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Staying Well Within the Law

A newsletter on the current legal issues facing today's health care industry

Winter Issue 2010

Physicians Can Expect New Rules in the New Year

By Anne E. Jorgensen & Barry D. Shapiro, CPA, WithumSmith+Brown, PC

Physicians beware: change is in the air for 2010 on both the national and local fronts, and not so much for the positive. On a national level, federal agencies are attempting to adjust fee schedules that could negatively affect Medicare reimbursement.* Locally, a greater scrutiny is being placed on the relationships between docs and vendors.

National Level

The Centers for Medicare and Medicaid Services (CMS) announced this fall a 21.2 percent pay cut in 2010 for physicians participating in Medicare. According to the CMS web site, the Medicare law requires CMS to adjust the Medicare Physician Fee Schedule (MPFS) payment rates annually based on an updated formula that includes application of the Sustainable Growth Rate (SGR) that was adopted in the Balanced Budget Act of 1997. This formula has yielded negative updates every year beginning in CY 2002, although CMS was able to take administrative steps to avert a reduction in CY 2003, and Congress has taken a series of legislative actions to prevent reductions in CYs 2004-2009.

In response, Rep. John Dingell (D-MI15) sponsored a bill to amend title XVIII of the Social Security Act to reform the Medicare SGR payment system for physicians and to reinstitute and update the Pay-As-You-Go requirement of budget neutrality on new tax and mandatory spending legislation. The Act, titled the Medicare Physician Payment Reform Act of 2009 (H.R. 3961), also repealed the 21.2 percent cut in Medicare reimbursement for physician services in 2010.

Prior to the House vote on the Act, 127 national and state medical societies sent a letter to House Speaker Nancy Pelosi (D-Calif.) urging passage of the bill. Though the Senate voted against a bill this fall that would have frozen physician payments where they currently stand, Pelosi has said that Congress is seeking to pass a permanent fix and she preferred that it be included as part of a health care reform package.

The Act passed the House of Representatives by a vote of 243-183 on November 9 and was sent to the Senate for a vote. Rather than vote on the Act, the Senate passed temporary measures as part of the Defense appropriations bill to delay the implementation of the pay cut until February 28, 2010. While the Reform Act remains in debate, physicians are left with the same uncertainty regarding Medicare cuts that they currently undergo year after year. Furthermore, physicians must wait to see if the SGR formula is revised according to their concerns, without addressing their concerns or not at all.

Leaders of the American Medical Association (AMA) and other major societies have maintained that a permanent revision to the SGR formula was an essential part of health care reform and that without such a revision they may not continue to back other reform initiatives. In a letter to Senate Majority Leader Harry Reid (D-Nev.), the AMA cautioned Congress that the "fatally flawed physician reimbursement formula, the Sustainable Growth Rate" must be reformed for the AMA to continue to support such reforms.

Without a viable resolution in sight, physician practices should be mindful of dropping reimbursement rates with regard to Medicare and with regard to other third-party payor contracts, as many of those third-party contracts pay physicians based on a certain percentage of the Medicare rate. Therefore, a drop in Medicare rates would necessarily drop third-party payor reimbursement rates as well. When renegotiating these third-party payor contracts, physician practices should consider using a different base rate from which to determine reimbursement.

Furthermore, should Congress fail to address Medicare reimbursement, physicians will begin to face new questions including, "Do I want to continue

*On January 28, 2010, the Senate passed so-called pay-go legislation that would require Congress to pay for much of its future spending without adding to the deficit. However, it exempted $82 billion from the requirement to prevent reductions to doctors' Medicare reimbursement rates. This legislation represents a temporary fix to stave off five years' worth of Medicare cuts. Nonetheless, Congress must still authorize the spending, and lawmakers are expected to consider the measure sometime in February. If Congress is not successful, doctors would face the 21 percent cut in reimbursement rates beginning in March.

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participating in the Medicare program?" and "Can I afford to continue participating in the Medicare program?" For many physicians, participation in the Medicare program is necessary due to the demographics of the area or the type of practice established. However, if cuts in Medicare reimbursement are in the future, many physicians may need to consider the viability of a practice that has "opted-out" of the Medicare program.

