

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.

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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:

August Nemec, (410) 786-0612.

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.

In December 1998, we issued CMS Ruling 98-1, which outlined the appeals process that 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 for 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 final 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 final 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.

In the October 25, 1999 **Federal Register** (64 FR 57431), we published a proposed rule Appeals of Carrier Terminations that a Supplier Fails to Meet the Requirements for Medicare Billing Privileges that would revise § 405.874 by extending appeal rights to all suppliers whose enrollment applications for Medicare billing privileges are disallowed by a carrier or whose Medicare billing privileges are revoked, except for those suppliers covered under existing appeals provisions of our regulations.

Since we did not publish our earlier rulemaking effort within 3 years as required by section 902 of the MMA, we published a new proposed rule on March 2, 2007. This proposed rule included changes mandated by section 936(a) and (b) of the MMA.

II. Provisions of the March 2, 2007 Proposed Rule

In the March 2, 2007 **Federal Register** (72 FR 9479), we published a proposed rule that set forth standard provider and supplier appeal procedures as established in section 936 of the MMA and proposed certain other provisions associated with Medicare's provider and

supplier enrollment process. We proposed to maintain § 405.874, which specifies provisions that would apply to certain suppliers as defined in § 405.802. In § 405.802, we proposed to define prospective supplier and suppliers by specifying the provisions of § 405.874 that would apply. In § 405.874(a), we proposed that if a CMS contractor (that is, a carrier, fiscal intermediary or Medicare administrative contractor (MAC)) denies a supplier's enrollment application, the CMS contractor 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; and (3) the address to which the written appeal must be mailed.

In § 405.874(b)(1), we proposed to 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 § 405.874(b)(2), we proposed to separate the procedures in existing § 405.874(a) and § 405.874(b). In § 405.874(b)(2), we proposed clarifying that a revocation of a supplier 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 privileges are revoked. Moreover, if CMS, or one of its designated contractors revokes Medicare billing privileges, we would not revoke an individual or organization's National Provider Identifier (NPI).

In § 405.874(b)(3), we proposed clarifying 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 Social Security Act (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 proposed that claims submitted to CMS contractors for items or services furnished during a period of supplier ineligibility are to be

rejected by the CMS contractor, not denied.

In § 405.874(c)(1), we proposed that a supplier's appeal rights would follow the processes detailed in part 498. In § 405.874(d), we proposed to revise this section 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 proposed if a revocation of a provider's or supplier's billing privileges is reversed upon appeal, the provider's or supplier's billing privileges are reinstated back to the date that the revocation became effective.

In § 405.874(d)(4), we proposed 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.

In § 405.874(e), we proposed that if a provider or supplier completes a corrective action plan and provides sufficient evidence to the CMS contractor that it has complied fully with Medicare requirements, the CMS contractor may reinstate the supplier's billing privileges.

In § 405.874(f), we proposed revising 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 privileges as not earlier than the date the CMS contractor made the determination to deny the supplier's enrollment application. Claims are rejected for services furnished before that effective date.

In § 405.874(g), we proposed that a provider or supplier succeeding in having its enrollment application denial or billing privileges revocation reversed, or in having its billing privileges reinstated, may submit claims to the

CMS contractor for services furnished during periods of Medicare qualification, subject to the limitations in § 424.44 of this chapter, regarding the timely filing of claims.

In § 405.874(h), we proposed establishing deadlines for the

adjudication of provider enrollment actions. We proposed that contractors adjudicate initial determinations and revalidations within 180 days of receipt and carriers adjudicate change-of-information and reassignment of payment request within 90 days of

receipt. In addition, we proposed to establish timeframes for each administrative level of appeal. The following table identifies who makes the determinations and the associated timeframes in which each determination is made.

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

In § 424.510(d)(2)(iv), we proposed 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.

In § 424.545(a), we proposed the following:

- 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).

In § 424.525(a)(1) and (a)(2), we proposed potential 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 proposed a reduction from 60 to 30 days for the period allowed to furnish all supporting documentation for submitting their enrollment application.

We proposed rejecting 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.

In § 424.535(a)(8), we proposed allowing Medicare FFS contractors, under the direction of CMS, 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.

In § 424.535(b)(2), we proposed a timeframe to wait for reapplication to the Medicare program when a provider or supplier is revoked. Specifically, we proposed 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.

In § 498.1(g), we proposed to establish 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 proposed revising the definition of a “supplier” to—(1) Include a supplier of 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 proposed adding a new definition for “prospective supplier.”

We also proposed 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 DHHS. We also proposed to revise the definition of “affected party” to specify that it includes CMS or a CMS contractor.

In § 498.5, we proposed revising this section by adding a new paragraph (l) that would be used 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.

We proposed revising § 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 proposed 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 proposed revising § 498.22(a) to add that we have delegated authority to our contractors to reconsider an initial determination. We also proposed revising § 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 proposed revising § 498.44 to remove the term Associate Commissioner for Hearings and Appeals, and we replaced 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.

In § 405.874(c)(2), we proposed clarifying 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 privileges. In § 498.56, we proposed adding 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 proposed revising § 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.

In § 498.78(a), we proposed to delete the provision that an affected party concur in writing or on the record with a CMS or Department of Health and Human Services 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 proposed 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 proposed 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.

III. Analysis of and Responses to Public Comments

We received approximately 30 comments in response to the March 2, 2007 proposed rule. The following is a summary of the comments received and our responses.

Comment: Several commenters recommended that we clarify whether the provisions of the proposed rule apply to all providers and suppliers.

Response: The provisions of the proposed and this final rule apply to all the providers and suppliers described in the § 405.802 or § 498.2. Therefore, in response to comments received, we are adding definitions for “prospective supplier” and “prospective provider” to § 405.802 and § 498.2. Since applicants (prospective provider and suppliers) who are not enrolled in the Medicare program still are afforded appeal rights based on an enrollment denial, we maintain that it is important to clarify that any prospective applicant (provider or supplier) is afforded appeal rights through this process.

Comment: One commenter recommended that we separately define “prospective provider” and modify the definition of provider accordingly.

Response: We agree with the commenter’s recommendations and have included a definition of “prospective provider” in § 405.802 and 498.2 and have revised the definition of “provider” at § 405.802 and § 498.2.

Comment: One commenter suggested that we change the definition of supplier to include occupational therapists in private practice.

Response: This comment falls outside the scope of the proposed rule. Therefore, we believe it would be inappropriate for us to address this comment in this final rule.

