treating provider can decline the peer-to-peer review and instead be subject to a physician review (referred to as a "read-only review" by Cigna), but the treating provider then loses the ability to request a peer-to-peer review if the read-only review results in a medical necessity denial. This results in a two-step clinical review process consisting of review by a care manager followed by the treating provider having to choose between a peer-to-peer review and a read-only review, without granting the treating provider the ability to request a third step prior to the option of an appeal.

Cigna's initial comparative analyses presented this difference in process between MH/SUD benefits and M/S benefits as compliant with MHPAEA based on the assertion

that the proactive peer-to-peer review is more favorable/advantageous for MH/SUD benefits. However, Cigna's support for this claim included only broad explanations, such as statements that its proactive peer-to-peer review "…resulted in approvals that may have otherwise resulted in a medical necessity denial," that "…the utilization management data reflecting higher medical necessity denial rates for M/S claims than for MH/SUD claims is representative of Cigna's proactive approach to peer-to-peer review," and that without this process "…services that were approved due to such peer-to-peer review, would have been much more likely to have resulted in a denial without additional information or discussion to meet clinical criteria." When the examiners communicated that this difference does not appear to be acceptable and that sufficient explanation/documentation was not provided to prove that the peer-to-peer review variation is more favorable for MH/SUD benefits, Cigna was given a second attempt to justify this difference in process. Cigna disagreed with the examiners and provided the following argument:

> …The BOI's characterization of Cigna's proactive peer-to-peer process for MH/SUD services to be unnecessary and burdensome to the provider and member is erroneous. The objective of proactively seeking a peer-to-peer review is to minimize the risk of issuing a denial where, in fact, the enrollee's clinical situation warrants an approval for medically necessary care yet the provider's request may have incompletely or imprecisely stated the case for medical necessity, or, if a denial is nonetheless issued, mitigating disruption if the loss of coverage results in the enrollee moving to a different treatment type or level of care….

The examiners maintained the finding of non-compliance and stated that Cigna has not substantiated its claim that the difference in question is more favorable beyond an explanation that seems to place responsibility entirely on the treating provider for potential medical necessity denials. Cigna's explanations and new comparative analyses also failed to alleviate the concerns of these scenarios:

- For M/S benefits, if a peer-to-peer review is requested after a medical necessity denial from a physician reviewer, the clinical review process as a whole would involve a review by a nurse, a review by a physician, and an additional review by a physician (as part of the peer-to-peer review) to verify that the correct determination was made by Cigna. However, for MH/SUD benefits, the clinical review process as a whole would involve a review by a care manager and, if the submission is not approved by the care manager, only one review by a physician to verify that the correct determination was made by Cigna.

- The proactive peer-to-peer review is not mandatory and can be declined by the treating provider or patient. However, peer-to-peer review is a process that involves more scrutiny placed on the submission and requires more time and resources of the treating provider than a physician review does in that the treating provider must schedule and participate in a phone call with Cigna. It appears that Cigna is indirectly imposing an automatic peer-to-peer review in the case of MH/SUD benefits, which is potentially more burdensome than the physician review that is used for M/S benefits. Also, if the treating provider or patient prefers a physician review as the first option for a service that cannot be approved by a care manager and declines the proactive peer-to-peer review, they essentially lose a step in the process and have only the option of an appeal in the event of a medical necessity denial.

In addition, the denial rates provided by Cigna did not support more favorable outcomes for MH/SUD benefits regarding peer-to-peer review, as discussed in more detail under the "In-Operation Deficiencies and Disparities" heading.

BOI Determination

Cigna's comparative analyses were insufficient to justify the variation in peer-to-peer review, and this variation results in a process, as written and in operation, used in applying prior authorization to MH/SUD benefits that is not comparable to and is more stringently applied than the process used in applying prior authorization to M/S benefits.

Factors Not Sufficiently Defined

Cigna's comparative analyses stated that the Company determines which MH/SUD benefits and M/S benefits in the "Outpatient, In-Network, All Other" and "Outpatient, Out-of-Network, All Other" sub-classifications are subject to prior authorization based on whether or not the service in question implicates at least one of five qualitative factors and "generally" exceeds a return-on-investment ("ROI") ratio of 3.0. However, the comparative analyses also explained that there are exceptions that can result in a service requiring prior authorization without meeting the aforementioned requirements, and that ultimately Cigna's precertification committee decides which MH/SUD benefits and M/S benefits require prior authorization. Below are examples of concerns identified by the examiners regarding the ROI ratio, the other five factors, exceptions to the ROI, and committee considerations/other components:

ROI Ratio of 3.0

Cigna's initial comparative analyses included an explanation of how the Company calculates the ROI ratio. The examiners deemed the provided information to be

insufficient, as the provided formula included higher percentages and dollar amounts for MH/SUD benefits as compared to M/S benefits with no explanation of how the differences were compliant with MHPAEA. Cigna was given a second attempt to justify and explain the differences in the formula between MH/SUD benefits and M/S benefits.

Cigna's additional comparative analyses provided broad explanations that included reiterating the dollar amounts and percentages from the initial comparative analyses and making statements such as "Cigna bases its ROI assessment on what proportion of the business on prior authorization is guaranteed cost business…," "The business has determined the cost to place a behavioral health code on prior auth is higher than a medical code…," and "Some of this value is related to where and how the claim is processed." However, Cigna failed to provide complete explanations of these elements, including how the Company defines "guaranteed cost business," how the dollar amounts and percentages were specifically determined, and the specific reasons for differences between the figures for MH/SUD benefits and M/S benefits.

Please note that a more detailed assessment of Cigna's outpatient and inpatient ROI calculations is discussed in Section VII of this Report under the "FINDINGS: RETURN-ON-INVESTMENT RATIO CALCULATIONS" heading.

Other Five Factors

As an example of the other five factors where at least one must be implicated in addition to exceeding an ROI of 3.0 for a service to require prior authorization, Cigna's initial comparative analyses provided the following as a factor and definition:

> Variability in cost, quality and utilization based upon diagnosis, treatment, provider type and/or geographic region: Variability in cost is identified as a high unit cost per service for consideration in requiring precertification. The volume of services per year is also reviewed, including a review of high denial rates. Cigna does not discriminate by provider type or region of the country. Coverage policies apply to all providers working within the scope of their licensure (for example, Cigna would not consider a coverage request for neurosurgery from a chiropractor). The ideal candidate for precertification is a service that is expensive ($300 or more), not routinely performed and for which data exists from national standards such as "Choosing Wisely" or other professional society recommendations that a denial rate of 15% or more would be expected when the individual request is measured against Cigna's published criteria coverage (Cigna developed Coverage Policy, MCG, or ASAM).

The examiners deemed the information presented regarding this factor to be insufficient. The examiners instructed Cigna to provide the source(s) for the information and to define "high unit cost," "volume of services per year," "high denial rates," and "not routinely performed," as well as to explain what a "denial rate of 15%" is based on. Cigna was given a second attempt to provide this information.

Cigna's additional comparative analyses largely provided the same information again with language added stating that this is a "qualitative factor." The additional comparative analyses continued to fail to define "high unit cost," "volume of services per year," and "high denial rates," and Cigna removed the sentence altogether that included references to "not routinely performed" and "denial rate of 15%" with no explanation of why these elements would no longer apply.

In addition, the only new explanation Cigna provided regarding the source(s) of this information in its additional comparative analyses was a broad reference to "historical Cigna claim data" without any further elaboration.

Exceptions to the ROI Ratio of 3.0

Cigna's additional comparative analyses also introduced the explanation that there are exceptions to the ROI ratio of 3.0, which can result in services that do not implicate the aforementioned factors to still be subject to prior authorization. The Company described these exceptions with language such as "services that may be abused" and "certain services that identify customers that should be referred to a case management program."

With this language, Cigna introduced new factors into the comparative analyses but failed to provide specific definitions for them. Based on the information provided, it is unclear how these exceptions are applied by Cigna.

Committee Considerations and Other Components

Cigna's initial and additional comparative analyses, as well as its supplemental response, also included other elements that determine which MH/SUD benefits and M/S benefits are subject to prior authorization and when they qualify for removal from the prior authorization list. Examples of explanations include the following:

> …Codes with ROI greater than 3 are considered as operationally effective and are not typically considered for removal, while codes with ROI less than 3 are considered for removal…Individual codes up for review are discussed, including volume, approval rates, denial rates, and ROI are factors incorporated into these discussions…

> …a committee of Cigna-employed Medical Directors determines which M/S and MH/SUD services shall be subject to Prior Authorization…
>
> …There is another process whereby stakeholders in the organization weigh in on the impacts to placing a code on prior authorization. Those impacts are fed into a business model to determine if the ROI is met. Additional considerations include the experience to the customer and provider…
>
> …There are qualitative aspects of this analysis and not a quantitative absolute. If a code is high dollar but Cigna always approves coverage, it does not make sense to add the code to precertification. If a service is low dollar and has a high anticipated denial rate, these codes may be most suitable for a post-service claim review….

With this language, Cigna introduced new factors into the comparative analyses but failed to provide specific definitions for them and the details of processes associated with them, such as how Cigna's committee determines which services require prior authorization, how additions and deletions to the prior authorization list are considered, how the committee decisions interact with the other factors described in the comparative analyses, how the process is conducted where "impacts are fed into a business model…," and how discretion may be applied by the committee members in making their determinations.

BOI Determination

Cigna's comparative analyses were insufficient to demonstrate comparability regarding how the Company determines which MH/SUD benefits and M/S benefits are subject to prior authorization. Cigna's comparative analyses as presented allowed for too much subjectivity to the extent that prior authorization can be imposed at Cigna's complete discretion, resulting in factors, as written and in operation, used in applying prior authorization to MH/SUD benefits that are not comparable to and are more stringently applied than the factors used in applying prior authorization to M/S benefits.

In-Operation Deficiencies and Disparities

The in-operation portion of a comparative analysis regarding utilization management protocols (e.g., prior authorization, concurrent review, retrospective review) must demonstrate adherence to internal procedures and protocols, adherence to clinical criteria in making correct medical necessity determinations, and appropriate application of any discretion/clinical judgment granted to physician reviewers, as well as comparability of outcomes data (e.g., denial rates, rates of overturned appeals). The examiners identified the below examples of deficiencies and disparities regarding in-operation compliance.

Failure to Perform and Document Internal Audits

The examiners deemed Cigna's initial comparative analyses to be insufficient for the failure to adequately document methods of quality assurance oversight, such as internal audits performed to ensure that correct medical necessity determinations were made and that appropriate protocols were applied by nurses and physician reviewers. Cigna's initial comparative analyses relied heavily on the explanation that the Company's Inter-Rater Reliability ("IRR") process, which involves Cigna's clinical reviewers taking a test where they are graded on their ability to correctly apply clinical criteria to case study scenarios, is used to evaluate consistency in clinical decision making. While the examiners acknowledge that IRR is one relevant component of quality assurance oversight, IRR only evaluates consistency of clinical reviewers in a testing/case study format and does not reflect real-time application or outcomes of actual prior authorization submissions. Therefore, additional measures must be documented to demonstrate compliance. Cigna was given a second attempt to document quality assurance oversight, and the examiners instructed Cigna to document and discuss the results of any internal audits involving the first-level review process, the physician review process, and the peer-to-peer review process.

Cigna's additional comparative analyses included copies of internal audit reports as supporting documentation. However, Cigna failed to discuss the results of the audits or provide the necessary context for them in the comparative analyses, and a review of the reports revealed that the internal audits did not evaluate determinations made as part of first-level review, physician review, and peer-to-peer review.

BOI Determination

Cigna failed to demonstrate in-operation compliance regarding adequate methods of quality assurance oversight.

Denial Rates and Rates of Overturned Appeals

Cigna's initial comparative analyses included only minimal documentation of metrics regarding denial rates and rates of overturned appeals, and the metrics were inclusive of plan types outside of the BOI's regulatory authority. The initial comparative analyses also failed to explain how the Company accounts for coverage modifications/partial denials (e.g., where a lower level of care or lower number of days/visits is approved as compared to the level of care or number of days/visits requested by the treating provider) in its tracking and reporting of in-operation data. The examiners deemed Cigna's initial comparative analyses to be insufficient, and Cigna was given a second attempt to provide sufficient metrics specific to Virginia fully-insured policies based on elaboration provided by the examiners regarding the required parameters.

Cigna provided more detailed metrics as part of its additional comparative analyses. However, limitations continued to exist, such as aggregation of some of the data (e.g., the data combined appeals resulting from prior authorization, concurrent review, and retrospective review, and some of the denial rates combined different classifications) and the failure to identify coverage modifications/partial denials.

Despite limitations in the provided data, the examiners identified the following in-operation disparities between MH/SUD benefits and M/S benefits:

- **Peer-to-Peer Review Denial Rates:** For inpatient and outpatient benefits in the aggregate, 100% (8 out of 8) of pre-service MH/SUD peer-to-peer reviews resulted in medical necessity denials as compared to only 36.68% (252 out of 687) of pre-service M/S peer-to-peer reviews resulting in medical necessity denials. While the examiners acknowledge that the numbers provided by Cigna were aggregated, the documentation as presented indicates disparities between MH/SUD benefits and M/S benefits regarding medical necessity denials rendered during Cigna's peer-to-peer review process. As discussed earlier under the "Peer-to-Peer Variation" heading, these numbers do not support Cigna's assertion that its proactive peer-to-peer review process is more favorable for MH/SUD benefits.

Cigna's additional comparative analyses failed to provide explanations for these disparities.

BOI Determination

While disparate results alone are not determinative of MHPAEA non-compliance, disparities in the provided metrics between MH/SUD benefits and M/S benefits indicate red flags that warrant, at a minimum, further review of a company's processes, strategies, evidentiary standards, and other factors. Further review revealed that Cigna's comparative analyses were insufficient to demonstrate comparability as written/in design due to deficiencies such as subjective factors and impermissible peer-to-peer review variation, and that Cigna's comparative analyses were insufficient to demonstrate comparability in operation due to deficiencies such as the failure to perform and document internal audits. When considered in combination with the other existing deficiencies in Cigna's comparative analyses, the disparities in Cigna's in-operation metrics go beyond disparate results alone and indicate that the processes, strategies, evidentiary standards, or other factors used in applying prior authorization to MH/SUD benefits are more stringently applied in operation than the processes, strategies, evidentiary standards, or other factors used in applying prior authorization to M/S benefits.

Corrective Action: Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for prior

authorization that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently.

FINDINGS: CONCURRENT REVIEW

NQTL Description: Concurrent review involves utilization review for medical necessity conducted during a patient's stay or course of treatment in a facility, the office of a health care professional, or other inpatient or outpatient health care setting. Concurrent review decisions involve the extension of previously approved coverage, the denial of continued coverage as previously approved, or the approval of coverage for an alternative level of care. Concurrent review processes are essentially new prior authorizations, and certain features of these two NQTLs may overlap.

Finding: The Company's comparative analyses for concurrent review were insufficient and in violation of § 38.2-3412.1 B of the Code for the failure to comply with 45 CFR 146.136(c)(4)(i) and 42 USC 300gg-26(a)(8)(A).

Discussion: As discussed in Review Sheet MH01-JM, Cigna's comparative analyses in each applicable classification or sub-classification were insufficient to demonstrate compliance with MHPAEA and/or indicated that processes, strategies, evidentiary standards, or other factors were not comparable between MH/SUD benefits and M/S benefits. Examples of deficiencies are discussed below.

Similar Issues to the Prior Authorization Comparative Analyses

Many of Cigna's processes, strategies, evidentiary standards, or other factors were identical between prior authorization and concurrent review. As such, several of the same deficiencies identified in the prior authorization comparative analyses were also present in the concurrent review comparative analyses, including peer-to-peer review variation and the failure to sufficiently define the factors that determine which benefits are subject to the NQTL. Cigna also failed to adequately account for all forms of concurrent review, including the failure to provide complete comparative analyses for non-clinical review/fast certification. However, there were some variations in the reasons for those deficiencies.

For example, Cigna utilized the same ROI ratio of 3.0 as one of the factors to determine which MH/SUD benefits and M/S benefits in the "Outpatient, In-Network, All Other" and "Outpatient, Out-of-Network, All Other" sub-classifications are subject to concurrent review. While Cigna's initial and additional concurrent review comparative analyses included the same deficiencies as the prior authorization comparative analyses regarding

different figures for MH/SUD benefits and M/S benefits, Cigna's additional concurrent review comparative analyses added an explanation that "The M/S cost to review is lower than the MH/SUD cost to review because the MH/SUD review model utilizes more frequently higher-paid, on-shore employees than the M/S review model…," and that "The variation of review cost is principally due to Cigna's contracts with offshore reviewers for certain M/S reviews…." However, these explanations still failed to specifically explain the necessary elements of the formula for the ROI ratio.

Additional Factors Not Sufficiently Defined

Cigna's initial comparative analyses included the following factors and definitions to explain how the Company determines when and how frequently concurrent review takes place for MH/SUD benefits and M/S benefits:

> …Service may be subject to Concurrent Review, when such Service requires (1) the ongoing assessment to determine or continue to establish the medical necessity of continued services; and (2) appropriateness of current level of care for the severity; or (3) one or more of the following:
>
> - Complexity of the condition and if extension, expansion, or reduction of services is appropriate based on nationally recognized guidelines
> - Expected timeframe for clinical response/outcomes based on literature
> - Efficacy of the treatment modality
> - Progress toward goals of therapy
> - Discharge/transition planning….

The examiners deemed Cigna's initial comparative analyses to be insufficient for the failure to explain how the items in each provided bullet point determine that a concurrent review will be initiated, the failure to provide clear and understandable information regarding the interaction of items (1), (2), and (3) in the sentence before the bullet points, and the failure to provide definitive information about the NQTL by only referring to services that "*may* be subject" to concurrent review. Cigna was given a second attempt to provide the necessary context and definitive information regarding these factors.

Cigna's additional comparative analyses provided the same information again without additional elaboration and failed to address the identified deficiencies. In addition, Cigna's supplemental response appeared to contradict the factors in the Company's comparative analyses by stating that concurrent review is initiated by the expiration of the

initial authorization and/or the anticipated discharge date needing to be extended, and Cigna's M/S provider manual appeared to contradict the factors in both the Company's supplemental response and comparative analyses by stating that concurrent review takes place based on the approved length-of-stay plus or minus a specified number of days. Cigna's comparative analyses failed to reconcile all of this information and failed to explain whether concurrent review is initiated by Cigna, the provider, or either, depending on the situation.

BOI Determination

Cigna's comparative analyses were insufficient to demonstrate comparability regarding how the Company determines when and how frequently concurrent review takes place for MH/SUD benefits and M/S benefits. Cigna's comparative analyses as presented allowed for too much subjectivity to the extent that concurrent review can be imposed at Cigna's complete discretion, resulting in factors, as written and in operation, used in applying concurrent review to MH/SUD benefits that are not comparable to and are more stringently applied than the factors used in applying concurrent review to M/S benefits.

In-Operation Deficiencies and Disparities

The in-operation portion of a comparative analysis regarding utilization management protocols (e.g., prior authorization, concurrent review, and retrospective review) must demonstrate adherence to internal procedures and protocols, adherence to clinical criteria in making correct medical necessity determinations, and appropriate application of any discretion/clinical judgment granted to physician reviewers, as well as comparability of outcomes data (e.g., denial rates and rates of overturned appeals). The examiners identified the below examples of deficiencies and disparities regarding in-operation compliance.

