

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

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

Subpart WW—Washington

■ 2. Section 52.2475 is amended by adding paragraph (a)(4) to read as follows:

§ 52.2475 Approval of plans.

(a) * * *

(4) Vancouver.

(i) EPA approves as a revision to the Washington State Implementation Plan, the Vancouver Air Quality Maintenance Area Second 10-year Carbon Monoxide Maintenance Plan submitted by the Washington Department of Ecology on April 25, 2007.

(ii) [Reserved]

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[FR Doc. E8-14518 Filed 6-26-08; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Part 401**

[CMS-6032-F]

RIN 0938-AO27

Medicare Program; Use of Repayment Plans

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

ACTION: Final rule.

SUMMARY: This final rule modifies Medicare regulations to implement section 935(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 pertaining to the use of repayment plans (also known as extended repayment schedules or “ERS”) for Medicare provider and supplier overpayments. Under this provision, we are granting a provider or a supplier an ERS under certain terms and conditions as defined in the statute. This final rule establishes criteria and procedures to apply this requirement and to define the concepts of “hardship” and “extreme hardship.”

DATES: *Effective Date:* These regulations are effective on July 28, 2008.

FOR FURTHER INFORMATION CONTACT: Tom Noplock, (410) 786-3378.

SUPPLEMENTARY INFORMATION:

I. Background**A. Medicare Overpayment**

Medicare overpayments are Medicare funds an individual, provider, or supplier has received that exceed amounts due and payable under the Medicare statute and regulations (plus any applicable interest and penalties assessed on the overpayment). Section 400.202 defines a “supplier” as “a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare.”

Generally, overpayments result when payment is made by Medicare for items or services that are not covered, exceeds the amount allowed by Medicare for an item or service, or is made for items or services that should have been paid by another insurer (for example, Medicare secondary payer obligations). Once a determination and any necessary adjustments in the amount of the overpayment have been made, the remaining amount is a debt owed to the United States Government.

Section 1870 of the Social Security Act (the Act) provides a framework within which liability for such Medicare overpayments is determined and recoupment of overpayments is pursued. This framework prescribes a decision making process that the agency follows when pursuing the recoupment of Medicare overpayments.

The regulation governing the liability for Medicare overpayments is located at 42 CFR part 401 (subpart F).

B. Statutory Authority

The Federal Claims Collection Act of 1966 (Pub. L. 89-508) (FCCA), 80 Stat. 308 (amended by the Debt Collection Improvement Act of 1996 (Pub. L. 104-134) (DCIA) (codified at 31 U.S.C. 3711)) is the Federal government’s basic statutory authority for debt management practices. The Congress intended the FCCA to reduce the amount of litigation previously required to collect claims and to reduce the volume of private relief legislation in the Congress. The FCCA was intended to be independent of the other authorities we use to collect debt and added to, rather than supplanted, our other authorities, including common law authority.

The FCCA authorized the head of an agency to collect claims in any amount. This statute also provided that the head of an agency may, under certain conditions, compromise a claim, or suspend or terminate collection action on a claim. Uncollectible claims in excess of \$100,000, exclusive of interest, must be referred to the Department of Justice for compromise. The FCCA was

amended in 1996 and is now referred to as the Debt Collection Improvement Act of 1996 (Pub. L. 104-134) (DCIA), 110 Stat. 1321, 1358 (April 26, 1996) (codified at 31 U.S.C. 3711).

In the November 2, 1977 **Federal Register** (42 FR 57351), the Secretary of the Department of Health and Human Services (the Secretary) published a rule to delegate authority to the Department Claims Officer generally, and the Administrator of the Centers for Medicare & Medicaid Services (the Administrator) for necessary claims collection actions under our programs. The authority delegated to the Administrator covers all of our activities in the Medicare program (Title XVIII) and pertains to claims up to \$20,000. (This amount has been increased to \$100,000; see 31 U.S.C. 3711.)

In the August 29, 1983 **Federal Register** (48 FR 39060), we published the “Federal Claims Collection Act; Claims Collection and Compromise” final rule with comment period in accordance with the FCCA. In that final rule with comment period, we adopted the applicable debt collection tools made available to us under the FCCA including the ability to collect or compromise claims, or suspend or terminate collection action, as appropriate. The final rule with comment period also set forth the requirements we use to evaluate debtors’ requests for extended repayment agreements specified in § 401.607.

