116TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPT. 116–692
Part 1

STRENGTHENING BEHAVIORAL HEALTH PARITY ACT

DECEMBER 24, 2020.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. PALLONE, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 7539]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 7539) to strengthen parity in mental health and substance use disorder benefits, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Strengthening Behavioral Health Parity Act".

SEC. 2. STRENGTHENING PARITY IN MENTAL HEALTH AND SUBSTANCE USE DISORDER BENEFITS.

(a) PHSA.—

(1) IN GENERAL.—Title XXVII of the Public Health Service Act (42 U.S.C. 300gg–11 et seq.) is amended by adding at the end the following new part:

"PART D—ADDITIONAL COVERAGE PROVISIONS

"SEC. 2799A–1. PARITY IN MENTAL HEALTH AND SUBSTANCE USE DISORDER BENEFITS.

"(a) IN GENERAL.—

"(1) AGGREGATE LIFETIME LIMITS.—In the case of a group health plan or a health insurance issuer offering group or individual health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits—

"(A) NO LIFETIME LIMIT.—If the plan or coverage does not include an aggregate lifetime limit on substantially all medical and surgical benefits, the plan or coverage may not impose any aggregate lifetime limit on mental health or substance use disorder benefits.

"(B) LIFETIME LIMIT.—If the plan or coverage includes an aggregate lifetime limit on substantially all medical and surgical benefits (in this paragraph referred to as the 'applicable lifetime limit'), the plan or coverage shall either—

"(i) apply the applicable lifetime limit both to the medical and surgical benefits to which it otherwise would apply and to mental health and substance use disorder benefits and not distinguish in the application of such limit between such medical and surgical benefits and mental health and substance use disorder benefits; or

"(ii) not include any aggregate lifetime limit on mental health or substance use disorder benefits that is less than the applicable lifetime limit.

"(C) RULE IN CASE OF DIFFERENT LIMITS.—In the case of a plan or coverage that is not described in subparagraph (A) or (B) and that includes no or different aggregate lifetime limits on different categories of medical and surgical benefits, the Secretary shall establish rules under which subparagraph (B) is applied to such plan or coverage with respect to mental health and substance use disorder benefits by substituting for the applicable lifetime limit an average aggregate lifetime limit that is computed taking into account the weighted average of the aggregate lifetime limits applicable to such categories.

"(2) ANNUAL LIMITS.—In the case of a group health plan or a health insurance issuer offering group or individual health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits—

"(A) NO ANNUAL LIMIT.—If the plan or coverage does not include an annual limit on substantially all medical and surgical benefits, the plan or coverage may not impose any annual limit on mental health or substance use disorder benefits.

"(B) ANNUAL LIMIT.—If the plan or coverage includes an annual limit on substantially all medical and surgical benefits (in this paragraph referred to as the 'applicable annual limit'), the plan or coverage shall either—

"(i) apply the applicable annual limit both to medical and surgical benefits to which it otherwise would apply and to mental health and substance use disorder benefits and not distinguish in the application of such limit between such medical and surgical benefits and mental health and substance use disorder benefits; or

"(ii) not include any annual limit on mental health or substance use disorder benefits that is less than the applicable annual limit.

"(C) RULE IN CASE OF DIFFERENT LIMITS.—In the case of a plan or coverage that is not described in subparagraph (A) or (B) and that includes no or different annual limits on different categories of medical and surgical benefits, the Secretary shall establish rules under which subparagraph (B) is applied to such plan or coverage with respect to mental health and substance use disorder benefits by substituting for the applicable annual limit an average annual limit that is computed taking into account the weighted average of the annual limits applicable to such categories.

"(3) FINANCIAL REQUIREMENTS AND TREATMENT LIMITATIONS.—

"(A) IN GENERAL.—In the case of a group health plan or a health insurance issuer offering group or individual health insurance coverage that pro-

vides both medical and surgical benefits and mental health or substance use disorder benefits, such plan or coverage shall ensure that—

"(i) the financial requirements applicable to such mental health or substance use disorder benefits are no more restrictive than the predominant financial requirements applied to substantially all medical and surgical benefits covered by the plan (or coverage), and there are no separate cost sharing requirements that are applicable only with respect to mental health or substance use disorder benefits; and

"(ii) the treatment limitations applicable to such mental health or substance use disorder benefits are no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits covered by the plan (or coverage) and there are no separate treatment limitations that are applicable only with respect to mental health or substance use disorder benefits.

"(B) DEFINITIONS.—In this paragraph:

"(i) FINANCIAL REQUIREMENT.—The term 'financial requirement' includes deductibles, copayments, coinsurance, and out-of-pocket expenses, but excludes an aggregate lifetime limit and an annual limit subject to paragraphs (1) and (2).

"(ii) PREDOMINANT.—A financial requirement or treatment limit is considered to be predominant if it is the most common or frequent of such type of limit or requirement.

"(iii) TREATMENT LIMITATION.—The term 'treatment limitation' includes limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment.

"(4) AVAILABILITY OF PLAN INFORMATION.—The criteria for medical necessity determinations made under the plan with respect to mental health or substance use disorder benefits (or the health insurance coverage offered in connection with the plan with respect to such benefits) shall be made available by the plan administrator (or the health insurance issuer offering such coverage) in accordance with regulations to any current or potential participant, beneficiary, or contracting provider upon request. The reason for any denial under the plan (or coverage) of reimbursement or payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary shall, on request or as otherwise required, be made available by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary in accordance with regulations.

"(5) OUT-OF-NETWORK PROVIDERS.—In the case of a plan or coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits, if the plan or coverage provides coverage for medical or surgical benefits provided by out-of-network providers, the plan or coverage shall provide coverage for mental health or substance use disorder benefits provided by out-of-network providers in a manner that is consistent with the requirements of this section.

"(6) COMPLIANCE PROGRAM GUIDANCE DOCUMENT.—

"(A) IN GENERAL.—Not later than 12 months after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary, the Secretary of Labor, and the Secretary of the Treasury, in consultation with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury, shall issue a compliance program guidance document to help improve compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, and section 9812 of the Internal Revenue Code of 1986, as applicable. In carrying out this paragraph, the Secretaries may take into consideration the 2016 publication of the Department of Health and Human Services and the Department of Labor, entitled 'Warning Signs - Plan or Policy Non-Quantitative Treatment Limitations (NQTLs) that Require Additional Analysis to Determine Mental Health Parity Compliance'.

"(B) EXAMPLES ILLUSTRATING COMPLIANCE AND NONCOMPLIANCE.—

"(i) IN GENERAL.—The compliance program guidance document required under this paragraph shall provide illustrative, de-identified examples (that do not disclose any protected health information or individually identifiable information) of previous findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, based on investigations of violations of such sections, including—

"(I) examples illustrating requirements for information disclosures and nonquantitative treatment limitations; and

"(II) descriptions of the violations uncovered during the course of such investigations.

"(ii) NONQUANTITATIVE TREATMENT LIMITATIONS.—To the extent that any example described in clause (i) involves a finding of compliance or noncompliance with regard to any requirement for nonquantitative treatment limitations, the example shall provide sufficient detail to fully explain such finding, including a full description of the criteria involved for approving medical and surgical benefits and the criteria involved for approving mental health and substance use disorder benefits.

"(iii) ACCESS TO ADDITIONAL INFORMATION REGARDING COMPLIANCE.—In developing and issuing the compliance program guidance document required under this paragraph, the Secretaries specified in subparagraph (A)—

"(I) shall enter into interagency agreements with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury to share findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable; and

"(II) shall seek to enter into an agreement with a State to share information on findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.

"(C) RECOMMENDATIONS.—The compliance program guidance document shall include recommendations to advance compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, and encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements. Such internal controls may include illustrative examples of nonquantitative treatment limitations on mental health and substance use disorder benefits, which may fail to comply with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, in relation to nonquantitative treatment limitations on medical and surgical benefits.

"(D) UPDATING THE COMPLIANCE PROGRAM GUIDANCE DOCUMENT.—The Secretary, the Secretary of Labor, and the Secretary of the Treasury, in consultation with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury, shall update the compliance program guidance document every 2 years to include illustrative, de-identified examples (that do not disclose any protected health information or individually identifiable information) of previous findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.

"(7) ADDITIONAL GUIDANCE.—

"(A) IN GENERAL.—Not later than 12 months after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary, the Secretary of Labor, and the Secretary of the Treasury shall issue guidance to group health plans and health insurance issuers offering group or individual health insurance coverage to assist such plans and issuers in satisfying the requirements of this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.

"(B) DISCLOSURE.—

"(i) GUIDANCE FOR PLANS AND ISSUERS.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods that group health plans and health insurance issuers offering group or individual health insurance coverage may use for disclosing information to ensure compliance with the requirements under this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of

1986, as applicable, (and any regulations promulgated pursuant to such sections, as applicable).

"(ii) DOCUMENTS FOR PARTICIPANTS, BENEFICIARIES, CONTRACTING PROVIDERS, OR AUTHORIZED REPRESENTATIVES.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods that group health plans and health insurance issuers offering group or individual health insurance coverage may use to provide any participant, beneficiary, contracting provider, or authorized representative, as applicable, with documents containing information that the health plans or issuers are required to disclose to participants, beneficiaries, contracting providers, or authorized representatives to ensure compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, compliance with any regulation issued pursuant to such respective section, or compliance with any other applicable law or regulation. Such guidance shall include information that is comparative in nature with respect to—

"(I) nonquantitative treatment limitations for both medical and surgical benefits and mental health and substance use disorder benefits;

"(II) the processes, strategies, evidentiary standards, and other factors used to apply the limitations described in subclause (I); and

"(III) the application of the limitations described in subclause (I) to ensure that such limitations are applied in parity with respect to both medical and surgical benefits and mental health and substance use disorder benefits.

"(C) NONQUANTITATIVE TREATMENT LIMITATIONS.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods, processes, strategies, evidentiary standards, and other factors that group health plans and health insurance issuers offering group or individual health insurance coverage may use regarding the development and application of nonquantitative treatment limitations to ensure compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, (and any regulations promulgated pursuant to such respective section), including—

"(i) examples of methods of determining appropriate types of nonquantitative treatment limitations with respect to both medical and surgical benefits and mental health and substance use disorder benefits, including nonquantitative treatment limitations pertaining to—

"(I) medical management standards based on medical necessity or appropriateness, or whether a treatment is experimental or investigative;

"(II) limitations with respect to prescription drug formulary design; and

"(III) use of fail-first or step therapy protocols;

"(ii) examples of methods of determining—

"(I) network admission standards (such as credentialing); and

"(II) factors used in provider reimbursement methodologies (such as service type, geographic market, demand for services, and provider supply, practice size, training, experience, and licensure) as such factors apply to network adequacy;

"(iii) examples of sources of information that may serve as evidentiary standards for the purposes of making determinations regarding the development and application of nonquantitative treatment limitations;

"(iv) examples of specific factors, and the evidentiary standards used to evaluate such factors, used by such plans or issuers in performing a nonquantitative treatment limitation analysis;

"(v) examples of how specific evidentiary standards may be used to determine whether treatments are considered experimental or investigative;

"(vi) examples of how specific evidentiary standards may be applied to each service category or classification of benefits;

"(vii) examples of methods of reaching appropriate coverage determinations for new mental health or substance use disorder treatments, such as evidence-based early intervention programs for individuals with a serious mental illness and types of medical management techniques;

"(viii) examples of methods of reaching appropriate coverage determinations for which there is an indirect relationship between the covered mental health or substance use disorder benefit and a traditional covered medical and surgical benefit, such as residential treatment or hospitalizations involving voluntary or involuntary commitment; and

"(ix) additional illustrative examples of methods, processes, strategies, evidentiary standards, and other factors for which the Secretary determines that additional guidance is necessary to improve compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.

"(D) PUBLIC COMMENT.—Prior to issuing any final guidance under this paragraph, the Secretary shall provide a public comment period of not less than 60 days during which any member of the public may provide comments on a draft of the guidance.

"(8) COMPLIANCE REQUIREMENTS.—

"(A) NONQUANTITATIVE TREATMENT LIMITATION (NQTL) REQUIREMENTS.—In the case of a group health plan or a health insurance issuer offering group or individual health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits and that imposes nonquantitative treatment limitations (referred to in this section as 'NQTL') on mental health or substance use disorder benefits, the plan or issuer offering health insurance coverage shall perform comparative analyses of the design and application of NQTLs in accordance with subparagraph (B), and, beginning 45 days after the date of enactment of this paragraph, make available to the applicable State authority (or, as applicable, the Secretary), upon request, the comparative analyses and the following information:

"(i) The specific plan or coverage terms regarding the NQTL, that applies to such plan or coverage, and a description of all mental health or substance use disorder and medical or surgical benefits to which it applies in each respective benefits classification.

"(ii) The factors used to determine that the NQTL 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 NQTL 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 design the NQTL, as written, and the operation processes and strategies as written and in operation that are used to apply the NQTL for mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to design the NQTL, as written, and the operation processes and strategies as written and in operation that are used to apply the NQTL to medical or surgical benefits.

"(v) A disclosure of the specific findings and conclusions reached by the plan or coverage that the results of the analyses described in this subparagraph indicate that the plan or coverage is in compliance with this section.

"(B) SECRETARY REQUEST PROCESS.—

"(i) SUBMISSION UPON REQUEST.—The Secretary shall request that a group health plan or a health insurance issuer offering group or individual health insurance coverage submit the comparative analyses described in subparagraph (A) for plans that involve potential violations of this section or complaints regarding noncompliance with this section that concern NQTLs and any other instances in which the Secretary determines appropriate. The Secretary shall request not fewer than 20 such analyses per year.

"(ii) ADDITIONAL INFORMATION.—In instances in which the Secretary has concluded that the plan or coverage has not submitted sufficient information for the Secretary to review the comparative analyses described in subparagraph (A), as requested under clause (i), the Secretary shall specify to the plan or coverage the information the plan or coverage must submit to be responsive to the request under clause (i) for the Secretary to review the comparative analyses described in sub-

paragraph(A) for compliance with this section. Nothing in this paragraph shall require the Secretary to conclude that a plan is in compliance with this section solely based upon the inspection of the comparative analyses described in subparagraph (A), as requested under clause (i).

"(iii) REQUIRED ACTION.—

"(I) IN GENERAL.—In instances in which the Secretary has reviewed the comparative analyses described in subparagraph (A), as requested under clause (i), and determined that the plan or coverage is not in compliance with this section, the plan or coverage—

"(aa) shall specify to the Secretary the actions the plan or coverage will take to be in compliance with this section and provide to the Secretary comparative analyses described in subparagraph (A) that demonstrate compliance with this section not later than 45 days after the initial determination by the Secretary that the plan or coverage is not in compliance; and

"(bb) following the 45-day corrective action period under item (aa), if the Secretary determines that the plan or coverage still is not in compliance with this section, not later than 7 days after such determination, shall notify all individuals enrolled in the plan or coverage that the plan or coverage has been determined to be not in compliance with this section.

"(II) EXEMPTION FROM DISCLOSURE.—Documents or communications produced in connection with the Secretary's recommendations to the plan or coverage shall not be subject to disclosure pursuant to section 552 of title 5, United States Code.

"(iv) REPORT.—Not later than 1 year after the date of enactment of this paragraph, and not later than October 1 of each year thereafter, the Secretary shall submit to Congress, and make publicly available, a report that contains—

"(I) a summary of the comparative analyses requested under clause (i), including the identity of each plan or coverage that is determined to be not in compliance after the final determination by the Secretary described in clause (iii)(I)(bb);

"(II) the Secretary's conclusions as to whether each plan or coverage submitted sufficient information for the Secretary to review the comparative analyses requested under clause (i) for compliance with this section;

"(III) for each plan or coverage that did submit sufficient information for the Secretary to review the comparative analyses requested under clause (i), the Secretary's conclusions as to whether and why the plan or coverage is in compliance with the requirements under this section;

"(IV) the Secretary's specifications described in clause (ii) for each plan or coverage that the Secretary determined did not submit sufficient information for the Secretary to review the comparative analyses requested under clause (i) for compliance with this section; and

"(V) the Secretary's specifications described in clause (iii) of the actions each plan or coverage that the Secretary determined is not in compliance with this section must take to be in compliance with this section, including the reason why the Secretary determined the plan or coverage is not in compliance.

"(C) COMPLIANCE PROGRAM GUIDANCE DOCUMENT UPDATE PROCESS.—

"(i) IN GENERAL.—The Secretary shall include instances of noncompliance that the Secretary discovers upon reviewing the comparative analyses requested under subparagraph (B)(i) in the compliance program guidance document described in paragraph (6), as it is updated every 2 years, except that such instances shall not disclose any protected health information or individually identifiable information.

"(ii) GUIDANCE AND REGULATIONS.—Not later than 18 months after the date of enactment of this paragraph, the Secretary shall finalize any draft or interim guidance and regulations relating to mental health parity under this section. Such draft guidance shall include guidance to clarify the process and timeline for current and potential participants and beneficiaries (and authorized representatives and health care providers of such participants and beneficiaries) with respect to plans to file complaints of such plans or issuers being in violation of this sec-

tion, including guidance, by plan type, on the relevant State, regional, or national office with which such complaints should be filed.

"(iii) STATE.—The Secretary shall share information on findings of compliance and noncompliance discovered upon reviewing the comparative analyses requested under subparagraph (B)(i) with the State where the group health plan is located or the State where the health insurance issuer is licensed to do business for coverage offered by a health insurance issuer in the group market, in accordance with paragraph (6)(B)(iii)(II).

"(b) CONSTRUCTION.—Nothing in this section shall be construed—

"(1) as requiring a group health plan or a health insurance issuer offering group or individual health insurance coverage to provide any mental health or substance use disorder benefits; or

"(2) in the case of a group health plan or a health insurance issuer offering group or individual health insurance coverage that provides mental health or substance use disorder benefits, as affecting the terms and conditions of the plan or coverage relating to such benefits under the plan or coverage, except as provided in subsection (a).

"(c) EXEMPTIONS.—

"(1) SMALL EMPLOYER EXEMPTION.—This section shall not apply to any group health plan and a health insurance issuer offering group or individual health insurance coverage for any plan year of a small employer (as defined in section 2791(e)(4), except that for purposes of this paragraph such term shall include employers with 1 employee in the case of an employer residing in a State that permits small groups to include a single individual).

"(2) COST EXEMPTION.—

"(A) IN GENERAL.—With respect to a group health plan or a health insurance issuer offering group or individual health insurance coverage, if the application of this section to such plan (or coverage) results in an increase for the plan year involved of the actual total costs of coverage with respect to medical and surgical benefits and mental health and substance use disorder benefits under the plan (as determined and certified under subparagraph (C)) by an amount that exceeds the applicable percentage described in subparagraph (B) of the actual total plan costs, the provisions of this section shall not apply to such plan (or coverage) during the following plan year, and such exemption shall apply to the plan (or coverage) for 1 plan year. An employer may elect to continue to apply mental health and substance use disorder parity pursuant to this section with respect to the group health plan (or coverage) involved regardless of any increase in total costs.

"(B) APPLICABLE PERCENTAGE.—With respect to a plan (or coverage), the applicable percentage described in this subparagraph shall be—

"(i) 2 percent in the case of the first plan year in which this section is applied; and

"(ii) 1 percent in the case of each subsequent plan year.

"(C) DETERMINATIONS BY ACTUARIES.—Determinations as to increases in actual costs under a plan (or coverage) for purposes of this section shall be made and certified by a qualified and licensed actuary who is a member in good standing of the American Academy of Actuaries. All such determinations shall be in a written report prepared by the actuary. The report, and all underlying documentation relied upon by the actuary, shall be maintained by the group health plan or health insurance issuer for a period of 6 years following the notification made under subparagraph (E).

"(D) 6-MONTH DETERMINATIONS.—If a group health plan (or a health insurance issuer offering coverage in connection with a group health plan) seeks an exemption under this paragraph, determinations under subparagraph (A) shall be made after such plan (or coverage) has complied with this section for the first 6 months of the plan year involved.

"(E) NOTIFICATION.—

"(i) IN GENERAL.—A group health plan (or a health insurance issuer offering coverage in connection with a group health plan) that, based upon a certification described under subparagraph (C), qualifies for an exemption under this paragraph, and elects to implement the exemption, shall promptly notify the Secretary, the appropriate State agencies, and participants and beneficiaries in the plan of such election.

"(ii) REQUIREMENT.—A notification to the Secretary under clause (i) shall include—

"(I) a description of the number of covered lives under the plan (or coverage) involved at the time of the notification, and as appli-

cable, at the time of any prior election of the cost-exemption under this paragraph by such plan (or coverage);

"(II) for both the plan year upon which a cost exemption is sought and the year prior, a description of the actual total costs of coverage with respect to medical and surgical benefits and mental health and substance use disorder benefits under the plan; and

"(III) for both the plan year upon which a cost exemption is sought and the year prior, the actual total costs of coverage with respect to mental health and substance use disorder benefits under the plan.

