c. ''(DAB)'', wherever it appears, is removed.

2. Throughout this chapter IV, ''a SNF'', and ''a NF'', wherever they appear, are revised to read ''an SNF'' and ''an NF'', respectively.

3. Throughout chapter IV, ''intermediate care facility for the mentally retarded'' wherever it appears, is revised to read ''intermediate care facility for persons with mental retardation and related conditions''.

4. In the following locations, ''co-payment'' wherever it appears, is revised to read ''copayment'': §§ 447.54(a)(3) (table heading), 447.55(a) and (b), 447.56, and 447.58.

5. In § 447.54(a)(3) text, ''co-payments'' is revised to read ''copayments''.

6. In the following locations, ''the OIG, as appropriate,'' is removed: § 498.20(a)(1), § 498.25(b)(1), and § 498.32(a)(1).

7. In the following locations, ''or the OIG'' is removed:§ 498.32(b)(2), § 498.56(a)(2), § 498.56(d), heading and text, § 498.66(b)(2),§ 498.78(a), and § 498.83(a), heading and text.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance; Program No. 93.778, Medical Assistance)

Dated: August 8, 2001.

Ruben J. King-Shaw, Jr.,

Deputy Administrator and Chief Operating Officer, Centers for Medicare & Medicaid Services.

Dated: September 9, 2001.

Tommy G. Thompson,

Secretary.

[FR Doc. 02–1065 Filed 1–24–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 401

[CMS–6011–P]

RIN 0938–AK45

Medicare Program; Reporting and Repayment of Overpayments

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would supplement and modify the notice of proposed rulemaking that was published on March 25, 1998 (63 FR 14506). That notice proposed to amend the Medicare regulations governing liability for overpayments from the Centers for Medicare & Medicaid services (CMS) to providers, suppliers, and individuals to eliminate application of certain regulations of the Social Security Administration and to replace them with regulations more specific to circumstances involving Medicare overpayments.

This proposed regulation would supplement and modify that notice in order to establish, in regulations, the longstanding resp[onsibility of providers, suppliers, individuals and also managed care organizations contracting with us to report and return overpayments to us. This proposed would establish the timeframe and process for making the reports and returning the overpayments.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on March 26, 2002.

ADDRESSES: Mail written comments (one original and three copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6011–P, PO Box 8013, Baltimore, MD 21244–8013.

If you prefer, you may deliver, by courier, your written comments (one original and three copies) to one of the following addresses: Hubert H. Humphrey Building, Room 443–G, 200 Independence Avenue, SW., Washington, DC 20201, or Centers for Medicare & Medicaid Services, C5–14–03, Central Building, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Comments mailed to those addresses designated for courier delivery may be delayed and could be considered late. Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Please refer to file code CMS–6011–P on each comment.

Comments received timely will be available for public inspection as they are received, beginning approximately 3 weeks after publication of this document, in room C5–12–08 of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland, Monday through Friday of each week from 8:30 a.m. to 5 p.m. Please call (410) 786–7197 to make an appointment to view comments.

FOR FURTHER INFORMATION CONTACT: Paul Reed (410) 786–4001.

SUPPLEMENTARY INFORMATION:

I. Background

On March 25, 1998 we published in the **Federal Register** (63 FR 14506) a notice of proposed rulemaking that would amend the Medicare regulations governing liability for overpayments to eliminate application of certain regulations of the Social Security Administration and to replace them with regulations more specific to circumstances involving Medicare overpayments.

Section 401.310 of those proposed regulations defined overpayment as those Medicare funds that a provider, supplier, or individual has received in excess of amounts payable under the Medicare statute and regulations. The notice of proposed rulemaking described the types of overpayments, and gave examples of causes of overpayments, such as payments made by Medicare for noncovered services, Medicare payments in excess of the allowable amount for an identified covered service, errors and nonreimbursable expenditures in cost reports, duplicate payments, and Medicare payment when another entity had the primary responsibility for payment (63 FR 14517). It also stated that once a determination and any adjustments in the amount of the overpayments have been made, the remaining amount is a debt owed to the United States Government. After publishing that notice of proposed rulemaking, we received several comments on their provisions. In addition, on June 26, 1998, we published the Medicare+Choice (M+C) interim final rules (63 FR 34968) in which we addressed a process for reporting to us violations of the law, including overpayments. We stated that we wanted M+C organizations to self identify when they had been overpaid. While the amount of estimated overpayments has decreased in recent years, the number and amount of overpayments continue to be a significant issue in the Medicare program.