As part of the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191) (HIPAA), the Congress added section 1893 to the Act establishing the Medicare integrity program (MIP) to carry out Medicare program integrity activities that are funded from the Medicare Trust Funds. Section 1893 of the Act expands our contracting authority to allow us to contract with eligible entities to perform MIP activities. These activities include review of provider and supplier activities including medical, fraud, and utilization review; cost report audits; Medicare secondary payer determinations; education of providers, suppliers, beneficiaries, and other persons regarding payment integrity and benefit quality assurance issues; and developing and updating a list of durable medical equipment items that are subject to prior authorization (42 U.S.C. 1395ddd). These MIP contractors assist us in the identification and collection of Medicare provider and supplier overpayments.

C. Overview of Current Policy

The current policy that CMS and its contractors use for the evaluation of extended repayment schedules (ERSs) is based on the existing regulations at § 401.607(c)(2) and guidance in the Medicare Financial Management Manual, Pub. 100-6 (Chapter 4, Section 50). Under our current policy, we determine the frequency and amount of the installment payments based on the factors set forth at the current § 401.607(c)(2) which include the following: (1) The amount of the claim; (2) the debtor's ability to pay; and (3) the cost to CMS of administering an installment agreement.

Under the current ERS review process, we primarily focus on the second factor, the debtor's ability to repay the overpayment, by conducting a review of the debtor's financial status, similar to how banks assess applicants for a loan. In almost all cases, we try to work with the provider or supplier to recover the overpayment. In general, it has been our experience that it is in both CMS and the debtor's best interests to work out a reasonable repayment schedule to recoup an overpayment rather than demand immediate collection of the debt within 30 days, which could place a provider or supplier at financial risk or bring the provider or supplier a step closer to bankruptcy.

Under our existing procedures we review financial documentation submitted by the provider or supplier to assess the provider's or supplier's ability to repay the Medicare overpayment. This documentation must include, at a minimum, a statement of financial position (for example, a balance sheet), a statement of financial performance (for example, an income statement), and a statement of future viability (for example, a projected statement of cash flow). In addition, the provider must include a letter from a financial institution proving that it cannot obtain financing from an alternative source.

D. Medicare Prescription Drug, Improvement, and Modernization Act of 2003

On December 8, 2003, the Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) (MMA). This legislation contained provisions affecting the recovery of provider and supplier overpayments under the Medicare program. Section 935(a) of the MMA amended title XVIII of the Act by adding a new section 1893(f)(1) to the Act to require us to use certain statutory

criteria in evaluating whether a provider or supplier should be granted a repayment schedule of at least 6 months and up to 5 years.

II. Provisions of the Proposed Regulations

The following is an overview of the provisions we proposed in the Use of Repayment Plans proposed rule published in the November 27, 2006 **Federal Register** (71 FR 68519).

1. Hardship Provision

Under section 1893(f)(1) of the Act, we may grant a provider or a supplier upon request, a repayment schedule of at least 6 months, if repaying an overpayment within 30 days would constitute a "hardship" on the provider or supplier, provided that certain criteria are met.

The new statute at section 1893(f)(1)(B)(i) of the Act defines "hardship" based on the relationship between the amount of the Medicare overpayment(s) not covered under an existing ERS owed by a provider or supplier and the total amount of Medicare payments made to that provider or supplier over the most recently submitted cost report or for the previous calendar year.

Under section 1893(f)(1)(B) of the Act, a provider or supplier's repayment of an overpayment within 30 days is deemed to be a "hardship" when the total amount of all outstanding overpayments not included in an approved existing repayment schedule is 10 percent or greater than the total Medicare payments made for the cost reporting period covered by the most recently submitted cost report (for a provider filing a cost report), or the previous calendar year (for a supplier or non cost report provider). We proposed to interpret "outstanding overpayments" to include both principal and accrued interest. We read the newly added section 1893(f)(1)(B)(iii) of the Act to exclude overpayments already being repaid under an approved ERS.

We proposed to interpret the new "hardship" test under section 935(a) of the MMA as not to supersede our ERS regulations currently at § 401.607(c)(2), (which we proposed to redesignate as § 401.607(c)(3)). Since our existing regulations governing ERSs are issued under the FCCA, we do not plan to eliminate the criteria and procedures currently used to grant providers and suppliers ERSs. Instead, we proposed to add an initial "hardship" test to existing regulations and procedures for determining a debtor's ERS.

