CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 316	Date: December 4, 2009
	Change Request 6487

SUBJECT: Administrative Appeals Process for Provider Enrollment

I. SUMMARY OF CHANGES: This change request implements a number of provisions that are applicable to all providers and suppliers including DMEPOS suppliers whose Medicare enrollment application has been denied or whose Medicare billing privileges have been revoked. In addition the requirement to send denial letters by certified mail has been removed.

NEW / REVISED MATERIAL
EFFECTIVE DATE: January 4, 2010
IMPLEMENTATION DATE: January 4, 2010

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	10/6.2/Denials
R	10/19/Administrative Appeals

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Unless otherwise specified, the effective date is the date of service.

Attachment - Business Requirements

Pub. 100-08	Transmittal: 316	Date: December 4, 2009	Change Request: 6487

SUBJECT: Administrative Appeals Process for Provider Enrollment

EFFECTIVE DATE: January 4, 2010
IMPLEMENTATION DATE: January 4, 2010

I. GENERAL INFORMATION

A. Background: This change request implements a number of provisions that are applicable to all providers and suppliers including durable medical equipment, orthotics, prosthetics and supplies (DMEPOS) whose enrollment application has been denied or whose Medicare billing privileges have been revoked. Further instruction is provided regarding the correction action plan (CAP) process.

B. Policy: Pub. 100-08, PIM, chapter 10, section 19, changes are aligned with the provisions in the appeals regulation (CMS-6003).

II. BUSINESS REQUIREMENTS TABLE

Use"Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6487.1	Contractors shall notify the provider or supplier by letter when a decision to deny is made.	X		X	X						NSC
6487.2	Contractors shall accept an appeal from a provider or supplier, as identified in Pub. 100-08, PIM, chapter 10, section 6.1.4, for any type of application submitted (i.e., initial application, change request or reassignment).	X			X						
6487.3	Contractors shall emphasize to providers and suppliers, through denial/revocation letters, that the submission of a CAP addressing the issues that resulted in the denial or revocation of billing privileges will expedite the enrollment process and issue a faster determination.	X		X	X						NSC
6487.4	Contractor shall process corrective actions plans (CAPs) in accordance with Pub. 100-08, PIM, chapter 10.	X			X						NSC
6487.5	All CAPs and reconsideration requests received for certified providers and certified suppliers shall be processed by CMS.	X		X	X						CMS
6487.5.1	Contractors shall forward all CAP and reconsideration requests received for certified providers and certified suppliers to:	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	Centers for Medicare & Medicaid Services Division of Provider & Supplier Enrollment 7500 Security Blvd. Mailstop C3-02-16 Baltimore, MD 21244-1850										

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	None										

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s): Alisha Banks, Alisha.banks@cms.hhs.gov, 410-786-0671
Post-Implementation Contact(s): Alisha Banks, Alisha.banks@cms.hhs.gov, 410-786-0671

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs),* and/or *Carriers*:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: ***For Medicare Administrative Contractors (MACs)*****:**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

6.2 – Denials

(Rev. 316; Issued: 12-04-09; Effective/Implementation Date: 01-04-10)

A. Denial Reasons

Per 42 CFR §424.530(a), contractors must deny an enrollment application if any of the situations described below are present, and must provide appeal rights.

When issuing a denial, the contractor shall insert the appropriate regulatory basis (e.g., 42 CFR §424.530(a)(1)) into its determination letter. The contractor shall not use provisions from this chapter as the basis for denial.

Note that if the applicant is a certified provider or certified supplier and one of the denial reasons listed below is implicated, the contractor need not submit a recommendation for denial to the State/RO. The contractor can simply: (1) deny the application, (2) close out the PECOS record, and (3) send a denial letter to the provider in a format similar to that which is used for carrier denials of non-certified supplier applications (see sections 14 and 19 of this chapter). The contractor shall copy the State and the RO on said letter.

