How to Win Payment for Radiation Oncology Claims Denied by Medicare
&
How to Use Pre-Hearing Briefs at the ALJ Level of Appeal

I. Why you should you read this white paper and what you should know about Medicare's "medically reasonable and necessary" standard.

No matter how experienced you are and no matter how much you think you know about this topic, you will learn at least one thing you will immediately adopt and apply to your Medicare appeals.

To make this easier to understand and follow, the questions and problems are presented as they naturally arise during the appeals process, along with the answers to those questions and problems. However, you will get much more out of this article if you read "*The Medicare Appeals Process: Five Levels to Protect Providers, Physicians and Other Suppliers"* publication first.

Where can you find a good overview of the Medicare appeals process?

The Medicare Appeals Process: Five Levels to Protect Providers, Physicians and Other Suppliers publication has been updated and is available as a downloadable PDF file. To view the PDF file, visit http://www.cms.hhs.gov/MLNProducts/downloads/MedicareAppealsProcess.pdf.

Which radiation oncology claims should be appealed?

Every Medicare-denied radiation oncology claim should be appealed for two reasons. First, you deserve to be paid for the radiation oncology services you provide and second, almost without exception every radiation oncology claim can be won at the Administrative Law Judge (ALJ) level of appeal. But here is the **caveat**: There are no shortcuts. You have to put in the necessary time and effort and you have to follow all of the rules through the redetermination, reconsideration, and ALJ hearing levels of appeal.

What is the single most important thing you can do to make the ALJ hearing come out in your favor?

You must take advantage of the opportunity to submit a pre-hearing brief to the Administrative Law Judge. That brief will allow you to "frame the issues" raised by the carrier and the QIC and will allow you to present the Judge with your roadmap of the dispute. You will always, always present your strongest arguments first in the pre-hearing brief. You will also embrace and neutralize the denial reasons offered by the carrier and the QIC, because ignoring those arguments will be fatal. By presenting the Judge with

the clear and concise reasons why you should win, and by explaining why the denial reasons are wrong, you can start the hearing with the Judge leaning way over in your favor.

Why is Medicare the "gold standard" for all radiation oncology claims?

Radiation oncology is a "Medicare" subspecialty. Most cancers occur in the "Medicare" age group and this is especially true for lung and prostate cancer.

Because Medicare sets the industry standard, all of the for-profit insurance companies give significant weight to Medicare guidelines. In the event of arbitration with a for-profit insurance company, the arbitrator will also give great weight to CMS/Medicare radiation oncology "coverage" standards.

Why will you be receiving more Medicare denials and why will the ALJ hearings be more difficult to fight and win?

Money. The Federal government is trying to save money by paying you less. And radiation therapy claims are "big ticket" items. So radiation oncology is squarely in the cross hairs of CMS.

In the "good old days" there were ALJ offices in every major city in the country, the ALJs tried to "do the right thing", and the ALJ made his/her decision based on the doctor's presentation and the patient's medical record. Now, the Medicare rules will not allow an ALJ to admit any "new" evidence (e.g. evidence not submitted at or before the QIC determination) for the ALJ hearing without a showing of "good cause"; the ALJ is not allowed to rule in your favor on the basis of a finding that the applicable LCD is in error; and the doctor has the burden of proving the QIC denial rationale is wrong by a "preponderance of the evidence."

When and why did this change? The new ALJ hearing rules were instituted in March of 2005. The old rules were changed because the doctors were winning too many hearings and, as a result, too much money.

What are the reasons offered by the Medicare carriers to justify denial of payment for radiation oncology services?

The most common reason for denial of payment for radiation oncology services is: "According to the applicable LCD, the radiation oncology services you provided are not medically reasonable and necessary for the patient's problem."

What does the phrase "not medically reasonable or necessary" mean?

This is a Medicare 'term of art' that does not mean what it sounds like. The phrase actually means the service in question is not allowed because there is at least one CMS, Medicare, or carrier rule that prohibits payment for the service. A medical service may be perfectly reasonable and necessary in the ordinary use of the phrase but will not be paid, for example, because of the place of service, because of the frequency of the service, because the apparent wrong subspecialty has provided the service,

because an incorrect diagnosis code has been linked to the service, or because a carrier has reached an incorrect conclusion regarding the requirements for payment of the service.

The phrase "medically reasonable and necessary" is part of section 1862(a)(1)(A) of the Social Security Act (the "Act"):

> Sec. 1862. [42 U.S.C. 1395y] (a) Notwithstanding any other provision of this title, **no payment may be made** under part A or part B **for** any expenses incurred for items or **services**—
>
> (1)(A) **which**, except for items and services described in a succeeding subparagraph, **are not reasonable and necessary for the diagnosis or treatment of illness** or injury or to improve the functioning of a malformed body member. Emphasis added.

The elements of the phrase "medically reasonable and necessary" are more specifically detailed in the Medicare Program Integrity Manual [Chapter 13 – Local Coverage Determinations § 13.5.1 "Reasonable and Necessary Provisions in LCDs"].

You will use §13.5.1 whenever you use written or oral argument in an ALJ hearing. Make a copy of §13.5.1 and keep it in front of you every time you write a pre-hearing brief. **Caveat**: You must address each element of 13.5.1 in your pre-hearing brief and in your oral argument to the ALJ.

> § 13.5.1: A service may be covered by a contractor if it is reasonable and necessary under 1862(a)(1)(A) of the Act. Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:
>
> Safe and effective;
>
> Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
>
> Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
>
> - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
> - Furnished in a setting appropriate to the patient's medical needs and condition;
> - Ordered and furnished by qualified personnel;
> - One that meets, but does not exceed, the patient's medical need; and
> - At least as beneficial as an existing and available medically appropriate alternative.

II. How the appeal process works for denied radiation oncology claims

Who is your target audience in the appeals process?

The ALJ! Practically speaking, the redetermination and reconsideration appeals are procedural roadblocks that only serve to discourage the appellant and to eliminate those claims where the statute of limitation is exceeded by the unwary. Everything you do during the appeals process should be done with the ALJ in mind as the target audience because the ALJ hearing is your first opportunity to present your case before a truly neutral third party. And that neutral third party will almost always decide your claims fairly and correctly. The Administrative Law Judge hearing is where and when you will win payment for your denied claims.

How often will you prevail at the redetermination and reconsideration levels of appeal?

Almost never. More specifically, you will never, ever win a redetermination appeal with the carrier and you will almost never win a reconsideration appeal with the QIC.

Why should you expect to lose at the carrier (redetermination) and QIC (reconsideration) levels of appeal?

The carrier isn't going to rule against itself and the QIC makes a huge amount of money by doing little more than parroting back the carrier denial reasons and by adding a paragraph or two from a pull-down menu of poorly written and poorly researched denial rationales.

If the Redetermination and Reconsideration appeals are hopeless, why not go right away to an ALJ appeal?

You can't. Because of the "exhaustion of remedies" doctrine in administrative law, you are required to complete the redetermination appeal first, and the reconsideration appeal second, before you are entitled to an ALJ hearing. Your appeals always have to be submitted in the correct order and always have to be submitted within the designated time requirement for each level of appeal.

What happens if you miss the time limit at any level of appeal?

Once you miss an appeal deadline (statute of limitations), that claim is dead in the water. Although there are "good cause" exceptions listed in the CFR (42 CFR § 405.942), most late submitted appeals will have to be written off. This is the biggest reason why you should submit your appeals: immediately upon receiving the original carrier denial, immediately upon receiving the redetermination appeal denial, and immediately upon receiving the reconsideration appeal denial. Appeal early and often.