We proposed that all requests for an ERS first be evaluated under the new

"hardship" test. Under section 935(a) of the MMA, if "hardship" is determined and no statutory exception applies under § 401.607(c)(2)(iv), then the statute requires that the Secretary grant a provider or supplier a repayment period of at least 6 months but not longer than 3 years.

Section 935(a) of the MMA requires that the Secretary establish rules for cases when a provider or a supplier was not paid during the previous year or paid for only a portion of that year. For these cases, we proposed to use the last 12 months of Medicare payments made to the provider or supplier. In cases where there is less than a 12-month payment history, we proposed that the number of months available be annualized to equal an approximate yearly Medicare payment level for the provider or supplier. (For detailed examples on how to apply the new "hardship" test provided in section 1893(f)(1) of the Act, please see the November 27, 2006 proposed rule, "Use of Repayment Plans" (71 FR 68521).)

2. Exceptions Under the "Hardship" Provision in Section 935(a) of the MMA

Section 935(a) of the MMA sets out exceptions to granting a provider or supplier an extended repayment schedule even if the provider or supplier meets the "hardship" test. These exceptions occur when there is reason to suspect the provider or supplier may file for bankruptcy, cease to do business, discontinue participation in the program, or when there is an indication of fraud or abuse committed against the program. (We proposed that contractors continue to use existing procedures and definitions applicable to bankruptcy and fraud or abuse.) In such cases, CMS or its contractors are prohibited from granting an ERS.

3. Extreme Hardship Provision

Under the provisions of § 401.607(c)(2)(vi) of this final rule, the Secretary may grant a provider or a supplier a repayment schedule of 36 months and up to 60 months if repaying an overpayment would constitute an "extreme hardship" unless a statutory exception applies under § 401.607(c)(2)(iv). Since the Congress left the definition of "extreme hardship" to our discretion, we considered different approaches for defining "extreme hardship" and sought public comment on this section.

We considered proposing a new financial threshold to determine if a provider or supplier was in extreme financial hardship, such as using a 15 percent threshold. We rejected this

approach because it could result in discriminating against providers and suppliers who may be similarly financially situated but may attribute more of their total revenue to Medicare income. This could occur for example with a home health agency (HHA) which may attribute 100 percent of its revenue to Medicare business and a skilled nursing facility (SNF) which may only attribute 20 percent of its business to Medicare.

We proposed to define “extreme hardship” when a provider or supplier qualifies under the “hardship” provision defined above and the provider’s or supplier’s request for an ERS is approved under newly redesignated § 401.607(c)(3). If we determine the request meets the criteria in the redesignated § 401.607(c)(3) and meets the CMS manual guidance set forth in the Medicare Financial Management Manual, Pub. 100–6, Chapter 4, Section 50, we proposed that the provider or supplier may be granted an ERS between 36 and 60 months. We also proposed that contractors apply the statutory exceptions to “extreme hardship” cases in a similar manner as they do to “hardship” cases. We solicited comments on other alternative approaches to define “extreme hardship” that could distinguish between the most extreme cases requiring ERSs between 36 and 60 months.

4. Extended Repayment Schedules (ERSs)

We proposed to initially handle ERS requests differently than we have under our current regulations. We proposed to allow providers or suppliers that meet the “hardship” test and request only a 6-month ERS period, the opportunity to pay back the Medicare debt in 6 months without having to submit financial documentation to the contractor in accordance with the existing instructions in the Medicare Financial Management Manual, CMS, Pub. 100–6, Chapter 4, Section 50. We believe that by waiving the requirement to submit financial documentation (such as financial statements or a bank denial letter) for a 6-month ERS, we allow a provider or supplier time to generate or secure the necessary capital to liquidate the debt without having to file extensive documentation in order to secure a repayment schedule.

We therefore proposed that a provider or supplier that requests a 6-month ERS, meets the “hardship” test, does not fall within an exception, and elects not to submit financial documentation would be approved for a 6-month ERS. Any provider or supplier qualifying for the 6-

month ERS under the “hardship” provision has the choice to turn down the 6-month ERS and either pay off the debt within 30 days of the date of determination or request a longer than 6-month ERS. In addition, we proposed not to prohibit any provider or supplier under the 6-month “hardship” provision ERS from applying for a longer ERS if it later desires to do so under § 401.607(c)(3).