Failure to Perform and Document Internal Audits

Cigna's initial and additional comparative analyses included the same deficiencies as its prior authorization comparative analyses regarding the failure to perform and document internal audits. Based on this information, Cigna failed to demonstrate in-operation compliance regarding adequate methods of quality assurance oversight.

Denial Rates and Rates of Overturned Appeals

Cigna's initial comparative analyses included only minimal documentation of metrics regarding denial rates and rates of overturned appeals, and the metrics were inclusive of plan types outside of the BOI's regulatory authority. The initial comparative analyses also failed to explain how the Company accounts for coverage modifications/partial denials

(e.g., where a lower level of care or lower number of days/visits is approved as compared to the level of care or number of days/visits requested by the treating provider) in its tracking and reporting of in-operation data. The examiners deemed Cigna's initial comparative analyses to be insufficient, and Cigna was given a second attempt to provide sufficient metrics specific to Virginia fully-insured policies based on elaboration provided by the examiners regarding the required parameters.

Cigna provided more detailed metrics as part of its additional comparative analyses. However, limitations continued to exist, such as aggregation of some of the data (e.g., the data combined appeals resulting from prior authorization, concurrent review, and retrospective review, and some of the denial rates combined different classifications) and the failure to identify coverage modifications/partial denials.

Despite limitations in the provided data, the examiners identified the following in-operation disparities between MH/SUD benefits and M/S benefits:

- **Concurrent Review Denial Rates:** In the "Outpatient, In-Network, All Other" sub-classification, 4.40% (51 out of 1,160) of MH/SUD concurrent reviews resulted in medical necessity denials as compared to only 0.73% (9 out of 1,226) of M/S concurrent reviews resulting in medical necessity denials. The documentation as presented indicates disparities between MH/SUD benefits and M/S benefits regarding medical necessity denials rendered by Cigna as part of concurrent review.

- **Peer-to-Peer Review Denial Rates:** For inpatient and outpatient benefits in the aggregate, 57.26% (67 out of 117) of concurrent MH/SUD peer-to-peer reviews resulted in medical necessity denials as compared to only 47.79% (65 out of 136) of concurrent M/S peer-to-peer reviews resulting in medical necessity denials. While the examiners acknowledge that the numbers provided by Cigna were aggregated, the documentation as presented indicates disparities between MH/SUD benefits and M/S benefits regarding medical necessity denials rendered during Cigna's peer-to-peer review process. As discussed earlier in reference to the prior authorization comparative analyses, these numbers do not support Cigna's assertion that its proactive peer-to-peer review process, which is also applied to concurrent review, is more favorable for MH/SUD benefits.

- **Physician Review Denial Rates:** For inpatient and outpatient benefits in the aggregate, 93.18% (41 out of 44) of concurrent MH/SUD physician (referred to by Cigna as "read only") reviews resulted in medical necessity denials as compared to only 10.07% (384 out of 3,815) of concurrent M/S physician reviews (referred to by Cigna as "medical director decisions") resulting in medical necessity denials. While the examiners acknowledge that the numbers provided by Cigna were

aggregated, the documentation as presented indicates disparities between MH/SUD benefits and M/S benefits regarding medical necessity denials rendered during Cigna's physician review process.

- **Frequency of Concurrent Review:** In the "Inpatient, Out-of-Network" classification, 461 MH/SUD concurrent reviews took place as compared to only 82 M/S concurrent reviews. In the "Outpatient, Out-of-Network, All Other" sub-classification, 254 MH/SUD concurrent reviews took place as compared to only 21 M/S concurrent reviews. While the examiners acknowledge limitations in the numbers provided by Cigna, the documentation as presented indicates disparities between MH/SUD benefits and M/S benefits regarding the frequency of concurrent reviews that are required for coverage approval. The concern related to the greater frequency of concurrent reviews imposed on MH/SUD Out-of-Network benefits is also intensified by Cigna's failure to explain how it determines when and how frequently concurrent review occurs, as discussed earlier under the "Additional Factors Not Sufficiently Defined" heading.

Regarding the medical necessity denial rates in the "Outpatient, In-Network, All Other" sub-classification, Cigna's additional comparative analyses offered only the explanation that the MH/SUD denial rates are "nominally higher" and that "the variability does not rise to the level illustrative of a parity violation…." The examiners would respond that the MH/SUD medical necessity denial rate of 4.40% is more than five times the M/S medical necessity denial rate of 0.73% and that Cigna failed to explain why these disparate outcomes should be considered comparable.

Cigna's additional comparative analyses failed to provide explanations for the peer-to-peer review disparities, the physician review disparities, and the disparities regarding the frequency of concurrent review.

BOI Determination

While disparate results alone are not determinative of MHPAEA non-compliance, disparities in the provided metrics between MH/SUD benefits and M/S benefits indicate red flags that warrant, at a minimum, further review of a company's processes, strategies, evidentiary standards, and other factors. Further review revealed that Cigna's comparative analyses were insufficient to demonstrate comparability as written/in design due to deficiencies such as subjective factors and impermissible peer-to-peer review variation, and that Cigna's comparative analyses were insufficient to demonstrate comparability in operation due to deficiencies such as the failure to perform and document internal audits. When considered in combination with the other existing deficiencies in Cigna's comparative analyses, the disparities in Cigna's in-operation metrics go beyond disparate results alone and indicate that the processes, strategies, evidentiary standards,

or other factors used in applying concurrent review to MH/SUD benefits are more stringently applied in operation than the processes, strategies, evidentiary standards, or other factors used in applying concurrent review to M/S benefits.

Corrective Action: Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for concurrent review that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently.

FINDINGS: RETROSPECTIVE REVIEW

NQTL Description: Retrospective review concerns carrier review for coverage authorizations that were not approved on a pre-service basis, and the review takes place after a service is performed but before a claim is paid or denied. These may occur because a prior authorization request was not timely made before service initiation or as a review for an emergency care situation.

Finding: The Company's comparative analyses for retrospective review were insufficient and in violation of § 38.2-3412.1 B of the Code for the failure to comply with 45 CFR 146.136(c)(4)(i) and 42 USC 300gg-26(a)(8)(A).

Discussion: As discussed in Review Sheet MH02-JM, Cigna's comparative analyses in each applicable classification or sub-classification were insufficient to demonstrate compliance with MHPAEA and/or indicated that processes, strategies, evidentiary standards, or other factors were not comparable between MH/SUD benefits and M/S benefits. Examples of deficiencies are discussed below.

Prior Authorization and Retrospective Review

Cigna's initial comparative analyses explained that retrospective review is only performed if prior authorization was required but not obtained, which means that the factors that determine which MH/SUD benefits and M/S benefits are subject to the NQTL should be the same for retrospective review as for prior authorization and that the primary driver of retrospective review being initiated is the failure of the provider to obtain authorization before the service is performed. However, the examiners deemed Cigna's initial comparative analyses to be insufficient because the factors and evidentiary standards provided by Cigna for retrospective review varied from those provided for prior authorization, and Cigna failed to provide an analysis of the necessary elements in step

four. Cigna was given a second attempt to reconcile its processes, strategies, evidentiary standards, and other factors.

Cigna's additional retrospective review comparative analyses removed, revised, or replaced the factors and evidentiary standards initially provided and added the as-written analysis to step four to be consistent with the information in the Company's prior authorization comparative analyses. Cigna's additional comparative analyses also stated that "it is impossible to have a comprehensive description or reasoned discussion of retrospective review without fully incorporating and addressing prior authorization as well." The examiners agreed and responded that, as retrospective review is essentially a consequence of the failure to obtain a required prior authorization, Cigna's retrospective review comparative analyses cannot be sufficient to demonstrate compliance until Cigna brings its prior authorization comparative analyses into compliance, including demonstrating that its factors (e.g., the ROI formula, committee considerations) and processes (e.g., first-level review, physician review, peer-to-peer review) are comparable between MH/SUD benefits and M/S benefits.

Differences in Process

The examiners deemed Cigna's initial comparative analyses to be insufficient for the failure to explain the terms of retrospective review, including the details of when and how it takes place for MH/SUD benefits and M/S benefits and what determines whether a claim will be denied versus reviewed retrospectively for the failure to obtain prior authorization. Cigna was given a second attempt to provide these terms of the NQTL.

Cigna's additional comparative analyses explained that, for MH/SUD benefits, a retrospective review is always performed upon claim submission if a prior authorization was required but not obtained. However, for M/S benefits, Cigna denies the claim if a prior authorization was required but not obtained, unless the provider contacts Cigna within a certain number of days after performing the service.

BOI Determination

While differences in processes between MH/SUD benefits and M/S benefits do not automatically indicate MHPAEA non-compliance, and this difference regarding retrospective review does not necessarily appear more restrictive on the surface, FAQ 45, Q2, # 5 requires the comparative analysis to describe the process and factors used to establish any variation between MH/SUD benefits and M/S benefits. As Cigna failed to explain the basis for why the Company performs a retrospective review of MH/SUD benefits but denies M/S benefits for the failure to obtain prior authorization, the comparative analyses were insufficient to demonstrate compliance with MHPAEA regarding differences in process.

Contradictions and Unclear Explanations

The examiners deemed Cigna's initial comparative analyses to be insufficient because the only information provided to demonstrate comparability as written in step four was a broad statement that Cigna's retrospective review processes "…reflect they are comparable and no more stringent for MH/SUD services within a classification of benefits than for medical/surgical services within the same classification of benefits," which fails to demonstrate comparability or describe any processes that take place as part of retrospective review. Cigna was given a second attempt to explain its processes in a manner that demonstrates comparability, including which types of review apply to the NQTL (e.g., first-level review, physician review, peer-to-peer review), where similarities and differences exist between prior authorization and retrospective review, and when and how retrospective review takes place for MH/SUD benefits and M/S benefits. Below are examples of concerns identified by the examiners regarding contradictory and unclear explanations with respect to the requested information.

Peer-to-Peer Review

Cigna's supplemental response included with its additional comparative analyses stated the following:

> The processes are identical for prior authorization and retrospective review, with the sole exception that Cigna does not offer a proactive peer-to-peer review as part of the retrospective review process for MH/SUD services as it does for prior authorization of MH/SUD services.

However, Cigna's accompanying additional retrospective review comparative analyses appeared to contradict this explanation by including language such as the following:

> Cigna ensures that any potential denial of MH/SUD benefits is preceded by a proactive offer to the provider of a peer-to-peer review.

The examiners responded that one of Cigna's explanations indicated that proactive peer-to-peer review does not take place as part of retrospective review, but the accompanying comparative analyses indicated that proactive peer-to-peer review does take place as part of retrospective review, resulting in contradictory and unclear information in the comparative analyses.

Terms of Retrospective Review

Cigna's additional comparative analyses for the "Outpatient, In-Network, All Other" sub-classification included the following language regarding when retrospective review takes place:

> Retrospective reviews are only performed when a service requires prior authorization, and that authorization was never obtained or secured. If the provider performs the service without prior authorization then either one of two things may occur: (1) if the provider within fifteen (15) days submits the authorization request, post-service, then a retrospective review is performed, conducted as if it were a standard prior authorization request despite the lack of prior authorization; or (2) the provider bills Cigna and a claim is received. In the latter situation, for a medical/ surgical service, the claim is generally denied for failing to secure authorization, which is an administrative denial and does not involve a medical necessity review. In contrast, for MH/SUD services, Cigna always performs a retrospective review, and never denies the claim for failure to obtain a prior authorization. Cigna denies the claim and performs a retrospective review upon appeal to determine medical necessity, just as it would had the prior authorization request been submitted in advance.

The examiners responded that the above excerpt states that Cigna denies the claim and that Cigna never denies the claim, and it is unclear what is being conveyed with this explanation.

BOI Determination

Due to contradictory and unclear explanations, Cigna's comparative analyses were insufficient to demonstrate comparability regarding the terms of retrospective review and the processes that take place as part of the NQTL.

Extent of Medical Records Required

The examiners deemed Cigna's initial comparative analyses to be insufficient for the failure to explain how the Company ensures that the extent of medical records required to be submitted as part of retrospective review is comparable between MH/SUD benefits and M/S benefits. Cigna was given a second attempt to provide this information.

Cigna's supplemental response provided with its additional comparative analyses stated that medical records are always required for retrospective review, but that they are not always required when the authorization is submitted before the service is rendered. However, Cigna's response failed to explain how the Company ensures that the volume of medical records and type of information required for MH/SUD benefits and M/S benefits is comparable. For example, if MH/SUD providers are required to document months of medical records as part of a retrospective review, but M/S providers are required to provide the notes from one date of service, that would not be comparable. The examiners

also note that Cigna failed to explain when medical records are and are not required for prior authorization.

BOI Determination

Cigna's comparative analyses were insufficient to demonstrate compliance with MHPAEA regarding the extent of medical records required.

In-Operation Deficiencies and Disparities

The in-operation portion of a comparative analysis regarding utilization management protocols (e.g., prior authorization, concurrent review, and retrospective review) must demonstrate adherence to internal procedures and protocols, adherence to clinical criteria in making correct medical necessity determinations, and appropriate application of any discretion/clinical judgment granted to physician reviewers, as well as comparability of outcomes data (e.g., denial rates and rates of overturned appeals). The examiners identified the below examples of deficiencies and disparities regarding in-operation compliance.

Failure to Perform and Document Internal Audits

Cigna's initial and additional comparative analyses included the same deficiencies as its prior authorization and concurrent review comparative analyses regarding the failure to perform and document internal audits. Based on this information, Cigna failed to demonstrate in-operation compliance regarding adequate methods of quality assurance oversight.

Denial Rates and Rates of Overturned Appeals

Cigna's initial comparative analyses failed to include any documentation of metrics regarding denial rates and rates of overturned appeals, and the only information provided by Cigna was a broad statement that "Cigna has conducted a review of its application of the Retrospective Review NQTL, specifically approvals and denial information, which revealed no statistically significant discrepancies in denial rates as between MH/SUD and M/S benefits." The examiners deemed Cigna's initial comparative analyses to be insufficient for the failure to document this statement regarding in-operation compliance, and Cigna was given a second attempt to provide sufficient metrics specific to Virginia fully-insured policies based on elaboration provided by the examiners regarding the required parameters.

Cigna provided documentation of metrics as part of its additional comparative analyses. However, limitations continued to exist, such as aggregation of some of the data (e.g.,

the data combined appeals resulting from prior authorization, concurrent review, and retrospective review) and the failure to identify coverage modifications/partial denials.

Despite limitations in the provided data, the examiners identified the following in-operation disparities between MH/SUD benefits and M/S benefits:

- **Retrospective Review Denial Rates:** In the "Inpatient, Out-of-Network" classification, 33.33% (4 out of 12) of MH/SUD retrospective reviews resulted in medical necessity denials as compared to only 16.67% (4 out of 24) of M/S retrospective reviews resulting in medical necessity denials. The documentation as presented indicates disparities between MH/SUD benefits and M/S benefits regarding medical necessity denials rendered by Cigna as part of retrospective review.

- **Retrospective Review Response Times:** In the "Inpatient, In-Network" classification, the average turnaround time for responding to retrospective reviews for MH/SUD benefits was 34.7 days as compared to only 2 days for M/S benefits. In the "Inpatient, Out-of-Network" classification, the average turnaround time for responding to retrospective reviews for MH/SUD benefits was 35.9 days as compared to only 3 days for M/S benefits. In the "Outpatient, In-Network, All Other" sub-classification, the average turnaround time for responding to retrospective reviews for MH/SUD benefits was 32 days as compared to only 23 days for M/S benefits.

As part of its additional comparative analyses when providing these metrics, Cigna stated that the Company should have been allowed to incorporate denial rates and turnaround times from its national book of business, which is also inclusive of Administrative Services Only ("ASO") plans, instead of being limited to Virginia fully-insured policies as requested by the examiners. Cigna stated that "with a larger set of data, the aberrational differences as between medical necessity and administrative denials would subside…."

Regarding turnaround times, Cigna acknowledged that it is working to improve these time frames. However, Cigna also emphasized that "in the context of retrospective review…the service has already been provided, so neither the enrollee nor the provider is waiting on a determination from Cigna."

The examiners disagreed with Cigna's explanations and stated that, while the data is limited for retrospective reviews, Virginia fully-insured policies are the focus of this examination. In addition, for scenarios where the percentages show disparities in denial rates based on a low overall number of retrospective reviews (e.g., the 33.33% denial rate is 4 denied retrospective reviews out of 12 submitted), Cigna could have researched and explained the specific denial reasons to support the Company's assertion that it is in

compliance. The examiners also stated that, even though the services have already been provided, the provider and member are still being subjected to longer response times to be informed as to whether or not the benefits will be covered and eligible for reimbursement and to receive reimbursement.

BOI Determination

While disparate results alone are not determinative of MHPAEA non-compliance, disparities in the provided metrics between MH/SUD benefits and M/S benefits indicate red flags that warrant, at a minimum, further review of a company's processes, strategies, evidentiary standards, and other factors. Further review revealed that Cigna's comparative analyses were insufficient to demonstrate comparability as written/in design due to deficiencies such as subjective factors and the failure to explain the processes and terms of the NQTL, and that Cigna's comparative analyses were insufficient to demonstrate comparability in operation due to deficiencies such as the failure to perform and document internal audits. When considered in combination with the other existing deficiencies in Cigna's comparative analyses, the disparities in Cigna's in-operation metrics go beyond disparate results alone and indicate that the processes, strategies, evidentiary standards, or other factors used in applying retrospective review to MH/SUD benefits are more stringently applied in operation than the processes, strategies, evidentiary standards, or other factors used in applying retrospective review to M/S benefits.

Corrective Action: Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for retrospective review that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently.

FINDINGS: POST-PAYMENT RETROSPECTIVE REVIEW

NQTL Description: Post-payment retrospective review concerns retrospective or retroactive review of services where the claims have already been paid. These reviews commonly involve identifying paid claims as outliers and performing audits or investigations regarding medical necessity, deficiencies in documentation, fraudulent activity, and other elements, as well as recoupment or retraction of previously paid amounts from the treating provider.

Finding: The Company's comparative analyses for post-payment retrospective review were insufficient and in violation of § 38.2-3412.1 B of the Code for the failure to comply with 45 CFR 146.136(c)(4)(i) and 42 USC 300gg-26(a)(8)(A).

Discussion: As discussed in Review Sheet MH03-HW, Cigna's comparative analyses in each applicable classification or sub-classification were insufficient to demonstrate compliance with MHPAEA and/or indicated that processes, strategies, evidentiary standards, or other factors were not comparable between MH/SUD benefits and M/S benefits. Examples of deficiencies are discussed below.

Failure to Account for All Forms of Post-Payment Retrospective Review

There are multiple forms of post-payment retrospective review utilized by carriers, which include the following: clinical review (i.e., medical necessity review) that occurs post-claim payment; coding edits (i.e., claims adjudication rules that identify services that are ineligible for payment) that occur post-claim payment; fraud, waste, and abuse ("FWA") (i.e., provider attempts to obtain improper payment or create unnecessary cost) investigations that occur post-claim payment; and any other post-claim payment review functions the carrier may utilize. Each form of post-payment retrospective review utilized by the carrier must be accounted for throughout the five steps of a comparative analysis, and the processes, strategies, evidentiary standards, or other factors may vary among these different forms. Cigna's initial comparative analyses accounted for the FWA investigation form of post-payment retrospective review but failed to account for any of the other forms. Cigna was given a second attempt to account for all forms of the NQTL.