Denial Reason 1 (42 CFR §424.530(a)(1))

The provider or supplier is determined not to be in compliance with the Medicare enrollment requirements described in this section or on the enrollment application applicable to its provider or supplier type, and has not submitted a plan of corrective action as outlined in 42 CFR part 488.

Note that this denial reason shall be used in the situations described in section 3.1.2, of this chapter.

Denial Reason 2 (42 CFR §424.530(a)(2))

The provider or supplier, or any owner, managing employee, authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier who is required to be reported on the CMS-855 is—

- Excluded from Medicare, Medicaid, or any other Federal health care program, as defined in 42 CFR §1001.2, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867 or 1892 of the Social Security Act, or

- Debarred, suspended, or otherwise excluded from participating in any other Federal procurement or nonprocurement program or activity in accordance with section 2455 of the Federal Acquisition Streamlining Act.

Denial Reason 3 (42 CFR §424.530(a)(3))

The provider, supplier, or any owner of the provider or supplier was, within the 10 years preceding enrollment or revalidation of enrollment, convicted of a Federal or State felony offense that CMS has determined to be detrimental to the best interests of the program and its beneficiaries. Offenses include--

- Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

- Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

- Any felony that placed the Medicare program or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.

- Any felonies outlined in section 1128 of the Social Security Act.

While, as discussed in section 13.2(D), of this chapter, the contractor will establish an enrollment bar for providers and suppliers whose billing privileges are revoked, this in no way precludes the contractor from denying re-enrollment to a provider or supplier who was convicted of a felony within the preceding 10-year period or who otherwise does not meet all criteria necessary to enroll in Medicare.

Denial Reason 4 (42 CFR §424.530(a)(4))

The provider or supplier submitted false or misleading information on the enrollment application to gain enrollment in the Medicare program. (The contractor shall contact its DPSE contractor liaison prior to issuing or recommending denial of an application on this ground.)

Denial Reason 5 (42 CFR §424.530(a)(5))

The CMS determines, upon onsite review or other reliable evidence, that the provider or supplier is not operational to furnish Medicare covered items or services, or does not meet Medicare enrollment requirements to furnish Medicare covered items or services. This includes, but is not limited to, the following situations:

- The applicant does not have a license(s) or is not authorized by the Federal/State/local government to perform the services for which it intends to render. (In its denial letter, the contractor shall cite the appropriate statute and/or regulations containing the licensure/certification/authorization requirements for that provider or supplier type. For a listing of said statutes and regulations, refer to section 12 et seq. of this chapter. Note that the contractor must identify in the denial letter the exact provision within said statute/regulation that the provider/supplier has failed to comply with.)

- The applicant does not have a physical business address or mobile unit where services can be rendered and/or does not have a place where patient records are stored to determine the amounts due such provider or other person (as set forth in §1833(e) of the Social Security Act.)

- The applicant does not meet CMS regulatory requirements for the specialty. (In containing the licensure/certification/authorization requirements for that its denial letter, the contractor shall cite the appropriate statutory and/or regulatory citations provider or supplier type. For a listing of said statutes and regulations, refer to section 12 et seq. of this chapter. Note that the contractor must identify in the denial letter the exact provision within said statute/regulation that the provider/supplier is not in compliance with.)

- The applicant does not qualify as a provider of services or a supplier of medical and health services. An entity seeking Medicare payment must be able to receive reassigned benefits from physicians in accordance with the Medicare reassignment provisions in §1842(b)(6) of the Act (42 U.S.C. 1395u(b)).

NOTE: This denial provision should be used in cases where the applicant is not recognized by any Federal statute as a Medicare provider or supplier (e.g., marriage counselors.

- The applicant does not provide a valid SSN/EIN for the applicant, owner, partner, managing organization/employee, officer, director, medical director, and/or delegated or authorized official.

- A home health agency (HHA) does not meet the capitalization requirements outlined in 42 CFR §489.28.