"(iii) CONFIDENTIALITY.—A notification to the Secretary under clause (i) shall be confidential. The Secretary shall make available, upon request and on not more than an annual basis, an anonymous itemization of such notifications, that includes—

"(I) a breakdown of States by the size and type of employers submitting such notification; and

"(II) a summary of the data received under clause (ii).

"(F) AUDITS BY APPROPRIATE AGENCIES.—To determine compliance with this paragraph, the Secretary may audit the books and records of a group health plan or health insurance issuer relating to an exemption, including any actuarial reports prepared pursuant to subparagraph (C), during the 6 year period following the notification of such exemption under subparagraph (E). A State agency receiving a notification under subparagraph (E) may also conduct such an audit with respect to an exemption covered by such notification.

"(d) SEPARATE APPLICATION TO EACH OPTION OFFERED.—In the case of a group health plan that offers a participant or beneficiary two or more benefit package options under the plan, the requirements of this section shall be applied separately with respect to each such option.

"(e) DEFINITIONS.—For purposes of this section—

"(1) AGGREGATE LIFETIME LIMIT.—The term 'aggregate lifetime limit' means, with respect to benefits under a group health plan or health insurance coverage, a dollar limitation on the total amount that may be paid with respect to such benefits under the plan or health insurance coverage with respect to an individual or other coverage unit.

"(2) ANNUAL LIMIT.—The term 'annual limit' means, with respect to benefits under a group health plan or health insurance coverage, a dollar limitation on the total amount of benefits that may be paid with respect to such benefits in a 12-month period under the plan or health insurance coverage with respect to an individual or other coverage unit.

"(3) MEDICAL OR SURGICAL BENEFITS.—The term 'medical or surgical benefits' means benefits with respect to medical or surgical services, as defined under the terms of the plan or coverage (as the case may be), but does not include mental health or substance use disorder benefits.

"(4) MENTAL HEALTH BENEFITS.—The term 'mental health benefits' means benefits with respect to services for mental health conditions, as defined under the terms of the plan and in accordance with applicable Federal and State law.

"(5) SUBSTANCE USE DISORDER BENEFITS.—The term 'substance use disorder benefits' means benefits with respect to services for substance use disorders, as defined under the terms of the plan and in accordance with applicable Federal and State law.".

(2) SUNSET.—Section 2726 of the Public Health Service Act (42 U.S.C. 300gg–26) is amended by adding at the end the following new subsection

"(f) SUNSET.—The provisions of this section shall have no force or effect after the date of the enactment of the Strengthening Behavioral Health Parity Act.".

(3) ADMINISTRATION; CONFORMING AMENDMENTS.—

(A) APPLICATION OF IMPLEMENTATION REGULATIONS.—The provisions of sections 146.136 and 147.160 of title 45, Code of Federal Regulations shall apply to section 2799A–1 of the Public Health Service Act, as added by paragraph (1), in the same manner as such provisions applied to section 2726 of the Public Health Service Act (42 U.S.C. 300gg–26) before the date of the enactment of this Act.

(B) CONFORMING AMENDMENTS.—

(i) Section 2722 of the Public Health Service Act (42 U.S.C. 300gg–21) is amended—

(I) in subsection (a)(1), by inserting "and part D" after "subparts 1 and 2";

(II) in subsection (b), by inserting "and part D" after "subparts 1 and 2";

(III) in subsection (c)(1), by inserting "and part D" after "subparts 1 and 2";

(IV) in subsection (c)(2), by inserting "and part D" after "subparts 1 and 2";

(V) in subsection (c)(3), by inserting "and part D" after "this part"; and

(VI) in subsection (d), in the matter preceding paragraph (1), by inserting "and part D" after "this part".

(ii) Section 2723 of the Public Health Service Act (42 U.S.C. 300gg–22) is amended—

(I) in subsection (a)(1), by inserting "and part D" after "this part";

(II) in subsection (a)(2), by inserting "or part D" after "this part";

(III) in subsection (b)(1), by inserting "or part D" after "this part";

(IV) in subsection (b)(2)(A), by inserting "or part D" after "this part"; and

(V) in subsection (b)(2)(C)(ii), by inserting "and part D" after "this part".

(iii) Section 2724 of the Public Health Service Act (42 U.S.C. 300gg–23) is amended—

(I) in subsection (a)(1)—

(aa) by striking "this part and part C insofar as it relates to this part" and inserting "this part, part D, and part C insofar as it relates to this part or part D"; and

(bb) by inserting "or part D" after "requirement of this part";

(II) in subsection (a)(2), by inserting "or part D" after "this part"; and

(III) in subsection (c), by inserting "or part D" after "this part (other than section 2704)".

(b) ERISA.—Section 712(a) of the Employee Retirement Income Security Act of 1974 (1185a(a)) is amended by adding at the end the following new paragraphs:

"(6) COMPLIANCE PROGRAM GUIDANCE DOCUMENT.—

"(A) IN GENERAL.—Not later than 12 months after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury, in consultation with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury, shall issue a compliance program guidance document to help improve compliance with this section, section 2799A–1 of the Public Health Service Act, and section 9812 of the Internal Revenue Code of 1986, as applicable. In carrying out this paragraph, the Secretaries may take into consideration the 2016 publication of the Department of Health and Human Services and the Department of Labor, entitled 'Warning Signs - Plan or Policy Non-Quantitative Treatment Limitations (NQTLs) that Require Additional Analysis to Determine Mental Health Parity Compliance'.

"(B) EXAMPLES ILLUSTRATING COMPLIANCE AND NONCOMPLIANCE.—

"(i) IN GENERAL.—The compliance program guidance document required under this paragraph shall provide illustrative, de-identified examples (that do not disclose any protected health information or individually identifiable information) of previous findings of compliance and noncompliance with this section, section 2799A–1 of the Public Health Service Act, or section 9812 of the Internal Revenue Code of 1986, as applicable, based on investigations of violations of such sections, including—

"(I) examples illustrating requirements for information disclosures and nonquantitative treatment limitations; and

"(II) descriptions of the violations uncovered during the course of such investigations.

"(ii) NONQUANTITATIVE TREATMENT LIMITATIONS.—To the extent that any example described in clause (i) involves a finding of compliance or noncompliance with regard to any requirement for nonquantitative treatment limitations, the example shall provide sufficient detail to fully explain such finding, including a full description of the criteria involved for approving medical and surgical benefits and the criteria involved for approving mental health and substance use disorder benefits.

"(iii) ACCESS TO ADDITIONAL INFORMATION REGARDING COMPLIANCE.—In developing and issuing the compliance program guidance document required under this paragraph, the Secretaries specified in subparagraph (A)—

"(I) shall enter into interagency agreements with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury to share findings of compliance and noncompliance with this section, section 2799A–1 of the Public Health Service Act, or section 9812 of the Internal Revenue Code of 1986, as applicable; and

"(II) shall seek to enter into an agreement with a State to share information on findings of compliance and noncompliance with this section, section 2799A–1 of the Public Health Service Act, or section 9812 of the Internal Revenue Code of 1986, as applicable.

"(C) RECOMMENDATIONS.—The compliance program guidance document shall include recommendations to advance compliance with this section, section 2799A–1 of the Public Health Service Act, or section 9812 of the Internal Revenue Code of 1986, as applicable, and encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements. Such internal controls may include illustrative examples of nonquantitative treatment limitations on mental health and substance use disorder benefits, which may fail to comply with this section, section 2799A–1 of the Public Health Service Act, or section 9812 of the Internal Revenue Code of 1986, as applicable, in relation to nonquantitative treatment limitations on medical and surgical benefits.

"(D) UPDATING THE COMPLIANCE PROGRAM GUIDANCE DOCUMENT.—The Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury, in consultation with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury, shall update the compliance program guidance document every 2 years to include illustrative, de-identified examples (that do not disclose any protected health information or individually identifiable information) of previous findings of compliance and noncompliance with this section, section 2799A–1 of the Public Health Service Act, or section 9812 of the Internal Revenue Code of 1986, as applicable.

"(7) ADDITIONAL GUIDANCE.—

"(A) IN GENERAL.—Not later than 12 months after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury shall issue guidance to group health plans and health insurance issuers offering group or individual health insurance coverage to assist such plans and issuers in satisfying the requirements of this section, section 2799A–1 of the Public Health Service Act, or section 9812 of the Internal Revenue Code of 1986, as applicable.

"(B) DISCLOSURE.—

"(i) GUIDANCE FOR PLANS AND ISSUERS.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods that group health plans and health insurance issuers offering group or individual health insurance coverage may use for disclosing information to ensure compliance with the requirements under this section, section 2799A–1 of the Public Health Service Act, or section 9812 of the Internal Revenue Code of 1986, as applicable, (and any regulations promulgated pursuant to such sections, as applicable).

"(ii) DOCUMENTS FOR PARTICIPANTS, BENEFICIARIES, CONTRACTING PROVIDERS, OR AUTHORIZED REPRESENTATIVES.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods that group health plans and health insurance issuers offering group or individual health insurance coverage may use to provide any participant, beneficiary, contracting provider, or authorized representative, as applicable, with documents containing information that the health plans or issuers are required to disclose to participants, beneficiaries, contracting providers, or authorized representatives to ensure compliance with this section, section 2799A–1 of the Public Health Service Act, or section 9812 of the Internal Revenue Code of 1986, as applicable, compliance with any regulation issued pursuant to such respective section, or compliance with any other applica-

ble law or regulation. Such guidance shall include information that is comparative in nature with respect to—

"(I) nonquantitative treatment limitations for both medical and surgical benefits and mental health and substance use disorder benefits;

"(II) the processes, strategies, evidentiary standards, and other factors used to apply the limitations described in subclause (I); and

"(III) the application of the limitations described in subclause (I) to ensure that such limitations are applied in parity with respect to both medical and surgical benefits and mental health and substance use disorder benefits.

"(C) NONQUANTITATIVE TREATMENT LIMITATIONS.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods, processes, strategies, evidentiary standards, and other factors that group health plans and health insurance issuers offering group or individual health insurance coverage may use regarding the development and application of nonquantitative treatment limitations to ensure compliance with this section, section 2799A–1 of the Public Health Service Act, or section 9812 of the Internal Revenue Code of 1986, as applicable, (and any regulations promulgated pursuant to such respective section), including—

"(i) examples of methods of determining appropriate types of nonquantitative treatment limitations with respect to both medical and surgical benefits and mental health and substance use disorder benefits, including nonquantitative treatment limitations pertaining to—

"(I) medical management standards based on medical necessity or appropriateness, or whether a treatment is experimental or investigative;

"(II) limitations with respect to prescription drug formulary design; and

"(III) use of fail-first or step therapy protocols;

"(ii) examples of methods of determining—

"(I) network admission standards (such as credentialing); and

"(II) factors used in provider reimbursement methodologies (such as service type, geographic market, demand for services, and provider supply, practice size, training, experience, and licensure) as such factors apply to network adequacy;

"(iii) examples of sources of information that may serve as evidentiary standards for the purposes of making determinations regarding the development and application of nonquantitative treatment limitations;

"(iv) examples of specific factors, and the evidentiary standards used to evaluate such factors, used by such plans or issuers in performing a nonquantitative treatment limitation analysis;

"(v) examples of how specific evidentiary standards may be used to determine whether treatments are considered experimental or investigative;

"(vi) examples of how specific evidentiary standards may be applied to each service category or classification of benefits;

"(vii) examples of methods of reaching appropriate coverage determinations for new mental health or substance use disorder treatments, such as evidence-based early intervention programs for individuals with a serious mental illness and types of medical management techniques;

"(viii) examples of methods of reaching appropriate coverage determinations for which there is an indirect relationship between the covered mental health or substance use disorder benefit and a traditional covered medical and surgical benefit, such as residential treatment or hospitalizations involving voluntary or involuntary commitment; and

"(ix) additional illustrative examples of methods, processes, strategies, evidentiary standards, and other factors for which the Secretary determines that additional guidance is necessary to improve compliance with this section, section 2799A–1 of the Public Health Service Act, or section 9812 of the Internal Revenue Code of 1986, as applicable.

"(D) PUBLIC COMMENT.—Prior to issuing any final guidance under this paragraph, the Secretary shall provide a public comment period of not less than 60 days during which any member of the public may provide comments on a draft of the guidance.

"(8) COMPLIANCE REQUIREMENTS.—

"(A) NONQUANTITATIVE TREATMENT LIMITATION (NQTL) REQUIREMENTS.—Beginning 45 days after the date of enactment of this paragraph, in the case of a group health plan or a health insurance issuer offering group health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits and that imposes nonquantitative treatment limitations (referred to in this section as 'NQTL') on mental health or substance use disorder benefits, the plan or issuer offering health insurance coverage shall perform comparative analyses of the design and application of NQTLs in accordance with subparagraph (B), and make available to the applicable State authority (or, as applicable, the Secretary), upon request, the following information:

"(i) The specific plan or coverage terms regarding the NQTL, that applies to such plan or coverage, and a description of all mental health or substance use disorder and medical or surgical benefits to which it applies in each respective benefits classification.

"(ii) The factors used to determine that the NQTL 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 NQTL 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 design the NQTL, as written, and the operation processes and strategies as written and in operation that are used to apply the NQTL for mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to design the NQTL, as written, and the operation processes and strategies as written and in operation that are used to apply the NQTL to medical or surgical benefits.

"(v) A disclosure of the specific findings and conclusions reached by the plan or coverage that the results of the analyses described in this subparagraph indicate that the plan or coverage is in compliance with this section.

"(B) SECRETARY REQUEST PROCESS.—

"(i) SUBMISSION UPON REQUEST.—The Secretary shall request that a group health plan or a health insurance issuer offering group health insurance coverage submit the comparative analyses described in subparagraph (A) for plans that involve potential violations of this section or complaints regarding noncompliance with this section that concern NQTLs and any other instances in which the Secretary determines appropriate. The Secretary shall request not fewer than 20 such analyses per year.

"(ii) ADDITIONAL INFORMATION.—In instances in which the Secretary has concluded that the plan or coverage has not submitted sufficient information for the Secretary to review the comparative analyses described in subparagraph (A), as requested under clause (i), the Secretary shall specify to the plan or coverage the information the plan or coverage must submit to be responsive to the request under clause (i) for the Secretary to review the comparative analyses described in subparagraph(A) for compliance with this section. Nothing in this paragraph shall require the Secretary to conclude that a plan is in compliance with this section solely based upon the inspection of the comparative analyses described in subparagraph (A), as requested under clause (i).

"(iii) REQUIRED ACTION.—

"(I) IN GENERAL.—In instances in which the Secretary has reviewed the comparative analyses described in subparagraph (A), as requested under clause (i), and determined that the plan or coverage is not in compliance with this section, the plan or coverage—

"(aa) shall specify to the Secretary the actions the plan or coverage will take to be in compliance with this section and provide to the Secretary comparative analyses described in subparagraph (A) that demonstrate compliance with this section not later than 45 days after the initial determination by the Secretary that the plan or coverage is not in compliance; and

"(bb) following the 45-day corrective action period under item (aa), if the Secretary determines that the plan or coverage still is not in compliance with this section, not later than 7 days after such determination, shall notify all individuals enrolled in the plan or coverage that the plan or coverage has been determined to be not in compliance with this section.

"(II) EXEMPTION FROM DISCLOSURE.—Documents or communications produced in connection with the Secretary's recommendations to the plan or coverage shall not be subject to disclosure pursuant to section 552 of title 5, United States Code.

"(iv) REPORT.—Not later than 1 year after the date of enactment of this paragraph, and not later than October 1 of each year thereafter, the Secretary shall submit to Congress, and make publicly available, a report that contains—

"(I) a summary of the comparative analyses requested under clause (i), including the identity of each plan or coverage that is determined to be not in compliance after the final determination by the Secretary described in clause (iii)(I)(bb);

"(II) the Secretary's conclusions as to whether each plan or coverage submitted sufficient information for the Secretary to review the comparative analyses requested under clause (i) for compliance with this section;

"(III) for each plan or coverage that did submit sufficient information for the Secretary to review the comparative analyses requested under clause (i), the Secretary's conclusions as to whether and why the plan or coverage is in compliance with the requirements under this section;

"(IV) the Secretary's specifications described in clause (ii) for each plan or coverage that the Secretary determined did not submit sufficient information for the Secretary to review the comparative analyses requested under clause (i) for compliance with this section; and

"(V) the Secretary's specifications described in clause (iii) of the actions each plan or coverage that the Secretary determined is not in compliance with this section must take to be in compliance with this section, including the reason why the Secretary determined the plan or coverage is not in compliance.

"(C) COMPLIANCE PROGRAM GUIDANCE DOCUMENT UPDATE PROCESS.—

"(i) IN GENERAL.—The Secretary shall include instances of noncompliance that the Secretary discovers upon reviewing the comparative analyses requested under subparagraph (B)(i) in the compliance program guidance document described in paragraph (6), as it is updated every 2 years, except that such instances shall not disclose any protected health information or individually identifiable information.

"(ii) GUIDANCE AND REGULATIONS.—Not later than 18 months after the date of enactment of this paragraph, the Secretary shall finalize any draft or interim guidance and regulations relating to mental health parity under this section. Such draft guidance shall include guidance to clarify the process and timeline for current and potential participants and beneficiaries (and authorized representatives and health care providers of such participants and beneficiaries) with respect to plans to file complaints of such plans or issuers being in violation of this section, including guidance, by plan type, on the relevant State, regional, or national office with which such complaints should be filed.

"(iii) STATE.—The Secretary shall share information on findings of compliance and noncompliance discovered upon reviewing the comparative analyses requested under subparagraph (B)(i) with the State where the group health plan is located or the State where the health insurance issuer is licensed to do business for coverage offered by a health insurance issuer in the group market, in accordance with paragraph (6)(B)(iii)(II).".

(c) IRC.—Section 9812 of the Internal Revenue Code of 1986 is amended by adding at the end the following new paragraphs:

"(6) COMPLIANCE PROGRAM GUIDANCE DOCUMENT.—

"(A) IN GENERAL.—Not later than 12 months after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary, the Secretary of Labor, and the Secretary of Health and Human Services, in consultation with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of

Labor, and the Inspector General of the Department of the Treasury, shall issue a compliance program guidance document to help improve compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, and section 2799A–1 of the Public Health Service Act, as applicable. In carrying out this paragraph, the Secretaries may take into consideration the 2016 publication of the Department of Health and Human Services and the Department of Labor, entitled 'Warning Signs - Plan or Policy Non-Quantitative Treatment Limitations (NQTLs) that Require Additional Analysis to Determine Mental Health Parity Compliance'.

"(B) EXAMPLES ILLUSTRATING COMPLIANCE AND NONCOMPLIANCE.—

"(i) IN GENERAL.—The compliance program guidance document required under this paragraph shall provide illustrative, de-identified examples (that do not disclose any protected health information or individually identifiable information) of previous findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 2799A–1 of the Public Health Service Act, as applicable, based on investigations of violations of such sections, including—

"(I) examples illustrating requirements for information disclosures and nonquantitative treatment limitations; and

"(II) descriptions of the violations uncovered during the course of such investigations.

"(ii) NONQUANTITATIVE TREATMENT LIMITATIONS.—To the extent that any example described in clause (i) involves a finding of compliance or noncompliance with regard to any requirement for nonquantitative treatment limitations, the example shall provide sufficient detail to fully explain such finding, including a full description of the criteria involved for approving medical and surgical benefits and the criteria involved for approving mental health and substance use disorder benefits.

"(iii) ACCESS TO ADDITIONAL INFORMATION REGARDING COMPLIANCE.—In developing and issuing the compliance program guidance document required under this paragraph, the Secretaries specified in subparagraph (A)—

"(I) shall enter into interagency agreements with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury to share findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 2799A–1 of the Public Health Service Act, as applicable; and

"(II) shall seek to enter into an agreement with a State to share information on findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 2799A–1 of the Public Health Service Act, as applicable.

"(C) RECOMMENDATIONS.—The compliance program guidance document shall include recommendations to advance compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 2799A–1 of the Public Health Service Act, as applicable, and encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements. Such internal controls may include illustrative examples of nonquantitative treatment limitations on mental health and substance use disorder benefits, which may fail to comply with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 2799A–1 of the Public Health Service Act, as applicable, in relation to nonquantitative treatment limitations on medical and surgical benefits.

"(D) UPDATING THE COMPLIANCE PROGRAM GUIDANCE DOCUMENT.—The Secretary, the Secretary of Labor, and the Secretary of Health and Human Services, in consultation with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury, shall update the compliance program guidance document every 2 years to include illustrative, de-identified examples (that do not disclose any protected health information or individually identifiable information) of previous findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 2799A–1 of the Public Health Service Act, as applicable.