Local Level

With many states deciding to restrict relationships between doctors and vendors, the New Jersey Attorney General recently stated his recommendations on the ways physicians should limit their interactions with drug and device makers. If these recommendations were to be enacted, it is thought that New Jersey would have some of the toughest rules in the U.S. *The Wall Street Journal* reported that these changes would include:

- Banning physicians and their office staff from accepting food from drug companies, whether in their office, at facilities or in commercial venues like restaurants. Laws in Vermont and Massachusetts recently went into effect imposing similar restrictions.
- Requiring doctors renewing their licenses to disclose whether they accepted more than $200 worth of payments and/or gifts from industry during the prior two years.
- Mandating the state to create a public database of physician disclosures.
- Restricting the sale of "prescriber-identifiable" prescription data for commercial databases, which refers to the practice of buying prescription data from pharmacies, "crunching the data," then selling it to drug companies so they can learn which doctors are prescribing.

Physician practices and the medical associations that support docs must pay close attention to these pending policies and regulations. They say the only thing that's constant is change. But changes like these can dramatically – and negatively – affect their bottom line.

For more information about this topic, contact Anne E. Jorgensen at 610.458.4950 or ajorgensen@foxrothschild.com.

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When an ASC Dials 911: The Basics of Hospital Transfer Agreements

By Albert R. Riviezzo

From economics to efficiency to ownership, there are many reasons why a surgeon might opt to perform cases in an ambulatory surgery center's OR. But not every ASC is prepared in terms of staffing and equipment to handle every emergency situation that might arise. Hospital transfer agreements serve as a safety net, enabling an ASC's patients to be transported to and treated at a hospital in the event of unanticipated medical complications. Here is a review of what you should know about arranging, evaluating and reviewing a hospital transfer agreement.

Federal and State Regulations

Any ASC that treats Medicare beneficiaries must be certified by the Medicare program and, accordingly, comply with the federal government's requirements for ASCs. One of these requirements dictates that ASCs must have a written transfer agreement with a local, Medicare-participating hospital or a non-participating hospital that meets the Medicare program's requirements for emergency service payments. If the ASC does not have a transfer agreement in place, every physician performing surgery in the ASC must have admitting privileges at a designated, CMS-compliant hospital.

While 43 states require ASCs to be licensed, only 30 require them to plan for the possibility of obtaining external emergency care. Fifteen of them demand that they have a hospital transfer agreement in place. The others require either an agreement or hospital admitting privileges for the ASC's surgeons. (See sidebar "State Situations.")

Ohio's regulation is representative of the first group, stating that an ASC "shall have a written transfer agreement with a hospital for transfer of patients in the event of medical complications, emergency situations, and for other needs as they arise." Under the Texas regulation, on the other hand, an ASC "shall have a written transfer agreement with a hospital or all physicians performing surgery at the ASC shall have admitting privileges at a local hospital."

Florida addresses the issue from the standpoint of physician qualifications. If a physician does not hold staff privileges to perform his ASC procedures at a hospital within a reasonable distance, a transfer agreement must be arranged in advance. And Georgia notes that hospitals "shall not unreasonably deny a transfer agreement to the [ASC]."

Certain states require that the hospital with which the ASC arranges transfers be within a certain travel time of the ASC. Illinois and Mississippi, for instance, specify 15 minutes, while Oklahoma specifies 20 minutes and Florida 30 minutes.

Transfer Agreement in Action

An effective emergency transfer depends upon the existence of an established procedure, which is why the creation of a written agreement between the ASC and its designated local hospital is strongly advised even when it is not mandated by government regulations or accrediting agencies.

A hospital transfer agreement should address the circumstances under which an emergency transfer should take place, specify who is authorized to make the decision to transfer a patient and list the documentation that must accompany the patient to the hospital. The agreement should describe the procedure for accomplishing the transfer, including the assignment of roles and responsibilities to surgical facility staff and pre-arrangements

for the method of transportation by which patients will be conveyed to the hospital.