B. Denial Letters

When a decision to deny is made, the carrier shall send a letter to the supplier identifying the reason(s) for denial and furnishing appeal rights. The letter shall follow the format of that shown in section 14 of this chapter.

No reenrollment bar shall be established for denied applications. Reenrollment bars apply only to revocations.

C. Post-Denial Submission of Enrollment Application

A provider or supplier that is denied enrollment in the Medicare program cannot submit a new enrollment application until the following has occurred:

- If the denial was not appealed, the provider or supplier may reapply after its appeal rights have lapsed.

- If the denial was appealed, the provider or supplier may reapply after it received notification that the determination was upheld.

D. 30-Day Effective Date of Denial

A denial is effective 30 calendar days after the contractor sends its denial notice to the provider.

As stated in 42 CFR §424.530(c), if the denial was due to adverse activity (sanction, exclusion, debt, felony) of an owner, managing employee, an authorized or delegated official, medical director, supervising physician, or other health care personnel of the provider or supplier furnishing Medicare services, the denial may be reversed if the provider or supplier submits proof that it has terminated its business relationship with that individual or organization within 30 days of the denial notification.

E. Provider Enrollment Appeals Process

For more information regarding the provider enrollment appeals process, see section 19, of this chapter.

19 - Administrative Appeals

(Rev. 316; Issued: 12-04-09; Effective/Implementation Date: 01-04-10)

A provider or supplier whose Medicare enrollment is denied or whose Medicare billing privilege is revoked can request an appeal of that determination. *In addition, some providers and suppliers (identified in section 6.1.4 of this chapter) may submit an appeal for any type of application submitted (i.e., initial application, change request or reassignment) that resulted in a denial.*

This appeal process applies to all providers and suppliers, not just those defined in 42 CFR §498, and ensures that all applicants receive a fair and full opportunity to be heard. With the implementation of the appeals provision of Section 936 of the Medicare Prescription Drug Modernization and Improvement Act (MMA), all providers and suppliers that wish to appeal will be given the opportunity to request an appeal of a reconsideration decision to an administrative law judge (ALJ) of the Department of Health and Human Services (DHHS). Providers and suppliers then can seek review by the Departmental Appeals Board (DAB) and then may request judicial review.

Denial/Revocation of Medicare Billing Privileges

A. Carriers (including NSC and A/B MACs)

If a Medicare contractor reviews an initial enrollment application for a provider or supplier and finds a basis for denying the application pursuant to 42 CFR §424.530, such as; the provider or supplier does not meet one or more of the Federal or State

requirements, the Medicare contractor shall deny the application and notify the provider or supplier by letter (*see section 14 of this chapter).* The denial letter shall contain:

- *A legal (i.e., regulatory) basis for each reason for the denial*;

- *A clear explanation of why the application is being denied, including the facts or evidence used by the contractor in making their determination*;

- *An explanation of why the provider or supplier does not meet the enrollment criteria or program requirement to enroll in the Medicare program;*

- *P*rocedures for submitting a corrective action plan (CAP); and

- *Complete and accurate information about the provider or supplier's further appeal rights*.

Similarly, when a Medicare contractor discovers that there is a basis for revoking a provider or supplier's billing privileges, such as; the provider or supplier no longer meets one of the requirements for billing privileges, the contractor shall revoke billing privileges and notify the provider or supplier by letter. The revocation letter shall contain:

- *A legal (i.e., regulatory) basis for each reason for revocation*;

- *A clear explanation of why Medicare billing privileges are being revoked, including the facts or evidence used by the contractor in making their determination*;

- *An explanation of why the provider or supplier does not meet the enrollment criteria or program requirement to maintain enrollment in the Medicare program;*

- *T*he effective date of the revocation (30 days from the date the notice is mailed for providers or suppliers, or 15 days from the date the notice is mailed for DMEPOS suppliers. A revocation based on a Federal exclusion or debarment is effective with *t*he date of the exclusion or debarment. The effective date of a license suspension/revocation is effective with the date of the suspension/revocation;

- *P*rocedures for submitting a CAP; and

- *Complete and accurate information about the provider or supplier's further appeal rights.*

Corrective Actions Plan (CAP)

A CAP is the process that gives the provider or supplier an opportunity to correct the deficiencies (if possible) that resulted in the denial or revocation of billing privileges. The CAP should provide evidence that the provider or supplier is in compliance with Medicare requirements.