The June 29, 2000 final M+C regulation (65 FR 40170) eliminated any requirement for self-reporting of overpayments on the basis that it was arguably unfair to impose a self-reporting requirement on M+C organizations, but not on other types of providers and suppliers participating in the Medicare program. The preamble to that regulation stated:

''While we are withdrawing all requirements for self-reporting in this rule, we believe that the required reporting of overpayments is an effective tool for promoting Medicare

program integrity generally. Accordingly, HCFA intends to develop policies through separate notice and comment rulemaking in cooperation with the HHS Office of Inspector General that would require all Medicare providers, suppliers, and contractors to report overpayments to HCFA.'' (65 FR 40265)

With this proposed modification to the March 25, 1998 notice of proposed rulemaking, we intend to issue one comprehensive rule on this subject.

The obligation to report and return overpayments is derived from sections 1870, 1871, and 1102 of the Social Security Act (the Act). Section 1870 of the Act establishes that providers and suppliers are liable for overpayments unless determined to be without fault, as defined in proposed § 401.323, with respect to the overpayments. Individuals may be liable in certain circumstances unless the individual is determined to be without fault, as defined in proposed § 401.355, and the recovery of the overpayment would either defeat the purposes of the statute or be against equity and good conscience.

Section 1102 of the Act requires that the Secretary make and publish such rules and regulations, not inconsistent with the Act, as may be necessary for the efficient administration of the functions with which the Secretary is charged under the Act. Under section 1871 of the Act, the Secretary must prescribe such regulations as may be necessary to carry out the administration of the insurance programs under the Medicare statute. In certain contexts, formal guidance requires providers to report overpayments through our Medicare Credit Balance Report, and suppliers to report overpayments through their reporting mechanisms. This proposed rule would further memorialize the longstanding responsibility for all providers, suppliers, individuals, and other entities, including managed care organizations contracting with us, to report overpayments and establish the time frame and process for making those reports.

In addition, section 1128B(a)(3) of the Act establishes that persons are under a legal duty to disclose the occurrence of events affecting the right to payment or benefits by a Federal health care program. Specifically, this section makes it a felony for a person, ''having knowledge of the occurrence of any event affecting * * * his initial or continued right to any [Federal health care] benefit or payment * * *, [to conceal or fail] to disclose such event with an intent fraudulently to secure such benefit or payment * * *.'' Thus, failure to notify us of an overpayment within a reasonable period of time may, in certain circumstances, establish criminal liability, and result in a referral to the Office of Inspector General.

II. Provisions of the Proposed Rule

In this rule we are proposing to modify and supplement the notice of proposed rulemaking that was published in the **Federal Register** on March 25, 1998 (63 FR 14506). We are revising the definition of overpayment to cover not just excess Medicare funds received by a provider, supplier, or individual, but also funds received by other entities. We are also adding a definition of other entities, which defines them as entities, including managed care organizations contracting with us in accordance with 42 CFR parts 417 or 422, that are not providers, suppliers, or individuals, that provide Medicare services to Medicare beneficiaries. The new definition makes clear that other entities include managed care organizations contracting with us in accordance with 42 CFR parts 417 or 422. We are also adding a paragraph to memorialize in regulations the responsibility and procedures for returning overpayments to us. The March 25, 1998 notice of proposed rulemaking would amend the Medicare regulations governing liability for overpayments in order to eliminate application of certain regulations of the Social Security Administration and replace them with regulations more specific to circumstances involving Medicare overpayments. This proposed rule would modify and supplement the March 25, 1998 notice of proposed rulemaking. It would require providers, suppliers, and individuals that have identified a Medicare payment received in excess of amounts payable under the Medicare statute and regulations to report and return the overpayment, within 60 days of identifying the overpayment, to the appropriate intermediary or carrier at the correct address. In the case of a managed care organization contracting with us, the managed care organization must, within 60 days of identifying the overpayment, notify us either in a manner consistent with certification of payment data requirements described at 42 CFR 422.502(l) or in a manner consistent with our cost settlement processes described at 42 CFR part 417, subparts O and U, so that we can adjust the identified overpayment appropriately. For overpayments identified by managed care organizations for a period beyond which payment data have already been certified or settled, the managed care organization must notify us in writing of the overpayment within 60 days of identifying or learning of the excess payment, so that we can recover the identified overpayment appropriately. For overpayments identified by other entities, other than managed care organizations, the other entities must notify us in writing of the overpayment within 60 days of identifying or learning of the excess payment, so that we can recover the identified overpayment appropriately. Submission of corrected bills in conformance with our policy, within 60 days, fulfills these requirements for providers, suppliers, and individuals. Our existing certification requirements for M+C organizations, described at § 422.502(l), and cost settlement processes for cost-based contractors, described at 42 CFR part 417, subparts O and U, and this new requirement for overpayments reported after payment certifications have already been submitted, provide the process for notifying, documenting, and correcting overpayments for managed care organizations contracting with us.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60 days notice in the **Federal Register** and solicit public comment when 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 PRA requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the 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.

