analysis and documentation under that section.

Under figure 2–1, paragraph (34)(h), of the Instruction, an ''Environmental Analysis Check List'' and a ''Categorical Exclusion Determination'' are not required for this rule. Comments on this section will be considered before we make the final decision on whether to categorically exclude this rule from further environmental review.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to temporarily amend 33 CFR Part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

1. The authority citation for Part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; Department of Homeland Security Delegation No. 0170.1.

2. In § 100.525, from 8 a.m. to 6 p.m. on April 21 and 22, 2007, temporarily suspend paragraph (c).

3. In § 100.525, from 8 a.m. to 6 p.m. on April 21 and 22, 2007, temporarily add a new paragraph (d) to read as follows:

§ 100.525 Western Branch, Elizabeth River, Portsmouth, Virginia.

* * * * *

(d) *Enforcement period.* This section will be enforced from 8 a.m. to 6 p.m. on April 21 and 22, 2007. A notice of enforcement of this section will be disseminated through the Fifth Coast Guard District Local Notice to Mariners announcing the specific event date and times. Notice will also be made via marine Safety Radio Broadcast on VHF–FM marine band radio channel 22 (157.1 MHz).

Dated: February 15, 2007.

Larry L. Hereth,

Rear Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. E7–3638 Filed 3–1–07; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 424, and 498

[CMS–6003–P2]

RIN 0938–AI49

Medicare Program; Appeals of CMS or 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: Proposed rule.

SUMMARY: This proposed rule would establish an appeals process for providers and suppliers whose applications for enrollment or renewal of enrollment were denied. It would also grant providers and suppliers the right to a hearing by an Administrative Law Judge (ALJ) within the Department of Health and Human Services after an adverse decision at the reconsideration level when a provider or supplier's Medicare enrollment application is denied to those situations in which the provider or supplier's Medicare billing privileges are revoked. In addition, this proposed rule would grant providers and suppliers the right to Departmental Appeals Board review of an adverse ALJ decision.

It would also establish timeframes for deciding enrollment appeals by an ALJ or the DAB. This proposed rule would also establish the use of electronic funds transfer (EFT) be used for all Federal payments to providers and suppliers.

Finally, this proposed rule would implement section 936(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which specifies the timeframes in which contractors must process all provider and supplier enrollment actions (initial enrollments, change of information actions, revalidations, etc.).

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on May 1, 2007.

ADDRESSES: In commenting, please refer to file code CMS–6003-P2. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Submit electronic comments on CMS regulations with an open comment period.'' (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–6003–P2, P.O. Box 8017, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6003–P2, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410)786–7195 in advance to schedule your arrival with one of our staff members.

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: August Nemec, (410) 786–0612.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–6003–P2.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Electronic Comments on CMS Regulations'' on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

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, B, or C 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 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 independent laboratories; suppliers of portable x-ray services; rural health clinics; federally qualified health centers; ambulatory surgical centers; end-stage renal disease treatment facilities; and chiropractors and physical therapists in private practice. For the purposes of Part 498, the term ''provider'' refers to a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility (CORF), home health agency or hospice, that has in effect an agreement to participate in Medicare; or a clinic, rehabilitation agency, or pubic health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services; or community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services.

In addition, our regulations at § 405.874 provide an appeals process for suppliers of Durable Medical Equipment, Prosthetics and Orthotics and Supplies (DMEPOS) that wish to contest a denial of an application for a billing number or the revocation of an existing billing number. The § 405.874 appeals process affords DMEPOS suppliers the right to a carrier hearing before a carrier 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.

In December 1998, we issued CMS Ruling 98–1, regarding the appeals process Medicare carriers must provide to physicians, nonphysician practitioners, and to certain entities that receive reassigned benefits from physicians and nonphysician practitioners. CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of statute or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters. CMS Rulings are binding on all our components, Medicare contractors, the Provider Reimbursement Review Board, the Medicare Geographic Classification Review Board, and ALJs who hear Medicare appeals. These Rulings promote consistency in interpretation of policy and adjudication of disputes. This proposed rule is different from the clarification of appeals procedures found in CMS Ruling 98–1, because it adds provisions in order to comply with the MMA. Whereas the ruling followed the procedures in § 405.874, this proposed rule would grant suppliers the right, after denial or revocation of a supplier's Medicare billing privileges, to a hearing by an ALJ after an adverse decision at the reconsideration level as well as judicial review.

II. Provisions of the Proposed Rule Published on October 25, 1999

In the October 25, 1999 **Federal Register** (64 FR 57431), we published a proposed rule that set forth proposed revisions to § 405.874 (Appeals of carrier decisions that supplier standards are not met) to extend appeal rights to all suppliers whose enrollment applications for Medicare billing privileges are revoked, except for those suppliers covered under the appeals provisions of part 498. The proposed rule stated that these administrative appeal rights would apply to suppliers of durable medical equipment, prosthetics, orthotics, and supplies; ambulance service providers; independent diagnostic testing facilities; physicians; and other suppliers such as physician assistants. We also proposed revisions to the existing procedures in § 405.874.

Since section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) prohibits the Secretary from finalizing a proposed rule that was published more than 3 years earlier except under exceptional circumstances, we are not seeking comment on our earlier proposed rule. In addition, we have revised the October 25, 1999 proposed rule in order to comply with section 936 of the MMA. However, we are including a summary discussion of the significant provisions stated in the October 25, 1999 proposed rule in order to provide historical background regarding the development of this proposed rule. The following is a summary of the procedural changes found in the October 25, 1999 proposed rule.

In our October 1999 proposed rule we proposed to:

- Set forth the procedures to be followed by carriers concerning notifying a supplier of the denial of an enrollment application for supplier billing privileges.
- Clarify that a revocation of a supplier billing number that is based on a Federal exclusion or debarment is effective with the effective date of the exclusion or debarment, regardless of the date of the notice from the carrier that the billing number is revoked.
- Change the language in current § 405.874(c) that requires a carrier

hearing officer to schedule a hearing to be held within 1 week.

- Clarify that we would not pay for services furnished by suppliers during a period in which the supplier's billing privileges have been denied or revoked.
- Clarify that the supplier must be in compliance with all requirements in order to have its billing number reinstated, and that we must be satisfied that the supplier is in compliance and will remain in compliance.
- Permit the carrier, carrier hearing officer, or CMS (then HCFA) official to reopen and revise its initial determination
- Restrict DMEPOS suppliers from billing for services prior to the date that their billing number was issued.
- Describe the procedure for submitting claims after a reversal of a supplier enrollment application denial or billing number revocation, or after a billing number reinstatement.

III. Analysis of and Responses to Public Comments Received From the Proposed Rule Published on October 25, 1999

The following is a summary of our comments and responses to the October 25, 1999 proposed rule. Notwithstanding the presentation of these comments and responses, we are only soliciting comments on this proposed rule.

Comment: One commenter suggested that we simplify the enrollment application (Form CMS 855) instead of removing the requirement that a carrier must accept or reject an entity's enrollment application for a billing number or request additional information within 15 days of the receipt of the enrollment application.

Response: Since the publication of our October 25, 1999 proposed rule we have published several notices requesting public comment on the enrollment applications in the **Federal Register** including one on February 2, 2001, (66 FR 8807). The final approval notice was granted on September 25, 2001. Most recently, we sought public comments on our revised provider enrollment application on July 8, 2005. In the April 25, 2003 **Federal Register** (68 FR 22064), we published a proposed rule concerning our provider enrollment procedures entitled ''Requirements for Establishing and Maintaining Medicare Billing Privileges,'' that includes proposed revisions to the CMS 855 enrollment applications. In addition, to be consistent with the nomenclature in this proposed rule and existing manual instructions, we are changing the term ''disallowance'' to the term ''denial'' throughout this proposed rule.

