

# The RAP Sheet

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—from a declaration of the American Bar Association

## Understanding Medicare's Physician Supervision Rules

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There was a time when Medicare's varied and complex physician supervision rules were beyond the purview of most healthcare attorneys. Instead, healthcare attorneys would structure the transaction, analyze the self-referral and kickback concerns, obtain any necessary authorizations to deliver the service and, if healthcare attorneys were lucky, ultimately close the transaction, leaving the day-to-day operational aspects of delivery of the service to other more clinically inclined folks. Unfortunately, our days of innocence are long behind us. For more than a decade now, not only have healthcare attorneys had to focus on the operational details of whether a particular service is structured in a manner to facilitate adequate physician supervision to bill Medicare, but healthcare attorneys have had to do so in a landscape of shifting physician supervision rules, interpretations, clarifications, and restatements.

The Centers for Medicare & Medicaid Services (CMS) generally takes the approach that the provision of a service without the requisite level of physician supervision amounts to the delivery of care that is not "reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member."<sup>1</sup> In other words, such services are excluded from Medicare coverage under Section 1862(a)(1)(A) of the Social Security Act.<sup>2</sup> Accordingly, in order to ensure payment for services furnished to Medicare beneficiaries, it is essential that the underlying service complies with the applicable physician supervision standard.

However, the difficulty arises in determining the applicable physician supervision standard. In an ideal world, we would be able to examine the service itself and conclusively determine the level of physician supervision required. However, under the various Medicare Part B physician supervision rules, it is also necessary to determine where the service is being furnished and, ultimately, the statutory basis for payment. For instance, although the provision of an "incident to" service or supply in a physician's office and a hospital outpatient department both require "direct supervision," CMS defines direct supervision in a slightly different way in each setting. Further, the particular setting in which a service is furnished may require one level of supervision but the applicable Medicare coverage criteria for the service may require a different, often higher level of physician supervision. This article will attempt

## Tips for RAC Appeal Strategies

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Recovery Audit Contractor (RAC) appeal strategies run the gamut. Provider approaches range from highly aggressive—challenging everything prior to recoupment—to the polar opposite—allowing recoupment and appealing virtually nothing. With the exception of a few outliers, most providers will and should fall somewhere in between. This article summarizes the RAC appeal process and discusses tips for a provider's RAC appeal strategy.

### Background: Review of the RAC Appeals Process

The Centers for Medicare & Medicaid Services (CMS) is in the process of implementing the permanent RAC program under the Tax Relief and Health Care Act of 2006,<sup>1</sup> following a three-year RAC demonstration project authorized by the Medicare Modernization Act.<sup>2</sup> RAC appeals follow the uniform Medicare Part A and Part B appeals process, summarized in the sections below.<sup>3</sup>

RACs are highly motivated to discover overpayments because they are paid as a percentage of recovery. During the demonstration project, the RACs were entitled to retain their contingency fees for any determinations sustained through the first level of appeal. Even if the provider ultimately prevailed and a determination was overturned at a higher level of appeal, the RACs did not have to pay back their contingency fees. In the permanent program, RACs must now refund any contingency fees they receive if an overpayment determination is overturned at any level in the appeals process.

RACs mail the overpayment determination to the provider at the address it has on file. It is important to verify that the RAC in your region has the correct contact person and address. If RAC communications are received by anyone else at the organization, correct this information immediately to avoid the potential for missed deadlines, with concomitant repercussions including automatic recoupment and loss of appeal rights when requested records are not timely provided.

#### **Initial Determination—RAC Demand Letter**

The demand letter from the RAC will include, among other information, the reason for conducting the review, the basis for the alleged overpayment, and a list of claims with recoupment amounts and reasons for noncoverage. It will also set forth the right to submit a rebuttal prior to recoupment; Medicare's right to recoup and charge interest; and the provider's payment options, appeal rights, and applicable timelines.

#### **Rebuttal**

The provider can submit a rebuttal in writing within fifteen days of the date on the demand letter or can choose to appeal without a rebuttal. Rebuttals go to the CMS claim processing contractor—the Medicare Administrative Contractor, the fiscal intermediary,



or the carrier, as applicable (Medicare Contractor). A provider may also initiate a discussion with the RAC. Rebuttals and discussion periods fall outside the formal appeals process and do not extend the deadlines for appeal or stop recoupment.