The Medicare contractors shall emphasize to the providers and suppliers, through denial/revocation letters, that the submission of a CAP addressing the issues that resulted in the denial or revocation of billing privileges will expedite the enrollment process and issue a faster determination.

The Medicare contractor, including the NSC, shall accept, for review, the submission of a CAP for denied or revoked billing privileges if the CAP is submitted within 30 days from the date of the notice. *All part B certified supplier CAP requests should be forwarded to CMS for processing at:*

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop C3-02-16
Baltimore, MD 21244-1850

The CAPs shall be submitted in the form of a letter and shall contain, at a minimum, verifiable evidence of provider or supplier compliance with enrollment requirements. The letter shall be signed and dated by the individual provider, the authorized or delegated official or a legal representative. Contractors may also create a standard CAP form to be sent out with their denial letters to easily identify it as a CAP when it is returned.

Contractors may accept a CAP by fax. If all the missing information originally requested is not received contractors should make one contact to the provider or supplier, *preferably via e-mail or fax,* to obtain the additional information before making a final determination. Contractor may use the model development letter, found in section 14 of this chapter, to request the information.

If a CAP for a denied application or revoked billing privileges is approved by a Medicare contractor, billing privileges can be issued. Contractors shall notify the applicant via letter that the enrollment has been approved. The effective date *of Medicare billing privileges* is based on the date the provider or supplier came into compliance with all Medicare requirements *or the receipt date of the application. For an approved CAP, contractors shall use the receipt date of the CAP request as the receipt date they enter in PECOS.*

For DMEPOS suppliers the effective date is the date it is awarded by the NSC. CMS' approval is required prior to restoring billing privileges.

The Medicare contractor shall process a CAP within 60 days. During this process, the contractor shall not toll the filing requirements associated with an appeal. However, the contractor can make a good cause determination in order to accept any appeal that has been submitted beyond the timely filing period.

NOTE: If a CAP and a reconsideration request (i.e., appeal request) are submitted concurrently, the Medicare contractor shall first process and make a determination on the CAP. The reconsideration request should then be processed by a Hearing Officer (HO) unrelated to the initial determination or CAP to ensure the applicant receives an independent review of their reconsideration. The Medicare contractor and the HO shall coordinate prior to acting on a CAP or reconsideration request to determine if the other party has received a request. If the CAP is accepted, the standard approval letter shall be sent to the provider or supplier acknowledging enrollment into Medicare and that their reconsideration request should be withdrawn. If the CAP is denied, the provider or supplier shall be notified by letter and may continue with the appeals process if it has filed a request for reconsideration or is preparing to submit such a request *and has not exceeded the timeframe to do so*. *Providers and suppliers may not appeal a corrective action plan decision.*

Reconsideration (formerly Contractor Hearing)

A *provider, supplier or DMEPOS supplier* that wishes to request a reconsideration must file its request, in writing, with the Medicare contractor within 60 days after the postmark of the notice to be considered timely filed. Medicare contractors shall extend the filing period an additional 5 days to allow for mail time. Reconsideration requests submitted on the 65th day of which falls on a weekend or holiday should still be considered timely filed and not rejected. The date the request is received by the Medicare contractor is treated as the date of filing. The request must be signed by the physician, non-physician practitioner, *a legal representative,* or any responsible authorized official within the entity. For DMEPOS suppliers, the request must be signed by the authorized representative, delegated official, owner or partner. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review.