"(7) ADDITIONAL GUIDANCE.—

"(A) IN GENERAL.—Not later than 12 months after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary, the Secretary of Labor, and the Secretary of Health and Human Services shall issue guidance to group health plans and health insurance issuers offering group or individual health insurance coverage to assist such plans and issuers in satisfying the requirements of this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 2799A–1 of the Public Health Service Act, as applicable.

"(B) DISCLOSURE.—

"(i) GUIDANCE FOR PLANS AND ISSUERS.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods that group health plans and health insurance issuers offering group or individual health insurance coverage may use for disclosing information to ensure compliance with the requirements under this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 2799A–1 of the Public Health Service Act, (and any regulations promulgated pursuant to such sections, as applicable).

"(ii) DOCUMENTS FOR PARTICIPANTS, BENEFICIARIES, CONTRACTING PROVIDERS, OR AUTHORIZED REPRESENTATIVES.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods that group health plans and health insurance issuers offering group or individual health insurance coverage may use to provide any participant, beneficiary, contracting provider, or authorized representative, as applicable, with documents containing information that the health plans or issuers are required to disclose to participants, beneficiaries, contracting providers, or authorized representatives to ensure compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 2799A–1 of the Public Health Service Act, as applicable, compliance with any regulation issued pursuant to such respective section, or compliance with any other applicable law or regulation. Such guidance shall include information that is comparative in nature with respect to—

"(I) nonquantitative treatment limitations for both medical and surgical benefits and mental health and substance use disorder benefits;

"(II) the processes, strategies, evidentiary standards, and other factors used to apply the limitations described in subclause (I); and

"(III) the application of the limitations described in subclause (I) to ensure that such limitations are applied in parity with respect to both medical and surgical benefits and mental health and substance use disorder benefits.

"(C) NONQUANTITATIVE TREATMENT LIMITATIONS.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods, processes, strategies, evidentiary standards, and other factors that group health plans and health insurance issuers offering group or individual health insurance coverage may use regarding the development and application of nonquantitative treatment limitations to ensure compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 2799A–1 of the Public Health Service Act, as applicable, (and any regulations promulgated pursuant to such respective section), including—

"(i) examples of methods of determining appropriate types of nonquantitative treatment limitations with respect to both medical and surgical benefits and mental health and substance use disorder benefits, including nonquantitative treatment limitations pertaining to—

"(I) medical management standards based on medical necessity or appropriateness, or whether a treatment is experimental or investigative;

"(II) limitations with respect to prescription drug formulary design; and

"(III) use of fail-first or step therapy protocols;

"(ii) examples of methods of determining—

"(I) network admission standards (such as credentialing); and

"(II) factors used in provider reimbursement methodologies (such as service type, geographic market, demand for services, and provider supply, practice size, training, experience, and licensure) as such factors apply to network adequacy;

"(iii) examples of sources of information that may serve as evidentiary standards for the purposes of making determinations regarding the development and application of nonquantitative treatment limitations;

"(iv) examples of specific factors, and the evidentiary standards used to evaluate such factors, used by such plans or issuers in performing a nonquantitative treatment limitation analysis;

"(v) examples of how specific evidentiary standards may be used to determine whether treatments are considered experimental or investigative;

"(vi) examples of how specific evidentiary standards may be applied to each service category or classification of benefits;

"(vii) examples of methods of reaching appropriate coverage determinations for new mental health or substance use disorder treatments, such as evidence-based early intervention programs for individuals with a serious mental illness and types of medical management techniques;

"(viii) examples of methods of reaching appropriate coverage determinations for which there is an indirect relationship between the covered mental health or substance use disorder benefit and a traditional covered medical and surgical benefit, such as residential treatment or hospitalizations involving voluntary or involuntary commitment; and

"(ix) additional illustrative examples of methods, processes, strategies, evidentiary standards, and other factors for which the Secretary determines that additional guidance is necessary to improve compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 2799A–1 of the Public Health Service Act, as applicable.

"(D) PUBLIC COMMENT.—Prior to issuing any final guidance under this paragraph, the Secretary shall provide a public comment period of not less than 60 days during which any member of the public may provide comments on a draft of the guidance.

"(8) COMPLIANCE REQUIREMENTS.—

"(A) NONQUANTITATIVE TREATMENT LIMITATION (NQTL) REQUIREMENTS.—Beginning 45 days after the date of enactment of this paragraph, in the case of a group health plan that provides both medical and surgical benefits and mental health or substance use disorder benefits and that imposes nonquantitative treatment limitations (referred to in this section as 'NQTL') on mental health or substance use disorder benefits, the plan shall perform comparative analyses of the design and application of NQTLs in accordance with subparagraph (B), and make available to the applicable State authority (or, as applicable, the Secretary), upon request, the following information:

"(i) The specific plan terms regarding the NQTL, that applies to such plan or coverage, and a description of all mental health or substance use disorder and medical or surgical benefits to which it applies in each respective benefits classification.

"(ii) The factors used to determine that the NQTL 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 NQTL 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 design the NQTL, as written, and the operation processes and strategies as written and in operation that are used to apply the NQTL for mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to design the NQTL, as written, and the operation processes and strategies as written and in operation that are used to apply the NQTL to medical or surgical benefits.

"(v) A disclosure of the specific findings and conclusions reached by the plan that the results of the analyses described in this subparagraph indicate that the plan is in compliance with this section.

"(B) SECRETARY REQUEST PROCESS.—

"(i) SUBMISSION UPON REQUEST.—The Secretary shall request that a group health plan submit the comparative analyses described in subparagraph (A) for plans that involve potential violations of this section or complaints regarding noncompliance with this section that concern NQTLs and any other instances in which the Secretary determines appropriate. The Secretary shall request not fewer than 20 such analyses per year.

"(ii) ADDITIONAL INFORMATION.—In instances in which the Secretary has concluded that the plan has not submitted sufficient information for the Secretary to review the comparative analyses described in subparagraph (A), as requested under clause (i), the Secretary shall specify to the plan the information the plan or coverage must submit to be responsive to the request under clause (i) for the Secretary to review the comparative analyses described in subparagraph(A) for compliance with this section. Nothing in this paragraph shall require the Secretary to conclude that a plan is in compliance with this section solely based upon the inspection of the comparative analyses described in subparagraph (A), as requested under clause (i).

"(iii) REQUIRED ACTION.—

"(I) IN GENERAL.—In instances in which the Secretary has reviewed the comparative analyses described in subparagraph (A), as requested under clause (i), and determined that the plan is not in compliance with this section, the plan—

"(aa) shall specify to the Secretary the actions the plan will take to be in compliance with this section and provide to the Secretary comparative analyses described in subparagraph (A) that demonstrate compliance with this section not later than 45 days after the initial determination by the Secretary that the plan is not in compliance; and

"(bb) following the 45-day corrective action period under item (aa), if the Secretary determines that the plan still is not in compliance with this section, not later than 7 days after such determination, shall notify all individuals enrolled in the plan or coverage that the plan has been determined to be not in compliance with this section.

"(II) EXEMPTION FROM DISCLOSURE.—Documents or communications produced in connection with the Secretary's recommendations to the plan or coverage shall not be subject to disclosure pursuant to section 552 of title 5, United States Code.

"(iv) REPORT.—Not later than 1 year after the date of enactment of this paragraph, and not later than October 1 of each year thereafter, the Secretary shall submit to Congress, and make publicly available, a report that contains—

"(I) a summary of the comparative analyses requested under clause (i), including the identity of each plan that is determined to be not in compliance after the final determination by the Secretary described in clause (iii)(I)(bb);

"(II) the Secretary's conclusions as to whether each plan submitted sufficient information for the Secretary to review the comparative analyses requested under clause (i) for compliance with this section;

"(III) for each plan that did submit sufficient information for the Secretary to review the comparative analyses requested under clause (i), the Secretary's conclusions as to whether and why the plan or coverage is in compliance with the requirements under this section;

"(IV) the Secretary's specifications described in clause (ii) for each plan that the Secretary determined did not submit sufficient information for the Secretary to review the comparative analyses requested under clause (i) for compliance with this section; and

"(V) the Secretary's specifications described in clause (iii) of the actions each plan hat the Secretary determined is not in compliance with this section must take to be in compliance with this section, including the reason why the Secretary determined the plan or coverage is not in compliance.

"(C) COMPLIANCE PROGRAM GUIDANCE DOCUMENT UPDATE PROCESS.—

"(i) IN GENERAL.—The Secretary shall include instances of noncompliance that the Secretary discovers upon reviewing the comparative analyses requested under subparagraph (B)(i) in the compliance program

guidance document described in paragraph (6), as it is updated every 2 years, except that such instances shall not disclose any protected health information or individually identifiable information.

"(ii) GUIDANCE AND REGULATIONS.—Not later than 18 months after the date of enactment of this paragraph, the Secretary shall finalize any draft or interim guidance and regulations relating to mental health parity under this section. Such draft guidance shall include guidance to clarify the process and timeline for current and potential participants and beneficiaries (and authorized representatives and health care providers of such participants and beneficiaries) with respect to plans to file complaints of such plans or issuers being in violation of this section, including guidance, by plan type, on the relevant State, regional, or national office with which such complaints should be filed.

"(iii) STATE.—The Secretary shall share information on findings of compliance and noncompliance discovered upon reviewing the comparative analyses requested under subparagraph (B)(i) with the State where the group health plan is located or the State where the health insurance issuer is licensed to do business for coverage offered by a health insurance issuer in the group market, in accordance with paragraph (6)(B)(iii)(II).".

(d) IMPLEMENTATION.—The Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury may implement the paragraph (8) of section 2799A–1(a) of the Public Health Service Act, added by subsection (a), the paragraph (8) of section 712(a) of the Employee Retirement Income Security Act of 1974, as addedby subsection (b), and the paragraph (8) of section 9812(a) of the Internal Revenue Code of 1986, as added by subsection (c), by program instruction, guidance, or otherwise.

I. PURPOSE AND SUMMARY

H.R. 7539, the "Strengthening Behavioral Parity Act" was introduced by Representative Joseph P. Kennedy III (D–MA), Katie Porter (D–CA), Gus M. Bilirakis (R–FL), and Fred Upton (R–MI) and referred to the Committee on Energy and Commerce.

The goal of H.R. 7539 is to help improve and strengthen enforcement of existing mental health parity laws. The legislation would increase transparency with respect to how health insurance plans are applying mental health parity laws by requiring plans to make available certain analyses of how they are applying non-quantitative treatment limits (NQTLs) to mental health and substance use disorder benefits, in comparison to medical and surgical benefits. The bill would also require Federal regulators to request no fewer than 20 comparative analyses per year, including for health plans where there have been potential violations or complaints regarding noncompliance with mental health parity standards.

II. BACKGROUND AND NEED FOR LEGISLATION

The Mental Health Parity Act of 1996 (MHPA) prevented large group health plans from imposing annual or lifetime dollar limits on mental health benefits that are less favorable than such limits imposed on medical and surgical benefits. In 2008, Congress passed the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), which requires parity between mental health or substance use disorder benefits, and medical and surgical benefits. MHPAEA prohibits coverage requirements for mental health and substance disorder benefits from being more restrictive than those for medical and surgical benefits, and prevents health insurance plans that provide mental health or substance use disorder benefits from imposing less favorable financial requirements and treatment limitations on those benefits than on medical and surgical benefits. The Affordable Care Act (ACA)

amended MHPAEA and applied the mental health parity provisions to individual market plans, including qualified health plans offered through the ACA Marketplaces.

The MHPAEA provided important protections for millions of individuals enrolled in private insurance coverage. Many challenges, however, remain. A Government Accountability Office (GAO) report found that the extent of compliance with parity requirements is unknown.[1] The same report also concluded that the complexity of assessing NQTLs makes it difficult for regulators to identify instances of non-compliance. The report found, however, that in 11 of the 14 States surveyed, noncompliance with parity standards was related to NQTLs half the time or more.[2] Similarly, the Department of Labor reported that 55 percent of noncompliance was related to NQTLs in fiscal year 2018.[3] Greater transparency and standardization of NQTLs will help regulators more easily identify instances of noncompliance and will aid in enforcement of parity laws.

Between 2010 and 2018, Federal regulators conducted 1,700 investigations in connection with MHPAEA, and found more than 300 violations that involved mental health and substance use disorder benefits.[4] Federal regulators lack the statutory authority, however, to actively enforce MHPAEA directly against insurers by requiring them to correct noncompliant health insurance policies that are sold by insurers to numerous employers in the group health market.[5]

H.R. 7539 would help improve and strengthen enforcement of existing mental health parity laws. The bill would increase transparency with respect to how health insurance plans are applying mental health parity laws, by requiring health plans to make available certain analyses of how plans are applying NQTLs to mental health and substance use disorder benefits, in comparison to medical and surgical benefits. The legislation would require Federal regulators to request comparative analyses for health plans that have been involved in potential violations or complaints regarding noncompliance with mental health parity standards, and to request no fewer than 20 comparative analyses per year. For health plans that are found to be out of compliance with mental health parity laws, the bill would require plans to take corrective action to come into compliance, or notify all individuals enrolled in noncompliant plans of plan's violations.

III. COMMITTEE HEARINGS

For the purposes of section 103(i) of H. Res. 6 of the 116th Congress, the following hearing was used to develop or consider H.R. 7539:

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[1] U.S. Government Accountability Office, *Mental Health and Substance Use, State and Federal Oversight of Compliance with Parity Requirements Vary* (2019) (www.gao.gov/assets/710/703239.pdf)

[2] *Id.*

[3] *Id.*

[4] U.S. Department of Labor, *Report to Congress, Pathway to Full Parity* (2018) U.S. Department of Labor, *Report to Congress, Pathway to Full Parity* (2018) (www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/dol-report-to-congress-2018-pathway-to-full-parity.pdf).

[5] *Id.*

On June 30, 2020, the Subcommittee on Health held a hearing on a number of bills to address behavioral health treatment and access, including H.R. 2874 and H.R. 3165, entitled "High Anxiety and Stress: Legislation to Improve Mental Health During Crisis." H.R. 2874 and H.R. 3165 covered the topics of the provisions in H.R. 7539. The Subcommittee received testimony from:

- The Honorable Patrick J. Kennedy, Founder, The Kennedy Forum, and former Member of Congress
- Dr. Arthur C. Evans, Jr., Chief Executive Officer, American Psychological Association
- Dr. Jeffrey L. Geller, President, American Psychiatric Association
- Arriana Gross, National Youth Advisory Board Member, Sandy Hook Promise Students Against Violence Everywhere (SAVE) Promise Club.

IV. Committee Consideration

H.R. 7539 was introduced on July 9, 2020, by Representatives Kennedy, Porter, Bilirakis, and Upton and referred to the Committee on Energy and Commerce. The bill was subsequently referred to the Subcommittee on Health on July 10, 2020.

On July 15, 2020, H.R. 7539 was discharged from the Subcommittee on Health as the bill was called up by the full Committee. The Committee on Energy and Commerce met in virtual open markup session, pursuant to notice, on July 15, 2020, to consider H.R. 7539. During the bill's consideration, a manager's amendment offered by Mr. Kennedy was agreed to by a voice vote. The Committee then agreed to a motion on final passage offered by Mr. Pallone, Chairman of the committee, to order H.R. 7539 reported favorably to the House, amended, by a voice vote, a quorum being present.

V. Committee Votes

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list each record vote on the motion to report legislation and amendments thereto. The Committee advises that there were no record votes taken on H.R.7539, including on the motion by Mr. Pallone ordering H.R. 7539 favorably reported to the House, amended.

VI. Oversight Findings

Pursuant to clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the oversight findings and recommendations of the Committee are reflected in the descriptive portion of the report.

VII. New Budget Authority, Entitlement Authority, and Tax Expenditures

Pursuant to 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the estimate of new budget authority, entitlement authority, or tax expenditures or revenues contained in the cost estimate prepared by the Director of

the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

The Committee has requested but not received from the Director of the Congressional Budget Office a statement as to whether this bill contains any new budget authority, spending authority, credit authority, or an increase or decrease in revenues or tax expenditures.

VIII. Federal Mandates Statement

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

IX. EXCHANGE OF LETTERS

December 22, 2020

The Honorable Frank Pallone, Jr.
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Pallone:

I write concerning H.R. 7539, the *Strengthening Behavioral Health Parity Act*. This bill was primarily referred to the Committee on Energy and Commerce and additionally to the Committee on Ways and Means and the Committee on Education and Labor. As a result of Leadership and the Committee on Energy and Commerce having consulted with me concerning this bill generally, I agree to forgo formal consideration of the bill so the bill may proceed expeditiously to the House floor.

The Committee on Education and Labor takes this action with our mutual understanding that by forgoing formal consideration of H.R. 7539, we do not waive any jurisdiction over the subject matter contained in this or similar legislation, and we will be appropriately consulted and involved as the bill or similar legislation moves forward so we may address any remaining issues within our Rule X jurisdiction.

Specifically, I appreciate you having worked with me on making changes to the text of the bill as it moved with H.R. 2, the *Moving Forward Act* this Congress.

I also request that you support my request to name members of the Committee on Education and Labor to any conference committee to consider such provisions.

Finally, I would appreciate a response confirming this understanding and ask that a copy of our exchange of letters on this matter be included in the committee report for H.R. 7539 and in the *Congressional Record* during floor consideration thereof.

Sincerely,

Robert C. "Bobby" Scott
Chairman

cc: The Honorable Virginia Foxx, Ranking Member, Committee on Education and Labor
The Honorable Greg Walden, Ranking Member, Committee on Energy and Commerce
The Honorable Nancy Pelosi, Speaker
The Honorable Steny Hoyer, Majority Leader
The Honorable Jason Smith, Parliamentarian

FRANK PALLONE, JR., NEW JERSEY
CHAIRMAN

GREG WALDEN, OREGON
RANKING MEMBER

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927

December 23, 2020

The Honorable Robert C. "Bobby" Scott
Chairman
Committee on Education and Labor
2176 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Scott:

I write concerning H.R. 7539, the "Strengthening Behavioral Health Parity Act," which was additionally referred to the Committee on Energy and Commerce (Committee).

In recognition of the desire to expedite consideration of H.R. 7539, the Committee agrees to waive formal consideration of the bill as to provisions that fall within the Rule X jurisdiction of the Committee. The Committee takes this action with the mutual understanding that we do not waive any jurisdiction over the subject matter contained in this or similar legislation, and that the Committee will be appropriately consulted and involved as this bill or similar legislation moves forward so that we may address any remaining issues within our jurisdiction. I also request that you support my request to name members of the Committee to any conference committee to consider such provisions.

Finally, I would appreciate the inclusion of this letter in the committee report on H.R. 7539 and into the *Congressional Record* during floor consideration of the measure.

Sincerely,

Frank Pallone, Jr.
Chairman

cc: The Honorable Nancy Pelosi, Speaker
The Honorable Steny Hoyer, Majority Leader
The Honorable Greg Walden, Ranking Member, Committee on Energy and Commerce
The Honorable Virginia Foxx, Ranking Member, Committee on Education and Labor
The Honorable Jason Smith, Parliamentarian, U.S. House of Representatives

X. Statement of General Performance Goals and Objectives

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to help improve and strengthen enforcement of existing mental health parity laws. The bill would increase transparency with respect to how health insurance plans are applying mental health parity laws by requiring plans to make available certain analyses of how plans are applying non-quantitative treatment limits (NQTLs) to mental health and substance use disorder benefits, in comparison to medical and surgical benefits.

XI. Duplication of Federal Programs

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 7539 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111–139 or the most recent Catalog of Federal Domestic Assistance.

XII. Committee Cost Estimate

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

XIII. Earmarks, Limited Tax Benefits, and Limited Tariff Benefits

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 7539 contains no earmarks, limited tax benefits, or limited tariff benefits.

XIV. Advisory Committee Statement

No advisory committee within the meaning of section 5(b) of the Federal Advisory Committee Act was created by this legislation.

XV. Applicability to Legislative Branch

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

XVI. Section-by-Section Analysis of the Legislation

Section 1. Short title

Section 1 designates that the short title may be cited as the "Strengthening Behavioral Parity Act".

Sec. 2. Strengthening parity in mental health and substance use disorder benefits

Section 2 amends title XXVII of the Public Health Service Act (PHSA) by inserting the following new part.

Part D—Additional Coverage Provisions

Sec. 2799A–1. Parity in mental health and substance use disorder benefits

Section 2799A–1 sunsets section 2726 of the PHSA that contains the Federal mental health parity requirements, and reestablishes those requirements under the new part D, section 2799A–1. By sunsetting section 2726 of the PHSA, the section does not make any substantive policy changes to amend the law, and the Federal mental health parity requirements are still in effect. The section merely reestablishes the mental health parity requirements under the new part D.