Comment: Several commenters recommended that we clarify whether a provider or supplier who uses a corrective action plan (CAP) is precluded from also appealing the contractor, carrier, MAC, or FI decision.

Response: A CAP is the plan that allows a provider or supplier an opportunity to correct deficiencies (if possible) that resulted in a denial or revocation of billing privileges. The CAP should provide evidence that the provider or supplier is in compliance with Medicare enrollment requirements. A provider or supplier that uses a CAP is not precluded from also appealing the FFS contractor’s (that is in a MAC, FI, or carrier) decision. The Medicare FFS contractor, including the National Supplier Clearinghouse (NSC), will accept the submission of a corrective action plan for revoked billing privileges if the corrective action plan is submitted within 15 days from the date of the notice for DMEPOS suppliers or within 30 days from the date of the notice for all other providers and suppliers.

Comment: Several commenters recommended that we clarify that an independent contractor hearing officer will conduct the reconsideration of an adverse enrollment decision.

Response: For the purpose of this final rule, the term an independent contractor hearing officer means that a reconsideration will be handled by a hearing officer not involved in the initial determination. We believe this will ensure that the appellant receives a fair and impartial reconsideration. It is also important to note that while the claims appeals process uses a “qualified independent contractor” to conduct reviews, the provider enrollment appeals process does not use a “qualified independent contractor.”

Comment: Several commenters recommended that we clarify when a provider or supplier may resubmit a new initial enrollment application after an enrollment denial.

Response: Since the denial of enrollment application conveys appeal rights, a provider or supplier cannot resubmit a new initial enrollment application until after the 60 day appeal period has ended. This will ensure that the Medicare contractor is not processing an initial application during the timely filing period of an appeal. In addition, if a provider or supplier submits a new initial enrollment application during the timely appeals

filing period, the Medicare contractor will return the application to the applicant.

Comment: One commenter recommended that we change our proposed language concerning a remand by an ALJ to specify that CMS does not have authority to request a remand when the Agency is also a party to an ALJ proceeding.

Response: We believe that we should have all the rights afforded to an appellant. Further, by allowing CMS to request a remand, we believe that the designated contractor or CMS Regional Office will be able to review or re-examine the administrative record to update or provide documentation to establish a complete administrative record. By doing so, we believe higher levels of appeal will have the information needed to effectuate a timely decision. Therefore, we do not agree with the commenter’s recommendation to revise the language to prohibit our authority to request a remand.

Comment: One commenter recommended that we adopt a 45-day time period for adjudication of ALJ and DAB decisions.

Response: We believe that a 45-day time period is not practical. While we understand the desire to establish an efficient appeals process, we are adopting similar time frames as had been established for deciding a claims appeal before an ALJ or DAB (see § 405.1016(c)). As stated previously, the early presentation of evidence will allow the contractor hearing officer or the CMS Regional Office to make decisions using all relevant facts as applied to the appeal. In doing so, the hearing officer or regional office will issue their findings to establish a complete administrative record for the future appeal levels. We believe that a complete administrative record will help facilitate decision making at higher levels of appeal.

Comment: Several commenters stated that a reconsideration is an unnecessary delay in the appeals process, and that applicants should be able to appeal directly to an ALJ.

Response: We determined that the most effective way to implement the requirements of section 936(j)(2) of the MMA was to amend the existing appeals procedures in part 498. The appeals procedures under part 498 include reconsideration as a level of review before an appeal is made to an ALJ. We believe that the reconsideration level provides an additional opportunity for the matter to be resolved prior to the filing of an appeal to an ALJ.

Comment: One commenter requested clarification of § 405.874(c)(2), which discussed the reconsideration of a determination to deny or revoke a provider or supplier's Medicare billing privileges.

Response: The reconsideration of a determination to deny or revoke a provider or supplier's Medicare billing privileges will be handled by a carrier hearing officer not involved in the initial determination or a CMS Regional Office for a Part A determination.

There are distinct appeals provisions for claims processing and provider enrollment. While the claims process uses claims determination and qualified independent contractors (QICs) as part of the appeals process, the provider enrollment process does not. The first level of appeal of adverse actions is to either a contractor hearing officer for noncertified suppliers or to the CMS Regional Office for certified providers or suppliers. Subsequently, appellants may appeal adverse provider enrollment determinations by a hearing officer or regional office to an ALJ, then the DAB, and then to Federal District Court.

Comment: One commenter recommended that § 498.86(a) concerning evidence admissible on review by the DAB, adopt and follow the good cause exception set forth in proposed § 498.56(e) for ALJ proceedings.

Response: By the time the DAB hears the provider enrollment appeal, the applicant has been afforded ample opportunity to submit any evidence germane to the adverse determination. Accordingly, we do not believe it is efficient or administratively effective to establish a "good cause" provision within the language at § 498.86(a).

Comment: While we received a number of comments supporting our proposal to prohibit providers and suppliers from submitting new evidence during the ALJ and DAB levels of appeal, several commenters stated they were opposed to this proposal.

Response: Consistent with the provisions of our April 21, 2006 final rule titled "Requirements for Establishing and Maintaining Medicare Billing Privileges and Provider Enrollment Process" (71 FR 20754), we believe all providers and suppliers must meet and maintain all Federal and State requirements for their provider or supplier type to enroll or maintain their enrollment in the Medicare Program.

When a Medicare contractor makes an adverse enrollment determination (for example, enrollment denial or revocation of billing privileges), providers and suppliers are afforded appeal rights. However, these appeal

rights are limited to provider or supplier eligibility at the time the Medicare contractor made the adverse determination. Thus, if a Medicare contractor determines that a provider or supplier does not meet State licensure requirements on June 1, 2007, it is the provider's responsibility to demonstrate during the appeals process that State licensure requirements were met on June 1, 2007. Conversely, if a provider only can demonstrate that State licensure requirements were met on a later date; such as, August 16, 2007, we believe that the contractor made the correct determination, and that the provider or supplier may reapply for Medicare billing privileges. Accordingly, a provider or supplier is required to furnish the evidence that demonstrates that the Medicare contractor made an error at the time an adverse determination was made, not that the provider or supplier is now in compliance. Thus, we believe that it is essential that providers and suppliers submit documentation that supports their eligibility to participate in the Medicare program during the reconsideration step of the provider enrollment appeals process. This will allow a hearing officer to review and make a decision using all applicable facts. Moreover, the early presentation of evidence will help to ensure an efficient and effective administrative appeals process.