Cigna's additional comparative analyses continued to fail to address post-claim payment coding edits altogether, and the only reference made to clinical review was to state that "Cigna does not routinely impose medical necessity review on a retrospective basis," with no comparative analysis provided and no explanation of what is meant by "routinely."

BOI Determination

Based on Cigna's failure to account for all forms of post-payment retrospective review, Cigna's comparative analyses were insufficient to demonstrate compliance with MHPAEA.

Factors Not Sufficiently Defined

Cigna's initial comparative analyses failed to include any factors that determine which MH/SUD benefits and M/S benefits are subject to post-payment retrospective review. Instead, Cigna listed activities performed by its Special Investigations Unit ("SIU"), provided definitions for "fraud," "waste," and "abuse," and broadly stated that the

Company "utilizes analytics to identify areas of risk" and that "those areas are analyzed for potential investigation." Cigna was given a second attempt to provide the factors, definitions, evidentiary standards, and sources that determine which benefits are subject to the NQTL and when post-payment retrospective review is initiated. Cigna was instructed by the examiners to explain all protocols, algorithms, and outlier identification methodologies that determine which previously paid claims are reviewed.

Below are examples of continued concerns identified by the examiners regarding the factors in Cigna's additional comparative analyses.

Analytics, Data Mining, Algorithms

Cigna's additional comparative analyses elaborated on its use of analytics, data mining, and algorithms regarding FWA. However, Cigna focused on explaining what these elements are rather than how they are used to identify outliers. The comparative analyses continued to fail to explain what methodology these elements rely on, what billing patterns they are looking for that would constitute outliers, what triggers a paid claim to be put through the analytics (e.g., high-cost services identified as outliers), what priorities the analytics/algorithms/data mining are looking for, and whether or not all paid claims are subject to being mined.

"Red Flags" for Fraud, Waste, and Abuse

Cigna's additional comparative analyses listed new factors indicated to be "red flags" for potential FWA, such as "Treatment does not match diagnosis," "Treatment dates closely follow enrollment period," and "Unusually high number of patients coded as new patients to gain higher reimbursement." Cigna also stated that it "does not rely on any specific threshold in determining whether one or more of the factors results in the opening of an SIU investigation…."

The examiners responded that in order for comparability and compliance with MHPAEA to be demonstrated, there must be definitive standards that implicate the NQTL. Cigna must either have quantitative thresholds, such as high-cost claims or a provider identified as an outlier for billing a code a certain percentage higher than the average (with calculations and supporting documentation to justify this), or Cigna must provide well-explained, specific, and reasoned examples of how qualitative factors implicate the NQTL and how comparability is ensured. In addition, the factors provided by Cigna included language such as "Treatment dates **closely follow** enrollment period" and "**Unusually high number** of patients coded as new patients to gain higher reimbursement" (emphasis added), which do indicate the use of specific thresholds and contradict Cigna's explanation that it "does not rely on any specific threshold."

BOI Determination

Cigna's comparative analyses were insufficient to demonstrate comparability regarding how the Company determines which MH/SUD benefits and M/S benefits are subject to post-payment retrospective review and when post-payment retrospective review is initiated. Cigna's comparative analyses as presented allowed for too much subjectivity to the extent that post-payment retrospective review can be imposed at Cigna's complete discretion, resulting in factors, as written and in operation, used in applying post-payment retrospective review to MH/SUD benefits that are not comparable to and are more stringently applied than the factors used in applying post-payment retrospective review to M/S benefits.

Processes Not Sufficiently Explained

The examiners deemed Cigna's initial comparative analyses to be insufficient for the failure to adequately explain the processes in step four that take place as part of post-payment retrospective review in a manner that demonstrates comparability. Cigna was given a second attempt to provide this information.

Cigna's additional comparative analyses continued to fail to provide this information aside from a broad statement that "Cigna has developed specific written policies governing the investigation of substance use disorder benefits and laboratory services where potentially fraudulent activity is commonly reported." Cigna also argued the following in its supplemental response:

> …All CPT codes and revenue codes are potentially subject to some form of post-payment retrospective review. Cigna respectfully submits that this underscores the fact that the programs satisfy the "in writing" element in demonstrating comparability between M/S and MH/SUD benefits under the plan: the programs are generally designed without regard to whether services or claims are M/S or MH/SUD (in which case the factors, evidentiary standards, etc. are identical)….

The examiners responded that MHPAEA requires deliberate recognition of MH/SUD benefits and ensuring that procedures are not discriminatory against MH/SUD benefits, as well as ensuring that procedures do not result in a more stringent application to MH/SUD benefits. A factor or process may be identical as written between MH/SUD benefits and M/S benefits, but this does not mean that the design and application of the factor is automatically comparable. For example, Cigna may use a factor that allows discretion in applying an NQTL that is not captured in detail in its written procedures, which may not be comparable in practice when investigating MH/SUD claims as compared to when investigating M/S claims. As another example, Cigna may have

written processes that are comparable between MH/SUD benefits and M/S benefits, but that are applied in a more stringent manner to MH/SUD benefits than to M/S benefits in operation. As a third example, a written procedure may scrutinize MH/SUD claims and M/S claims for FWA based on a factor such as the amount of time a service is performed, which is identical as written, but this may result in being applied more restrictively to timed psychotherapy sessions. Cigna must explain how it assured itself that issues such as these are not present, and simply stating that elements are designed without regard to whether claims are for MH/SUD benefits or M/S benefits is insufficient to demonstrate compliance with MHPAEA.

Using FWA investigations as an example, these generally involve identification of outliers, contact made to a provider, requests for medical records and other documentation, a review of medical records and other documentation, a decision on whether or not FWA is present, and a decision to take action. The action may involve recoupment of payments, extrapolation to other claims, provider education, progressive corrective action (e.g., placement on pre-payment review, flagging of claims, and pending claims), or something entirely different. Cigna failed to explain which of these processes it utilizes, how it determines that FWA is present, how it decides which action to take, how extrapolation is performed, and how all of these elements are comparable between MH/SUD benefits and M/S benefits.

BOI Determination

Cigna's comparative analyses were insufficient to demonstrate comparability regarding the processes that take place for MH/SUD benefits and M/S benefits as part of post-payment retrospective review. Cigna's comparative analyses as presented allowed for too much subjectivity to the extent that post-payment retrospective review processes and decision making are left to Cigna's complete discretion, resulting in processes, as written and in operation, used in applying post-payment retrospective review to MH/SUD benefits that are not comparable to and are more stringently applied than the factors used in applying post-payment retrospective review to M/S benefits.

In-Operation Deficiencies and Disparities

The in-operation portion of a comparative analysis regarding post-payment retrospective review must demonstrate adherence to internal procedures and protocols, adherence to clinical criteria in making correct medical necessity determinations, and appropriate decision-making regarding findings of FWA/overpayments and actions taken, as well as comparability of outcomes data (e.g., number paid claims recouped, number of paid claims with findings of FWA, and frequency of different actions taken). The examiners identified the below examples of deficiencies and disparities regarding in-operation compliance.

Failure to Perform and Document Internal Audits

The examiners deemed Cigna's initial comparative analyses to be insufficient for the failure to adequately document comparability regarding final carrier disposition options and results regarding adverse decisions. Cigna was given a second attempt to provide this information.

Cigna's additional comparative analyses included only broad statements such as the following:

> Cigna applies general policies without regard to whether a given service is an MH/SUD or M/S service. Cigna has developed specific written policies governing the investigation of substance use disorder benefits and laboratory services where potentially fraudulent activity is commonly reported.

The examiners responded that this information is insufficient to demonstrate compliance and that going forward Cigna must incorporate the results of internal audits that were performed regarding post-claim payment FWA, post-claim payment clinical review, post-claim payment coding edits, and any other post-claim payment functions that Cigna utilizes.

BOI Determination

Cigna failed to demonstrate in-operation compliance regarding adequate methods of quality assurance oversight.

Insufficient Outcomes Data

Cigna's initial comparative analyses included only a chart identified as an "overview of the claims breakdown" with no explanation of what the included numbers represented, and data for all of the classifications or sub-classifications was combined. The examiners deemed this documentation to be insufficient for the failure to present the metrics in an acceptable format and the failure to provide specific disposition results, including rates of retraction/recoupment of paid amounts, rates of placement on progressive corrective action, and rates of any other applicable outcomes. Cigna was given a second attempt to provide sufficient metrics based on elaboration provided by the examiners regarding the required parameters.

Cigna's additional comparative analyses provided the same chart again with further explanation that the chart demonstrates that "the majority of claims that result in an investigation are for M/S claims vs. MH/SUD claims," and that "M/S claims represented 88.2 percent of claims subject to SIU activity…." Cigna also provided other charts

including fields such as “Total Spend %,” “Total Recovery %,” as well as information reflecting the method of contacting providers and timing for outreach.

The examiners responded that the number of claims investigated is only one component of the NQTL and that Cigna failed to provide information on the dispositions as instructed. Cigna also failed to explain the parameters of the data provided, failed to explain how the data demonstrates comparability (e.g., what conclusions are being drawn from analyzing “Total Spend %” and “Total Recovery %”), and continued to fail to present the data separately for each classification or sub-classification. Going forward, Cigna must provide the percentage of claims for MH/SUD benefits and M/S benefits that were investigated and the percentage of claims that resulted in each of the possible outcomes (e.g., how many were retracted, how many resulted in extrapolation to other claims, and how many resulted in progressive corrective actions), as well as provide a detailed discussion of its analysis of the data.

BOI Determination

Due to the failure to provide the necessary information in its comparative analyses, Cigna failed to demonstrate in-operation compliance regarding outcomes data.

BOI Data Analysis

Upon notifying Cigna that its initial comparative analyses were deemed insufficient regarding in-operation compliance, the examiners also requested a population of previously paid MH/SUD claims and M/S claims that were subsequently recouped or retracted so that the BOI could perform its own analysis of the data.

Cigna provided this population, but limitations continued to exist, such as no claims involving mental health diagnoses being identified by Cigna as recouped or retracted for place-of-service codes that make up the “Outpatient, In-Network, All Other” and “Outpatient, Out-of-Network, All Other” sub-classifications.

Despite limitations in the provided data, the examiners identified the following in-operation disparities between MH/SUD benefits and M/S benefits:

- **Inpatient Claims Recouped or Retracted:** For the place-of-service codes that make up the “Inpatient, In-Network” and “Inpatient, Out-of-Network” classifications, the provided population indicated that 411 MH/SUD claims, including 120 substance use disorder inpatient hospital claims (place-of-service 21) were recouped as compared to only 2 M/S claims. The documentation as presented indicates disparities between MH/SUD benefits and M/S benefits regarding investigations performed on paid claims and Cigna’s recoupment process.

- **Outpatient Claims Recouped or Retracted:** For the place-of-service codes that make up the "Outpatient, In-Network, All Other" and "Outpatient, Out-of-Network, All Other" sub-classifications, although the provided population didn't include claims involving mental health diagnoses, the data indicated that 139 substance use disorder on-campus outpatient hospital claims (place-of-service 22) were recouped as compared to only 123 M/S claims for the same place-of-service. While the disparity does not appear large on the surface, it is important to note that the universe of paid M/S claims is significantly larger than the universe of paid MH/SUD claims, so a higher number of MH/SUD claims being recouped appears to be a material difference. The documentation as presented indicates disparities between MH/SUD benefits and M/S benefits regarding investigations performed on paid claims and Cigna's recoupment process.

BOI Determination

While disparate results alone are not determinative of MHPAEA non-compliance, disparities in the provided metrics between MH/SUD benefits and M/S benefits indicate red flags that warrant, at a minimum, further review of a company's processes, strategies, evidentiary standards, and other factors. Further review revealed that Cigna's comparative analyses were insufficient to demonstrate comparability as written/in design due to deficiencies such as subjective factors and unexplained processes, and that Cigna's comparative analyses were insufficient to demonstrate comparability in operation due to deficiencies such as the failure to perform and document internal audits. When considered in combination with the other existing deficiencies in Cigna's comparative analyses, the disparities in Cigna's in-operation metrics go beyond disparate results alone and indicate that the processes, strategies, evidentiary standards, or other factors used in applying post-payment retrospective review to MH/SUD benefits are more stringently applied in operation than the processes, strategies, evidentiary standards, or other factors used in applying post-payment retrospective review to M/S benefits.

Additional Retrospective Review NQTLs

Cigna's post-payment retrospective review comparative analyses also stated that the SIU performs functions related to pre-payment savings. While this was not the initial subject of the BOI's request, this explanation indicates that Cigna also performs FWA functions and others during the pre-claim payment phase. Cigna is cautioned that its retrospective review comparative analyses, as discussed earlier in this Report under the "FINDINGS: RETROSPECTIVE REVIEW" heading, must also include any other forms of the NQTL that may be utilized, including pre-payment review (e.g., where all claims or a subset of claims for a specific provider or facility are audited upon claim submission due to a history of overutilization or a finding of FWA) and pre-claim payment FWA investigations.

Corrective Actions:

- Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for pre-payment review (e.g., a provider or facility is flagged for a history of overutilization or a finding of FWA, and either all or a subset of that provider's or facility's claims are subject to review/audit upon claim submission) and pre-claim payment FWA investigations that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A).

- Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for post-payment retrospective review that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently.

FINDINGS: MEDICAL NECESSITY

NQTL Description: Medical necessity concerns the standard/definition and criteria used to determine whether or not a service or procedure meets requirements such as safety and effectiveness to qualify for benefit coverage under the policy. The criteria analyzed as part of this NQTL are used by the carrier in making medical necessity determinations as part of other NQTLs, such as prior authorization, concurrent review, and retrospective review.

Finding: The Company's comparative analyses for medical necessity were insufficient and in violation of § 38.2-3412.1 B of the Code for the failure to comply with 45 CFR 146.136(c)(4)(i) and 42 USC 300gg-26(a)(8)(A).

Discussion: As discussed in Review Sheet MH01-HW, Cigna's comparative analyses in each applicable classification or sub-classification were insufficient to demonstrate compliance with MHPAEA and/or indicated that processes, strategies, evidentiary standards, or other factors were not comparable between MH/SUD benefits and M/S benefits. Examples of deficiencies are discussed below.

Development, Selection, and Adoption of Clinical Criteria

Cigna's comparative analyses explained that the Company uses the guidelines published by the American Society of Addiction Medicine ("ASAM Criteria") to make medical necessity determinations regarding substance use disorders, and that the Company uses

the guidelines published by MCG Health ("MCG Guidelines") and Cigna's internally-developed clinical criteria (referred to by Cigna as "coverage policies") to make medical necessity determinations regarding medical/surgical conditions and mental health conditions. This means that Cigna uses a combination of externally-developed third-party clinical criteria and internally-developed clinical criteria to make medical necessity determinations. Below are examples of concerns identified by the examiners regarding Cigna's development, selection, and adoption process with respect to these criteria.

Development of Coverage Policies

The examiners deemed Cigna's initial comparative analyses to be insufficient for the failure to explain the development process of its internally-developed coverage policies. Cigna's initial comparative analyses included broad statements that the Company has "assessed" policies and has measures to "ensure consistency," and information regarding a "Levels of Scientific Evidence Table" was provided. However, the provided information did not specifically explain the development process. Cigna was given a second attempt to provide this information.

While Cigna's additional comparative analyses provided more information, the analyses continued to include broad explanations about the Company's Medical Technology Assessment Committee ("MTAC"), such as the following:

> …The MTAC develops clinical criteria to assist both M/S and MH/SUD medical directors in determining whether a technology is medically necessary, not medically necessary, or experimental, investigational, or unproven, based on an evaluation of peer reviewed, evidence based scientific literature, information from appropriate governing regulatory bodies (e.g. US Food and Drug Administration), and professional society recommendations…
>
> …MTAC uses the principles of evidence-based medicine in its evaluation of clinical literature, in development of its reviews, in its deliberative process, and in preparing published medical coverage policies…
>
> …Levels of evidence…are assigned to the publications based upon underlying study characteristics, including but not limited to incidence and prevalence of disease, health disparity and health equity factors, study design, number of subjects, clinical outcomes of relevance, statistics used and significance, and assessment of flaws and bias. Consideration of the strength of the evidence includes recognition of a hierarchy of evidence, where increased weight is placed on those studies where the design and characteristics of the study confer a greater degree of statistical certainty

> between the intervention in a specific patient population, and the clinical outcome. A research team performs an assessment of the literature in order to determine if there is a sufficiently evidence-based proven relationship between the intervention and improved health outcomes. This information is presented to the committee who makes a final determination regarding coverage criteria...

The examiners responded that, while this language explains that coverage policies are developed by a committee, it does not explain specifically how the committee develops the coverage policies. Cigna's description of the "Levels of Scientific Evidence Table" provides no information other than a list of the types of sources consulted and confirmation that some are weighted more heavily than others. The comparative analyses fail to explain how information is compiled from this hierarchy of evidence, how the information is specifically reviewed and evaluated, and where the hierarchy fits in with the writing of Cigna's coverage policies. At a minimum, Cigna should have provided detailed, specific examples of this process, such as selecting an MH/SUD coverage policy and an M/S coverage policy, providing the sources and evidentiary standards consulted, and explaining how the material was compiled, evaluated, and transferred to a coverage policy in a way that is comparable between MH/SUD benefits and M/S benefits.

Comparability of Externally-Developed Third-Party Clinical Criteria

The examiners deemed Cigna's initial comparative analyses to be insufficient for the failure to explain how the Company assured itself that the externally-developed third-party clinical criteria (i.e., the ASAM Criteria and the MCG Guidelines) utilized by the Company are comparable in content between MH/SUD benefits and M/S benefits. Cigna was given a second attempt to provide a specific explanation of how these two sets of criteria were reviewed and evaluated by Cigna to confirm comparability.

Cigna's additional comparative analyses and supplemental responses included arguments such as the following:

> Cigna reviewed nationally accepted criteria sets (MCG and Interqual) for M/S and mental health (MH) criteria, and ASAM for substance use disorder (SUD) criteria. In doing so, the process for determining the criteria is the same for MHSUD as for Medical/Surgical. It is Cigna's position that identical process for the criteria development by the nationally accepted clinical criteria from the same company clearly meets the requirements for parity compliance. ASAM is the national standard for SUD criteria and as many states moved to make ASAM mandatory, Evernorth uses ASAM. Their process for development is aligned with MCG, meeting regulatory requirements.

> As stated in Step 3 of the comparative analysis, Cigna uses MCG for medical and MH clinical criteria and ASAM for SUD criteria. The use of ASAM Criteria for SUD medical necessity determinations is required by multiple states. The states recognize ASAM Criteria as flexible and transparent with generally accepted standards of care for the treatment of Substance Use Disorders…
>
> …MCG Health ensures that each guideline undergoes external review by clinically active experts…to confirm the clinical appropriateness, accuracy, validity, and applicability of each guideline. A supervising clinical editor evaluates all comments from these external reviewers and makes necessary changes to the guideline. Updated and new MCG Health guidelines are presented to the MTAC committee annually. Following a review and discussion of the changes and new guidelines, the committee votes to approve and implement the guidelines…
>
> …MCG states on their website – "Our clinical editors analyze and classify peer-reviewed papers and research studies each year to develop the care guidelines in strict accordance with the principles of evidence-based medicine. Annually, thousands of references are reviewed and ranked, with unique citations."

