permits, and Reporting and recordkeeping requirements.

Dated: September 19, 2001.

Robert W. Varney,

Regional Administrator, EPA New England.

Part 70, title 40 of the Code of Federal Regulations is amended as follows:

PART 70—[AMENDED]

1. The authority citation for part 70 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

2. Appendix A to part 70 is amended by revising paragraph (b) in the entry for Massachusetts to read as follows:

Appendix A to Part 70—Approval Status of State and Local Operating Permits Programs

* * * * *

Massachusetts

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(b) The Massachusetts Department of Environmental Services submitted program revisions on November, 19, 1996 and May 11, 2001. EPA is hereby granting Massachusetts full approval effective on November 27, 2001.

* * * * *

[FR Doc. 01–24064 Filed 9–27–01; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

42 CFR Parts 402 and 405

CMS–6145–FC

RIN 0938–AK49

Medicare Program; Civil Money Penalties, Assessments, and Revised Sanction Authorities

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

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period is a technical rule that updates our civil money penalty (CMP) regulations to add CMP authorities already enacted as part of the Balanced Budget Act of 1997 (BBA) and delegated to us. The rule delineates our authority to assess penalties for: failure to bill outpatient therapy services or comprehensive outpatient rehabilitation services (CORS) on an assignment-related basis, failure to bill ambulance services on an assignment-related basis, failure to provide an itemized statement for Medicare items and services to a Medicare beneficiary upon his/her request, and failure of physicians or nonphysician practitioners to provide diagnostic codes for items or services they furnish or failure to provide this information to the entity furnishing the item or service ordered by the practitioner. The rule also contains technical changes to further conform our current CMP rules to changes in the statute enacted by the BBA.

DATES: These regulations are effective on October 29, 2001. We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on November 27, 2001.

ADDRESSES: Mail written comments (one original and three copies) to the following address only: Centers for Medicare and Medicaid Services, Department of Health and Human Services, Attention: CMS–6145–FC, P.O. Box 8013, Baltimore, MD 21244–8013.

Since comments must be *received* by the date specified above, please allow sufficient time for mailed comments to be received timely in the event of delivery delays. If you prefer, you may deliver your written comments (one original and three copies) by courier to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–16–03, Central Building, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Comments mailed to the two above addresses may be delayed and received too late to be considered. Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code CMS–6145–FC.

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC 20201, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

FOR FURTHER INFORMATION CONTACT: Joel Cohen, (410) 786–3349.

SUPPLEMENTARY INFORMATION:

I. Background

On December 14, 1998, we published a final rule in the **Federal Register** (63 FR 68687), the procedures for pursuing civil money penalties (CMPs) and assessments now set forth at 42 CFR part 402. We are now amending part 402, subpart B, to incorporate additional CMPs authorized by sections 4541(a)(2), 4531(b)(2), 4311(b), and 4317 of the Balanced Budget Act of 1997 (BBA), Public Law 105–33. This final rule with comment period incorporates the statutory revisions of the BBA concerning CMPs and assessments into our existing CMP and assessment regulations at 42 CFR part 402, subparts A and B, as well as makes technical changes to existing delegated authority. BBA statutory revisions that would affect subpart C, which addresses our exclusion authority, are not addressed in this final rule, but will be addressed in a separate rulemaking.

II. Provisions of the Final Rule

This final rule amends 42 CFR part 402, to incorporate changes resulting from the enactment of the BBA. Specifically, we are revising §§ 402.1(c), 402.1(d), 402.105(d), and 402.107 and adding § 402.105(g) with regard to the following statutory authorities that are delegated to us:

A. Payment for Outpatient Therapy Services and Comprehensive Outpatient Rehabilitation Services

Section 4541(a)(2) of the BBA adds subsection (k) to section 1834 of the Social Security Act (the Act), Payment for Outpatient Therapy Services and Comprehensive Outpatient Rehabilitation Services. Subsection (k)(6), through its cross-reference to section 1842(b)(18) of the Act, requires that billing for therapy services be subject to the mandatory assignment requirements of the Medicare statute. Failure to bill on an assignment-related basis may subject the violator to certain sanctions, including assessments and CMPs, as provided by section 1842(j)(2) of the Act. (See § 402.105(d)(3).)

B. Fee Schedule for Ambulance Services

Section 4531(b)(2) of the BBA adds paragraph (l) to section 1834 of the Act, Establishment of Fee Schedule for Ambulance Services. This provision requires the establishment of a fee schedule for ambulance services furnished and requires, in section 1834(l)(6) of the Act, suppliers of ambulance services to accept assignment (that is, to accept Medicare's approved payment amount as payment in full). Failure to bill on an assignment-related basis may subject the violator to sanctions, including assessments and CMPs, as provided by section 1842(j)(2) of the Act. (See § 402.105(d)(4).)