A longer explanation regarding late filed appeals may be found in the "Medicare Claims Processing Manual, Chapter 29 – Appeals of Claims Decisions, Section 240 – Time Limits for Filing Appeals and Good Cause for Extension of the Time Limit for Filing Appeals." Put that long title in the Google search bar and it will come right up.

How are coverage decisions made by Medicare for radiation oncology different from coverage decisions made by the private insurance companies?

Medicare makes coverage decisions **without** regard to cost. Although this approach is ridiculous, the carrier representatives/experts sound as though they are proud of this fact. Medicare makes radiation oncology decisions based on the "opinions" of the Carrier Medical Directors, based on ASTRO policy, and sometimes based on input from the CAC representatives.

The for-profit insurance companies pretend to make coverage decisions without regard to cost. The for-profit companies carefully craft coverage policies that are based on defensible medical policy, but are likely to be "money-saving" for the insurance company when compared to other treatment options. This provides a huge opening for the use of innovative treatments that can reduce cost while delivering equivalent or better care than other technologies.

Why are Medicare coverage policies different from State to State / Why do different Medicare carriers have different rules for the use of various radiation oncology technologies?

The Social Security Act (SSA) was passed in 1935. The Medicare Act was passed in 1965 as an amendment to the SSA. In order to get the Medicare Act passed by Congress, President Lyndon Johnson had to allow each State the right to determine its own Medicare coverage policies. This approach resulted from the hold-over political concept of "States' Rights."

During Medicare's formative years each State had a Part A Medicare Intermediary and a Part B Medicare Carrier. As a result of the Medicare Modernization Act (MMA) of 2003 we know have Part A/B MACs (Medicare Administrative Contractors) that are each responsible for several States.

Based on history, and based on the financial forces at work, it is reasonable to think we will eventually have a single set of Medicare "coverage requirements" for the use of a particular radiation oncology treatment throughout the entire country, as we should for all medical services.

Why we will use the term "carrier" instead of the newer term "MAC".

Carriers are now referred to as Medicare Administrative Contractors or MACs. Unfortunately, the Medicare Appeals Council, the level of appeal above the ALJ hearing, shares the same acronym: MAC. So we will stay with the designation "carrier" when we are referring to the Medicare Administrative Contractors.

Does Medicare treat all radiation oncology technologies fairly?

The short answer is "yes" and "no."

Yes. CMS publishes the preliminary and final rules for all hospital-affiliated, outpatient (OPPS) radiation therapy services in the Federal Register. The CMS rules are straightforward, are based on reported data from the hospital providers, and are fairly written.

No. The individual carriers write their own coverage (indications and limitations) policies and the individual carriers get to determine their own fees for the Part B, outpatient codes designated as "carrier-priced" by CMS. As a result, differences remain in coverage policies and in the carrier-priced fees on the local versions of the National Physician Fee Schedule. However, it appears the reduction in the number of carriers is helping to reduce the variations in both policies and pricing.

III. A practical, step-by-step approach to your appeal

What is the one thing you can do to move the "date" in your favor when you are up against a time limit for an appeal?

Not infrequently, the date on the Redetermination or Reconsideration letter will be significantly earlier than the postmarked date on the envelope containing the Redetermination and/or Reconsideration denial decision. **Always** staple the Redetermination and Reconsideration denial envelopes to the Redetermination and Reconsideration denial letters. This may protect you in the event your next appeal is deemed "untimely" based on the date of the denial letter.

Although you are allowed 5 days from the date of the letter for the purpose of calculating the statute of limitations for the next letter of appeal, the actual postmarked date on the envelope may be more than a week after the date on the first page of the actual letter. **Caveat**: ALWAYS SAVE DENIAL ENVELOPES. This will allow you to argue that the correct arrival date for your appeal request is the postmarked date on the envelope + 5 days, and **not** the date on the first page of the letter + 5 days.

How long do you have to submit a claim after providing a service?

One year.

Why would you want to hold onto claims instead of submitting them immediately after providing the service?

You wouldn't. While it is reasonable to wait until all of the radiation therapy treatments have been provided before all of the services are billed for a single patient, it makes no sense to wait until a number of patients have completed treatment before sending the claims for payment. All of the codes for all of the services should be submitted to Medicare within 24 hours of finishing the last treatment session for a patient.

If your billing department isn't maintaining this standard, you want to know why not.

Why should you designate one person in your group to handle all Medicare appeals?

Because the calendar is your enemy. You want to be sure your billing people have submitted the redetermination and reconsideration appeals in a timely manner, and that the documents you must submit at or before the reconsideration appeal request (see below) are also timely submitted. Making one person responsible for all of this is the time-proven best way to avoid blowing the statute of limitation and is the best way to avoid "good cause" arguments for the late submission of evidence at the ALJ hearing level of appeal.

How should you structure the appeals process in your practice?

Here is a brief outline of a structural approach for Medicare appeals, and for all other insurance claim denials as well. For that **one** compulsively organized person in your group who has accepted the task of handling **all** denied claims:

1. Every notice of denial should be stapled to the envelope it comes in – without exception.
2. Every denial should be calendared for each step in the appeal process.
3. A master list of denied claims should be kept and updated every week.
4. A master file should be created **for each patient** and each master file should contain:
    b. A **signed** copy of the radiation oncology consultation note for that patient,
    c. A **signed** copy of the treatment summary (the dates of treatment and the amount of radiation delivered on each date),
    d. A copy of the submitted claim form(s),
    e. A copy of each denial response,
    f. A list of the documents that apply to the denied claim:
        1. The applicable LCD,
        2. The "literature" cited by the LCD,
        3. The radiation oncology articles that refute the LCD rule relied on by the carrier,
        4. LCDs from other Medicare jurisdictions that support your appeal,
        5. The Medicare Manual sections cited by the QIC, and
        6. The reasons why the Medicare Manual sections cited by the QIC do not apply.
5. A single master **computer** file with all of this information will do. You do not have to print and keep paper copies of all the above for each denied claim/set of claims.
    a. Recommendation: Get the Fujitsu ScanSnap S1500 desktop scanner. It is inexpensive (<$400), scans 20 pages (double-sided) a minute, it converts each scanned set of documents into a pdf file, and it takes no room on the desk.
    b. We create an individual folder for each patient (last name, first name) and all documents for each patient are labeled by date of document/title of document.
        1. **Caveat:** the "date of the document" is **not** the date you put the document into your computer file. The date of the document is the date **on** the document, e.g. the date on the redetermination denial notice.
    c. You want your computer file to be an accurate chronology of the events as they unfold for each claim denial.

d. **Caveat**: You want anyone in your group to be able to access any claim file, and to be able to find any document in that claim file in a matter of seconds.

Why do you have to keep the Medicare envelopes associated with all of the Medicare appeal documents?

This is important enough to repeat. You will invariably run up against a claim that gets lost in the appeals process. When you come across that claim you discover you are up against the statute of limitations. Because the CFR allows five days past the postmarked date on the envelope in which the denial was sent, you do not want to be victimized by the date on the first page of the denial letter. It is not uncommon for denial letters to be dated up to a week prior to the actual postmarked date on the envelope. After this happens the first time, you will be a believer and will keep all denial envelopes.

Why do you have to keep a calendar for the Medicare appeals?

Again…too many claims, too many dates, too easy to drop a claim.

