§ 146.137 Nonquantitative treatment limitation comparative analysis requirements.

(a) *Meaning of terms.* Unless otherwise stated in this section, the terms of this section have the meanings indicated in § 146.136(a)(2).

(b) *In general.* In the case of a group health plan (or health insurance issuer offering coverage in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits and that imposes any nonquantitative treatment limitation on mental health or substance use disorder benefits, the plan or issuer must perform and document a comparative analysis of the design and application of each nonquantitative treatment limitation applicable to mental health or substance use disorder benefits. Each comparative analysis must comply with the content requirements of paragraph (c) of this section and be made available to the Secretary, upon request, in the manner required by paragraphs (d) and (e) of this section.

(c) *Comparative analysis content requirements.* With respect to each nonquantitative treatment limitation applicable to mental health or substance use disorder benefits under a group health plan (or health insurance coverage offered in connection with a group health plan), the comparative analysis performed by the plan or issuer must include, at minimum, the elements specified in this paragraph (c). In addition to the comparative analysis for each nonquantitative treatment limitation, each plan or issuer must prepare and make available to the Secretary, upon request, a written list of all nonquantitative treatment limitations imposed under the plan or coverage.

(1) *Description of the nonquantitative treatment limitation.* The comparative analysis must include, with respect to the nonquantitative treatment limitation that is the subject of the comparative analysis:

(i) Identification of the nonquantitative treatment limitation, including the specific terms of the plan or coverage or other relevant terms regarding the nonquantitative treatment limitation, the policies or guidelines (internal or external) in which the nonquantitative treatment limitation appears or is described, and the applicable sections of any other relevant documents, such as provider contracts, that describe the nonquantitative treatment limitation;

(ii) Identification of all mental health or substance use disorder benefits and medical/surgical benefits to which the nonquantitative treatment limitation applies, including a list of which benefits are considered mental health or substance use disorder benefits and which benefits are considered medical/surgical benefits; and

(iii) A description of which benefits are included in each classification set forth in § 146.136(c)(2)(ii)(A).

(2) *Identification and definition of the factors and evidentiary standards used to design or apply the nonquantitative treatment limitation.* The comparative analysis must include, with respect to every factor considered or relied upon to design the nonquantitative treatment limitation or apply the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits:

(i) Identification of every factor considered or relied upon, as well as the evidentiary standards considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived, in determining which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the nonquantitative treatment limitation; and

(ii) A definition of each factor, including:

(A) A detailed description of the factor;

(B) A description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard) identified under paragraph (c)(2)(i) of this section; and

(C) A description of any steps the plan or issuer has taken to correct, cure, or supplement any information, evidence, sources, or standards that would otherwise have been considered biased or not objective under § 146.136(c)(4)(i)(B)(*1*) in the absence of such steps.

(3) *Description of how factors are used in the design and application of the nonquantitative treatment limitation.* The comparative analysis must include a description of how each factor identified and defined under paragraph (c)(2) of this section is used in the design or application of the nonquantitative treatment limitation to mental health and substance use disorder benefits and medical/surgical benefits in a classification, including:

(i) A detailed explanation of how each factor identified and defined in paragraph (c)(2) of this section is used to determine which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the nonquantitative treatment limitation;

(ii) An explanation of the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors or relied upon in designing and applying the nonquantitative treatment limitation, including in the determination of whether and how mental health or substance use disorder benefits or medical/surgical benefits are subject to the nonquantitative treatment limitation;

(iii) If the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designations and qualifications of each decision maker;

(iv) If more than one factor is identified and defined in paragraph (c)(2) of this section, an explanation of:

(A) How all of the factors relate to each other;

(B) The order in which all the factors are applied, including when they are applied;

(C) Whether and how any factors are given more weight than others; and

(D) The reasons for the ordering or weighting of the factors; and

(v) Any deviations or variations from a factor, its applicability, or its definition (including the evidentiary standards used to define the factor and the information or sources from which each evidentiary standard was derived), such as how the factor is used differently to apply the nonquantitative treatment limitation to mental health or substance use disorder benefits as compared to medical/surgical benefits, and a description of how the plan or issuer establishes such deviations or variations.