For all ERS requests greater than 6 months, we proposed to rely on current regulations and procedures that require the provider or supplier to submit financial documentation in accordance with the Medicare Financial Management Manual, CMS Pub. 100–6, Chapter 4, Section 50. A provider or supplier must continue to submit a written request that refers to the specific overpayment for which an ERS is being requested, the number of months requested in the ERS, and include the first payment with its request. The contractor would determine the duration of the ERS based on its review of the provider or supplier’s documentation in accordance with CMS manual guidance.

If a provider or supplier misses one installment payment in any ERS granted under section 935(a) of the MMA, the statute permits us to immediately collect the entire overpayment. However, we proposed to impose this penalty only on the “automatic” 6-month ERS. With all other ERSs, we proposed to continue to use the existing procedures that define a default of an ERS as missing two consecutive installment payments.

We proposed to revise § 401.601(a) to read as follows: “This subpart implements the following provisions: (1) For CMS the Debt Collection Improvement Act of 1996 (Pub. L. 104–134) (DCIA), 110 Stat. 1321, 1358 (April 26, 1996) (codified at 31 U.S.C. 3711), and conforms to the regulations (31 CFR parts 900–904) issued jointly by the Department of the Treasury and the Department of Justice that generally prescribe claims collection standards and procedures under the DCIA for the Federal government; (2) section 1893(f)(1) of the Act regarding the use of repayment plans.”

In addition, in § 401.603 we proposed to add a definition for an “extended repayment schedule.”

We proposed to redesignate § 401.607(c)(2) as § 401.607(c)(3). In addition, we proposed a new § 401.607(c)(2), Extended repayment schedule, in accordance with section 1893(f)(1) of the Act. We proposed to implement the provisions of section 1893(f)(1) of the Act, as amended by

section 935(a) of the MMA, in new § 401.607(c)(2), Extended repayment schedule.

III. Analysis of and Responses to Public Comments

We received 6 public comments on the November 27, 2006 proposed rule. The following is a summary of the major issues and our responses.

Comment: One commenter believed that the provisions of the proposed rule were not equitable between provider types because 10 percent of total Medicare reimbursement for a provider with a 50 percent Medicare fee-for-service revenue is a greater threshold to reach than a provider with a 5 percent Medicare fee-for-service revenue.

Response: We agree with the comment that the proposed rule may not in all cases treat different provider types similarly. However, the statute was written to define hardship as a ratio of Medicare overpayments to total Medicare payments/reimbursement in a given time period. The statute does not allow CMS to take into account the percentage of patient revenue from other sources when defining “hardship.” For all other ERS requests, we proposed to rely on current regulations and procedures that require the provider or supplier to submit financial documentation in accordance with the Medicare Financial Management Manual, CMS Pub. 100–6, Chapter 4, Section 50.

Comment: Some commenters believed it would be more consistent and more fair to providers if we would use the definition of default for all ERSs as missing two consecutive installment payments.

Response: While the statute permits us to immediately collect on an entire overpayment if a provider or supplier misses one installment payment in any ERS granted under section 935(a) of the MMA, we have decided to impose the 1-month missed payment rule only for the 6-month “hardship-based” ERS. We chose not to apply the two missed payment rule to 6-month ERSs because we do not want a provider or supplier to be too far in arrears if they miss payments in such a short ERS. A provider or supplier that is behind two payments in a 6-month ERS has a greater amount of its payments in arrears than a provider or supplier that is behind two payments in a 36-month or 60-month ERS. For example, two missed payments on the amortization of an overpayment covered under a 6-month ERS (2 divided by 6) is equal to approximately 33.3 percent of the total overpayment whereas 2 missed payments under a 36-month ERS (2

divided by 36) is equal to a much lower 5.5 percent of the total overpayment. On a 60-month ERS, two missed payments would only equal 3.3 percent of the total overpayment (2 divided by 60).

Comment: Some commenters were concerned that we may be inadvertently legally binding providers to the "automatic" 6-month ERS and not offering providers a future opportunity to request a second ERS under § 401.607(c).

