PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 1. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Amend § 424.32 by—

■ A. Revising paragraphs (d)(1)(v); (d)(1)(vi); (d)(3)(ii), and (d)(4) introductory text.

■ B. Redesignating (d)(4)(iii) as paragraph (d)(4)(v).

■ C. Adding paragraphs (d)(4)(iii) and (iv).

The revisions and additions read as follows:

§ 424.32 Basic requirements for all claims.

(d) * * *

(1) * * *

(v) *Initial Medicare claim* means a claim submitted to Medicare for payment under Part A or Part B of the Medicare Program under title XVIII of the Act for initial processing, including claims sent to Medicare for the first time for secondary payment purposes. Initial Medicare claim excludes any adjustment or appeal of a previously submitted claim, and claims submitted for payment under Part C of the Medicare program under title XVIII of the Act.

(vi) *Physician, practitioner, facility, or supplier* is a Medicare provider or supplier other than a provider of services.

* * * * *

(3) * * *

(i) * * *

(ii) The entity submitting the claim is a small provider of services or small supplier.

(4) *Unusual cases.* The Secretary may waive the requirement of paragraph (d)(2) of this section in unusual cases as the Secretary finds appropriate. Unusual cases are deemed to exist in the following situations:

* * * * *

(iii) The entity submitting the claim submits fewer than 10 claims to Medicare per month, on average.

(iv) The entity submitting the claim only furnishes services outside of the U.S. territory.

* * * * *

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

Dated: May 2, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: August 15, 2005.

Michael O. Leavitt,

Secretary.

Editorial Note: This document was received at the **Federal Register** on November 17, 2005.

[FR Doc. 05–23080 Filed 11–23–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services

45 CFR Parts 144, 146, 148, and 150

[CMS–4091–F]

RIN 0938–AN35

Federal Enforcement in Group and Individual Health Insurance Markets

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

ACTION: Final rule.

SUMMARY: This rule makes final an interim final rule that details procedures we use for enforcing title XXVII of the Public Health Service Act as added by the Health Insurance Portability and Accountability Act of 1996, and as amended by the Mental Health Parity Act of 1996, the Newborns' and Mothers' Health Protection Act of 1996, and the Women's Health and Cancer Rights Act of 1998. Specifically, we are responsible for enforcing title XXVII requirements in States that do not enact the legislation necessary to enforce those requirements, or otherwise fail to substantially enforce the requirements. We are also responsible for taking enforcement actions against non-Federal governmental plans. The regulation describes the process we use in both enforcement contexts. This final rule deletes an appendix to the interim rule that listed examples of violations of title XXVII and corrects the description of a cross-reference, but makes no substantive changes to the interim final rule.

DATES: These regulations are effective on December 27, 2005.

FOR FURTHER INFORMATION CONTACT: David Mlawsky (877) 267–2323, ext. 61565.

SUPPLEMENTARY INFORMATION

I. Background

Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) created a new title XXVII of the Public Health Service (PHS) Act (42 U.S.C. 300gg, *et seq.*) that requires group health plans and health insurance issuers to provide certain guarantees for availability and renewability of health coverage in the group and individual health insurance markets.

HIPAA created a series of parallel provisions that were placed in the Employee Retirement Income Security Act (ERISA), which is within the jurisdiction of the Department of Labor; the Public Health Service (PHS) Act, which is within the jurisdiction of the Department of Health and Human Services; and the Internal Revenue Code, which is within the jurisdiction of the Department of the Treasury. These ''shared provisions'' set forth Federal requirements relating to portability of and access to group health plan coverage, as well as group health insurance coverage provided by issuers. The shared provisions contain rules limiting the use of preexisting condition exclusion periods, and prohibiting discrimination against participants and beneficiaries based on health status.

Section 104 of Title I of HIPAA requires that the Secretaries of the three Departments ensure through an interagency Memorandum of Understanding (MOU) that regulations, rulings, and interpretations issued by each of the Departments relating to the same matter over which two or more departments have jurisdiction, are administered so as to have the same effect at all times. Under section 104, the Departments, through the MOU, are to provide for coordination of policies relating to enforcement of the same requirements in order to have a coordinated enforcement strategy that avoids duplication of enforcement efforts and assigns priorities in enforcement. The Secretaries of the three departments signed and published the MOU in 1999 (64 FR 70164).

HIPAA also added certain provisions governing insurance in the group and individual markets, and with respect to non-Federal governmental plans, which are contained only in the Public Health Service Act and are not within the regulatory jurisdiction of the Department of Labor or the Department of the Treasury.

