Seven Elements of a "Payable Claim" are an Essential Tool When Preparing for a ZPIC Audit

(September 21, 2012): Each year, our attorneys and paralegals review and assess literally thousands of Medicare claims which have been audited (and denied) by Zone Program Integrity Contractors (ZPICs) and other contractors working for the Centers for Medicare and Medicaid Services (CMS). As intensive ZPIC audits continue, it is essential that health care providers review their processes to better ensure that services provided fully comply with applicable coverage, coding and billing requirements. While defending physicians and other health care providers in ZPIC audits and government reviews, we have identified a relatively straight-forward approach for determining whether a particular claim qualifies for coverage and payment. Generally, we refer to this approach as an examination of the "***Seven Elements of a Payable Claim.***" Notably, this has proven to be extremely helpful tool when developing an effective Compliance Plan for a client. As set out below, physicians and other non-hospital health care providers can often use this approach to determine whether specific services billed to Medicare, Medicaid, and/or private payors should be paid.

I. Seven Elements of a Payable Claim:

A discussion of the seven elements which must be carefully assessed for each and every claim is provided below:

Element #1: ***Medical Necessity -- In addressing this element, a treating health care provider should ask the following question: "Were the services administered medically necessary?"***

When considering this question, it is important to keep in mind that the medical necessity is essentially a "standalone" determination, separate from each of the other elements. In other words, a physician may find that a specific course of treatment is medically necessary in light of a patient's clinical profile and needs. Nevertheless, just because a certain treatment regime is medically necessary does not mean that it will be covered by one or more payors. Over the years, we have seen numerous instances where a physician determined that a course of treatment was medically necessary but it was not covered by Medicare, Medicaid, or a private payor plan.

We believe that this element constitutes the most important question to be answered by a provider. Services which are not medically necessary should never be performed. However, a provider may choose to provide medically necessary services regardless of whether he or she anticipates a payor to find that the care qualifies for coverage and payment.

Element #2: ***Services Were Provided – The second issue addressed is whether the services at issue were actually provided.***

As you can imagine, regardless of the fact that services ordered were medically necessary, the services must actually be administered in order for those services to be billed and paid. Absent clear,

unambiguous evidence that services were provided, they should not be submitted for reimbursement.

Equally important, services must actually be provided at a level of quality consistent with Medicare's expectations or the expectations of the covering payor.

Element #3: ***No Statutory Violations – Are the services "tainted" by any statutory or regulatory violation, such as the Stark Law, federal Anti-Kickback or a False Claims Act violation?***

When examining whether a claim is "payable," you need to remember that even though the medical service at issue may have been medically necessary and qualified for payment, if it is the result of an illegal activity, it will be tainted and will likely not qualify for payment.

Therefore, when you are reviewing a service or claim, you must consider whether there is any indication of possible statutory or regulatory violations. For instance, is there any evidence that the service or claim is linked in any way to a breach of the federal Anti-Kickback Statute or Stark's prohibition against improper self-referrals? Similarly, is the service or claim associated with a possible violation of the civil False Claims Act? The bottom line is fairly straight-forward: it is insufficient to merely show that a claim appears to meet the payor's basic billing rules. Rather, a broad view of the service or claim should be made to better ensure that it is not otherwise non-payable due to a statutory breach.

Element #4: ***Meets all Coverage Rules – Do the services meet Medicare's coverage requirements?***

The next point to be addressed when auditing a claim is to determine whether or not it is covered under a payor's plan. It is important to keep in mind that a service or claim can be medically necessary yet still not qualify for coverage and payment. Ultimately, every service or claim, regardless of whether the beneficiary is a Medicare, Medicaid, or private plan participant, must be examined to see if it qualifies for coverage.