Why should you keep a master list (Excel spreadsheet) of all your Medicare-denied claims?

The master list enables you to write the name of the patient, the procedure code(s) at issue, the date at each level of denial, and the calculated date for each required appeal response. **Caveat**: Review and update the Excel spreadsheet once a day. Other than entering new claims on the spreadsheet, the review won't take more than one minute and will enable you to avoid death by statute of limitation.

IV. Redetermination and Reconsideration basics

How long after you receive the original denial from the carrier do you have to submit a redetermination appeal?

You have **120 days** from the date you receive the notice of the initial determination The date of receipt of the initial determination will be presumed to be **5 calendar days** after the date of the notice of initial determination [42 C.F.R. § 405.942]. Keep the envelope the denial came in!

What should you do if you find a typographical error on the original claim form (you submitted) as you are preparing the redetermination appeal request?

If your original claim is denied, and you find a typographical error on your original claim form, you will submit a request for a "**reopening**" instead of a request for a redetermination.

Where can you find the details on "reopenings" for typographical errors?

Put: "Medicare Claims Processing Manual, Chapter 34 - Reopening and Revision of Claim Determinations and Decisions, Section 10.4" into the Google search bar and that section will come right up.

What kinds of typographical errors can you fix with a reopening?

All of the following typographical errors on the original claim form can be corrected with a "reopening" request: mathematical or computational mistakes; transposed procedure or diagnostic codes; inaccurate data entry; misapplication of a fee schedule; computer errors; denial of claims as duplicates which the party believes were incorrectly identified as a duplicate; and incorrect data items, such as provider number, use of a modifier or date of service.

What should you do if you find mistakes on the initial EOMB received from the Medicare carrier?

If the initial EOMB denying payment of a claim contains significant errors made by the carrier (e.g. date(s) of service), make a copy of the EOMB, highlight the EOMB error(s) on the copy, attach the highlighted EOMB copy to your **redetermination** appeal request, and begin your redetermination appeal with a sentence that details the errors on the EOMB. **Caveat**: Although this may seem very obvious, you must go back and make sure the claim you initially submitted did not contain the same error(s).

If the EOMB error(s) were present on the original claim, submit a reopening request for the claim instead of a redetermination request.

Where do you send the redetermination appeal request?

The address will be on the initial determination notice.

Who makes the redetermination appeal decision whether to pay you?

A clerk with a limited number of options.

What should you expect with redetermination appeals?

The only time you will prevail at the first level of appeal is when you have a simple typographical ("minor clerical") error on the claim form that can be "claim corrected" and resubmitted for a reopening (as opposed to a redetermination).

What happens when you request a reopening and the carrier responds by correcting the typographical errors on the claim form but the carrier also denies payment?

Then you should submit a request for a redetermination appeal.

Can you skip the redetermination appeal and immediately request an ALJ hearing?

Absolutely not!

Why not?

The exhaustion of remedies doctrine requires doctors to appeal all denied Medicare claims in the correct order of appeal every time. After the claim has been initially denied you have to submit the claim for a redetermination appeal. After the redetermination appeal has been denied you have to

submit the claim for a reconsideration (QIC) appeal. After the reconsideration appeal has been denied you are allowed to submit a request for an ALJ hearing.

What does the acronym "QIC" stand for?

The acronym QIC stands for **Q**ualified **I**ndependent **C**ontractor.

Are radiation oncology services Part A or Part B Medicare services?

All radiation oncology services **not** performed as part of an inpatient stay are Medicare Part **B** services. Whether the outpatient services are provided as part B services on the **OPPS** fee schedule in a hospital-affiliated radiation therapy center, or the outpatient services are provided as part B services on the **PFS** fee schedule in a non-hospital-affiliated, free standing center, all outpatient radiation oncology services are part B services.

How many Part B QICs are there?

There are only two Part B QICs for the whole country: a Part B North QIC and a Part B South QIC.

The Part B North QIC, **C2C Solutions**, handles reconsiderations for the North jurisdiction that includes the following: Alaska, American Samoa, Arizona, California, Delaware, District of Columbia, Guam, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New York, , North Dakota, Northern Mariana Islands, Ohio, Oregon, Pennsylvania, Rhode Island, South Dakota, Utah, Vermont, Washington, Wisconsin, and Wyoming. C2C is owned by TMF Health Quality Institute.

The Part B South QIC, **Q2 Administrators**, handles reconsiderations for the South jurisdiction that includes Alabama, Arkansas, Colorado, Connecticut, Florida, Georgia, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, Puerto Rico, South Carolina, Tennessee, Texas, Virginia, Virgin Islands, and West Virginia. Q2A is owned by Maximus.

What do the QICs do?

Ostensibly, the QICs do "independent", on-the-record reviews of the initial determination decisions.

Caveat: The denial reasons offered by the QIC, in the "Explanation of the Decision" section of the QIC decision, are **the** issues that will be addressed by the ALJ at your hearing. If an issue is **not** cited by the QIC in the QIC denial decision, the ALJ will "probably" **not** raise that issue at the time of your ALJ hearing.

Caveat: However, and this is an incredibly important caveat, you must **always** be prepared to defend "medical necessity" at the time of the ALJ hearing, even if the QIC did not raise "medical necessity" in the QIC decision. This means you **MUST ALWAYS** send copies of the critical medical records for each patient when you send the request for the reconsideration appeal. Otherwise, you may find yourself in front of a Judge who places medical necessity at issue during the ALJ hearing and there you are, without the necessary documents to prove the services were medically necessary.

Caveat: For both the pre-hearing brief and the ALJ hearing, prepare and present complete answers to the denial reasons offered by the QIC. If the QIC cites documents that do not apply to the dispute, you will point that out calmly and politely.

Caveat: Do **not** begin the brief and do **not** begin your presentation to the Judge with arguments not related to the QIC denial reasons. Whether the Judge is reading your pre-hearing brief or is listening to your oral argument during hearing, the Judge will be focused on the QIC denial reasons. You want to be focused on the same thing the Judge is focused on.

Caveat: The ALJ does not want drama. You may be outraged by the conduct of the carrier and the QIC but the ALJ will only be outraged if you start behaving emotionally. The ALJ is simply doing his/her job and will be very annoyed by an emotionally-laden presentation.

How long after you receive the redetermination denial do you have to submit a reconsideration appeal?

A request for a reconsideration appeal must be filed (received by the QIC) within **180** calendar days from the date the party receives the notice of the redetermination [42 C.F.R. § 405.962]. The date of receipt of the redetermination decision will be presumed to be 5 calendar days after the notice of redetermination (the date on the redetermination envelope you were smart enough to keep).

Where do you send the reconsideration appeal request?

The address will be in the redetermination decision. Be careful. **Caveat**: Do **not** send the request for a reconsideration (QIC) appeal to the same address for redetermination appeals.

Who makes the reconsideration decision whether to pay you?

Under 42 C.F.R. § 405.968, the QIC decision is an "independent on the record review of the initial determination" and "must involve consideration by a panel of physicians or other appropriate health professionals." However, in my experience, QIC decisions almost always duplicate the exact denial reasons offered in the redetermination denials.

V. The reconsideration "trap": the biggest procedural weapon used against you

What documents must you send, EVERY TIME AND WITHOUT EXCEPTION, at or before the QIC appeal request?

You should send copies of:

1. the signed radiation oncology consultation note (that includes the reasons why the specific treatment was recommended over other forms of radiation therapy available for that patient),
2. the signed radiation treatment summary note, and
3. the submitted claim forms.