Comment: Two commenters suggested that carriers be given a timeframe for processing these applications, such as 30 or 45 days. Many commenters recommended that we maintain and enforce a time limit for the carrier to process enrollment applications and expressed concern about delays in billing or the inability to bill for Medicare items and services.

Response We do maintain and enforce provider enrollment processing standards for carriers. Currently, the time limit for the carrier to process an initial determination, can be found in Program Integrity Manual, Chapter 10-Healthcare Provider/Supplier Enrollment. Carriers are evaluated against this standard in the Contractor Performance Evaluation process.

In addition, section 936(a) of the MMA adds a new section 1866(j)(1)(B) to the Act, requiring the Secretary to ''* * * establish by regulation procedures under which there are deadlines for actions on applications for enrollment (and, if applicable, renewal of enrollment). The Secretary shall monitor the performance of Medicare Administrative Contractors in meeting the deadlines * * *'' In this proposed rule, we would establish deadlines for processing all provider and supplier enrollment actions as discussed in greater detail in section IV. of the preamble of this proposed rule.

Comment: Several commenters suggested that we should provide temporary provider numbers during the enrollment process to permit suppliers to submit claims for their provision of items and services prior to receiving a permanent supplier billing number.

Response: Since the publication of the October 25, 1999 proposed rule, we published the Requirements for Providers and Suppliers to Establish and Maintain Medicare enrollment final rule(71 FR 20754), where we required that providers and suppliers obtain billing numbers before enrolling in the Medicare program. The purpose of the enrollment process is to ensure that we enroll qualified, eligible individuals and entities as providers and suppliers of Medicare services. Allowing providers and suppliers to submit claims prior to enrollment in the Medicare program would undermine this process.

Comment: Two commenters suggested that a supplier should not have to prove compliance with all enrollment qualifications because this allows the carrier to raise new objections without warning and shifts the burden of proof to the supplier.

Response: Since the publication of the October 25, 1999 proposed rule, we published the Requirements for Providers and Suppliers to Establish and Maintain Medicare enrollment final rule (April 21, 2006, 71 FR 20754). In this final rule, we require providers and supplier to meet and maintain all Federal and State requirements to be issued and retain Medicare billing privileges. When suppliers enroll in the Medicare program, they are required to sign a certification statement that they are in compliance with all Medicare enrollment requirements. This appeals proposed rule would not alter the burden of proof already placed on the supplier in the initial application process.

Comment: Two commenters suggested that we should propose a separate enrollment process for those suppliers whose enrollment applications have been denied, who have lost their appeal, and who decide to submit a new enrollment application to the carrier.

Response: We maintain that if a supplier's enrollment application has been denied and the denial was upheld by the appeals process, then that supplier would still be eligible to reapply for a Medicare supplier number. If the supplier still wanted to enroll, we assume that the supplier would correct the reasons for the denial. The supplier would be required to submit the enrollment application as an initial enrollment. Therefore, a separate enrollment process for applicants who were denied enrollment would not be practical.

Comment: A commenter stated that we had established the effective date for purposed for billing Medicare for DMEPOS services in a change of ownership (CHOW) situation to be ''the date of the actual change in ownership, rather than the date of assignment of the National Supplier Clearinghouse.''

Response: We agree with the commenter. This is the current policy as long as at the time of the CHOW, all CMS Medicare DMEPOS supplier standards specified in § 424.57 are met.

Comment: Three commenters stated that physicians should not be characterized as suppliers.

Response: For purposes of Medicare terminology, it has been a longstanding practice for physicians to be considered as suppliers. Our regulations at § 400.202 define a supplier as a physician or other practitioner, or an entity other than a provider that furnishes health care services under Medicare. In addition, section 901(b) of the MMA amended section 1861 of the Act by adding paragraph (d), which defines a supplier to include a physician. Therefore, we are retaining the current definition for the purpose of this proposed rule.

Comment: A commenter stated that it is unclear whether this regulation applies to physicians.

Response: This proposed rule would apply to physicians, as physicians are considered suppliers in accordance with the definitions specified in § 400.202.

Comment: One commenter stated that this regulation should have been incorporated into a rule that established requirements for obtaining and maintaining Medicare billing privileges.

Response: As stated previously, we finalized CMS–6002-F, Requirements for Provider and Suppliers to Establish and Maintain Medicare Enrollment, on April 21, 2006 (71 FR 20754). Accordingly, we are not able to adopt this suggestion.

Comment: A commenter suggested that we add an exception to this rule for time periods during which a supplier is unaware of the debarment or exclusion of another entity with which it is doing business.

Response: While we understand this comment, we believe that information on excluded or debarred entities is readily available to the public. For example, the Office of Inspector General's (OIG's) Web site pages which include the following:

• OIG's ''List of Excluded Individuals and Entities.'' This list is commonly referred to as the ''OIG Sanction List'' for those parties excluded by the OIG from participation in the Medicare, Medicaid, and all Federal health care programs (as defined in section 1128B(f) of the Act);

• ''List of Parties Excluded from Federal Procurement and Non-procurement Programs,'' known as the ''GSA Debarment List'', for those parties debarred, suspended or otherwise excluded by other Federal agencies from participation in Federal procurement and nonprocurement programs and activities.

The aforementioned lists are in accordance with the Federal Acquisition and Streamlining Act of 1994, and with the HHS Common Rule at 45 CFR part 76. The Web site for the OIG exclusion list can be found at *http://www.oig.hhs.gov* and the Web site for the debarment list can be found at *http://www.epls.arnet.gov.*

Comment: Two commenters suggested that we should more clearly distinguish between those suppliers whose initial enrollment applications had been denied and those whose enrollment had been revoked.

Response: With the publication of Requirements for Provider and Suppliers to Establish and Maintain Medicare Enrollment final rule (April 21, 2006, 71 FR 20754), we believe we have clarified the differences between a denial of billing privileges and revocation of billing privileges. In addition, we believe that only one appeals process is necessary to resolve adverse administrative enrollment decisions.

Comment: One commenter stated that the appeal rights of a supplier that has been excluded by the OIG are more expansive than the appeal rights contained in this regulation for a supplier whose billing number has been revoked, since an excluded supplier may request an Administrative Law Judge (''ALJ'') hearing.

Response: This proposed rule reflects the requirements of section 936(a) of the MMA to grant the right to an ALJ hearing, judicial review, and DAB review to a revoked supplier. Therefore, an excluded supplier would no longer have more expansive appeal rights.

Comment: Several commenters noted that § 405.874(a) should clearly state that the carrier should fully inform the supplier in detail as to why it has denied the supplier's enrollment application or revoked the supplier's enrollment.

Response: We agree with the commenters. In this proposed rule, we are proposing in § 405.874(a) and (b) that the carrier provide the reason why a supplier's enrollment application was denied or why its billing number was revoked.

Comment: Several commenters were opposed to reducing the timeframe to file an appeal of a denial of an enrollment application or the revocation of a Medicare billing number from 90 to 60 days.

Response: We are proposing to follow the longstanding processes of part 498, which allow 60 days for filing an appeal.

Comment: A few commenters contended that we should accept a postmark as the reliable date to determine when suppliers have learned of a carrier decision to deny an application or revoke Medicare billing privileges.

Response: We agree with the commenters. We believe that § 498.22(b)(3), § 498.22(d), and § 498.40 clearly address when we must accept a postmark as the reliable date to determine when suppliers have learned of a carrier decision to deny an application or revoke Medicare billing privileges.