In making coverage determinations, CMS has interpreted the phrase **"*reasonable and necessary*"** to reflect that the item or service in question is safe and effective and not experimental or investigational.[1] CMS stated that the relevant tests for applying these terms are whether the item or service has been proven safe and effective based on authoritative evidence, or alternatively, whether the item or service is generally accepted in the medical community as safe and effective for the condition for which it is used.[2] A device is investigational if it has not been approved by the Food and Drug Administration (FDA) through a premarket approval process or the "*510(k) certification process*."[3] Additional guidance to be reviewed includes any applicable **National Coverage Determination** rules, and any relevant **Local Coverage Determination** provisions:

National Coverage Determination Rules (NCDs): In its most general form, the Secretary of the U.S. Department of Health and Human Services (HHS) may articulate "*reasonable and necessary*" standards through formal regulations that have the force and effect of law throughout the administrative process.[4] More specifically, the Secretary may publish a formal administrative ruling in the Federal Register setting forth how Medicare statutes and regulations are to be applied in particular circumstances.[5] These regulations and administrative rulings are binding at all stages of the administrative process.[6] The first type of formal regulations are publications known as National Coverage Determinations (NCDs).[7] NCDs are national policy statements that grant, limit, or exclude Medicare coverage for a particular item or service and apply nationally to all Medicare beneficiaries who meet the criteria for coverage.[8] More precisely, NCDs are **"*determination[s] by the Secretary with respect to whether or not a particular item is covered nationally*"** by Medicare.[9] NCDs **"***conditions for which a* ***service is considered to be covered (or not***

***covered)*"** and **"*are usually issued as a program instruction.*"**[10] NCDs are often published detailing how a particular patient population may or may not receive Medicare reimbursement for a covered item or service.[11] Thus, NCDs relate only to issues of *coverage*. NCDs do not reflect a determination of the amount of *payment* made for a particular item or service.[12] Moreover, any interested party, including beneficiaries, may make an external request for a new NCD.[13] Most of these external requests, however, are made by organizations such as drug, device, or medical product manufacturers or by professional medical organizations, providers, or suppliers.[14] In addition, CMS may make its own internal request if it determines that an NCD is "in the interest of the general health and safety of Medicare beneficiaries."[15] Importantly, because of the judicial deference given to the Secretary in making his or her coverage determinations, all requirements set forth within an NCD are binding on coverage determinations made by Medicare Administrative Contractors (MACs) and Administrative Law Judges (ALJs) during the appeals process.[16] Finally, the Secretary may **"*further define when and under what circumstances services may be covered (or not covered)*"** under the reasonable and necessary standard through **"*coverage provisions*"** in **"*interpretive manuals*"**.[17] Manual instructions are often issued in the form of program memoranda, such as the "Medicare Program Integrity Manual."

Local Coverage Determinations (LCDs): The Secretary of HHS may also delegate its responsibilities, under section 1395y (a), to Medicare contractors.[18] Therefore, in the absence of an NCD, MACs are responsible for promulgating their own reasonable and necessary coverage determinations.[19] These determinations are published as Local Coverage Determinations (LCDs). LCDs are defined as **"*determination[s] by a [contractor] under. . . part B. . . respecting whether or not a particular item or service is covered. . . in accordance with section 1395y(a)(1)(A).*"**[20] MACs make these coverage determinations by applying the Act and federal regulations, as well as additional guidance provided by CMS in the form of Rulings, Medical Manual Provisions, and other forms of guidance.[21] In fact, the vast majority of coverage decisions are made at the local level by clinicians who work with the MACs during the claims review process.[22] CMS' Medicare Program Integrity Manual (PIM) outlines how LCDs are to be promulgated. Each LCD must reflect local medical practice within the contractor's jurisdiction and must be supported by substantial medical evidence.[23] MACs develop LCDs by considering medical literature, the advice of medical societies and consultants, public comments, and comments from the Medicare provider community.[24] Like NCDs, an LCD's coverage guidance on whether an item is medically "reasonable and necessary" means that the item is safe and effective and not experimental or investigational as determined by the FDA approval process.[25] The contractor must also ensure that LCDs are consistent with the Medicare statute, regulations, NCDs, and other applicable federal guidance.[26] The PIM also requires that contractors engage in a notice and comment process before publishing coverage policies.[27] Unlike NCDs, ALJs and the Medicare Appeals Council (Appeals Council)—not to be confused with the Medicare Administrative Contractor (MAC)—are not bound by LCDs or CMS program guidance, such as program memoranda and manual instructions.[28] However, they will give substantial deference to these policies if they are applicable to a particular case.[29] This deference is due to interpretations that arise under a **"*complex and highly technical regulatory program*,"** where even "***the identification and classification of relevant criteria necessarily require significant expertise, and entail the exercise of judgment grounded in policy concerns***."[30] If either an ALJ or the Appeals Council declines to follow a policy in a particular case, the ALJ and/or Appeals Council decision must explain the reasons why the policy was not followed.[31] An ALJ or Appeals Council decision to disregard that policy applies only to the specific claim being considered and does not