Section 2799A–1 establishes new requirement on health insurance plans with respect to how health insurance plans are applying existing mental health parity laws. The section requires health plans to make available comparative analyses of how health plans are applying NQTLs to mental health and substance use disorder benefits, in comparison to medical and surgical benefits, and to make available the analyses to State and Federal regulators upon request. The section would require the Secretary of Health and Human Services (HHS) to request no fewer than 20 comparative analyses per year, including for health plans that involve potential violations or complaints regarding noncompliance with mental health parity standards.

For health plans that are found to be out of compliance with mental health parity laws, the section would require the Secretary to specify corrective action for the plan to come into compliance, which the plan will have 45 days to implement. If the plan is still not in compliance after those 45 days, the section would require the plan to notify all individuals enrolled in noncompliant plans within 7 days.

The section would require the Secretary of HHS to publish and submit to Congress an annual report that includes a summary of the comparative analyses, the Secretary's conclusions as to whether each plan submitted sufficient information for the Secretary to review the comparative analyses, the Secretary's conclusions as to whether and why the plan is in compliance with the mental health parity requirements, and the identity of each plan that is determined to be out of compliance after the final determination. Lastly, the section requires the Secretary to include instances of noncompliance in the compliance program document that is updated every two years.

Section 2 also amends section 712 of the Employee Retirement Security Act of 1974 and section 9812 of the Internal Revenue Code of 1986, and establishes the same new requirement on group health insurance plans with respect to how group health plans are applying existing mental health parity laws.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, and existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

TITLE XXVII—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

PART A—INDIVIDUAL AND GROUP MARKET REFORMS

* * * * * * *

Subpart II—Improving Coverage

* * * * * * *

SEC. 2726. PARITY IN MENTAL HEALTH AND SUBSTANCE USE DISORDER BENEFITS.

(a) IN GENERAL.—

(1) AGGREGATE LIFETIME LIMITS.—In the case of a group health plan or a health insurance issuer offering group or individual health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits—

(A) NO LIFETIME LIMIT.—If the plan or coverage does not include an aggregate lifetime limit on substantially all medical and surgical benefits, the plan or coverage may not impose any aggregate lifetime limit on mental health or substance use disorder benefits.

(B) LIFETIME LIMIT.—If the plan or coverage includes an aggregate lifetime limit on substantially all medical and surgical benefits (in this paragraph referred to as the "applicable lifetime limit"), the plan or coverage shall either—

(i) apply the applicable lifetime limit both to the medical and surgical benefits to which it otherwise would apply and to mental health and substance use disorder benefits and not distinguish in the application of such limit between such medical and surgical benefits and mental health and substance use disorder benefits; or

(ii) not include any aggregate lifetime limit on mental health or substance use disorder benefits that is less than the applicable lifetime limit.

(C) RULE IN CASE OF DIFFERENT LIMITS.—In the case of a plan or coverage that is not described in subparagraph (A) or (B) and that includes no or different aggregate lifetime limits on different categories of medical and surgical benefits, the Secretary shall establish rules under which subparagraph (B) is applied to such plan or coverage with respect to mental health and substance use disorder benefits by substituting for the applicable lifetime limit an average aggregate lifetime limit that is computed taking into account the weighted average of the aggregate lifetime limits applicable to such categories.

(2) ANNUAL LIMITS.—In the case of a group health plan or a health insurance issuer offering group or individual health in-

surance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits—

(A) NO ANNUAL LIMIT.—If the plan or coverage does not include an annual limit on substantially all medical and surgical benefits, the plan or coverage may not impose any annual limit on mental health or substance use disorder benefits.

(B) ANNUAL LIMIT.—If the plan or coverage includes an annual limit on substantially all medical and surgical benefits (in this paragraph referred to as the "applicable annual limit"), the plan or coverage shall either—

(i) apply the applicable annual limit both to medical and surgical benefits to which it otherwise would apply and to mental health and substance use disorder benefits and not distinguish in the application of such limit between such medical and surgical benefits and mental health and substance use disorder benefits; or

(ii) not include any annual limit on mental health or substance use disorder benefits that is less than the applicable annual limit.

(C) RULE IN CASE OF DIFFERENT LIMITS.—In the case of a plan or coverage that is not described in subparagraph (A) or (B) and that includes no or different annual limits on different categories of medical and surgical benefits, the Secretary shall establish rules under which subparagraph (B) is applied to such plan or coverage with respect to mental health and substance use disorder benefits by substituting for the applicable annual limit an average annual limit that is computed taking into account the weighted average of the annual limits applicable to such categories.

(3) FINANCIAL REQUIREMENTS AND TREATMENT LIMITATIONS.—

(A) IN GENERAL.—In the case of a group health plan or a health insurance issuer offering group or individual health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits, such plan or coverage shall ensure that—

(i) the financial requirements applicable to such mental health or substance use disorder benefits are no more restrictive than the predominant financial requirements applied to substantially all medical and surgical benefits covered by the plan (or coverage), and there are no separate cost sharing requirements that are applicable only with respect to mental health or substance use disorder benefits; and

(ii) the treatment limitations applicable to such mental health or substance use disorder benefits are no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits covered by the plan (or coverage) and there are no separate treatment limitations that are applicable only with respect to mental health or substance use disorder benefits.

(B) DEFINITIONS.—In this paragraph:

(i) FINANCIAL REQUIREMENT.—The term "financial requirement" includes deductibles, copayments, coinsurance, and out-of-pocket expenses, but excludes an aggregate lifetime limit and an annual limit subject to paragraphs (1) and (2).

(ii) PREDOMINANT.—A financial requirement or treatment limit is considered to be predominant if it is the most common or frequent of such type of limit or requirement.

(iii) TREATMENT LIMITATION.—The term "treatment limitation" includes limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment.

(4) AVAILABILITY OF PLAN INFORMATION.—The criteria for medical necessity determinations made under the plan with respect to mental health or substance use disorder benefits (or the health insurance coverage offered in connection with the plan with respect to such benefits) shall be made available by the plan administrator (or the health insurance issuer offering such coverage) in accordance with regulations to any current or potential participant, beneficiary, or contracting provider upon request. The reason for any denial under the plan (or coverage) of reimbursement or payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary shall, on request or as otherwise required, be made available by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary in accordance with regulations.

(5) OUT-OF-NETWORK PROVIDERS.—In the case of a plan or coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits, if the plan or coverage provides coverage for medical or surgical benefits provided by out-of-network providers, the plan or coverage shall provide coverage for mental health or substance use disorder benefits provided by out-of-network providers in a manner that is consistent with the requirements of this section.

(6) COMPLIANCE PROGRAM GUIDANCE DOCUMENT.—

(A) IN GENERAL.—Not later than 12 months after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary, the Secretary of Labor, and the Secretary of the Treasury, in consultation with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury, shall issue a compliance program guidance document to help improve compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, and section 9812 of the Internal Revenue Code of 1986, as applicable. In carrying out this paragraph, the Secretaries may take into consideration the 2016 publication of the Department of Health and Human Services and the Department of Labor, entitled "Warning Signs - Plan or Policy Non-Quantitative Treatment Limitations (NQTLs) that Require Additional Analysis to Determine Mental Health Parity Compliance".

(B) EXAMPLES ILLUSTRATING COMPLIANCE AND NONCOMPLIANCE.—

(i) IN GENERAL.—The compliance program guidance document required under this paragraph shall provide illustrative, de-identified examples (that do not disclose any protected health information or individually identifiable information) of previous findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, based on investigations of violations of such sections, including—

(I) examples illustrating requirements for information disclosures and nonquantitative treatment limitations; and

(II) descriptions of the violations uncovered during the course of such investigations.

(ii) NONQUANTITATIVE TREATMENT LIMITATIONS.—To the extent that any example described in clause (i) involves a finding of compliance or noncompliance with regard to any requirement for nonquantitative treatment limitations, the example shall provide sufficient detail to fully explain such finding, including a full description of the criteria involved for approving medical and surgical benefits and the criteria involved for approving mental health and substance use disorder benefits.

(iii) ACCESS TO ADDITIONAL INFORMATION REGARDING COMPLIANCE.—In developing and issuing the compliance program guidance document required under this paragraph, the Secretaries specified in subparagraph (A)—

(I) shall enter into interagency agreements with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury to share findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable; and

(II) shall seek to enter into an agreement with a State to share information on findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.

(C) RECOMMENDATIONS.—The compliance program guidance document shall include recommendations to advance compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, and encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and

program requirements. Such internal controls may include illustrative examples of nonquantitative treatment limitations on mental health and substance use disorder benefits, which may fail to comply with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, in relation to nonquantitative treatment limitations on medical and surgical benefits.

(D) UPDATING THE COMPLIANCE PROGRAM GUIDANCE DOCUMENT.—The Secretary, the Secretary of Labor, and the Secretary of the Treasury, in consultation with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury, shall update the compliance program guidance document every 2 years to include illustrative, de-identified examples (that do not disclose any protected health information or individually identifiable information) of previous findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.

(7) ADDITIONAL GUIDANCE.—

(A) IN GENERAL.—Not later than 12 months after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary, the Secretary of Labor, and the Secretary of the Treasury shall issue guidance to group health plans and health insurance issuers offering group or individual health insurance coverage to assist such plans and issuers in satisfying the requirements of this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.

(B) DISCLOSURE.—

(i) GUIDANCE FOR PLANS AND ISSUERS.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods that group health plans and health insurance issuers offering group or individual health insurance coverage may use for disclosing information to ensure compliance with the requirements under this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, (and any regulations promulgated pursuant to such sections, as applicable).

(ii) DOCUMENTS FOR PARTICIPANTS, BENEFICIARIES, CONTRACTING PROVIDERS, OR AUTHORIZED REPRESENTATIVES.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods that group health plans and health insurance issuers offering group or individual health insurance coverage may use to provide any participant, beneficiary, contracting provider, or authorized representative, as applicable, with documents containing information that the health plans or issuers

are required to disclose to participants, beneficiaries, contracting providers, or authorized representatives to ensure compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, compliance with any regulation issued pursuant to such respective section, or compliance with any other applicable law or regulation. Such guidance shall include information that is comparative in nature with respect to—

(I) nonquantitative treatment limitations for both medical and surgical benefits and mental health and substance use disorder benefits;

(II) the processes, strategies, evidentiary standards, and other factors used to apply the limitations described in subclause (I); and

(III) the application of the limitations described in subclause (I) to ensure that such limitations are applied in parity with respect to both medical and surgical benefits and mental health and substance use disorder benefits.

(C) NONQUANTITATIVE TREATMENT LIMITATIONS.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods, processes, strategies, evidentiary standards, and other factors that group health plans and health insurance issuers offering group or individual health insurance coverage may use regarding the development and application of nonquantitative treatment limitations to ensure compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, (and any regulations promulgated pursuant to such respective section), including—

(i) examples of methods of determining appropriate types of nonquantitative treatment limitations with respect to both medical and surgical benefits and mental health and substance use disorder benefits, including nonquantitative treatment limitations pertaining to—

(I) medical management standards based on medical necessity or appropriateness, or whether a treatment is experimental or investigative;

(II) limitations with respect to prescription drug formulary design; and

(III) use of fail-first or step therapy protocols;

(ii) examples of methods of determining—

(I) network admission standards (such as credentialing); and

(II) factors used in provider reimbursement methodologies (such as service type, geographic market, demand for services, and provider supply, practice size, training, experience, and licensure) as such factors apply to network adequacy;

(iii) examples of sources of information that may serve as evidentiary standards for the purposes of making determinations regarding the development and application of nonquantitative treatment limitations;

(iv) examples of specific factors, and the evidentiary standards used to evaluate such factors, used by such plans or issuers in performing a nonquantitative treatment limitation analysis;

(v) examples of how specific evidentiary standards may be used to determine whether treatments are considered experimental or investigative;

(vi) examples of how specific evidentiary standards may be applied to each service category or classification of benefits;

(vii) examples of methods of reaching appropriate coverage determinations for new mental health or substance use disorder treatments, such as evidence-based early intervention programs for individuals with a serious mental illness and types of medical management techniques;

(viii) examples of methods of reaching appropriate coverage determinations for which there is an indirect relationship between the covered mental health or substance use disorder benefit and a traditional covered medical and surgical benefit, such as residential treatment or hospitalizations involving voluntary or involuntary commitment; and

(ix) additional illustrative examples of methods, processes, strategies, evidentiary standards, and other factors for which the Secretary determines that additional guidance is necessary to improve compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.

(D) PUBLIC COMMENT.—Prior to issuing any final guidance under this paragraph, the Secretary shall provide a public comment period of not less than 60 days during which any member of the public may provide comments on a draft of the guidance.

(b) CONSTRUCTION.—Nothing in this section shall be construed—

(1) as requiring a group health plan or a health insurance issuer offering group or individual health insurance coverage to provide any mental health or substance use disorder benefits; or

(2) in the case of a group health plan or a health insurance issuer offering group or individual health insurance coverage that provides mental health or substance use disorder benefits, as affecting the terms and conditions of the plan or coverage relating to such benefits under the plan or coverage, except as provided in subsection (a).

(c) EXEMPTIONS.—

(1) SMALL EMPLOYER EXEMPTION.—This section shall not apply to any group health plan and a health insurance issuer

offering group or individual health insurance coverage for any plan year of a small employer (as defined in section 2791(e)(4), except that for purposes of this paragraph such term shall include employers with 1 employee in the case of an employer residing in a State that permits small groups to include a single individual).

(2) COST EXEMPTION.—

(A) IN GENERAL.—With respect to a group health plan or a health insurance issuer offering group or individual health insurance coverage, if the application of this section to such plan (or coverage) results in an increase for the plan year involved of the actual total costs of coverage with respect to medical and surgical benefits and mental health and substance use disorder benefits under the plan (as determined and certified under subparagraph (C)) by an amount that exceeds the applicable percentage described in subparagraph (B) of the actual total plan costs, the provisions of this section shall not apply to such plan (or coverage) during the following plan year, and such exemption shall apply to the plan (or coverage) for 1 plan year. An employer may elect to continue to apply mental health and substance use disorder parity pursuant to this section with respect to the group health plan (or coverage) involved regardless of any increase in total costs.

(B) APPLICABLE PERCENTAGE.—With respect to a plan (or coverage), the applicable percentage described in this subparagraph shall be—

(i) 2 percent in the case of the first plan year in which this section is applied; and

(ii) 1 percent in the case of each subsequent plan year.

(C) DETERMINATIONS BY ACTUARIES.—Determinations as to increases in actual costs under a plan (or coverage) for purposes of this section shall be made and certified by a qualified and licensed actuary who is a member in good standing of the American Academy of Actuaries. All such determinations shall be in a written report prepared by the actuary. The report, and all underlying documentation relied upon by the actuary, shall be maintained by the group health plan or health insurance issuer for a period of 6 years following the notification made under subparagraph (E).

(D) 6-MONTH DETERMINATIONS.—If a group health plan (or a health insurance issuer offering coverage in connection with a group health plan) seeks an exemption under this paragraph, determinations under subparagraph (A) shall be made after such plan (or coverage) has complied with this section for the first 6 months of the plan year involved.

(E) NOTIFICATION.—

(i) IN GENERAL.—A group health plan (or a health insurance issuer offering coverage in connection with a group health plan) that, based upon a certification described under subparagraph (C), qualifies for an exemption under this paragraph, and elects to imple-

ment the exemption, shall promptly notify the Secretary, the appropriate State agencies, and participants and beneficiaries in the plan of such election.

(ii) REQUIREMENT.—A notification to the Secretary under clause (i) shall include—

(I) a description of the number of covered lives under the plan (or coverage) involved at the time of the notification, and as applicable, at the time of any prior election of the cost-exemption under this paragraph by such plan (or coverage);

(II) for both the plan year upon which a cost exemption is sought and the year prior, a description of the actual total costs of coverage with respect to medical and surgical benefits and mental health and substance use disorder benefits under the plan; and

(III) for both the plan year upon which a cost exemption is sought and the year prior, the actual total costs of coverage with respect to mental health and substance use disorder benefits under the plan.

(iii) CONFIDENTIALITY.—A notification to the Secretary under clause (i) shall be confidential. The Secretary shall make available, upon request and on not more than an annual basis, an anonymous itemization of such notifications, that includes—

(I) a breakdown of States by the size and type of employers submitting such notification; and

(II) a summary of the data received under clause (ii).

(F) AUDITS BY APPROPRIATE AGENCIES.—To determine compliance with this paragraph, the Secretary may audit the books and records of a group health plan or health insurance issuer relating to an exemption, including any actuarial reports prepared pursuant to subparagraph (C), during the 6 year period following the notification of such exemption under subparagraph (E). A State agency receiving a notification under subparagraph (E) may also conduct such an audit with respect to an exemption covered by such notification.

(d) SEPARATE APPLICATION TO EACH OPTION OFFERED.—In the case of a group health plan that offers a participant or beneficiary two or more benefit package options under the plan, the requirements of this section shall be applied separately with respect to each such option.

(e) DEFINITIONS.—For purposes of this section—

(1) AGGREGATE LIFETIME LIMIT.—The term "aggregate lifetime limit" means, with respect to benefits under a group health plan or health insurance coverage, a dollar limitation on the total amount that may be paid with respect to such benefits under the plan or health insurance coverage with respect to an individual or other coverage unit.

(2) ANNUAL LIMIT.—The term "annual limit" means, with respect to benefits under a group health plan or health insurance coverage, a dollar limitation on the total amount of

benefits that may be paid with respect to such benefits in a 12-month period under the plan or health insurance coverage with respect to an individual or other coverage unit.

(3) MEDICAL OR SURGICAL BENEFITS.—The term "medical or surgical benefits" means benefits with respect to medical or surgical services, as defined under the terms of the plan or coverage (as the case may be), but does not include mental health or substance use disorder benefits.

(4) MENTAL HEALTH BENEFITS.—The term "mental health benefits" means benefits with respect to services for mental health conditions, as defined under the terms of the plan and in accordance with applicable Federal and State law.

(5) SUBSTANCE USE DISORDER BENEFITS.—The term "substance use disorder benefits" means benefits with respect to services for substance use disorders, as defined under the terms of the plan and in accordance with applicable Federal and State law.

(f) SUNSET.—The provisions of this section shall have no force or effect after the date of the enactment of the Strengthening Behavioral Health Parity Act.

* * * * * * *

Subpart 2—Exclusion of Plans; Enforcement; Preemption

SEC. 2722. EXCLUSION OF CERTAIN PLANS.

(a) LIMITATION ON APPLICATION OF PROVISIONS RELATING TO GROUP HEALTH PLANS.—

(1) IN GENERAL.—The requirements of subparts 1 and 2 *and part D* shall apply with respect to group health plans only—

(A) subject to paragraph (2), in the case of a plan that is a nonfederal governmental plan, and

(B) with respect to health insurance coverage offered in connection with a group health plan (including such a plan that is a church plan or a governmental plan).

(2) TREATMENT OF NONFEDERAL GOVERNMENTAL PLANS.—

(A) ELECTION TO BE EXCLUDED.—Except as provided in subparagraph (D) or (E), if the plan sponsor of a nonfederal governmental plan which is a group health plan to which the provisions of subparts 1 and 2 otherwise apply makes an election under this subparagraph (in such form and manner as the Secretary may by regulations prescribe), then the requirements of such subparts insofar as they apply directly to group health plans (and not merely to group health insurance coverage) shall not apply to such governmental plans for such period except as provided in this paragraph.

(B) PERIOD OF ELECTION.—An election under subparagraph (A) shall apply—

(i) for a single specified plan year, or

(ii) in the case of a plan provided pursuant to a collective bargaining agreement, for the term of such agreement.

An election under clause (i) may be extended through subsequent elections under this paragraph.

(C) NOTICE TO ENROLLEES.—Under such an election, the plan shall provide for—

(i) notice to enrollees (on an annual basis and at the time of enrollment under the plan) of the fact and consequences of such election, and

(ii) certification and disclosure of creditable coverage under the plan with respect to enrollees in accordance with section 2701(e).

(D) ELECTION NOT APPLICABLE TO REQUIREMENTS CONCERNING GENETIC INFORMATION.—The election described in subparagraph (A) shall not be available with respect to the provisions of subsections (a)(1)(F), (b)(3), (c), and (d) of section 2702 and the provisions of sections 2701 and 2702(b) to the extent that such provisions apply to genetic information.

(E) ELECTION NOT APPLICABLE.—The election described in subparagraph (A) shall not be available with respect to the provisions of subparts I and II.

(b) EXCEPTION FOR CERTAIN BENEFITS.—The requirements of subparts 1 and 2 *and part D* shall not apply to any individual coverage or any group health plan (or group health insurance coverage) in relation to its provision of excepted benefits described in section 2791(c)(1).

(c) EXCEPTION FOR CERTAIN BENEFITS IF CERTAIN CONDITIONS MET.—

(1) LIMITED, EXCEPTED BENEFITS.—The requirements of subparts 1 and 2 *and part D* shall not apply to any individual coverage or any group health plan (and group health insurance coverage offered in connection with a group health plan) in relation to its provision of excepted benefits described in section 2791(c)(2) if the benefits—

(A) are provided under a separate policy, certificate, or contract of insurance; or

(B) are otherwise not an integral part of the plan.

