DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Consumer Information and Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201

The Centers for Medicare & Medicaid Services (CMS) has concluded that Aetna Life Insurance Company (WY) is not in compliance with the requirements of the Mental Health Parity and Addiction Equity Act (MHPAEA), as codified at Public Health Service Act § 2726 (42 U.S.C. § 300gg-26), and its implementing regulations. The Issuer must, by January 24, 2025, notify all individuals enrolled in health insurance coverage offered by the Issuer subject to this non-quantitative treatment limitation (NQTL) that the coverage it is not compliant with the requirements of MHPAEA and its implementing regulations. Please provide a copy of the letter, with the date(s) the letter was sent, and a list of recipients to CMS by January 24, 2025.

January 14, 2025

Aetna Life Insurance Company – Wyoming – HIOS #44325

Darcey Gartner, Executive Director
Corporate Compliance
dxgartner@aetna.com

Re: Final Determination Letter - Finding of Non-Compliance – Mental Health Parity and Addiction Equity Act (MHPAEA) Non-Quantitative Treatment Limitation (NQTL) Comparative Analysis Review – Concurrent review for outpatient, in-network services.

Dear Darcey Gartner:

This letter informs you that a review of the Corrective Action Plan (CAP) and additional comparative analyses submitted on July 3, 2023, and July 25, 2023, to address the instances of non-compliance noted in the Initial Determination Letter for this MHPAEA NQTL Analysis Review (Review) is complete.

The purpose of the Review was to assess Aetna Life Insurance Company's (Issuer) compliance with the following requirements under Title XXVII of the Public Health Service Act (PHS Act) and its implementing regulations:

> PHS Act § 2726, 45 C.F.R. §§ 146.136 and 147.160[1] - Parity In Mental Health And Substance Use Disorder Benefits (MHPAEA and its implementing regulations).

[1] In this document, references to C.F.R. §§ 146.136 and 147.160 refer to the regulations applicable during the 2022 plan year.

The Review covered concurrent review requirements for outpatient, in-network services for the 2022 plan year (hereinafter referred to as "the NQTL").

CMS conducted this Review on behalf of the Secretary of Health and Human Services pursuant to PHS Act § 2726(a)(8)(A) and (B), as added by Section 203 of Title II of Division BB of the Consolidated Appropriations Act, 2021.[2] CMS contracted with Examination Resources, LLC to assist CMS with conducting this Review.

After reviewing the CAP and additional comparative analysis provided, CMS is finalizing the initial determination that the Issuer violated PHS Act § 2726 and its implementing regulations at 45 C.F.R. §§ 146.136 and 147.160 by:

- imposing an impermissible separate treatment limitation applicable only to certain mental health and substance use disorder (MH/SUD) benefits and not to medical and surgical (M/S) benefits in the same benefit classification; and
- failing to provide a sufficient comparative analysis as required under PHS Act § 2726(a)(8)(A).

This Final Determination Letter identifies the ways that the Issuer's CAP and comparative analysis fail to comply with PHS Act § 2726 and its implementing regulations. This letter also specifies additional corrective actions for the Issuer to address the findings of non-compliance.

On May 19, 2023, CMS provided an Initial Determination Letter of non-compliance to the Issuer and directed the Issuer to submit a CAP and additional comparative analysis to CMS to demonstrate compliance with MHPAEA and its implementing regulations. After reviewing the Issuer's July 3, 2023, and July 25, 2023 CAP submissions and revised comparative analysis, CMS is finalizing the initial determination of non-compliance with MHPAEA and its implementing regulations in the following areas noted in the May 19, 2023, Initial Determination Letter and discussed below:

I. Separate Treatment Limitation, in Violation of PHS Act § 2726(a)(3)(A)(ii).

PHS Act § 2726(a)(3)(A)(ii) prohibits "separate treatment limitations that are applicable only with respect to mental health or substance use disorder benefits." CMS identified violations of this provision in the following instances:

1. **The treatment plan must be reevaluated every six months for concurrent review determinations for applied behavior analysis (ABA), a MH/SUD service, but such reevaluation is not required for any M/S services.**

The Issuer provided the coverage policy used to make concurrent review determinations for ABA services in its supplemental response.[3] The coverage policy for ABA services requires members receiving ABA services to be reevaluated every six months to assess the need for continued ABA services. Benefits for ABA services are determined not medically necessary and

[2] Pub. L. 116-260 (Dec. 27, 2020).
[3] applied-behavioral-analysis.

terminated if the six-month reevaluation does not occur.[4] The Issuer does not require the reevaluation of treatment plans every six months for any M/S services in the same benefit classification. CMS identified the evaluation requirement as an impermissible separate treatment limitation applied only to ABA services in the Initial Determination Letter.[5]

The Issuer acknowledged that it does not require the reevaluation of treatment plans every six months for any M/S service in its CAP response.[6] However, the Issuer identified other M/S services that it argued are subject to reevaluation on a more frequent basis than ABA services. Physical therapy, speech therapy, acupuncture and dry needling, cognitive rehabilitation, and occupational therapy are all M/S services that the Issuer asserted are subject to monthly reevaluations.[7] The Issuer provided coverage policies for each of the M/S services it identified as being subject to monthly evaluations. However, the coverage policies provided do not clearly mandate monthly reevaluations in order to receive coverage for the service. For example, the coverage policy provided for physical therapy noted that, *"[t]he patient **should** be reevaluated regularly (at least monthly), and there **should** be documentation of progress made toward the goals of physical therapy"* (emphasis added).[8] Use of the word "should" implies that such evaluations are not required in order for a concurrent review request to be approved for physical therapy. As another example, the Issuer provided the occupational coverage policy that contains both mandatory and non-mandatory language. The occupational therapy coverage policy notes that members, *"**should** be re-evaluated regularly (at least monthly), and there **should** be documentation of progress made toward the goals of occupational therapy"* (emphasis added).[9] This policy also contains mandatory requirements such as *"The plan of care **must** be signed by the member's attending physician and occupational therapist"* (emphasis added).[10]

Use of both the words "should" and "must" within the same coverage policy indicates a distinction between obligatory and non-obligatory items. All of the M/S coverage policies cited by the Issuer contain the non-obligatory word "should" in relation to these evaluations. It is therefore unclear the extent to which these evaluations are actually required as a condition of coverage. In contrast, the coverage policy for ABA services uses obligatory language with respect to evaluations of response to treatment. The coverage policy for ABA services provides a set of six criteria that must be met for a member to continue to receive coverage for ABA services. The coverage policy for ABA services stated: *"All the following criteria **must** be met"* (emphasis added).[11] Included within the set of six criteria is a requirement that, *"[r]e-evaluation of interventions and progress has been performed (Every six months) to assess the need for ongoing ABA."*[12] The coverage policy for ABA services goes on to state that, *"[a]ll six criteria above **must** be evaluated"* (emphasis added).[13] This further emphasizes the mandatory nature of fulfilling each of the six criteria. Even if, in operation, M/S services are generally subject to

[4] applied-behavioral-analysis, pg. 4.
[5] Aetna LIC WY_Initial Determination Letter_CR_Final, pg. 2.
[6] WY ALIC and AHofU Concurrent Review Response, pg. 1.
[7] WY ALIC and AHofU Concurrent Review Response, pg. 1.
[8] Exhibit 1 and 2.CPB 0325 Physical Therapy, pg. 69.
[9] Exhibit I.1 and 2. CPB 0250 Occupational Therapy, pg. 25
[10] Exhibit I.1 and 2. CPB 0250 Occupational Therapy, ps. 25.
[11] applied-behavioral-analysis, pg. 4.
[12] applied-behavioral-analysis, pg. 4.
[13] applied-behavioral-analysis, pg. 4.

some form of evaluation, the M/S coverage policies, as written, do not require reevaluations as the coverage policy for ABA services does.