Medicare contractor reconsiderations shall be conducted by a HO or senior staff having expertise in provider enrollment and who was independent from the initial decision to deny or revoke enrollment.

The NSC reconsiderations shall be conducted by a HO. *All part B certified supplier reconsiderations will be conducted by CMS and shall be forwarded to:*

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop C3-02-16
Baltimore, MD 21244-1850

Upon receipt of the reconsideration, the HO shall send a letter to the provider or supplier to acknowledge receipt of their request. In its acknowledgment letter, the HO shall advise the requesting party that the reconsideration will be conducted and a determination issued within 90 days from the date of the request. The HO shall include a copy of its acknowledgment letter in the reconsideration file.

If a timely request for a reconsideration is made, the HO, not involved in the original adverse determination, must hold an on-the-record reconsideration and issue a determination within 90 days from the date of the appeal request. The provider, supplier or the Medicare contractor may offer new evidence. It is the responsibility of the provider or supplier to show that its enrollment application was incorrectly denied or that its billing privileges were revoked erroneously.

In reviewing an initial enrollment decision or a revocation, the HO should limit the scope of its review to the Medicare contractor's reason for imposing a denial or revocation at the time it issued the action and whether the Medicare contractor made the correct decision (i.e., denial/revocation). Medicare contractors cannot introduce new denial or revocation reasons or change a denial or revocation reason listed in the initial determination during the reconsideration process. If a provider or supplier provides evidence that demonstrates or proves that they met or maintained compliance after the date of denial or revocation, the HO shall exclude this information from the scope of its review.

If a request for reconsideration is filed late, the HO shall make a finding of good cause before taking any other action on the appeal. The time limits may be extended if good cause for late filing is shown. Good cause may be found when the record clearly shows, or the party alleges and the record does not negate that the delay in filing was due to one of the following:

- Unusual or unavoidable circumstances, the nature of which demonstrate that the individual could not reasonably be expected to have been aware of the need to file timely; or

- Destruction by fire, or other damage, of the individual's records when the destruction was responsible for the delay in filing.

The HO shall issue a written decision within 90 days from the date of the request and forward the decision to the Medicare contractor and by mail to the provider, supplier or the authorized representative. The reconsideration letter shall include:

- The re-stated facts and findings, including the regulatory basis for the action as determined by the contractor in their initial determination;

- A summary of the documentation submitted by the prospective provider/supplier or the enrolled provider/supplier;

- *A* clear explanation of why the HO is upholding or overturning the denial or revocation action in sufficient detail for the provider or supplier to understand the nature of its deficiencies;

- *I*f applicable, the regulatory basis to support each reason or reasons for the denial or revocation;

- *A*n explanation of how the provider or supplier does not meet the enrollment criteria or requirements to enroll;

- *F*urther appeal rights, procedures for requesting an administrative law judge (ALJ) hearing, and the address to which the written appeal must be mailed; and

- *I*nformation the appellant must include with their appeal (name/legal business name, provider/supplier number (if applicable), their Internal Revenue Service TIN/EIN, and a copy of the reconsideration decision).

If an appeal for a denied application or revoked billing privileges is approved by a Medicare contractor, billing privileges can be issued. The effective date of Medicare billing privileges is based on the date the provider or supplier came into compliance with all Medicare requirements or the receipt date of the application being appealed. Contractors shall use the receipt date of the appeal as the receipt date they enter in PECOS.

A request for reconsideration may be withdrawn at any time prior to the mailing of the reconsideration decision either by the party that filed the appeal request or their authorized representative. The request for withdrawal must be in writing, signed, and filed with the Medicare contractor.

When the Medicare contractor receives a withdrawal request, it sends a letter to the provider or supplier acknowledging its receipt and advising that the reconsideration action will be terminated.