Response: In the proposed rule, we stated that any provider or supplier qualifying for the 6-month ERS under the "hardship" provision has the choice to turn down the 6-month ERS and either pay off the debt within 30 days of the date of determination or request a longer ERS under newly redesignated § 401.607(c)(3). In addition, we will not prohibit any provider or supplier under the 6-month "hardship" provision ERS from applying for a longer ERS if it later desires to do so under § 401.607(c)(3).

Comment: One commenter believed that there is no practical reason for why we have not adopted a parallel numerical threshold approach to extreme hardship by using some percentage above the numerical 10 percent threshold for hardship.

Response: The 10 percent used in this final rule to define hardship is required by statute. As stated in the proposed rule, we considered proposing a new financial threshold to determine if a provider or supplier was in extreme financial hardship, such as using a 15 percent threshold. However, we rejected this approach because it could result in discriminating against providers and suppliers who may be similarly financially situated but may attribute more of their total revenue to Medicare income. This could occur for example with a home health agency (HHA) which may attribute 100 percent of its revenue to Medicare business and a skilled nursing facility (SNF) which may only attribute 20 percent of its business to Medicare. In addition, the ERS review process is a multivariable financial analysis and it would not be practical or equitable to either the provider/supplier or the Medicare program to reduce the ERS process down to a single variable. We believe keeping the definition of extreme hardship broader than a single variable is in the best interests of the provider and supplier community and is the most effective way to ensure that overpayments will be collected and returned to the Medicare Trust Fund.

Comment: One commenter stated that there is confusion as to why the burden of producing financial documentation can be removed for the "automatic" 6-

month ERS but not for ERS plans longer than 6 months.

Response: We removed the financial documentation requirement for 6-month ERSs because the contractor already has the requisite information needed to determine if a provider or supplier meets the statutory hardship test. However, in order to grant an ERS longer than 6 months, we continue to need financial documentation to determine a provider or supplier's ability to make future ERS payments. We also need financial data to determine the length of the ERS or payback period that should be granted to the provider or supplier. While a short ERS may cause a provider or supplier to go out of business, the longer the ERS period the greater the delay in the overpayment recovery and the greater the financial risk to the Medicare program. We believe the increased risk associated with a longer repayment or amortization period requires that we give an ERS request greater financial scrutiny.

Comment: We received comments that were outside the scope of the proposed rule (for example, regarding the effects on State Medicaid programs).

Response: We are not responding in this final rule to comments that are outside of the scope of the proposed rule.

IV. Provisions of the Final Regulations

As a result of our review of the public comments, we do not find any cause to alter the provisions of the proposed rule. Therefore, we are finalizing the provisions as proposed.

V. Collection of Information Requirements

This final rule does not impose any new information collection or recordkeeping requirements. The information collection requirements discussed in the preamble pertain to the extension of repayment schedules. The requirements and associated paperwork burden are approved under Office of Management and Budget (OMB) control number 0938-0270, with a current expiration date of January 31, 2011.

We plan to submit a revised information collection request (ICR) to OMB to address the reduction of burden associated with the "hardship test" and 6-month ERS period. As discussed in Section I. of the preamble, providers or suppliers that meet the "hardship" test and request only a 6-month ERS period, will have the opportunity to pay back the Medicare debt in 6 months without having to submit financial documentation to the contractor. This new requirement reduces the

information collection burden placed on providers and suppliers. We will announce the revisions to 0938-0270 under separate notice and comment periods prior to submitting the revisions for OMB approval.

VI. Regulatory Impact Statement

A. 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 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Order 13258 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 will not reach the economic threshold and thus is not considered a major rule. There will be no additional costs or documented savings resulting from the implementation of this final 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 small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6.5 million to \$31.5 million in any 1 year. For purposes of the RFA, approximately 95 percent of the health care industry is considered small businesses according to the Small Business Administration's size standards with total revenues of \$6.5 million to \$31.5 million or less in any 1 year. Individuals and States are not included in the definition of a small entity. Because there are no additional costs or documented savings resulting from the implementation of this rule, the Secretary has determined that this final 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. Because there are no additional costs or documented savings resulting from the implementation of this final rule, this final 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 whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$127 million. This final rule will not impose spending costs on State, local, or tribal governments in the aggregate, or by the private sector, of \$127 million.