The M/S policies do not require the regular evaluations that the coverage policy for ABA services does. Therefore, this NQTL is an impermissible separate treatment limitation under PHS Act § 2726(a)(3)(A)(ii), and its implementing regulations at 45 C.F.R. §§ 146.136 and 147.160, that the Issuer applied only to MH/SUD benefits and not to M/S benefits in the same benefit classification.

2. Validated assessments are required in order to demonstrate response to intervention for concurrent review determinations for ABA services, but such assessments are not required for any M/S services.

The Issuer provided the coverage policy used to make concurrent review determinations for ABA services in its supplemental response.[1] The coverage policy for ABA services requires that specific validated assessments are performed to demonstrate response to treatment. Benefits for ABA services are determined not medically necessary and denied if a validated assessment is not performed or response to treatment is not demonstrated by a validated assessment.[15] The Issuer does not require validated assessments to demonstrate response to treatment for any M/S services in the same benefit classification. CMS identified the validated assessment requirement as an impermissible separate treatment limitation applied only to ABA services in the Initial Determination Letter.[16]

The Issuer asserted that nearly all M/S services subject to concurrent review require some form of periodic reassessment to demonstrate response to treatment in its CAP response.[17] The Issuer identified examples of M/S services purportedly subject to some form of evaluation. The Issuer cited the speech therapy coverage policy which notes that members should be evaluated regularly and that, *"There **should** be documentation of progress made toward the goals of speech therapy, and if needed, changes made in the treatment program as a result of the evaluation"* (emphasis added).[18] The Issuer argued that the evaluations referenced in the identified M/S coverage policies are equivalent to the assessment requirement present in the coverage policy for ABA services. The Issuer stated, in reference to the cited speech therapy coverage policy: *"That language is describing, albeit in different words, the need for periodic assessments ('evaluations') to demonstrate response to the interventions ('progress toward goals')."*[19] However, the coverage policy for ABA services clearly distinguishes between evaluations and assessments, as it requires both an evaluation and an assessment as part of its concurrent review approval process. The coverage policy for ABA services mandates that, "*[r]e-evaluation of interventions and progress has been performed (Every six months) to assess the need for ongoing ABA; AND a repeated validated assessment (e.g., Vineland, ABAS, VB-MAPP or ABLLS) has been done every 6-12 months to demonstrate response to intervention"* in order

[14] applied-behavioral-analysis.
[15] applied-behavioral-analysis, pg. 4.
[16] Aetna LIC WY_Initial Determination Letter_CR_Final, pgs. 2-3.
[17] WY ALIC and AHofU Concurrent Review Response, pgs. 1-2.
[18] Exhibit I.1 and 2. CPB 0243 Speech Therapy, pg. 38.
[19] WY ALIC and AHofU Concurrent Review Response, pg. 1.

for a concurrent review request for continued coverage of ABA services to be approved.[20] Use of the conjunction "AND" clearly establishes the evaluation and validated assessment as two separate requirements. None of the M/S services identified by the Issuer require both an evaluation of a patient's progress and a validated assessment demonstrating response to treatment as the coverage policy for ABA services does. Even if the form of evaluation of response to treatment to which some M/S services may be subject to could be considered the same kind of limitation applicable to ABA services, the validated assessment requirement in conjunction with the evaluation requirement imposed on ABA services result in a concurrent review determination process that is not comparable and is more stringent as written and in operation as applied to ABA services compared to M/S services, in violation of 45 C.F.R. § 146.136(c)(4)(i).

Requirements concerning specific validated assessments demonstrating response to treatment are not present in the coverage policies for the M/S services identified by the Issuer. Therefore, this NQTL is an impermissible separate treatment limitation under PHS Act § 2726(a)(3)(A)(ii), and its implementing regulations at 45 C.F.R. §§ 146.136 and 147.160, that the Issuer applied only to MH/SUD benefits and not to M/S benefits in the same benefit classification.