Comment: One commenter stated that it is confusing to base the revocation of a billing number on the effective date of the Federal action (exclusion or debarment), regardless of the date of notice from the carrier.

Response: The OIG sends an exclusion notice to the supplier and the carrier at the same time explaining that the supplier is being excluded from Medicare, Medicaid, and other Federal health care programs. The effective date of the exclusion is 20 days after the date the notice is sent to the supplier and the carrier (see § 1001.2002(b)). The carrier does not establish the date for the exclusion nor can the carrier alter the effective date of OIG exclusion.

Comment: One commenter stated that the carrier should not have the discretion to implement a carrier hearing officer's decision to deny or revoke a supplier billing number pending a possible appeal. This commenter suggested that carriers be required to decide within 15 days whether to appeal a hearing officer's reversal decision, and if the carrier chooses not to appeal, then it must immediately implement the decision.

Response: In accordance with section 936(1)(b)(1) of the MMA, we propose to follow the process of part 498. These procedures have specific timeframes.

Comment: Several commenters stated that an ALJ, rather than a CMS official, should conduct the appeal that follows the carrier hearing.

Response: Section 936(l)(b)(1) of the MMA provides for an ALJ hearing. Therefore, we are proposing to modify our regulations to address this concern.

Comment: One commenter stated that when a revocation of a supplier billing number is reversed upon appeal, the supplier billing number should be reinstated to the date upon which the revocation became effective.

Response: We agree. In this proposed rule, we would revise § 405.874(d), to provide that in the case of a reversal of a revocation on appeal, a supplier billing number is reinstated back to the date that the revocation became effective.

Comment: One commenter suggested that we should establish clear guidelines as to when and why a carrier or a carrier hearing officer can reopen an existing decision or determination, and another commenter suggested that reopening of decisions should be limited to situations where good cause has been established and new and material evidence has been uncovered.

Response: While we considered establishing a reopening process, we believe that the appeals process that would be established in this proposed rule affords providers and suppliers with sufficient protections. We would appreciate receiving additional public comments regarding the benefits associated with expanding on the

reopening process established in § 498.30.

Comment: One commenter stated that the provisions relating to the rejection of claims fails to distinguish between suppliers whose billing numbers have been revoked and those whose enrollment applications are pending. The commenter also was concerned that payments will be rejected only when a supplier's enrollment has been revoked because a carrier's rejection of claims affords no appeal rights.

Response: It is true that the provision that claims be rejected does not in fact, distinguish between those suppliers whose billing numbers are revoked and those whose enrollment applications are pending. Claims are rejected when the supplier does not have valid billing privileges at the time that claims were submitted. When a supplier's application is approved and it is assigned a billing number, these claims may be resubmitted and paid retroactively, except for DMEPOS suppliers, who do not have retroactive billing privileges. In addition, we maintain that claims are rejected for those suppliers whose billing privileges are revoked so the contractor does not have to hold the claims in its system indefinitely.

Comment: Two commenters stated that we should ensure that all decisions are reached and implemented prior to the claims expiration date, or the agency should allow exceptions in circumstances when the timeframe to pay allowable claims has expired.

Response: The timely filing requirements for claims submission, as specified in § 424.44, are not affected by an enrollment application pending processing or by the appeal of the Agency's enrollment decision. As specified in § 405.874(i), if a supplier is successful in overturning its denial or revocation, it has up to 1 year after the reversal decision to file any claims for items furnished during the overturned period.

IV. Provisions of This Proposed Rule

After consideration of the comments reviewed, analysis of specific issues, and the provisions of section 936(l)(b)(1) of the MMA we are modifying the October 25, 1999 proposed rule by making clarifying and editorial changes, and revising the sections affected by 936(l)(b)(1) of the MMA.

With the implementation of the National Provider Identifier (NPI) (which is a standard unique identifier for health care providers) scheduled for May 23, 2007, we believe that it is appropriate to propose use of the term ''Medicare billing privileges'' in lieu of the term ''Medicare billing number.'' (See the January 23, 2004 final rule (69 FR 3469) for more detailed information regarding the NPI.) After implementation of the NPI, providers or suppliers will have to obtain an NPI before initiating enrollment in the Medicare program. Medicare will use the NPI as the billing number. However, providers and suppliers must still enroll with a fee-for-service contractor in order to bill the Medicare program. Thus, the fee-for-service contractor will convey billing privileges.

We propose to maintain § 405.874, which specifies provisions that would apply to certain suppliers as defined in § 405.802.

In § 405.802, we propose to define prospective supplier and suppliers by specifying the provisions of § 405.874 that would apply. These suppliers include an independent laboratory; supplier of durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS); ambulance service provider; independent diagnostic testing facility; physician, other practitioner such as physician assistant; physical therapist in independent practice; clinical laboratories; supplier of portable x-ray services; rural health clinic (RHC); Federally qualified health center (FQHC); ambulatory surgical center (ASC); an entity approved by CMS to furnish outpatient diabetes self-management training, or end-stage renal disease (ESRD) treatment facility that is approved by CMS as meeting the conditions for coverage of its services, and prospective supplier means any of the listed entities that seek to be approved for coverage of its services under Medicare.

In new § 405.874(a), Denial of a supplier enrollment application, we propose that if a carrier denies a supplier's enrollment application, the carrier must notify the supplier by certified mail. The notice must include the following: (1) The reason for denial in sufficient detail to allow the supplier to understand the nature of its deficiencies; (2) the right to appeal in accordance with part 498; and (3) the address to which the written appeal must be mailed.

We propose these changes to comply with section 936(a)(2) of the MMA. Part 498 of these regulations includes the right of a supplier to a reconsideration of a determination that it does not qualify for Medicare billing privileges. This reconsideration would be performed by a carrier hearing officer not involved in the original determination. Part 498 also grants suppliers the right to a hearing by an ALJ, DAB review and judicial review. These various levels of appeal would also apply to revocations of Medicare billing privileges.

In proposed § 405.874(b)(1), Notice of revocation, we would clarify that if a carrier revokes a supplier's Medicare billing privileges that the carrier must notify the supplier by certified mail and that the notice must include—(1) the reason for the revocation in sufficient detail for the supplier to understand the nature of its deficiencies; (2) the right to appeal in accordance with part 498 of this chapter; (3) the address to which the written appeal must be mailed.

In proposed § 405.874(b)(2), Revocation of a supplier's billing privileges, we would separate the procedures in existing § 405.874(a) and § 405.874(b) because we believe the language in the October 29, 1999 proposed rule was not sufficiently clear. In proposed § 405.874(b)(2), we clarify that a revocation of a supplier's billing privileges that is based on a Federal exclusion or debarment is effective with the effective date of the exclusion or debarment, regardless of the date of the notice from the carrier that the billing number is revoked. Moreover, if CMS, or one of its designated contractors revokes Medicare billing privileges, we would not revoke an individual or organization's NPI.

In proposed § 405.874(b)(3), Payment, we would revise this section to clarify that suppliers are not paid for items or services furnished during a period in which a supplier does not have billing privileges or its billing privileges have been revoked. Concerning DMEPOS suppliers, section 1834(j)(1) of the Act states that, with the exception of medical equipment and supplies furnished incident to a physician's service, no payment may be made by Medicare for items and supplies unless the supplier has active Medicare billing privileges. We further propose that claims submitted to carriers for items or services furnished during a period of supplier ineligibility are to be rejected by the carrier, not denied.