(4) *Demonstration of comparability and stringency as written.* The comparative analysis must evaluate whether, in any classification, under the terms of the plan (or health insurance coverage) as written, any processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation with respect to medical/surgical benefits. The comparative analysis must include, with respect to the nonquantitative treatment limitation and the factors used in designing and applying the nonquantitative treatment limitation:

(i) Documentation of each factor identified and defined in paragraph (c)(2) of this section that was applied to determine whether the nonquantitative treatment limitation applies to mental health or substance use disorder benefits and medical/surgical benefits in a classification, including, as relevant:

(A) Quantitative data, calculations, or other analyses showing whether, in each classification in which the nonquantitative treatment limitation applies, mental health or substance use disorder benefits and medical/surgical benefits met or did not meet any applicable threshold identified in the relevant evidentiary standard to determine that the nonquantitative treatment limitation would or would not apply; and

(B) Records maintained by the plan or issuer documenting the consideration and application of all factors and evidentiary standards, as well as the results of their application;

(ii) In each classification in which the nonquantitative treatment limitation applies to mental health or substance use disorder benefits, a comparison of how the nonquantitative treatment limitation, as written, is designed and applied to mental health or substance use disorder benefits and to medical/surgical benefits, including the specific provisions of any forms, checklists, procedure manuals, or other documentation used in designing and applying the nonquantitative treatment limitation or that address the application of the nonquantitative treatment limitation;

(iii) Documentation demonstrating how the factors are comparably applied, as written, to mental health or substance use disorder benefits and medical/surgical benefits in each classification, to determine which benefits are subject to the nonquantitative treatment limitation; and

(iv) An explanation of the reasons for any deviations or variations in the application of a factor used to apply the nonquantitative treatment limitation, or the application of the nonquantitative treatment limitation, to mental health or substance use disorder benefits as compared to medical/surgical benefits, and how the plan or issuer establishes such deviations or variations, including:

(A) In the definition of the factors, the evidentiary standards used to define the factors, and the sources from which the evidentiary standards were derived;

(B) In the design of the factors or evidentiary standards; or

(C) In the application or design of the nonquantitative treatment limitation.

(5) *Demonstration of comparability and stringency in operation.* The comparative analysis must evaluate whether, in any classification, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the limitation with respect to medical/surgical benefits. The comparative analysis must include, with respect to the nonquantitative treatment limitation and the factors used in designing and applying the nonquantitative treatment limitation:

(i) A comprehensive explanation of how the plan or issuer evaluates whether, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation with respect to medical/surgical benefits, including:

(A) An explanation of any methodology and underlying data used to demonstrate the application of the nonquantitative treatment limitation, in operation;

(B) The sample period, inputs used in any calculations, definitions of terms used, and any criteria used to select the mental health or substance use disorder benefits and medical/surgical benefits to which the nonquantitative treatment limitation is applicable;

(C) With respect to a nonquantitative treatment limitation for which relevant data is temporarily unavailable as described in § 146.136(c)(4)(iii)(A)(*3*)(*i*), a detailed explanation of the lack of relevant data, the basis for the plan's or issuer's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed; and

(D) With respect to a nonquantitative treatment limitation for which no data exist that can reasonably assess any relevant impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits as described in § 146.136(c)(4)(iii)(A)(*3*)(*ii*), a reasoned justification as to the basis for the conclusion that there are no data that can reasonably assess the nonquantitative treatment limitation's impact, an explanation of why the nature of the nonquantitative treatment limitation prevents the plan or issuer from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure that the nonquantitative treatment limitation complies with § 146.136(c)(4);

(ii) Identification of the relevant data collected and evaluated, as required under § 146.136(c)(4)(iii)(A);

(iii) Documentation of the outcomes that resulted from the application of the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits, including:

(A) The evaluation of relevant data as required under § 146.136(c)(4)(iii)(A); and