Why should you send these documents at or before the QIC appeal request and why do these documents have to be submitted before the QIC decision is issued?

The 42 CFR § 405.976(b)(ii) states: "All evidence that is not submitted prior to the issuance of the reconsideration will **not** be considered at an ALJ level , or made part of the administrative record, unless the appellant demonstrates good cause as to why the evidence was not provided prior to the issuance of the QIC's reconsideration."

What is and what is not "new" evidence?

Records specific to a single patient are always "new" evidence. This would include the radiation oncology consultation note for the patient as well as the treatment summary note.

Documents published by CMS/Medicare/carrier are not "new" evidence. Federal Register proposed and final rules for the type of radiation therapy used, CMS Manual sections, and LCDs are also examples of documents that are not "new" evidence.

Do you have to send documents more than once when you appeal a denied claim?

No. If you have already submitted the above documents at the time of the redetermination, you do not have to send them again. Medicare is obligated to forward those documents to each succeeding level of appeal. See: Medicare Claims Processing Manual, Chapter 29 – Appeals of Claims Decisions, Sections 320.3 – 320.5

What documents should you not send as part of the appeal?

Do **not** send anything other than the radiation oncology consultation note and the treatment summary. The Judge will **not** look at graphs or other documents (e.g. CT or MRI images, dosimetry plans, etc.) that are purely technical and have no influence on the outcome of the case.

What should you expect with reconsideration appeals?

In my experience, if you are lucky enough to get one of the QIC nurses assigned to your Reconsideration appeal, you might just win at this level of appeal. The nurses seem willing to review the redetermination denials in an even-handed manner and seem willing to put the time in to analyze the claims.

In my experience, if you are unlucky enough to get one of the QIC physicians assigned to your Reconsideration appeal, you will almost always get a reconsideration denial that incorporates the word-for-word reasoning of the redetermination denial.

Why is the reconsideration appeal the CRITICAL STEP in the appeal process?

Before the rules were changed in March of 2005, it was easier to get the ALJs to admit any evidence the provider wanted the Judge to consider. One of the most important changes in the rules centered on "new evidence" being admitted after the reconsideration appeal. The folks who wrote the new rules

appreciated the fact most providers will not hire an attorney before the ALJ appeal level is reached. So the easiest way to prevent evidence - that would be outcome determinative in favor of the provider - from being admitted for the ALJ hearing was to make a rule that all evidence has to be submitted at or before the reconsideration appeal.

Caveat: CMS also has attorneys whose job it is to look at the various ways the Medicare appeals process can work in favor of the carrier/CMS/HHS. And this evidentiary roadblock is one of the most effective traps for doctors who are experts at providing care but are amateurs when it comes to litigating denied claims. And even if you have been lucky enough to have ALJs who have admitted your late evidence, there are plenty of ALJs who won't.

As you can easily imagine, if there is no evidence in the record supporting your assertions regarding the patient whose claim is at issue, there is no chance you will prevail.

For those of you who think the rules are not skewed…

Think about what happens with Medicare overpayments and underpayments. As soon as a carrier decides there has been an "overpayment", interest immediately attaches to the amount of the overpayment. But when there is an "underpayment", no interest attaches until there has been a final determination by an ALJ regarding the disputed amount. See 42 CFR § 405.378

There are cases in which providers have won at the ALJ level, only to have the case appealed by the carrier to the Medicare Appeals Council, who then reverses the ALJ's decision and remands the case back to the ALJ for further determinations, etc., etc. This process may go on for 5 or more years before a "final" ALJ determination is reached. But no interest attaches to the claim amount until after the "final" ALJ determination. Even then, interest does not attach to the "underpayment" until 30 days after the "final" ALJ decision has been published.

In a 2 to 1 decision by the 5th Circuit Court of Appeals in Tex. Clinical Labs., Inc. v. Sebelius, 612 F.3d 771 , the **dissenting Circuit Judge, E. Grady Jolly**, wrote the following regarding when interest attaches to an underpayment: "This case only too well proves that point: had it not been for the agency's (Medicare's) three administrative appeals, each of which arose from the agency's groundless claim that evidence existed to support its travel-allowance-calculation methodology, there would be no question that interest began to accrue in 1992 (five years earlier and in favor of the doctors). **Plainly said in street language that all such victims understand, the bureaucracy has been "jerking the plaintiffs around"--and we should *not* sanction an unreasonable, self-serving, and tendentious interpretation of the regulations that enables such abusive behavior."**

Again, "overpayment" interest attaches immediately while "underpayment" interest attaches only after a "final" ALJ decision. The net effect is the government makes more than 1 **b**illion dollars a year on overpayments and pays less than 100 **m**illion a year on underpayments. Pretty good business model, huh?

But what happens if you want to submit new evidence at the ALJ hearing, evidence that was not submitted at or before the QIC appeal?

Before you submit the "new" evidence, think: What would the Judge have to hear to make this late submission acceptable? Here are two examples of arguments that have at least a chance of working.

1. The records of 5 patients were submitted, but the records of one patient were left out. Therefore, the failure to submit the evidence was a "purely clerical" error;
2. The records are being submitted to authenticate the HCPCS codes and the ICD-9 codes submitted on the claim forms that are already part of the appeal record. There is nothing in the late submitted records that does more than substantiate what has already been submitted to the carrier.

Please note most of the ALJs are reasonable regarding new evidence. In my experience there have only been one or two ALJs who have rigidly enforced the late submitted, new evidence rule. Unfortunately, they are also the Judges who look for any excuse to deny payment of your claim.

VI. Overview of the ALJ Appeal

How long after you receive the reconsideration denial do you have to submit a request for an ALJ hearing?

The ALJ request must arrive at the ALJ office within **60** days after receiving notice of the reconsideration decision [42 C.F.R. § 4051002]. The date of receipt of the reconsideration decision is presumed to be **5** calendar days after the date of the reconsideration (postmark on the envelope).

Where do you send the request for the ALJ hearing?

See the instruction in the reconsideration appeal decision.

When and how should you send a pre-hearing brief to the ALJ?

As soon as you receive the pre-hearing notice that designates the Judge assigned to your case, you should send the pre-hearing brief to that Judge. The pre-hearing brief, like all of the other documents you send in the appeal process, should be sent by proof of delivery mail.

What is it you are trying to accomplish with the pre-hearing brief?

The pre-hearing brief allows you to "frame the argument." In one example, when a carrier reconsideration denial stated a service was "not medically reasonable or necessary" for the beneficiary's prostate cancer - based on their LCD coverage policy - I framed the argument like this:

> The applicable LCD coverage policy was based on outdated information. The applicable LCD "Sources of Information and Basis for Decision" section states the carrier adopted its policy from another carrier that relied on two radiation oncology textbooks published in 200**3** and 200**5**.

The 2003 text reference was limited to a two paragraph description of the radiation therapy device in question and the 2005 text referenced a single case study in which a different type of radiation therapy device was used to treat a single patient.

Current radiation oncology, peer-reviewed, journal articles support the exact treatment provided for the patient.

Based on the out-of-date and inapplicable LCD references, and based on the enclosed, recent articles from peer-reviewed journals - supporting the use of the radiation therapy device in question for localized prostate cancer and citing the advantages of this device over other conventional forms of treatment - the claims at issue should be paid.

In addition to "framing the argument", the pre-hearing brief should be used to make the dispute understandable to the Judge.