In addition, the policy should include provisions for emergency care and stabilizing treatment at the ASC, within the bounds of the ASC staff's capabilities, until the patient is transferred. The staff must be trained to implement this policy in the event that a medical emergency occurs, so periodic in-service education sessions and mock drills might prove valuable in a moment of crisis.

ASC and Hospital Roles

Transfer agreements must clearly establish the respective responsibilities of the ASC and the hospital in a number of areas, including the transfer of patient information; the provision of transportation; the sharing of services, equipment and personnel; the provision of care in relation to the facility and agency capability; and the confidentiality of patient records.

In a typical agreement, the ASC will agree to:

- Supply the hospital with copies of all pertinent medical histories, results of examinations, treatment records and powers of attorney concerning any patient transferred from its care into that of the hospital.
- Supply the hospital with all available insurance and payment information for any transferred patient in order to assist it in billing for services.
- Assume responsibility for the delivery of transferred patients' personal effects, money and any other items brought with them into the ASC.
- Assume responsibility for notifying and explaining to patients, patients' families or other guardians or responsible parties the need for the transfer prior to its occurrence. (In extreme emergencies, however, notification may be given as soon as possible following the transfer.)
- Provide the hospital with notice of a transfer as far in advance as reasonably possible.

Typically, a hospital will agree to:

- Provide emergency medical assessments, examinations, treatments and testing for transferred patients for a specified length of time (typically 24 hours).
- Admit patients as promptly as possible, provided they meet the hospital's admission standards, the hospital has adequate bed capacity and the hospital's medical staff deems such hospitalization appropriate.
- Give patients who have been identified as emergency cases by their attending physicians from the ASC priority status.
- Provide copies of any treatment reports or test results to the ASC.

Ground Rules

The active terms of a hospital transfer agreement vary from case to case and must be set forth in the written document. A transfer agreement may have an expiration date, or it may state that it will remain in effect until such time as one party terminates the agreement.

For billing, collections and insurance obligations, the specifics are typically, in essence, protect yourself and each to his own. A solid hospital transfer agreement should require each party to maintain professional liability insurance or comparable self-insurance to cover their facilities and their employees against claims made during and after the termination of the agreement. Additionally, each party should be responsible for collecting its own charges for services rendered and should not be held responsible for collecting for services performed by the other party.

Lastly, this emergency policy should include an indemnity clause, which allows either party to seek reimbursement from the other in order to cover any liability, claim, action, loss, cost, damage or expense that arises from one of their actions or omissions in the carrying out of the agreement.

State Situations

30 states have legislation requiring ASCs to prepare plans for external emergency care.

15 states require a hospital transfer agreement:

Alabama
Alaska
Arkansas
Connecticut
Illinois
Kentucky
Mississippi
Nevada
New York
North Carolina
Ohio
South Dakota
Tennessee
Washington
Wyoming

15 states require either a hospital transfer agreement or surgeons to have admitting privileges at a designated hospital:

Colorado
Florida
Georgia
Indiana
Kansas
Maine
Maryland
Massachusetts
Missouri
Oklahoma
Pennsylvania
Rhode Island
South Carolina
Texas
Utah

For more information about this topic, contact Albert R. Riviezzo at 610.458.4949 or ariviezzo@foxrothschild.com.

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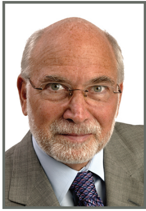
Foreign Health Care Workers and H-1B Classification

By Robert S. Whitehill and Catherine V. Wadhwani



Foreign-born health care workers play a critical role in our country's health care delivery system. A fundamental non-immigrant classification for foreign health care workers is the H-1B temporary worker visa.

This article gives a brief outline of this very valuable visa in part to demystify it and in part to encourage its use in securing skilled and indispensable workers who happen to be foreign born.

Limited Number of New H-1B Petition Filings

The H-1B is not limited to use by health care employers. In the past, it has been so popular that the annual supply has been exhausted before the fiscal year has begun. But not this year, or at least not yet, thanks to the down-turned economy. Of the 65,000 new cap-subject H-1Bs that are available annually, a very limited number were still available as of early December 2009.