Finally, in order to expedite the provider enrollment appeals process, we believe that applicants must present all relevant facts and supporting documentation prior to or during the first level of appeal (that is, reconsideration). This will enable a contractor hearing officer or the CMS Regional Office personnel to review and make a determination based on all available facts. Moreover, the early presentation of facts and supporting documentation can be used to build the administrative record and help facilitate timely decisions at higher levels of appeals.

Comment: One commenter suggested that we continue to follow the existing ALJ and DAB procedures in part 498 to allow for consideration and for submission of additional evidence related to a provider or supplier enrollment appeal after the initial information is submitted.

Response: As stated previously in this final rule, in order to expedite the provider enrollment appeals process, we believe that applicants must present all relevant facts and supporting documentation prior to or during the first level of appeal (that is, reconsideration). This will enable a

contractor hearing officer or the CMS Regional Office personnel to review and make a determination based on all available facts. Moreover, the early presentation of facts and supporting documentation can be used to build the administrative record and help facilitate timely decisions at higher levels of appeals.

Comment: Several commenters stated that we used the terms "billing number" and "billing privileges" interchangeably in the proposed rule and that caused confusion.

Response: We appreciate these comments and will revise the final rule to use the term "billing privileges" throughout. With the implementation of the National Provider Identifier on May 23, 2008, Medicare will no longer issue a billing number to providers and suppliers, but will, in fact, convey billing privileges to a provider or supplier if they meet and maintain all Federal and/or State requirements to enroll or remain enrolled in the Medicare program.

Comment: Several commenters recommended that physicians be allowed to appeal rejected claims once Medicare billing privileges are granted.

Response: Physicians, as well as providers and other suppliers, are required to enroll in the Medicare program before submitting a Medicare claim. Accordingly, if a claim is rejected because the physician is not enrolled, a physician must resubmit the claims after he or she is enrolled in the Medicare program in compliance with Medicare's provision for timely filing (§ 424.44).

Comment: One commenter recommended that we not require the submission of the Electronic Funds Transfer Authorization Agreement (EFT) form (CMS-588) if a provider or supplier is already receiving payments electronically.

Response: We agree with this commenter. We believe an enrolled provider or supplier who is already receiving Medicare payments electronically is not required to submit the CMS-588 with a change in enrollment unless the provider or supplier is seeking to change its depository information.

Comment: Several commenters recommended that we address concerns regarding operational issues associated with the requirement to obtain payments electronically. Specifically, these commenters recommended that we address in this final rule the practice of reversing entry procedures where we may overpay the provider or supplier and then later reclaim that overpayment.

Response: We appreciate this comment and understand this concern; however, this issue is outside the scope of the proposed rule.

Comment: Several commenters stated that the provisions of this rule eliminated a physician's right to retroactively bill for services as is the current practice for some physicians.

Response: This rule did not propose a change in the current provisions regarding retroactive billing; therefore, we believe this comment is outside the scope of the proposed rule.

Comment: Several commenters supported our proposal to reduce from 60 to 30 days for information required to process an enrollment application, and they wanted to know if they could retroactively apply the provision to pending inventories.

Response: We appreciate the support for our proposal to reduce the time allotted to produce the necessary documentation to process enrollment applications from 60 days to 30 days before allowing a contractor to reject an enrollment application. However, we will prohibit our contractors from retroactively applying this change to pending inventories. Accordingly, any applications received after the effective date of this final rule will be subject to its provisions.

Comment: Several commenters recommended that we not reduce the amount of time providers or suppliers have to respond to a request from Medicare FFS contractor, (that is, carrier, FI, or MAC) for additional information from 60 days to 30 days as proposed in § 425.525(a)(2).

Response: We continue to believe that it is essential that providers and suppliers submit a complete application, including all supporting documentation, at the time of filing or at a minimum, respond to a contractor's request for information in a timely manner. Accordingly, absent the submission of a complete application, we believe that it is appropriate that providers and suppliers respond to a contractor's request for additional information in a timely manner. We believe that allowing a provider or supplier 30 days is more than enough time to obtain and submit the requested information or documentation. Finally, we believe that this change will lead to processing efficiencies for not only the Medicare program but also for those providers and suppliers who seek to enroll or make a change in their existing Medicare enrollment information.

Comment: One commenter requested that we clarify our requirement for furnishing requested enrollment documentation with respect to the 30-

day timeframe before the rejection of an enrollment application.

Response: We believe that a contractor may reject the provider or supplier's enrollment application if the provider or supplier fails to respond to a request for information in a complete and timely manner (that is, within 30 days of the contractor request for additional information.)

For example, assume that an applicant submits an enrollment application on May 1, 2008. While processing the enrollment application the contractor determines that the applicant did not complete section 3 of the application and did not submit the required supporting documentation to receive payments electronically. On May 16, 2008, the contractor notifies the applicant about the missing documentation. Assuming that the applicant does not submit all requested information by June 15, 2008 (that is, 30 days from the contractor request), the contractor may reject the application.

Comment: Several commenters stated that the proposed enrollment application processing timeframes stated in proposed § 405.874(h) were too long and would inhibit suppliers from enrolling or re-enrolling in the Medicare Program.

Response: We are also concerned about delays associated with the enrollment process. However, we recognize that many of the delays are the result of providers and suppliers not submitting a complete application at the time of filing or failing to submit complete and timely responses to a contractor's request for information.

In addition, we believe that it is appropriate to establish meaningful Medicare contractor processing timeliness standards and, as necessary, update or revise processing standards through the manual instructions and through contracts with Medicare contractors. Finally, while this final rule establishes an outer boundary for processing enrollment application, we fully expect that most enrollment applications will be processed in accordance with CMS processing requirements found in Publication 100-8, Chapter 10 of the Program Integrity Manual (PIM). The PIM establishes processing standards for initial applications, changes of information, and reassignments that all Medicare contractors must follow. Specifically, we currently require Medicare contractors to process 80 percent of initial applications within 60 days, 90 percent of initial applications within 120 days, and 99 percent of initial applications within 180 days. We also require Medicare contractors to process

80 percent of changes of information and reassignments within 45 days, 90 percent of changes of information and reassignments within 60 days and 99 percent of such applications within 90 calendar days of receipt.

With the implementation of the Provider Enrollment, Chain and Ownership System (PECOS) Web, an Internet version of the Medicare enrollment process, in FY 2008, we have established more stringent contractor processing timeliness standards for applications for enrollment submitted via PECOS Web. On January 4, 2008, we revised the processing requirements in Publication 100-8, Section 2, Chapter 10 of the PIM to establish the following processing requirements for PECOS Web applications:

Specifically, we will require Medicare contractors to process 90 percent of initial applications within 45 days, 95 percent of initial applications within 60 days, and 99 percent of initial applications within 90 days. We also require Medicare contractors to process 80 percent of changes of information and reassignments within 45 days, 90 percent of changes of information and reassignments within 60 days and 99 percent of such applications within 90 calendar days of receipt.