(B) A reasoned justification and analysis that explains why the plan or issuer concluded that any differences in the relevant data do or do not suggest the nonquantitative treatment limitation contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits, in accordance with § 146.136(c)(4)(iii)(B)(*2*);

(iv) A detailed explanation of any material differences in access demonstrated by the outcomes evaluated under paragraph (c)(5)(iii) of this section, including:

(A) A reasoned explanation of any material differences in access that are not attributable to differences in the comparability or relative stringency of the nonquantitative treatment limitation as applied to mental health or substance use disorder benefits and medical/surgical benefits (including any considerations beyond a plan's or issuer's control that contribute to the existence of material differences) and a detailed explanation of the bases for concluding that material differences are not attributable to differences in the comparability or relative stringency of the nonquantitative treatment limitation; and

(B) To the extent differences in access to mental health or substance use disorder benefits are attributable to generally recognized independent professional medical or clinical standards or carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits, and such standards or measures are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation, documentation explaining how any such differences are attributable to those standards or measures, as required in § 146.136(c)(4)(iii)(B)(*2*)(*ii*); and

(v) A discussion of the actions that have been or are being taken by the plan or issuer to address any material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits, including the actions the plan or issuer has taken or is taking under § 146.136(c)(4)(iii)(B)(*1*) to address material differences to comply, in operation, with § 146.136(c)(4), including, as applicable:

(A) A reasoned explanation of any material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits that persist despite reasonable actions that have been or are being taken; and

(B) For a plan or issuer designing and applying one or more nonquantitative treatment limitations related to network composition, a discussion of the actions that have been or are being taken to address material differences in access to in-network mental health and substance use disorder

benefits as compared to in-network medical/surgical benefits, including those listed in § 146.136(c)(4)(iii)(C).

(6) *Findings and conclusions.* The comparative analysis must address the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation, and include:

(i) Any findings or conclusions indicating that the plan or coverage is or is not (or might or might not be) in compliance with the requirements of § 146.136(c)(4), including any additional actions the plan or issuer has taken or intends to take to address any potential areas of concern or noncompliance;

(ii) A reasoned and detailed discussion of the findings and conclusions described in paragraph (c)(6)(i) of this section;

(iii) Citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described in paragraph (c)(6)(i) of this section not otherwise discussed in the comparative analysis;

(iv) The date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and

(v) If the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.

(d) *Requirements related to submission of comparative analyses to the Secretary upon request—* (1) *Initial request by the Secretary for comparative analysis.* A group health plan (or health insurance issuer offering coverage in connection with a group health plan) must make the comparative analysis required by paragraph (b) of this section available and submit it to the Secretary within 10 business days of receipt of a request from the Secretary (or an additional period of time specified by the Secretary).

(2) *Additional information required after a comparative analysis is deemed to be insufficient.* In instances in which the Secretary determines that the plan or issuer has not submitted sufficient information under paragraph (d)(1) of this section for the Secretary to determine whether the comparative analysis required in paragraph (b) of this section complies with paragraph (c) of this section or whether the plan or issuer complies with § 146.136(c)(4), the Secretary will specify to the plan or issuer the additional information the plan or issuer must submit to the Secretary to be responsive to the request under paragraph (d)(1). Any such information must be provided to the Secretary by the plan or issuer within 10 business days after the Secretary specifies the additional information to be submitted (or an additional period of time specified by the Secretary).

(3) *Initial determination of noncompliance, required action, and corrective action plan.* In instances in which the Secretary reviewed the comparative analysis submitted under paragraph (d)(1) of this section and any additional information submitted under paragraph (d)(2) of this section, and made an initial determination that the plan or issuer is not in compliance with the requirements of § 146.136(c)(4) or this section, the plan or issuer must respond to the initial determination by the Secretary and specify the actions the plan or issuer will take to bring the plan or coverage into compliance, and provide to the Secretary additional comparative analyses meeting the requirements of paragraph (c) of this section that demonstrate compliance with § 146.136(c)(4), not later than 45 calendar days after the Secretary's initial determination that the plan or issuer is not in compliance.