(2) NONCOORDINATED, EXCEPTED BENEFITS.—The requirements of subparts 1 and 2 *and part D* shall not apply to any individual coverage or any group health plan (and group health insurance coverage offered in connection with a group health plan) in relation to its provision of excepted benefits described in section 2791(c)(3) if all of the following conditions are met:

(A) The benefits are provided under a separate policy, certificate, or contract of insurance.

(B) There is no coordination between the provision of such benefits and any exclusion of benefits under any group health plan maintained by the same plan sponsor.

(C) Such benefits are paid with respect to an event without regard to whether benefits are provided with respect to such an event under any group health plan maintained by the same plan sponsor or, with respect to individual coverage, under any health insurance coverage maintained by the same health insurance issuer.

(3) SUPPLEMENTAL EXCEPTED BENEFITS.—The requirements of this part *and part D* shall not apply to any individual coverage or any group health plan (and group health insurance coverage) in relation to its provision of excepted benefits de-

scribed in section 27971(c)(4) if the benefits are provided under a separate policy, certificate, or contract of insurance.

(d) TREATMENT OF PARTNERSHIPS.—For purposes of this part *and part D*—

(1) TREATMENT AS A GROUP HEALTH PLAN.—Any plan, fund, or program which would not be (but for this subsection) an employee welfare benefit plan and which is established or maintained by a partnership, to the extent that such plan, fund, or program provides medical care (including items and services paid for as medical care) to present or former partners in the partnership or to their dependents (as defined under the terms of the plan, fund, or program), directly or through insurance, reimbursement, or otherwise, shall be treated (subject to paragraph (2)) as an employee welfare benefit plan which is a group health plan.

(2) EMPLOYER.—In the case of a group health plan, the term "employer" also includes the partnership in relation to any partner.

(3) PARTICIPANTS OF GROUP HEALTH PLANS.—In the case of a group health plan, the term "participant" also includes—

(A) in connection with a group health plan maintained by a partnership, an individual who is a partner in relation to the partnership, or

(B) in connection with a group health plan maintained by a self-employed individual (under which one or more employees are participants), the self-employed individual,

if such individual is, or may become, eligible to receive a benefit under the plan or such individual's beneficiaries may be eligible to receive any such benefit.

SEC. 2723. ENFORCEMENT.

(a) STATE ENFORCEMENT.—

(1) STATE AUTHORITY.—Subject to section 2723, each State may require that health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State in the individual or group market meet the requirements of this part *and part D* with respect to such issuers.

(2) FAILURE TO IMPLEMENT PROVISIONS.—In the case of a determination by the Secretary that a State has failed to substantially enforce a provision (or provisions) in this part *or part D* with respect to health insurance issuers in the State, the Secretary shall enforce such provision (or provisions) under subsection (b) insofar as they relate to the issuance, sale, renewal, and offering of health insurance coverage in connection with group health plans or individual health insurance coverage in such State.

(b) SECRETARIAL ENFORCEMENT AUTHORITY.—

(1) LIMITATION.—The provisions of this subsection shall apply to enforcement of a provision (or provisions) of this part *or part D* only—

(A) as provided under subsection (a)(2); and

(B) with respect to individual health insurance coverage or group health plans that are non-Federal governmental plans.

(2) IMPOSITION OF PENALTIES.—In the cases described in paragraph (1)—

(A) IN GENERAL.—Subject to the succeeding provisions of this subsection, any non-Federal governmental plan that is a group health plan and any health insurance issuer that fails to meet a provision of this part *or part D* applicable to such plan or issuer is subject to a civil money penalty under this subsection.

(B) LIABILITY FOR PENALTY.—In the case of a failure by—

(i) a health insurance issuer, the issuer is liable for such penalty, or

(ii) a group health plan that is a non-Federal governmental plan which is—

(I) sponsored by 2 or more employers, the plan is liable for such penalty, or

(II) not so sponsored, the employer is liable for such penalty.

(C) AMOUNT OF PENALTY.—

(i) IN GENERAL.—The maximum amount of penalty imposed under this paragraph is $100 for each day for each individual with respect to which such a failure occurs.

(ii) CONSIDERATIONS IN IMPOSITION.—In determining the amount of any penalty to be assessed under this paragraph, the Secretary shall take into account the previous record of compliance of the entity being assessed with the applicable provisions of this part *and part D* and the gravity of the violation.

(iii) LIMITATIONS.—

(I) PENALTY NOT TO APPLY WHERE FAILURE NOT DISCOVERED EXERCISING REASONABLE DILIGENCE.—No civil money penalty shall be imposed under this paragraph on any failure during any period for which it is established to the satisfaction of the Secretary that none of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that such failure existed.

(II) PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN 30 DAYS.—No civil money penalty shall be imposed under this paragraph on any failure if such failure was due to reasonable cause and not to willful neglect, and such failure is corrected during the 30-day period beginning on the first day any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that such failure existed.

(D) ADMINISTRATIVE REVIEW.—

(i) OPPORTUNITY FOR HEARING.—The entity assessed shall be afforded an opportunity for hearing by the Secretary upon request made within 30 days after the date of the issuance of a notice of assessment. In such hearing the decision shall be made on the record pursuant to section 554 of title 5, United States Code. If

no hearing is requested, the assessment shall constitute a final and unappealable order.

(ii) HEARING PROCEDURE.—If a hearing is requested, the initial agency decision shall be made by an administrative law judge, and such decision shall become the final order unless the Secretary modifies or vacates the decision. Notice of intent to modify or vacate the decision of the administrative law judge shall be issued to the parties within 30 days after the date of the decision of the judge. A final order which takes effect under this paragraph shall be subject to review only as provided under subparagraph (E).

(E) JUDICIAL REVIEW.—

(i) FILING OF ACTION FOR REVIEW.—Any entity against whom an order imposing a civil money penalty has been entered after an agency hearing under this paragraph may obtain review by the United States district court for any district in which such entity is located or the United States District Court for the District of Columbia by filing a notice of appeal in such court within 30 days from the date of such order, and simultaneously sending a copy of such notice by registered mail to the Secretary.

(ii) CERTIFICATION OF ADMINISTRATIVE RECORD.—The Secretary shall promptly certify and file in such court the record upon which the penalty was imposed.

(iii) STANDARD FOR REVIEW.—The findings of the Secretary shall be set aside only if found to be unsupported by substantial evidence as provided by section 706(2)(E) of title 5, United States Code.

(iv) APPEAL.—Any final decision, order, or judgment of the district court concerning such review shall be subject to appeal as provided in chapter 83 of title 28 of such Code.

(F) FAILURE TO PAY ASSESSMENT; MAINTENANCE OF ACTION.—

(i) FAILURE TO PAY ASSESSMENT.—If any entity fails to pay an assessment after it has become a final and unappealable order, or after the court has entered final judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney General who shall recover the amount assessed by action in the appropriate United States district court.

(ii) NONREVIEWABILITY.—In such action the validity and appropriateness of the final order imposing the penalty shall not be subject to review.

(G) PAYMENT OF PENALTIES.—Except as otherwise provided, penalties collected under this paragraph shall be paid to the Secretary (or other officer) imposing the penalty and shall be available without appropriation and until expended for the purpose of enforcing the provisions with respect to which the penalty was imposed.

(3) ENFORCEMENT AUTHORITY RELATING TO GENETIC DISCRIMINATION.—

(A) GENERAL RULE.—In the cases described in paragraph (1), notwithstanding the provisions of paragraph (2)(C), the succeeding subparagraphs of this paragraph shall apply with respect to an action under this subsection by the Secretary with respect to any failure of a health insurance issuer in connection with a group health plan, to meet the requirements of subsection (a)(1)(F), (b)(3), (c), or (d) of section 2702 or section 2701 or 2702(b)(1) with respect to genetic information in connection with the plan.

(B) AMOUNT.—

(i) IN GENERAL.—The amount of the penalty imposed under this paragraph shall be $100 for each day in the noncompliance period with respect to each participant or beneficiary to whom such failure relates.

(ii) NONCOMPLIANCE PERIOD.—For purposes of this paragraph, the term "noncompliance period" means, with respect to any failure, the period—

(I) beginning on the date such failure first occurs; and

(II) ending on the date the failure is corrected.

(C) MINIMUM PENALTIES WHERE FAILURE DISCOVERED.—Notwithstanding clauses (i) and (ii) of subparagraph (D):

(i) IN GENERAL.—In the case of 1 or more failures with respect to an individual—

(I) which are not corrected before the date on which the plan receives a notice from the Secretary of such violation; and

(II) which occurred or continued during the period involved;

the amount of penalty imposed by subparagraph (A) by reason of such failures with respect to such individual shall not be less than $2,500.

(ii) HIGHER MINIMUM PENALTY WHERE VIOLATIONS ARE MORE THAN DE MINIMIS.—To the extent violations for which any person is liable under this paragraph for any year are more than de minimis, clause (i) shall be applied by substituting "$15,000" for "$2,500" with respect to such person.

(D) LIMITATIONS.—

(i) PENALTY NOT TO APPLY WHERE FAILURE NOT DISCOVERED EXERCISING REASONABLE DILIGENCE.—No penalty shall be imposed by subparagraph (A) on any failure during any period for which it is established to the satisfaction of the Secretary that the person otherwise liable for such penalty did not know, and exercising reasonable diligence would not have known, that such failure existed.

(ii) PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN CERTAIN PERIODS.—No penalty shall be imposed by subparagraph (A) on any failure if—

(I) such failure was due to reasonable cause and not to willful neglect; and

(II) such failure is corrected during the 30-day period beginning on the first date the person otherwise liable for such penalty knew, or exercising

reasonable diligence would have known, that such failure existed.

(iii) OVERALL LIMITATION FOR UNINTENTIONAL FAILURES.—In the case of failures which are due to reasonable cause and not to willful neglect, the penalty imposed by subparagraph (A) for failures shall not exceed the amount equal to the lesser of—

(I) 10 percent of the aggregate amount paid or incurred by the employer (or predecessor employer) during the preceding taxable year for group health plans; or

(II) $500,000.

(E) WAIVER BY SECRETARY.—In the case of a failure which is due to reasonable cause and not to willful neglect, the Secretary may waive part or all of the penalty imposed by subparagraph (A) to the extent that the payment of such penalty would be excessive relative to the failure involved.

SEC. 2724. PREEMPTION; STATE FLEXIBILITY; CONSTRUCTION.

(a) CONTINUED APPLICABILITY OF STATE LAW WITH RESPECT TO HEALTH INSURANCE ISSUERS.—

(1) IN GENERAL.—Subject to paragraph (2) and except as provided in subsection (b), [this part and part C insofar as it relates to this part] *this part, part D, and part C insofar as it relates to this part or part D* shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with individual or group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement of this part *or part D*.

(2) CONTINUED PREEMPTION WITH RESPECT TO GROUP HEALTH PLANS.—Nothing in this part *or part D* shall be construed to affect or modify the provisions of section 514 of the Employee Retirement Income Security Act of 1974 with respect to group health plans.

(b) SPECIAL RULES IN CASE OF PORTABILITY REQUIREMENTS.—

(1) IN GENERAL.—Subject to paragraph (2), the provisions of this part relating to health insurance coverage offered by a health insurance issuer supersede any provision of State law which establishes, implements, or continues in effect a standard or requirement applicable to imposition of a preexisting condition exclusion specifically governed by section 701 which differs from the standards or requirements specified in such section.

(2) EXCEPTIONS.—Only in relation to health insurance coverage offered by a health insurance issuer, the provisions of this part do not supersede any provision of State law to the extent that such provision—

(i) substitutes for the reference to "6-month period" in section 2701(a)(1) a reference to any shorter period of time;

(ii) substitutes for the reference to "12 months" and "18 months" in section 2701(a)(2) a reference to any shorter period of time;

(iii) substitutes for the references to "63" days in sections 2701(c)(2)(A) and 2701(d)(4)(A) a reference to any greater number of days;

(iv) substitutes for the reference to "30-day period" in sections 2701(b)(2) and 2701(d)(1) a reference to any greater period;

(v) prohibits the imposition of any preexisting condition exclusion in cases not described in section 2701(d) or expands the exceptions described in such section;

(vi) requires special enrollment periods in addition to those required under section 2701(f); or

(vii) reduces the maximum period permitted in an affiliation period under section 2701(g)(1)(B).

(c) RULES OF CONSTRUCTION.—Nothing in this part (other than section 2704) *or part D* shall be construed as requiring a group health plan or health insurance coverage to provide specific benefits under the terms of such plan or coverage.

(d) DEFINITIONS.—For purposes of this section—

(1) STATE LAW.—The term "State law" includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia shall be treated as a State law rather than a law of the United States.

(2) STATE.—The term "State" includes a State (including the Northern Mariana Islands), any political subdivisions of a State or such Islands, or any agency or instrumentality of either.

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PART D—ADDITIONAL COVERAGE PROVISIONS

SEC. 2799A–1. PARITY IN MENTAL HEALTH AND SUBSTANCE USE DISORDER BENEFITS.

(a) IN GENERAL.—

(1) AGGREGATE LIFETIME LIMITS.—In the case of a group health plan or a health insurance issuer offering group or individual health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits—

(A) NO LIFETIME LIMIT.—If the plan or coverage does not include an aggregate lifetime limit on substantially all medical and surgical benefits, the plan or coverage may not impose any aggregate lifetime limit on mental health or substance use disorder benefits.

(B) LIFETIME LIMIT.—If the plan or coverage includes an aggregate lifetime limit on substantially all medical and surgical benefits (in this paragraph referred to as the "applicable lifetime limit"), the plan or coverage shall either—

(i) apply the applicable lifetime limit both to the medical and surgical benefits to which it otherwise would apply and to mental health and substance use disorder benefits and not distinguish in the application of such limit between such medical and surgical bene-

fits and mental health and substance use disorder benefits; or

(ii) not include any aggregate lifetime limit on mental health or substance use disorder benefits that is less than the applicable lifetime limit.

(C) RULE IN CASE OF DIFFERENT LIMITS.—In the case of a plan or coverage that is not described in subparagraph (A) or (B) and that includes no or different aggregate lifetime limits on different categories of medical and surgical benefits, the Secretary shall establish rules under which subparagraph (B) is applied to such plan or coverage with respect to mental health and substance use disorder benefits by substituting for the applicable lifetime limit an average aggregate lifetime limit that is computed taking into account the weighted average of the aggregate lifetime limits applicable to such categories.

(2) ANNUAL LIMITS.—In the case of a group health plan or a health insurance issuer offering group or individual health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits—

(A) NO ANNUAL LIMIT.—If the plan or coverage does not include an annual limit on substantially all medical and surgical benefits, the plan or coverage may not impose any annual limit on mental health or substance use disorder benefits.

(B) ANNUAL LIMIT.—If the plan or coverage includes an annual limit on substantially all medical and surgical benefits (in this paragraph referred to as the "applicable annual limit"), the plan or coverage shall either—

(i) apply the applicable annual limit both to medical and surgical benefits to which it otherwise would apply and to mental health and substance use disorder benefits and not distinguish in the application of such limit between such medical and surgical benefits and mental health and substance use disorder benefits; or

(ii) not include any annual limit on mental health or substance use disorder benefits that is less than the applicable annual limit.

(C) RULE IN CASE OF DIFFERENT LIMITS.—In the case of a plan or coverage that is not described in subparagraph (A) or (B) and that includes no or different annual limits on different categories of medical and surgical benefits, the Secretary shall establish rules under which subparagraph (B) is applied to such plan or coverage with respect to mental health and substance use disorder benefits by substituting for the applicable annual limit an average annual limit that is computed taking into account the weighted average of the annual limits applicable to such categories.

(3) FINANCIAL REQUIREMENTS AND TREATMENT LIMITATIONS.—

(A) IN GENERAL.—In the case of a group health plan or a health insurance issuer offering group or individual health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits, such plan or coverage shall ensure that—

(i) the financial requirements applicable to such mental health or substance use disorder benefits are no more restrictive than the predominant financial requirements applied to substantially all medical and surgical benefits covered by the plan (or coverage), and there are no separate cost sharing requirements that are applicable only with respect to mental health or substance use disorder benefits; and

(ii) the treatment limitations applicable to such mental health or substance use disorder benefits are no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits covered by the plan (or coverage) and there are no separate treatment limitations that are applicable only with respect to mental health or substance use disorder benefits.

(B) DEFINITIONS.—In this paragraph:

(i) FINANCIAL REQUIREMENT.—The term "financial requirement" includes deductibles, copayments, coinsurance, and out-of-pocket expenses, but excludes an aggregate lifetime limit and an annual limit subject to paragraphs (1) and (2).

(ii) PREDOMINANT.—A financial requirement or treatment limit is considered to be predominant if it is the most common or frequent of such type of limit or requirement.

(iii) TREATMENT LIMITATION.—The term "treatment limitation" includes limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment.

(4) AVAILABILITY OF PLAN INFORMATION.—The criteria for medical necessity determinations made under the plan with respect to mental health or substance use disorder benefits (or the health insurance coverage offered in connection with the plan with respect to such benefits) shall be made available by the plan administrator (or the health insurance issuer offering such coverage) in accordance with regulations to any current or potential participant, beneficiary, or contracting provider upon request. The reason for any denial under the plan (or coverage) of reimbursement or payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary shall, on request or as otherwise required, be made available by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary in accordance with regulations.

(5) OUT-OF-NETWORK PROVIDERS.—In the case of a plan or coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits, if the plan or coverage provides coverage for medical or surgical benefits provided by out-of-network providers, the plan or coverage shall provide coverage for mental health or substance use disorder benefits provided by out-of-network providers in a manner that is consistent with the requirements of this section.

(6) COMPLIANCE PROGRAM GUIDANCE DOCUMENT.—

(A) IN GENERAL.—Not later than 12 months after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary, the Secretary of Labor, and the Secretary of the Treasury, in consultation with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury, shall issue a compliance program guidance document to help improve compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, and section 9812 of the Internal Revenue Code of 1986, as applicable. In carrying out this paragraph, the Secretaries may take into consideration the 2016 publication of the Department of Health and Human Services and the Department of Labor, entitled "Warning Signs - Plan or Policy Non-Quantitative Treatment Limitations (NQTLs) that Require Additional Analysis to Determine Mental Health Parity Compliance".

(B) EXAMPLES ILLUSTRATING COMPLIANCE AND NON-COMPLIANCE.—

(i) IN GENERAL.—The compliance program guidance document required under this paragraph shall provide illustrative, de-identified examples (that do not disclose any protected health information or individually identifiable information) of previous findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, based on investigations of violations of such sections, including—

(I) examples illustrating requirements for information disclosures and nonquantitative treatment limitations; and

(II) descriptions of the violations uncovered during the course of such investigations.

(ii) NONQUANTITATIVE TREATMENT LIMITATIONS.—To the extent that any example described in clause (i) involves a finding of compliance or noncompliance with regard to any requirement for nonquantitative treatment limitations, the example shall provide sufficient detail to fully explain such finding, including a full description of the criteria involved for approving medical and surgical benefits and the criteria involved for approving mental health and substance use disorder benefits.

(iii) ACCESS TO ADDITIONAL INFORMATION REGARDING COMPLIANCE.—In developing and issuing the compliance program guidance document required under this paragraph, the Secretaries specified in subparagraph (A)—

(I) shall enter into interagency agreements with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury to share findings

of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable; and

(II) shall seek to enter into an agreement with a State to share information on findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.

(C) RECOMMENDATIONS.—The compliance program guidance document shall include recommendations to advance compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, and encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements. Such internal controls may include illustrative examples of nonquantitative treatment limitations on mental health and substance use disorder benefits, which may fail to comply with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, in relation to nonquantitative treatment limitations on medical and surgical benefits.

(D) UPDATING THE COMPLIANCE PROGRAM GUIDANCE DOCUMENT.—The Secretary, the Secretary of Labor, and the Secretary of the Treasury, in consultation with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury, shall update the compliance program guidance document every 2 years to include illustrative, de-identified examples (that do not disclose any protected health information or individually identifiable information) of previous findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.

(7) ADDITIONAL GUIDANCE.—

(A) IN GENERAL.—Not later than 12 months after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary, the Secretary of Labor, and the Secretary of the Treasury shall issue guidance to group health plans and health insurance issuers offering group or individual health insurance coverage to assist such plans and issuers in satisfying the requirements of this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.

(B) DISCLOSURE.—

(i) GUIDANCE FOR PLANS AND ISSUERS.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods that group health plans and health insurance issuers

offering group or individual health insurance coverage may use for disclosing information to ensure compliance with the requirements under this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, (and any regulations promulgated pursuant to such sections, as applicable).