You should use the pre-hearing brief to "dumb-down" the radiation oncology issues to simple statements. You should also use the pre-hearing brief to present the Judge with a logical roadmap of the Medicare authorities (CMS publications, Medicare Manual sections, and carrier policies), and the non-Medicare authorities (specialty society publications, textbook sections cited in the applicable LCD, and peer-reviewed journal articles) that you will rely on at the time of hearing. Copies of all these authorities should be included with the pre-hearing brief as attachments. Caveat: The ALJ assigned to hear your case has many, many other cases to hear and decide at the same time. Make it easy for the Judge to decide in your favor by giving the Judge copies of all cited authorities, as attachments to your brief. Caveat: Place a numbered tab on each attachment to your pre-hearing brief and include a single-page, master list of attachments that you will insert in front of the first attachment.

Most importantly, you should use the pre-hearing brief to provide the Judge with a concise, easy-to-follow, common sense argument why you should win, and you should use the pre-hearing brief to provide the Judge with immediate access to all documents cited in the reconsideration decision and all of the supporting documents you will be relying on in your written and oral arguments.

We know the ALJ is the target audience but what level of scientific sophistication are you aiming for with the brief?

Some ALJs have significant science backgrounds and others do not. As a result, you should be writing the brief as though you are writing for an intelligent person with little or no background in science, who will read your brief once and only once, and who knows ABSOLUTELY NOTHING about radiation oncology.

Do not underestimate the ALJ's lack of knowledge regarding your issues. When you finish with your brief, give it to one of your support staff who has no medical background. Have that person read the brief and then ask them to tell you what the brief says. This is the fastest, fool-proof way to find out if your brief successfully communicates your message.

What is your burden of proof?

You have to prove to the ALJ, by a "preponderance of the evidence", that you should prevail. This means you only have to prove it is 51% more likely you are right as compared to the 49% conclusion the carrier is right. You have to just tip the balance in your favor in order to win. Compare this to the 75% "clear and convincing" standard applied in some civil cases and the 95% "beyond a reasonable doubt" standard applied in criminal cases. You only have to prove it is slightly more likely you are correct and the carrier is wrong.

Caveat: Your story must make sense to the Judge at a common sense level and you must show the Judge how and why you have complied with the legal and medical authorities that apply to your claim.

Will the carrier send a representative to the hearing?

Most commonly, the carrier will **not** send a representative to the hearing. So it will just be you and the ALJ.

When will you know this?

In the "Notice of Hearing" documents you receive from the ALJ, you will be told if the carrier will be present (will send a representative to the hearing).

When a carrier sends a "representative" to an ALJ hearing, who is that representative most likely to be?

A carrier "representative" is most commonly an attorney from the carrier's legal department.

If the carrier intends to have an attorney at the hearing, what should your response be?

If the carrier is going to send an attorney to the hearing, you would be foolish not to have an attorney representing you at the hearing. **Caveat**: Do not make this decision at the last minute. You will know when you receive the “Notice of Hearing” documents that the carrier intends to have a representative at the hearing. That is the time to hire an attorney because your attorney will have to get up to speed on the medicine and the law in order to represent you competently.

If you hire an attorney, what kind of attorney are you looking for?

You want a healthcare attorney who is familiar with Medicare law and has many, many ALJ hearings under his/her belt.

Does your attorney have to practice law in your state/be admitted to practice law in your state?

No. An attorney licensed (admitted by the Bar) to practice law in any state is allowed to represent Medicare providers in every state.

Do carriers ever have one of their doctors represent the carrier at an ALJ hearing?

Although it may happen sometime, I know of **no** ALJ hearing regarding denied radiation oncology claims where the carrier has asked a doctor to appear on behalf of the carrier. In addition, I know of **no** ALJ hearing regarding denied radiation oncology claims where the ALJ has asked a doctor to appear as a "neutral" witness.

When will you know if a doctor representing the carrier, or a "neutral" doctor requested by the ALJ, will be at the hearing?

The Notice of Hearing will contain this information.

How should you handle a doctor appearing for the carrier, or appearing as a neutral expert for the ALJ, at the time of the hearing?

You shouldn't. This is another example where you should be represented by an attorney who will be appropriately polite, but who knows how to cross examine an opposing expert.

Does your case have to be perfect?

No. Your case does not have to be perfect. No case ever is. You just have to get the Judge on your side by a 51 to 49% margin, based on the medical records and based on your presentation of the facts applied to the applicable Medicare rules.

VII. A pre-hearing brief PITFALL and the controlling documents in the dispute

What must you avoid doing with the pre-hearing brief?

You must not fail to address and defeat the denial reasons offered in the reconsideration decision. No matter how inapplicable the reconsideration denial reasons may be, ignoring those denial reasons will be **fatal** to your case. List all of the QIC arguments and do not put a line through any QIC argument until you have addressed it in your brief.

Now, how do you prepare for and win at the ALJ level of appeal?

Do it the way an experienced attorney would do it. Read the "Explanation of the Decision" section of the QIC written decision. That is where the ALJ will look for the issues to be heard at the time of your hearing.

How does the ALJ determine the issues to be heard in your case?

The Judge has literally hundreds of cases on her desk waiting to be heard and/or waiting for decisions after hearing. The Judge is not going to create issues that are not already present in your case. This

means the Judge (i.e. one of the Judge's legal assistants who is an attorney) will take the issues as stated in the "Explanation of the Decision" section of the QIC decision as the issues to be decided in your case. Those QIC issues should also reappear in the "Notice of Hearing" document your office receives from the ALJ's assistant, telling you when the ALJ Hearing is scheduled.

Now that you have read the QIC decision, what's next?

Go back and read it again, very slowly and very carefully. Then read it again. The third time through you should highlight each denial reason offered by the QIC and you should put all of the denial reasons in order of importance, with the most important reason at the top. Next, write down every QIC citation to LCD(s), billing guidelines, Medicare Manual sections, etc., and then find and photocopy each of these QIC-cited authorities. Once you complete this portion of the analysis you will have all of the stated reasons for the QIC denial along with a complete library of the authorities that supposedly support those reasons for denial.

What are LCDs, who writes them, and how do LCDs apply to your appeals for denied radiation therapy claims?

1. LCDs are **L**ocal **C**overage **D**eterminations.
2. LCDs are written by the individual carriers/MACs.
3. LCDs state when and where the intervention may be used.

Does an ALJ have to follow the coverage rules in an LCD?

No. An ALJ may decline to follow the rules stated in an LCD, but the ALJ must clearly state why the LCD rule is not being followed in the ALJ written decision.

The 42 CFR §405.1062 states in part:

(a) ALJs are **not** bound by LCDs, but will give substantial deference to these policies if they are applicable to a particular case.
(b) If an ALJ declines to follow a policy in a particular case, the ALJ decision **must explain** the reasons why the policy was not followed.
(c) AN ALJ may **not** set aside or review the validity of an LCD for the purpose of a claim appeal.

What parts of the LCD apply to the medically reasonable and necessary standard for radiation therapy?

Long answer: Although each LCD has a section titled something like: "Indications and Limitations of Coverage and/or Medical Necessity", you should read every word of the LCD because seemingly inapplicable sections may be very helpful to your argument. For example, from 03-01-2008 until 01-30-2012, a carrier policy relied word-for-word on an outdated policy of another carrier. Then, reading the last (most recent version) of the policy, the reader is quickly aware of the fact that the negative coverage policy was based on inapplicable sections from outdated textbooks on radiation oncology.

