

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 8, 2004.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.167 is amended by revising the table in paragraph (a) to read as follows:

§ 180.167 Nicotine-containing compounds; tolerances for residues.

(a) * * *

Commodity	Parts per million	Expiration/Revocation Date
Cucumber	2.0	12/4/05
Lettuce	2.0	12/4/05
Tomato	2.0	12/4/05

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■ 3. Section 180.173 is amended by revising the table in paragraph (a) to read as follows:

§ 180.173 Ethion; tolerances for residues.

(a) * * *

Commodity	Parts per million	Expiration/Revocation Date
Cattle, fat	0.2	10/1/08
Cattle, meat (fat basis)	0.2	10/1/08
Cattle, meat by-products	0.2	10/1/08
Citrus, dried pulp	25.0	10/1/08
Fruit, citrus, group 10	5.0	10/1/08
Goat, fat	0.2	10/1/08
Goat, meat	0.2	10/1/08
Goat, meat by-products	0.2	10/1/08
Hog, fat	0.2	10/1/08
Hog, meat	0.2	10/1/08
Hog, meat by-products	0.2	10/1/08
Horse, fat	0.2	10/1/08
Horse, meat	0.2	10/1/08
Horse, meat by-products	0.2	10/1/08
Milk, fat, reflecting negligible residues in milk	0.5	10/1/08
Sheep, fat	0.2	10/1/08

Commodity	Parts per million	Expiration/Revocation Date
Sheep, meat	0.2	10/1/08
Sheep, meat by-products	0.2	10/1/08

* * * * *

§ 180.179 [Removed]

■ 4. Section 180.179 is removed.
 ■ 5. Section 180.276 is amended by revising paragraph (a) to read as follows:

§ 180.276 Formetanate hydrochloride; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide formetanate hydrochloride (m-[[[(dimethylamino)methylene]amino]phenyl methylcarbamate hydrochloride) in or on raw agricultural commodities as follows:

Commodity	Parts per million
Apple	3.0
Grapefruit	4.0
Lemon	4.0
Lime	4.0
Nectarine	4.0
Orange, sweet	4.0
Peach	5.0
Pear	3.0
Tangerine	4.0

* * * * *

§ 180.307 [Removed]

■ 6. Section 180.307 is removed.

§ 180.319 [Amended]

■ 7. Section 180.319 is amended by removing from the table the first entry for Isopropyl m-chlorocarbanilate (CIPC) which is the entry for “spinach.”

■ 8. Section 180.325 is revised to read as follows:

§ 180.325 2-(m-Chlorophenoxy) propionic acid; tolerances for residues.

(a) *General.* A tolerance is established for negligible residues of the plant regulator 2-(m-chlorophenoxy) propionic acid from application of the acid or of 2-(m-chlorophenoxy)propionamide in or on the following raw agricultural commodity:

Commodity	Parts per million	Expiration/Revocation Date
Pineapple	0.3	2/1/07

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

■ 9. Section 180.341 is amended by revising paragraph (a) to read as follows:

§ 180.341 2,4-Dinitro-6-octylphenyl crotonate and 2,6-dinitro-4-octylphenyl crotonate; tolerances for residues.

(a) *General.* Tolerances are established for combined negligible residues of a fungicide and insecticide that is a mixture of 2,4-dinitro-6-octylphenyl crotonate and 2,6-dinitro-4-octylphenyl crotonate in or on raw agricultural commodities as follows:

Commodity	Parts per million
Apple ¹	0.1
Grape ¹	0.1

¹There are no U.S. registrations on apple and grape as of October 24, 2002.

* * * * *

§ 180.344, 180.382, 180.424, 180.1012, 180.1051, and 180.1078 [Removed]

■ 10. Sections 180.344, 180.382, 180.424, 180.1012, 180.1051, and 180.1078 are removed.

[FR Doc. 04-16718 Filed 7-22-04; 8:45 am]

BILLING CODE 6560-50-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

45 CFR Part 146

[CMS-2152-F2]

RIN 0938-AL42

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 23, 2004.

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 23, 2004, through December 30, 2004. Under the extended sunset date, MHPA requirements do not apply to benefits for services furnished on or after December 31, 2004.

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.

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 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. 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 23, 2004. 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, and Pub. L. 108-197).

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), section 1102(b) of the Social Security Act, 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 108-197. 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.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

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), and amended by MHPA (Pub. L. 104-204, as amended by Pub. L. 107-116, Pub. L. 107-313, and Pub. L. 108-197), NMHPA (Pub. L. 104-204), and WHCRA (Pub. L. 105-277), 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, 2003" and adding in its place the date "December 31, 2004."

■ b. Paragraph (g)(2) is amended by removing the date "December 31, 2003" and adding in its place the date "December 31, 2004."

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

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

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(i) *Sunset.* This section does not apply to benefits for services furnished on or after December 31, 2004.

Dated: April 2, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 20, 2004.

Tommy G. Thompson,

Secretary, Department of Health and Human Services.

[FR Doc. 04-16826 Filed 7-22-04; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

45 CFR Part 146

[CMS-2033-F]

RIN 0938-AK00

Requirements for the Group Health Insurance Market; Non-Federal Governmental Plans Exempt From HIPAA Title I Requirements

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

ACTION: Final rule.

SUMMARY: This rule finalizes existing exemption election requirements that