(ii) DOCUMENTS FOR PARTICIPANTS, BENEFICIARIES, CONTRACTING PROVIDERS, OR AUTHORIZED REPRESENTATIVES.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods that group health plans and health insurance issuers offering group or individual health insurance coverage may use to provide any participant, beneficiary, contracting provider, or authorized representative, as applicable, with documents containing information that the health plans or issuers are required to disclose to participants, beneficiaries, contracting providers, or authorized representatives to ensure compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, compliance with any regulation issued pursuant to such respective section, or compliance with any other applicable law or regulation. Such guidance shall include information that is comparative in nature with respect to—

(I) nonquantitative treatment limitations for both medical and surgical benefits and mental health and substance use disorder benefits;

(II) the processes, strategies, evidentiary standards, and other factors used to apply the limitations described in subclause (I); and

(III) the application of the limitations described in subclause (I) to ensure that such limitations are applied in parity with respect to both medical and surgical benefits and mental health and substance use disorder benefits.

(C) NONQUANTITATIVE TREATMENT LIMITATIONS.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods, processes, strategies, evidentiary standards, and other factors that group health plans and health insurance issuers offering group or individual health insurance coverage may use regarding the development and application of nonquantitative treatment limitations to ensure compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable, (and any regulations promulgated pursuant to such respective section), including—

(i) examples of methods of determining appropriate types of nonquantitative treatment limitations with respect to both medical and surgical benefits and mental

health and substance use disorder benefits, including nonquantitative treatment limitations pertaining to—

(I) medical management standards based on medical necessity or appropriateness, or whether a treatment is experimental or investigative;

(II) limitations with respect to prescription drug formulary design; and

(III) use of fail-first or step therapy protocols;

(ii) examples of methods of determining—

(I) network admission standards (such as credentialing); and

(II) factors used in provider reimbursement methodologies (such as service type, geographic market, demand for services, and provider supply, practice size, training, experience, and licensure) as such factors apply to network adequacy;

(iii) examples of sources of information that may serve as evidentiary standards for the purposes of making determinations regarding the development and application of nonquantitative treatment limitations;

(iv) examples of specific factors, and the evidentiary standards used to evaluate such factors, used by such plans or issuers in performing a nonquantitative treatment limitation analysis;

(v) examples of how specific evidentiary standards may be used to determine whether treatments are considered experimental or investigative;

(vi) examples of how specific evidentiary standards may be applied to each service category or classification of benefits;

(vii) examples of methods of reaching appropriate coverage determinations for new mental health or substance use disorder treatments, such as evidence-based early intervention programs for individuals with a serious mental illness and types of medical management techniques;

(viii) examples of methods of reaching appropriate coverage determinations for which there is an indirect relationship between the covered mental health or substance use disorder benefit and a traditional covered medical and surgical benefit, such as residential treatment or hospitalizations involving voluntary or involuntary commitment; and

(ix) additional illustrative examples of methods, processes, strategies, evidentiary standards, and other factors for which the Secretary determines that additional guidance is necessary to improve compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 9812 of the Internal Revenue Code of 1986, as applicable.

(D) PUBLIC COMMENT.—Prior to issuing any final guidance under this paragraph, the Secretary shall provide a public comment period of not less than 60 days during which any member of the public may provide comments on a draft of the guidance.

(8) COMPLIANCE REQUIREMENTS.—

(A) NONQUANTITATIVE TREATMENT LIMITATION (NQTL) REQUIREMENTS.—In the case of a group health plan or a health insurance issuer offering group or individual health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits and that imposes nonquantitative treatment limitations (referred to in this section as "NQTL") on mental health or substance use disorder benefits, the plan or issuer offering health insurance coverage shall perform comparative analyses of the design and application of NQTLs in accordance with subparagraph (B), and, beginning 45 days after the date of enactment of this paragraph, make available to the applicable State authority (or, as applicable, the Secretary), upon request, the comparative analyses and the following information:

(i) The specific plan or coverage terms regarding the NQTL, that applies to such plan or coverage, and a description of all mental health or substance use disorder and medical or surgical benefits to which it applies in each respective benefits classification.

(ii) The factors used to determine that the NQTL 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 NQTL 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 design the NQTL, as written, and the operation processes and strategies as written and in operation that are used to apply the NQTL for mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to design the NQTL, as written, and the operation processes and strategies as written and in operation that are used to apply the NQTL to medical or surgical benefits.

(v) A disclosure of the specific findings and conclusions reached by the plan or coverage that the results of the analyses described in this subparagraph indicate that the plan or coverage is in compliance with this section.

(B) SECRETARY REQUEST PROCESS.—

(i) SUBMISSION UPON REQUEST.—The Secretary shall request that a group health plan or a health insurance issuer offering group or individual health insurance coverage submit the comparative analyses described in subparagraph (A) for plans that involve potential violations of this section or complaints regarding noncompliance with this section that concern NQTLs and

any other instances in which the Secretary determines appropriate. The Secretary shall request not fewer than 20 such analyses per year.

(ii) ADDITIONAL INFORMATION.—In instances in which the Secretary has concluded that the plan or coverage has not submitted sufficient information for the Secretary to review the comparative analyses described in subparagraph (A), as requested under clause (i), the Secretary shall specify to the plan or coverage the information the plan or coverage must submit to be responsive to the request under clause (i) for the Secretary to review the comparative analyses described in subparagraph(A) for compliance with this section. Nothing in this paragraph shall require the Secretary to conclude that a plan is in compliance with this section solely based upon the inspection of the comparative analyses described in subparagraph (A), as requested under clause (i).

(iii) REQUIRED ACTION.—

(I) IN GENERAL.—In instances in which the Secretary has reviewed the comparative analyses described in subparagraph (A), as requested under clause (i), and determined that the plan or coverage is not in compliance with this section, the plan or coverage—

(aa) shall specify to the Secretary the actions the plan or coverage will take to be in compliance with this section and provide to the Secretary comparative analyses described in subparagraph (A) that demonstrate compliance with this section not later than 45 days after the initial determination by the Secretary that the plan or coverage is not in compliance; and

(bb) following the 45-day corrective action period under item (aa), if the Secretary determines that the plan or coverage still is not in compliance with this section, not later than 7 days after such determination, shall notify all individuals enrolled in the plan or coverage that the plan or coverage has been determined to be not in compliance with this section.

(II) EXEMPTION FROM DISCLOSURE.—Documents or communications produced in connection with the Secretary's recommendations to the plan or coverage shall not be subject to disclosure pursuant to section 552 of title 5, United States Code.

(iv) REPORT.—Not later than 1 year after the date of enactment of this paragraph, and not later than October 1 of each year thereafter, the Secretary shall submit to Congress, and make publicly available, a report that contains—

(I) a summary of the comparative analyses requested under clause (i), including the identity of each plan or coverage that is determined to be not

in compliance after the final determination by the Secretary described in clause (iii)(I)(bb);

(II) the Secretary's conclusions as to whether each plan or coverage submitted sufficient information for the Secretary to review the comparative analyses requested under clause (i) for compliance with this section;

(III) for each plan or coverage that did submit sufficient information for the Secretary to review the comparative analyses requested under clause (i), the Secretary's conclusions as to whether and why the plan or coverage is in compliance with the requirements under this section;

(IV) the Secretary's specifications described in clause (ii) for each plan or coverage that the Secretary determined did not submit sufficient information for the Secretary to review the comparative analyses requested under clause (i) for compliance with this section; and

(V) the Secretary's specifications described in clause (iii) of the actions each plan or coverage that the Secretary determined is not in compliance with this section must take to be in compliance with this section, including the reason why the Secretary determined the plan or coverage is not in compliance.

(C) COMPLIANCE PROGRAM GUIDANCE DOCUMENT UPDATE PROCESS.—

(i) IN GENERAL.—The Secretary shall include instances of noncompliance that the Secretary discovers upon reviewing the comparative analyses requested under subparagraph (B)(i) in the compliance program guidance document described in paragraph (6), as it is updated every 2 years, except that such instances shall not disclose any protected health information or individually identifiable information.

(ii) GUIDANCE AND REGULATIONS.—Not later than 18 months after the date of enactment of this paragraph, the Secretary shall finalize any draft or interim guidance and regulations relating to mental health parity under this section. Such draft guidance shall include guidance to clarify the process and timeline for current and potential participants and beneficiaries (and authorized representatives and health care providers of such participants and beneficiaries) with respect to plans to file complaints of such plans or issuers being in violation of this section, including guidance, by plan type, on the relevant State, regional, or national office with which such complaints should be filed.

(iii) STATE.—The Secretary shall share information on findings of compliance and noncompliance discovered upon reviewing the comparative analyses requested under subparagraph (B)(i) with the State where the group health plan is located or the State where the health insurance issuer is licensed to do

business for coverage offered by a health insurance issuer in the group market, in accordance with paragraph (6)(B)(iii)(II).

(b) CONSTRUCTION.—Nothing in this section shall be construed—

(1) as requiring a group health plan or a health insurance issuer offering group or individual health insurance coverage to provide any mental health or substance use disorder benefits; or

(2) in the case of a group health plan or a health insurance issuer offering group or individual health insurance coverage that provides mental health or substance use disorder benefits, as affecting the terms and conditions of the plan or coverage relating to such benefits under the plan or coverage, except as provided in subsection (a).

(c) EXEMPTIONS.—

(1) SMALL EMPLOYER EXEMPTION.—This section shall not apply to any group health plan and a health insurance issuer offering group or individual health insurance coverage for any plan year of a small employer (as defined in section 2791(e)(4), except that for purposes of this paragraph such term shall include employers with 1 employee in the case of an employer residing in a State that permits small groups to include a single individual).

(2) COST EXEMPTION.—

(A) IN GENERAL.—With respect to a group health plan or a health insurance issuer offering group or individual health insurance coverage, if the application of this section to such plan (or coverage) results in an increase for the plan year involved of the actual total costs of coverage with respect to medical and surgical benefits and mental health and substance use disorder benefits under the plan (as determined and certified under subparagraph (C)) by an amount that exceeds the applicable percentage described in subparagraph (B) of the actual total plan costs, the provisions of this section shall not apply to such plan (or coverage) during the following plan year, and such exemption shall apply to the plan (or coverage) for 1 plan year. An employer may elect to continue to apply mental health and substance use disorder parity pursuant to this section with respect to the group health plan (or coverage) involved regardless of any increase in total costs.

(B) APPLICABLE PERCENTAGE.—With respect to a plan (or coverage), the applicable percentage described in this subparagraph shall be—

(i) 2 percent in the case of the first plan year in which this section is applied; and

(ii) 1 percent in the case of each subsequent plan year.

(C) DETERMINATIONS BY ACTUARIES.—Determinations as to increases in actual costs under a plan (or coverage) for purposes of this section shall be made and certified by a qualified and licensed actuary who is a member in good standing of the American Academy of Actuaries. All such determinations shall be in a written report prepared by the actuary. The report, and all underlying documentation relied upon by the actuary, shall be maintained by the group

health plan or health insurance issuer for a period of 6 years following the notification made under subparagraph (E).

(D) 6-MONTH DETERMINATIONS.—If a group health plan (or a health insurance issuer offering coverage in connection with a group health plan) seeks an exemption under this paragraph, determinations under subparagraph (A) shall be made after such plan (or coverage) has complied with this section for the first 6 months of the plan year involved.

(E) NOTIFICATION.—

(i) IN GENERAL.—A group health plan (or a health insurance issuer offering coverage in connection with a group health plan) that, based upon a certification described under subparagraph (C), qualifies for an exemption under this paragraph, and elects to implement the exemption, shall promptly notify the Secretary, the appropriate State agencies, and participants and beneficiaries in the plan of such election.

(ii) REQUIREMENT.—A notification to the Secretary under clause (i) shall include—

(I) a description of the number of covered lives under the plan (or coverage) involved at the time of the notification, and as applicable, at the time of any prior election of the cost-exemption under this paragraph by such plan (or coverage);

(II) for both the plan year upon which a cost exemption is sought and the year prior, a description of the actual total costs of coverage with respect to medical and surgical benefits and mental health and substance use disorder benefits under the plan; and

(III) for both the plan year upon which a cost exemption is sought and the year prior, the actual total costs of coverage with respect to mental health and substance use disorder benefits under the plan.

(iii) CONFIDENTIALITY.—A notification to the Secretary under clause (i) shall be confidential. The Secretary shall make available, upon request and on not more than an annual basis, an anonymous itemization of such notifications, that includes—

(I) a breakdown of States by the size and type of employers submitting such notification; and

(II) a summary of the data received under clause (ii).

(F) AUDITS BY APPROPRIATE AGENCIES.—To determine compliance with this paragraph, the Secretary may audit the books and records of a group health plan or health insurance issuer relating to an exemption, including any actuarial reports prepared pursuant to subparagraph (C), during the 6 year period following the notification of such exemption under subparagraph (E). A State agency receiving a notification under subparagraph (E) may also con-

duct such an audit with respect to an exemption covered by such notification.

(d) SEPARATE APPLICATION TO EACH OPTION OFFERED.—In the case of a group health plan that offers a participant or beneficiary two or more benefit package options under the plan, the requirements of this section shall be applied separately with respect to each such option.

(e) DEFINITIONS.—For purposes of this section—

(1) AGGREGATE LIFETIME LIMIT.—The term "aggregate lifetime limit" means, with respect to benefits under a group health plan or health insurance coverage, a dollar limitation on the total amount that may be paid with respect to such benefits under the plan or health insurance coverage with respect to an individual or other coverage unit.

(2) ANNUAL LIMIT.—The term "annual limit" means, with respect to benefits under a group health plan or health insurance coverage, a dollar limitation on the total amount of benefits that may be paid with respect to such benefits in a 12-month period under the plan or health insurance coverage with respect to an individual or other coverage unit.

(3) MEDICAL OR SURGICAL BENEFITS.—The term "medical or surgical benefits" means benefits with respect to medical or surgical services, as defined under the terms of the plan or coverage (as the case may be), but does not include mental health or substance use disorder benefits.

(4) MENTAL HEALTH BENEFITS.—The term "mental health benefits" means benefits with respect to services for mental health conditions, as defined under the terms of the plan and in accordance with applicable Federal and State law.

(5) SUBSTANCE USE DISORDER BENEFITS.—The term "substance use disorder benefits" means benefits with respect to services for substance use disorders, as defined under the terms of the plan and in accordance with applicable Federal and State law.

EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

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TITLE I—PROTECTION OF EMPLOYEE BENEFIT RIGHTS

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SUBTITLE B—REGULATORY PROVISIONS

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PART 7—GROUP HEALTH PLAN REQUIREMENTS

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SUBPART B—OTHER REQUIREMENTS

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SEC. 712. PARITY IN MENTAL HEALTH AND SUBSTANCE USE DISORDER BENEFITS.

(a) IN GENERAL.—

(1) AGGREGATE LIFETIME LIMITS.—In the case of a group health plan (or health insurance coverage offered in connection with such a plan) that provides both medical and surgical benefits and mental health or substance use disorder benefits—

(A) NO LIFETIME LIMIT.—If the plan or coverage does not include an aggregate lifetime limit on substantially all medical and surgical benefits, the plan or coverage may not impose any aggregate lifetime limit on mental health or substance use disorder benefits.

(B) LIFETIME LIMIT.—If the plan or coverage includes an aggregate lifetime limit on substantially all medical and surgical benefits (in this paragraph referred to as the "applicable lifetime limit"), the plan or coverage shall either—

(i) apply the applicable lifetime limit both to the medical and surgical benefits to which it otherwise would apply and to mental health and substance use disorder benefits and not distinguish in the application of such limit between such medical and surgical benefits and mental health and substance use disorder benefits; or

(ii) not include any aggregate lifetime limit on mental health or substance use disorder benefits that is less than the applicable lifetime limit.

(C) RULE IN CASE OF DIFFERENT LIMITS.—In the case of a plan or coverage that is not described in subparagraph (A) or (B) and that includes no or different aggregate lifetime limits on different categories of medical and surgical benefits, the Secretary shall establish rules under which subparagraph (B) is applied to such plan or coverage with respect to mental health and substance use disorder benefits by substituting for the applicable lifetime limit an average aggregate lifetime limit that is computed taking into account the weighted average of the aggregate lifetime limits applicable to such categories.

(2) ANNUAL LIMITS.—In the case of a group health plan (or health insurance coverage offered in connection with such a plan) that provides both medical and surgical benefits and mental health or substance use disorder benefits—

(A) NO ANNUAL LIMIT.—If the plan or coverage does not include an annual limit on substantially all medical and surgical benefits, the plan or coverage may not impose any annual limit on mental health or substance use disorder benefits.

(B) ANNUAL LIMIT.—If the plan or coverage includes an annual limit on substantially all medical and surgical benefits (in this paragraph referred to as the "applicable annual limit"), the plan or coverage shall either—

(i) apply the applicable annual limit both to medical and surgical benefits to which it otherwise would apply and to mental health and substance use disorder benefits and not distinguish in the application of such

limit between such medical and surgical benefits and mental health and substance use disorder benefits; or

(ii) not include any annual limit on mental health or substance use disorder benefits that is less than the applicable annual limit.

(C) RULE IN CASE OF DIFFERENT LIMITS.—In the case of a plan or coverage that is not described in subparagraph (A) or (B) and that includes no or different annual limits on different categories of medical and surgical benefits, the Secretary shall establish rules under which subparagraph (B) is applied to such plan or coverage with respect to mental health and substance use disorder benefits by substituting for the applicable annual limit an average annual limit that is computed taking into account the weighted average of the annual limits applicable to such categories.

(3) FINANCIAL REQUIREMENTS AND TREATMENT LIMITATIONS.—

(A) IN GENERAL.—In the case of a group health plan (or health insurance coverage offered in connection with such a plan) that provides both medical and surgical benefits and mental health or substance use disorder benefits, such plan or coverage shall ensure that—

(i) the financial requirements applicable to such mental health or substance use disorder benefits are no more restrictive than the predominant financial requirements applied to substantially all medical and surgical benefits covered by the plan (or coverage), and there are no separate cost sharing requirements that are applicable only with respect to mental health or substance use disorder benefits; and

(ii) the treatment limitations applicable to such mental health or substance use disorder benefits are no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits covered by the plan (or coverage) and there are no separate treatment limitations that are applicable only with respect to mental health or substance use disorder benefits.

(B) DEFINITIONS.—In this paragraph:

(i) FINANCIAL REQUIREMENT.—The term "financial requirement" includes deductibles, copayments, coinsurance, and out-of-pocket expenses, but excludes an aggregate lifetime limit and an annual limit subject to paragraphs (1) and (2),

(ii) PREDOMINANT.—A financial requirement or treatment limit is considered to be predominant if it is the most common or frequent of such type of limit or requirement.

(iii) TREATMENT LIMITATION.—The term "treatment limitation" includes limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment.

(4) AVAILABILITY OF PLAN INFORMATION.—The criteria for medical necessity determinations made under the plan with respect to mental health or substance use disorder benefits (or

the health insurance coverage offered in connection with the plan with respect to such benefits) shall be made available by the plan administrator (or the health insurance issuer offering such coverage) in accordance with regulations to any current or potential participant, beneficiary, or contracting provider upon request. The reason for any denial under the plan (or coverage) of reimbursement or payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary shall, on request or as otherwise required, be made available by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary in accordance with regulations.

(5) OUT-OF-NETWORK PROVIDERS.—In the case of a plan or coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits, if the plan or coverage provides coverage for medical or surgical benefits provided by out-of-network providers, the plan or coverage shall provide coverage for mental health or substance use disorder benefits provided by out-of-network providers in a manner that is consistent with the requirements of this section.

(6) COMPLIANCE PROGRAM GUIDANCE DOCUMENT.—

(A) IN GENERAL.—Not later than 12 months after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury, in consultation with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury, shall issue a compliance program guidance document to help improve compliance with this section, section 2799A–1 of the Public Health Service Act, and section 9812 of the Internal Revenue Code of 1986, as applicable. In carrying out this paragraph, the Secretaries may take into consideration the 2016 publication of the Department of Health and Human Services and the Department of Labor, entitled "Warning Signs - Plan or Policy Non-Quantitative Treatment Limitations (NQTLs) that Require Additional Analysis to Determine Mental Health Parity Compliance".

(B) EXAMPLES ILLUSTRATING COMPLIANCE AND NONCOMPLIANCE.—

(i) IN GENERAL.—The compliance program guidance document required under this paragraph shall provide illustrative, de-identified examples (that do not disclose any protected health information or individually identifiable information) of previous findings of compliance and noncompliance with this section, section 2799A–1 of the Public Health Service Act, or section 9812 of the Internal Revenue Code of 1986, as applicable, based on investigations of violations of such sections, including—

(I) examples illustrating requirements for information disclosures and nonquantitative treatment limitations; and

(II) descriptions of the violations uncovered during the course of such investigations.