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 final rule will not have a substantial effect on State or local governments.

B. Anticipated Effects

1. Effects on Medicare Providers and Suppliers

This final rule could affect all Medicare provider and supplier types with a Medicare overpayment. This final rule will allow Medicare providers or suppliers falling within these provisions a 6 month period to pay back debt owed to Medicare without being required to file extensive financial documentation. We believe that this short repayment time period could provide a provider or supplier time to generate or secure the necessary capital to liquidate the debt without having to file the financial documentation required to secure a longer repayment schedule.

2. Effects on Other Providers

There will be no effect on other providers.

3. Effects on the Medicare and Medicaid Programs

There will be no additional costs or documented savings resulting from the

implementation of this final rule. There may be savings due to a possible reduction in paperwork.

C. Alternatives Considered

We considered adopting mathematically precise distinctions between “hardship” and “extreme hardship,” but rejected this approach. To select any type of numerical threshold, for example, defining “extreme hardship” as 15 percent of total overpayments in an effort to distinguish it from the test for “hardship,” will result in inequitable outcomes for different providers and suppliers as discussed in the “extreme hardship” section in section II. of this final rule, Provisions of the Proposed Regulations.

In implementing section 935(a) of the MMA, we want to assure providers and suppliers that we will be looking closely at the financial picture each of them has that has prompted them to seek an ERS. Analyzing these financial profiles is a complex undertaking that does not lend itself to overly simplified numerical cutoffs that may qualify some for longer repayment periods but deny them to others that ought to be just as eligible. We solicited comments on other alternative ways to distinguish between “hardship” and “extreme hardship” in an effort to establish a standardized approach to applying the two definitions.

D. Conclusion

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

List of Subjects in 42 CFR Part 401

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

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

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

■ 1. The authority citation for part 401 is revised to read as follows:

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

Subpart F—Claims Collection and Compromise

■ 2. In § 401.601, paragraph (a) is revised to read as follows:

§ 401.601 Basis and scope.

(a) *Basis.* This subpart implements the following statutory provisions:

(1) For CMS the Debt Collection Improvement Act of 1996 (Pub. L. 104–134) (DCIA), 110 Stat. 1321, 1358 (April 26, 1996) (codified at 31 U.S.C. 3711), and conforms to the regulations (31 CFR parts 900–904) issued jointly by the Department of the Treasury and the Department of Justice that generally prescribe claims collection standards and procedures under the DCIA for the Federal government.

(2) Section 1893(f)(1) of the Act regarding the use of repayment plans.

* * * * *

■ 3. In § 401.603, add a new definition for “Extended repayment schedule” to read as follows:

§ 401.603 Definitions.

* * * * *

Extended repayment schedule means installment payments to pay back a debt.

§ 401.607 [Amended]

■ 4. In § 401.607—

■ A. Redesignate paragraph (c)(2) as paragraph (c)(3).

■ B. Add a new paragraph (c)(2).

The addition reads as follows:

§ 401.607 Claims collection.

* * * * *

(c) * * *

(2) *Extended repayment schedule.*

(i) For purposes of this paragraph (c)(2), the following definitions apply:

Extreme hardship exists when a provider or supplier qualifies as being in “hardship” as defined in this paragraph and the provider’s or supplier’s request for an extended repayment schedule (ERS) is approved under paragraph (c)(3) of this section.

Hardship exists when the total amount of all outstanding overpayments (principal and interest) not included in an approved, existing repayment schedule is 10 percent or greater than the total Medicare payments made for the cost reporting period covered by the most recently submitted cost report for a provider filing a cost report, or for the previous calendar year for a supplier or non cost-report provider.

(ii) CMS or its contractor reviews a provider’s or supplier’s request for an ERS. For a provider or a supplier not paid by Medicare during the previous year or paid only during a portion of that year, the contractor or CMS will use the last 12 months of Medicare payments. If less than a 12-month payment history exists, the number of months available is annualized to equal an approximate yearly Medicare payment level for the provider or supplier.

(iii) For a provider or supplier requesting an ERS, CMS or its contractor

evaluates the request based on the definitions and information submitted under this paragraph (c)(2). For a provider or supplier whose situation does not meet the definitions in paragraph (c)(2)(i) of this section, CMS or its contractor evaluates the ERS request using the information in paragraph (c)(3) of this section in deciding to grant an ERS.