Not all new H-1B petitions are subject to numerical limitation or "cap." If an individual is working for or at a qualifying nonprofit institution of higher learning or for or at a qualifying nonprofit entity affiliated with an institution of higher learning, his or her H-1B visa is cap exempt. In other words, there are no numerical limits when working for or at such an employer. So if a foreign physician is employed by a private practice, but is physically working at a nonprofit entity affiliated with an institution of higher learning, the H petition is cap exempt.

Basic H-1B Requirements

An H-1B petition has three basic components:

1. The foreign national must be offered a position (part- or full-time) that usually requires attainment of a bachelor's degree or higher level of education.
2. The foreign national must be qualified for the position by having earned at least a bachelor's degree or equivalent.
   a. Extra Requirements for Physicians Engaged in Patient Care:
      1) USMLE steps 1, 2 and 3
      2) ECFMG certificate
      3) License or other legal authorization to perform the patient care duties of the position

      If the physician is recognized as renowned in the field, the USMLE and ECFMG requirements may be waived.

   b. Extra Requirements for Nurses

      To be qualified, a nurse must have credentials that had been evaluated and found to have been the U.S. equivalent (visa screen) by the CGFNS. The nurse must have passed the foreign nurses exam (NCLEX-RN) and similar to the physician, a nurse needs to be licensed. Unfortunately, as most nurse positions do not require a bachelor's level or equivalent education, it is difficult to secure an H-1B visa for a nurse.

   c. Other Health Care Professionals

      To qualify for H-1B classification, physical therapists, speech pathologists, medical technicians and other health care providers must have appropriate credentials for their occupation and those credentials must have been evaluated as being the equivalent to the required U.S. credentials.
3. The foreign national must be offered compensation equal to the higher of the prevailing or actual wage. The prevailing wage is the amount that an individual will earn, on average, performing the job in the specific geographic area of his or her employment. The prevailing wage figure is calculated by the Department of Labor (DOL). The DOL provides two different wage calculations: one for employees of institutions of higher learning and another for all other employees. The actual wage is the amount that the employer pays similarly employed individuals.

The H-1B Petition Process

For an employer, the process of preparing an H-1B petition usually begins by providing to a competent immigration attorney a copy of the job description and the proposed compensation. This allows the attorney to determine whether the position will support an H-1B petition and whether the wage is at least adequate to satisfy the DOL's requirements. The employee must also provide the attorney with a copy of his or her immigration and credentials documents.

The DOL's certification of the Labor Condition Application (LCA) (discussed below) is a necessary pre-condition to filing the H-1B petition. The certified LCA identifies such things as the position, the level of compensation, work location(s) and duration of time that the employer will seek to employ the foreign worker.

An employer may seek petition approval for up to three years at one time. The status may be extended for another three years and beyond the sixth year in limited circumstances.

The LCA is joined with a completed immigration form, the I-129, evidence of the employee's credentials and an employer support letter. The employer support letter describes the employer, the position and the offer of employment and represents that if the employer terminates the employee, the employer will offer to pay the individual's return transportation to her or his last residence abroad.

The H-1B classification is employer-specific. So, if an employee will have more than one payroll source, receiving more than one paycheck from more than one EIN number, he or she will need more than one approved H1-B petition. The application applies only to the petitioning employer, and the employee may not use one employer's petition approval to work for any other employer.

If the new alien worker is in the United States and is maintaining another legal status, then the employer may seek an in-country change of status to an H-1B or an in-country extension of the H petition.

The LCA, Employer Attestations and the Public Access File

To ensure that the employer will not undercut the U.S. labor market by offering lesser terms of employment to foreign workers, the employer must comply with an attestation process. The attestation form is known as the Labor Condition Application (LCA). While the name is similar to "alien labor certification," which is part of the permanent residence process, it is not the same. The LCA contains four employer attestations:

1. The employer will pay the alien worker the higher of the prevailing or actual wage;
2. The alien is not being hired during a strike or lockout;
3. Notice of the H-1B petition filing has been appropriately provided; and
4. Working conditions for the alien will not adversely affect working conditions of similarly situated workers.