The examiners maintained the finding of non-compliance and stated that both the content and development of medical necessity criteria must be comparable between MH/SUD benefits and M/S benefits to comply with MHPAEA. While the examiners agree that scrutiny should not be placed on the ASAM Criteria due to these being a generally accepted standard of medical practice, the MCG Guidelines are not universally recognized as such. There is no documentation to date that MCG has ever reviewed its own guidelines or performed a comparative analysis to demonstrate MHPAEA compliance. Cigna's response fails to explain the details of MCG's "external review by clinically active experts," including how this review is sufficient to demonstrate MHPAEA compliance, and a quote from the MCG website that includes broad information is not adequate to demonstrate MHPAEA compliance.

In order for comparability to be ensured regarding the content of externally-developed third-party clinical criteria, Cigna must confirm that the MCG Guidelines are compliant with MHPAEA in the context that 1) MCG medical/surgical and MCG mental health criteria are comparable in content and 2) MCG medical/surgical criteria are consistent with the standards set by ASAM substance use disorder criteria in content. Ensuring comparability in content would entail thoroughly reviewing the entirety of the mental health criteria and also thoroughly reviewing the entirety of the medical/surgical criteria. Cigna would then need to explain how and why it determined that, overall, the mental health

criteria were comparable to the medical/surgical criteria with examples provided as evidence. The same process is needed to then produce a similar explanation as to how and why the ASAM substance use disorder criteria and the MCG medical/surgical criteria are comparable, again with examples provided as evidence.

BOI Determination

Cigna's comparative analyses were insufficient to demonstrate comparability regarding the development, selection, and adoption of coverage policies and the review of externally-developed third-party clinical criteria for MH/SUD benefits and M/S benefits. Cigna's comparative analyses allowed for too much subjectivity as presented, resulting in processes, strategies, evidentiary standards, or other factors, as written, used in applying medical necessity criteria to MH/SUD benefits that are not comparable to and are more stringently applied than the processes, strategies, evidentiary standards, or other factors used in applying medical necessity criteria to M/S benefits.

Clinical Judgment and Discretion

The examiners deemed Cigna's initial comparative analyses to be insufficient for the failure to demonstrate comparability regarding clinical judgment/discretion used in applying medical necessity criteria. As industry standard, physician reviewers commonly have discretion to deviate from written medical necessity criteria, and Cigna's initial comparative analyses failed to account for this information. Cigna was given a second attempt to demonstrate comparability regarding policies or procedures that govern when clinical judgment, in lieu of written criteria, is acceptable for physician reviewers.

Cigna's supplemental response provided with its additional comparative analyses stated the following:

> Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines.
>
> Cigna's internal policy HM_CLN_043, section A.2.e, states: Permits Utilization Review staff to deviate from the medical necessity criteria by authorizing benefit coverage as medically necessary to ensure the customer's safety and/or to ensure the customer receives clinically appropriate care based upon the individual's unique clinical needs, risk factors and/or circumstances in accordance with the terms and conditions of the customer's health plan.

> Cigna is URAC and NCQA accredited for their utilization management services. Both accrediting bodies provide standards around medical decision-making.
>
> Specifically, under NCQA, "UM 2: Clinical Criteria for UM Decisions" provides that "The organization uses written criteria based on sound clinical evidence to make utilization decisions and specifies procedures for appropriately applying the criteria."

The examiners maintained the finding of non-compliance and stated that satisfying accreditation standards does not automatically constitute MHPAEA compliance. In addition, the accreditation language cited by Cigna does not speak specifically to clinical judgment/discretion to deviate from written criteria. While the examiners acknowledge that Cigna does have procedures in place as part of policy HM_CLN_043 that speak to this topic, Cigna has not provided any explanation of how this internal policy is comparably applied between MH/SUD benefits and M/S benefits in its comparative analyses. Cigna failed to define what is meant by the language “to ensure the customer’s safety and/or to ensure the customer receives clinically appropriate care based upon the individual’s unique clinical needs, risk factors and/or circumstances…” for MH/SUD benefits and M/S benefits, failed to provide specific examples of these situations, and failed to explain whether or not this procedure applies to both nurses/care managers and physician reviewers.

BOI Determination

Based on this information, Cigna’s comparative analyses were insufficient to demonstrate comparability regarding the application of clinical judgment for MH/SUD benefits and M/S benefits. Cigna’s comparative analyses allowed for too much subjectivity as presented, resulting in a process, as written, used in applying clinical judgment to MH/SUD benefits that is not comparable to and is more stringently applied than the process used in applying clinical judgement to M/S benefits.

Corrective Action: Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for medical necessity that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently.

FINDINGS: EXPERIMENTAL/INVESTIGATIONAL/UNPROVEN

NQTL Description: Experimental/Investigational/Unproven ("EIU") concerns services that a carrier considers to be experimental/investigational/unproven and are not covered under the terms of the policy. An EIU service is generally defined by a carrier as a treatment, procedure, facility, type of equipment, drug, service, or supply ("intervention") that has been determined not to be medically effective for the condition being treated.

Finding: The Company's comparative analyses for EIU were insufficient and in violation of § 38.2-3412.1 B of the Code for the failure to comply with 45 CFR 146.136(c)(4)(i) and 42 USC 300gg-26(a)(8)(A).

Discussion: The examiners did not initially request Cigna's EIU comparative analyses for review. However, Cigna included EIU as a subset of its medical necessity comparative analyses. In addition, a service being deemed EIU was also a factor utilized by Cigna for determining which MH/SUD benefits and M/S benefits are subject to prior authorization, concurrent review, and retrospective review. As elements of EIU overlapped with other NQTLs reviewed by the examiners, the EIU NQTL was also reviewed.

As discussed in Review Sheet MH01-HW, Cigna's comparative analyses in each applicable classification or sub-classification were insufficient to demonstrate compliance with MHPAEA and/or indicated that processes, strategies, evidentiary standards, or other factors were not comparable between MH/SUD benefits and M/S benefits. Examples of deficiencies are discussed below.

Factors Not Sufficiently Defined

Cigna's initial prior authorization, concurrent review, and retrospective review comparative analyses included the factor of "services that are determined to be experimental, investigational, or unproven" for determining which MH/SUD benefits and M/S benefits are subject to those NQTLs. The examiners deemed these initial comparative analyses to be insufficient for the failure to provide a definitive standard for determining that services are EIU, as the only standard provided was a statement that the determination is made "according to available clinical evidence." Cigna was given a second attempt to provide a definitive standard for determining that MH/SUD benefits and M/S benefits are EIU.

Cigna's additional comparative analyses for prior authorization, concurrent review, and retrospective review provided more information regarding EIU determinations, and Cigna's additional comparative analyses for medical necessity also incorporated information regarding EIU processes, strategies, evidentiary standards, and other factors. This information included the following explanation:

The terms experimental, investigational and unproven (collectively "EIU") are used together or interchangeably and this phrase reflects a common intent. Cigna considers medical, surgical, diagnostic, behavioral health or other health care technologies, supplies, treatments, procedures, or devices to be EIU if any of the following criteria is met:

- inadequate volume of existing peer-reviewed, evidence-based, scientific literature to establish whether or not a technology, supplies, treatments, procedures, or devices is safe and effective for treating or diagnosing the condition or sickness for which its use is proposed;
- when subject to U.S. Food and Drug Administration (FDA) or other appropriate regulatory agency review, is not approved to be lawfully marketed for the proposed use;
- the subject of review or approval by an Institutional Review Board for the proposed use except as provided in a clinical trial, as outlined in the applicable policy and/or benefit plan document; or
- the subject of an ongoing phase I, II or III clinical trial, except for routine patient care costs related to qualified clinical trials.

The MTAC's evidence-based medicine approach ranks the categories of evidence and assigns greater weight to categories with higher levels of scientific evidence as set forth below in Cigna's "Levels of Scientific Evidence Table" adapted from the Centre for Evidence Based Medicine, University of Oxford, March 2009 and evidenced in Cigna's Medical Technology Assessment and Coverage Process for Determination of Medical Necessity Coverage Criteria Recommendations Policy and set forth below:

> Level 1: Randomized Controlled Trials (RCT). Randomized, blinded, placebo-controlled, clinical trials and systematic reviews of RCTs and meta-analysis of RCTs.
>
> Level 2: Non-randomized controlled trials (an experimental study, but not an ideal design). Also, systematic reviews and meta-analyses of non-randomized controlled trials.
>
> Level 3: Observational studies – e.g. cohort, case-control studies (non-experimental studies). Also, systematic reviews and meta-analyses of observational studies.

> Level 4: Descriptive studies, case reports, case series, panel studies (non-experimental studies), and retrospective analyses of any kind. Also, systematic reviews and meta-analyses of retrospective studies.
>
> Level 5: Professional/organizational recommendations when based upon a valid evidence-based assessment of the available literature.

The examiners responded that this information continues to fail to provide a definitive standard for determining how MH/SUD services and M/S services are deemed EIU. At a minimum, Cigna must provide a detailed, specific explanation and definitive standard that demonstrates comparability for what constitutes an "inadequate volume" and what "existing peer-reviewed, evidence-based, scientific literature" is utilized. As previously discussed regarding Cigna's medical necessity comparative analyses, Cigna's "Levels of Scientific Evidence" table appears to only be a list of the types of sources consulted to determine if a treatment is proven. There is no explanation regarding how Cigna ensures comparability between MH/SUD benefits and M/S benefits regarding the following elements: the number of sources/studies considered for treatments under review; the number of randomized controlled trials completed before a treatment is considered proven; information regarding clinical trials; consideration of sample sizes; evaluation of the existence of or lack of control groups; evaluation of the existence of or lack of follow-up data/evidence; evaluation of potential blinding; and any other applicable elements.

BOI Determination

Cigna's comparative analyses were insufficient to demonstrate comparability regarding how the Company determines which MH/SUD benefits and M/S benefits are EIU. Cigna's comparative analyses allowed for too much subjectivity as presented, resulting in factors, as written and in operation, used in applying EIU determinations to MH/SUD benefits that are not comparable to and are more stringently applied than the factors used in applying EIU determinations to M/S benefits.

Corrective Action: Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for experimental/investigational/unproven ("EIU") that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently.

FINDINGS: BLANKET POLICY EXCLUSIONS

NQTL Description: Blanket policy exclusions concern contractual exclusions regarding services that are not covered benefits under the terms of the policy.

Discussion: The examiners did not initially request Cigna's blanket policy exclusions comparative analyses for review. However, a review of the sample policies revealed that the list of NQTLs provided by Cigna at the beginning of the examination did not account for several excluded MH/SUD benefits, and Cigna's comparative analyses for other NQTLs, such as medical necessity, did not specifically account for these exclusions. The exclusions in question included complementary and alternative medicine (e.g., art therapy, animal therapy, and wilderness therapy), non-medical counseling or ancillary services (e.g., work hardening programs and educational programs), and cosmetic surgeries in the context of gender dysphoria. As the basis for these exclusions was not clear from information initially provided by Cigna, the examiners requested Cigna's rationale for how the exclusion of these services complies with MHPAEA.

A review of Cigna's rationale revealed that the services in question were excluded due to being considered not medically necessary or being considered EIU, and Cigna provided criteria to support these determinations. Based on this information, these exclusions are expressions of the medical necessity and EIU NQTLs. However, the factors provided for excluding these services were not included in Cigna's medical necessity or EIU comparative analyses, such as assessments of whether or not the health care providers are licensed or certified under state law and whether or not the service in question has a unique billing code.

While additional violations will not be assessed regarding blanket policy exclusions as a separate and distinct NQTL, Cigna's additional explanations further contribute to Cigna's medical necessity and EIU comparative analyses being insufficient. Cigna is also cautioned that its blanket policy exclusions are problematic for external review purposes. If a service is excluded due to medical necessity or being EIU, it should either not be listed as a blanket exclusion (it should be contemplated under the already-existing exclusion referencing any service that is not medically necessary or any service that is EIU) or it should be specified in the policy that the excluded service is based on medical necessity or being EIU for transparency regarding external review rights.

Cigna is also cautioned that, if the Company applies any blanket policy exclusions for MH/SUD benefits that are not related to medical necessity or EIU, it must perform and document a separate comparative analysis to justify those exclusions.

Recommendations:

- Cigna will either remove its blanket policy exclusions for all MH/SUD benefits and M/S benefits that are based on the service being not medically necessary or being EIU and allow them to be contemplated under the already-existing exclusions for any service that is not medically necessary or any service that is EIU, or Cigna will

specify in the policy that the excluded service is based on medical necessity or EIU for transparency regarding external review rights.

- Cigna will review its individual and large group policies and identify whether or not Cigna applies any blanket policy exclusions for MH/SUD benefits that are not related to medical necessity or EIU. If any such exclusions are identified, Cigna will perform and document a comparative analysis to justify the exclusion(s).

VII. OTHER NQTL ISSUES

The examiners requested additional documentation and explanations regarding more granular topics to supplement the information provided in Cigna's comparative analyses. This included reviews of supporting documentation provided as part of Cigna's comparative analyses, reviews of specific coverage policies, and other reviews to substantiate information that was provided by Cigna.

The examiners reviewed Cigna's additional documentation and explanations to determine compliance with various requirements, including but not limited to the following:

- § 38.2-3412.1 B of the Code
- § 38.2-3418.17 of the Code
- § 38.2-3449.1 of the Code
- 45 CFR 146.136(c)(4)(i)
- 42 USC 300gg-26(a)(8)(A)

The BOI notes that reviews of this additional documentation are time consuming and complex and that these reviews involve a high volume of information. While this Report includes examples of the deficiencies identified, it does not provide an exhaustive list of all of the deficiencies.

FINDINGS: MEDICAL NECESSITY CRITERIA FOR AUTISM AND ABA

Background: As part of Cigna's medical necessity comparative analyses, the Company provided the examiners access to its internally-developed clinical criteria ("coverage policies"). Cigna utilized two coverage policies to make medical necessity determinations regarding autism spectrum disorders ("ASD"). One coverage policy was titled Autism Spectrum Disorders/Pervasive Developmental Disorders: Assessment and Treatment, and this document addressed the medical necessity criteria for treatments such as psychotherapy. The other coverage policy was titled Intensive Behavioral Interventions, and this document addressed the medical necessity criteria for applied behavior analysis ("ABA"). The examiners reviewed these coverage policies for compliance with § 38.2-3418.17 of the Code and MHPAEA.

Finding: Cigna's coverage policies were in violation of § 38.2-3418.17 A of the Code and in violation of § 38.2-3412.1 B of the Code for the failure to comply with 45 CFR 146.136(c)(4)(i) and 42 USC 300gg-26(a)(8)(A).

Discussion: As discussed in Review Sheet MH02-BL, Cigna's two ASD coverage policies were inconsistent with and in violation of the medical necessity standard required under § 38.2-3418.17 of the Code. The standard for medical necessity and other requirements specified in Cigna's coverage policies also appeared to limit treatment for MH/SUD benefits in a more restrictive manner than the standards and requirements imposed on M/S benefits, and Cigna's explanations to justify the content of its coverage policies were insufficient to demonstrate compliance with MHPAEA. Examples of deficiencies are discussed below.

Medical Necessity Standard

Section 38.2-3418.17 A of the Code requires coverage for medically necessary treatment of ASD. This statute defines medically necessary as follows:

> "Medically necessary" means **in accordance with the generally accepted standards of mental disorder or condition care** and clinically appropriate in terms of type, frequency, site, and duration, based upon evidence and reasonably expected to do any of the following: (i) prevent the onset of an illness, condition, injury, or disability; (ii) reduce or ameliorate the physical, mental, or developmental effects of an illness, condition, injury, or disability; or (iii) **assist to achieve or maintain maximum functional capacity in performing daily activities**, taking into account both the functional capacity of the individual and the functional capacities that are appropriate for individuals of the same age (emphasis added).

In addition, generally accepted standards of medical practice (or "generally accepted standards of mental disorder or condition care," as referenced in the statute) establish that treatment for MH/SUD conditions that is expected to maintain a level of functioning or prevent deterioration should be considered medically necessary. As an example, the Applied Behavior Analysis Treatment of Autism Spectrum Disorder: Practice Guidelines for Healthcare Funders and Managers Second Edition[2] published by the Council of Autism Service Providers ("CASP") (herein referred to as the "CASP Guidelines") state, "The guidelines in this document are pertinent to the use of ABA as a behavioral health treatment to **develop**, **maintain**, or restore, to the maximum extent practicable, the **functioning** of an individual with ASD" (emphasis added). This means that § 38.2-3418.17 of the Code allows for any one of three scenarios to be met for medical

[2]CASP published the third edition of its ABA Practice Guidelines on April 29, 2024. However, the second edition is referenced in this Report because this version was in effect during the examination time frame.

necessity to be demonstrated for ASD treatments, including treatment that is expected to achieve or maintain functioning, and this standard is consistent with generally accepted standards of medical practice, which are also referenced in the statute.

However, Cigna's Autism Spectrum Disorders/Pervasive Developmental Disorders: Assessment and Treatment coverage policy required the stipulation that "meaningful and measurable improvement is expected from the therapy" for ASD treatment to be considered medically necessary by the Company, and Cigna's Intensive Behavioral Interventions coverage policy required that "There is evidence of measurable and ongoing improvement…" for continued treatment with ABA to be considered medically necessary by the Company. This medical necessity standard appeared to be inconsistent with the requirements of the Code and appeared to place unnecessary restrictions on ASD treatments, as an expectation or demonstration of "improvement" creates a more difficult threshold for the provider or patient to meet than an expectation to "assist to achieve or maintain maximum functional capacity in performing daily activities." The examiners communicated these concerns, and Cigna was given an opportunity to provide justification for the requirements of its coverage policies and to demonstrate how comparable requirements are imposed on M/S benefits.

Cigna disagreed, and its arguments included the following:

- Cigna provided an internal procedure regarding the development of medical necessity criteria and stated the following:

  > …Cigna uses multiple resources in making coverage determinations, as noted by the policy. Cigna applies federal and state mandates prior to the application of Cigna policies. Most noticeably, where there may be a discrepancy between state mandates and Cigna policies, Cigna applies the state mandate….

- Cigna argued that its Intensive Behavioral Interventions coverage policy contemplates the requirements of the Code by allowing for medical necessity under the following scenario:

  > When progress toward mastering treatment and/or stakeholder goals, or evidence of measurable and ongoing improvement is not demonstrated, barriers toward progress have been identified, and there is a specific and documented plan to address barriers and evidence of interventions being adjusted through protocol modification, with continued data monitoring and assessment for effectiveness by the provider.

- Cigna argued that coverage policies for physical therapy, occupational therapy, and speech therapy also require standards based on improvement for the treatment to be considered medically necessary by the Company, so comparable requirements are imposed on M/S benefits.

The examiners maintained the finding of non-compliance based on the following:

- Regarding Cigna's explanation that state mandates are applied if there is a discrepancy between those mandates and the coverage policies, the internal procedure referenced by Cigna (which is also included in its coverage policies) actually states the following:

  > Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation….

  The language in question appears to speak to scenarios where services referenced as excluded under coverage policies may be covered in certain plans rather than speaking to medical necessity definitions. In addition, Cigna's broad reference to the consideration of "any applicable laws/regulations" does not absolve the Company of the requirement to incorporate the medical necessity standard from the Code into its medical necessity criteria. Furthermore, even if Cigna's explanation was acceptable, the Company failed to explain how the premise of the Code's definition of medically necessary superseding Cigna's coverage policy would be applied in practice.