In § 405.874(c)(1) Appeal rights, we propose that a supplier's appeal rights would follow the processes detailed in part 498.

We are proposing to revise § 405.874(d), Impact of reversal of carrier determination on claims processing, to reflect that claims for services furnished to Medicare beneficiaries during a period in which the supplier's billing privileges were not effective are rejected and not denied. If a provider or supplier is determined not to have qualified for billing privileges in one period but qualified in another, contractors process claims for services

furnished to beneficiaries during the period for which the provider or supplier was Medicare-qualified. Subpart C of this part sets forth the requirements for recovery of overpayments. The appeals process for denied claims should not apply if a provider or supplier does not have billing privileges.

In § 405.874(d)(3), we propose that if a revocation of a provider's or supplier's billing privileges are reversed upon appeal, the provider's or supplier's billing privileges are reinstated back to the date that the revocation became effective.

Section 405.874(d)(4) would specify that if a denial of a provider's or supplier's billing privileges is reversed upon appeal, then the appeal decision establishes the date that the provider's or supplier's billing privileges will become effective.

We propose revising § 405.874(e), Reinstatement of provider's or supplier's billing privileges following corrective action, to state that if a provider or supplier completes a corrective action plan and provides sufficient evidence to the carrier that it has complied fully with the Medicare requirements, the carrier may reinstate the supplier's billing privileges. The carrier may pay for services furnished on or after the effective date of the reinstatement. The effective date of the reinstatement will be based on the date the provider or supplier is in full compliance with all Medicare requirements. However, a carrier's refusal to reinstate billing privileges based on the submission of a corrective action plan is not an initial determination and may not be appealed. We believe that allowing suppliers to appeal an adverse corrective action plan would establish two separate appeal processes and result in an administratively inefficient appeals process. Any supplier seeking to appeal a carrier's determination to deny or revoked billing privileges must submit an appeal within the timely filing period established for reconsideration, regardless of the submission of a corrective action plan.

In § 405.874(f) we propose to revise the effective date for DMEPOS supplier's billing privileges. If a carrier, carrier hearing officer, or ALJ determines that a DMEPOS supplier's denied enrollment application meets the standards in § 424.57 of this chapter and any other requirements that may apply (for example, reinstatement after an OIG exclusion), the determination establishes the effective date of the billing number as not earlier than the date the carrier made the determination to deny the supplier's enrollment application. Claims are rejected for services furnished before that effective date.

In § 405.874(g), Submission of claims, we propose that a provider or supplier succeeding in having its enrollment application denial or billing number revocation reversed, or in having its billing number reinstated, may submit claims to the carrier for services furnished during periods of Medicare qualification, subject to the limitations in § 424.44 of this chapter, regarding the timely filing of claims. If the claims previously were filed timely but were rejected, they would be considered filed timely upon resubmission. Previously denied claims for items or services rendered during a period of denial or revocation may be resubmitted to CMS within 1 year after the date of reinstatement or reversal.

In § 424.510(d)(2)(iv) Submittal of electronic funds transfer (EFT) authorization form, we propose that at the time of enrollment, an enrollment change request or revalidation, providers and suppliers shall submit the CMS–588 form to receive payments via electronic funds transfer.

Consistent with the authority found at 31 U.S.C. 3332(f)(1), all Federal payments, including Medicare payments to providers and suppliers, shall be made by electronic funds transfer (EFT). Further, under 31 U.S.C. 3332(g), each recipient of Federal payments required to be made by electronic funds transfer shall designate 1 or more financial institutions or other authorized agents to which the payments shall be made and provide the information to CMS. While the statutory provisions at 31 CFR part 208 govern the Department of Treasury, they apply to all Federal government agencies.

Consequently, we want to clarify that the EFT requirement applies to providers and suppliers enrolling in the Medicare program or making changes to enrollment. We are proposing to require the EFT payments for—(1) providers and suppliers initially enrolling in the Medicare program; and (2) providers and suppliers submitting a CMS–855 change request who are not currently receiving payments via EFT. Note if a provider or supplier is not enrolled in the Medicare program or is not submitting a change in their enrollment information, no action is necessary. We will continue to encourage all providers and suppliers to switch to EFT payments voluntarily.

We believe that this change will reduce the paperwork burden for the public and reduce our administrative costs. Moreover, we believe that the transition to EFT will help ensure that payments are made to the provider or supplier of services. Finally, in the event of a national disaster, such as Hurricane Katrina, providers and suppliers utilizing EFT would be ensured a continuity of payment. We are proposing to revise § 424.545(a), provider and supplier appeal rights, which was part of the April 21, 2006 final rule (71 FR 20754), regarding the Requirements for Providers and Suppliers To Establish and Maintain Medicare Enrollment. The existing provision states that a revocation of billing privileges also results in the termination of a corresponding provider agreement. Therefore, we are proposing to revise § 424.545(a) by—

- Redesignating the first sentence of current paragraph(a) as the introductory text and revising that text to remove the reference to part 405 subpart H.
- Redesignating the second sentence of current paragraph (a) as paragraph (a)(1)(i).
- Adding paragraph (a)(1)(ii) to clarify that if a provider appeals both of these sanctions, then both matters will be resolved using a single appeals process.
- Redesignating the last sentence of current paragraph (a) as paragraph (a)(2).

We believe that our proposal (the addition of paragraph (a)(1)(ii) is not a change from the current regulatory provision. In fact, the current provision in § 424.545(a) provides that a final decision would apply both to the revocation and the termination. However, this proposal is an effort to clarify that a provider will be able to appeal both sanctions using one appeals process. We also are proposing that this process would follow the appeals procedures established for revocations. We believe that a single appeals process would result in less administrative burden for both the agency and any affected provider.

We are proposing to add § 405.874(h) to establish deadlines for the adjudication of provider enrollment actions. We are proposing that contractors adjudicate initial determinations and revalidations within 180 days of receipt and that carriers adjudicate change-of-information and reassignment of payment request within 90 days of receipt.

To assist the reader in understanding the provider enrollment appeals process discussed in this proposed rule, the chart below provides first the established timeframes in which a provider or supplier must file an appeal to an adverse determination (that is, denial of billing privileges or revocation

of billing privileges), and second our proposed adjudication timeframes. Additional information regarding the appeals process is described in the following preamble.

Medicare provider enrollment determination	Timeframe to file an appeal (days)	Proposed maximum adjudication timeframe (days)
Initial	60	180
Reconsideration	60	60
Administrative Law Judge Review	60	180
Departmental Appeals Board Review	60	180
Federal District Court	N/A	N/A

We are proposing to update § 424.525(a)(1) and § 424.525(a)(2) for reasons for rejecting enrollment applications by reducing the amount of time that a provider or supplier must furnish complete information requested by a contractor from 60 to 30 days. Additionally, we are proposing a reduction from 60 to 30 days for the period allowed to furnish all supporting documentation for submitting their enrollment application.

We are proposing to reject an application that is submitted by a provider or supplier if it is incomplete or if it fails to include all required supporting documentation on the enrollment application within 30 days of receipt. We are proposing this change because approximately 70 percent of the submitted applications are incomplete or lack the supporting documents for enrollment. This change will help facilitate the enrollment process and reduce the administrative burden associated with processing these applications.

We are also proposing to expand revocations by the addition of a revocation for the abuse of billing privileges to § 424.535. In the new § 424.535(a)(8) we are proposing to allow Medicare fee-for-service (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. Specifically, we believe that it is both appropriate and necessary that CMS' FFS contractors be given the ability to revoke billing privileges when services could not have been furnished by a provider or supplier. We have found numerous examples of situations where a physician or other practitioner has billed for services furnished to beneficiaries that are undeliverable, including but not limited to situations where the beneficiary was deceased, the directing physician or beneficiary was not in the State or country when services were furnished, or when the beneficiary was in another setting where these services could not be administered, or the equipment necessary for testing was not present where the testing is said to have occurred.