Medicare contractors shall maintain a report detailing the number of reconsideration requests they receive and their outcome (e.g., decision withheld, reversed, or further appeal requested or requests withdrawn). Medicare contractors are not required to submit this information to *CMS* but it must be provided upon request.

Administrative Law Judge (ALJ) Hearing

The CMS, a Medicare contractor, or a provider or supplier dissatisfied with a reconsidered determination is entitled to a hearing before an ALJ. The ALJ has delegated authority from the Secretary of the Department of Health and Human Services (DHHS) to exercise all duties, functions, and powers relating to holding hearings and rendering decisions. Such an appeal must be filed, in writing, within 60 days from receipt of the reconsideration decision. ALJ requests should be sent to:

Department of Health and Human Services
Departmental Appeals Board (DAB)
Civil Remedies Division, Mail Stop 6132
330 Independence Avenue, S.W.
Cohen Bldg, Room G-644
Washington, D.C. 20201
ATTN: CMS Enrollment Appeal

Failure to timely request an ALJ hearing is deemed a waiver of all rights to further administrative review.

Upon receipt of the request to file an ALJ hearing, an ALJ at the DAB will issue a letter by certified mail to the provider or supplier, CMS and the regional office of General Counsel (OGC) acknowledging receipt of an appeals request and detailing a scheduled pre-hearing conference. The OGC will assign an attorney that will represent CMS during the appeals process and who will also serve as the DAB point of contact. Neither CMS *n*or the Medicare contractor are required to participate in the pre-hearing conference but should coordinate among themselves and the OGC attorney prior to the pre-hearing to discuss any issues. The Medicare contractors shall work with and provide the OGC attorney with all necessary documentation. Any settlement proposals, as a result of the pre-hearing conference, will be addressed with CMS.

Departmental Appeals Board (DAB) Hearing

The CMS, a Medicare contractor, or a provider or supplier dissatisfied with the ALJ hearing decision may request Board review by the DAB. Such request must be filed within 60 days after the date of receipt of the ALJ's decision. Failure to timely request a review by the DAB is deemed a waiver of all rights to further administrative review.

The DAB will use the information in the case file established at the reconsideration level and any additional evidence introduced at the ALJ hearing to make its determination. The DAB may admit additional evidence into the record if the DAB considers it relevant and material to an issue before it. Before such evidence is admitted, notice is mailed to the parties stating that evidence will be received regarding specified issues. The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues. If additional information is presented orally to the DAB, then a transcript will be prepared and made available to any party upon request.

Judicial Review

A provider or supplier dissatisfied with a DAB decision has a right to seek judicial review by timely filing a civil action in a United States District Court. Such request shall be filed within 60 days from receipt of the notice of the DAB's decision.

B. Fiscal Intermediary

If a Medicare contractor reviews an initial enrollment application for a provider or certified supplier and finds that the application should be denied pursuant to 42 CFR §424.530, such as a facility's failure to meet one or more of the Federal or State requirements, the Medicare contractor shall deny/recommend denial to the regional office (RO) and notify the provider or certified supplier by letter *(see section 14 of this chapter)*. The denial letter shall contain:

- *A legal (i.e., regulatory) basis for each reason for the denial*;
- *A clear explanation of why the application is being denied, including the facts or evidence used by the contractor in making their determination*;
- *An explanation of why the provider or supplier does not meet the enrollment criteria or program requirement to enroll in the Medicare program;*
- *P*rocedures for submitting a corrective action plan (CAP); and
- *Complete and accurate information about the provider or supplier's further appeal rights*.