- Regarding Cigna's provision speaking to barriers to ongoing improvement, it appears that requiring "measurable and ongoing improvement" with a potential exception if there is a plan to address barriers to such is a more difficult threshold

for the provider or patient to meet than the standard required in the Code that is based on treatment expected to assist to achieve or maintain maximum functional capacity. Contemplating the standard in the Code as a potential exception to a standard based on improvement is not sufficient to meet the requirements of the statute. The examiners also note that the provision addressing barriers to ongoing improvement is only in the Intensive Behavioral Interventions coverage policy, so even if Cigna's argument regarding the provision in question was sufficient, it would only apply to one of the two coverage policies.

- Regarding the M/S coverage policies referenced by Cigna, the examiners acknowledge that these M/S benefits also require a medical necessity standard based on improvement. However, Cigna has not sufficiently demonstrated or substantiated how its physical therapy, occupational therapy, and speech therapy coverage policies were developed based on generally accepted standards of medical practice and how Cigna determined that the evidence-based sources would translate to its own standard requiring improvement. Cigna's ASD coverage policies appear to deviate from generally accepted standards of medical practice, and the Company has failed to provide sufficient information to explain whether or not the development of its M/S coverage policies also involves such deviation.

- As an additional argument regarding the M/S coverage policies referenced by Cigna, the Company's M/S physical therapy coverage policy specifically allows for habilitative therapy to be medically necessary, including language such as "There is an expectation that the therapy will improve function, assist development of function, or keep an acceptable level of functioning." As Cigna considers the MH/SUD benefit of ABA for ASD to be medically necessary when there is an expectation or demonstration of "improvement," this means that ABA is only being contemplated as a rehabilitative service, creating a more restrictive standard for MH/SUD benefits.

BOI Determination

The standard for medical necessity in Cigna's ASD coverage policies was in violation of § 38.2-3418.17 A of the Code.

In addition, Cigna's medical necessity criteria appeared to be more restrictive for MH/SUD benefits as compared to M/S benefits, and as discussed in a previous section of this Report, Cigna's medical necessity comparative analyses were insufficient to demonstrate comparability regarding the development of coverage policies for MH/SUD benefits and M/S benefits. Cigna's failure to provide sufficient comparative analyses and failure to provide sufficient explanations to justify the requirements of its specific coverage policies result in processes, strategies, evidentiary standards, or other factors, as written, used in

applying medical necessity criteria to MH/SUD benefits that are not comparable to and are more stringently applied than the processes, strategies, evidentiary standards, or other factors used in applying medical necessity criteria to M/S benefits.

Treatment Plan Requirements

Cigna's Intensive Behavioral Interventions coverage policy also included requirements that appeared to place unnecessary restrictions on ABA regarding the treatment plan documentation needed for continued treatment to be considered medically necessary by the Company. For example, the coverage policy included a requirement to "provide the name, credentials, and type of licensure of the individual who made the diagnosis and the date on which the diagnosis was made." The examiners communicated these concerns, and Cigna was given an opportunity to provide justification for the treatment plan requirements of its coverage policies and to demonstrate how comparable requirements are imposed on M/S benefits.

Cigna disagreed, but the Company's response included only excerpts from other coverage policies without the necessary context and offered only broad explanations such as "radiation oncology and speech therapy are medical services that require a clear diagnosis, documentation of a treatment plan, and demonstration of progress and/or improvement to continue coverage."

The examiners maintained the finding of non-compliance and stated that, while Cigna has provided speech therapy as an example of an M/S benefit that also requires "clear diagnosis," a review of Cigna's speech therapy coverage policy reveals that this policy makes no reference to a requirement to document a diagnosis (e.g., being required to provide the name, credentials, type of licensure of the individual, and date) other than a statement that the evaluation report "*may* include" (emphasis added) the diagnosis, indicating that the information is optional and that the documentation requirements are more lenient. The documentation specified by Cigna regarding diagnosis of ASD appears to be a more restrictive requirement placed on MH/SUD benefits that Cigna has failed to explain.

In addition, Cigna's failure to provide detailed responses to the examiners' observations indicates that the Company has not performed a treatment plan comparative analysis. This analysis would address issues such as how many MH/SUD benefits require treatment plans and/or demonstration of progress as compared to M/S benefits, whether treatment plans are comparable and applied no more stringently, and how "progress" or "improvement" is measured and defined.

BOI Determination

Cigna's treatment plan requirements specified in its ASD coverage policy appeared to be more restrictive for MH/SUD benefits as compared to M/S benefits, and as discussed in a previous section of this Report, Cigna's medical necessity comparative analyses were insufficient to demonstrate comparability regarding the development of coverage policies for MH/SUD benefits and M/S benefits. Cigna's failure to provide sufficient explanations to justify the treatment plan requirements of its specific coverage policies results in processes, strategies, evidentiary standards, or other factors, as written, used in applying treatment plans to MH/SUD benefits that are not comparable to and are more stringently applied than the processes, strategies, evidentiary standards, or other factors used in applying treatment plans to M/S benefits.

Corrective Actions:

- Cigna will revise its internally-developed clinical criteria ("coverage policies"), including Intensive Behavioral Interventions, Autism Spectrum Disorders/Pervasive Developmental Disorders: Assessment and Treatment, and any other coverage policies that may apply to autism spectrum disorders, to comply with the standard for medical necessity and coverage requirements set forth in § 38.2-3418.17 A of the Code and to remove any requirements that do not comply with MHPAEA.

- Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for treatment plans that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently. This analysis must include, among other elements, a demonstration of comparability regarding the content, nature, and volume of information required in treatment plans for MH/SUD benefits and M/S benefits and a demonstration of comparability regarding the decision of whether or not a treatment plan is needed to determine medical necessity for MH/SUD benefits, specifically ABA for autism spectrum disorders, and M/S benefits.

FINDINGS: MEDICAL NECESSITY CRITERIA FOR GENDER DYSPHORIA

Background: As part of Cigna's medical necessity comparative analyses, the Company provided the examiners access to its coverage policies. Cigna utilized a coverage policy to make medical necessity determinations regarding gender dysphoria titled Gender

Dysphoria Treatment. The examiners reviewed this coverage policy for compliance with § 38.2-3449.1 of the Code and MHPAEA.

Finding: Cigna's coverage policy was in violation of § 38.2-3412.1 B of the Code for the failure to comply with 45 CFR 146.136(c)(4)(i) and 42 USC 300gg-26(a)(8)(A).

Discussion: As discussed in Review Sheet MH04-BL, the requirements specified in Cigna's gender dysphoria coverage policy appeared to limit treatment for MH/SUD benefits in a more restrictive manner than the requirements imposed on M/S benefits, and Cigna's explanations to justify the content of its policy were insufficient to demonstrate compliance with MHPAEA. The deficiencies are discussed below.

Parental Consent and Letters of Support

Cigna's gender dysphoria coverage policy indicated that one of the sources/evidentiary standards used in its development is the Standards of Care for the Health of Transgender and Gender Diverse People, Version 8 published by the World Professional Association for Transgender Health ("WPATH") (herein referred to as the "WPATH SOC 8"), and this source is also recognized as a generally accepted standard of medical practice. The WPATH SOC 8 makes the following recommendations regarding gender affirming surgery in adolescents:

> We recommend when gender-affirming medical or surgical treatments are indicated for adolescents, health care professionals working with transgender and gender diverse adolescents involve parent(s)/guardian(s) in the assessment and treatment process, unless their involvement is determined to be harmful to the adolescent or not feasible…
>
> …We recommend health care professionals involve relevant disciplines, including mental health and medical professionals, to reach a decision about whether puberty suppression, hormone initiation, or gender-related surgery for gender diverse and transgender adolescents are appropriate and remain indicated throughout the course of treatment until the transition is made to adult care…
>
> …If written documentation or a letter is required to recommend gender-affirming medical and surgical treatment (GAMST), only one letter of assessment from a member of the multidisciplinary team is needed. This letter needs to reflect the assessment and opinion from the team that involves both medical and mental health professionals (MHPs)….

Therefore, under the above generally accepted standard of medical practice, as cited by Cigna, the involvement of the parent/guardian is encouraged as part of the assessment

and treatment process, but it is not required for the treatment to be clinically indicated. This standard also requires that medical necessity regarding gender affirming surgery in adolescents is generally assessed by a multidisciplinary team inclusive of mental health providers and medical/surgical providers, and that no more than one letter of recommendation reflecting the opinion of this team is needed for medical and surgical treatment to be considered medically necessary by a treating provider.

However, Cigna's coverage policy required the following for an initial mastectomy for an individual between 15 and 17 years of age to be considered medically necessary:

> …Parental/guardian consent, when applicable…
>
> …Two separate letters of support, each from an independent mental health provider experienced in adolescent mental health and the diagnosis and treatment of childhood gender dysphoria. Each mental health evaluation must confirm a diagnosis of gender dysphoria, confirm it is marked and sustained over time (e.g., two years), address any mental health comorbidities, and document the individual's emotional and cognitive maturity necessary to provide informed consent….

These requirements appeared to place restrictions on MH/SUD treatments regarding the stipulations for initial mastectomy for ages 15 to 17 that are inconsistent with the generally accepted standard of medical practice, as set forth above. The examiners communicated these concerns, and Cigna was instructed to document the evidence-based sources that these requirements are based on, to explain how Cigna derived these requirements from the evidence-based sources in the event that the requirements are not stated verbatim in the source material, and to explain/document how comparable requirements are imposed on M/S benefits, including an explanation of the evidence-based sources and how they were translated to language in the M/S coverage policy. Cigna was given an opportunity to provide justification for the content of its gender dysphoria coverage policy and to demonstrate how comparable requirements are imposed on M/S benefits.

Cigna disagreed and provided only broad explanations such as the following:

> Cigna believes that there needs to be reasonable guardrails around gender dysphoria treatments, specifically for adolescents…
>
> …in prior WPATH SOC iterations it went from requiring two letters of support in SOC 7 to one letter in SOC 8 with no evidence, and Cigna believes that is harmful. Thus, in the absence of the evidence Cigna believes it to be inappropriate to change the requirement and is unsafe…

> …Cigna's rationale is not to hinder care, but to support safe and effective care…
>
> …In M/S, on the cancer side, Cigna uses National Comprehensive Cancer Network "NCCN" for cancer coverage. NCCN guidelines are specific with some guidelines and vague with others; it leaves the decision to the company to implement guardrails. Thus, on the M/S side Cigna adopts specific NCCN guidelines when supported by the evidence….

The examiners maintained the finding of non-compliance based on the following:

- With respect to Cigna's parental consent requirement, 18 VAC 85-20-28 A 3 and Section 54.1-2969 of the Code address parental consent regarding surgery in minors in Virginia. These are non-insurance laws that, as a threshold matter, providers must follow when rendering care to minors. The requirement under Virginia law for a provider to obtain parental consent is separate from a carrier's medical necessity determination. With respect to Cigna's requirement for two letters, gender affirming surgery in adolescents is generally rendered based on the recommendation of a multidisciplinary team. As this recommendation/letter would reflect the opinion of a mental health provider, an endocrinologist, a primary care physician, and others, Cigna's stipulation for two letters from two mental health providers would potentially require the patient to seek an opinion from a provider in addition to those on the multidisciplinary team to obtain a second letter, resulting in additional costs to the patient and a delay in receiving care.

- Contrary to Cigna's claim that WPATH lowered its recommendation from two letters to one letter when updating from the SOC 7 to the SOC 8, it appears that the WPATH SOC 7 from 2012 made the following recommendation regarding the number of letters of support for all ages regarding the procedure in question:

  > …One referral from a qualified mental health professional is needed for breast/chest surgery (e.g., mastectomy, chest reconstruction, or augmentation mammoplasty)….

  Cigna's statement that WPATH went from two letters to one letter appears to be incorrect. The examiners note, however, that WPATH did lower its recommendation from two letters to one letter for genital surgery, but evidence was cited for this change, and the procedure in question for this examination is chest surgery rather than genital surgery.

- It is insufficient to state that the NCCN Clinical Practice Guidelines in Oncology ("NCCN Guidelines") are "specific with some guidelines and vague with others" and that "Cigna adopts specific NCCN guidelines when supported by the evidence"

without further examples and explanation. Cigna failed to provide examples of scenarios where it follows the NCCN guidelines and considers them to be evidence based, where Cigna deviates from those guidelines and how it decided to do so, where Cigna implements guardrails based on the guidelines being "vague," how the requirements Cigna adopts based on (or not based on) NCCN guidelines are similar in nature to the requirements it has adopted regarding the number of provider letters and parental consent for gender dysphoria treatment, and how comparability is demonstrated between MH/SUD benefits and M/S benefits.

- A review of Cigna's coverage policy titled Bariatric Surgery and Procedures indicates that Cigna has not adopted parental consent or the opinion of an additional provider as stipulations for medical necessity regarding M/S benefits, such as bariatric surgery in adolescents. However, in comparison, Cigna has adopted parental consent and an additional opinion/letter of support as stipulations for medical necessity regarding the MH/SUD benefit of gender affirming chest surgery in adolescents, which appears to create a more restrictive requirement as written placed on MH/SUD benefits.

BOI Determination

Cigna's medical necessity requirements specified in its gender dysphoria coverage policy appeared to be more restrictive for MH/SUD benefits as compared to M/S benefits, and as discussed in a previous section of this Report, Cigna's medical necessity comparative analyses were insufficient to demonstrate comparability regarding the development of coverage policies for MH/SUD benefits and M/S benefits. Cigna failed to provide sufficient explanations to justify the letters of support and parental consent requirements of its specific coverage policy, resulting in processes, strategies, evidentiary standards, or other factors, as written, used in applying medical necessity criteria to MH/SUD benefits that are not comparable to and are more stringently applied than the processes, strategies, evidentiary standards, or other factors used in applying medical necessity criteria to M/S benefits.

Corrective Action: Cigna will amend its internally-developed medical necessity criteria ("coverage policies"), including Gender Dysphoria Treatment and any other coverage policies that may apply to gender dysphoria, to revise any requirements that do not comply with MHPAEA.

FINDINGS: RETURN-ON-INVESTMENT RATIO CALCULATIONS

Background: As part of Cigna's prior authorization, concurrent review, and retrospective review comparative analyses, Cigna explained that a return-on-investment ("ROI") ratio is one of the factors that determines which MH/SUD benefits and M/S benefits are subject to these NQTLs. An ROI ratio in this context is essentially a calculation of the savings

achieved by subjecting benefits to the NQTL (e.g., prior authorizations that are denied as not medically necessary) divided by the cost of performing the review (e.g., salaries of the clinical reviewers).

Cigna defined its ROI ratio by stating that benefits in the "Outpatient, In-Network, All Other" and "Outpatient, Out-of-Network, All Other" sub-classifications must exceed a ratio of 3.0 to be subject to prior authorization, concurrent review, and retrospective review, and that benefits in the "Inpatient, In-Network" and "Inpatient, Out-of-Network" classifications must exceed a ratio of 1.0 to be subject to prior authorization, concurrent review, and retrospective review. As part of reviewing Cigna's comparative analyses, the examiners requested documentation of Cigna's ROI calculations. The examiners reviewed these calculations for compliance with MHPAEA.

Finding: Cigna's method of ROI ratio calculations was in violation of § 38.2-3412.1 B of the Code for the failure to comply with 45 CFR 146.136(c)(4)(i) and 42 USC 300gg-26(a)(8)(A).

Discussion: As discussed in Review Sheet MH03-BL, Cigna's methodology for calculating its ROI ratio appeared to be impermissible, and Cigna's explanations to justify its methodology were insufficient to demonstrate compliance with MHPAEA. Examples of deficiencies are discussed below.

Combining Multiple Classifications and NQTLs

The examiners deemed Cigna's initial documentation to be insufficient because its inpatient and outpatient ROI ratio calculations appeared to combine data for in-network benefits and out-of-network benefits, and Cigna's inpatient and outpatient calculations appeared to combine the data for prior authorization, concurrent review, and retrospective review. This practice did not appear to be permissible under the required NQTL and classification structure of MHPAEA. The examiners communicated this concern, and Cigna was given an opportunity to justify its methodology.

Cigna disagreed and provided arguments such as the following:

> …Cigna's ROI methodology does not distinguish, nor does the NQTL requirement mandate that it distinguish, between prior authorization and concurrent review when defining factors, such as Return on Investment, by reference to specific data sources. This is because *any* service subject to prior authorization may also be subject to concurrent review if the provider requests an extension of coverage for services already approved pursuant to a prior authorization review…

> …MHPAEA does not require factors and evidentiary standards used in evaluating whether to apply an NQTL to MH/SUD or M/S benefits to leverage data that is unique to the classification…
>
> …Differentiating the ROI calculations, or other calculations considered in its methodology for applying utilization management to services like cost, claim volume, or denial rate, by out-of-network and in-network would introduce a material risk to the data's usefulness in the form of problems like insufficient sample sizes or periodic fluctuations in the application of the formulae that could in turn result in periodic disruptions to customers and providers if prior authorization were removed or applied to a service/treatment multiple times over a given period of time. Further, this risk could manifest in not only resulting in customer/provider confusion or disruption, but it could also dis-incentivize providers from contracting with a payer like Cigna if the provider evaluated that prior authorization or concurrent review would not apply to out-of-network claims, this creating a potential risk for the adequacy of the network…
>
> …the NQTL requirement does not dictate that the data sources used to define and/or measure whether a factor/standard is met must be limited to narrowly-defined, related NQTLs like prior authorization and concurrent review…
>
> …an analysis of out-of-network or in-network data isn't necessary….

The examiners maintained the finding of non-compliance and stated that 45 CFR 146.136(c)(4)(i) sets forth the following:

> A group health plan (or health insurance coverage) may not impose ***a*** **nonquantitative treatment limitation** with respect to mental health or substance use disorder benefits in ***any*** **classification** unless, under the terms of the plan (or health insurance coverage) as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying ***the*** **nonquantitative treatment limitation** to mental health or substance use disorder 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 medical/surgical benefits in ***the*** **classification** (emphasis added).

The examiners also pointed out that page 22 of the DOL Self-Compliance Tool states the following:

> If a benefit includes multiple components (e.g., outpatient and prescription drug classifications), and each component is subject to a different type of NQTL (e.g., prior authorization and limits on treatment dosage or duration), ***each NQTL must be analyzed separately*** (emphasis added).

As supported by the references above, each NQTL and classification must be analyzed independently and must be able to stand on its own to demonstrate compliance, which includes any data used in calculating factors. Contrary to Cigna's arguments, MHPAEA specifically requires that compliance is contained within each NQTL and classification and cannot spread beyond the singular NQTL and classification in question. As the goal of comparative analysis is demonstrating compliance with the NQTL regulatory text, the only logical conclusion is that comparative analyses, including the data used for calculations, must be similarly contained.

It appears unlikely that a carrier as large as Cigna would have difficulty establishing sample sizes that are meaningful while adhering to the parameters of the required classifications. If performing the calculations within the required construct of the MHPAEA classifications would result in prior authorization being removed or applied multiple times over a given period of time, it appears that Cigna's current methodology is insufficient to justify the application of prior authorization, concurrent review, and retrospective review to MH/SUD benefits. The examiners also comment that nothing in MHPAEA expressly prohibits Cigna from using different factors for in-network benefits versus out-of-network benefits and designing/applying them in a way that could still incentivize providers to participate with Cigna. The responsibility lies with Cigna to account for these scenarios while still adhering to the regulatory framework and required classifications of MHPAEA.