We do not believe the determination made by the CMS FFS contractors constitutes a determination of fraud. In addition we believe that this new revocation authority is in line with other revocations already used by CMS and its FFS contractors. Further, providers and suppliers may appeal a contractor revocation using the process outlined in part 498.

We believe that this type of provision is essential to the efficient operation of the Medicare program because it would enable us to take an important step in protecting the expenditure of public monies with respect to service providers whose motives and billing practices are questionable, at best, and, at worst, of a sort that might prompt an aggressive response from the law enforcement community. The Medicare program ought not be forced to rely solely on its authority to deny claims on a piecemeal basis while having to devote extensive resources to maintaining the kind of close scrutiny of each of these providers and suppliers that would be required to minimize the program's exposure to the payment of claims that, by anyone's definition, ought not be tolerated. For this reason, we are proposing this provision in accordance with our broad rulemaking authorities in sections 1871 and 1102 of the Act.

We should note that providers or suppliers that expressly flag claims that they believe might be perceived by us as being in this category would not face prosecution under the False Claims Act.

In the new § 424.535(c), we are proposing a timeframe to wait for reapplication to the Medicare program when a provider or supplier is revoked. We are proposing that when a provider or supplier, including all authorized officials, delegating officials and practitioners, is revoked for any of the reasons listed at § 424.535 that the provider, supplier, delegated official or authorizing official be prohibited from enrolling for 3 years. We believe that revocations are serious matters and must be treated as such to maintain the integrity of the program. We invite public comment on whether we should consider different (that is, shorter or longer) timeframes for prohibiting a provider or supplier from re-enrolling in the Medicare program after a revocation has been issued.

Under the Medicare regulations, we know from experience that it is often the case that providers, and particularly some suppliers, simply react to a termination from the program by turning around and immediately seeking reentry into the program, oftentimes in another location or with a different name. Such practices make a sham of the enforcement process leaving us with the obligation to constantly monitor suspect providers and suppliers, forcing the agency to stand by while the same offenders engage in the same noncompliant billing practices that led to their expulsion in the first place. We do not believe it is consistent with our mandate to administer an efficient program or to protect the expenditure of public monies by being compelled to take such a passive approach to what are clearly substandard practices. By having a regulatory provision that would keep such entities out of the program for 3 years, we believe we would be establishing a credible deterrent to these substandard billing practices where providers and suppliers would know that there are real consequences to their actions. The Medicare program ought not have to choose to do business with all entities simply because they express their willingness to accept Federal payment for services that they have demonstrated are too often suspicious or so poorly presented that they cause the program to devote too many resources to determine their accuracy.

We are proposing to revise in § 498.1(g) in accordance with section

936(a)(2) of the MMA to provide an ALJ hearing, and judicial review for any provider or supplier whose application for enrollment or reenrollment in Medicare has been denied.

In § 498.2, we are proposing to revise the definition of a ''supplier'' to—(1) include a supplier of durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS); ambulance service provider; independent diagnostic testing facility; physician; and other practitioner such as physician assistant; and (2) remove the reference to ''prospective supplier.'' In § 498.2, we are also proposing to add a separate definition of ''prospective supplier.'' We are removing the definition of the ''Office of Hearings and Appeals (OHA)'' because the function of this office has been moved from the Social Security Administration to the Department of Health and Human Services. We are also proposing to revise the definition of ''affected party'' to specify that it includes CMS or a CMS contractor.

We are proposing to revise § 498.5 by adding a new paragraph (l) to clarify the administrative process that a prospective provider, existing provider, prospective supplier or existing supplier dissatisfied with an initial determination or revised initial determination related to the denial or revocation of Medicare billing privileges would use.

We are proposing to revise § 498.5(f)(2) to be consistent with the change in § 498.1(g). This would implement the mandate of section 936(a)(2) of the MMA regarding judicial review. We are proposing these standards because the FFS contractors need sufficient time to adjudicate the facts and make a reasoned decision. Moreover, while we are establishing an outside limit for processing these applications, the vast majority of these decisions are made within 120 days. We are requesting comment on this existing standard.

We are proposing to revise § 498.22(a) to add that we have delegated authority to our contractors to reconsider an initial determination. We are also proposing to revise § 498.22(b)(1) to state that a reconsideration request is to be filed with CMS or with the State survey agency, or, in the case of prospective suppliers, the entity specified in the notice of initial determination. We are proposing to revise § 498.44 to remove the term Associate Commissioner for Hearings and Appeals, and we are replacing it with the Secretary, because this function is no longer under the Social Security Administration; it is now under the Department of Health and Human Services.

With the proposed revision to § 405.874(c)(2), we want to clarify that a provider or supplier is required to prove that it is in compliance with all Medicare requirements for billing privileges, and that the Medicare FFS contractor incorrectly denied or revoked the supplier's billing number. Accordingly, we believe that the burden of proof is on the provider or supplier to show that it met all requirements upon application, or at the time of revocation. In § 498.56, we are proposing to add a new paragraph (e) that specifies the ''good cause'' exception to the admission of new evidence at the ALJ and DAB appeal levels.

Accordingly, we propose to revise § 498.56 and § 498.86 to prohibit providers and suppliers from submitting new provider enrollment issues or evidence at the ALJ and DAB levels of review. We believe that the efficiency and accuracy of the appeals process is enhanced when the provider or supplier submits all necessary documentation with their appeal request to prove that they are in compliance with all Medicare requirements for enrollment. If supporting evidence is not submitted with the request for a reconsideration, the contractor will contact the supplier to try to obtain the missing evidence. The contractor must make a decision based on the information in the case file.

The contractor may accept any additional documentation, even if it is not specified in the appeal notice. If the provider/supplier fails to submit evidence before the reviewing official issues its decision, the provider/supplier would be precluded from introducing the evidence at higher levels of the appeals process. It is presumed that the Medicare FFS contractor made a reasonable determination in its denial or revocation of a supplier's billing privileges based on information it had at the time of the decision. The provider/supplier would be required to furnish the evidence that clearly shows the determination was in error at the time it was made.

We are proposing to revise § 498.78(a) to delete the provision that an affected party concur in writing or on the record with a CMS or Office of Inspector General (OIG) request for remand. We believe that the appeals process can be enhanced by allowing an ALJ to remand a provider enrollment case to the Medicare FFS contractor when CMS requests a remand. Further, we believe that a remand request could result in either a favorable decision to the appellant or an administrative record that is complete.

In § 498.79, we are proposing that when a request for an ALJ hearing is filed after CMS or a FFS contractor has denied an enrollment application, that an ALJ must issue a decision, dismissal order or remand to CMS, as appropriate, no later than 180 days after the initial request for a hearing.

Finally, in § 498.88(g), we are proposing that when a request for a Board review is filed after an ALJ has issued a decision or dismissal order, that the Board must issue a decision, dismissal order or remand to the ALJ, as appropriate, no later than 180 days after the appeal was received by the Board.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comments on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques. However, we believe the information collection activities referenced in § 405.874 are exempt under the terms of the PRA for the following reasons:
- As defined in 5 CFR 1320.4(a)(2), information collections conducted or sponsored during the conduct of criminal or civil action, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities are exempt from the PRA.
- As described in 5 CFR 1320.3(h)(9), facts or opinions obtained or solicited through nonstandardized follow-up questions designed to clarify responses to approved collections, are exempt from the PRA; and
- Nonstandardized information collections directed to less than 10 persons do not constitute information collections as outlined in 5 CFR 1320.3(c).