(ii) NONQUANTITATIVE TREATMENT LIMITATIONS.—To the extent that any example described in clause (i) involves a finding of compliance or noncompliance with regard to any requirement for nonquantitative treatment limitations, the example shall provide sufficient detail to fully explain such finding, including a full description of the criteria involved for approving medical and surgical benefits and the criteria involved for approving mental health and substance use disorder benefits.

(iii) ACCESS TO ADDITIONAL INFORMATION REGARDING COMPLIANCE.—In developing and issuing the compliance program guidance document required under this paragraph, the Secretaries specified in subparagraph (A)—

(I) shall enter into interagency agreements with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury to share findings of compliance and noncompliance with this section, section 2799A–1 of the Public Health Service Act, or section 9812 of the Internal Revenue Code of 1986, as applicable; and

(II) shall seek to enter into an agreement with a State to share information on findings of compliance and noncompliance with this section, section 2799A–1 of the Public Health Service Act, or section 9812 of the Internal Revenue Code of 1986, as applicable.

(C) RECOMMENDATIONS.—The compliance program guidance document shall include recommendations to advance compliance with this section, section 2799A–1 of the Public Health Service Act, or section 9812 of the Internal Revenue Code of 1986, as applicable, and encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements. Such internal controls may include illustrative examples of nonquantitative treatment limitations on mental health and substance use disorder benefits, which may fail to comply with this section, section 2799A–1 of the Public Health Service Act, or section 9812 of the Internal Revenue Code of 1986, as applicable, in relation to nonquantitative treatment limitations on medical and surgical benefits.

(D) UPDATING THE COMPLIANCE PROGRAM GUIDANCE DOCUMENT.—The Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury, in consultation with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury, shall update the compliance program guidance document every 2 years to include illustrative, de-identified examples (that do not disclose any

protected health information or individually identifiable information) of previous findings of compliance and noncompliance with this section, section 2799A–1 of the Public Health Service Act, or section 9812 of the Internal Revenue Code of 1986, as applicable.

(7) ADDITIONAL GUIDANCE.—

(A) IN GENERAL.—Not later than 12 months after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary, the Secretary of Health and Human Services, and the Secretary of the Treasury shall issue guidance to group health plans and health insurance issuers offering group or individual health insurance coverage to assist such plans and issuers in satisfying the requirements of this section, section 2799A–1 of the Public Health Service Act, or section 9812 of the Internal Revenue Code of 1986, as applicable.

(B) DISCLOSURE.—

(i) GUIDANCE FOR PLANS AND ISSUERS.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods that group health plans and health insurance issuers offering group or individual health insurance coverage may use for disclosing information to ensure compliance with the requirements under this section, section 2799A–1 of the Public Health Service Act, or section 9812 of the Internal Revenue Code of 1986, as applicable, (and any regulations promulgated pursuant to such sections, as applicable).

(ii) DOCUMENTS FOR PARTICIPANTS, BENEFICIARIES, CONTRACTING PROVIDERS, OR AUTHORIZED REPRESENTATIVES.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods that group health plans and health insurance issuers offering group or individual health insurance coverage may use to provide any participant, beneficiary, contracting provider, or authorized representative, as applicable, with documents containing information that the health plans or issuers are required to disclose to participants, beneficiaries, contracting providers, or authorized representatives to ensure compliance with this section, section 2799A–1 of the Public Health Service Act, or section 9812 of the Internal Revenue Code of 1986, as applicable, compliance with any regulation issued pursuant to such respective section, or compliance with any other applicable law or regulation. Such guidance shall include information that is comparative in nature with respect to—

(I) nonquantitative treatment limitations for both medical and surgical benefits and mental health and substance use disorder benefits;

(II) the processes, strategies, evidentiary standards, and other factors used to apply the limitations described in subclause (I); and

(III) the application of the limitations described in subclause (I) to ensure that such limitations are

applied in parity with respect to both medical and surgical benefits and mental health and substance use disorder benefits.

(C) NONQUANTITATIVE TREATMENT LIMITATIONS.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods, processes, strategies, evidentiary standards, and other factors that group health plans and health insurance issuers offering group or individual health insurance coverage may use regarding the development and application of nonquantitative treatment limitations to ensure compliance with this section, section 2799A–1 of the Public Health Service Act, or section 9812 of the Internal Revenue Code of 1986, as applicable, (and any regulations promulgated pursuant to such respective section), including—

(i) examples of methods of determining appropriate types of nonquantitative treatment limitations with respect to both medical and surgical benefits and mental health and substance use disorder benefits, including nonquantitative treatment limitations pertaining to—

(I) medical management standards based on medical necessity or appropriateness, or whether a treatment is experimental or investigative;

(II) limitations with respect to prescription drug formulary design; and

(III) use of fail-first or step therapy protocols;

(ii) examples of methods of determining—

(I) network admission standards (such as credentialing); and

(II) factors used in provider reimbursement methodologies (such as service type, geographic market, demand for services, and provider supply, practice size, training, experience, and licensure) as such factors apply to network adequacy;

(iii) examples of sources of information that may serve as evidentiary standards for the purposes of making determinations regarding the development and application of nonquantitative treatment limitations;

(iv) examples of specific factors, and the evidentiary standards used to evaluate such factors, used by such plans or issuers in performing a nonquantitative treatment limitation analysis;

(v) examples of how specific evidentiary standards may be used to determine whether treatments are considered experimental or investigative;

(vi) examples of how specific evidentiary standards may be applied to each service category or classification of benefits;

(vii) examples of methods of reaching appropriate coverage determinations for new mental health or substance use disorder treatments, such as evidence-based early intervention programs for individuals with a serious mental illness and types of medical management techniques;

(viii) examples of methods of reaching appropriate coverage determinations for which there is an indirect relationship between the covered mental health or substance use disorder benefit and a traditional covered medical and surgical benefit, such as residential treatment or hospitalizations involving voluntary or involuntary commitment; and

(ix) additional illustrative examples of methods, processes, strategies, evidentiary standards, and other factors for which the Secretary determines that additional guidance is necessary to improve compliance with this section, section 2799A–1 of the Public Health Service Act, or section 9812 of the Internal Revenue Code of 1986, as applicable.

(D) PUBLIC COMMENT.—Prior to issuing any final guidance under this paragraph, the Secretary shall provide a public comment period of not less than 60 days during which any member of the public may provide comments on a draft of the guidance.

(8) COMPLIANCE REQUIREMENTS.—

(A) NONQUANTITATIVE TREATMENT LIMITATION (NQTL) REQUIREMENTS.—Beginning 45 days after the date of enactment of this paragraph, in the case of a group health plan or a health insurance issuer offering group health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits and that imposes nonquantitative treatment limitations (referred to in this section as "NQTL") on mental health or substance use disorder benefits, the plan or issuer offering health insurance coverage shall perform comparative analyses of the design and application of NQTLs in accordance with subparagraph (B), and make available to the applicable State authority (or, as applicable, the Secretary), upon request, the following information:

(i) The specific plan or coverage terms regarding the NQTL, that applies to such plan or coverage, and a description of all mental health or substance use disorder and medical or surgical benefits to which it applies in each respective benefits classification.

(ii) The factors used to determine that the NQTL 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 NQTL 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 design the NQTL, as written, and the operation processes and strategies as written and in operation that are used to apply the NQTL for mental health or substance use disorder benefits are comparable to, and are applied no more stringently than,

the processes, strategies, evidentiary standards, and other factors used to design the NQTL, as written, and the operation processes and strategies as written and in operation that are used to apply the NQTL to medical or surgical benefits.

(v) A disclosure of the specific findings and conclusions reached by the plan or coverage that the results of the analyses described in this subparagraph indicate that the plan or coverage is in compliance with this section.

(B) SECRETARY REQUEST PROCESS.—

(i) SUBMISSION UPON REQUEST.—The Secretary shall request that a group health plan or a health insurance issuer offering group health insurance coverage submit the comparative analyses described in subparagraph (A) for plans that involve potential violations of this section or complaints regarding noncompliance with this section that concern NQTLs and any other instances in which the Secretary determines appropriate. The Secretary shall request not fewer than 20 such analyses per year.

(ii) ADDITIONAL INFORMATION.—In instances in which the Secretary has concluded that the plan or coverage has not submitted sufficient information for the Secretary to review the comparative analyses described in subparagraph (A), as requested under clause (i), the Secretary shall specify to the plan or coverage the information the plan or coverage must submit to be responsive to the request under clause (i) for the Secretary to review the comparative analyses described in subparagraph(A) for compliance with this section. Nothing in this paragraph shall require the Secretary to conclude that a plan is in compliance with this section solely based upon the inspection of the comparative analyses described in subparagraph (A), as requested under clause (i).

(iii) REQUIRED ACTION.—

(I) IN GENERAL.—In instances in which the Secretary has reviewed the comparative analyses described in subparagraph (A), as requested under clause (i), and determined that the plan or coverage is not in compliance with this section, the plan or coverage—

(aa) shall specify to the Secretary the actions the plan or coverage will take to be in compliance with this section and provide to the Secretary comparative analyses described in subparagraph (A) that demonstrate compliance with this section not later than 45 days after the initial determination by the Secretary that the plan or coverage is not in compliance; and

(bb) following the 45-day corrective action period under item (aa), if the Secretary determines that the plan or coverage still is not in compliance with this section, not later than 7

days after such determination, shall notify all individuals enrolled in the plan or coverage that the plan or coverage has been determined to be not in compliance with this section.

(II) EXEMPTION FROM DISCLOSURE.—Documents or communications produced in connection with the Secretary's recommendations to the plan or coverage shall not be subject to disclosure pursuant to section 552 of title 5, United States Code.

(iv) REPORT.—Not later than 1 year after the date of enactment of this paragraph, and not later than October 1 of each year thereafter, the Secretary shall submit to Congress, and make publicly available, a report that contains—

(I) a summary of the comparative analyses requested under clause (i), including the identity of each plan or coverage that is determined to be not in compliance after the final determination by the Secretary described in clause (iii)(I)(bb);

(II) the Secretary's conclusions as to whether each plan or coverage submitted sufficient information for the Secretary to review the comparative analyses requested under clause (i) for compliance with this section;

(III) for each plan or coverage that did submit sufficient information for the Secretary to review the comparative analyses requested under clause (i), the Secretary's conclusions as to whether and why the plan or coverage is in compliance with the requirements under this section;

(IV) the Secretary's specifications described in clause (ii) for each plan or coverage that the Secretary determined did not submit sufficient information for the Secretary to review the comparative analyses requested under clause (i) for compliance with this section; and

(V) the Secretary's specifications described in clause (iii) of the actions each plan or coverage that the Secretary determined is not in compliance with this section must take to be in compliance with this section, including the reason why the Secretary determined the plan or coverage is not in compliance.

(C) COMPLIANCE PROGRAM GUIDANCE DOCUMENT UPDATE PROCESS.—

(i) IN GENERAL.—The Secretary shall include instances of noncompliance that the Secretary discovers upon reviewing the comparative analyses requested under subparagraph (B)(i) in the compliance program guidance document described in paragraph (6), as it is updated every 2 years, except that such instances shall not disclose any protected health information or individually identifiable information.

(ii) GUIDANCE AND REGULATIONS.—Not later than 18 months after the date of enactment of this paragraph,

the Secretary shall finalize any draft or interim guidance and regulations relating to mental health parity under this section. Such draft guidance shall include guidance to clarify the process and timeline for current and potential participants and beneficiaries (and authorized representatives and health care providers of such participants and beneficiaries) with respect to plans to file complaints of such plans or issuers being in violation of this section, including guidance, by plan type, on the relevant State, regional, or national office with which such complaints should be filed.

(iii) STATE.—The Secretary shall share information on findings of compliance and noncompliance discovered upon reviewing the comparative analyses requested under subparagraph (B)(i) with the State where the group health plan is located or the State where the health insurance issuer is licensed to do business for coverage offered by a health insurance issuer in the group market, in accordance with paragraph (6)(B)(iii)(II).

(b) CONSTRUCTION.—Nothing in this section shall be construed—

(1) as requiring a group health plan (or health insurance coverage offered in connection with such a plan) to provide any mental health or substance use disorder benefits; or

(2) in the case of a group health plan (or health insurance coverage offered in connection with such a plan) that provides mental health or substance use disorder benefits, as affecting the terms and conditions of the plan or coverage relating to such benefits under the plan or coverage, except as provided in subsection (a).

(c) EXEMPTIONS.—

(1) SMALL EMPLOYER EXEMPTION.—

(A) IN GENERAL.—This section shall not apply to any group health plan (and group health insurance coverage offered in connection with a group health plan) for any plan year of a small employer.

(B) SMALL EMPLOYER.—For purposes of subparagraph (A), the term "small employer" means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 2 (or 1 in the case of an employer residing in a State that permits small groups to include a single individual) but not more than 50 employees on business days during the preceding calendar year.

(C) APPLICATION OF CERTAIN RULES IN DETERMINATION OF EMPLOYER SIZE.—For purposes of this paragraph—

(i) APPLICATION OF AGGREGATION RULE FOR EMPLOYERS.—Rules similar to the rules under subsections (b), (c), (m), and (o) of section 414 of the Internal Revenue Code of 1986 shall apply for purposes of treating persons as a single employer.

(ii) EMPLOYERS NOT IN EXISTENCE IN PRECEDING YEAR.—In the case of an employer which was not in existence throughout the preceding calendar year, the

determination of whether such employer is a small employer shall be based on the average number of employees that it is reasonably expected such employer will employ on business days in the current calendar year.

(iii) PREDECESSORS.—Any reference in this paragraph to an employer shall include a reference to any predecessor of such employer.

(2) COST EXEMPTION.—

(A) IN GENERAL.—With respect to a group health plan (or health insurance coverage offered in connection with such a plan), if the application of this section to such plan (or coverage) results in an increase for the plan year involved of the actual total costs of coverage with respect to medical and surgical benefits and mental health and substance use disorder benefits under the plan (as determined and certified under subparagraph (C)) by an amount that exceeds the applicable percentage described in subparagraph (B) of the actual total plan costs, the provisions of this section shall not apply to such plan (or coverage) during the following plan year, and such exemption shall apply to the plan (or coverage) for 1 plan year. An employer may elect to continue to apply mental health and substance use disorder parity pursuant to this section with respect to the group health plan (or coverage) involved regardless of any increase in total costs.

(B) APPLICABLE PERCENTAGE.—With respect to a plan (or coverage), the applicable percentage described in this subparagraph shall be—

(i) 2 percent in the case of the first plan year in which this section is applied; and

(ii) 1 percent in the case of each subsequent plan year.

(C) DETERMINATIONS BY ACTUARIES.—Determinations as to increases in actual costs under a plan (or coverage) for purposes of this section shall be made and certified by a qualified and licensed actuary who is a member in good standing of the American Academy of Actuaries. All such determinations shall be in a written report prepared by the actuary. The report, and all underlying documentation relied upon by the actuary, shall be maintained by the group health plan or health insurance issuer for a period of 6 years following the notification made under subparagraph (E).

(D) 6-MONTH DETERMINATIONS.—If a group health plan (or a health insurance issuer offering coverage in connection with a group health plan) seeks an exemption under this paragraph, determinations under subparagraph (A) shall be made after such plan (or coverage) has complied with this section for the first 6 months of the plan year involved.

(E) NOTIFICATION.—

(i) IN GENERAL.—A group health plan (or a health insurance issuer offering coverage in connection with a group health plan) that, based upon a certification

described under subparagraph (C), qualifies for an exemption under this paragraph, and elects to implement the exemption, shall promptly notify the Secretary, the appropriate State agencies, and participants and beneficiaries in the plan of such election.

(ii) REQUIREMENT.—A notification to the Secretary under clause (i) shall include—

(I) a description of the number of covered lives under the plan (or coverage) involved at the time of the notification, and as applicable, at the time of any prior election of the cost-exemption under this paragraph by such plan (or coverage);

(II) for both the plan year upon which a cost exemption is sought and the year prior, a description of the actual total costs of coverage with respect to medical and surgical benefits and mental health and substance use disorder benefits under the plan; and

(III) for both the plan year upon which a cost exemption is sought and the year prior, the actual total costs of coverage with respect to mental health and substance use disorder benefits under the plan.

(iii) CONFIDENTIALITY.—A notification to the Secretary under clause (i) shall be confidential. The Secretary shall make available, upon request and on not more than an annual basis, an anonymous itemization of such notifications, that includes—

(I) a breakdown of States by the size and type of employers submitting such notification; and

(II) a summary of the data received under clause (ii).

(F) AUDITS BY APPROPRIATE AGENCIES.—To determine compliance with this paragraph, the Secretary may audit the books and records of a group health plan or health insurance issuer relating to an exemption, including any actuarial reports prepared pursuant to subparagraph (C), during the 6 year period following the notification of such exemption under subparagraph (E). A State agency receiving a notification under subparagraph (E) may also conduct such an audit with respect to an exemption covered by such notification.

(d) SEPARATE APPLICATION TO EACH OPTION OFFERED.—In the case of a group health plan that offers a participant or beneficiary two or more benefit package options under the plan, the requirements of this section shall be applied separately with respect to each such option.

(e) DEFINITIONS.—For purposes of this section—

(1) AGGREGATE LIFETIME LIMIT.—The term "aggregate lifetime limit" means, with respect to benefits under a group health plan or health insurance coverage, a dollar limitation on the total amount that may be paid with respect to such benefits under the plan or health insurance coverage with respect to an individual or other coverage unit.

(2) ANNUAL LIMIT.—The term "annual limit" means, with respect to benefits under a group health plan or health insurance coverage, a dollar limitation on the total amount of benefits that may be paid with respect to such benefits in a 12-month period under the plan or health insurance coverage with respect to an individual or other coverage unit.

(3) MEDICAL OR SURGICAL BENEFITS.—The term "medical or surgical benefits" means benefits with respect to medical or surgical services, as defined under the terms of the plan or coverage (as the case may be), but does not include mental health or substance use disorder benefits.

(4) MENTAL HEALTH BENEFITS.—The term "mental health benefits" means benefits with respect to services for mental health conditions, as defined under the terms of the plan and in accordance with applicable Federal and State law.

(5) SUBSTANCE USE DISORDER BENEFITS.—The term "substance use disorder benefits" means benefits with respect to services for substance use disorders, as defined under the terms of the plan and in accordance with applicable Federal and State law.

(f) SECRETARY REPORT.—The Secretary shall, by January 1, 2012, and every two years thereafter, submit to the appropriate committees of Congress a report on compliance of group health plans (and health insurance coverage offered in connection with such plans) with the requirements of this section. Such report shall include the results of any surveys or audits on compliance of group health plans (and health insurance coverage offered in connection with such plans) with such requirements and an analysis of the reasons for any failures to comply.

(g) NOTICE AND ASSISTANCE.—The Secretary, in cooperation with the Secretaries of Health and Human Services and Treasury, as appropriate, shall publish and widely disseminate guidance and information for group health plans, participants and beneficiaries, applicable State and local regulatory bodies, and the National Association of Insurance Commissioners concerning the requirements of this section and shall provide assistance concerning such requirements and the continued operation of applicable State law. Such guidance and information shall inform participants and beneficiaries of how they may obtain assistance under this section, including, where appropriate, assistance from State consumer and insurance agencies.

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INTERNAL REVENUE CODE OF 1986

TITLE 26—INTERNAL REVENUE CODE

Subtitle K—Group Health Plan Requirements

CHAPTER 100—GROUP HEALTH PLAN REQUIREMENTS

Subchapter B—OTHER REQUIREMENTS

* * * * * * *

SEC. 9812. PARITY IN MENTAL HEALTH AND SUBSTANCE USE DISORDER BENEFITS.

(a) IN GENERAL.—

(1) AGGREGATE LIFETIME LIMITS.—In the case of a group health plan that provides both medical and surgical benefits and mental health or substance use disorder benefits—

(A) NO LIFETIME LIMIT.—If the plan does not include an aggregate lifetime limit on substantially all medical and surgical benefits, the plan may not impose any aggregate lifetime limit on mental health or substance use disorder benefits.

(B) LIFETIME LIMIT.—If the plan includes an aggregate lifetime limit on substantially all medical and surgical benefits (in this paragraph referred to as the "applicable lifetime limit"), the plan shall either—

(i) apply the applicable lifetime limit both to the medical and surgical benefits to which it otherwise would apply and to mental health and substance use disorder benefits and not distinguish in the application of such limit between such medical and surgical benefits and mental health and substance use disorder benefits; or

(ii) not include any aggregate lifetime limit on mental health or substance use disorder benefits that is less than the applicable lifetime limit.

(C) RULE IN CASE OF DIFFERENT LIMITS.—In the case of a plan that is not described in subparagraph (A) or (B) and that includes no or different aggregate lifetime limits on different categories of medical and surgical benefits, the Secretary shall establish rules under which subparagraph (B) is applied to such plan with respect to mental health and substance use disorder benefits by substituting for the applicable lifetime limit an average aggregate lifetime limit that is computed taking into account the weighted average of the aggregate lifetime limits applicable to such categories.