You wouldn't know all of this from reading the "Indications and Limitations of Coverage" section of the LCD, but these facts practically jump off the page when you read the "Sources of Information and Basis for Decision" section of the policy, and then read the earlier version.

Short answer: Every part of the LCD should be carefully read because the entire LCD will apply to the question of "medically reasonable and necessary."

How do you find the LCD that applies to use of the treatment in question in your State?

1. Go to the internet browser on your computer.
2. Put "Medicare Coverage Center" in the search bar
3. Under the heading "Coverage Process", double click on "Local Coverage Determinations"
4. Select "LCD indexes"
5. Select "Local Coverage"
6. Select "LCDs by State"
7. Select your State (or portion of your State)
8. Click on the name of your MAC under the Part B tab.
9. Scroll down alphabetically to view that radiation therapy LCD for your State.

How do you find the LCDs that apply in other States?

You can obviously put in the names of States outside your carrier's jurisdiction or you can scroll through the entire list of LCDs by doing the following.

1. Go to the internet browser on your computer.
2. Put "Medicare Coverage Center" in the search bar
3. Under the heading "Coverage Process", double click on "Local Coverage Determinations"
4. Select "LCD indexes"
5. Select "Local Coverage"
6. Select "LCDs listed alphabetically"
7. Select the first letter of the policy from the alphabet at the top of the page and scroll to the long list of LCDs on that topic.

Where does an LCD cite the literature relied upon by the authors of that LCD?

In the back of the LCD there is a section titled something like: "Sources of Information and Basis for Decision." That section will tell you the literature relied upon by the authors.

VIII. The mistakes made by LCD authors and by the carriers who continue to publish those LCDs.

What are the most common "mistakes" made by the LCD authors when it comes to relying on "source documents?"

The source documents are frequently:

Out of date (but the carrier continues to publish the out-of-date coverage conclusions without asking whether newer information applies),

Misleading (The source documents do not say what the LCD implies the source documents say), or

Inapplicable (The topic in the source document has little or nothing to do with the subject at issue).

Caveat: The ALJ may not know anything about the radiation therapy in question, but the ALJ will understand the concept of inapplicable source documents better than you ever will, so this is a chord you want to play loudly and clearly for the ALJ.

What literature will the ALJ recognize as <u>authoritative</u> in refuting the LCD?.

If CMS has issued a rule that contradicts the LCD rule relied upon by the carrier that would be authoritative.

What literature will the ALJ recognize as <u>persuasive</u> in refuting the LCD?

If the LCD rule has been changed following the date of your claim denial,

A more recent version of a textbook, where the earlier version has been cited in the LCD and the more recent version is supportive of your argument,

A change in a specialty society policy since the LCD was published,

Peer reviewed journal articles that have been published since the unfavorable coverage policy was first published, and

LCD coverage policies from other jurisdictions that allow for the services at issue, would all be persuasive.

How can you use the LCD to your advantage, even if the LCD expressly prohibits the use of a specific radiation oncology intervention for the claim(s) at issue?

If the carrier has written an LCD extolling the performance characteristics of the radiation treatment platform at issue, use the carrier's own words to defend the use of that treatment platform.

This is a wonderful opening that allows you to explain, in simple language to the Judge, how and why the radiation platform you used for the case(s) at issue was a better choice than the other radiation platforms that could have been used.

You should use the carrier's own words to show the ALJ the huge disconnect between the carrier's LCD statements regarding the virtues of the radiation platform you used and the carrier's illogical LCD conclusions, prohibiting the use of that platform.

How can you prove that while the language in the carrier LCD denies the services at issue, in practice the carrier pays for these services?

If the language in a carrier's LCD suggests, or even clearly states the service will not be paid for a given reason, but you know the carrier pays when that service is used for that reason, here is what you should do. Provide the ALJ with copies of EOMBs (now known as an Electronic Remittance Advice) that demonstrate payment for that service, despite language in the LCD saying otherwise. For example, several carriers have LCDs with ambiguous or clearly negative language regarding payment for certain radiation oncology services. That LCD language is rendered harmless as soon as you provide the ALJ with the EOMBs from that carrier proving payment for the services supposedly prohibited by the LCD.

What if your State does not have published LCDs on the radiation therapy at issue?

1. If your center is located in a carrier (MAC) jurisdiction that has no LCD on the radiation therapy at issue, the QIC written determination will/should state which "outside" LCD the QIC decision has relied on.

How do you find any "Billing Guidelines" that apply to the service in your State?

1. "Billing Guidelines" will either be found erroneously published in the body of the LCD for your State or will be found listed at the end of the LCD under the bolded heading **"Related Documents."**

What are Medicare Manual Sections?

1. The entire current Medicare Manual has been broken down into sections and published on the internet. The QIC frequently refers to these Medicare Manual sections as IOM (**I**nternet **O**nly **M**anual) sections.
2. The QIC decision will frequently reference sections of the Medicare Manual and you can find these IOM sections of the Medicare Manual easily on the internet.

How do you find the Medicare Manual sections cited by the QIC?

1. Go to the internet browser
2. Put "CMS home" into the search bar.
2. Select "Regulations and Guidance."
3. Under "Guidance" select "Manuals."
4. Under "Manuals" on the left hand side of the page select Internet Only Manuals (IOMs).

Can you ignore a Medicare Manual Section cited in the QIC decision?

Absolutely not! You must address and defeat every Medicare Manual Section cited by the QIC in the "Explanation of the Decision." Failure to do so will be fatal.

The ALJ wants to hear about the issues raised by the QIC. The ALJ is not interested in reading about issues not raised by the QIC.

1. You must write the pre-hearing brief the Judge wants and **not** the brief you think the Judge should read.
2. Write the pre-hearing brief that will help you get paid and **not** the pre-hearing brief that angers the Judge because you have not addressed the issues raised by the QIC – but you have wasted the Judge's time.
3. Write the pre-hearing brief that tells the Judge you know what you are talking about, you are on point, and you deserve to be paid.
4. Once you have concisely addressed all of the issues raised by the QIC, you are welcome to address "non-issues" (issues not raised by the QIC) in attachments to the main brief. Don't worry, the Judge will recognize the attachments as "non-issues" and will read them if so inclined.

IX. Why it is important to write a pre-hearing brief for the ALJ <u>every time</u>

Make it easy for the Judge to decide in your favor.

A pre-hearing brief allows you to frame all of the issues raised by the QIC in a light most favorable to you.

A pre-hearing brief forces you to analyze, by disassembling and then reassembling, all of the issues raised by the QIC. As a result, by the time you are finished with the brief YOU KNOW WHAT YOU ARE TALKING ABOUT, YOU CAN MAKE YOUR ARGUMENTS IN ORDER OF IMPORTANCE, YOU CAN CITE THE DOCUMENTS THAT SUPPORT YOUR CLAIM, AND YOU ARE PREPARED FOR ALMOST ANYTHING THE ALJ WILL ASK AT THE TIME OF HEARING.

A pre-hearing brief, hopefully no longer than 5 pages, with all referenced documents included as attachments, allows the Judge to write the ALJ decision quickly and efficiently.

Caveat: Some Judges will you encourage you to write a brief that includes everything you think germane to the topic. The long brief on my website was written for just such an ALJ. But you must call and check with the Judge's assistant (attorney) before you submit a long brief. These Judges tend to read your pre-hearing brief very carefully before hearing and are obviously up to speed on the subject matter as the hearing unfolds. Be grateful for these Judges. They most likely to decide fairly.