We believe that the collection requirements are part of the administrative process, and collected in a nonstandardized manner. Since each case will be different, based on the reasons for denial or revocation, and evidence presented, they fall under these exceptions.

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

Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, *Attn.:* William Parham, CMS–6003–P2, Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503. *Attn.:* Carolyn Lovett, CMS Desk Officer, CMS–6003–P2, *carolyn_lovett@omb.eop.gov*. Fax (202) 395–6974.

VI. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, 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, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VII. Regulatory Impact Statement

We have examined the impact 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, and Executive Order 13132).

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 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief for small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 to $29 million in any one year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this rule will not have a significant economic impact on a substantial number of small entities.

We maintain that this proposed rule would not have an adverse impact on small entities; in fact, it would afford small suppliers a measure of protection against adverse actions by us, and extend protection to a larger group of suppliers beyond the DMEPOS suppliers currently covered under § 405.874. Because this proposed rule would merely clarify, expand, and update our current policy and administrative appeal rights, we anticipate slight, if any, economic impact on small entities.

According to data submitted to us by carriers in calendar year 2003, approximately 166,500 enrollment applications were submitted to the Medicare carriers by suppliers seeking to receive billing privileges. We believe that a vast majority of these applicants were small businesses. Of those applications, approximately 2,000 were denied, and approximately 200 applicants requested a reconsideration. Because we have already granted appeal rights to the affected suppliers via instructions to carriers, we estimate that this regulation would have minimal impact on carrier workloads.

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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and we determined, that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals. There is no negative impact on the program or on small businesses.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $120 million. This rule does not mandate expenditures by either the governments mentioned or the private sector, therefore no analysis is required.

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. Since this regulation does not impose any costs on State or local governments, the requirements of E.O 13132 are not applicable.

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

Lists of Subjects

42 CFR Part 405

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

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

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

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

1. The authority citation for Part 405, subpart H, continues to read as follows:

Authority: Secs. 1102, 1842(b)(3)(C), 1869(b), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395u(b)(3)(C), 1395ff(b) and 1395hh).

Subpart H—Appeals Under the Medicare Part B Program

2. Section 405.802 is revised by adding the definitions of ''prospective supplier'' and ''supplier'' in alphabetical order to read as follows:

§ 405.802 Definitions.

* * * * *

Prospective supplier means any of the listed entities specified in the definition of supplier that seeks to be approved for coverage of its services under Medicare.

* * * * *

Supplier means an independent laboratory; supplier of durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS); ambulance service provider; independent diagnostic testing facility; physician or other practitioner such as physician assistant; physical therapist in independent practice; clinical laboratories; supplier of portable X-ray services; rural health clinic (RHC); Federally qualified health center (FQHC); ambulatory surgical center (ASC); an entity approved by CMS to furnish outpatient diabetes self-management training; or end-stage renal disease (ESRD) treatment facility that is approved by CMS as meeting the conditions for coverage of its services.

* * * * *

3. Section 405.874 is revised to read as follows:

§ 405.874 Appeals of carrier determinations that a supplier fails to meet the requirements for Medicare billing privileges.

(a) *Denial of a supplier enrollment application.* If a carrier denies a supplier's enrollment application, the carrier must notify the supplier by certified mail. The notice must include the following:

(1) The reason for the denial in sufficient detail to allow the supplier to understand the nature of its deficiencies.

(2) The right to appeal in accordance with part 498 of this chapter.

(3) The address to which the written appeal must be mailed.

(b) *Revocation of Medicare billing privileges.* (1) *Notice of revocation.* If a carrier revokes a supplier's Medicare billing privileges, the carrier must notify the supplier by certified mail. The notice must include the following:

(i) The reason for the revocation in sufficient detail for the supplier to understand the nature of its deficiencies.

(ii) The right to appeal in accordance with part 498 of this chapter.

(iii) The address to which the written appeal must be mailed.

(2) *Revocation of a supplier's billing privileges.* The revocation of a supplier's billing privileges is effective 15 days after the carrier mails the notice of its determination to the supplier. A revocation based on a Federal exclusion or debarment is effective with the date of the exclusion or debarment.

(3) *Payment.* (i) Medicare does not pay for any items or services furnished by a supplier during a period in which a supplier does not have billing privileges or its billing privileges are revoked.

(ii) Carriers do not pay for services furnished by the supplier beginning with the effective date of a revocation.

(iii) Medicare does not pay for items and supplies unless the supplier has a valid, active Medicare billing number.

(iv) Claims for items or services furnished to Medicare beneficiaries after the effective date of the revocation are rejected. Rejections of claims because a supplier does not have a valid billing number may not be appealed by the supplier. Claims submitted to carriers for items or services furnished during a period of supplier ineligibility are rejected by the carrier, and not denied by the carrier.

(c) *Appeal rights.* (1) A provider or supplier may appeal the initial determination to deny a provider or supplier's enrollment application, or if applicable, to revoke a current billing number by following the procedures specified in part 498 of this chapter.

(2) The reconsideration of a determination to deny or revoke a provider or supplier's Medicare billing privileges may be handled by a carrier hearing officer not involved in the initial determination.

(3) Providers and suppliers have the opportunity to submit evidence related to the enrollment action. Providers and suppliers must, at the time of their request, submit all evidence that they want to be considered.

(4) If supporting evidence is not submitted with the appeal request, the contractor contacts the provider or supplier to try to obtain the evidence.

(5) If the provider or supplier fails to submit this evidence before the contractor issues its decision, the provider or supplier is precluded from introducing new evidence at higher levels of the appeals process.

(d) *Impact of reversal of carrier determination on claims processing.*

(1) Claims for services furnished to Medicare beneficiaries during a period in which the supplier billing privileges was not effective are rejected.

(2) If a supplier is determined not to have qualified for a billing privileges in one period but qualified in another, carriers process claims for services furnished to beneficiaries during the period for which the supplier was Medicare-qualified. Subpart C of this part sets forth the requirements for recovery of overpayments.

(3) If a revocation of a supplier's billing privilege is reversed upon appeal, the supplier's billing privileges are reinstated back to the date that the revocation became effective.

(4) If denial of a supplier's billing privileges is reversed upon appeal and becomes binding, then the appeal decision establishes the date that the supplier's billing privileges becomes effective.

(e) *Reinstatement of supplier billing privilege following corrective action.* If a supplier completes a corrective action and provides sufficient evidence to the carrier that it has complied fully with the Medicare requirements, the carrier may reinstate the supplier's billing privileges. The carrier may pay for services furnished on or after the effective date of the reinstatement. The effective date is based on the date the supplier is in compliance with all Medicare requirements. A carrier's refusal to reinstate a supplier's billing privileges based on a corrective action is not an initial determination under part 498 of this chapter.

(f) *Effective date for DMEPOS supplier's billing privileges.* If a carrier, carrier hearing officer, or ALJ determines that a DMEPOS supplier's denied enrollment application meets the standards in § 424.57 of this chapter and any other requirements that may apply, the determination establishes the effective date of the billing privileges as not earlier than the date the carrier made the determination to deny the DMEPOS supplier's enrollment application. Claims are rejected for services furnished before that effective date.