Since PECOS Web will improve the accuracy of applications submitted to contractors and reduce the time necessary to receive, verify and make a final determination regarding an enrollment action, we believe that the public should benefit from these processing efficiencies. Accordingly, we maintain that establishing a separate processing time standard for applications submitted via PECOS Web is appropriate.

Comment: Several commenters raised concerns as to whether we will be changing the processing standards to non-tiered percentages for processing initial applications (including revalidations), as well as with regard to changes of information (including reassignments not submitted in conjunction with an initial enrollment package).

Response: While we will maintain a tiered system we are establishing an outer boundary for the number of days for processing Medicare enrollment applications in this final rule, we will maintain more specific processing standards in Chapter 10 of the PIM.

Comment: One commenter asked if the proposed regulation will change the processing standard found in Section 2 of Chapter 10 of the PIM.

Response: This final rule does not change the provider enrollment

processing standards found in Section 2 of Chapter 10 of the PIM.

Comment: One commenter agreed with the 30-day timeframe for submitting supporting information as long as our contractors are required to follow this same timeframe for processing enrollment applications.

Response: While we are proposing an outside limit of 180 days for processing applications, we have established shorter processing timeframes in manual guidance which must be adhered to by CMS contractors.

However, we believe that 30 days does not provide contractors with sufficient time to process all enrollment applications. While we believe in holding contractors responsible for meeting our defined processing standards, it is essential that providers and suppliers submit a complete application at the time of filing in order to lessen processing timeframes.

Comment: One commenter asked for clarifications as to whether the 90-day timeframe requirement for change of information and reassignment of payment requests submitted applies to both fiscal intermediaries, as well as carriers.

Response: The 90-day processing standard applies to changes in information submitted to a fiscal intermediary/MAC or a change of information or reassignment submitted to a carrier/MAC. Therefore, § 405.874(h)(3) applies to both providers and suppliers. We note that DMEPOS suppliers are required to submit changes in information to the NSC within 30 days of the changes as specified in § 424.57(c)(2).

Comment: One commenter recommended that we allow academic medical centers to submit enrollment applications at least 6 months in advance of a physician's start date.

Response: By submitting a complete enrollment application and all supporting documentation at the time of filing, a physician can efficiently enroll in the Medicare program. Additionally, with the implementation of PECOS Web, we believe that physicians will be able to enroll in a more efficient manner. Finally, since we require our contractors to verify the information provided in the enrollment application, and this cannot be accomplished if the physician is not yet working at the academic medical center, we are not able to adopt this recommendation.

Comment: One commenter suggested that the 180-day processing time for enrollment decisions was not workable for providers undergoing a change of ownership (CHOW) as specified in § 489.18.

Response: Since Medicare contractors can only process applications that are complete at the time of filing and have the necessary supporting documentation, it is essential that CHOWs are complete when submitted. When completed applications are submitted, Medicare contractors will encounter fewer obstacles in processing an application. While we are establishing an outside processing timeframe in this rule, we have established more stringent processing requirements in the manual. We recognize the importance of processing CHOWs in a timely manner and will continue to establish processing standards in the manual which seek to ensure continuity of payment.

Comment: While several commenters offered support for our proposal in § 424.535 to preclude provider or supplier billing for a period of 3 years after Medicare billing privileges are revoked, several commenters stated that a 3-year ban is too long.

Response: We agree that Medicare contractors should consider the reason associated with revocation before determining whether the contractor should establish a re-enrollment bar for a provider or supplier. The goal of the re-enrollment bar is to ensure that Medicare billing privileges are given to trustworthy providers and suppliers. Consequently, if a Medicare contractor determines that a provider's or supplier's Medicare billing privileges should be revoked, then we believe that establishing an enrollment bar is appropriate. We will provide contractors with guidance on the establishment of an enrollment bar via manual instructions. With this guidance, we believe that the contractor has discretion to establish a re-enrollment bar from 1 to 3 years depending on the severity of the basis for revocation. For example, failure to respond to revalidation request may warrant a 1-year ban whereas failure to report an adverse legal action that could preclude payment would warrant a 3-year ban.

In addition, if a contractor makes a decision to revoke Medicare billing privileges, we believe that the duration of the re-enrollment bar should not be less than 1 year. Finally, while we believe that providers and suppliers can appeal the revocation determination, we do not believe that providers and suppliers can appeal the duration of the re-enrollment bar for Medicare billing privilege. We also believe that providers and suppliers have an obligation to maintain their billing privileges and to report changes that would preclude enrollment or continued enrollment in

accordance with § 410.33(g), § 424.57(c)(2), and § 424.520(b). In addition, we believe that establishing a re-enrollment bar for Medicare billing privileges that have been revoked will help protect the Medicare Trust Funds, and beneficiaries from potentially unqualified providers and suppliers.

Comment: One commenter stated that the 3-year waiting period in proposed § 424.502 was a punitive action and is not within our legal authority, and that only the OIG has been granted legal authority to exclude individuals and entities from the Medicare program.

Response: We believe that we have the obligation to protect the Medicare Trust Funds when billing privileges are revoked. We believe providers and suppliers whose billing privileges are revoked should be prevented from immediately re-entering the program. Accordingly, we believe that establishing a re-enrollment bar is appropriate and within our authority. Unlike OIG exclusions which apply government-wide and which generally last for 5 years or longer, the re-enrollment bar only applies to those billing the Medicare program.

Comment: Several commenters recommended that we do not revoke a physician's billing privileges for 3 years because the physician did not respond to a revalidation request.

Response: In the April 21, 2006 final rule, providers and suppliers learned about our intent to begin a revalidation process. Specifically, § 424.515 states that a provider or supplier (other than a DMEPOS supplier), must resubmit and recertify the accuracy of its enrollment information every 5 years. Therefore, providers and suppliers that enrolled in the Medicare program prior to 2003, but who have not completed a Medicare enrollment application since then, have had more than 2 years to come into voluntary compliance with our enrollment criteria by submitting a complete enrollment application. With this final rule, we are again notifying physicians, providers, and suppliers that they may voluntarily complete and submit a Medicare enrollment application and the necessary supporting documentation prior to our formal request for revalidation. Accordingly, providers and suppliers who choose not to come into voluntary compliance or fail to respond to a revalidation request in a complete and timely manner fail to satisfy our enrollment criteria and may be subject to revocation of their billing privileges.