Other Judges will not read anything over 5 pages and a few (thankfully only a few) Judges read nothing sent to them. These Judges are easily recognized because they come to hearing and ask you to send

them a written copy of the expert's CV, even though the expert's CV is one of the first attachments in your brief. Be afraid of these Judges. They are least likely to decide fairly.

Caveat: There are no shortcuts. Do it right. Do it to win. And even if you are unlucky enough to be assigned one of the "few" ALJs, write your pre-hearing brief as though the very best ALJ has been assigned to your case. Why? Because the next level of appeal, the Medicare Appeals Council in Washington, D.C., will rely very heavily on your pre-hearing brief in making their decision.

Do you think the ALJs talk to each other about their cases and about the Appellants who appear before them?

They do. So here is the next **caveat**: You must be scrupulously honest with each Judge and completely prepared for each hearing. Otherwise, the Judges will be talking to each other about your radiation oncology group as less than honest and/or unprepared for hearing. As a result, you will begin your hearing with no credibility as far as the Judge is concerned, and you will be facing an extraordinary uphill battle from the first minute of the hearing.

Caveat: Although you only have to prove, by a "preponderance of the evidence" (51% more likely you are right), that you should be paid, you **always** have to prove "beyond a reasonable doubt" that the Judge can trust what you say during the hearing. Once you lose that trust it is almost impossible to get it back.

Also, if you are unprepared and your presentation is rambling and incoherent, the Judge will most likely fall back on the safer position of relying on the QIC decision. Why? First, you are annoying the Judge and making extra work for someone who is already overworked. Second, and more important, the ALJ knows the carrier may protest a decision in your favor to the Medicare Appeals Council in Washington. The ALJ does not want to be reversed by the MAC. Trust me, the MAC looks to support the carriers and the QICs. Your case should be close to air-tight so the Judge will be willing to step out on the ledge and rule in your favor.

When you are reading and analyzing the QIC Explanation of the Decision, why do you have to put yourself in the position of the person who wrote the QIC decision?

You already know what you know. Unless you take on the role of the QIC author, you will miss some of the reasoning used by that author. Even if you end up laughing at the stupidity of the QIC author, you must understand what that author was thinking and that requires serious role playing.

Caveat: This is a mistake attorneys make all the time. They tell themselves their own version of the case so many times that they become blinded to the other side of the story. Unless you put yourself in the position of the person who wrote the QIC decision you will not be able to understand why that person wrote what you are reading

How do you approach the written QIC decision?

Taking each denial rationale one at a time, ask the following questions:

1. Does the rationale make sense at a common sense level?
2. Is a Medicare 'term of art' contained within the denial rationale? If so, get the Medicare regulation or CFR code section that explains how that 'term of art' is to be applied.
3. Did the QIC apply the 'term of art' correctly? If not, write out exactly how and why it was applied incorrectly.

How should you analyze the QIC's application of each cited authority to the claim(s) at issue?

1. Reading each authority cited by the QIC, does that authority support the QIC's argument? Many of authorities cited by the QICs have nothing to do with the claim at issue and/or are supportive of your position rather than being supportive of the position taken by the QIC.
2. Once you have completed your analysis of the QIC decision, from the point of view of the QIC author, you are ready to do the responsive analysis in favor of payment.

Now, how do you perform the responsive analysis in favor of payment?

Using a lined pad of paper, write the most important denial reason cited by the QIC at the top of the page. Draw a horizontal line under the denial reason and then draw a line down the middle of the page, dividing the rest of the page into two vertical columns.

In the left hand column, list every reason you can think of why that denial reason could be **right**. In the right hand column, write down all of the reasons why that denial rationale is **wrong**. Don't worry about prioritizing at first. Just write all of the reasons in the left hand column why that denial rational may be right, and all of the reasons in the right hand column why that denial rational is wrong.

When you complete this approach for the first and most important denial rationale, draw a thick transverse line on the page that separates that denial rationale from the next denial rationale.

Go to the next rationale and repeat the process until you have done this for every denial rationale offered by the QIC.

On more occasions than I would like to admit, thinking through a seemingly crazy rationale has led to a new understanding of the QIC's approach to the entire claim dispute.

Do not worry if you are using the same arguments over and over in your rebuttal of the QIC denial reasons. That is exactly what happens in a legal response to a claim where multiple, overlapping denial explanations are offered.

Repeat this process for every authority cited by the QIC in the "Explanation of the decision."

Keep one clean copy of each printed QIC-cited authority that will be sent as an attachment to the pre-hearing brief to be submitted to the ALJ. The ALJs are very busy and are very appreciative of your

efforts to make their lives easier. Complementary copies of Medicare rules, regulations, definitions, etc. should always be sent as attachments to your pre-hearing brief. See below.

If possible, scan the clean copy of the authority into your computer as a pdf document contained in a master file to be titled: "QIC-cited Medicare authorities." The same authorities will come up over and over again with other denied claims and you should only have to look them up and scan them into your computer once.

Caveat: When you have completed your analysis, leave it overnight. You will be amazed at how many more things occur to you a day later for both the left and right hand columns.

X. What do you do when the LCD expressly prohibits use of the radiation platform you used, for the exact problem for which your patient was treated?

You will assert the LCD policy has been **misinterpreted** or **misapplied** by the carrier. You will **not** assert the LCD policy is wrong.

What you cannot ask the ALJ to do and how this must be addressed.

Caveat: Although you will be refuting the LCD policy, the ALJ is <u>not allowed</u> to set aside or review the validity of the LCD.

Under 42 CFR § 405.1062, the "ALJ will give substantial deference to the LCD as it applies to the claim. However, the ALJ is not bound by the LCD." You will explain why the ALJ should decline to follow the contractor's interpretation of the LCD policy for the claim at issue. You must not ask the ALJ to set aside or review the validity of the LCD for the purpose of your appeal.

You will tell the ALJ how the carrier has "misinterpreted" or "misapplied" the LCD policy rather than asserting the LCD policy is "wrong." Here is key language you can and should use. "The ALJ should decline to follow the contractor's interpretation of the LCD for the claim at issue. However, the Appellant is **not** asking the ALJ to set aside or review the validity of the LCD for the purpose of this appeal."

But what if you really do want to refute the LCD policy?

That is another fight for another day. You may do an "LCD challenge" if you have a patient who signed an ABN (Advance Beneficiary Notice) prior to treatment by your center, or you may request an "LCD Reconsideration" by the carrier. Both of those options are available and will be the subject of a future article. Briefly, an LCD Challenge is conducted in front of an impartial ALJ and is, therefore, worthwhile. On the other hand, an LCD Reconsideration is a loser because an LCD Reconsideration is "reconsidered" by the same carrier that wrote the LCD policy. So the carrier has the final say on whether to change its own LCD, and guess what? The carrier is not going to rule against itself.

How will you present your case at the ALJ hearing?

You should choose the **phone hearing** option.

You will already be starting out with a huge advantage. Thanks to your pre-hearing brief, the ALJ will be familiar with your case and, hopefully, leaning in your direction.

With the phone hearing option you can have the claims person from your billing department sitting in the room with you during the hearing. The claims person should be looking for any of the documents the Judge is referring to during the hearing that you do not have in front of you. This will allow you to concentrate on the hearing exchange without having to worry about finding documents.

How should you prepare for the actual ALJ hearing?

Your presentation should be structured the same as the presentation would be structured by an attorney.

Opening statement

Your opening statement for the ALJ should take no longer than 2-3 minutes.