Cigna's explanation that "*any* service subject to prior authorization may also be subject to concurrent review if the provider requests an extension of coverage for services already approved…," is inconsistent with other information available and provided by Cigna. As discussed earlier in Section VI of this Report under the "FINDINGS: CONCURRENT REVIEW" heading, Cigna's comparative analyses failed to explain how the Company determines when concurrent review is initiated and whether it is initiated by Cigna, by the provider, or either, depending on the situation. In addition to the fact that combining NQTLs for calculation of the ROI is impermissible according to the framework of the MHPAEA regulation, Cigna's attempt to justify combining NQTLs for its ROI formula by stating that any service subject to prior authorization may also be subject to concurrent review cannot be considered until a sufficient explanation is provided for when and how concurrent review is initiated.

BOI Determination

Cigna's comparative analyses and supporting documentation were insufficient to demonstrate comparability regarding how the Company determines which MH/SUD benefits and M/S benefits are subject to prior authorization, concurrent review, and retrospective review. Cigna's comparative analyses relied on methodology that was impermissible under the requirements of MHPAEA, resulting in factors and evidentiary standards, as written and in operation, used in applying prior authorization, concurrent review, and retrospective review to MH/SUD benefits that are not comparable to and are more stringently applied than the factors and evidentiary standards used in applying prior authorization, concurrent review, and retrospective review to M/S benefits.

Corrective Action: Cigna will revise its inpatient and outpatient return-on-investment ("ROI") ratio calculations for MH/SUD benefits and M/S benefits and make necessary documentation available to substantiate comparability of the formulas to comply with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A). This includes ensuring that ROI ratio calculations are performed and documented separately for each classification or sub-classification and performed and documented separately for each NQTL.

FINDINGS: AMERICAN SPECIALTY HEALTH MEDICAL NECESSITY REVIEW

Background: While reviewing Cigna's comparative analyses as part of this NQTL target examination, the examiners identified inconsistencies based on information provided as part of the first target examination regarding Cigna's physical therapy, occupational therapy, and chiropractic services vendor, American Specialty Health ("ASH"). The examiners requested additional explanation from Cigna regarding this discrepancy, and the examiners reviewed the explanations provided by Cigna for compliance with MHPAEA.

Finding: Cigna's prior authorization, concurrent review, and retrospective review comparative analyses failed to contemplate processes, strategies, evidentiary standards, and other factors involving ASH, resulting in the comparative analyses being insufficient to demonstrate compliance. Processes and factors applied by ASH also appeared to result in more favorable treatment for M/S benefits as compared to MH/SUD benefits. Cigna's comparative analyses and the processes and factors applied by ASH were in violation of § 38.2-3412.1 B of the Code for the failure to comply with 45 CFR 146.136(c)(4)(i) and 42 USC 300gg-26(a)(8)(A).

Discussion: As discussed in Review Sheet MH01-BL, ASH was named as being contemplated in Cigna's comparative analyses, but this vendor appeared to apply a different form of medical necessity review than those described in Cigna's comparative

analyses that resulted in potential exceptions granted regarding prior authorization, concurrent review, and retrospective review for M/S benefits. The deficiencies are discussed below.

ASH Medical Necessity Review Factors and Process

As discussed earlier in Section VI of this Report under the "FINDINGS: PRIOR AUTHORIZATION" heading, Cigna's comparative analyses stated that the Company determines which MH/SUD benefits and M/S benefits in the "Outpatient, In-Network, All Other" and "Outpatient, Out-of-Network, All Other" sub-classifications are subject to prior authorization and concurrent review (and retrospective review, if an authorization was not obtained) based on whether or not the service in question implicates at least one of five qualitative factors and "generally" exceeds a return-on-investment ("ROI") ratio of 3.0. There are also exceptions that can result in a service requiring prior authorization or concurrent review without meeting the aforementioned requirements, and Cigna's precertification committee decides which MH/SUD benefits and M/S benefits require prior authorization.

However, the examiners identified during the first target examination that ASH does not require the same form of authorization mentioned in Cigna's comparative analyses, despite the fact that ASH is named as being contemplated under the provided analyses regarding M/S benefits. The providers contracted with ASH are only required to submit a "medical necessity review form" within 180 days after the service is performed before a claim will be paid.

The examiners inquired about this process and received the following explanation from Cigna regarding how ASH determines when physical therapy, occupational therapy, and chiropractic M/S benefits are subject to medical necessity review:

> …Contracted ASH providers are placed into one of the following six (6) clinical oversight tiers that define the point at which ASH will require services to be verified as medically necessary in order to be covered:
>
> Tier 1: initial examination is covered without review, all other services require submission for medical necessity review.
>
> Tier 2: not currently active.
>
> Tier 3: providers are allowed to see the patient for 5 office visits before medical necessity review is required (providers are typically initially credentialed into Tier 3).
>
> Tier 4: providers are allowed to see the patient 8 visits before medical necessity is required.

> Tier 5: providers are allowed 12 visits before medical necessity is required; and
>
> Tier 6: providers do not need to submit for medical necessity review.
>
> Through the annual review process, as providers display performance meeting expected goals, they move up in tier levels. Providers that are under some form of clinical corrective action are placed in Tier 1 where only the initial examination is covered without review, all other services require submission for medical necessity review….

These guidelines appeared to allow M/S benefits administered by ASH to be subject to a less restrictive form of prior authorization and concurrent review where no services require medical necessity review prior to allowing the service to be rendered. In addition, the factors that determine whether or not a service requires medical necessity review by ASH are the tiering status of the provider and the number of visits the patient has been seen for, which appeared to contradict the factors provided in Cigna's comparative analyses and potentially exempt certain M/S benefits from medical necessity review (e.g., if the patient receives treatment from a provider that is in Tier 6). The examiners communicated this concern, and Cigna was given an opportunity to justify the apparent exceptions granted to M/S benefits by ASH.

Cigna disagreed and provided arguments such as the following:

> The application of the tiering referenced above applies equally to both MH/SUD and M/S services provided by providers contracted with ASH. As you know, under MHPAEA, the determination of whether a given benefit is considered a MH/SUD or M/S benefit relies on the underlying condition, not on the specific provider type (although certain provider types nearly always offer MH/SUD or M/S benefits depending on their area of specialty). In this case, ASH providers offer both MH/SUD and M/S services for which the quality of care can be reliably determined by ASH (as Cigna's delegated vendor). These clinical oversight tiers are independent of and agnostic to whether the service is being performed for an underlying MH/SUD condition or a M/S condition. So, for example, an ASH provider might offer PT for autism spectrum disorders and be included in a tier with relatively lower clinical oversight just as an ASH provider who performs PT for a joint injury might be a relatively higher tier with greater clinical oversight. As such, the tiering system above applies equally to MH/SUD and M/S benefits….

The examiners maintained the finding of non-compliance and stated that Cigna's comparative analyses for prior authorization, concurrent review, and retrospective review failed to include any reference to provider tiering and number of visits as factors for

determining which MH/SUD benefits and M/S benefits are subject to these NQTLs, which indicates that Cigna did not contemplate ASH's model in the context of MHPAEA until questioned by the BOI.

While Cigna argued that the tiering "applies equally to both MH/SUD and M/S services provided by providers contracted with ASH," the examiners clarified that the lack of demonstrated comparability is not due to the treatment of MH/SUD benefits and M/S benefits under ASH (i.e., physical therapy and occupational therapy that can be used in connection with both MH/SUD benefits and M/S benefits). The issue with comparability is that the MH/SUD benefits of partial hospitalization, transcranial magnetic stimulation, and applied behavior analysis trigger the requirements of one of five factors plus an ROI of 3.0 and are always subject to prior authorization and concurrent review (and potentially retrospective review, if an authorization was not obtained). In comparison, the M/S benefits of physical therapy, occupational therapy, and chiropractic services trigger the same required factors but are subject to a less restrictive form of authorization and may not be subject to medical necessity review at all, depending on the tiering status of the provider, number of visits incurred, etc.

BOI Determination

Cigna's comparative analyses and additional explanations were insufficient to demonstrate comparability regarding how the Company determines which MH/SUD benefits and M/S benefits are subject to prior authorization, concurrent review, and retrospective review. The information identified by the BOI appeared to allow for exceptions to medical necessity review to be made for subsets of services that are largely M/S benefits, resulting in factors, as written and in operation, used in applying prior authorization, concurrent review, and retrospective review to MH/SUD benefits that are not comparable to and are more stringently applied than the factors used in applying prior authorization, concurrent review, and retrospective review to M/S benefits.

Corrective Action: Cigna will revise its prior authorization, concurrent review, and retrospective review comparative analyses in the "Outpatient, In-Network, All Other" sub-classification to specifically contemplate the clinical oversight tiers and number of visits used as factors by American Specialty Health ("ASH"), as well as the review process used by ASH that allows for submission of a medical necessity review form 180 days after the date of service, in order to comply with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A). This includes revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL that are not comparable between MH/SUD benefits and M/S benefits.

FINDINGS: SUB-CLASSIFICATION OF OUTPATIENT BENEFITS

Background: While reviewing Cigna's comparative analyses as part of this NQTL target examination, the examiners identified inconsistencies regarding the application of sub-classifications based on financial requirement/QTL and claims documentation reviewed as part of the first target examination. The examiners requested additional explanation from Cigna regarding this discrepancy, and the examiners reviewed Cigna's explanations for compliance with MHPAEA.

Finding: Cigna's comparative analyses for each NQTL relied on impermissible sub-classification methodology and were in violation of § 38.2-3412.1 B of the Code for the failure to comply with 45 CFR 146.136(c)(4)(i) and 42 USC 300gg-26(a)(8)(A).

Discussion: As discussed in Review Sheet MH01-AV, Cigna inconsistently sub-classified outpatient benefits between its testing/application of financial requirements/QTLs and NQTL comparative analyses. The deficiencies are discussed below.

Impermissible Sub-Classification of Outpatient Benefits

Under the requirements of MHPAEA, financial requirements/QTLs and NQTLs must be evaluated within the following six classifications set forth in 45 CFR 146.136(c)(2)(ii):

- Inpatient, In-Network
- Inpatient, Out-of-Network
- Outpatient, In-Network
- Outpatient, Out-of-Network
- Emergency Care
- Prescription Drugs

However, 45 CFR 146.136(c)(3)(iii)(C) states that, for purposes of determining parity for outpatient benefits (in-network and out-of-network), a carrier may divide its benefits furnished on an outpatient basis into two sub-classifications: (1) office visits; and (2) all other outpatient items and services.

During the first target examination of Cigna involving a review of financial requirements/QTLs, Cigna indicated that it sub-classified outpatient benefits into the "office visits" and "all other outpatient items and services" categories for its large group policies but did not sub-classify outpatient benefits for its individual policies. However,

for this NQTL examination, Cigna's comparative analyses indicated that Cigna sub-classified outpatient benefits for all policies, including both individual and large group.

If a carrier opts to establish or not establish sub-classifications for financial requirements/QTLs, it must also apply the same methodology to NQTLs. Since Cigna does not sub-classify for financial requirements/QTLs under individual policies, the Company cannot do so for NQTLs under individual policies. It appeared that Cigna's comparative analyses for each NQTL were insufficient due to the failure to apply a foundational step of MHPAEA correctly. The examiners communicated this concern, and Cigna was given an opportunity to justify its methodology for applying sub-classifications.

Cigna disagreed and stated the following:

> Cigna respectfully disagrees that there is anything in the law or regulations that requires a plan or issuer to use an all-or-nothing approach to sub-classifications of benefits. The MHPAEA regulations permit, but do not require, plans and issuers to sub-classify outpatient benefits as either (1) outpatient – office visits or (2) outpatient – all other services. The regulations are clear that plans and issuers have discretion as to whether to sub-classify outpatient benefits in this manner, or whether to simply treat all outpatient benefits as a single benefit classification (still broken out separately for in-network outpatient vs. out of network outpatient). Whether a plan or issuer decides to sub-classify outpatient benefits in this manner for purposes of financial requirements and quantitative treatment limitations (QTL) testing has no bearing on whether the plan or issuer sub-classifies outpatient benefits in this manner for purposes of non-quantitative treatment limitations ("NQTL") and any NQTL comparative analyses.

The examiners maintained the finding of non-compliance and explained that 45 CFR 146.136(c)(3)(iii)(C) states the following:

> *Sub-classifications permitted for office visits, separate from other outpatient services.* For purposes of applying the financial requirement and treatment limitation rules of this paragraph (c), a plan or issuer may divide its benefits furnished on an outpatient basis into the two sub-classifications described in this paragraph (c)(3)(iii)(C). After the sub-classifications are established, the plan or issuer may not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(3)(i) of this section. Sub-classifications other than

> these special rules, such as separate sub-classifications for generalists and specialists, are not permitted. The two sub-classifications permitted under this paragraph (c)(3)(iii)(C) are….

45 CFR 146.136(c)(3)(iii)(C) allows the sub-classification option "for the purposes of applying the financial requirement ***and*** ***treatment limitation*** **rules of this paragraph (c)**" (emphasis added), wherein paragraph (c) consists of (c)(1), (c)(2), (c)(3), (c)(4), and (c)(5). Paragraph (c)(2) addresses financial requirements and QTLs, and paragraph (c)(4) addresses NQTLs. Paragraph (c)(3)(iii)(C) sets forth that sub-classifications are applicable to any financial requirement and treatment limitation rules established in the entirety of paragraph (c), with "treatment limitations" also being specifically defined in the regulation as being inclusive of QTLs and NQTLs. This means that the decision to sub-classify or not to sub-classify is applicable to all of the rules of paragraph (c), and that "financial requirements and treatment limitations" (i.e., financial requirements/QTLs and NQTLs) are specifically contemplated together if the sub-classification option is chosen by the company.

As the only conclusion that can be drawn from a literal reading of the Final Rules is that financial requirement and treatment limitation rules must be contemplated together regarding sub-classification, and the Final Rules do not otherwise specifically allow for inconsistent sub-classification, there is no basis for the sub-classification of NQTLs where financial requirements/QTLs are not also sub-classified under the same policy type, or vice versa. The preamble to the Final Rules also reiterates these requirements and confirms that the "parity analysis" (which is inclusive of financial requirements/QTLs and NQTLs) must be performed in each classification or sub-classification. The referenced language further confirms that, if a carrier chooses to sub-classify outpatient benefits for financial requirements/QTLs, it must also do so for NQTL analysis, and if a carrier chooses not to sub-classify outpatient benefits for financial requirements/QTLs, it must retain the six classifications without sub-classifications for NQTL analysis.

The rules of MHPAEA are sequential and interrelated, which means that a carrier must define services as MH/SUD benefits or M/S benefits based on the condition or disorder, map the benefits to the applicable classifications or sub-classifications, and then perform the required analyses, inclusive of financial requirements/QTLs and NQTLs, within the classifications or sub-classifications that remain static. It is impermissible for a carrier to have a different approach to sub-classification for financial requirements/QTLs versus NQTLs in the same way that it is impermissible for a carrier to change the classification a benefit is placed in or change its determination of whether a service is an MH/SUD benefit or M/S benefit for purposes of financial requirements/QTLs versus NQTLs.

BOI Determination

Cigna's comparative analyses for each NQTL were performed in impermissible outpatient sub-classifications for certain policies and were insufficient to demonstrate comparability regarding processes, strategies, evidentiary standards, or other factors, as written and in operation, used in applying each NQTL to MH/SUD benefits and to M/S benefits.

Corrective Action: Cigna will consistently apply methodology regarding the sub-classification of outpatient benefits for the purposes of financial requirements/QTLs and NQTL comparative analyses to ensure compliance with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A).

VIII. CORRECTIVE ACTION PLAN

Based on the findings stated in this Report, Cigna is required to implement the following Corrective Actions:

1. Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for prior authorization that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently;

2. Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for concurrent review that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently;

3. Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for retrospective review that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently;

4. Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for

pre-payment review (e.g., a provider or facility is flagged for a history of overutilization or a finding of FWA, and either all or a subset of that provider's or facility's claims are subject to review/audit upon claim submission) and pre-claim payment FWA investigations that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A);

5. Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for post-payment retrospective review that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently;

6. Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for medical necessity that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently;

7. Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for experimental/investigational/unproven ("EIU") that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently;

8. Cigna will revise its internally-developed clinical criteria ("coverage policies"), including Intensive Behavioral Interventions, Autism Spectrum Disorders/Pervasive Developmental Disorders: Assessment and Treatment, and any other coverage policies that may apply to autism spectrum disorders, to comply with the standard for medical necessity and coverage requirements set forth in § 38.2-3418.17 A of the Code and to remove any requirements that do not comply with MHPAEA;

9. Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for treatment plans that complies with the requirements of § 38.2-3412.1 B of the

Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently. This analysis must include, among other elements, a demonstration of comparability regarding the content, nature, and volume of information required in treatment plans for MH/SUD benefits and M/S benefits and a demonstration of comparability regarding the decision of whether or not a treatment plan is needed to determine medical necessity for MH/SUD benefits, specifically ABA for autism spectrum disorders, and M/S benefits;

10. Cigna will amend its internally-developed medical necessity criteria ("coverage policies"), including Gender Dysphoria Treatment and any other coverage policies that may apply to gender dysphoria, to revise any requirements that do not comply with MHPAEA;

11. Cigna will revise its inpatient and outpatient return-on-investment ("ROI") ratio calculations for MH/SUD benefits and M/S benefits and make necessary documentation available to substantiate comparability of the formulas to comply with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A). This includes ensuring that ROI ratio calculations are performed and documented separately for each classification or sub-classification and performed and documented separately for each NQTL;

12. Cigna will revise its prior authorization, concurrent review, and retrospective review comparative analyses in the "Outpatient, In-Network, All Other" sub-classification to specifically contemplate the clinical oversight tiers and number of visits used as factors by American Specialty Health ("ASH"), as well as the review process used by ASH that allows for submission of a medical necessity review form 180 days after the date of service, in order to comply with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A). This includes revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL that are not comparable between MH/SUD benefits and M/S benefits; and

13. Cigna will consistently apply methodology regarding the sub-classification of outpatient benefits for the purposes of financial requirements/QTLs and NQTL comparative analyses to ensure compliance with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A).

Cigna will acknowledge that these items will be completed on or before December 31, 2024, with the exception of CAP Item Number 8, which will be completed on or before March 31, 2025.

For any NQTL where Cigna fails to provide a sufficient comparative analysis demonstrating compliance with MHPAEA by the deadline set forth above, Cigna will be required to remove that NQTL from all MH/SUD benefits in the classifications or sub-classifications reviewed as part of this examination, until Cigna can provide sufficient comparative analyses demonstrating compliance with MHPAEA to justify the application of the NQTL to MH/SUD benefits. This includes the potential removal of prior authorization, concurrent review, retrospective review, post-payment retrospective review, and treatment plan requirements, as well as providing coverage for any MH/SUD benefits currently excluded as EIU or as not medically necessary.

IX. ACKNOWLEDGMENT

The courteous cooperation extended to the examiners by Cigna's officers and employees during the course of this examination is gratefully acknowledged.

Brant Lyons, MCM, Avani Verma, MCM, Heather Webb, MCM, APIR, Jarod Mentzer, MCM, Larry Gibson, AIE, MCM, PIR, ALMI, and Tiffany Fontenot, MCM, PIR, ALMI, AIRC participated in the work of the examination and writing of the Report.