(4) *Requirement to notify participants and beneficiaries of final determination of noncompliance* —(i) *In general.* If the Secretary makes a final determination of noncompliance, the plan or issuer must notify all participants and beneficiaries enrolled in the plan or coverage that the plan or issuer has been determined to not be in compliance with the requirements of § 146.136(c)(4) or this section with respect to such plan or coverage. Such notice must be provided within 7 business days of receipt of the final determination of noncompliance, and the plan or issuer must provide a copy of the notice to the Secretary, any service provider involved in the claims process, and any fiduciary responsible for deciding benefit claims within the same timeframe.

(ii) *Content of notice.* The notice to participants and beneficiaries required in paragraph (d)(4)(i) of this section shall be written in a manner calculated to be understood by the average plan participant and must include, in plain language, the following information in a standalone notice:

(A) The following statement prominently displayed on the first page, in no less than 14-point font: “Attention! The Department of Health and Human Services has determined that [insert the name of group health plan or health insurance issuer] is not in compliance with the Mental Health Parity and Addiction Equity Act.”;

(B) A summary of changes the plan or issuer has made as part of its corrective action plan specified to the Secretary following the initial determination of noncompliance, including an explanation of any opportunity for a participant or beneficiary to have a claim for benefits submitted or reprocessed;

(C) A summary of the Secretary's final determination that the plan or issuer is not in compliance with § 146.136(c)(4) or this section, including any provisions or practices identified as being in violation of § 146.136(c)(4) or this section, additional corrective actions identified by the Secretary in the final determination notice, and information on how participants and beneficiaries can obtain from the plan or issuer a copy of the final determination of noncompliance;

(D) Any additional actions the plan or issuer is taking to come into compliance with § 146.136(c)(4) or this section, when the plan or issuer will take such actions, and a clear and accurate statement explaining whether the Secretary has concurred with those actions; and

(E) Contact information for questions and complaints, and a statement explaining how participants and beneficiaries can obtain more information about the notice, including:

(*1*) The plan's or issuer's phone number and an email or web portal address; and

(*2*) The Centers for Medicare & Medicaid Services' phone number and email or web portal address.

(iii) *Manner of notice.* The plan or issuer must make the notice required under paragraph (d)(4)(i) of this section available in paper form, or electronically (such as by email or an internet posting) if:

(A) The format is readily accessible;

(B) The notice is provided in paper form free of charge upon request; and

(C) In a case in which the electronic form is an internet posting, the plan or issuer timely notifies the participant or beneficiary in paper form (such as a postcard) or email, that the documents are available on the internet, provides the internet address, includes the statement required in paragraph (d)(4)(ii)(A) of this section, and notifies the participant or beneficiary that the documents are available in paper form upon request.

(e) *Requests for a copy of a comparative analysis.* In addition to making a comparative analysis available upon request to the Secretary, a plan or issuer must make available a copy of the comparative analysis required by paragraph (b) of this section when requested by:

(1) Any applicable State authority; and

(2) A participant or beneficiary (including a provider or other person acting as a participant's or beneficiary's authorized representative) who has received an adverse benefit determination related to mental health or substance use disorder benefits.

(f) *Rule of construction.* Nothing in this section or § 146.136 shall be construed to prevent the Secretary from acting within the scope of existing authorities to address violations of § 146.136 or this section.

(g) *Applicability.* The provisions of this section apply to group health plans and health insurance issuers offering group health insurance coverage described in § 146.136(e), to the extent the plan or issuer is not exempt under § 146.136(f) or (g), on the first day of the first plan year beginning on or after January 1, 2025, except the requirements of paragraphs (c)(2)(ii)(C), (c)(5)(i)(C) and (D), and (c)(5)(ii) through (v) of this section apply on the first day of the first plan year beginning on or after January 1, 2026.

(h) *Severability.* If any provision of this section is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

[89 FR 77747, Sept. 23, 2024]