Under section 101(b) of HIPAA the Department of Labor is not authorized to enforce any of the portability requirements of part 7 of ERISA (the ''shared'' provisions) against a health insurance issuer offering health

insurance coverage in connection with a group health plan, although individuals covered under ERISA can bring suit against the issuer. Also, governmental plans, while they are defined in section 3(32) of ERISA, are exempt from ERISA requirements. (See section 4(b)(1) of ERISA.) Thus, the scope of the MOU is limited, with respect to coordination of enforcement activities, to enforcement of shared provisions. Enforcement of these provisions constitutes only a relatively small portion of our responsibilities.

The Newborns' and Mothers' Health Protection Act of 1996 (NMHPA) amended the PHS Act and ERISA (with corresponding provisions in the Tax Code) to provide protections for mothers and their newborn children with regard to the length of hospital stay following childbirth. The Mental Health Parity Act of 1996 (MHPA) further amended the PHS Act and ERISA (with corresponding provisions in the Tax Code) to provide for parity in the application of certain annual and lifetime dollar limits on mental health benefits with annual and lifetime dollar limits on medical/surgical benefits. The Women's Health and Cancer Rights Act of 1998 (WHCRA) amended the PHS Act (and ERISA) to provide certain protections for patients who elect breast reconstruction in connection with a mastectomy. (As used hereafter in this preamble, ''HIPAA'' refers to title XXVII of the PHS Act, as added by the Health Insurance Portability and Accountability Act of 1996, and later amended by MHPA, NMHPA, and WHCRA).

HIPAA added two preemption provisions to the PHS Act. With respect to HIPAA's preexisting condition exclusion rules, and the special enrollment rights contained in section 2701 of the PHS Act, State law cannot differ in any way from the Federal requirements, except to expand the protections in one of several ways specifically permitted by the statute. (See section 2723(b) of the PHS Act.) With respect to HIPAA's other requirements (except for NMHPA and WHCRA), including the non-discrimination provisions in section 2702 of the PHS Act, State laws are preempted only to the extent they prevent the application of any requirement of HIPAA. (See section 2723(a) of the PHS Act.) In addition, the NMHPA does not apply to health insurance issuers in States that have certain types of laws regulating coverage for the length of post-childbirth hospitalization. WHCRA does not preempt State laws in effect on the date of WHCRA's enactment with respect to health insurance coverage that requires coverage of at least the coverage of reconstructive breast surgery otherwise required under WHCRA.

HIPAA affirms that the States are the primary regulators of health insurance coverage in each State. However, in the event that a State either does not enact legislation that meets or exceeds the Federal requirements, or if it otherwise fails to substantially enforce the HIPAA standards, we enforce the HIPAA requirements that apply to health insurance issuers offering coverage within that State.

We are also responsible for enforcing the HIPAA requirements with respect to non-Federal governmental plans. Non-Federal governmental plans that self-insure, rather than purchasing health insurance coverage may elect exemption from one or more requirements of HIPAA, but must comply with requirements regarding certification and disclosure of creditable coverage.

II. Provisions of the Interim Final Regulations

Subpart A—General Provisions

Section 150.101 Basis and Scope

On April 8, 1997, we published regulations to implement HIPAA by adding 45 CFR parts 144, 146, and 148. Included in those regulations were enforcement provisions. After gaining some experience with direct Federal enforcement in some States, we determined that it was necessary to provide more detail on the procedures that will be used to enforce HIPAA when a State does not do so. Therefore, on August 20, 1999, we published interim final regulations (HCFA–2019–IFC) (64 FR 45786) that added a new part that revised and expanded the provisions contained in § 146.184, § 148.200, and § 148.202. Those sections were deleted.

That new part, 45 CFR part 150, consists of four subparts. Subpart A explains the basis and scope of the regulation and presents definitions that supplement definitions located in 45 CFR 144.103 and 148.103. Subpart B describes how we determine whether to assume enforcement authority in a State and explains the process for transferring authority back to the State. Subpart C describes procedures for assessing civil money penalties. Examples of specific situations that may trigger the assessment are listed in Appendix A to subpart C. Subpart D describes the administrative appeals process.

We refer the reader to the August 20, 1999, interim final rule with comment period for greater detail.

III. Analysis of and Responses to Public Comments

We received no public comments on the August 20, 1999 interim final rule.

IV. Provisions of the Final Regulations

The provisions of this final rule are identical to the provisions of the August 20, 1999, interim final rule with comment period, except that we have deleted the appendix to subpart C that listed examples of specific situations that may trigger the assessment of civil money penalties. We believe the inclusion of that document is unnecessary, in light of the fact that assessments are triggered by breaches of the provisions within the regulation itself.

Additionally, in § 150.311(e), the cross-reference made to the document described in § 150.307 incorrectly identified that document as the notice of intent to assess a penalty. We are correcting that cross-reference in 150.311(e) so it references the notice to the responsible entity or entities described in § 150.307.