#### **Redetermination<sup>4</sup>**

Requests for redetermination (first level of appeal) must be made to the Medicare Contractor 120 days after the initial determination. There is a thirty-day deadline on filing the redetermination request if the provider wants to prevent recoupment, which otherwise will start on the forty-first day. There is no amount in controversy requirement. The Medicare Contractor will issue a Medicare Redetermination Notice after its review.

#### **Reconsideration<sup>5</sup>**

If redetermination is not successful and a provider elects to appeal, the request for reconsideration (second level of appeal) must be made to the Qualified Independent Contractor (QIC) in writing 180 calendar days after the redetermination decision. There is a sixty-day deadline on filing the reconsideration request if the provider wants to prevent recoupment, which otherwise will start on the seventy-sixth day. If the QIC fails to send a determination within sixty days, a letter will be issued notifying the provider of its right to escalate the appeal to the next level within five days or wait (indefinitely) for the QIC's determination. There

is no amount in controversy requirement. Significantly, requests for reconsideration now need to include all the evidence that the provider plans to use for all subsequent appeals, including those before the Administrative Law Judge (ALJ) and federal courts. Additional evidence will not be considered absent a determination of good cause.

### ***ALJ Hearing<sup>6</sup>***

Requests for a hearing before an ALJ with the Office of Medicare Hearings and Appeals must be filed in writing sixty days following the reconsideration decision. At this and subsequent stages of appeal, CMS is authorized to recoup the alleged overpayment. There is an amount in controversy requirement that increases annually, currently \$130 for 2010. The ALJ will determine whether to conduct an actual hearing or decide the merits of the appeal on the written record. No new evidence other than oral testimony can be submitted unless allowed by the ALJ. If the ALJ does not issue a decision within ninety days, the provider can request that the appeal be escalated to the next level, though this is not particularly advantageous in most cases.

### ***Medicare Appeals Council (MAC) Review<sup>7</sup>***

MAC review requests must be filed in writing sixty days following receipt of the ALJ's decision. At this and subsequent stages of appeal, CMS is authorized to recoup the alleged overpayment. There is no amount in controversy requirement.

### ***Federal District Court Judicial Review<sup>8</sup>***

Appeals to the federal district court must be filed sixty days following receipt of MAC decision. At this and subsequent stages of appeal, CMS is authorized to recoup the alleged overpayment. There is an amount in controversy requirement that increases annually, currently \$1260 for 2010. The findings of fact sustained through the MAC review are deemed conclusive if supported by substantial evidence.

## **Initial Steps in Developing a Workable RAC Appeal Strategy**

A workable RAC appeals strategy involves prior planning and a concerted, coordinated approach involving representatives across the organization. Providers that use an assigned team to plan and execute the process will find themselves in a much better position to meet the challenges of RAC appeals. Standardizing the process and tracking deadlines are also important to help ensure efficiency.

### ***Assemble an Appeals Team***

A successful appeals strategy starts with the right team. Responding to the RACs and maximizing the potential for successful appeals will be a challenge, regardless of the provider's size. Small providers may find it easier to coordinate communications than larger providers, but unless concerted attention is given in advance to working out a coordinated RAC response and appeals process, providers will find themselves scrambling to react using already limited resources.

The cornerstone of workable RAC appeals is a good team coordinator. One of the first tasks of the team coordinator will be to

assemble the rest of the team. Typically, a RAC response team would include individuals from: financial services; billing and coding; compliance; legal; case management; utilization review; medical records; and with a database manager to keep track of the status of claims, document the receipt of key correspondence, and monitor due dates. Having the medical records department represented on the team helps ensure timely responses, not only to initial records requests from the RACs, but also when locating and assembling information during the appeals process. It is very important to designate a point of contact in the medical records department and make sure that they understand what will be required during the process so that they can develop their own workable department protocols for handling the RAC appeals.

Additional personnel likely will be needed to make sure all the bases are covered. Who will round out the team will depend on the organization and infrastructure of the particular provider.

More claims were denied during the RAC demonstration program based on alleged failures to meet Medicare medical necessity criteria than on any other basis.<sup>9</sup> It is imperative to line up clinical personnel to assist with review of this category of claims being considered for appeal. Designated clinical personnel—physicians, nurses, therapists, and others, as applicable depending on the provider—should be prepared to contribute their time when clinical input is needed, such as with medical necessity analyses and certain types of coding questions. In addition, treating physicians should understand in advance that they will likely need to be called upon to help with the process.