have precedential effect.[32] Furthermore, an LCD made by one MAC is not binding on the other Medicare contractors across the country.[33] The Secretary of HHS is also responsible for overseeing the evaluation of new LCDs to determine whether they should be adopted nationally and to what extent can consistency be achieved among LCDs.[34] Because LCDs are established by each individual MACs, variances between LCDs are common. Notably, while assessing common coverage and documentation requirements from one region to another, we have found that the differences between one LCD and another can be significant. Finally, if there is no NCD or LCD in place, **"*contractors may make individual claim determinations,"*** including whether a particular item or service meets the statutory requirement of being **"*reasonable and necessary".***[35]

Challenging NCDs and LCDs: When a beneficiary is confronted with a denied claim and wishes to challenge that denial, the beneficiary has the option of pursuing review through the claims appeal process, seeking review of the applicable LCD or NCD, or both.[36] However, any challenge to an NCD or LCD is distinct from the general Medicare claims appeal process set forth in 42 U.S.C. § 405(g).[37] In fact, challenging these determinations permits an aggrieved beneficiary to seek review of an entire policy or provision rather than just a specific claim denial.[38] Nevertheless, when the LCD review process was created, the existing claims appeal procedures remained unaltered. As a result, a beneficiary who wishes to challenge an NCD or LCD still has access to a *de novo* review by ALJ or to federal district court review, if necessary.[39] When challenging an NCD or LCD, ALJs and the Appeals Council are responsible for reviewing the reasonableness of these determinations under certain guidance. In determining whether LCDs or NCDs are valid, the adjudicator must uphold a challenged policy (or a provision or provisions of a challenged policy) if the findings of fact, interpretations of law, and applications of fact to law by the contractor or CMS are reasonable based on the LCD or NCD record and the relevant record developed before the ALJ or the Appeals Council.[40] As previously indicated, NCDs are determinations promulgated by the Secretary and are therefore given substantial deference when challenged. Nevertheless, the administrative appeals process affords this same level of deference to LCDs, despite the fact that these determinations are published by independent, private MACs. 42 C.F.R. § 405.1062(a) affirms that ALJs and the Appeals Council are not bound by LCDs or CMS program guidance, such as program memoranda and manual instructions but will also give substantial deference to these policies if they are applicable to a particular case. In doing so, the ALJs or the Appeals Council must apply the same "reasonableness standard" when conducting a challenge to an LCD as it does to an NCD.[41] What exactly constitutes a "*reasonableness standard*"? In *Subject: NCD Complaint—Intraocular Lens (CMS Ruling 05-01)*,[42] the Appeals Council acknowledged a complaint challenging an NCD that barred coverage of presbyopia-correcting intraocular lenses (PC-IOL) inserted after cataract surgery. After reviewing the NCD Record and the challenger's contentions, the Board upheld the validity of the NCD.[43] The Board outlined its standard of review for an NCD appeal and acknowledged that Section 1869(f)(1)(A)(iii)(I) of the Act limited its review of an NCD "*to evaluat[ing] the reasonableness*" of the NCD.[44] Section 1869(f)(1)(A)(iii)(III) also provides that the Board "shall defer only to the reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary."[45] The Board recognized that this reasonableness standard required it to uphold the challenged NCD "if the findings of fact, interpretations of law, and applications of fact to law" by CMS are reasonable based on the NCD record and the relevant record developed before it.[46] The Board also noted that federal regulations provide a two-stage process for reviewing a challenged NCD. First, if it found the NCD record to be complete and adequate to support the validity of the NCD, it would issue a decision to uphold the NCD. This would effectively end its review process. On the other hand, if the Board found that the NCD record was incomplete and inadequate to support the validity of the challenged NCD, it would conduct a review process that permitted discovery and evidence submission, as well as a formal hearing, if necessary.[47] "Policy Articles" are closely related to LCDs, though they are distinct documents. While LCDs contain only the reasonable and