Comment: Several commenters recommended that we allow providers and suppliers to participate in the Medicare program if their revocation is

successfully overturned at a higher level of appeal.

Response: Section 405.874(d)(3) states a provider or supplier's billing privileges will be reinstated back to the date that their revocation became effective if it was reversed at a higher level of appeal.

Comment: Several commenters recommended that we clarify that the period of provider or supplier ineligibility be linked to the date on which the supplier had provided a service to a beneficiary and not the date that a claim would be received or processed by a carrier.

Response: We are clarifying that this is our intent. Revocation actions concerning provider and supplier ineligibility are based upon the date on which the provider or supplier had furnished a service to a beneficiary and not the date that a claim was received or processed by a carrier or MAC.

For example, if a provider submits a claim for services provided on June 22, 2007, and the beneficiary dies on June 23, 2007, but the claim for the June 22, 2007 services was not received until August 1, 2007, if any action is taken regarding this claim, it would be with regard to the June 22, 2007 date.

Comment: One commenter suggested that there are several instances where the date of service being billed could actually be the day after the date of death and that an honest billing of the service could be perceived as fraud, and therefore cause a provider or supplier to be incorrectly revoked.

Response: We understand that there are certain situations when the date of service may legitimately be the day after the date of death of the beneficiary. Accordingly, Medicare contractors and CMS will review the specific details associated with each claim before taking any revocation action.

Comment: We received several comments regarding implementation of the proposed changes to be set forth at § 424.535(a)(8) which allows Medicare 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, where the commenter believed there was not enough guidance given to the contractors to filter these claims which could cause overburdened contractors to implement this policy too widely.

Response: CMS, not a Medicare contractor, will make the determination for revocation under the authority at § 424.535(a)(8). We will direct contractors to use this basis of revocation after identifying providers or suppliers that have these billing issues.

We have found numerous examples of situations where a physician claims to have furnished a service to a beneficiary more than a month after their recorded death, or when the provider or supplier was out of State when the supposed services had been furnished. In these instances, the provider has billed the Medicare program for services which were not provided and has submitted Medicare claims for service to a beneficiary who could not have received the service which was billed. This revocation authority is not intended to be used for isolated occurrences or accidental billing errors. Rather, this basis for revocation is directed at providers and suppliers who are engaging in a pattern of improper billing.

In making a revocation determination under § 424.535(a)(8), we will make the revocation determination based upon information presented by a Medicare contractor, a CMS Regional Office, or one of our Program Integrity field offices. We believe that it is both appropriate and necessary that we have the ability to revoke billing privileges when services could not have been furnished by a provider or supplier. We recognize the impact that this revocation has, and a revocation will not be issued unless sufficient evidence demonstrates abusive billing patterns. Accordingly, we will not revoke billing privileges under § 424.535(a)(8) unless there are multiple instances, at least three, where abusive billing practices have taken place. Furthermore, providers and suppliers may appeal a contractor revocation using the process outlined in part 498 if they believe that they were unduly revoked. In conclusion, we believe that providers and suppliers are responsible for the claims they submit or the claims submitted on their behalf. We believe that it is essential that providers and suppliers take the necessary steps to ensure they are billing appropriately for services furnished to Medicare beneficiaries.

Comment: Several commenters believed that contractors would be issuing revocations based upon the submission of claims for services that could not be delivered.

Response: As stated above, we will instruct Medicare contractors to issue a revocation under § 424.535(a)(8).

Comment: One commenter suggested several procedural changes regarding the processing of enrollment applications; such as, withdrawing an application and reopening a closed enrollment decision, be included in this regulation as opposed to our original procedural proposals.

Response: As outlined in § 424.510, the current enrollment application procedures allow providers and suppliers a clear means to complete and submit enrollment applications with the necessary documentation to participate in the Medicare program. Prospective providers or suppliers are responsible for obtaining the necessary documentation that demonstrates that they meet the program requirements for their provider or supplier type. If a provider or supplier cannot supply the necessary documentation at the time of filing or in response to a contractor request, then the contractor is required to reject their application and the prospective provider or supplier must begin the enrollment process anew. Finally, a prospective provider or supplier may withdraw their Medicare enrollment application at any time by informing the designated contractor in writing of the withdrawal of the application. A withdrawal request must be made by the applicant or the Authorized Official as defined in § 424.502 and in the Medicare enrollment application (CMS-855).

Unlike the claims appeals process where minor errors and omissions can be resolved through the reopening process in an effective and efficient manner, the issues involved in Provider Enrollment denials and revocations do not readily lend themselves to the reopening process. Accordingly, we have not adopted a reopening procedure in this final rule.

Comment: One commenter recommended that we revise our 2002 "Do Not Forward" policy because of the change in processing timeframes for enrollment applications.

Response: We believe this issue is outside the scope of the proposed rule and can not be addressed in this final rule.

Comment: One commenter recommended that if we make a change in the Medicare enrollment application that we use the processing guidelines in effect at the time of the postmark date so that the application will be treated as submitted prior to the implementation date.

Response: If we make a change in the Medicare enrollment application in the future, we will establish a transition period between the use of the prior version of the application and the new version of the application.

Comment: One commenter stated that electronic funds transfer (EFT) should be developed in concert with the CMS-855 transaction standard to ensure that there is a clear connection between the two files.

Response: We believe this issue is outside the scope of the proposed rule and can not be addressed in this final rule.

Comment: One commenter urged us to clarify that the reassignment exception still exists with regard to EFT which currently exempts individuals reassigning their benefits to a group practice from the EFT requirement.

Response: Individuals reassigning all of their benefits to a group practice are still exempt from the EFT requirement. We will update its manuals to state that only individuals and organizations receiving payments directly must receive them through EFT.

Comment: One commenter suggested that we consult with hospital-based faculty practices to determine the best way to implement EFT in this particular setting.

Response: We will continue to conduct outreach efforts to ensure that all providers and suppliers are informed about EFT policies.

Comment: One commenter recommended that adequate notification and education be provided to all who have chosen or are required to accept funds via EFT.

Response: We will continue to conduct outreach efforts to ensure that all providers and suppliers are informed about EFT policies. We believe this issue is outside the scope of the proposed rule and can not be addressed in this final rule.

Comment: One commenter recommended that notice of precertification completion be provided to group practices prior to the payment of funds via EFT.