In many organizations, compliance personnel function as team leaders initially, since compliance departments have often spearheaded the provider's RAC readiness efforts, pre-RAC self assessments, and similar activities. Legal involvement is also very important, particularly given the requirement that the record be fully developed by the time of the second level of formal appeal (i.e., the reconsideration request to the QIC). Legal input will help to ensure that the documentation submitted on appeal contains appropriate legal arguments and defenses, and that there is sufficient evidence to support the appeal. On balance, the substance and intensity of the legal arguments will tend to increase with the level of appeal.

### ***Standardize the Appeals Process***

Develop procedures to standardize the appeals process to the extent practicable. Many providers have already planned how they will handle medical records requests. Unless they were involved in the demonstration project, however, fewer have attempted to put together a standardized appeals process. Appeal components amenable to standardization include the basic content of cover letters and tables summarizing clinical information, as well as standard procedures to track determinations, deadlines, provider submissions, claims appeal status, and overpayment recoupments.

It is important to effectively advocate the provider's position using a cover letter or position paper outlining supporting facts, law, documents, and applicable defenses combined with summary tables that function to organize materials, communicate claim-

specific arguments, and tie together information from medical records and other sources. To streamline the process, consider using templates for cover letters and summary tables whenever possible. These will vary with the appeal level because the focus is somewhat different at each appeal level. It is useful to develop templates with blanks for clinical information and arguments to be inserted. Templates can be particularly important to facilitate a consistent approach for providers with multiple facilities.

## **Track Deadlines and Submissions**

The worst excuse for not filing an appeal is a missed deadline. In fact, even before the formal appeals process is initiated, providers need to pay close attention to medical records request deadlines because the RACs are authorized to make an automatic overpayment determination when requested medical records are not received within forty-five days.<sup>10</sup> It is important to use a system for tracking the determination letters and pay attention to the dates received and deadlines to appeal. Some providers develop these themselves, while others purchase a commercially available system.

Provider appeals are paper document submissions, not electronic filings. Accordingly, all or part of an appeal record can and have been lost on the receiving end. To help avoid this, plan to send the appeal documents using some form of standard process that includes a mail tracking mechanism. In some situations, affidavits may ultimately need to be offered up as proof that the documents were sent. Consecutive numbering of the documents and making copies of everything sent add another layer of protection against lost documents at the receiving end. Unfortunately, with the current system, if documents are claimed to be lost, even these efforts may not be enough to prevent a dismissal on the basis that documentation was never received.

## **Responding to a RAC Demand Letter**

Providers have several options to consider after receiving a demand letter from the RAC, including:

- (1) Do not rebut or appeal and allow recoupment, pay the amount indicated, or request a payment plan;
- (2) Submit a rebuttal (with or without initiating a discussion with the RAC);
- (3) Initiate an appeal by submitting a redetermination request in time to halt recoupment (thirty days from date of the demand letter, with recoupment authorized on day forty-one); and
- (4) Initiate an appeal by submitting a redetermination request after recoupment but prior to the 120-day deadline to appeal.

There are strategic reasons for choosing one path over another, ultimately requiring the provider to conduct what is essentially a complex, multifactorial cost-benefit analysis. Among the factors considered are the likelihood of reversal on appeal, the total dollar amount involved, and the number of similar claims. If a provider decides not to pursue a rebuttal or appeal, requesting a payment plan is an alternative to full payment or recoupment.

Bear in mind that interest will accrue (currently at 11.375%) during the appeals process from the date of the initial demand letter. The loser pays the interest. Depending on the provider's

financial ability to allow recoupment, this is actually not a bad return on investment for a provider who ultimately prevails. On the other hand, it may make more sense for some providers to hold onto the money despite the risk of having to pay interest at the end of the day. Although providers may write a check for the alleged overpayment in lieu of allowing recoupment, if this path is chosen, they will not be entitled to interest if they prevail.

The rebuttal and discussion process is considered by some providers to be a waste of resources because reversals at that level are rare. Instead, providers may elect to appeal as the initial push-back. Nevertheless, there may be circumstances that warrant a rebuttal or discussion attempt, such as technical errors on the part of the RAC in making its determination, in which new information is submitted to support a claim or when a provider submits additional information to support a diagnosis-related group (DRG) for denials based on DRG ICD-9-CM coding.<sup>11</sup> Some arguments are not likely to result in reversal at this stage, including those based on medical necessity.