C. Request for Itemized Statement for Medicare Items and Services

Section 4311(b) of the BBA adds section 1806 to the Act. Section 1806(b), Request For Itemized Statement For Medicare Items and Services, provides that a Medicare beneficiary has the right

to request and receive an itemized statement from health care providers (for example, hospitals, nursing facilities, home health agencies, physicians, practitioners, and Durable Medical Equipment Prosthetics, Orthotics and Supplies (DMEPOS) suppliers). From the date of the beneficiary's request, the health care provider has 30 days to furnish this statement to the beneficiary. Any provider or supplier who fails to provide an itemized statement may be subject to a CMP of $100 for each failure. (See § 402.105(g).)

D. Provision of Diagnostic Codes

Section 4317 of the BBA amends section 1842(p) of the Act to include nonphysician practitioners under the requirement to provide diagnostic codes for items and services they furnish or to provide this information (if required) to the entity furnishing the item or service if ordered by the physician or nonphysician practitioner. Failure of these practitioners to supply required diagnostic codes subjects them, through a cross-reference to section 1842(j)(2) of the Act, to sanctions including assessments. (See § 402.1(c)(16).)

E. Technical Amendment/Revision

Section 4031(a)(2) of the BBA adds a new paragraph as section 1882(s)(3) of the Act. As a result, the original section 1882(s)(3) of the Act is redesignated as section 1882(s)(4) of the Act. We have conformed the regulations to reflect this redesignation. (See § 402.1(c)(29) and § 402.1(e)(vii).)

F. Technical Correction

Finally, this final rule makes a technical correction to § 405.520(c), which currently lists the maximum civil money penalty amount as $2,000 for each bill or request for payment in which a beneficiary was billed in excess of Medicare coinsurance and deductible amounts. Section 231(c) of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191, increases the maximum civil money penalty amount to $10,000 for certain acts described in section 1128A(a) of the Act. Section 1128A(a) of the Act provides the basis for the amount of CMPs that may be imposed under § 405.520(c). We are accordingly clarifying that the maximum CMP amount under § 405.520(c) is $10,000 for each bill or request for payment. To do this, we are revising § 405.520(c) because the CMP it describes was again addressed in part 402 when it was published on December 14, 1998 (63 FR 68690). Specifically, §§ 402.1(c)(11) and 402.105(d)(2)(viii) address CMPs that we may impose when practitioners bill for services on a nonassigned basis in violation of section 1842(b)(18) of the Act. When part 402 was published, however, it did not take into account the existing provision in § 405.520(c) that addresses the same issues. To eliminate any confusion that the duplication may cause, we are revising the CMP provision that appears in § 405.520(c) to make the appropriate cross-reference to the provision that now appears in §§ 402.1(c)(11), 402.105(d)(2)(viii), and 402.107(b)(8). This conforming change serves as a cross-reference to the appropriate CMP provisions and automatically corrects the maximum penalty amount for the CMP described in § 405.520(c).

III. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite prior public comment on proposed rules. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

In the present rulemaking, we find that subjecting this rule to a notice and comment period is unnecessary because this final rule with comment period incorporates technical changes to previously published CMP authorities and codifies additional authorities that result from the enactment of sections 4541(a)(2), 4531(b)(2), 4311(b), 4317, and 4031(a)(2) of the BBA and section 231(c) of the HIPAA. This final rule with comment period does not alter the legal responsibilities and regulatory requirements of the affected program participants, and does nothing more than update our regulations to reflect already existing statutory obligations.

Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a 60-day comment period for the public.

IV. Regulatory Impact Statement

We have examined the requirements of Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980 Public Law 96–354), Executive Order 13132 (August 4, 1999, Federalism) and the Unfunded Mandates Reform Act of 1995 (2 USC 1532).

Executive Order 12866 found in 58 FR 51735 directs agencies taking ''significant regulatory action'' to reflect consideration of 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). This technical rule is not a significant regulatory action as defined by section 3(e) of Executive Order 12866. We believe that there are no significant costs associated with this technical rule that would impose any mandates on State, local or tribal governments, or the private sector that would result in an expenditure of $100 million in any given year. This rule incorporates technical changes to previously published CMP authorities and establishes in regulation additional authorities mandated by the BBA. We expect that all program participants will comply with the statutory and regulatory requirements making unnecessary the imposition of a CMP. Therefore, we do not anticipate more than a de minimis economic impact as a result of this technical change. Further, any impact that may occur will only affect those limited few individuals or entities that engage in prohibited behavior. We do not anticipate any savings or costs as a result of this technical change.

