

requirements that might significantly or uniquely affect small government entities. Thus, the requirements of section 203 of the UMRA do not apply to this rule.

5. Executive Order 13132: Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among various levels of government."

This rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among various levels of government, as specified in Executive Order 13132. This rule addresses the authorization of pre-existing State rules. Thus, Executive Order 13132 does not apply to this rule.

6. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." This rule does not have tribal implications, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

7. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

Executive Order 13045 applies to any rule that: (1) Is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably

feasible alternatives considered by the Agency.

This rule is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866 and because the Agency does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

8. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This rule is not subject to Executive Order 13211, "Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) because it is not a "significant regulatory action" as defined under Executive Order 12866.

9. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law 104-113, 12(d) (15 U.S.C. 272) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus bodies. The NTTAA directs EPA to provide Congress, through the OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This rule does not involve "technical standards" as defined by the NTTAA. Therefore, EPA is not considering the use of any voluntary consensus standards.

10. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low Income Populations

To the greatest extent practicable and permitted by law, and consistent with the principles set forth in the report on the National Performance Review, each Federal agency must make achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health and environmental effects of its programs, policies, and activities on minority populations and low-income populations in the United States and its territories and possessions, the District of Columbia, the Commonwealth of Puerto Rico, and the Commonwealth of

the Mariana Islands. Because this rule addresses authorizing pre-existing State rules and there are no anticipated significant adverse human health or environmental effects, the rule is not subject to Executive Order 12898.

11. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective on the date the rule is published in the **Federal Register**.

List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Indians-lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

Authority: This action is issued under the authority of sections 2002(a), 3006 and 7004(b) of the Solid Waste Disposal Act as amended 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: July 14, 2005.

Michelle Pirzadeh,

Acting Regional Administrator, Region 10.

[FR Doc. 05-14545 Filed 7-21-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

45 CFR Part 146

[CMS-4094-F3]

RIN 0938-AN22

Amendment to the Interim Final Regulation for Mental Health Parity

AGENCY: Centers for Medicare & Medicaid Services (CMS), DHHS.

ACTION: Amendment to interim final regulation.

SUMMARY: This document contains an amendment to the interim final regulation that implements the Mental Health Parity Act (MHPA) to conform the sunset date of the regulation to the sunset date of the statute under legislation passed by the 108th Congress.

DATES: *Effective date:* The amendment to the regulation is effective August 22, 2005.

Applicability dates: Under the amendment, the requirements of the MHPA interim final regulation apply to group health plans and health insurance issuers offering health insurance coverage in connection with a group health plan during the period commencing August 22, 2005 through December 31, 2005. Under the extended sunset date, MHPA requirements do not apply to benefits for services furnished after December 31, 2005.

FOR FURTHER INFORMATION CONTACT: Dave Mlawsky, Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, at 1-877-267-2323, ext. 61565.

SUPPLEMENTARY INFORMATION:

I. Background

The Mental Health Parity Act of 1996 (MHPA) was enacted on September 26, 1996 (Pub. L. 104-204). MHPA amended the Public Health Service Act (PHS Act) and the Employee Retirement Income Security Act of 1974 (ERISA) to provide for parity in the application of annual and lifetime dollar limits on mental health benefits with dollar limits on medical/surgical benefits. Provisions implementing MHPA were later added to the Internal Revenue Code of 1986 (Code) under the Taxpayer Relief Act of 1997 (Pub. L. 105-34).

The provisions of MHPA are set forth in Title XXVII of the PHS Act, Part 7 of Subtitle B of Title I of ERISA, and Chapter 100 of Subtitle K of the Code. The Secretaries of Health and Human Services, Labor, and the Treasury share jurisdiction over the MHPA provisions. These provisions are substantially similar, except as follows:

The MHPA provisions in the PHS Act generally apply to health insurance issuers that offer health insurance coverage in connection with group health plans and to certain State and local governmental plans. States, in the first instance, enforce the PHS Act for issuers. Only if a State does not substantially enforce the MHPA provisions under its insurance laws will the Department of Health and Human

Services enforce the provisions, through the imposition of civil money penalties. Moreover, no enforcement action may be taken by the Secretary of Health and Human Services against any group health plan except certain State and local governmental plans.

The MHPA provisions in ERISA generally apply to all group health plans other than governmental plans, church plans, and certain other plans. These provisions also apply to health insurance issuers that offer health insurance coverage in connection with those group health plans. Generally, the Secretary of Labor enforces the MHPA provisions in ERISA, except that no enforcement action may be taken by the Secretary against issuers. However, individuals may generally pursue actions against issuers under ERISA and, in some circumstances, under State law.

The MHPA provisions in the Code generally apply to all group health plans other than governmental plans, but they do not apply to health insurance issuers. A taxpayer that fails to comply with these provisions may be subject to an excise tax under section 4980D of the Code.

II. Overview of MHPA

The MHPA provisions are set forth in section 2705 of the PHS Act, section 712 of ERISA, and section 9812 of the Code. MHPA applies to a group health plan (or health insurance coverage offered by issuers in connection with a group health plan) that provides both medical/surgical benefits and mental health benefits. MHPA's original text included a sunset provision specifying that MHPA's provisions would not apply to benefits for services furnished on or after September 30, 2001. On December 22, 1997, the Departments of Health and Human Services, Labor, and the Treasury issued interim final regulations under MHPA in the **Federal Register** (62 FR 66931). The interim final regulations included this statutory sunset date.