Respectfully submitted,

Bryan Wachter, CIE, AIRC, FLMI, MCM
BOI Manager, Health Market Conduct Section
Life and Health Market Regulation Division
Bureau of Insurance

X. AREA VIOLATIONS SUMMARY BY REVIEW SHEET

COMPARATIVE ANALYSES
Prior Authorization
§ 38.2-3412.1 B & MHPAEA, violation, MH02-HW
Concurrent Review
§ 38.2-3412.1 B & MHPAEA, violation, MH01-JM
Retrospective Review
§ 38.2-3412.1 B & MHPAEA, violation, MH02-JM
Post-Payment Retrospective Review
§ 38.2-3412.1 B & MHPAEA, violation, MH03-HW
Medical Necessity
§ 38.2-3412.1 B & MHPAEA, violation, MH01-HW
Experimental/Investigational/Unproven ("EIU")
§ 38.2-3412.1 B & MHPAEA, violation, MH01-HW
OTHER NQTL ISSUES
Medical Necessity Criteria for Autism and ABA
§ 38.2-3412.1 B & MHPAEA, violation, MH02-BL
§ 38.2-3418.17 A, violation, MH02-BL
Medical Necessity Criteria for Gender Dysphoria
§ 38.2-3412.1 B & MHPAEA, violation, MH04-BL
Return-on-Investment Ratio Calculations
§ 38.2-3412.1 B & MHPAEA, violation, MH03-BL
American Specialty Health Medical Necessity Review
§ 38.2-3412.1 B & MHPAEA, violation, MH01-BL
Sub-classification of Outpatient Benefits
§ 38.2-3412.1 B & MHPAEA, violation, MH01-AV

COMMONWEALTH OF VIRGINIA

SCOTT A. WHITE
COMMISSIONER OF INSURANCE
STATE CORPORATION COMMISSION
BUREAU OF INSURANCE

P.O. BOX 1157
RICHMOND, VIRGINIA 23218

1300 E. MAIN STREET
RICHMOND, VIRGINIA 23219

TELEPHONE: (804) 371-9741
scc.virginia.gov

September 19, 2024

SENT VIA ELECTRONIC MAIL

Loleta Keith
Legal Compliance Advisor, Market Conduct
State Government Affairs – Regulatory Operations
Cigna Health and Life Insurance Company

RE: Market Conduct Examination Report
Exposure Draft

Dear Ms. Keith:

Recently, the Bureau of Insurance conducted a Target Market Conduct Examination of Cigna Health and Life Insurance Company's ("Cigna") NQTL comparative analyses for policies issued or in force on January 1, 2022. A preliminary draft of the Report is enclosed for your review.

Draft Report Response – Due 10/21/24

Since it appears from a reading of the Report that there have been violations of Virginia insurance statutes on the part of Cigna, I would urge you to read the enclosed draft and furnish me with your written response within 30 days of the date of this letter. For the corrective action items in Section VIII of the Report, provide an acknowledgement that Cigna will complete these items on or before December 31, 2024. Please also refer to the instructions in the first paragraph of Appendix A. Do not include any personally identifiable information in the response. Revised comparative analyses will not be considered until the review of Cigna's corrective action documentation.

Please note that Cigna's response(s) to the draft Report will be attached to and become part of the final Report.

Once we have received and reviewed your response, we will respond noting any justified revisions to the Report and any areas where we maintained our position. At that time, we will communicate the next steps regarding the appropriate disposition of this matter.

Document Compliance with the Corrective Action Plan ("CAP") – Due 12/31/24

As part of its CAP and as a supplement to its new comparative analyses reflecting compliance, Cigna will provide a response after the Report is finalized and on or before December 31, 2024 to the attached Appendix A explaining in detail how the Company has addressed each specific deficiency listed in that Appendix. The BOI is also including Appendix B, which includes detailed instructions for reference addressing each of the NQTLs reviewed as part of this examination. Please note that Appendix B also includes instructions for a treatment plan comparative analysis, which is required to be performed and documented by Cigna under Corrective Action Item Number 9, and Appendix B includes instructions for a retrospective review comparative analysis that contemplates pre-payment review and pre-claim payment FWA, which is required to be performed and documented by Cigna under Corrective Action Item Number 4.

If restitution payments are required to be made to insureds or providers as part of the CAP, a spreadsheet will be provided to document those payments with all required details. Please note that Appendix A and Appendix B will not become part of the final Report. Cigna is encouraged to contact the exam team with questions as the Company prepares new comparative analyses and a response to Appendix A.

Thank you for your prompt attention to this matter.

Yours truly,

Bryan Wachter
BOI Manager
Health Market Conduct Section
Life and Health Division
Bureau of Insurance
(804) 371-9745

BDW:mhh
Enclosure
cc: Julie Blauvelt

Loleta Keith
Legal Compliance Senior Advisor

October 21, 2024

Loleta.Keith@CignaHealthcare.com
Telephone: 540.240.8327

VIA EMAIL

Bryan Wachter, BOI Manager
Health Market Conduct Section
Life and Health Division
Virginia Bureau of Insurance
1300 E. Main Street
Richmond, VA 23219

RE: Cigna Health and Life Insurance Company, Inc.
Market Conduct Examination Exposure Draft Report

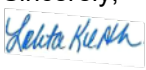
Dear Mr. Wachter:

In response to the recent Target Market Conduct Examination of Cigna Health and Life Insurance Company, Inc. (Cigna, CHLIC, the Company) and the issuance of the Exposure Draft Report by the Virginia Bureau of Insurance, please find attached the Company's written response. Cigna has provided a response to each corrective action listed within the Exposure Draft Report.

Please note, for response #8 we are requesting additional time to submit the corrective action plan detail and an explanation is provided in our response.

If you have any questions or need additional information, please do not hesitate to contact me.

Sincerely,



Loleta Keith
Legal Compliance Senior Advisor

Enclosures: VA BOI Draft Report of CHLIC_Cigna Response

Copy to: Julie Blauvelt

Target Market Conduct Examination Report
Response to Corrective Action Items in Section VIII
Cigna Health and Life Insurance Company (CHLIC)

Please find below Cigna's responses to each of the corrective actions included in the draft report for Cigna Health and Life Insurance Company (Cigna/CHLIC/the Company).

1. Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for prior authorization that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently.

   Cigna Response: Cigna acknowledges that the Company will complete these items on or before December 31, 2024.

2. Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for concurrent review that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently.

   Cigna Response: Cigna acknowledges that the Company will complete these items on or before December 31, 2024.

3. Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for retrospective review that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently.

   Cigna Response: Cigna acknowledges that the Company will complete these items on or before December 31, 2024.

4. Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for pre-payment review (e.g., a provider or facility is flagged for a history of overutilization or a finding of FWA, and either all or a subset of that provider's or facility's claims are subject to review/audit upon claim submission) and pre-claim payment FWA investigations that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A);

   Cigna Response: Cigna acknowledges that the Company will complete these items on or before December 31, 2024.

5. Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for post-payment retrospective review that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other

factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently.

Cigna Response: Cigna acknowledges that the Company will complete these items on or before December 31, 2024.

6. Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for medical necessity that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently.

   Cigna Response: Cigna acknowledges that the Company will complete these items on or before December 31, 2024.

7. Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for experimental/investigational/unproven ("EIU") that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently.

   Cigna Response: Cigna acknowledges that the Company will complete these items on or before December 31, 2024.

8. Cigna will revise its internally-developed clinical criteria ("coverage policies"), including Intensive Behavioral Interventions, Autism Spectrum Disorders/Pervasive Developmental Disorders: Assessment and Treatment, and any other coverage policies that may apply to autism spectrum disorders, to comply with the standard for medical necessity and coverage requirements set forth in § 38.2-3418.17 A of the Code and to remove any requirements that do not comply with MHPAEA.

   Cigna Response: Cigna acknowledges that the Company will complete these items. We have already taken action to revise our internally developed coverage policies noted above. However, we would note that it may not be possible to fully revise them before December 31, 2024. Cigna is revising its criteria to use MCG, but the full implementation of this is significant and multi-faceted, requiring extensive provider notification and training, among other things. This timeline will necessitate going past this deadline into 2025. That said, we have already taken steps in this direction and anticipate full completion of all revisions to the coverage policies noted above by mid-2025.

9. Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for treatment plans that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently. This analysis must include, among other elements, a demonstration of comparability regarding the content, nature, and volume of information required in treatment plans for MH/SUD benefits and M/S benefits and a demonstration of comparability regarding the decision of whether or not a treatment plan is needed to determine medical necessity for MH/SUD benefits, specifically ABA for autism spectrum disorders, and M/S benefits

Cigna Response: Cigna acknowledges that the Company will complete these items on or before December 31, 2024.

10. Cigna will amend its internally-developed medical necessity criteria ("coverage policies"), including Gender Dysphoria Treatment and any other coverage policies that may apply to gender dysphoria, to revise any requirements that do not comply with MHPAEA. This includes removing or revising the requirements regarding two letters of support from two mental health providers and parental consent for initial mastectomy for ages 15 to 17.

Cigna Response: Cigna respectfully disagrees with this finding. Cigna is committed to supporting the needs of transgender youth and adolescence in a safe, supportive, and effective manner. Our treatment decisions are guided by the best available evidence and are intended to promote access to care while minimizing long-term untoward consequences. It is well-documented in the scientific literature (see references below) that persistence of an incongruous gender identity is variable between childhood and adulthood, with some studies reporting a less than 10% persistence of a trans identity into adulthood. Because of this, Cigna takes a particularly thoughtful and careful approach to authorizing interventions for children and adolescents. It is indisputable that, for a child who undergoes an irreversible intervention such as surgery for an erroneous diagnosis of gender dysphoria, the long term consequences would be devastating. As such, Cigna contends that requiring two independent letters of confirmation of the diagnosis of gender dysphoria prior to irreversible surgical interventions for children and adolescents is appropriate to support the necessary level of confidence in the diagnosis, and thereby minimizes long term adverse outcomes. From a clinical standpoint, we do not believe that this is overly burdensome in the context of long term outcomes.

Korte, et al. "Gender identity disorders in childhood and adolescence" Dtsc Arztebl Int 2008; 105(48): 834-41
Drummond, et al. "A follow up study of girls with gender identity disorder". Dev Psychol 2008 Jan; 44(1): 34-45
Katz-Wise, et al. "Fluidity in gender identity and sexual orientation identity in transgender and non binary youth". The journal of sex research, 2023. 61 (9), 1367-1376

We believe that our existing coverage policies and medical necessity criteria applicable to gender dysphoria treatment meet the requirements under MHPAEA and its NQTL rules. The coverage policies applicable to gender dysphoria treatment are consistent with generally recognized independent standards of current medical practice, and are comparable to, and no more restrictive than, the coverage policies applicable to medical/surgical services in the same benefit classification under the plan. As a result, Cigna respectfully disagrees with this finding and conclusion.

11. Cigna will revise its inpatient and outpatient return-on-investment ("ROI") ratio calculations for MH/SUD benefits and M/S benefits and make necessary documentation available to substantiate comparability of the formulas to comply with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A). This includes ensuring that ROI ratio calculations are performed and documented separately for each classification or sub-classification and performed and documented separately for each NQTL.

Cigna Response: Cigna acknowledges that the Company will complete these items on or before December 31, 2024.

12. Cigna will revise its prior authorization, concurrent review, and retrospective review comparative analyses in the "Outpatient, In-Network, All Other" sub-classification to specifically contemplate the clinical oversight tiers and number of visits used as factors by American Specialty Health ("ASH"), as well as the review process used by ASH that allows for submission of a medical necessity review form 180 days after the date of service, in order to comply with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A). This includes revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL that are not comparable between MH/SUD benefits and M/S benefits.

    Cigna Response: Cigna acknowledges that the Company will complete these items on or before December 31, 2024.

13. Cigna will consistently apply methodology regarding the sub-classification of outpatient benefits for the purposes of financial requirements/QTLs and NQTL comparative analyses to ensure compliance with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A).

    Cigna Response: Cigna respectfully disagrees with this finding, as there is no legal basis or authority for requiring it. The federal statute cited above, 42 USC 300gg-26(a)(8)(A), contains the compliance requirements for NQTLs, including the NQTL general rule, and outlines the five step process required for any NQTL comparative analysis. While an NQTL comparative analysis must be performed and documented separately for each applicable benefit classification, this section does not say anything about sub-classification of outpatient benefits. Similarly, the federal regulations cited above, 45 CFR 146.136(c)(4)(i), contain the NQTL general rule. This section does not say anything about sub-classification of outpatient benefits. Finally, the section of the Virginia code cited above, 38.2-3412.1 B, requires coverage for MH/SUD benefits to be "in accordance with" the federal rules under MHPAEA, but also makes no mention of anything related to classification or sub-classification of benefits.

    Cigna agrees and acknowledges that an NQTL comparative analysis must be performed and documented separately for each applicable benefit classification. Similarly, Cigna agrees and acknowledges that the financial requirements, such as cost-sharing, and quantitative treatment limitations (QTLs) must be separately tested for each applicable benefit classification under the plan. For financial requirements, QTLs, and NQTL comparative analyses, plans and issuer are permitted – but not required – to sub-classify benefits only where expressly permitted, including sub-classification of outpatient benefits into (1) office visits and (2) all other outpatient services. Since it is permissible but not strictly required, Cigna sometimes uses sub-classification of outpatient benefits and sometimes does not. There does not appear to be any requirement in state or federal law that would mandate that a plan or issuer "always" or "never" sub-classify outpatient benefits, i.e., consistently do it or not do it. As a result, Cigna respectfully disagrees with this finding and conclusion.

SCOTT A. WHITE
COMMISSIONER OF INSURANCE
STATE CORPORATION COMMISSION
BUREAU OF INSURANCE

COMMONWEALTH OF VIRGINIA

P.O. BOX 1157
RICHMOND, VIRGINIA 23218

1300 E. MAIN STREET
RICHMOND, VIRGINIA 23219

TELEPHONE: (804) 371-9741
www.scc.virginia.gov/boi

November 25, 2024

VIA ELECTRONIC MAIL

Loleta Keith
Legal Compliance Advisor, Market Conduct
State Government Affairs – Regulatory Operations
Cigna Health and Life Insurance Company

RE: Response to the Draft Examination Report
Cigna Health and Life Insurance Company (Cigna)

Dear Ms. Keith:

The examiners have received and reviewed Cigna's October 21, 2024, response to the Draft Report. The BOI is providing the following attachments:

1. **The BOI's Response**

   In this response, the examiners have addressed Cigna's disagreements with the Report findings. The examiners have also addressed places where Cigna has stated that additional time is needed to complete the required corrective actions. The response also notes where changes have been made to the Report.

2. **A Revised Copy of the Report**

   The revised Report reflects places where the examiners made revisions. Please note that revisions related to Cigna's response are noted by the word "REVISED" included on the footer of the applicable pages. This revised Report contains the only substantive revisions we plan to make before the Report becomes final.

In response to this letter, Cigna must provide the following on or before December 4, 2024:

- Acknowledgement that the entire corrective action plan will be completed no later than December 31, 2024, with the exception of CAP Item Number 8, which will be completed no later than March 31, 2025.

Once we have received Cigna's acknowledgment on or before December 4, 2024, we will communicate the next steps regarding the settlement of this matter.

If you have any questions or need any additional information, please do not hesitate to contact me.

Thank you for your prompt attention to this matter.

Yours truly,

Bryan Wachter
BOI Manager
Health Market Conduct Section
Life and Health Division
Bureau of Insurance
(804) 371-9745

Market Conduct Examination Report
BOI Response
Cigna Health and Life Insurance Company (Cigna)

The examiners have received and reviewed Cigna's October 21, 2024, response to the Draft Report. The BOI acknowledges Cigna's cooperation to implement corrective actions and the steps the Company has already taken. This response addresses Cigna's concerns and proposed corrective actions for each area of review in the same order as presented in the Draft Report. Please note that this response only addresses situations where Cigna has expressed disagreement with the findings in the Draft Report or where the examiners have comments or concerns regarding Cigna's responses.

SECTION VII. OTHER NQTL ISSUES

CAP Item Number 8 (Medical Necessity Criteria for Autism and ABA)

The BOI acknowledges that Cigna has already taken action to revise its internally developed coverage policies and that the Company anticipates full completion of all revisions by mid-2025.

Please be advised that this time frame is not acceptable, and it does not appear that Cigna would need this amount of time to remediate an issue that the Company was made aware of in 2023. Cigna must complete this CAP Item by March 31, 2025.

CAP Item Number 10 (Medical Necessity Criteria for Gender Dysphoria)

The BOI continues to disagree with Cigna's position based on the below arguments.

Cigna's additional response to the Draft Report introduces three new articles that Cigna claims to support its newly introduced argument that "…persistence of an incongruous gender identity is variable between childhood and adulthood…." However, this response fails to address any of the concerns raised by the BOI on pages 54 through 57 of the Draft Report and fails to reconcile the arguments previously presented by Cigna. Cigna's initial argument was based on the Company's decision to utilize some of WPATH's recommendations but not others and based on comparisons to the NCCN guidelines for M/S benefits, which are entirely different premises than Cigna's new argument. The three articles presented by Cigna are also not identified as references in Cigna's coverage policy, so it appears that Cigna is introducing new information after the fact that was not utilized in the development of the coverage policy in question.

It is Cigna's responsibility to demonstrate compliance with MHPAEA. However, Cigna's response to the Draft Report includes only the titles and authors of three articles, along with a broad interpretation from the Company regarding the potential variability of trans identity from childhood to adulthood allegedly supporting Cigna's requirement for "two independent letters of confirmation of the diagnosis of gender dysphoria…." Cigna failed to provide documentation of these articles and their sources and failed to point to the specific language supporting the Company's position. Notwithstanding Cigna's failure to

document its evidentiary standards, the BOI researched the articles and identified the following deficiencies in the Company's position:

- Two of the articles were published in 2008 and rely on what appear to be outdated sources/studies/research ranging from 1948 to 2007. For example, the article titled Gender Identity Disorders in Childhood and Adolescence relies on information from the Diagnostic and Statistical Manual of Mental Disorders Fourth Edition (the "DSM-4") and The Harry Benjamin International Gender Dysphoria Association's Standards of Care for Gender Identity Disorders in Children and Adolescents (the "WPATH SOC 6"). Of note, the criteria for diagnosing gender dysphoria (previously referred to as gender identity disorder, which is the term used in these articles and studies) was revised with the introduction of the Diagnostic and Statistical Manual of Mental Disorders Fifth Edition (the "DSM-5") subsequent to the publishing of these articles, which would appear to have a material impact on the reliability of the articles referenced in Cigna's response. The coverage policy in question also indicates that Cigna utilized the Standards of Care for the Health of Transgender and Gender Diverse People, Version 8 (the "WPATH SOC 8") in its development, which is inconsistent with Cigna's new claim that it relied on an article referencing the WPATH SOC 6. In addition to relying on outdated information, the article titled A Follow-Up Study of Girls With Gender Identity Disorder acknowledges limitations of the studies performed, which were a small sample size and lack of a concurrent control group.

- The procedure in question in the Draft Report and Corrective Action is gender-affirming chest surgery for patients ages 15 to 17 with gender dysphoria. Gender Identity Disorders in Childhood and Adolescence and A Follow-Up Study of Girls With Gender Identity Disorder focus on whether or not gender identity disorder diagnosed in childhood (i.e., before the patient reaches puberty) is likely to continue to be present in adolescence and adulthood, with the former written in the context of whether or not puberty blockers are appropriate for children. Fluidity in Gender Identity and Sexual Orientation Identity in Transgender and Nonbinary Youth appears to focus on the frequency and pattern of changes in gender identity and sexual orientation identity across three months rather than focusing on gender dysphoria (where the clinical focus for diagnostic criteria is dysphoria rather than identity). It appears that the articles referenced by Cigna fail to display a strong connection to making determinations regarding gender-affirming chest surgery for patients ages 15 to 17.