Response: We believe this issue is outside the scope of the proposed rule and can not be addressed in this final rule.

Comment: One commenter stated we should not terminate a provider agreement when billing privileges are revoked.

Response: In the April 21, 2006 final rule, we stated in § 424.545(a) that the termination of both the provider agreement and billing privileges will happen concurrently. Accordingly, we believe that a provider cannot retain a provider agreement if its billing privileges have been revoked.

Comment: One commenter suggested that we amend the definition of supplier because they believed that the term ambulance service provider may not include suppliers of ambulance services.

Response: While we are not adopting this recommendation, we clarify in section IV. of this final rule (Provisions of the Final Regulation) that an

ambulance service provider includes all providers and suppliers of ambulance services.

Comment: One commenter recommended that we conduct increased outreach and education efforts for providers, suppliers and contractor enrollment staff.

Response: We will undertake the necessary steps to ensure that our contractors understand these new provisions and apply them consistently. In addition to publishing this final rule, we will issue operational guidance to our Medicare contractors.

IV. Provisions of the Final Regulation

Based on public comments, we are adopting the provisions of the proposed rule as final with the following changes: We are amending the provisions of this final rule to apply to all providers and suppliers, including DMEPOS suppliers.

In § 405.802, we have added a definition of prospective provider.

In § 405.874(a), we amended the proposed language and adopted the provision that if a carrier, fiscal intermediary, National Supplier Clearinghouse (NSC) or MAC denies a provider's or supplier's enrollment application, then the carrier, fiscal intermediary, NSC or MAC must notify the provider or supplier by mail. The notice must include the following: (1) The reason for denial in sufficient detail to allow the provider or 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.

In § 405.874(b)(1), we adopted the provision which clarified that if CMS or a CMS contractor, (that is, a carrier, fiscal intermediary, NSC or MAC) revokes a provider's or supplier's Medicare billing privileges, then CMS or its contractor must notify the provider or supplier by mail and that the notice must include—(1) The reason for the revocation in sufficient detail for the provider or 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 § 405.874(b)(2), we adopted the provision to separate the procedures in existing § 405.874(a) and § 405.874(b).

In addition, we adopted the provision clarifying that a revocation of provider's or supplier's billing privileges that is based on a Federal exclusion or debarment is effective with the effective date of the exclusion or debarment. Moreover, if CMS or a CMS contractor revokes Medicare billing privileges, then we would not revoke an individual

or organization's National Provider Identifier (NPI).

In § 405.874(b)(3), we modified our proposed provision to clarify that providers and suppliers are not paid for items or services furnished after the effective date of revocation. We removed proposed § 405.874(b)(3)(i) because it was not applicable to revocation of billing privileges. 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 also adopted the provision that claims submitted to carriers, fiscal intermediaries, NSC or MACs for items or services furnished during a period of provider or supplier ineligibility are to be rejected by the carrier or fiscal intermediary and not denied.

In § 405.874(c)(1), we adopted the provision that a provider's or supplier's appeal rights would follow the processes detailed in part 498. Generally denials or revocations issued by a fiscal intermediary would be handled by a CMS regional office (RO), and denials and revocations by carriers, including the NSC, would be handled by a carrier hearing officer. In those cases where a MAC issues a denial or revocation, the reconsideration would be handled by the CMS RO or a contractor hearing officer depending upon the provider or supplier type. The CMS RO's will generally be handling the Medicare Part A reconsiderations and the contractor hearing officer will generally be handling the Medicare Part B reconsiderations.

In § 405.874(d), we adopted the revisions to this section to reflect that claims for services furnished to Medicare beneficiaries during a period in which the provider's or 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 the 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 adopted the provision that when 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.

In § 405.874(d)(4), we adopted the provision 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.

In § 405.874(e), we adopted the provision that if a provider or supplier completes a corrective action plan and provides sufficient evidence to the carrier, fiscal intermediary, NSC or MAC that it has complied fully with the Medicare requirements, the carrier, fiscal intermediary or MAC may reinstate the supplier's billing privileges.

In § 405.874(f) we adopted the provision changing the effective date for DMEPOS supplier's billing privileges. If the NSC, NSC 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 privileges 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), we adopted the provision that a provider or supplier succeeding in having its enrollment application denial or billing privileges revocation reversed, or in having its billing privileges reinstated, may submit claims to the CMS contractor for services furnished during periods of Medicare qualification, subject to the limitations in § 424.44 of this chapter, regarding the timely filing of claims.

In § 424.510(d)(2)(iv), we adopted the provision that at the time of enrollment, an enrollment change request or revalidation, including reenrollment of DMEPOS suppliers, providers and suppliers shall submit the CMS-588 form to receive payments via electronic funds transfer (EFT) if they are not already receiving payments via EFT.

Consistent with the authority under 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 requiring EFT payments for the following: (1) Providers and suppliers initially enrolling in the Medicare program; (2) providers and suppliers submitting a CMS-855 change request who are not currently receiving payments via EFT; (3) provider and suppliers responding to a revalidation or DMEPOS re-enrollment request; and (4) when CMS changes a Medicare contractor for a State or contracting jurisdiction and the provider or supplier was already receiving payments via EFT. We believe that providers and suppliers already receiving payments via EFT should continue to receive payments via EFT when CMS changes a Medicare contractor for a State or contracting jurisdiction. We believe that requiring providers and suppliers who were already receiving Medicare payments via EFT prior to a change in Medicare contractors is consistent with the provisions of the proposed rule and does not impose a consequential burden on these providers and suppliers. In addition, we believe an enrolled provider or supplier who is already receiving Medicare payments electronically is not required to submit the CMS-588 with a change in enrollment unless the provider or supplier is seeking to change its depository information. Finally, we will continue to encourage all providers and suppliers to switch to EFT payments voluntarily.

In § 424.545(a), we adopted the following provisions:

- Redesignated the first sentence of current paragraph (a) as the introductory text and revised that text to remove the reference to part 405 subpart H.

- Redesignated the second sentence of current paragraph (a) as paragraph (a)(1)(i).

- Added paragraph (a)(1)(ii) to clarify that if a provider or supplier appeals both of these sanctions, then both matters will be resolved using a single appeals process.

- Redesignated the last sentence of current paragraph (a) as paragraph (a)(2).

In § 405.874(h), we adopted the provision that established deadlines for the processing of provider enrollment actions. We adopted the provision that contractors will process initial determinations and revalidations within

180 days of receipt and that carriers, fiscal intermediaries or MACs process change-of-information and reassignment of payment requests within 90 days of receipt.