Similarly, when a Medicare contractor discovers that there is a basis for revoking a provider or certified supplier's billing privileges, such as the provider or certified supplier no longer meets one of the requirements for billing privileges, the Medicare contractor shall revoke billing privileges and notify the provider or certified supplier by letter with a copy to the State and the RO. The revocation letter must contain:

- *A legal (i.e., regulatory) basis for <u>each</u> reason for revocation*;
- *A clear explanation of why Medicare billing privileges are being revoked, including the facts or evidence used by the contractor in making their determination*;
- *An explanation of why the provider or supplier does not meet the enrollment criteria or program requirement to maintain enrollment in the Medicare program;*
- *T*he effective date of the revocation (30 days from the date the notice is mailed. A revocation based on a Federal exclusion or debarment is effective with the date of the exclusion or debarment. The effective date of a license suspension/revocation is effective with the date of the suspension/revocation);
- *P*rocedures for submitting a CAP; and
- *Complete and accurate information about the provider or supplier's further appeal rights.*

Corrective Action Plan (CAP)

A CAP is the process that gives the provider or certified supplier an opportunity to correct the deficiencies (if possible) that resulted in the denial or revocation of billing privileges. The CAP should provide evidence that the provider or certified supplier is in compliance with Medicare requirements.

The Medicare contractors shall emphasize to the providers and suppliers, through denial/revocation letters, that the submission of a CAP addressing the issues that resulted in the denial or revocation of billing privileges will expedite the enrollment process and issue a faster determination.

*T*he submission of a CAP for denied or revoked billing privileges *must be* submitted within 30 days from the date of the notice. *The* CAP shall contain, at a minimum, verifiable evidence of the provider or certified supplier's compliance with enrollment requirements. *CAP requests should be sent to:*

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop C3-02-16
Baltimore, MD 21244-1850

If a CAP for a denied application or revoked billing privileges is approved by the *CMS*, billing privileges can be issued. The effective date is based on the date the provider or certified supplier came into compliance with all Medicare requirements. That is, once the provider or certified supplier has passed the state survey and been issued a certification date.

CAP requests will be processed within 60 days. During this process, the CMS will not toll the filing requirements associated with an appeal. However, the CMS can make a good cause determination in order to accept any appeal that has been submitted beyond the timely filing period.

Reconsideration

A provider or certified supplier that wishes to request a reconsideration must file its request, in writing, with the *CMS* within 60 days after the postmark of the notice to be considered timely filed. *The request for reconsideration should be sent to:*

Centers for Medicare & Medicaid Services
Division of Provider & Supplier Enrollment
7500 Security Blvd.
Mailstop: C3-02-16
Baltimore, MD 21244-1850

The date the request is received by the *CMS* is treated as the date of filing. The request may be signed by the authorized official within the entity. Failure to timely request a reconsideration is deemed a waiver of all rights to further administrative review.

If a timely request for a reconsideration is made, *the CMS will* hold an on-the-record reconsideration and issue a determination within 90 days from the date of the appeal request. The provider, certified supplier or the Medicare contractor may offer new evidence. It is the responsibility of the provider or certified supplier to show that its enrollment application was incorrectly denied or that its billing privileges were revoked erroneously.

In reviewing an initial enrollment decision or a revocation, the *CMS will* limit the scope of its review to the Medicare contractor/RO's initial reason for imposing a denial or revocation at the time that it issued the action and whether the Medicare contractor/ RO made the correct decision (i.e., denial/revocation). The Medicare contractor/ RO cannot introduce new denial or revocation reasons or change a denial or revocation reason listed in the initial determination during the reconsideration process. If a provider or certified supplier provides evidence that demonstrates or proves that they met or maintained compliance, after the date of denial or revocation, the *CMS will* exclude this information from the scope of its review.

If a reconsideration request is filed late, the *CMS will* make a finding of good cause before taking any other action on the appeal. These time limits may be extended if good cause for late filing is shown. Good cause may be found when the record clearly shows, or the party alleges and the record does not negate that the delay in filing was due to one of the following:

- Unusual or unavoidable circumstances, the nature of which demonstrate that the individual could not reasonably be expected to have been aware of the need to file timely; or

- Destruction by fire, or other damage, of the individual's records when the destruction was responsible for the delay in filing.