Caveat: The Judge is presumed to know the law. Do not waste your opening statement by telling the Judge what law applies. Use the opening statement to tell the Judge the story – **your** story. In **lay terms**, tell the Judge what the dispute is about, what your evidence will show, and why the Court should find in your favor. You want the Judge to be on your side following your two minute opening statement, and because you have already submitted the pre-hearing brief you should concentrate on just telling the story.

Caveat: First impressions count. Opening statements are always the most important part of your presentation, whether you are speaking to a Judge or even to an opposing attorney at a for-profit insurance company. Tell your story in non-technical, plain-speak English. Here is an example of what I told an opposing attorney at Anthem Blue Cross regarding a case.

> "The patient is a 66 year old male who was diagnosed with a particularly difficult to treat type of lung cancer called a "Pancoast" tumor. This tumor was at the uppermost portion of the patient's lung, right next to his heart, spinal cord and esophagus and the big question hanging over the treatment plan was how to kill the cancer without killing the patient.
>
> The treating radiation oncologist wanted to use, and did use, IMRT - the type of radiation therapy that: would give the patient the best chance for a cure; would give the patient the best chance of avoiding potential life-threatening injury to the immediately adjacent normal lung, heart, esophagus, and spinal cord; and would give the patient the best chance to heal following surgery, if surgery proved to be necessary after the patient's combined treatment of radiation therapy and chemotherapy.

Blue Cross denied payment based on Blue Cross Medical Policy #: RAD.00041. That policy says "IMRT for lung cancer is investigational and not medically necessary." Blue Cross wanted the patient to have the older, less expensive, and far less precise form of conventional radiation therapy that would have subjected the patient to potential life-threatening injury to the immediately adjacent normal lung, heart, esophagus, and spinal cord and would have given the patient a substantially reduced chance to heal following any subsequent surgery.

This dispute was submitted for an Independent Medical Review and the IMR was performed by Maximus. Two of the three Maximus doctors agreed with Blue Cross and one agreed with the treating doctor. We are now ready to submit this to arbitration, but the facts are so unfavorable for Blue Cross that I wanted to reach out and see if you would consider having one of your radiation oncologists take a look at this."

The opposing attorney did just that and called back within two weeks to tell me Blue Cross was going to pay based on the additional radiation oncology opinion.

Caveat: I didn't yell or carry on with the opposing attorney. I just told her the story in a way that made her think an additional radiation oncology opinion prior to arbitration might be worthwhile.

Caveat: A 2 to 1 decision against you in a Maximus IMR is the equivalent of a 3 to 0 decision in your favor in the real world of radiation oncology. Paid experts (radiation oncologists or otherwise) almost always find in favor of the insurance entity.

How do you get your opening statement down pat?

Practice your opening statement over and over again. Start with the entire opening statement written out. Read it to yourself in front of a mirror. After reading it over several times, reduce it to an outline. After doing it several more times, reduce the opening statement to the key words and dates on a 3 X 5 card. Do not read the statement to the Judge. Even though the hearing is by phone, the Judge will immediately lose interest as soon as you start reading from documents. And please do not think you can fool the Judge about "reading" during the hearing. The Judge is as familiar with the spoken and unspoken cues during hearings as you are familiar with the spoken and unspoken cues offered by patients during consultations.

Caveat: If the Judge tells you, during opening remarks, that he/she found your brief to be compelling on the issues, do not torture the Judge by sticking with your pre-determined outline for the hearing. Ask the Judge to give you guidance as to what the Court would like to hear, if anything, regarding the issues before the Court. Do not wrestle defeat from the jaws of victory.

Qualifying the expert radiation oncologist

Assuming the Judge wants to proceed with a full hearing, you will next qualify your expert radiation oncologist

Your Honor, Dr. _____'s CV was included as Attachment #__ in the pre-hearing brief.

Dr. _____, when were you board-certified as a radiation oncologist?

How many patients have you treated with the radiation platform at issue (e.g. for prostate cancer)?

Your Honor, will the court accept Dr. _____ as an expert testifying on behalf of the Appellant?

If you are the radiation oncologist expert for the hearing and you are also presenting the hearing for your group, you will present the opening argument as above and will ask the Court permission to give a brief summary of your credentials that qualify you as an expert.

Caveat: The Judge wants to know whether you are a board-certified radiation oncologist, how long you have been in practice, and how many patients you have personally treated with the radiation therapy at issue, for the same or similar problems the patient(s) had (who are the subject of the hearing).

Caveat: The Judge does not want to hear you were an Eagle scout or where you did your post-doctoral fellowship.

Direct examination of the expert radiation oncologist/testimony by the expert radiation oncologist

The direct examination should be written out in its entirety. Write the first question you will ask the expert. Write the answer to the question. Repeat this process until you have covered all of the subjects the expert will need to address.

If you are the radiation oncologist expert for the hearing and you are also presenting the hearing for your group, you will tell the Judge you would like to address each of the issues relevant to the dispute. You can read each of the issues from the list of issues before you, but look away from the list and address each issue conversationally before going back to the list for the next issue. Cross the issues out as you discuss them.

Caveat: A conversational explanation that is slightly incomplete trumps a stilted, read-from-a-piece-of-paper explanation every time.

Caveat: If the Judge stops the testimony from the expert or interrupts your oral argument with a question, STOP TALKING AND LISTEN VERY CAREFULLY TO WHAT YOU ARE BEING ASKED. Do **not** rephrase the Judge's question before you answer. That means: do **not** answer the question you think the Judge should have asked. Answer the exact question asked by the Judge. Keep your answer as concise as possible. But do **not** fail to answer the Judge's question.

If you don't know the answer to a question asked by the Judge, do not wing it! Instead, offer to submit a written response to the Judge's question within one week of the hearing.

When you get back to your list of issues, you can address whatever else you want to address that flows from the Judge's questions.

Caveat: When you are finished with the issue raised by the Judge, go back to your list and start where you left off.

Caveat: Do not waste the Court's time by covering issues that have already been addressed in response to the Judge's questions.

When you are through with the expert testimony, check your list of issues and see if there is anything you haven't checked off that **really, really** needs to be addressed. If the unchecked item doesn't add anything important, leave it.

Closing Argument

The closing argument should be no longer than 5 minutes.

Incorporate the LCD description of the virtues of the intervention and make your points specific to that form of radiation therapy.

> Who wouldn't want…?
>
> Why would anyone want a less accurate form of radiation when…?
>
> Why would anyone want…?

Summarize all of the authorities that support use of the radiation therapy in question and summarize all of the reasons why the denial reasons should not apply.

Ask for payment of all the claims at issue.

Caveat: Make your complete ALJ hearing presentation 2-3 times in front of a mirror. Speak slowly and in a conversational tone. Then make the presentation to a reasonably intelligent, non-medical person who works in your practice, e.g. a scheduling secretary. Then give her a quiz on the main points of the presentation.

At the end of the hearing, thank the Judge for her/his time.

After the hearing

Always request a CD copy of the hearing. You are entitled to one free copy and you will need it if you get a bad decision and want to appeal the decision to the Medicare Appeals Council.

What information does this article not contain?

The appeal process is incredibly nuanced at each step, but this is particularly true at the ALJ level. Just like the rest of life, there is no substitute for experience. While this white paper attempts to convey essential information regarding Medicare appeals for your claims, the actual process can be daunting.

Call or email (dmullens@mullenslawoffice.com) if you have a question regarding an appeal. The clock will not be running and I will try my best to steer you in the right direction.

David Mullens, Esq.