On January 10, 2002, President Bush signed H.R. 3061 (Pub. L. 107-116), the 2002 Appropriations Act for the Departments of Labor, Health and Human Services, and Education ("Appropriations Act"). (During the 107th Congress, legislation was passed by the Senate to amend and expand the substantive provisions of MHPA. This legislation was offered as an amendment to the provisions of H.R. 3061. The Conference Report accompanying the underlying provisions of H.R. 3061 states that instead of the amendment proposed by the Senate, the amendment to MHPA contained in H.R. 3061

extends the original sunset date of MHPA, so that MHPA's provisions will not apply to benefits for services furnished on or after December 31, 2002, H.R. Rep. 107-342, at 170 (2001)). This legislation extended MHPA's original sunset date under the PHS Act, ERISA, and the Code, so that MHPA's provisions in all three statutes would not sunset until December 31, 2002.

On March 9, 2002, President Bush signed H.R. 3090 (Pub. L. 107-147), the Job Creation and Worker Assistance Act of 2002 ("Job Creation Act"). That legislation amended section 9812 of the Code (the mental health parity provisions), but did not amend the corresponding MHPA provisions in the PHS Act or ERISA. The Job Creation Act extended the sunset date under the Code to December 31, 2003.

On December 2, 2002, President Bush signed H.R. 5716 (Pub. L. 107-313), the Mental Health Parity Reauthorization Act of 2002. This legislation further extended MHPA's sunset date under the PHS Act and ERISA so that MHPA's provisions would apply to any services furnished before December 31, 2003.

On December 19, 2003, President Bush signed S. 1929 (Pub. L. 108-197), the Mental Health Parity Reauthorization Act of 2003. That legislation further extends MHPA's sunset date under the PHS Act and ERISA so that MHPA's provisions apply to any services furnished before December 31, 2004.

As a result of those pieces of legislation, the Department published conforming changes to the interim final mental health parity regulations, conforming the regulatory sunset date to the new statutory sunset date. The Department also made conforming changes extending the duration of the increased cost exemption to be consistent with the new sunset date (68 FR 38206, June 27, 2003).

On October 4, 2004, President Bush signed H.R. 1308 (Pub. L. 108-311), the Working Families Tax Relief Act of 2004. That legislation further extends MHPA's sunset date under the PHS Act and ERISA so that MHPA's provisions apply to any services furnished through December 31, 2005. It also extends MHPA's sunset date under the Tax Code so that MHPA's provisions apply to any services furnished from October 4, 2002, through December 31, 2005.

This statutory amendment has not altered MHPA's scope. It continues to apply to a group health plan (or health insurance coverage offered by issuers in connection with a group health plan) that provides both medical/surgical benefits and mental health benefits. (The parity requirements under MHPA,

the interim regulations, and the amendment to the interim regulations do not apply to any group health plan (or health insurance coverage offered in connection with a group health plan) for any plan year of a small employer. The term "small employer" is defined as an employer who employed an average of at least 2 but not more than 50 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year.) As a result of this statutory amendment, and to assist employers, plan sponsors, health insurance issuers, and workers, the Department is publishing this amendment to the interim final regulations, conforming the regulatory sunset date to the new statutory sunset date. The Department is making the effective date of this amendment to the interim final regulations effective as of August 22, 2005. Since the extension of this sunset date is essentially self-implementing, this amendment to the MHPA regulations is published on an interim final basis under section 2792 of the PHS Act.

This amendment to the interim final regulations is adopted under the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92), as added by HIPAA (Pub. L. 104-191), and amended by MHPA (Pub. L. 104-204, as amended by Pub. L. 107-116, Pub. L. 107-313, Pub. L. 108-197, and Pub. L. 108-311).

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Regulatory Impact Statement

Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory

approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). According to the terms of the Executive Order, it has been determined that this action is not a "significant regulatory action" within the meaning of the Executive Order. Rather, it is an amendment to the 1997 interim final regulations that makes no substantive changes to those regulations, and merely extends the regulatory sunset date to conform to the new statutory sunset date added by Public Law 108-696. Because it is not a major rule, we are not required to perform an assessment of the costs and savings.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This rule will have no consequential effect on the governments mentioned or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this final rule and have determined that it will not have a substantial effect on State or local governments.

We have reviewed this rule and determined that, under the provisions of Public Law 104-121, the Contract with America Act, it is not a major rule.

List of Subjects in 45 CFR Part 146

Health care, Health insurance, Reporting and recordkeeping requirements, State regulation of health insurance.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 45 CFR part 146 as follows:

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

■ 1. The authority citation for part 146 is revised to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg-63, 300gg-91, and 300gg-92), as added by HIPAA (Pub. L. 104-191, 110 Stat. 1936), and amended by MHPA (Pub. L. 104-204, 110 Stat. 2944, as amended by Pub. L. 107-116, 115 Stat. 2177; Pub. L. 107-313, 116 Stat. 2457; Pub. L. 108-197, 117 Stat. 2898; and Pub. L. 108-311, 118 Stat. 1166), NMHPA (Pub. L. 104-204, 110 Stat. 2935), and WHCRA (Pub. L. 105-277, 112 Stat. 2681-436), sec. 102(c) of HIPAA.

§ 146.136 [Amended]

■ 2. In § 146.136, the following amendments are made:

■ a. The last sentence of paragraph (f)(1) is amended by removing the date "December 31, 2004" and adding in its place the date "December 31, 2005."

■ b. Paragraph (g)(2) is amended by removing the date "December 31, 2004" and adding in its place the date "January 1, 2006."

■ c. Paragraph (i) is revised to read as follows:

§ 146.136 Parity in the application of certain limits to mental health benefits.

* * * * *

(i) *Sunset.* This section does not apply to benefits for services furnished after December 31, 2005.

Dated: January 19, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Dated: April 11, 2005.

Michael O. Leavitt,

Secretary, Department of Health and Human Services.

[FR Doc. 05-14504 Filed 7-21-05; 8:45 am]

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