II. Failure to Provide Sufficient Information and Supporting Documentation, in Violation of PHS Act § 2726(a)(8)(A).

PHS Act § 2726(a)(8)(A)(ii), (iii), and (iv) requires that the Plan "make available to […] Secretary of Health and Human Services […] upon request, the comparative analyses" including "[t]he factors used to determine that the NQTLs will apply to mental health or substance use disorder benefits and medical or surgical benefits […] provided that every factor shall be defined" and "[t]he 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 same benefits classification." CMS identified violations of this provision in the following instances:

1. **Failure to provide sufficient information and supporting documentation regarding the factors considered in the design and application of the NQTL, as written and in operation.**

The Issuer identified return on investment (ROI) as a factor used to determine whether the NQTL will continue to apply to a service in its initial submission.[21] On May 18, 2022, CMS requested the Issuer provide additional information on the process used to determine that the NQTL will continue to apply to a service.[22] The Issuer noted in its response dated June 17, 2022, that the ROI factor is calculated annually for each service subject to a concurrent review requirement and that services with a ROI of 3:1 or greater continue to be subject to a concurrent

[20] applied-behavioral analysis, pg. 4.
[21] CMS-MO-WY NQTL Analysis, pgs. 4, 5, 13.
[22] Aetna HOU LIC_WY_CR_Insufficient Data Request, Request Item #4.A.

review requirement.[23] In addition, the Issuer provided a description of how the ROI factor is used in this process, but did not provide definitions of the elements that comprised the ROI factor calculation, as outlined by CMS in the Initial Determination Letter.[24]

Specifically, the Issuer defined its ROI factor as the *"health care cost expense savings related to denials of non-medically necessary care divided by administrative costs"* in its CAP response dated July 3, 2023.[25] The Issuer thereby defined the general formula used to calculate the ROI factor.[26] In the Issuer's CAP submission, the ROI formula was also defined as calculated by dividing (i) by (ii): "(i) Gross dollar amount of claims costs saved through appropriate denials of coverage for that service, and (ii) Gross dollar amount of costs to administer precertification for that service."[27] However, it did not provide further information on how it determines the "cost expense savings for a service" input or the "cost to administer concurrent review on a service" input used to input the ROI factor.

In addition, the Issuer indicated in its initial submission that it considers extenuating factors to apply the NQTL to MH/SUD services and M/S services that do not meet the 3:1 ROI threshold and provided a list of extenuating factors in its supplemental response dated June 17, 2022.[28, 29] However, the Issuer did not provide definitions for all the extenuating factors listed and did not provide supporting documentation explaining how the extenuating factors are applied to each service as outlined in the Initial Determination Letter.[30] The Issuer provided document "NPL Policy and Procedure_APPROVED 7.24.23" in its CAP response that included definitions for some of the extenuating factors. The document stated: *"Extenuating factors include,* ***but are not limited to****: […]"* (emphasis added) those enumerated in the document.[31] The language in the provided document indicates the factors identified in the document are not exhaustive of all the extenuating factors considered by the Issuer in applying the NQTL to MH/SUD services and M/S services. The Issuer therefore failed to identify and define all of the extenuating factors used in the application of the NQTL as outlined in the Initial Determination Letter.[32]

Therefore, the Issuer did not provide sufficient information regarding the application of the ROI factor and the extenuating factors considered in the design and application of the NQTL, as written and in operation, in violation of PHS Act § 2726(a)(8)(A)(ii) and (iii).

2. Failure to provide sufficient information and supporting documentation regarding the processes, strategies, evidentiary standards, and other factors used to apply the NQTL, as written and in operation.