If the provider decides to appeal and files a request for redetermination, the Medicare Contractor's decision should issue within sixty days. New evidence may be submitted during the decision period. This means that if a provider is running up against the deadline to request redetermination and has not yet assembled all the evidence for the appeal, the best course is to go ahead and file the appeal, laying out the issues and including the supporting evidence obtained to date. Additional evidence can then be submitted and will delay the Medicare Contractor's response up to an additional fourteen days after each submission. Although some providers may use this as a way to obtain the equivalent of a series of extensions, they run the risk that the decision will issue prior to all the evidence being submitted. In this case, information pertinent to the determination may not be before the Medicare Carrier and will have to wait until the next appeal level.

## **Strategies for All Levels of Appeal**

Below are some tips and strategies for all levels of appeal. There is no single approach, and no simple winning strategy. Even with a streamlined process, that uses templates and tracking mechanisms, each set of claims being appealed will require individualized attention.

### **Gear Content to the Reviewer**

All information should be presented in a manner that is easy to understand, using language that does not assume the reader has any knowledge of medicine, coding, coverage determinations, CMS manuals, or the law. Clearly cross reference the materials, using tabs and page numbers whenever possible. Identify the source of the records, if it is not clear, and the applicable caregivers. If the medical records are difficult to read, include a typed transcription of the pertinent sections.

At each appeal level, consider focusing the most attention on the content and arguments most likely to sway that particular category of reviewer. While many arguments may be included in the mix—and at the second level of appeal *all* evidence must be submitted to the QIC—certain arguments simply will not be

as persuasive if they are the primary focus. For example, at the reconsideration level, the QIC uses medical review panels for medical necessity determinations. If the services were provided by a physician, the QIC will include a physician reviewer. Bear this in mind when putting the arguments together.

While the factual evidence should be submitted in its entirety as of the reconsideration (QIC) level at the latest, the decision regarding when to start including legal arguments is handled differently by different providers. Some include detailed legal arguments from the outset. Others use a compromise approach that involves referencing the applicable legal arguments in the first appeal level, and then expanding out the legal content as additional appeals are submitted. Regardless of how this is handled in the early stages, submissions at the higher levels of appeal—starting with the ALJ—should include fully developed legal arguments.

### **Documentation Sources: Think Outside the Box**

Depending on the basis for the denials, appeal documentation will typically include a detailed cover letter, tables summarizing the evidence, portions from patient medical records, and sections from date-matched coding and coverage sources (e.g., Local Coverage Determinations (LCDs), National Coverage Determinations (NCDs), medical journals, U.S. Food and Drug Administration (FDA) labeling, and published coding criteria). While it is not necessary to use the official form provided on the CMS webpage, providers may find it useful as a double-check on the submitted information.<sup>12</sup> Certain basic claim-specific information should be included, along with the supporting documentation:

- Beneficiary name;
- Medicare Health Insurance Claim (HIC) number;
- Specific service and/or item(s) for which a redetermination is being requested;
- Specific date(s) of service; and
- Name and signature of the party or the representative of the party

At the reconsideration level, the name of the Medicare Contractor that rendered the redetermination decision should also be included.

While NCDs and CMS rulings are binding at every level, LCDs and CMS manuals and instructions are not. Although LCDs set forth the circumstances under which a service is generally considered to be “reasonable and necessary,” it is important to know that Medicare Contractors and RACs now have “the authority to apply an exception to the clinical reasonable and necessary requirements of a LCD in rare and unusual circumstances.”<sup>13</sup> Therefore, even in situations where it appears that an LCD contradicts the basis for an appeal, the medical literature should be closely examined. If an exception to the LCD would be consistent with the medical literature, the pertinent articles should be cited and explained in context of the particular medical records.