necessary language, Policy Articles contain any non-reasonable and necessary language a Medicare contractor wishes to communicate to providers. These Articles essentially provide additional details for coverage requirements and reimbursement procedures. And while Policy Articles are not LCDs, the Appeals Council has recognized a "long-standing practice to afford some deference" to these articles published by the MACs.[48] Ultimately, while challenges to the specific claims denials and challenges to the various coverage determinations follow different administrative appeals processes, the adjudicatory entities all afford the Secretary's decisions substantial deference due to the complex nature of the Medicare program. As a result, beneficiaries have a significant hurdle in trying to overturn any adverse decision.

To be clear, there is no "silver bullet" that can be used by a health care provider to avoid the scrutiny of contractors and law enforcement. Every small- and mid-sized provider should expect to be audited. Rather than wait for such an eventuality, your organization should affirmatively review its operations, coding, and billing practices to ensure that its practices fall within the rules.

Element #5: ***Full and Complete Documentation – Have the services rendered been properly and fully documented?***

It is essential that you pull each and every regulatory issuance, along with any guidance issued by the state which sets out the documentation requirements associated with a particular service or claim. After auditing literally thousands of claims, we have found that over a majority of the health care providers we have audited have never fully researched and reviewed applicable documentation requirements. As clinical reviewers of both Medicare and Medicaid, Recovery Audit Contractors (RACs) and ZPICs are quick to states in hearings before an Administrative Law Judge, ***"If it isn't documented, it didn't happen."*** When made during a hearing by a RAC or ZPIC, this point is quite effective—it is extremely difficult for a provider to prove that a service was provided if there is insufficient documentation of the work conducted in the patient's medical records. Therefore, research, review, and confirm the precise documentation requirements to be met, then ensure that you take the time to fully and accurately document the work you have performed.

ZPIC auditors are excellent at identifying one or more ways in which your claims do not meet applicable coverage requirements. While you may very well disagree with their assessments, especially in "medical necessity" determinations (when you file a request for redetermination appeal and later, a request for reconsideration appeal), you will find that your MAC and your Qualified Independent Contractor (QIC) agree with the ZPIC's denial decision. Rather than endure significant costs and stress when defending against an overpayment assessment, you need to take steps to avoid a denial in the first place. To that end, health care providers should ensure that clinical staff members are fully trained and educated regarding Medicare's documentation, coding, and billing processes.

We recognize that ***"perfect documentation"*** is neither required nor realistic to expect from your clinical staff. Nevertheless, using published reports of other cases, you can show your clinicians that ZPICs enforce a strict application of Medicare's documentation and coverage requirements. Through education and training, your clinical staff will understand why it is imperative that they review, understand and comply with:

- **Any applicable *National Coverage Determinations* *(NCDs).***
- **Any applicable *Local Coverage Determinations* *(LCDs).***
- **Any *Local Medical Review Policies* *(LMRPs).***
- **The *Medicare Policy Benefit Manual* *(MPBM).***

- **The *Medicare Program Integrity Manual* *(MPIM).***
- **Any *statutory provisions* which cover the services.**
- **Finally, any *additional relevant guidance issued by Medicare* which relates to the services at issue must also be carefully reviewed.**

Element #6: ***Proper Coding – Were the services rendered correctly coded?***

Unfortunately, even if the foregoing rules have been met, it is quite simple to make a coding mistake, therefore invalidating the claim. The coding rules are both complicated and dynamic, potentially changing from year to year. We recommend that you either engage a qualified third-party billing company to assist you with coding and billing or ensure that your in-house staff members handling these duties are experienced and provided regular opportunities for updated training.