(iv) CMS or its contractor is prohibited from granting an ERS to a provider or supplier if there is reason to suspect the provider or supplier may file for bankruptcy, cease to do business, discontinue participation in the Medicare program, or there is an indication of fraud or abuse committed against the Medicare program.

(v) CMS or its contractor may grant a provider or a supplier an ERS of at least 6 months if repaying an overpayment within 30 days will constitute a "hardship" as defined in paragraph (c)(2)(i) of this section. If a provider or supplier is granted an ERS under this paragraph, missing one installment payment constitutes a default and the total balance of the overpayment will be recovered immediately.

(vi) CMS or its contractor may grant a provider or a supplier an ERS of 36 months and up to 60 months if repaying an overpayment will constitute an "extreme hardship" as defined in paragraph (c)(2)(i) of this section.

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

Dated: *January 22, 2008.*

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: *February 27, 2008.*

Michael O. Leavitt,

Secretary.

Editorial Note: This document was received at the Office of the Federal Register on June 11, 2008.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 424, and 498

[CMS-6003-F]

RIN 0938-AI49

Medicare Program; Appeals of CMS or CMS Contractor Determinations When a Provider or Supplier Fails to Meet the Requirements for Medicare Billing Privileges

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

ACTION: Final rule.

SUMMARY: This final rule implements a number of regulatory provisions that are applicable to all providers and suppliers, including durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers. This final rule establishes appeals processes for all providers and suppliers whose enrollment, reenrollment or revalidation application for Medicare billing privileges is denied and whose Medicare billing privileges are revoked. It also establishes timeframes for deciding enrollment appeals by an Administrative Law Judge (ALJ) within the Department of Health and Human Services (DHHS) or the Departmental Appeals Board (DAB), or Board, within the DHHS; and processing timeframes for CMS' Medicare fee-for-service (FFS) contractors.

In addition, this final rule allows Medicare FFS contractors to revoke Medicare billing privileges when a provider or supplier submits a claim or claims for services that could not have been furnished to a beneficiary. This final rule also specifies that a Medicare contractor may establish a Medicare enrollment bar for any provider or supplier whose billing privileges have been revoked.

Lastly, the final rule requires that all providers and suppliers receive Medicare payments by electronic funds transfer (EFT) if the provider or supplier, is submitting an initial enrollment application to Medicare, changing their enrollment information, revalidating or re-enrolling in the Medicare program.

DATES: *Effective Date:* These regulations are effective on August 26, 2008.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

A Medicare beneficiary may obtain covered Medicare items or services from any person, or institution that is enrolled in the Medicare program and is qualified to furnish those services. Various provisions of the statute and regulations establish conditions of participation or standards that a healthcare provider or supplier must meet in order to receive Medicare payment. These standards differ depending on the type of provider or supplier involved and whether the services are furnished under Parts A or B of the Medicare statute. There are also differences in qualifications between providers and suppliers of services, and differences among the various types of suppliers, in how they are enrolled in the Medicare program. For some classifications of providers and suppliers, an on-site survey is required. For other individuals or entities, a determination can be made based largely on the information provided by the applicant.

The Medicare regulations in 42 CFR part 498 provide appeal rights for providers and suppliers that have been found to not meet certain conditions of participation or established standards. For the purposes of part 498, these suppliers include, but are not limited to, independent laboratories; suppliers of portable x-ray services; rural health clinics; federally qualified health centers; ambulatory surgical centers; entities approved by CMS to furnish outpatient diabetes self-management training or end-stage renal disease treatment facilities. For the purposes of part 498, the term "provider" refers to a hospital, critical access hospital (CAH), skilled nursing facility, comprehensive outpatient rehabilitation facility (CORF), home health agency or hospice (HHA), religious nonmedical health care institutions (RNHCIs) that has in effect an agreement to participate in Medicare; or a clinic, rehabilitation agency, or public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services.

In addition, § 405.874 provides an appeals process for suppliers of DMEPOS that wish to contest a denial of an application for billing privileges or the revocation of existing billing privileges. It also affords DMEPOS suppliers the right to a carrier or Medicare Administrative Contractor (MAC) hearing before an official who was not involved in the original determination, and the right to seek a review before a CMS official designated by the CMS Administrator.