Therefore, we are soliciting comments from the public, including the provider and supplier community, on each of these issues for the information collection requirements discussed below.

§ 401.310(e)—If a provider, supplier, or individual identifies a Medicare payment received in excess of the amounts payable under the Medicare statute and regulations, the provider, supplier, or individual must, within 60 days of identifying or learning of the

excess payment, notify the intermediary or carrier, in writing, of the reason for the overpayment, and return the overpayment to the appropriate intermediary or carrier, at the correct address.

It is estimated that there will be approximately 906,724 notifications submitted on an annual basis and that it will take 5 minutes per instance for providers, suppliers, or individuals to notify the appropriate intermediary or carrier. The total annual burden associated with this requirement is 75,560 hours.

If a managed care organization contracting with us in accordance with 42 CFR parts 417 or 422 identifies a Medicare payment received in excess of amounts payable under the Medicare statute and regulations before the payment data have been certified or settled, the managed care organization must notify us either in accordance with certification of payment data requirements described in § 422.502(l) or in accordance with cost settlement processes described in 42 CFR part 417, subparts O and U.

It is estimated that there will be no additional notifications submitted on an annual basis and that it will take 5 minutes per instance to notify us. The total annual burden associated with this requirement is zero hours.

If a managed care organization contracting with us in accordance with 42 CFR parts 417 or 422 identifies a Medicare payment received in excess of amounts payable under the Medicare statute and regulations after payment data have been certified or settled, it must notify us, in writing, of the overpayment within 60 days of identifying or learning of the overpayment so that we can recover the identified overpayment appropriately.

It is estimated that there will be no additional notifications submitted on an annual basis and that it will take 5 minutes per instance to notify us. The total annual burden associated with this requirement is zero hours.

If an other entity, other than a managed care organization contracting with us in accordance with 42 CFR parts 417 or 422, identifies a Medicare payment received in excess of amounts payable under the Medicare statute and regulations, it must notify us, in writing, of the overpayment within 60 days of identifying or learning of the overpayment so that we can recover the identified overpayment appropriately.

It is estimated that there will be no additional notifications submitted on an annual basis and that it will take 5 minutes per instance to notify us. The total annual burden associated with this requirement is zero hours.

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements in § 401.310. These requirements are not effective until they have been approved by OMB.

If you have any comments concerning any of these information collection and record keeping requirements, please mail one original and three copies within 60 days of this publication date to the following addresses:

Centers for Medicare & Medicaid Services, Office of Information Services, Information Technology Investment Management Group, Division of CMS Enterprise Standards, Room N2–14–26, 7500 Security Boulevard,Baltimore, MD 21244–1850, Attn: John Burke CMS–6011–P, and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, CMS Desk Officer.

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document. Because this document proposes to modify and supplement a notice of proposed rulemaking published on March 25, 1998 in the **Federal Register** (63 FR 14506), we will respond to all comments received concerning both that notice of proposed rulemaking and this proposed modification in the preamble to the combined subsequent document.

V. Regulatory Impact

A. Overall Impact

We have examined the impact of this proposed rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980, Public Law 96–354). Executive Order 12866 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 one year). This proposed rule is not a major rule. The requirements of this rule add another program integrity tool, but do not replace existing overpayment recovery efforts. Additionally, providers, suppliers, individuals, and other entities already report and return many overpayments. Any overpayments made by us are not amounts that are due to these entities. The cost of the required reporting should be minimal for providers, suppliers, individuals, and other entities, including managed care organizations contracting with us in accordance with 42 CFR parts 417 or 422.

The RFA also requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and governmental agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of between $5 million and $25 million annually. Individuals and States are not included in the definition of small entities. Under this proposed rule, providers, suppliers, individuals, and other entities, including managed care organizations contracting with us in accordance with 42 CFR parts 417 or 422, would be required to notify the Medicare intermediary or carrier, or us, as appropriate, in writing, within 60 days of identifying any payment that exceeds the amount payable under the Medicare statute and regulations.