In the event that Cigna can prove that it utilizes reliable evidentiary standards to support the premise that gender dysphoria diagnoses in patients ages 15 to 17 are potentially variable over time, the Company has still failed to demonstrate comparability between MH/SUD benefits and M/S benefits and failed to explain how discretion is comparably applied. Cigna has failed to explain how it takes information in the literature about a diagnosis that may be variable over time and translates that premise into a requirement in its gender dysphoria coverage policy for two letters of support from two providers, as well as how a similar process/strategy is applied to M/S benefits (e.g., are there scenarios where the literature for M/S benefits indicates a lack of clinical evidence and/or a variable diagnosis over time for a particular condition or service and Cigna uses discretion to require an opinion from an additional provider in its coverage policy?). It is also arguable

that Cigna has imposed separate treatment limitations on the MH/SUD condition of gender dysphoria (i.e., two letters of support and parental consent) that are not also imposed on M/S benefits. Cigna would either need to remove/revise these requirements (e.g., lower the requirement to one letter reflecting the opinion of a multidisciplinary team) or explain in detail how 1) these limitations are supported by current generally accepted standards of medical practice and 2) similar limitations are applied to M/S benefits, with emphasis on the use of discretion to translate concepts from the literature to the Company's medical necessity criteria.

The Report appears correct as written regarding the findings, and Cigna must complete the required Corrective Action.

CAP Item Number 13 (Sub-Classification of Outpatient Benefits)

The BOI continues to disagree with Cigna's position. Cigna has argued that "…there is no legal basis or authority…" for the finding in the Draft Report because 42 USC 300gg-26(a)(8)(A), 45 CFR 146.136(c)(4)(i), and § 38.2-3412.1 B of the Code do not specifically speak to sub-classification of outpatient benefits. Cigna is advised that 45 CFR 146.136(c)(4)(i) sets forth the NQTL general rule, 42 USC 300gg-26(a)(8)(A) sets forth the required steps for a comparative analysis demonstrating compliance with the NQTL general rule, and § 38.2-3412.1 B of the Code incorporates all requirements of MHPAEA, including the NQTL general rule and permissible classification/sub-classification methodology, into the Code of Virginia. Classifying benefits is a foundational step of MHPAEA that must be completed correctly before any of the required analyses (i.e., analyses for financial requirements/QTLs and NQTLs) can be performed. If a carrier does not correctly classify benefits and set up the classifications or sub-classifications in a permissible manner (i.e., consistently between financial requirements/QTLs and NQTLs), then any NQTL comparative analysis performed in these impermissible classifications or sub-classifications would be insufficient to demonstrate compliance with 42 USC 300gg-26(a)(8)(A) and 45 CFR 146.136(c)(4)(i) and would be in non-compliance § 38.2-3412.1 B of the Code.

In addition, Cigna's approach to classification/sub-classification of outpatient benefits would appear to have a material impact on its processes, strategies, evidentiary standards, and other factors. For example, Cigna's outpatient prior authorization (note that this is not the only NQTL that could be impacted) comparative analyses utilize sub-classification and indicate that, for individual and large group policies, the NQTL is applied to the "all other outpatient items and services" sub-classification and not applied to the "office visits" sub-classification. Cigna relies on several factors to determine which MH/SUD benefits and M/S benefits in the "all other outpatient items and services" sub-classification are subject to prior authorization, including an ROI of 3.0, and benefits in the "office visit" sub-classification are not analyzed to determine whether or not they implicate the factors. However, it is the BOI's understanding that, for purposes of financial requirements/QTLs, Cigna sub-classifies for large group policies but does not sub-classify for individual policies. This approach is permissible for purposes of financial requirements/QTLs, but, as explained by the BOI on pages 65 through 67 of the Draft Report, this means that Cigna must utilize a consistent approach for NQTLs. If Cigna performed its NQTL comparative analyses in a classification structure that is consistent with the Company's approach for financial requirements/QTLs (i.e., one set of comparative analyses for individual policies that are not sub-classified and one set of

comparative analyses for large group policies that are sub-classified), which is required by the regulation, then the Company would potentially need to utilize different factors and evidentiary standards to ensure that office visits are not implicated for prior authorization under Cigna's individual policies.

Cigna has also explained that "…Cigna sometimes uses sub-classification of outpatient benefits and sometimes does not…" and has argued that "…There does not appear to be any requirement in state or federal law that would mandate that a plan or issuer 'always' or 'never' sub-classify outpatient benefits, i.e., consistently do it or not do it…." However, this response fails to address any of the concerns and explanations presented by the BOI on pages 65 through 67 of the Draft Report and fails to introduce any new material information beyond Cigna's arguments that have already been addressed in the Review Sheet and the Draft Report.

The Report appears correct as written regarding the findings, and Cigna must complete the required Corrective Action.

REVISIONS TO REPORT

The Report has been revised to reflect the following changes:

- The Report has been reorganized to enhance readability, including moving the "Background of MHPAEA & NQTL Requirements" section to the beginning. The content of that section did not change.

- Additional details have been added to the "Executive Summary" section now that the Report process has progressed.

- CAP Item Number 10 has been revised for consistency to match the language used in the body of the Report. As Cigna is aware, further details regarding what is required by each CAP Item are provided in Appendix A.

- The deadline for completing CAP Item Number 8 has been revised to March 31, 2025.

Summary

A copy of the entire Report is attached for your review. The pages containing revisions made related to Cigna's response are marked revised. This copy of the Report contains the only substantive revisions we plan to make before the Report becomes final.

On the basis of our review of the entire file, it appears that Cigna violated §§ 38.2-3412.1 B and 38.2-3418.17 A of the Code.

Loleta Keith
Legal Compliance Senior Advisor

December 4, 2024

Loleta.Keith@CignaHealthcare.com
Telephone: 540.240.8327

VIA EMAIL

Bryan Wachter, BOI Manager
Health Market Conduct Section
Life and Health Division
Virginia Bureau of Insurance
1300 E. Main Street
Richmond, VA 23219

RE: Cigna Health and Life Insurance Company, Inc.
Market Conduct Examination Exposure Draft Report

Dear Mr. Wachter:

Cigna acknowledges the revised market conduct report and appreciates the responses from the Virginia Bureau of Insurance ("BOI") addressing Cigna's concerns and areas of disagreement. Cigna acknowledges the 12/31/2024 deadline that the BOI has established for completion of the entire corrective action plan, with the limited exception of CAP item #8 (medical necessity criteria for autism and ABA), and Cigna intends to complete every CAP item as soon as possible and is already working diligently toward this end. However, we would note that there may be some limited items for which we need more time and that run past 12/31/2024 despite our best efforts. Cigna takes MHPAEA compliance seriously, and making updates to NQTL comparative analyses is a complex process that involves careful evaluation and thoughtful analysis, including changes to our internal operational processes that may have significant consequences, and is not just an update to the written document. That said, the document itself is also lengthy and complex and that too takes time to thoughtfully update to ensure accuracy as well as continued parity compliance, as written and in operation. We are targeting 12/31/2024 for all applicable CAP items to be completed but wanted to note the possibility that some may take longer.

Please find attached the Company's written response to each corrective action listed within the revised Exposure Draft Report.

If you have any questions or need additional information, please do not hesitate to contact me.

Sincerely,

Loleta Keith
Legal Compliance Senior Advisor

Enclosures: VA BOI Revised Draft Report of CHLIC_Cigna Response

Copy to: Julie Blauvelt

Target Market Conduct Examination Report
Response to Corrective Action Items in Section VIII
Cigna Health and Life Insurance Company (CHLIC)

Please find below Cigna's responses to each of the corrective actions included in the revised draft report for Cigna Health and Life Insurance Company (Cigna/CHLIC/the Company).

1. Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for prior authorization that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently.

   Cigna Response: Cigna acknowledges that the Company will make every effort to complete these items on or before December 31, 2024.

2. Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for concurrent review that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently.

   Cigna Response: Cigna acknowledges that the Company will make every effort to complete these items on or before December 31, 2024.

3. Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for retrospective review that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently.

   Cigna Response: Cigna acknowledges that the Company will make every effort to complete these items on or before December 31, 2024.

4. Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for pre-payment review (e.g., a provider or facility is flagged for a history of overutilization or a finding of FWA, and either all or a subset of that provider's or facility's claims are subject to review/audit upon claim submission) and pre-claim payment FWA investigations that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A);

   Cigna Response: Cigna acknowledges that the Company will make every effort to complete these items on or before December 31, 2024.

5. Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for post-payment retrospective review that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other

factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently.

Cigna Response: Cigna acknowledges that the Company will make every effort to complete these items on or before December 31, 2024.

6. Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for medical necessity that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently.

   Cigna Response: Cigna acknowledges that the Company will make every effort to complete these items on or before December 31, 2024.

7. Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for experimental/investigational/unproven ("EIU") that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently.

   Cigna Response: Cigna acknowledges that the Company will make every effort to complete these items on or before December 31, 2024.

8. Cigna will revise its internally-developed clinical criteria ("coverage policies"), including Intensive Behavioral Interventions, Autism Spectrum Disorders/Pervasive Developmental Disorders: Assessment and Treatment, and any other coverage policies that may apply to autism spectrum disorders, to comply with the standard for medical necessity and coverage requirements set forth in § 38.2-3418.17 A of the Code and to remove any requirements that do not comply with MHPAEA;

   Cigna Response: Cigna acknowledges that the Company will make every effort to complete these items on or before March 31, 2024.

9. Cigna will perform and document a sufficient comparative analysis in each classification or sub-classification reviewed as part of this examination for treatment plans that complies with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A), including revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD benefits that are not comparable as written and/or are applied more stringently. This analysis must include, among other elements, a demonstration of comparability regarding the content, nature, and volume of information required in treatment plans for MH/SUD benefits and M/S benefits and a demonstration of comparability regarding the decision of whether or not a treatment plan is needed to determine medical necessity for MH/SUD benefits, specifically ABA for autism spectrum disorders, and M/S benefits

   Cigna Response: Cigna acknowledges that the Company will make every effort to complete these items on or before December 31, 2024.

10. Cigna will amend its internally-developed medical necessity criteria ("coverage policies"), including Gender Dysphoria Treatment and any other coverage policies that may apply to gender dysphoria, to revise any requirements that do not comply with MHPAEA;

    Cigna Response: With respect to CAP item #10 (medical necessity criteria for gender dysphoria), Cigna continues to disagree with the BOI's position and continues to believe that we have demonstrated compliance with MHPAEA with our current medical necessity criteria and coverage policy. In addition, where the BOI states at the top of page 2 that "the BOI researched the articles and identified the following deficiencies in the Company's position," we would note that this is the first time Cigna has received notice that such studies or articles are deemed to be insufficient by the BOI, or any regulator, and consequently this is not something Cigna has been aware of since 2023, or at any time up until December 2024.

    That being said, in order to satisfy the BOI, Cigna will nevertheless update its gender dysphoria coverage state-specific policy to reflect that, for the state of Virginia, Cigna will only require <u>one</u> letter of support from a healthcare professional for gender affirming surgery for minors ages 15-17. In addition, Cigna will incorporate the additional feedback from the BOI and will also update its separate, generally applicable gender dysphoria treatment coverage policy during the next revision cycle to better explain and document why two letters from healthcare professionals are generally required for gender affirming surgery for minors ages 15-17, absent state-specific variation as with plans offered in Virginia.

11. Cigna will revise its inpatient and outpatient return-on-investment ("ROI") ratio calculations for MH/SUD benefits and M/S benefits and make necessary documentation available to substantiate comparability of the formulas to comply with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A). This includes ensuring that ROI ratio calculations are performed and documented separately for each classification or sub-classification and performed and documented separately for each NQTL.

    Cigna Response: Cigna acknowledges that the Company will make every effort to complete these items on or before December 31, 2024.

12. Cigna will revise its prior authorization, concurrent review, and retrospective review comparative analyses in the "Outpatient, In-Network, All Other" sub-classification to specifically contemplate the clinical oversight tiers and number of visits used as factors by American Specialty Health ("ASH"), as well as the review process used by ASH that allows for submission of a medical necessity review form 180 days after the date of service, in order to comply with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A). This includes revising any processes, strategies, evidentiary standards, and other factors used to apply the NQTL that are not comparable between MH/SUD benefits and M/S benefits.

    Cigna Response: Cigna acknowledges that the Company will make every effort to complete these items on or before December 31, 2024.

13. Cigna will consistently apply methodology regarding the sub-classification of outpatient benefits for the purposes of financial requirements/QTLs and NQTL comparative analyses to ensure compliance with the requirements of § 38.2-3412.1 B of the Code, 45 CFR 146.136(c)(4)(i), and 42 USC 300gg-26(a)(8)(A).

Cigna Response: With respect to CAP item #13 (sub-classification of outpatient benefits), Cigna continues to disagree with the BOI's position. Cigna agrees classifying benefits is a foundational step of MHPAEA that must be completed correctly before any of the required analyses can be performed. However, the BOI continues to assert that benefits must be classified "consistently between financial requirements/QTLs and NQTLs," without any legal authority or basis for this statement. No other state or federal regulator has ever asserted this, in our experience. In fact, carriers are expressly permitted under the regulations to sub-classify outpatient benefits into office visits and all other outpatient services, without any further restrictions.

Nevertheless, in order to satisfy the BOI, Cigna will update its benefit classification methodology to ensure consistency between financial requirements/QTLs and NQTLs. In practice, this means we will sub-classify outpatient benefits for both NQTL comparative analyses and for financial requirements and cost-share testing. (Cigna does not apply any QTLs to any MH/SUD benefits under any plan.) No updates will therefore be needed to the NQTL comparative analyses in this regard, though Cigna will need to review its financial requirements and cost-share testing process to ensure all fully insured plans offered in Virginia, in both the individual market and the large group market, are always tested in a way that involves sub-classification of outpatient benefits.

Wilde Building, Routing B6LPA
900 Cottage Grove Road
Bloomfield, Connecticut 06002-2920

Julie Blauvelt
Deputy Commissioner
Virginia Bureau of Insurance
1300 East Main Street
Richmond, VA 23219

RE: Alleged violation of Code of Virginia §§ 38.2 3412.1 B and 38.2 3418.17 A
Case No. INS-2024-00135

Dear Ms. Blauvelt:

This will acknowledge receipt of the Bureau of Insurance's ("Bureau") letter dated December 18, 2024, concerning the above-referenced matter.

Cigna Health and Life Insurance Company ("Cigna") wishes to make a settlement offer for the alleged violations cited above. Specifically, we agree to:

1. Enclose with this letter a certified check, cashier's check or money order payable to the Treasurer of Virginia in the amount of $330,000;
2. Comply with, and continue to comply with, the corrective action plan set forth in the examination report;
3. Complete all corrective action plan items except corrective action plan item 8 and provide satisfactory documentation of completion thereof to the Bureau by December 31, 2024, or additional penalties may be assessed by the Bureau and Cigna may be required to remove noncompliant nonquantitative treatment limitations ("NQTLs") from Mental Health and Substance Use Disorder ("MH/SUD") benefits;
4. Complete corrective action plan item 8 and provide satisfactory documentation of completion thereof to the Bureau by March 31, 2025, or additional penalties may be assessed by the Bureau and Cigna may be required to remove noncompliant NQTLs from MH/SUD benefits; and
5. Acknowledge Cigna's right to a hearing before the State Corporation Commission in this matter and waive that right if the State Corporation Commission accepts this offer of settlement.

This offer is being made solely for the purpose of a settlement and does not constitute, nor should it be construed as, an admission of any violation of law.

Sincerely,
Cigna Health and Life Insurance Company

(Signed)

Katie Stewart
(Type or Print Name)

Regional Vice President
(Title)

January 08, 2025
(Date)

Enclosure

COMMONWEALTH OF VIRGINIA

STATE CORPORATION COMMISSION

AT RICHMOND, JANUARY 27,2025

COMMONWEALTH OF VIRGINIA, *ex rel.*

STATE CORPORATION COMMISSION

v.

CASE NO. INS-2024-00135

CIGNA HEALTH AND LIFE INSURANCE COMPANY,
Defendant

SETTLEMENT ORDER

Based on a target market conduct examination conducted by the Bureau of Insurance ("Bureau") and as set forth in the Bureau's Market Conduct Examination Report ("Report"), filed separately in this docket, the Bureau has alleged that Cigna Health and Life Insurance Company ("Defendant"), duly licensed by the State Corporation Commission ("Commission") to transact the business of insurance in the Commonwealth of Virginia, in certain instances violated § 38.2-3412.1 B of the Code of Virginia ("Code") by failing to provide coverage for mental health and substance use disorder benefits in parity with medical and surgical benefits in accordance with the federal Mental Health Parity and Addiction Equity Act of 2008; and § 38.2-3418.17 A of the Code by failing to provide coverage for autism spectrum disorder in accordance with the requirements of this Code section.

The Commission is authorized by §§ 38.2-218, 38.2-219, and 38.2-1040 of the Code to impose certain monetary penalties, issue cease and desist orders, and suspend or revoke a defendant's license upon a finding by the Commission, after notice and opportunity to be heard, that a defendant has committed the aforesaid alleged violations.

The Defendant has been advised of the right to a hearing in this matter whereupon the Defendant, without admitting or denying any violation of Virginia law, has made an offer of settlement to the Commission. Through its settlement offer, filed separately in this docket, the Defendant has agreed to comply with, and continue to comply with, the corrective action plan set forth in the Report; complete all corrective action plan items except corrective action plan item 8 and provide satisfactory documentation of completion thereof to the Bureau by December 31, 2024, or additional penalties may be assessed by the Bureau and the Defendant may be required to remove noncompliant nonquantitative treatment limitations ("NQTLs") from Mental Health and Substance Use Disorder ("MH/SUD") benefits; complete corrective action plan item 8 and provide satisfactory documentation of completion thereof to the Bureau by March 31, 2025, or additional penalties may be assessed by the Bureau and the Defendant may be required to remove noncompliant NQTLs from MH/SUD benefits; has tendered to the Treasurer of Virginia the amount of Three Hundred Thirty Thousand Dollars ($330,000); and has waived the right to a hearing.

The Bureau has recommended that the Commission accept the Defendant's settlement offer pursuant to the authority granted to the Commission in § 12.1-15 of the Code.

NOW THE COMMISSION, having considered this matter, is of the opinion and finds that the Defendant's settlement offer should be accepted.

Accordingly, IT IS ORDERED THAT:

(1) The Defendant's settlement offer is hereby accepted.

(2) The Defendant shall fully comply with the terms of the settlement.

(3) This case is continued and the Bureau shall advise the Commission when the Defendant has successfully complied with the corrective action plan.

A COPY hereof shall be sent by the Clerk of the Commission by electronic mail to: Loleta Keith, Legal Compliance Advisor, Market Conduct, State Government Affairs - Regulatory Operations, Cigna Health and Life Insurance Company, loleta.keith@cignahealthcare.com; and a copy shall be delivered to the Commission's Office of General Counsel and the Bureau of Insurance in care of Deputy Commissioner Julie Blauvelt.