[23] FINAL_Updated_Wyoming Insufficiency Letter_CR_Response_6.17.22, pgs. 16-18.
[24] Aetna LIC WY_Initial Determination Letter_CR_Final, pgs. 4-5.
[25] WY ALIC and AHofU Concurrent Review Response, pg. 3.
[26] WY ALIC and AHofU Concurrent Review Response, pg. 3.
[27] WY ALIC and AHofU Concurrent Review Response, pgs. 3-4.
[28] CMS-MO-WY NQTL Analysis, pg. 5.
[29] FINAL_Updated_Wyoming Insufficiency Letter_CR_Response_6.17.22, pg. 17.
[30] Aetna LIC WY_Initial Determination Letter_CR_Final, pgs. 4-5.
[31] NPL Policy and Procedure_APPROVED 7.24.23, pg. 5.
[32]Aetna LIC WY_Initial Determination Letter_CR_Final, pgs. 4-5.

The Issuer provided its "NCS 504 Timeliness Stnds P_P" document as part of its initial submission. This document detailed the timeframe standard used by the Issuer for urgent concurrent review requests but did not clearly establish the timeframe used by the Issuer for non-urgent concurrent review requests. CMS requested the Issuer provide the non-urgent concurrent review request timeframe standards with supporting documentation.[33] The Issuer stated that concurrent review requests *"[…] follow either urgent or the non-urgent turn-around-time (TAT) process and framework articulated in NCS 504-01 based on the discretion of the reviewing clinician."*[34] The Issuer did not provide information or supporting documentation on how the Issuer determines whether a concurrent review request will be subject to the urgent timeframe standard or non-urgent timeframe standard as outlined in the Initial Determination Letter.[35] The Issuer stated that non-urgent concurrent review requests use the same timeframe used for non-urgent prior authorization requests in its CAP response.[36] The Issuer cited its "Exhibit II.3.NCS 504 Including Attachment A" document which stated: *"The urgent precertification or non-urgent precertification determination time frame applies as appropriate when an ambulatory coverage request does not meet the definition of urgent concurrent care."*[37] The cited policy and procedure document states that either the urgent or non-urgent prior authorization timeframe may be used for outpatient non-urgent concurrent review requests, which is contrary to the narrative explanation provided.

It is unclear what factors are used by the Issuer to determine the timeframe that will be applied to a non-urgent concurrent review request, or how the process for determining timeframes for MH/SUD services and M/S services may differ. Without this information, CMS is unable to validate whether the processes, strategies, evidentiary standards, and other factors used to apply the NQTL to MH/SUD services are comparable to and no more stringently applied than those applied to M/S services. Therefore, the Issuer did not provide sufficient information and supporting documentation regarding the factors used to determine the timeframe for non-urgent concurrent review requests for MH/SUD benefits and M/S benefits, in violation of PHS Act § 2726(a)(8)(A)(iv).

III. Corrective Actions.

In order to resolve the identified instances of non-compliance, CMS identified the following corrective actions. Please take the following corrective actions by February 27, 2025:

- Remove the concurrent review NQTL for outpatient, in-network MH/SUD services from plans beginning with the 2022 plan year and for subsequent plan years, until such time as the Issuer demonstrates to CMS that the NQTL is in compliance with the requirements under MHPAEA and its implementing regulations;
- Provide to CMS an updated policy and procedure document that reflects the removal of concurrent review requirements for outpatient, in-network MH/SUD services beginning with the 2022 plan year and for subsequent plan years, until

[33] Aetna HOU LIC_WY_CR_Insufficient Data Request, Request Item #1.F.
[34] FINAL_Updated_Wyoming Insufficiency Letter_CR_Response_6.17.22, pg. 2.
[35] Aetna LIC WY_Initial Determination Letter_CR_Final, pgs. 7-8.
[36] WY ALIC and AHofU Concurrent Review Response, pg. 6.
[37] Exhibit II.3.NCS 504 Including Attachment A, pg. 5.

such time as the Issuer demonstrates to CMS that the NQTL is in compliance with the requirements under MHPAEA and its implementing regulations;