The Regulatory Flexibility Act of 1980 codified in 15 USC 603(a), as modified by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), requires agencies to determine whether this technical rule will have a significant economic effect on a substantial number of small entities and, if so, to identify regulatory options that could mitigate the impact when publishing a general notice of proposed rulemaking. We believe that any impact as a result of the technical rule will be minimal, since, as mentioned above, the only individuals or entities affected will be those limited few who engage in prohibited conduct. Since the vast majority of program participants comply with statutory and regulatory requirements, any aggregate economic impact will not be significant.

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 an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million (2 U.S.C. 1532). We believe that there are no

significant costs associated with this technical rule that would impose any mandates on State, local or tribal governments, or the private sector that would result in an expenditure of $100 million in any given year. As was previously mentioned, since the majority of program participants comply with statutory and regulatory requirements, any aggregate economic impact will not be significant. Accordingly, we believe that a full analysis under the Regulatory Flexibility Act is not necessary.

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 technical rule will not significantly affect the rights, roles, or responsibilities of the States. This rule does not impose substantial direct requirement costs on State or local governments, preempt State law, or otherwise implicate Federalism.

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

List of Subjects

42 CFR Part 402

Administrative practice and procedure, Health facilities, Health professions, Medicaid, Medicare, Penalties.

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

For the reasons stated in the preamble, the Centers for Medicare and Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 402—CIVIL MONEY PENALTIES, ASSESSMENTS, AND EXCLUSIONS

A. Part 402 is amended as set forth below:

1. The authority citation for part 402 continues to read as follows:

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

1. In § 402.1, the following changes are made:

A. Paragraph (c) introductory text is revised to read as set forth below.

B. Paragraph (c)(16) is revised to read as set forth below.

C. Paragraph (c)(29) introductory text is revised to read as set forth below.

D. Paragraphs (c)(31), (c)(32), and (c)(33) are added to read as set forth below.

E. Paragraph (d) introductory text is republished.

F. Paragraph (d)(2) is revised to read as set forth below.

G. Paragraph (e)(1) introductory text is republished.

H. Paragraph (e)(1)(ii) is revised to read as set forth below.

I. Paragraph (e)(1)(vii) is revised to read as set forth below.

§ 402.1 Basis and scope.

* * * * *

(c) *Civil money penalties.* CMS or OIG may impose civil money penalties against any person or other entity specified in paragraphs (c)(1) through (c)(33) of this section under the identified section of the Act. (The authorities that also permit imposition of an assessment or exclusion are noted in the applicable paragraphs.)

* * * * *

(16) Section 1842(p)(3)(A)—Any physician or practitioner who knowingly and willfully fails promptly to provide the appropriate diagnosis code or codes upon request by CMS or a carrier on any request for payment or bill not submitted on an assignment-related basis for any service furnished by the physician. (This violation, if it occurs in repeated cases, may also cause exclusion.)

* * * * *

(29) Section 1882(s)(4)—

* * * * *

(31) Sections 1834(k)(6) and 1842(j)(2)—Any person or entity who knowingly and willfully bills or collects for any outpatient therapy services or comprehensive outpatient rehabilitation services on other than an assignment-related basis. (This violation may also include an assessment and cause exclusion.)

(32) Sections 1834(l)(6) and 1842(j)(2)—Any supplier of ambulance services who knowingly and willfully bills or collects for any services on other than an assignment-related basis. (This violation may also include an assessment and cause exclusion.)

(33) Section 1806(b)(2)(B)—Any person who knowingly and willfully fails to furnish a beneficiary with an itemized statement of items or services within 30 days of the beneficiary's request.

(d) *Assessments.* CMS or OIG may impose assessments in addition to civil money penalties for violations of the following statutory sections:

* * * * *

(2) Section 1834: Paragraphs (a)(11)(A), (a)(18)(B), (b)(5)(C), (c)(4)(C), (h)(3), (j)(4), (k)(6), and (l)(6).

* * * * *

(e) *Exclusions.* (1) CMS or OIG may exclude any person from participation in the Medicare program on the basis of any of the following violations of the statute:

* * * * *

(ii) Section 1834: Paragraphs (a)(11)(A), (a)(18)(B), (b)(5)(C), (c)(4)(C), (h)(3), (j)(4), (k)(6), and (l)(6).

* * * * *

(vii) Section 1882: Paragraphs (a)(2), (p)(8), (p)(9)(C), (q)(5)(C), (r)(6)(A), (s)(4), and (t)(2).