In § 424.525(a)(1) and (a)(2), we adopted the provisions that state the 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 adopted the provision for a reduction from 60 to 30 days for the period allowed to furnish all supporting documentation for submitting their enrollment application. In this final rule, we are also making conforming changes in paragraph (b) of this section (that is, changing 60 days to 30 days).

In § 424.535(a)(8), we adopted the provision that allows Medicare FFS contractors to revoke Medicare billing privileges when instructed to do so by CMS when a provider or supplier submits a claim or claims for services that could not have been furnished to a beneficiary. 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 believe that this new revocation authority is consistent with the other types of revocations already used by CMS and its contractors under § 424.535. Further, providers and suppliers may appeal a contractor revocation using the process outlined in part 498.

This basis for revocation is essential to the efficient operation of the Medicare program, because it will enable us to take an important step in protecting the expenditure of public monies for service providers whose motive and billing practices are questionable, at best, and at worst, of a sort that might prompt an aggressive response from the law enforcement community. We also want to alert providers and suppliers that we may be proposing other provisions related to revocation of providers and suppliers in the calendar year 2009 physician fee schedule proposed rule.

In § 424.535(b)(2), we adopted the provision to establish a re-enrollment bar of not less than 1 year and not greater than 3 years when a provider or supplier's Medicare billing privileges are revoked. Specifically, we adopted the provision that when a provider or supplier, including all authorized officials, delegated 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 in the Medicare program for a period of not less than 1 year but not greater than 3 years. While we have adopted a provision to establish a re-enrollment bar for 1 year but not greater than 3 years, this enrollment bar does not preclude CMS or its contractor from denying re-enrollment if a provider or supplier was convicted of felony within the preceding 10-year period as described in § 424.530(a)(3) or is not in compliance with any other enrollment criteria.

In § 498.1(g), we adopted the provision for an ALJ hearing, and judicial review for any provider or supplier whose application for enrollment or reenrollment in Medicare has been denied or whose billing privileges have been revoked.

In § 498.2—

- Finalizing our definition of a “supplier” to include the following: (1) A supplier of DMEPOS; ambulance service provider; independent diagnostic testing facility; physician; and other practitioner such as physician assistant; and (2) remove the reference to “prospective supplier.” To further clarify the provisions applicable to providers and suppliers, we have added the definition of provider and prospective provider to § 405.802. We also note that we made technical edits to the definitions of supplier in § 405.802 and § 498.2.

- Revised the definition of provider to (1) remove the reference to prospective provider; and (2) make technical changes. These technical changes include correcting the term “hospital transplant center” to read “hospital, transplant center” and removing the phrase “that has in effect an agreement to participate in Medicare”.

- Added new definitions for “prospective supplier,” “prospective provider,” largely based upon comments received. Since applicants (prospective provider and suppliers) who are not enrolled in the Medicare program, still are afforded appeal rights based on an enrollment denial, we maintain that it is important to clarify that any prospective applicant (provider

or supplier) is afforded appeal rights through this process.

We also adopted the provision to remove 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 DHHS. Additionally, we adopted the provision that revised the definition of “affected party” to specify that it includes CMS or a CMS contractor.

In § 498.5, we adopted the provision that revised this section by adding a new paragraph (l) to clarify the administrative process that would be used by 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.

In § 498.5(f)(2), we adopted the provision to be consistent with the change in § 498.1(g). This implements the mandate of section 936(a)(2) of the MMA regarding judicial review. We have adopted these standards because the FFS contractors need sufficient time to adjudicate the facts and make a reasoned Medicare enrollment decision. Moreover, while we established an outside limit for processing these applications, the vast majority of these decisions are made within 120 days.

In § 498.22(a), we adopted the provision to add that we have delegated authority to our contractors to reconsider an initial determination. We also are adopting the provision 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. Additionally, we adopted the provision at § 498.44 to remove the term “Associate Commissioner for Hearings and Appeals,” and we have replaced it with the term “Secretary,” because this function is no longer under the Social Security Administration; it is now under the DHHS.

In § 405.874(c)(2), we adopted the provision which clarifies 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 privileges. At § 498.56, we added a new paragraph (e) that specifies the “good cause” exception to the admission of new evidence at the ALJ level of appeal.

In § 498.78(a), we adopted the proposal to delete the provision that an

affected party concur in writing or on the record with a CMS or OIG request for remand. We contend that the appeals process is 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 in the administrative record being complete.

In § 498.79, we adopted the provision 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.

We revised § 498.86 to prohibit providers and suppliers from submitting new provider enrollment issues or evidence at the DAB level of review.

Finally, in § 498.88(g), we adopted the provision 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 30-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)(4).

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-F, 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-F, carolyn_lovett@omb.eop.gov. Fax (202) 395-6974.

VI. 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 on Federalism, and the Congressional Review Act (U.S.C. 804(s)).

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 \$6.5 to \$31.5 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 final 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 final 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 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. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this final 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 amends 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: Sections 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 amended by adding the definitions of “provider”, “prospective provider”, “prospective supplier” and “supplier” in alphabetical order to read as follows:

§ 405.802 Definitions.

* * * * *

Prospective provider means any of the entities specified in the definition of provider under § 498.2 of this chapter that seeks to be approved for coverage of its services by Medicare.

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

Provider means either of the following:

(1) Any of the following entities that have in effect an agreement to participate in Medicare:

- (i) Hospital.
- (ii) Transplant center.
- (iii) Critical access hospital (CAH).
- (iv) Skilled nursing facility (SNF).
- (v) Comprehensive outpatient rehabilitation facility (CORF).
- (vi) Home health agency (HHA).
- (vii) Hospice.
- (viii) Religious nonmedical health care institution (RNHCI).

(2) Any of the following entities that have in effect an agreement to participate in Medicare but only to furnish outpatient physical therapy or outpatient speech pathology services.

- (i) Clinic.
- (ii) Rehabilitation agency.
- (iii) Public health agency.

* * * * *

Supplier means any of the following entities:

- (1) An independent laboratory.
- (2) Supplier of durable medical equipment Prosthetics, orthotics, or supplies (DMEPOS).
- (3) Ambulance service provider.
- (4) Independent diagnostic testing facility.
- (5) Physician or other practitioner such as physician assistant.
- (6) Physical therapist in independent practice.
- (7) Clinical laboratories.
- (8) Supplier of portable X-ray services.
- (9) Rural health clinic (RHC).
- (10) Federally qualified health center (FQHC).
- (11) Ambulatory surgical center (ASC).
- (12) An entity approved by CMS to furnish outpatient diabetes self-management training.
- (13) 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 CMS or a CMS contractor.