The cost of the required reporting should be minimal for providers, suppliers, individuals, and other entities, including managed care organizations contracting with us in accordance with 42 CFR parts 417 or 422. Because standard business practices dictate keeping accurate records concerning monies due and/or payable, the required reporting of overpayments will add minimal cost for some providers, suppliers, individuals, and other entities, and no cost for providers, suppliers, individuals, and other entities already reporting overpayments. Therefore, we have determined, and we certify, that this proposed regulation would not result in a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act (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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital located outside of a Metropolitan Statistical Area with fewer than 100 beds. The cost of the required reporting should be minimal for small rural hospitals. Because standard business practices dictate keeping accurate records concerning monies due and/or payable, the required reporting of overpayments will add minimal cost for some small rural hospitals and no cost for those hospitals already reporting overpayments. Therefore, we have determined, and we certify, that this proposed rule would not have a significant effect on the operations of a substantial number of rural hospitals.

B. The Unfunded Mandates Act

Section 202 of the Unfunded Mandates Reform Act of 1995 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 $110 million. This proposed rule would have no effect on the annual expenditures of any State, local, or tribal government, or the private sector. Any overpayments made by us to a provider, supplier, individual, or other entity that are reported and returned to us are not expenditures. The overpayments are not amounts owed to the provider, supplier, individual, or other entity and their return would have no economic impact. Therefore, we have determined, and we certify, that this proposed regulation would not result in an annual expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million.

C. Federalism

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. This proposed rule would impose no direct requirement costs on State and local governments, would not preempt State law, or have any Federalism implications. We are requiring providers, suppliers, individuals, and other entities that identify that we have overpaid them to report the overpayment to us and return the amount overpaid.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget. This proposed rule is not a major rule as defined at 5 U.S.C 804(2).

List of Subjects in 42 CFR Part 401

Claims, Freedom of information, Health facilities, Medicare, Privacy.

Accordingly, the Centers for Medicare & Medicaid Services proposes to amend the notice of proposed rulemaking at 63 FR 14506 (March 25, 1998), which proposed to amend 42 CFR chapter IV, part 401 by adding subpart D, as follows:

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

Subpart D—Recovery of Overpayments, Suspension of Payment, and Repayment of Scholarships and Loans

1. The authority citation for part 401, subpart D, continues to read as follows:

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

2. Proposed § 401.310 is amended by revising paragraph (a), adding a new paragraph (b)(4), and adding a new paragraph (e) as follows:

§ 401.310 Overpayments.

(a) *Definitions.* As used in this section, the following definitions apply:

Other entity means an entity, including a managed care organization contracting with CMS in accordance with parts 417 or 422 of this chapter, that is not a provider, a supplier, or an individual, that provides Medicare services to Medicare beneficiaries.

Overpayment means Medicare funds a provider, a supplier, an individual, or other entity, including a managed care organization contracting with CMS in accordance with parts 417 or 422 of this chapter, has received in excess of amounts payable under the Medicare statute and regulations.

* * * * *

(b) * * *

(4) Medicare overpayment to an other entity, including a managed care organization contracting with CMS in accordance with parts 417 or 422 of this chapter.

* * * * *

(e) *Reporting and returning overpayments.* Identified payments in excess of amounts payable under the Medicare statute and regulations must be reported and returned as follows:

(1) If a provider, supplier, or individual identifies a Medicare payment received in excess of amounts payable under the Medicare statute and regulations, the provider, supplier, or individual must, within 60 days of identifying or learning of the excess payment, return the overpayment to the appropriate intermediary or carrier, at the correct address, and notify the intermediary or carrier, in writing, of the reason for the overpayment.

(2) If a managed care organization contracting with CMS in accordance with parts 417 or 422 of this chapter identifies a Medicare payment received in excess of amounts payable under the Medicare statute and regulations before the payment data have been certified or settled, the managed care organization must, within 60 days of identifying or learning of the excess payment, notify CMS, either—

(i) In accordance with certification of payment data requirements described in § 422.502(1) of this chapter; or

(ii) In accordance with cost settlement processes described in part 417, subparts O and U of this chapter.

(3) If a managed care organization contracting with CMS in accordance with parts 417 or 422 of this chapter identifies a Medicare payment received in excess of amounts payable under the Medicare statute and regulations after payment data have been certified or settled, it must, within 60 days of identifying or learning of the excess payment, notify CMS, in writing so that CMS can recover the identified overpayment appropriately.

(4) If an other entity, other than a managed care organization contracting with CMS in accordance with 42 CFR parts 417 or 422, identifies a Medicare payment in excess of amounts payable under the Medicare statute and regulations it must, within 60 days of identifying or learning of the overpayment, notify CMS, in writing, so that CMS can recover the identified overpayment appropriately.

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

Dated: August 30, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 2, 2001.

Tommy G. Thompson,

Secretary.

[FR Doc. 02–1688 Filed 1–24–02; 8:45 am]

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