Element #7: ***Proper Billing Practices – Were the services rendered correctly billed to Medicare?***

As a final requirement, health care providers must ensure that the services or claims performed fully meet Medicaid and Medicare's billing rules. Once again, you need to ensure that your staff is properly trained to handle the organization's billing responsibilities. ***As you review your billing practices, you should abide by the following: First, "If it doesn't belong to you, give it back." Conversely, "If you don't owe the money, don't automatically throw in the towel."*** One of the attorneys in our firm is regularly asked to speak at provider conventions around the country. For years, we have told health care providers ***"If it doesn't belong to you, give it back."*** This simple concept covers a lot of ground when it comes to Medicare overpayments and is the single best policy you can employ as a good, compliant corporate citizen.

In summary, in order to qualify for payment, a claim must meet each of the seven components set out above.

II. Handling Deficiencies:

The likelihood that your practice or organization will be subjected to a Medicare or Medicaid audit is increasing every day. As a participating provider in one or more federal health care programs, you have an ***affirmative obligation*** to ensure that your claims are properly provided, documented, coded, and billed. ***Unfortunately, many health care providers have never researched and reviewed the proper rules covering the care and treatment services they provide***. When conducting a **"gap analysis"** of your organization, a sample of your claims is an important proactive step you can take to help ensure that your current practices are fully compliant with applicable laws and regulations; such analyses do not have to be statistically significant. Should you identify deficiencies, remedial steps should be taken (immediately) so that future claims for care and treatment will meet all applicable requirements. Keep in mind—any identified overpayments must be repaid promptly to the government in order to avoid possible False Claims Act liability.

III. Final Thoughts:

We strongly recommend that you foster a corporate culture which encourages coding and billing compliance. ZPICs and RACs have increased their audit activities dramatically in numerous areas of the country. Your organization's compliance with federal and state regulations, coupled with a consistent message to your employees, is essential. Establishing good intake and records management procedures, and continuing employee education and training efforts, can greatly facilitate the adoption

of an ethical, compliant corporate culture.

Robert W. Liles **represents health care providers in Medicare post-payment audits and appeals, and similar appeals under Medicaid. In addition, Robert counsels clients on regulatory compliance issues, performs gap analyses, conducts internal reviews, and trains healthcare professionals on various legal and compliance issues. For a free consultation, call Robert today at 1-800-475-1906.**

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[1] 54 Fed. Reg. 4302-02 at 4304 (Jan. 30, 1989) and United States ex. rel. Colquitt v. Abbott Laboratories, 2012 WL 1081453, 29 (N. D. Tex. March 30, 2012); 42 C.F.R. § 411.15(o).

[2] 60 Fed. Reg. 48417-01 (Sept. 19, 1995).

[3] Under the § 510(k) certification process, a manufacturer must submit to the FDA a premarket notification submission, commonly known as a 510(k) notice, before a device may be introduced into interstate commerce. 21 U.S.C. § 360(k); 21 C.F.R. § 807.81 (2010). The 510(k) notice must include, among other things, proposed labeling sufficient to describe the device, its intended use, and the directions for its use; a statement indicating the device is similar to or different from other products of comparable type in commercial distribution; and a statement that the submitter believes, to the best of the submitter's knowledge, that all information in the 510(k) notice is truthful and accurate, and that no material fact has been omitted. 21 C.F.R. § 807.87(e)-(h), (k).

Along with the 510(k) notice, a manufacturer must submit a "510(k) summary," which "shall be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence [to previously cleared devices]." Id. § 807.92(a). Among the information that must be contained in a 510(k) summary is "[a] description of the device ..., including ... the significant physical and performance characteristics of the device, such as device design, material used, and physical properties." Id. § 807.92(a)(4). The 510(k) summary must also include "[a] statement of the intended use of the device ... including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate." Id. § 807.92(a)(5).

[4] Willowood of Great Barrington, Inc. v. Sebelius, 638 F.Supp. 2d 98, 105 (D. Mass. 2009); 42 U.S.C. §§ 1395ff(a)(1), 1395hh.

[5] 42 C.F.R. § 401.108.

[6] 42 C.F.R. §§ 401.108(c), 405.1063.

[7] 42 U.S.C.