(2) ANNUAL LIMITS.—In the case of a group health plan that provides both medical and surgical benefits and mental health or substance use disorder benefits—

(A) NO ANNUAL LIMIT.—If the plan does not include an annual limit on substantially all medical and surgical benefits, the plan may not impose any annual limit on mental health or substance use disorder benefits.

(B) ANNUAL LIMIT.—If the plan includes an annual limit on substantially all medical and surgical benefits (in this paragraph referred to as the "applicable annual limit"), the plan shall either—

(i) apply the applicable annual limit both to medical and surgical benefits to which it otherwise would apply and to mental health and substance use disorder benefits and not distinguish in the application of such limit between such medical and surgical benefits and mental health and substance use disorder benefits; or

(ii) not include any annual limit on mental health or substance use disorder benefits that is less than the applicable annual limit.

(C) RULE IN CASE OF DIFFERENT LIMITS.—In the case of a plan that is not described in subparagraph (A) or (B) and that includes no or different annual limits on different categories of medical and surgical benefits, the Secretary shall establish rules under which subparagraph (B) is applied to such plan with respect to mental health and substance use disorder benefits by substituting for the applicable annual limit an average annual limit that is computed taking into account the weighted average of the annual limits applicable to such categories.

(3) FINANCIAL REQUIREMENTS AND TREATMENT LIMITATIONS.—

(A) IN GENERAL.—In the case of a group health plan that provides both medical and surgical benefits and mental health or substance use disorder benefits, such plan shall ensure that—

(i) the financial requirements applicable to such mental health or substance use disorder benefits are no more restrictive than the predominant financial requirements applied to substantially all medical and surgical benefits covered by the plan, and there are no separate cost sharing requirements that are applicable only with respect to mental health or substance use disorder benefits; and

(ii) the treatment limitations applicable to such mental health or substance use disorder benefits are no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits covered by the plan and there are no separate treatment limitations that are applicable only with respect to mental health or substance use disorder benefits.

(B) DEFINITIONS.—In this paragraph:

(i) FINANCIAL REQUIREMENT.—The term "financial requirement" includes deductibles, copayments, coinsurance, and out-of-pocket expenses, but excludes an aggregate lifetime limit and an annual limit subject to paragraphs (1) and (2).

(ii) PREDOMINANT.—A financial requirement or treatment limit is considered to be predominant if it is the most common or frequent of such type of limit or requirement.

(iii) TREATMENT LIMITATION.—The term "treatment limitation" includes limits on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment.

(4) AVAILABILITY OF PLAN INFORMATION.—The criteria for medical necessity determinations made under the plan with respect to mental health or substance use disorder benefits shall be made available by the plan administrator in accordance with regulations to any current or potential participant, beneficiary, or contracting provider upon request. The reason for any denial under the plan of reimbursement or payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary shall, on request or as otherwise required, be made available by the plan administrator to the participant or beneficiary in accordance with regulations.

(5) OUT-OF-NETWORK PROVIDERS.—In the case of a plan that provides both medical and surgical benefits and mental health or substance use disorder benefits, if the plan provides coverage for medical or surgical benefits provided by out-of-network providers, the plan shall provide coverage for mental health or substance use disorder benefits provided by out-of-network providers in a manner that is consistent with the requirements of this section.

(b) CONSTRUCTION.—Nothing in this section shall be construed—

(1) as requiring a group health plan to provide any mental health or substance use disorder benefits; or

(2) in the case of a group health plan that provides mental health or substance use disorder benefits, as affecting the terms and conditions of the plan relating to such benefits under the plan, except as provided in subsection (a).

(c) EXEMPTIONS.—

(1) SMALL EMPLOYER EXEMPTION.—

(A) IN GENERAL.—This section shall not apply to any group health plan for any plan year of a small employer.

(B) SMALL EMPLOYER.—For purposes of subparagraph (A), the term "small employer" means, with respect to a calendar year and a plan year, an employer who employed an average of at least 2 (or 1 in the case of an employer residing in a State that permits small groups to include a single individual) but not more than 50 employees on business days during the preceding calendar year. For purposes of the preceding sentence, all persons treated as a single employer under subsection (b), (c), (m), or (*o*) of section 414 shall be treated as 1 employer and rules similar to rules of subparagraphs (B) and (C) of section 4980D(d)(2) shall apply.

(2) COST EXEMPTION.—

(A) IN GENERAL.—With respect to a group health plan, if the application of this section to such plan results in an increase for the plan year involved of the actual total costs

of coverage with respect to medical and surgical benefits and mental health and substance use disorder benefits under the plan (as determined and certified under subparagraph (C)) by an amount that exceeds the applicable percentage described in subparagraph (B) of the actual total plan costs, the provisions of this section shall not apply to such plan during the following plan year, and such exemption shall apply to the plan for 1 plan year. An employer may elect to continue to apply mental health and substance use disorder parity pursuant to this section with respect to the group health plan involved regardless of any increase in total costs.

(B) APPLICABLE PERCENTAGE.—With respect to a plan, the applicable percentage described in this subparagraph shall be—

(i) 2 percent in the case of the first plan year in which this section is applied; and

(ii) 1 percent in the case of each subsequent plan year.

(C) DETERMINATIONS BY ACTUARIES.—Determinations as to increases in actual costs under a plan for purposes of this section shall be made and certified by a qualified and licensed actuary who is a member in good standing of the American Academy of Actuaries. All such determinations shall be in a written report prepared by the actuary. The report, and all underlying documentation relied upon by the actuary, shall be maintained by the group health plan for a period of 6 years following the notification made under subparagraph (E).

(D) 6-MONTH DETERMINATIONS.—If a group health plan seeks an exemption under this paragraph, determinations under subparagraph (A) shall be made after such plan has complied with this section for the first 6 months of the plan year involved.

(E) NOTIFICATION.—

(i) IN GENERAL.—A group health plan that, based upon a certification described under subparagraph (C), qualifies for an exemption under this paragraph, and elects to implement the exemption, shall promptly notify the Secretary, the appropriate State agencies, and participants and beneficiaries in the plan of such election.

(ii) REQUIREMENT.—A notification to the Secretary under clause (i) shall include—

(I) a description of the number of covered lives under the plan involved at the time of the notification, and as applicable, at the time of any prior election of the cost-exemption under this paragraph by such plan;

(II) for both the plan year upon which a cost exemption is sought and the year prior, a description of the actual total costs of coverage with respect to medical and surgical benefits and mental health and substance use disorder benefits under the plan; and

(III) for both the plan year upon which a cost exemption is sought and the year prior, the actual total costs of coverage with respect to mental health and substance use disorder benefits under the plan.

(iii) CONFIDENTIALITY.—A notification to the Secretary under clause (i) shall be confidential. The Secretary shall make available, upon request and on not more than an annual basis, an anonymous itemization of such notifications, that includes—

(I) a breakdown of States by the size and type of employers submitting such notification; and

(II) a summary of the data received under clause (ii).

(F) AUDITS BY APPROPRIATE AGENCIES.—To determine compliance with this paragraph, the Secretary may audit the books and records of a group health plan relating to an exemption, including any actuarial reports prepared pursuant to subparagraph (C), during the 6 year period following the notification of such exemption under subparagraph (E). A State agency receiving a notification under subparagraph (E) may also conduct such an audit with respect to an exemption covered by such notification.

(d) SEPARATE APPLICATION TO EACH OPTION OFFERED.—In the case of a group health plan that offers a participant or beneficiary two or more benefit package options under the plan, the requirements of this section shall be applied separately with respect to each such option.

(e) DEFINITIONS.—For purposes of this section:

(1) AGGREGATE LIFETIME LIMIT.—The term "aggregate lifetime limit" means, with respect to benefits under a group health plan, a dollar limitation on the total amount that may be paid with respect to such benefits under the plan with respect to an individual or other coverage unit.

(2) ANNUAL LIMIT.—The term "annual limit" means, with respect to benefits under a group health plan, a dollar limitation on the total amount of benefits that may be paid with respect to such benefits in a 12-month period under the plan with respect to an individual or other coverage unit.

(3) MEDICAL OR SURGICAL BENEFITS.—The term "medical or surgical benefits" means benefits with respect to medical or surgical services, as defined under the terms of the plan, but does not include mental health or substance use disorder benefits.

(4) MENTAL HEALTH BENEFITS.—The term "mental health benefits" means benefits with respect to services for mental health conditions, as defined under the terms of the plan and in accordance with applicable Federal and State law.

(5) SUBSTANCE USE DISORDER BENEFITS.—The term "substance use disorder benefits" means benefits with respect to services for substance use disorders, as defined under the terms of the plan and in accordance with applicable Federal and State law.

(6) COMPLIANCE PROGRAM GUIDANCE DOCUMENT.—

(A) IN GENERAL.—Not later than 12 months after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary, the Secretary of Labor, and the Secretary of Health and Human Services, in consultation with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury, shall issue a compliance program guidance document to help improve compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, and section 2799A–1 of the Public Health Service Act, as applicable. In carrying out this paragraph, the Secretaries may take into consideration the 2016 publication of the Department of Health and Human Services and the Department of Labor, entitled "Warning Signs - Plan or Policy Non-Quantitative Treatment Limitations (NQTLs) that Require Additional Analysis to Determine Mental Health Parity Compliance".

(B) EXAMPLES ILLUSTRATING COMPLIANCE AND NONCOMPLIANCE.—

(i) IN GENERAL.—The compliance program guidance document required under this paragraph shall provide illustrative, de-identified examples (that do not disclose any protected health information or individually identifiable information) of previous findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 2799A–1 of the Public Health Service Act, as applicable, based on investigations of violations of such sections, including—

(I) examples illustrating requirements for information disclosures and nonquantitative treatment limitations; and

(II) descriptions of the violations uncovered during the course of such investigations.

(ii) NONQUANTITATIVE TREATMENT LIMITATIONS.—To the extent that any example described in clause (i) involves a finding of compliance or noncompliance with regard to any requirement for nonquantitative treatment limitations, the example shall provide sufficient detail to fully explain such finding, including a full description of the criteria involved for approving medical and surgical benefits and the criteria involved for approving mental health and substance use disorder benefits.

(iii) ACCESS TO ADDITIONAL INFORMATION REGARDING COMPLIANCE.—In developing and issuing the compliance program guidance document required under this paragraph, the Secretaries specified in subparagraph (A)—

(I) shall enter into interagency agreements with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury to share findings

of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 2799A–1 of the Public Health Service Act, as applicable; and

(II) shall seek to enter into an agreement with a State to share information on findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 2799A–1 of the Public Health Service Act, as applicable.

(C) RECOMMENDATIONS.—The compliance program guidance document shall include recommendations to advance compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 2799A–1 of the Public Health Service Act, as applicable, and encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements. Such internal controls may include illustrative examples of nonquantitative treatment limitations on mental health and substance use disorder benefits, which may fail to comply with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 2799A–1 of the Public Health Service Act, as applicable, in relation to nonquantitative treatment limitations on medical and surgical benefits.

(D) UPDATING THE COMPLIANCE PROGRAM GUIDANCE DOCUMENT.—The Secretary, the Secretary of Labor, and the Secretary of Health and Human Services, in consultation with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury, shall update the compliance program guidance document every 2 years to include illustrative, de-identified examples (that do not disclose any protected health information or individually identifiable information) of previous findings of compliance and noncompliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 2799A–1 of the Public Health Service Act, as applicable.

(7) ADDITIONAL GUIDANCE.—

(A) IN GENERAL.—Not later than 12 months after the date of enactment of the Helping Families in Mental Health Crisis Reform Act of 2016, the Secretary, the Secretary of Labor, and the Secretary of Health and Human Services shall issue guidance to group health plans and health insurance issuers offering group or individual health insurance coverage to assist such plans and issuers in satisfying the requirements of this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 2799A–1 of the Public Health Service Act, as applicable.

(B) DISCLOSURE.—

(i) GUIDANCE FOR PLANS AND ISSUERS.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods that group health plans and health insurance issuers

offering group or individual health insurance coverage may use for disclosing information to ensure compliance with the requirements under this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 2799A–1 of the Public Health Service Act, (and any regulations promulgated pursuant to such sections, as applicable).

(ii) DOCUMENTS FOR PARTICIPANTS, BENEFICIARIES, CONTRACTING PROVIDERS, OR AUTHORIZED REPRESENTATIVES.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods that group health plans and health insurance issuers offering group or individual health insurance coverage may use to provide any participant, beneficiary, contracting provider, or authorized representative, as applicable, with documents containing information that the health plans or issuers are required to disclose to participants, beneficiaries, contracting providers, or authorized representatives to ensure compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 2799A–1 of the Public Health Service Act, as applicable, compliance with any regulation issued pursuant to such respective section, or compliance with any other applicable law or regulation. Such guidance shall include information that is comparative in nature with respect to—

(I) nonquantitative treatment limitations for both medical and surgical benefits and mental health and substance use disorder benefits;

(II) the processes, strategies, evidentiary standards, and other factors used to apply the limitations described in subclause (I); and

(III) the application of the limitations described in subclause (I) to ensure that such limitations are applied in parity with respect to both medical and surgical benefits and mental health and substance use disorder benefits.

(C) NONQUANTITATIVE TREATMENT LIMITATIONS.—The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods, processes, strategies, evidentiary standards, and other factors that group health plans and health insurance issuers offering group or individual health insurance coverage may use regarding the development and application of nonquantitative treatment limitations to ensure compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 2799A–1 of the Public Health Service Act, as applicable, (and any regulations promulgated pursuant to such respective section), including—

(i) examples of methods of determining appropriate types of nonquantitative treatment limitations with respect to both medical and surgical benefits and mental

health and substance use disorder benefits, including nonquantitative treatment limitations pertaining to—

(I) medical management standards based on medical necessity or appropriateness, or whether a treatment is experimental or investigative;

(II) limitations with respect to prescription drug formulary design; and

(III) use of fail-first or step therapy protocols;

(ii) examples of methods of determining—

(I) network admission standards (such as credentialing); and

(II) factors used in provider reimbursement methodologies (such as service type, geographic market, demand for services, and provider supply, practice size, training, experience, and licensure) as such factors apply to network adequacy;

(iii) examples of sources of information that may serve as evidentiary standards for the purposes of making determinations regarding the development and application of nonquantitative treatment limitations;

(iv) examples of specific factors, and the evidentiary standards used to evaluate such factors, used by such plans or issuers in performing a nonquantitative treatment limitation analysis;

(v) examples of how specific evidentiary standards may be used to determine whether treatments are considered experimental or investigative;

(vi) examples of how specific evidentiary standards may be applied to each service category or classification of benefits;

(vii) examples of methods of reaching appropriate coverage determinations for new mental health or substance use disorder treatments, such as evidence-based early intervention programs for individuals with a serious mental illness and types of medical management techniques;

(viii) examples of methods of reaching appropriate coverage determinations for which there is an indirect relationship between the covered mental health or substance use disorder benefit and a traditional covered medical and surgical benefit, such as residential treatment or hospitalizations involving voluntary or involuntary commitment; and

(ix) additional illustrative examples of methods, processes, strategies, evidentiary standards, and other factors for which the Secretary determines that additional guidance is necessary to improve compliance with this section, section 712 of the Employee Retirement Income Security Act of 1974, or section 2799A–1 of the Public Health Service Act, as applicable.

(D) PUBLIC COMMENT.—Prior to issuing any final guidance under this paragraph, the Secretary shall provide a public comment period of not less than 60 days during which any member of the public may provide comments on a draft of the guidance.

(8) COMPLIANCE REQUIREMENTS.—

(A) NONQUANTITATIVE TREATMENT LIMITATION (NQTL) REQUIREMENTS.—Beginning 45 days after the date of enactment of this paragraph, in the case of a group health plan that provides both medical and surgical benefits and mental health or substance use disorder benefits and that imposes nonquantitative treatment limitations (referred to in this section as "NQTL") on mental health or substance use disorder benefits, the plan shall perform comparative analyses of the design and application of NQTLs in accordance with subparagraph (B), and make available to the applicable State authority (or, as applicable, the Secretary), upon request, the following information:

(i) The specific plan terms regarding the NQTL, that applies to such plan or coverage, and a description of all mental health or substance use disorder and medical or surgical benefits to which it applies in each respective benefits classification.

(ii) The factors used to determine that the NQTL 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 NQTL 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 design the NQTL, as written, and the operation processes and strategies as written and in operation that are used to apply the NQTL for mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to design the NQTL, as written, and the operation processes and strategies as written and in operation that are used to apply the NQTL to medical or surgical benefits.

(v) A disclosure of the specific findings and conclusions reached by the plan that the results of the analyses described in this subparagraph indicate that the plan is in compliance with this section.

(B) SECRETARY REQUEST PROCESS.—

(i) SUBMISSION UPON REQUEST.—The Secretary shall request that a group health plan submit the comparative analyses described in subparagraph (A) for plans that involve potential violations of this section or complaints regarding noncompliance with this section that concern NQTLs and any other instances in which the Secretary determines appropriate. The Secretary shall request not fewer than 20 such analyses per year.

(ii) ADDITIONAL INFORMATION.—In instances in which the Secretary has concluded that the plan has not submitted sufficient information for the Secretary

to review the comparative analyses described in subparagraph (A), as requested under clause (i), the Secretary shall specify to the plan the information the plan or coverage must submit to be responsive to the request under clause (i) for the Secretary to review the comparative analyses described in subparagraph(A) for compliance with this section. Nothing in this paragraph shall require the Secretary to conclude that a plan is in compliance with this section solely based upon the inspection of the comparative analyses described in subparagraph (A), as requested under clause (i).

(iii) REQUIRED ACTION.—

(I) IN GENERAL.—In instances in which the Secretary has reviewed the comparative analyses described in subparagraph (A), as requested under clause (i), and determined that the plan is not in compliance with this section, the plan—

(aa) shall specify to the Secretary the actions the plan will take to be in compliance with this section and provide to the Secretary comparative analyses described in subparagraph (A) that demonstrate compliance with this section not later than 45 days after the initial determination by the Secretary that the plan is not in compliance; and

(bb) following the 45-day corrective action period under item (aa), if the Secretary determines that the plan still is not in compliance with this section, not later than 7 days after such determination, shall notify all individuals enrolled in the plan or coverage that the plan has been determined to be not in compliance with this section.

(II) EXEMPTION FROM DISCLOSURE.—Documents or communications produced in connection with the Secretary's recommendations to the plan or coverage shall not be subject to disclosure pursuant to section 552 of title 5, United States Code.

(iv) REPORT.—Not later than 1 year after the date of enactment of this paragraph, and not later than October 1 of each year thereafter, the Secretary shall submit to Congress, and make publicly available, a report that contains—

(I) a summary of the comparative analyses requested under clause (i), including the identity of each plan that is determined to be not in compliance after the final determination by the Secretary described in clause (iii)(I)(bb);

(II) the Secretary's conclusions as to whether each plan submitted sufficient information for the Secretary to review the comparative analyses requested under clause (i) for compliance with this section;

(III) for each plan that did submit sufficient information for the Secretary to review the comparative analyses requested under clause (i), the Secretary's conclusions as to whether and why the plan or coverage is in compliance with the requirements under this section;

(IV) the Secretary's specifications described in clause (ii) for each plan that the Secretary determined did not submit sufficient information for the Secretary to review the comparative analyses requested under clause (i) for compliance with this section; and

(V) the Secretary's specifications described in clause (iii) of the actions each plan hat the Secretary determined is not in compliance with this section must take to be in compliance with this section, including the reason why the Secretary determined the plan or coverage is not in compliance.

(C) COMPLIANCE PROGRAM GUIDANCE DOCUMENT UPDATE PROCESS.—

(i) IN GENERAL.—The Secretary shall include instances of noncompliance that the Secretary discovers upon reviewing the comparative analyses requested under subparagraph (B)(i) in the compliance program guidance document described in paragraph (6), as it is updated every 2 years, except that such instances shall not disclose any protected health information or individually identifiable information.

(ii) GUIDANCE AND REGULATIONS.—Not later than 18 months after the date of enactment of this paragraph, the Secretary shall finalize any draft or interim guidance and regulations relating to mental health parity under this section. Such draft guidance shall include guidance to clarify the process and timeline for current and potential participants and beneficiaries (and authorized representatives and health care providers of such participants and beneficiaries) with respect to plans to file complaints of such plans or issuers being in violation of this section, including guidance, by plan type, on the relevant State, regional, or national office with which such complaints should be filed.

(iii) STATE.—The Secretary shall share information on findings of compliance and noncompliance discovered upon reviewing the comparative analyses requested under subparagraph (B)(i) with the State where the group health plan is located or the State where the health insurance issuer is licensed to do business for coverage offered by a health insurance issuer in the group market, in accordance with paragraph (6)(B)(iii)(II).

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