The *CMS will* issue a written decision within 90 days from the date of the request and forwards the decision by certified mail to the Medicare contractor, the provider, certified supplier or the authorized representative. The reconsideration letter shall include:

- *T*he re-stated facts and findings, including regulatory basis for the action as, determined by the Medicare contractor/ RO in their initial determination;

- A summary of the documentation submitted by the prospective provider/supplier or the enrolled provider/supplier;

- *A* clear explanation of why the *CMS* is upholding or overturning the denial or revocation action in sufficient detail for the provider or certified supplier to understand the nature of its deficiencies;

- *I*f applicable, the regulatory basis to support each reason or reasons for the denial or revocation;

- *A*n explanation of how the provider or certified supplier does not meet the enrollment criteria or requirements to enroll;

- *F*urther appeal rights, procedures for requesting an ALJ hearing, and the address to which the written appeal must be mailed; and

- *I*nformation the appellant must include with their appeal (name/legal business name, provider/supplier number (if applicable), their Internal Revenue Service TIN/EIN, and a copy of the reconsideration decision).

A request for reconsideration may be withdrawn at any time prior to the mailing of the reconsideration decision either by the party that filed the appeal request or their authorized representative. The request for withdrawal must be in writing, signed, and filed with the *CMS.*

When the *CMS* receives a withdrawal request, it sends a letter to the provider or certified supplier acknowledging its receipt and advising that the reconsideration action will be terminated.

ALJ Hearing

The CMS, a Medicare contractor, or a provider or certified supplier dissatisfied with a reconsidered determination is entitled to a hearing before the ALJ. The ALJ has delegated authority from the Secretary of the Department of Health and Human Services (DHHS) to exercise all duties, functions, and powers relating to holding hearings and rendering decisions. Such an appeal must be filed, in writing, within 60 days from the receipt of the reconsideration decision. ALJ requests should be sent to:

Department of Health and Human Services
Departmental Appeals Board (DAB)
Civil Remedies Division, Mail Stop 6132
330 Independence Avenue, S.W.
Cohen Bldg, Room G-644
Washington, D.C. 20201
ATTN: CMS Enrollment Appeal

Failure to timely request the ALJ hearing is deemed a waiver of all rights to further administrative review.

Upon receipt of the request to file an ALJ hearing, an ALJ at the Departmental Appeals Board (DAB) will issue a letter by certified mail to the provider or certified supplier, CMS, the RO and the RO of General Counsel (OGC) acknowledging receipt of an appeals request and detailing a scheduled prehearing conference. The OGC will assign an attorney that will represent CMS during the appeal's process and who will also serve as the DAB point of contact. Neither CMS, the RO, *n*or the Medicare contractor are required to participate in the pre-hearing conference but should coordinate among themselves and the OGC attorney prior to the pre-hearing to discuss any issues. The Medicare contractor shall work with and provide the OGC attorney with all necessary documentation. Any settlement proposals, as a result of the pre-hearing conference, will be addressed with CMS.

DAB Hearing

The CMS, a Medicare contractor, or a provider or certified supplier dissatisfied with the ALJ hearing decision may request Board review by the DAB. Such request must be filed within 60 days after the date of receipt of the ALJ's decision. Failure to timely request a review by the DAB is deemed a waiver of all rights to further administrative review.

The DAB will use the information in the case file established at the reconsideration level and any additional evidence introduced at the ALJ hearing to make its determination. The DAB may admit additional evidence into the record if the DAB considers it relevant and material to an issue before it. Before such evidence is admitted, notice is mailed to the parties stating that evidence will be received regarding specified issues. The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues. If additional information is presented orally to the DAB then a transcript will be prepared and made available to any party upon request.

Judicial Review

A provider or certified supplier dissatisfied with DAB review has a right to seek judicial review by timely filing a civil action in a United States District Court. Such request shall be filed within 60 days from receipt of the notice of the DAB's decision.