* * * * *

3. In § 402.105, the following changes are made:

A. Paragraph (a) is revised to read as set forth below.

B. Paragraphs (d)(3) and (d)(4) are added to read as set forth below.

C. Paragraph (g) is added to read as set forth below.

§ 402.105 Amount of penalty.

(a) *$2,000.* Except as provided in paragraphs (b) through (g) of this section, CMS or OIG may impose a penalty of not more than $2,000 for each service, bill, or refusal to issue a timely refund that is subject to a determination under this part and for each incident involving the knowing, willful, and repeated failure of an entity furnishing a service to submit a properly completed claim form or to include on the claim form accurate information regarding the availability of other health insurance benefit plans (§ 402.1(c)(21)).

* * * * *

(d) * * *

(3) CMS or OIG may impose a penalty of not more than $10,000 for each violation, if a person or entity knowingly and willfully bills or collects for outpatient therapy or comprehensive rehabilitation services other than on an assignment-related basis.

(4) CMS or OIG may impose a penalty of not more than $10,000 for each violation, if a person or entity knowingly and willfully bills or collects for outpatient ambulance services other than on an assignment-related basis.

* * * * *

(g) *$100.* CMS or OIG may impose a penalty of not more than $100 for each violation if the person or entity does not furnish an itemized statement to a Medicare beneficiary within 30 days of the beneficiary's request.

4. In § 402.107, the introductory text to the section and paragraph (b) introductory text are republished, and

paragraph (b)(8) is revised to read as follows:

§ 402.107 Amount of assessment.

A person subject to civil money penalties specified in § 402.1(c) may be subject, in addition, to an assessment. An assessment is a monetary payment in lieu of damages sustained by HHS or a State agency.

* * * * *

(b) For the violations specified in this paragraph occurring after January 1, 1997, the assessment may not be more than three times the amount claimed for each service that was the basis for a civil money penalty. The violations are the following:

* * * * *

(8) Knowingly and willfully billing or collecting for any services on other than an assignment-related basis for a person or entity specified in sections 1834(k)(6), 1834(l)(6), or 1842(b)(18)(B) (§ 402.1(c)(11), (c)(31), or (c)(32)).

* * * * *

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart E—Criteria for Determining Reasonable Charges

B. Part 405, subpart E is amended as set forth below:

1. The authority citation for part 405, subpart E continues to read as follows:

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

2. In § 405.520, paragraph (c) is revised to read as follows:

§ 405.520 Payment for a physician assistant's, nurse practitioner's, and clinical nurse specialist's services and services furnished incident to their professional services.

* * * * *

(c) *Civil money penalties.* Any person or entity who knowingly and willingly bills a Medicare beneficiary amounts in excess of the appropriate coinsurance and deductible is subject to a civil money penalty as described in §§ 402.1(c)(11), 402.105(d)(2)(viii), and 402.107(b)(8) of this chapter.

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

Dated: September 19, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: September 21, 2001.

Tommy G. Thompson,

Secretary.

[FR Doc. 01–24326 Filed 9–27–01; 8:45 am]

BILLING CODE 4120–01–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 65

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, FEMA.

ACTION: Final rule.

SUMMARY: Modified base (1% annual chance) flood elevations are finalized for the communities listed below. These modified elevations will be used to calculate flood insurance premium rates for new buildings and their contents.

EFFECTIVE DATES: The effective dates for these modified base flood elevations are indicated on the following table and revise the Flood Insurance Rate Map(s) (FIRMs) in effect for each listed community prior to this date.

ADDRESSES: The modified base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the following table.

FOR FURTHER INFORMATION CONTACT: Matthew B. Miller, P.E., Chief, Hazards Study Branch, Federal Insurance and Mitigation Administration, Hazard Mapping Division, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–3461, or (email) matt.miller@fema.gov.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency makes the final determinations listed below of modified base flood elevations for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Acting Executive Associate Director has resolved any appeals resulting from this notification.

The modified base flood elevations are not listed for each community in this notice. However, this rule includes the address of the Chief Executive Officer of the community where the modified base flood elevation determinations are available for inspection.

The modifications are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR Part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified base flood elevations are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).

These modified elevations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, state or regional entities.

These modified elevations are used to meet the floodplain management requirements of the NFIP and are also used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in these buildings.

The changes in base flood elevations are in accordance with 44 CFR 65.4.

National Environmental Policy Act

This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act

The Acting Executive Associate Director, Mitigation Directorate, certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification

This final rule is not a significant regulatory action under the criteria of Section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism

This rule involves no policies that have