A CMS contractor's (that is, a carrier, Fiscal Intermediary or Medicare

Administrative Contractor (MAC)) determination that a provider or supplier fails to meet the requirements for Medicare billing privileges.

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

(1) The reason for the denial in sufficient detail to allow the provider or 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 CMS or a CMS contractor revokes a provider's or supplier's Medicare billing privileges, CMS or a CMS contractor must notify the supplier by certified mail. The notice must include the following:

(i) The reason for the revocation in sufficient detail for the provider or 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) *Effective date of revocation.* The revocation of a provider's or supplier's billing privileges is effective 30 days after CMS or the CMS contractor mails the notice of its determination to the provider or supplier. A revocation based on a Federal exclusion or debarment is effective with the date of the exclusion or debarment.

(3) *Payment after revocation.* Medicare does not pay and the CMS contractor rejects claims for services submitted with a service date on or after the effective date of a provider's or supplier's revocation.

(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 current billing privileges 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 will be handled by a CMS Regional Office or a contractor 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 contractor determinations on claims processing.*

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

(2) If a supplier is determined not to have qualified for billing privileges in one period but qualified in another, Medicare contractors 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 the 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 the 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 become effective.

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

(f) *Effective date for DMEPOS supplier's billing privileges.* If a CMS contractor, contractor 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 provider or 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 CMS contractor 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 or supplier 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 new paragraphs (d)(2)(iv) and (e) to read as follows:

§ 424.510 Requirements for enrolling in the Medicare program.

* * * * *

(d) * * *

(2) * * *

(iv) At the time of enrollment, an enrollment change request, revalidation or change of Medicare contractors where the provider or supplier was already receiving payments via EFT, providers and suppliers must agree to receive Medicare payments via EFT, if not already receiving payment through 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, change of Medicare contractors where the provider or supplier was already receiving payments via EFT 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), (a)(2) and (b).

The revisions read as follows:

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

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

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

(b) *Extension of 30-day period.* CMS, at its discretion, may choose to extend the 30 day period if CMS determines that the prospective provider or supplier is actively working with CMS to resolve any outstanding issues.

* * * * *

■ 7. Section 424.535 is amended by—

■ A. Adding a new paragraph (a)(8).

■ B. Redesignating paragraphs (c) through (f) as (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.

(b) * * *

(c) *Reapplying after revocation.* After a provider, supplier, delegated official, or authorizing official has had their billing privileges revoked, they are barred from participating in the Medicare program from the effective date of the revocation until the end of the re-enrollment bar. The re-enrollment bar is a minimum of 1 year, but not greater than 3 years depending on the severity of the basis for revocation.

* * * * *

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

§ 424.545 Provider and supplier appeal rights.

(a) *General.* A prospective provider or supplier that is denied enrollment in the Medicare program, or a provider or supplier 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 the definitions of “prospective provider” and “prospective supplier”.

■ D. Revising the definitions of “provider” and “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 provider means any of the entities specified in the definition of provider under this section that seeks to be approved for coverage of its services by Medicare or to have any facility or organization determined to be a department of the provider or provider-based entity under § 413.65 of this chapter.

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

Provider means either of the following:

(1) Any of the following entities that have in effect an agreement to participate in Medicare:

- (i) Hospital.
(ii) Transplant center.
(iii) Critical access hospital (CAH).
(iv) Skilled nursing facility (SNF).
(v) Comprehensive outpatient rehabilitation facility (CORF).
(vi) Home health agency (HHA).
(vii) Hospice.
(viii) Religious nonmedical health care institution (RNHCI).

(2) Any of the following entities that have in effect an agreement to participate in Medicare but only to furnish outpatient physical therapy or outpatient speech pathology services.

- (i) Clinic.
(ii) Rehabilitation agency.
(iii) Public health agency.

Supplier means any of the following entities that have in effect an agreement to participate in Medicare:

- (1) An independent laboratory.
(2) Supplier of durable medical equipment prosthetics, orthotics, or supplies (DMEPOS).
(3) Ambulance service provider.
(4) Independent diagnostic testing facility.
(5) Physician or other practitioner such as physician assistant.
(6) Physical therapist in independent practice.
(7) Supplier of portable X-ray services.
(8) Rural health clinic (RHC).
(9) Federally qualified health center (FQHC).
(10) Ambulatory surgical center (ASC).
(11) An entity approved by CMS to furnish outpatient diabetes self-management training.
(12) 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.*

(i) *If good cause exists.* If the ALJ finds that there is good cause for submitting new documentary evidence for the first time at the ALJ level, the ALJ must include evidence and may consider it in reaching a decision.

(ii) *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.

(2) *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 a 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, 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 of a denial of an enrollment application 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: November 16, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: March 17, 2008.

Michael O. Leavitt,

Secretary.

Editorial Note: This document was received in the Office of the Federal Register on June 20, 2008.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 406, 407, and 408

[CMS-4129-F]

RIN 0938-AO77

Medicare Program; Special Enrollment Period and Medicare Premium Changes

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

ACTION: Final rule.

SUMMARY: This final rule provides a special enrollment period (SEP) for Medicare Part B and premium Part A for certain individuals who are sponsored by prescribed organizations as volunteers outside of the United States and who have health insurance that covers them while outside the United States. Under the SEP provision, qualifying volunteers can delay enrollment in Part B and premium Part A, or terminate such coverage, for the period of service outside of the United States and reenroll without incurring a premium surcharge for late enrollment or reenrollment.

This final rule also codifies provisions that require certain beneficiaries to pay an income-related monthly adjustment amount (IRMAA) in addition to the standard Medicare Part B premium, plus any applicable increase for late enrollment or reenrollment. The income-related monthly adjustment amount is to be paid by beneficiaries who have a modified adjusted gross income that exceeds certain threshold amounts. It also represents the amount of decreases in the Medicare Part B premium subsidy, that is, the amount of the Federal government's contribution to the Federal Supplementary Medicare Insurance (SMI) Trust Fund.

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

FOR FURTHER INFORMATION CONTACT: Denise Cox, (410) 786-3195.

SUPPLEMENTARY INFORMATION:

I. Background

A. General

Medicare is a Federal health insurance program that helps millions of Americans pay for health care. Beneficiaries include eligible individuals age 65 or older and certain people younger than age 65 who also qualify to receive Medicare. These individuals include those who have