

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.

* * * * *

(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]

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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

apply to self-funded non-Federal governmental plans. In it, we clarify the conditions under which plan sponsors may exempt these plans from most of the requirements of title XXVII of the PHS Act, and provide guidance on the procedures, limitations, and documentation associated with exemption elections. Finally, we revise the requirements to reinforce beneficiary protections for exemption elections.

DATES: The regulations amending 45 CFR 146.180 became effective on September 24, 2002.

FOR FURTHER INFORMATION CONTACT: David Holstein (410) 786-1565.

SUPPLEMENTARY INFORMATION:

I. Background

Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) added a new title XXVII to the Public Health Service (PHS) Act to establish various reforms to the group and individual health insurance markets. The group market reforms are contained under Part A of title XXVII, which includes, among other things, guaranteed availability of coverage to small group market employers and renewability of coverage in the small and large group markets; limitations on pre-existing condition exclusion periods; special enrollment periods under certain circumstances; and prohibition of discrimination against individual participants and beneficiaries based on health status.

Part A of title XXVII was amended by the Newborns' and Mothers' Health Protection Act of 1996 (NMHPA), the Mental Health Parity Act of 1996 (MHPA), and the Women's Health and Cancer Rights Act of 1998 (WHCRA), which added new sections 2704, 2705 and 2706 (subpart 2 of Part A of title XXVII), respectively. NMHPA provides protections for mothers and newborn children for hospital stays following childbirth. MHPA, which applies to group health plans sponsored by employers with more than 50 employees, provides for parity between annual and lifetime dollar limits applicable to mental health benefits, and annual and lifetime dollar limits applicable to medical and surgical benefits. Originally, the MHPA sunset date was September 30, 2001, but subsequent legislation (Pub. L. 107-116 and Pub. L. 107-313) respectively extended the sunset date to December 31, 2002, and December 31, 2003. WHCRA requires group health plans that provide medical and surgical benefits for mastectomies to cover, among other things, reconstructive

surgery and prostheses following a mastectomy.

Section 2721(b)(2) of the PHS Act, as added by HIPAA and implemented at 45 CFR 146.180, permits non-Federal governmental employers to elect to exempt self-funded portions of their group health plans (that is, benefits not provided through health insurance coverage) from most of the requirements of title XXVII of the PHS Act. (This practice is sometimes referred to as "opting out of HIPAA.") However, health plans cannot be exempted from certification and disclosure of creditable coverage requirements under section 2701(e) of the PHS Act.

II. Summary of Provisions of the Interim Final Rule With Comment Period

On July 26, 2002, we published in the **Federal Register** (67 FR 48802) an interim final rule with comment period, "Technical Change to Requirements for the Group Health Insurance Market; Non-Federal Governmental Plans Exempt From HIPAA Title I Requirements" that amended existing exemption election requirements at § 146.180 that apply to self-funded non-Federal governmental plans. In the interim final rule with comment period, we clarified the conditions under which plan sponsors may exempt these plans from most of the requirements of title XXVII of the PHS Act, provided guidance on the procedures, limitations, and documentation associated with exemption elections, revised the exemption election requirements to reinforce beneficiary protections, and made a technical correction to § 146.150 "Guaranteed availability of coverage for employees in the small group market."

We refer the reader to the July 26, 2002, interim final rule with comment period for greater detail.

III. Analysis of and Responses to Public Comments

We received no public comments on the July 26, 2002, interim final rule.

IV. Provisions of the Final Regulations

The provisions of this final rule are identical to the provisions of the July 26, 2002, interim final rule with comment period.

V. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for

review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We received no comments.

The reporting and disclosure requirements referenced under § 146.180(b), (g), and (h) are currently approved under OMB number 0938-0702 (HIPAA Group Market Information Collection Requirements).

Under paragraph (e) of § 146.180, CMS may require that additional information be submitted after receiving an election to opt out. The burden of this requirement is the time it takes to gather and submit the additional information. This type of information collection is exempt from the requirements of the PRA under section 1320.4 as it is a collection of information during the conduct of an administrative action.

As required by section 3504(h) of the PRA, we have submitted a copy of this document to OMB for its review of these information collection requirements.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Attn: Julie Brown, Room C5-14-03, 7500 Security Boulevard, Baltimore, MD 21244-1850; and
Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer.

VI. Regulatory Impact Statement

We have examined the impacts of this final 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). This final rule is not economically significant and is not a major rule.

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. This final rule will have no significant impact on small businesses.

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 final rule does not impose unfunded mandates on State, local, or tribal governments.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates 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 determined that this final rule does not significantly affect the rights, roles, and responsibilities of State or local governments.

The July 26, 2002, interim final rule with comment period was reviewed by

the Office of Management and Budget (OMB) in accordance with provisions of Executive Order 12866.

List of Subjects in 45 CFR Part 146

Health care, Health insurance, Reporting and recordkeeping requirements.

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

■ Accordingly, the interim final rule with comment period amending 45 CFR part 146, which was published on July 26, 2002, in the **Federal Register** at 67 FR 48802–48814 is adopted as a final rule without change.

(Catalog of Federal Domestic Assistance Program No. 93.773), (Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: July 28, 2003.

Thomas A. Scully,
Administrator, Centers for Medicare & Medicaid Services.

Dated: March 1, 2004.

Tommy G. Thompson,
Secretary.

[FR Doc. 04–16792 Filed 7–22–04; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 031104274–4011–02; I.D. 071604E]

Fisheries of the Northeastern United States; Atlantic Mackerel, Squid, and Butterfish Fisheries; Inseason Adjustment of the Quarter III Fishery for Loligo Squid

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

ACTION: Inseason adjustment.

SUMMARY: NMFS announces that the Regional Administrator, Northeast Region, NMFS (Regional Administrator) is decreasing the commercial Loligo squid quota for Quarter III in the Exclusive Economic Zone (EEZ). This inseason adjustment is necessary due to overages in the commercial quota landed in the Quarter 1.

DATES: Effective 0001 hours, July 20, 2004, through 2400 hours, September 30, 2004.

FOR FURTHER INFORMATION CONTACT: Don Frei, Fishery Management Specialist, 978–281–9221, fax 978–281–9135, e-mail don.frei@noaa.gov.

SUPPLEMENTARY INFORMATION: Section 648.21 (f)(2) requires the Regional Administrator to subtract any overages of *Loligo* squid commercial quota landed during Quarter I from the allocation for Quarter III. Accordingly, the Regional Administrator, based on dealer reports and other available information, has determined that there was a 5.6 percent overage in Quarter I *Loligo* squid directed fishery. Therefore, the quota for the directed fishery for *Loligo* squid in Quarter III is reduced from 6,435,130 lb (2,918.9 mt) to 5,733,152 lb (2,600.5 mt). The regulations governing the Atlantic mackerel, squid, and butterfish fisheries require notification to the public of this adjustment.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: July 19, 2004.

Alan D. Risenhoover,
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.
[FR Doc. 04–16835 Filed 7–20–04; 3:58 pm]

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