V. 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.

VI. Regulatory Impact Statement

In drafting the interim regulation that this regulation finalizes, we had examined the impacts of the interim final regulation as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132. We published a Regulatory Impact Statement addressing all those impacts in the preamble to the interim regulation (64 FR 45786, 45792). This regulation merely finalizes that interim final regulation, and makes no substantive changes to it. Therefore, that Regulatory Impact Statement applies to this final regulation as well, and we refer the reader to it. However, we note that under Executive Order 12866 (58 FR 551735, October 4, 1993), the Department must determine whether a regulatory action is ''significant'' and therefore subject to the requirements of the Executive Order and subject to review by the Office of Management and Budget (OMB). Under section 3(f), the order defines a ''significant regulatory

action'' as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. We have determined that this action is not economically significant for the reasons stated in the preamble to the interim final regulation. The action also does not create any serious inconsistency or interfere with another agency's action or planned action, nor does it materially alter any budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof. Additionally, because this final regulation merely keeps in force an interim regulation already in effect before the publication of this final regulation, and makes no substantive changes to it, this final regulation does not raise any novel legal or policy issues.

We also note that Executive Order 12612 (''Federalism'') has been revoked subsequent to the issuance of the interim final regulation, and has been replaced by Executive Order 13132 (''Federalism''). Executive Order 13132 outlines fundamental principles of Federalism. It requires adherence to specific criteria by federal agencies in formulating and implementing policies that have ''substantial direct effects'' on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with State and local officials, and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the regulation.

In the Department's view, these final regulations have Federalism implications because they may have substantial direct effects on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. This is because the process set forth in these regulations impacts the relationship between national government and the States. However, in the Department's view, the Federalism implications of these final regulations are minimal. This is evidenced by the fact that no State submitted any comments on the interim final regulations suggesting that the regulations would in fact materially impact States' relationship with the national government, or would unduly infringe on States' historical function of regulating health insurance issuers. Additionally, the Department notes that the PHS Act provides that the States may enforce the provisions of title XXVII as they pertain to issuers, but that the Secretary of Health and Human Services must enforce any provisions that a State fails to substantially enforce. Currently, HHS enforces the title XXVII group market portability and nondiscrimination provisions in only one State [1] in accordance with that State's specific request to do so. Additionally, HHS enforces the NMHPA provisions in title XXVII in one State [2] that has not enacted conforming legislation, and has varying levels of direct enforcement responsibility in four States [3] with respect to the WHCRA provisions in title XXVII. In these instances, the Department complied with the procedures set forth in the interim final regulation (and this regulation) before assuming such enforcement responsibilities.[4] When exercising its responsibilities in this regard, HHS works cooperatively with the State for the purpose of addressing the State's concerns and avoiding conflicts with the exercise of State authority.

In compliance with Executive Order 13132's requirements that agencies examine closely any policies that may have Federalism implications or limit the policymaking discretion of the States, HHS has engaged in numerous efforts to consult and work cooperatively with affected State and local officials. For example, the Department has worked closely with State insurance regulators and the National Association of Insurance Commissioners (NAIC). The NAIC is a non-profit corporation established by the insurance commissioners of the 50 States, the District of Columbia, and four U.S. territories. In most States the insurance commissioner is appointed by the Governor, in approximately 14 States, the insurance commissioner is an elected official. Among other activities, it provides a forum for the development of uniform policy when uniformity is appropriate. Its members meet, discuss and offer solutions to mutual problems. The NAIC sponsors quarterly meetings to provide a forum for the exchange of ideas and in-depth consideration of insurance issues by regulators, industry representatives and consumers. CMS staff have been consistently attending these quarterly meetings to listen to the concerns of the State Insurance Departments regarding HIPAA enforcement and other issues. In addition to the general discussions, committee meetings, and task groups, the NAIC sponsors the standing CMS/Department of Labor meeting on HIPAA issues for members during the quarterly conferences. This meeting provides CMS (and the Department of Labor) with the opportunity to provide updates on enforcement actions, regulations, bulletins, and outreach efforts regarding, among other things, title XXVII of the PHS Act.

The Department has also cooperated with the States in several ongoing outreach initiatives, through which information on, among other things, title XXVII of the PHS Act, is shared among Federal regulators, State regulators, and the regulated community. In particular, CMS has sponsored conferences with the States—the consumer Outreach and Advocacy conferences in March 1999 and June 2000, and the Implementation and Enforcement of HIPAA National State-Federal Conferences in August 1999, 2000, 2001, 2002, and 2003. Furthermore, CMS websites offer links to important State websites and other resources, facilitating coordination between State and federal regulators and the regulated community. Throughout the process of developing these regulations, to the extent feasible, the Department has attempted to balance the States' interests in regulating health insurance issuers, and Congress' intent to ensure federal enforcement of the provisions of title XXVII in instances where a State fails to substantially enforce those provisions.

Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to these final regulations, the Department certifies that the CMS has complied with the requirements of Executive

[1] Missouri.

[2] Wisconsin.

[3] Colorado, Massachusetts, Rhode Island, and Wisconsin.

[4] Additionally, HHS applied the process set forth in the interim final regulation (and in this final regulation) with regard to several other States that had not enacted legislation conforming to NMHPA, WHCRA and MHPA. Largely as a result of initiating that process and working cooperatively with those States, every one of them enacted conforming legislation.

Order 13132 for the attached final regulation, Federal Enforcement in Group and Individual Health Insurance Markets (RIN 09–38–AN35), in a meaningful and timely manner.

In accordance with Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

45 CFR Parts 144 and 146

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 148

Administrative practice and procedure, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

45 CFR Part 150

Administrative practice and procedure, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

■ Accordingly, for the reasons set forth in the preamble, the interim final rule with comment period adding 45 CFR Part 150, Subparts A through D, which was published on August 20, 1999, in the **Federal Register** at 64 FR 45786 through 45807, is adopted as a final rule, with the following amendments:

PART 150—CMS ENFORCEMENT IN GROUP AND INDIVIDUAL INSURANCE MARKETS

■ 1. The authority citation for part 150 continues 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).

§ 150.307 [Amended]

■ 2. In § 150.307, paragraph (a) is amended by removing the parenthetical ''(See Appendix A to this subpart for examples of violations.)''

§ 150.311 [Amended]

■ 3. In § 150.311, paragraph (e) is amended by removing the phrase ''of intent to assess a penalty'' and adding in its place the phrase ''to the responsible entity or entities''.

Appendix A To Subpart C [Removed]

■ 4. In Part 150, ''Appendix A To Subpart C Of Part 150—Examples Of Violations'' is removed.

Dated: January 19, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicare Services.

Dated: August 15, 2005.

Michael O. Leavitt,

Secretary, Department of Health & Human Services.

Editorial Note: This document was received at the **Federal Register** on November 17, 2005.

[FR Doc. 05–23076 Filed 11–23–05; 8:45 am]

BILLING CODE 4120–01–U

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 11

[EB Docket No. 04–296; FCC 05–191]

Review of the Emergency Alert System

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) adopts rules that expand the reach of the Emergency Alert System (EAS), as currently constituted, to cover digital communications technologies that are increasingly being used by the American public to receive news and entertainment—digital television and radio, digital cable, and satellite television and radio. This *First Report and Order* is the most recent in a series of proceedings in which the Commission has sought to contribute to an efficient and technologically current public alert and warning system.

DATES: *Effective Date:* The rules set forth in the *First Report and Order* shall become effective for digital television broadcasters, digital audio broadcasters, digital cable systems and SDARS licensees on December 31, 2006, and for DBS providers on May 31, 2007, except §§ 11.15, 11.21, 11.35, 11.51, 11.52, 11.55 and 11.61 which contains information that has not been approved by OMB. The Commission will publish a document in the **Federal Register** announcing the effective dates of these sections.

Comment Date: Written comments by the public on the new and/or modified information collection requirements are due January 24, 2006.

ADDRESSES: Federal Communications Commission, 445 12th Street, SW., Room TW–A325, Washington, DC 20554. You may submit your Paperwork Reduction Act (PRA) comments by electronic mail or U.S. mail. To submit your PRA comments by electronic mail, send comments to: *PRA@fcc.gov.* To submit your PRA comments by U.S. mail, mark them to the attention of Judith B. Herman and address them to the Federal Communications Commission, Room 1–C804, 445 12th Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Jean Ann Collins, Senior Counsel, Office of Homeland Security, Enforcement Bureau, at (202) 418–1199. For additional information concerning the Paperwork Reduction Act information collection requirements contained in this document, send an e-mail to *PRA@fcc.gov* or contact Judith B. Herman at (202) 418–0214.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's First Report and Order in EB Docket No. 04–296, FCC 05–191, adopted November 3, 2005, and released November 10, 2005. The complete text of this document is available for inspection and copying during normal business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC, 20554. This document may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone (800) 378–3160 or (202) 863–2893, facsimile (202) 863–2898, or via e-mail at *http://www.bcpiweb.com.* It is also available on the Commission's Web site at *http://www.fcc.gov.* This document contains new information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public to comment on the information collection requirements contained in this document as required by the Paperwork Reduction Act of 1995, Public Law 104–13. Public and agency comments are due January 24, 2006. In addition, the Commission notes that pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4), the Commission previously sought specific comment on how the Commission might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

In this present document, the Commission has assessed the effects of expanding the reach of EAS to cover DTV, DAB, digital cable, DBS and SDARS providers, and finds that this imposes minimal regulation on small entities to the extent consistent with the Commission's goal of advancing its public safety mission.