- Update the medical management system to reflect the removal of concurrent review requirements for outpatient, in-network MH/SUD services. Provide to CMS evidence of the removal, or an attestation that this corrective action has been completed; and
- Identify and provide to CMS a list of the participants, beneficiaries, and enrollees who have been adversely affected by the application of the concurrent review requirement to MH/SUD services in plan year 2022 and any applicable MH/SUD claims that were affected by the concurrent review requirement, along with supporting documentation outlining the Issuer's methodology for identifying and notifying the affected individuals and claims, and provide evidence that all claims re-adjudications and payment have been completed. Please note that this is separate from and in addition to the seven-day notification requirement mentioned below which requires notice to all individuals regarding non-compliance with MHPAEA and its implementing regulations.
- In order for the Issuer to address this finding of non-compliance and reapply the NQTL for outpatient, in-network services in future plans, a comparative analysis demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply concurrent review to MH/SUD services are comparable to, and applied no more stringently than the processes, strategies, evidentiary standards, and other factors used to apply concurrent review to M/S services would be necessary. For example, the new comparative analysis should:
    - Demonstrate that the validated assessment and treatment plan requirements for ABA services are not impermissible separate treatment limitations. The Issuer may also choose to remove the validated assessment and evaluation requirements imposed on ABA services;
    - Demonstrate that the processes, strategies, evidentiary standards, and other factors used to impose the concurrent review NQTL on ABA services are comparable to, and applied no more stringently than, the same factors used to impose the concurrent review NQTL to M/S services;
    - Contain sufficient information and supporting documentation of all extenuating factors considered when determining whether to impose a concurrent review requirement on a service that does not meet the standard ROI threshold;
    - Contain sufficient information and supporting documentation regarding the cost expense savings and the cost to administer the concurrent review for a service used to calculate the ROI factor for MH/SUD services and M/S services; and
    - Contain sufficient information and supporting documentation that demonstrates clear established timeframes used by the Issuer for non-urgent concurrent review requests and the factors used to determine the application of those timeframes**.**

IV. Next Steps.

Pursuant to PHS Act § 2726(a)(8)(B)(iii)(I)(bb), the Issuer must, by January 24, 2025, notify all individuals enrolled in health insurance coverage offered by the Issuer subject to this NQTL that CMS has determined the coverage is not in compliance with the requirements under MHPAEA and its implementing regulations. Please provide a copy of the letter, with the date(s) the letter was sent, and a list of recipients to CMS by January 24, 2025.

If the Issuer fails to complete the identified corrective actions, provide appropriate notice to its enrollees, or provide documentation of these actions to CMS by the specified dates, CMS may pursue further enforcement action, as warranted, including initiating an investigation or market conduct examination, additional or modified CAPs, and/or assessing civil money penalties under section 2723(b) of the PHS Act and implementing regulations at 45 CFR Part 150, Subpart C and otherwise consistent with law.

CMS' findings detailed in this letter pertain only to the NQTL under review and do not bind CMS in any subsequent or further review of other plan provisions or their application for compliance with governing law, including MHPAEA and its implementing regulations. If additional information is provided to CMS regarding this NQTL or Issuer, CMS reserves the right to conduct an additional review for compliance with MHPAEA or other applicable PHS Act requirements.[38]

CMS' findings pertain only to the specific plans to which the NQTL under review applies and are offered by the Issuer and do not apply to any other plan or issuer, including other plans or coverage for which the Issuer acts as an Administrator. However, these findings should be shared with affiliated entities, and steps should be taken as appropriate to ensure compliance with applicable requirements.

CMS will include a summary of the comparative analysis, results of CMS' review, determination of non-compliance, and the identity of the Issuer in its annual report to Congress pursuant to PHS Act § 2726(a)(8)(B)(iv).

Sincerely,

Jeffrey C. Wu -S

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Date: 2025.01.10 18:05:37 -05'00'

Jeff Wu
Deputy Director of Policy
Center for Consumer Information and Insurance Oversight
Centers for Medicare & Medicaid Services

cc: Wyoming Department of Insurance

[38] See PHS Act § 2726(a)(8)(B)(i). See also 45 C.F.R. § 150.303.