Other documents can be included in the appeal to augment information in the medical records. For example, consider submitting utilization management reviews, information on preauthorizations from the Medicare Carrier itself, and affidavits from caregivers and possibly even the beneficiaries. For denials based on a lack of original documentation, include additional supporting documentation as evidence that the services were provided and were medically necessary, such as schedules and affidavits from the treating physician. If FDA drug-labeling is relevant, this can be submitted but bear in mind that FDA’s “safe and effective” standard does not necessarily directly translate to the pharmaceutical being reasonable and necessary for a particular patient. The burden will still be on the provider to prove the latter. Reference can be made to communications from the intermediary or carrier either to the individual provider or the provider community, including provider inquiries and preauthorizations. Supporting evidence could also include previous audits allowing payment, prior successful appeals, peer-reviewed scientific articles, and established medical publications.

### **Develop the Record Early and Keep the End Game in Sight**

The record on appeal should be fully developed at the time the request for reconsideration is submitted to the QIC. Reconsideration is the second level of formal appeal. A provider that neglects to pull together all the supporting documentation and provide copies along with the reconsideration request will be precluded from presenting the documentation at the later appeal stages, unless the applicable reviewer determines good cause exists

to allow additional submissions. This is an important time to consider having attorneys review the documents prior to submission, at least until the process for particular categories of claims is fully developed. The burden will be on the provider, not the government, to establish that the denied claims should be paid by Medicare. Accordingly, at this stage the appeal documents should not be limited to the specific reasons given for denial.

## Legal Arguments

Applicable legal arguments are an important cornerstone to successful RAC appeals. Providers may want to consider referencing applicable legal arguments and defenses at all appeal levels. This can provide additional ammunition for consideration in the early stages of appeal. As the appeal level increases, so should the extent of the legal argument.

### Treating Physician Rule

The notion that a patient's physician is in the best position to determine what is medically necessary has given rise to the "treating physician rule," a doctrine adopted by some courts that provides a degree of deference to medical necessity determinations by the treating physician unless contradicted by substantial evidence.<sup>14</sup> Even with contradictory evidence, some weight may still be accorded. This is an important argument in the arsenal for medical necessity appeals.

### Provider Without Fault<sup>15</sup>

When an overpayment is identified, as provided in Section 1870(b) of the Social Security Act, payment will be allowed if the provider was without fault. As set forth in the CMS Medicare Financial Management Manual, a provider is "without fault" if it exercised reasonable care in billing for services and accepting payment. In this context, reasonable care involves complying with all pertinent regulations, fully disclosing all material facts, and, based on the available information, having a reasonable basis to assume the payment was correct. Social Security Act Section 1870(b) effectively presumes no fault on a provider's part where an overpayment determination is made "subsequent to the third year following the year in which notice was sent to such individual that such amount had been paid" in the absence of evidence to the contrary. This argument was made by many providers in appealing overpayment determinations in the demonstration project, which had a four-year look-back period.

### Waiver of Liability Defense<sup>16</sup>

The "waiver of liability" defense applies to determinations that services were not medically necessary. The defense originates from the Social Security Act, which provides that payment may be made if the provider did not know and could not reasonably have been expected to know that payment would not be made. To demonstrate this, reference should be made to any applicable national coverage determinations, local coverage determinations, and communications from the intermediary or carrier either to the individual provider or the provider community, including provider inquiries and preauthorizations. Supporting evidence could also include previous audits allowing payment, prior

successful appeals, peer-reviewed scientific articles, and established medical publications.

### Failure to Follow the Reopening Timeframes<sup>17</sup>

This legal argument has eroded somewhat after a MAC decision finding that CMS lacked jurisdiction over reopening challenges. Although the regulations also provide that a contractor's, QIC's, ALJ's, or MAC's decision on whether to "reopen" is final and not subject to appeal, providers can still attempt to use the argument to challenge the decision on whether to "revise" the claims following reopening.

The regulations provide, in pertinent part, that a contractor may reopen and revise its initial determination or redetermination on its own motion:

- (1) Within one year from the date of the initial determination or redetermination for any reason;
- (2) Within four years from the date of the initial determination or redetermination for good cause; or
- (3) At any time if there exists reliable evidence that the initial determination was procured by fraud or similar fault.

Good cause may be established when:

- (1) There is new and material evidence that:
  - (a) Was not available or known at the time of the determination or decision; and
  - (b) May result in a different conclusion; or
- (2) The evidence that was considered in making the determination or decision clearly shows on its face that an obvious error was made at the time of the determination or decision.<sup>18</sup>

### Due Process

RAC review and recoupment processes raise substantive constitutional due process issues. Potential arguments include, among others: (1) RACs have a direct financial incentive to deny claims; (2) the standards on which overpayment determinations are based are vague; and (3) RAC methodologies, to the extent claimed to be "proprietary," have not been made available to providers.