(g) *Submission of claims.* A supplier succeeding in having its enrollment application denial or billing privileges revocation reversed in a binding decision, or in having its billing privileges reinstated, may submit claims to the carrier for services furnished during periods of Medicare qualification, subject to the limitations in § 424.44 of this chapter, regarding the timely filing of claims. If the claims previously were filed timely but were rejected, they are considered filed timely upon resubmission. Previously denied claims for items or services rendered during a period of denial or revocation may be resubmitted to CMS within 1 year after the date of reinstatement or reversal.

(h) *Deadline for processing provider enrollment initial determinations.* Contractors approve or deny complete provider enrollment applications to approval or denial within the following timeframes:

(1) *Initial enrollments.* Contractors process new enrollment applications within 180 days of receipt.

(2) *Revalidation of existing enrollments.* Contractors process revalidations within 180 days of receipt.

(3) *Change-of-information and reassignment of payment request.* Contractors process change-of-information and reassignment of payment requests within 90 days of receipt.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

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

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

5. Section 424.510 is amended by adding a new paragraphs *(d)(2)(iv) and* (e) to read as follows:

§ 424.510 Requirements for enrolling in the Medicare program.

* * * * *

(d)

(2) * * *

(iv) The revisions read as follows:

At the time of enrollment, an enrollment change request or revalidation, providers and suppliers must agree to receive Medicare payments via EFT. In order to receive Medicare payments via EFT, providers and suppliers must submit the CMS–588 form.

* * * * *

(e) Providers and suppliers must—(1) Agree to receive Medicare payment via electronic funds transfer (EFT) at the time of enrollment, revalidation or submission of an enrollment change request; and

(2) Submit the CMS–588 form to receive Medicare payment via electronic funds transfer.

6. Section 424.525 is amended by—

A. Republishing paragraph (a) introductory text.

B. Revising paragraphs (a)(1) and (a)(2).

The revisions read as follows:

§ 424.525 Rejection of a provider or supplier's enrollment application for Medicare enrollment.

(a) *Reasons for rejection.* CMS may reject a provider or supplier's enrollment application for the following reasons:

(1) The provider or supplier fails to furnish complete information on the provider/supplier enrollment application within 30 calendar days from the date of the contractor request for the missing information.

(2) The provider or supplier fails to furnish all required supporting documentation within 30 calendar days of submitting the enrollment application.

* * * * *

7. Section 424.535 is amended by—

A. Adding a new paragraph (a)(8).

B. Redesignating paragraphs (c) through (f) as paragraphs (d) through (g).

C. Adding a new paragraph (c).

The addition and revision read as follows:

§ 424.535 Revocation of enrollment and billing privileges from the Medicare program.

* * * * *

(a) * * *.

(8) *Abuse of billing privileges.* The provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service. These instances include but are not limited to situations where the beneficiary is deceased, the directing physician or beneficiary is not in the State or country when services were furnished, or when the equipment necessary for testing is not present where the testing is said to have occurred.

* * * * *

(c) *Reapplying after revocation.* After a provider, supplier, delegated official or authorizing official has had their billing privileges revoked, they must wait 3 years from the date of revocation before they can reapply to participate in the Medicare program.

* * * * *

8. Section 424.545 is amended by revising paragraph (a) to read as follows:

§ 424.545 Provider and supplier appeal rights.

(a) *General.* A provider or supplier that is denied enrollment in the Medicare program, or whose Medicare enrollment has been revoked may appeal CMS' decision in accordance with part 498, subpart A of this chapter.

(1) *Appeals resulting in the termination of a provider agreement.* (i) When revocation of billing privileges also results in the termination of a corresponding provider agreement, the provider may appeal CMS' decision in accordance with part 498 of this chapter with the final decision of the appeal applying to both the billing privileges and the provider agreement.

(ii) When a provider appeals the revocation of billing privileges and the termination of its provider agreement, there will be one appeals process which will address both matters. The appeal procedures for revocation of Medicare billing privileges will apply.

(2) *Payment of unpaid claims.* Payment is not made during the appeals process. If the provider or supplier is successful in overturning a denial or revocation, unpaid claims for services furnished during the overturned period may be resubmitted.

* * * * *

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/MR AND CERTAIN NFs IN THE MEDICAID PROGRAM

9. The authority citation for part 498 continues to read as follows:

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

Subpart A—General Provisions

10. Section 498.1 is amended by revising paragraph (g) to read as follows:

§ 498.1 Statutory basis.

* * * * *

(g) Section 1866(j) of the Act provides for a hearing and judicial review for any provider or supplier whose application for enrollment or reenrollment in Medicare is denied or whose billing privileges are revoked.

* * * * *

11. Section 498.2 is amended by—

A. Revising the definition of ''affected party''.

B. Removing the definition of ''OHA''.

C. Adding in alphabetical order the definition of ''prospective supplier''.

D. Revising the definition of ''supplier''.

The addition and revisions read as follows:

§ 498.2 Definitions.

* * * * *

Affected party means a provider, prospective provider, supplier, prospective supplier, or practitioner that is affected by an initial determination or by any subsequent determination or decision issued under this part, and ''party'' means the affected party or CMS, as appropriate. For provider or supplier enrollment appeals, an affected party includes CMS or a CMS contractor.

* * * * *

Prospective supplier means any of the listed entities specified in the definition of supplier that seek to be approved for coverage of its services under Medicare.

* * * * *

Supplier means an independent laboratory; supplier of portable X-ray services, rural health clinic (RHC); Federally qualified health center

(FQHC); ambulatory surgical center (ASC); a supplier of durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS); ambulance service provider; independent diagnostic testing facility; physician or other practitioner such as physician assistant, physical therapist in independent practice, clinical laboratories, an entity approved by CMS to furnish outpatient diabetes self-management training, or end-stage renal disease (ESRD) treatment facility that is approved by CMS as meeting the conditions for coverage of its services.

12. Section 498.5 is amended by—

A. Revising paragraph (f)(2).

B. Adding a new paragraph (l).

The revision and addition read as follows:

§ 498.5 Appeal rights.

* * * * *

(f) * * *

(2) A supplier or prospective supplier dissatisfied with an ALJ decision may request Board review, and has a right to seek judicial review of the Board's decision.

* * * * *

(l) *Appeal rights related to provider enrollment.*

(1) Any prospective provider, an existing provider, prospective supplier or existing supplier dissatisfied with an initial determination or revised initial determination related to the denial or revocation of Medicare billing privileges may request reconsideration in accordance with § 498.22(a).

(2) CMS, a CMS contractor, any prospective provider, an existing provider, prospective supplier or existing supplier dissatisfied with a reconsidered determination under paragraph (l)(1) of this section, or a revised reconsidered determination under § 498.30, is entitled to a hearing before an ALJ.

(3) CMS, a CMS contractor, any prospective provider, an existing provider, prospective supplier or existing supplier dissatisfied with a hearing decision may request Board review, and any prospective provider, an existing provider, prospective supplier, or existing supplier has a right to seek judicial review of the Board's decision.

Subpart B—Initial, Reconsidered, and Revised Determinations

13. Section 498.22 is amended by revising paragraphs (a) and (b)(1) to read as follows:

§ 498.22 Reconsideration.

(a) *Right to reconsideration.* CMS or one of its contractors reconsiders an initial determination that affects a prospective provider or supplier, or a hospital seeking to qualify to claim payment for all emergency hospital services furnished in a calendar year, if the affected party files a written request in accordance with paragraphs (b) and (c) of this section. For denial or revocation of enrollment, prospective providers and suppliers and providers and suppliers have a right to reconsideration.

(b) * * *

(1) With CMS or with the State survey agency, or in the case of prospective supplier the entity specified in the notice of initial determination;

* * * * *

Subpart D—Hearings

14. Section 498.40 is amended by revising paragraph (a)(1) to read as follows:

§ 498.40 Request for hearing.