### Statistics Challenges

RACs must follow the guidelines for conducting statistical extrapolations and have to get permission before using extrapolation methodology.<sup>19</sup> While the decision to use statistical sampling and extrapolation is not typically appealable, if the RACs do not follow all the guidelines, this could potentially form the basis of an appeal. As statistics begin to be used in RAC reviews, it will be vital to start closely examining any recoupments based on statistical extrapolation. However small, any flaw in the process can substantially magnify error and drastically inflate the amount of overpayment. This is one area where it can definitely pay to use an expert statistician to challenge the results as being invalid. One potential barrier to a successful defense is that it may be difficult to obtain the actual underlying statistical analyses used by the RACs. A variety of approaches may need to be tried as extrapolation methods are rolled out and hopefully a standard

mechanism for obtaining the analytical methodologies from the RACs can be developed. At things currently stand, Freedom of Information Act requests can be attempted, but these take a long time and may meet resistance; requests directly to the RAC or Medicare contractor may yield more information but, again, there are currently no guarantees.

## Conclusion

RACs are highly motivated to discover overpayments because they are paid as a percentage of recovery. Responding to the RACs and maximizing the potential for successful appeals will be a challenge, regardless of the provider's size. Assembling the right team is key to a robust appeal strategy. The team will need to be prepared to support provider decision-making on significant strategic issues, including the determination to appeal, whether to allow recoupment, the level of resources that will be devoted to the process and, ultimately, whether continue the appeals process. The team will also need to be prepared to help determine the arguments to be made and the evidence to be included. Providers will want to look for ways to streamline the appeals process to maximize efficiency and to make sure there is an effective tracking mechanism in place for the process. As appeals are undertaken, providers should make sure to gear their arguments to the particular reviewer, think outside the box in terms of locating and including supporting evidence, develop the record early, and always keep the end game in sight.

- 1 Tax Relief and Health Care Act of 2006, Section 302, P.L. 109-432.
- 2 Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Section 306, P.L. 108-173.
- 3 42 C.F.R. § 405.900 *et. seq.* (2009). See also *The Medicare Appeals Process*, CMS ICN006562 (January 2010) at [www.cms.hhs.gov/MLNProducts/downloads/medicareAppealsProcess.pdf](http://www.cms.hhs.gov/MLNProducts/downloads/medicareAppealsProcess.pdf).
- 4 42 C.F.R. §§ 405.940-958 (2009).
- 5 42 C.F.R. §§ 405.960-978 (2009).
- 6 42 C.F.R. §§ 405.1000-1054 (2009).
- 7 42 C.F.R. §§ 405.1100-1134 (2009).
- 8 42 C.F.R. § 405.1136 (2009).
- 9 Centers for Medicare & Medicaid Services, *The Medicare Recovery Audit Contractor (RAC) Program: An Evaluation of the 3-year Demonstration*, p. 19 (June 2008).
- 10 Centers for Medicare & Medicaid Services, *Statement of Work for the Recovery Audit Contractor Program*, p. 13.
- 11 See Orsini, John A: *Surviving the RAC: How to Take Back the Take-Backs*, Healthcare Financial Management (May 2008).
- 12 See Centers for Medicare & Medicaid Services Forms CMS-20027 (Redetermination) and CMS-20023 (Reconsideration) at [www.cms.hhs.gov/CMSForms/CMSForms/list.asp#TopOfPage](http://www.cms.hhs.gov/CMSForms/CMSForms/list.asp#TopOfPage).
- 13 Centers for Medicare & Medicaid Services Change Request 6586.
- 14 See also Centers for Medicare and Medicaid Services CMS Ruling 93-1 (treating physician opinion as evidence for Part A claims, but not presumptive evidence).
- 15 42 U.S.C. § 1395gg; Medicare Financial Management Manual (CMS Pub. 100-06), Chapter 3.
- 16 42 U.S.C. §§ 1395pp and 1395gg.
- 17 42 C.F.R. § 405.980(b) (2009).
- 18 42 C.F.R. § 405.986 (2009).
- 19 Centers for Medicare & Medicaid Services *Medicare Program Integrity Manual* (CMS Pub. 100-08) Chapter 3 § 3.10.

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