(a) * * * (1) An affected party entitled to a hearing under § 498.5 may file a request for a hearing with the ALJ office identified in the determination letter.

* * * * *

15. Section 498.44 is revised to read as follows:

§ 498.44 Designation of hearing official.

(a) The Secretary or his or her delegate designates an ALJ or a member or members of the Board to conduct hearings.

(b) If appropriate, the Secretary or the delegate may designate another ALJ or another member or other members of the Board to conduct the hearing.

(c) As used in this part, ''ALJ'' includes any ALJ of the Department of Health and Human Services or members of the Board who are designated to conduct a hearing.

16. Section 498.56 is amended by—

A. Revising paragraph (a)(2).

B. Adding a new paragraph (e).

The revision and addition read as follows:

§ 498.56 Hearing on new issues.

* * * * *

(a) * * *

(2) Except for provider or supplier enrollment appeals which are addressed in § 498.56(e), the ALJ may consider new issues even if CMS or the OIG has not made initial or reconsidered determinations on them, and even if they arose after the request for hearing was filed or after the prehearing conference.

* * * * *

(e) *Provider and supplier enrollment appeals: Good cause requirement.* (1) *Examination of any new documentary evidence.* After a hearing is requested but before it is held, the ALJ will examine any new documentary evidence submitted to the ALJ by a provider or supplier to determine whether the provider or supplier has good cause for submitting the evidence for the first time at the ALJ level.

(2) *Determining if good cause exists.* An ALJ finds good cause, for example, when the new evidence is material to an issue addressed in the reconsideration and that issue was not identified as a material issue before the reconsideration.

(3) *If good cause does not exist.* If the ALJ determines that there was not good cause for submitting the evidence for the first time at the ALJ level, the ALJ must exclude the evidence from the proceeding and may not consider it in reaching a decision.

(4) *Notification to all parties.* As soon as possible, but no later than the start of the hearing, the ALJ must notify all parties of any evidence that is excluded from the hearing.

17. Section 498.78 is amended by revising paragraph (a) to read as follows:

§ 498.78 Remand by the Administrative Law Judge.

(a) If CMS requests remand, the ALJ may remand any case properly before him or her to CMS.

* * * * *

18. A new § 498.79 is added to subpart D to read as follows:

§ 498.79 Timeframes for deciding an enrollment appeal before an ALJ.

When a request for an ALJ hearing is filed after CMS or a FFS contractor has denied an enrollment application, the ALJ must issue a decision, dismissal order or remand to CMS, as appropriate, no later than the end of the 180-day period beginning from the date the appeal was filed with an ALJ.

Subpart E—Departmental Appeals Board Review

19. Section 498.86 is amended by revising paragraph (a) to read as follows:

§ 498.86 Evidence admissible on review.

(a) Except for provider or supplier enrollment appeals which are addressed in § 498.56(e), the Board may admit evidence into the record in addition to the evidence introduced at the ALJ hearing (or the documents considered by the ALJ if the hearing was waived) if the Board considers that the additional evidence is relevant and material to an issue before it.

* * * * *

20. Section 498.88 is amended by adding a new paragraph (g) to read as follows:

§ 498.88 Decision or remand by the Departmental Appeals Board.

* * * * *

(g) When a request for Board review is filed after an ALJ has issued a decision or dismissal order, the Board must issue a decision, dismissal order or remand to the ALJ, as appropriate, no later than 180 days after the appeal was received by the Board.

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

Dated: August 30, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare and Medicaid Services.

Dated: November 8, 2006.

Micheal O. Leavitt,

Secretary.

[FR Doc. 07–870 Filed 2–23–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Part 98

RIN 0970–AC29

Child Care and Development Fund Error Rate Reporting

AGENCY: Administration for Children and Families (ACF), HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule revises the Child Care and Development Fund (CCDF) regulations to provide for the reporting of error rates in the expenditure of CCDF grant funds by the fifty States, the District of Columbia and Puerto Rico. The error rate reports will serve to implement provisions of the *Improper Payments Information Act of 2002 (IPIA)* and the *President's Management Agenda (PMA)'s* goal of ''Eliminating Improper Payments.'' For reasons that will be explained in the preamble to the rule, the initial information collection under this proposed rule will require States, the District of Columbia, and Puerto Rico to review and report on a random sample of cases estimated to achieve the calculation of annual improper authorizations for payment (rather than improper payments made) with a 90 percent confidence interval of +/-5.0 percent.

DATES: *Comment Period:* You may submit comments through May 1, 2007. We will not consider comments received after this date.

ADDRESSES: You may mail comments to the Administration for Children and Families, Child Care Bureau, 1250 Maryland Ave. SW., 8th Floor, Washington, DC 20024. Attention: Christine Calpin, Associate Director.

Commenters also may provide comments on the ACF website. To transmit comments electronically, or to download an electronic version of the proposed rule, please go to *http://regulations.acf.hhs.gov.* We will have comments available for public inspection Monday through Friday, 8:30 a.m. to 5 p.m. at the above address. The information collection related to this regulation can be found at *http://www.acf.hhs.gov/programs/ccb/ccdf/ipi/ipi.htm.*

FOR FURTHER INFORMATION CONTACT: Jeff Polich, Child Care Program Specialist, Child Care Bureau, at (202) 205–8696, or by email at *jpolich@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

This proposed rule adds a new subpart to the Child Care and Development Fund (CCDF) regulations that would require States, the District of Columbia and Puerto Rico to employ a case review process in calculating CCDF error rates in accordance with an error rate methodology established by the Secretary of Health and Human Services (the Secretary). The proposed rule would require States, the District of Columbia and Puerto Rico to report specified information regarding errors to the Department of Health and Human Services. The basic components of this error rate methodology, and how it was developed and pilot tested, are described in this proposed rule. The specifics of this methodology and how it will be implemented are detailed in the information collection forms and instructions associated with this rule, copies of which may be downloaded or requested as detailed in the section discussing the Paperwork Reduction Act below.

A. Child Care and Development Fund (CCDF)

CCDF provides Federal funds to States, Territories, Indian Tribes and tribal organizations for the purpose of assisting low-income families, including families receiving or transitioning from the Temporary Assistance for Needy Families program (TANF), in the purchase of child care services, thereby allowing parents to work or attend job training or an educational program. States and Territories must spend a portion of their CCDF allotment on expenditures to improve the quality and availability of child care. A principle goal of CCDF set forth in Section 658A of the Child Care and Development Block Grant (CCDBG) Act of 1990, as amended (42 U.S.C. 9858, *et seq.*), is to ''Allow each State maximum flexibility in developing child care programs and policies that best suit the needs of children and parents within such State.'' CCDF is provided only to States, Territories and Tribes—there is no provision for direct funding to individual families or providers.

Federal law establishes eligibility criteria for families receiving CCDF assistance; however, States and Territories administering CCDF funds may impose more restrictive eligibility standards. Regulations governing CCDF are codified in 45 CFR Parts 98 and 99, and the Federal definition of a child's eligibility for child care services is set forth in 45 CFR 98.20. This description includes eligibility requirements related to a child's age, a child's special needs or protective services status, family income and parent's work, training or educational activity. Lead Agencies of the CCDF Program—which are the State, territorial or tribal entities to which CCDF block grants are awarded and that are accountable for the use of the funds provided—have established policies and procedures that vary considerably across and even within jurisdictions, including, but not limited to, stricter income limits, special eligibility or priority for families receiving TANF and