DOL regulations also require employers to maintain a "Public Access File" for each H-1B worker. Among other things, this file contains a copy of the LCA documentation, an explanation of the system used by the employer to arrive at the wage to be paid and evidence that notice was given of the LCA.

Government Filing Fees

Not surprisingly, the law requires that the H-1B package be accompanied by several filing fees. There is an anti-fraud fee in the amount of $500 that must be paid by the employer. There is a U.S. worker training fee of $750 for employers with fewer than 25 employees and $1500 for employers with more than 25 employees. This training fee is waived if the employer is an institution of higher learning. There is filing fee in the amount of $320 that may be paid by employer or employee. The legal fees may be paid by either employer or employee, but if the employee pays the legal fee, it must not cause the employee's wage to fall below the required wage. There is an optional fee, known as a premium processing fee, which expedites processing and guarantees an adjudication within 15 business days. Premium processing requires an extra $1000 government fee.

J-1 Waivered Physician

In the case of a physician whose J-1, two-year home-residence requirement has been waived, the employer must secure the physician's H-1B status within 90 days of the grant of an interested government agency waiver. The waivered J-1 physician is obligated to work pursuant to the terms of the waiver for three years, usually in an underserved area, in H-1B status in order to perfect the waiver of the two-year home residence requirement. Requirements imposed by a J-1 waiver are in addition to the terms of the H-1B status.

Portability

The H-1B classification is very versatile. After a person has secured the status, he or she may "port" to a new employer. Portability allows a person who is moving from one H-1B employer to another to begin working with the new employer when the new employer's non-frivolous petition is received by Immigration. Of course, it's not quite that simple, but for the person to whom it applies, portability is a real benefit allowing expeditious change in employers by needed health care workers.

U.S. Permanent Residence

The H-1B status can be used as a stepping-stone to permanent residence for valuable employees. It provides the employer with the opportunity to see the work and the value of the foreign worker before embarking on the permanent residence process.

Conclusion

While the application has many moving parts, H-1B classification can be obtained swiftly and smoothly in most cases. Of course, as readers know, each situation presents unique facts, needs and issues. The "H" in H-1B visa is not for "health care," but could be because of its usefulness for health care providers.

For more information about this topic, contact Robert S. Whitehill at 412.394.5595 or rwhitehill@foxrothschild.com or Catherine V. Wadhwani at 412.394.5540 or cwadhwani@foxrothschild.com.

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Reduce the Risks of Renting Space in Physician Offices

By William H. Maruca

Willie Sutton reportedly claimed that he robbed banks "because that's where the money is." Businesses that want to reach consumers of health care services want to be where the patients are. That means physician offices. Doctors feeling the squeeze of declining reimbursement and increasing expenses don't mind some extra income, either, and patients like the convenience of one-stop shopping. But there are numerous regulatory considerations that if ignored can result in costly legal consequences for physician and subtenant alike. So how do you structure a lease of space in a physician office the right way?

Depending on the purpose of the leased space and the relationships between the parties, you may need to consider the Stark Law, the Anti-Kickback Law, the regulation of independent diagnostic testing facilities, the medical assistance regulations, certain durable medical equipment reimbursement rules and the policies of private insurers.

Stark Law

The Stark Law applies to financial relationships between physicians and entities that provide designated health services to their patients. Physicians can only refer Medicare patients for such services if the financial relationships meet an appropriate exception. (Stark applies to Medicaid, too, but not to Medicaid managed care plans). The designated health services (DHS) are clinical laboratory services; physical therapy services; occupational therapy services; radiology services, including MRI, CT and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. Keep in mind that the purpose of the lease of space does not have to involve any DHS for the Stark law to apply so long as the physician makes referrals to the entity for DHS services. Consider a hospital that rents space from an independent physician for non-DHS purposes such as hospital-employed physician visits — so long as the independent physician continues to admit Medicare patients to the hospital or refer them for outpatient services, the lease needs to satisfy Stark.

The Stark rules permit a referring physician to lease space to a DHS entity under a signed written agreement that specifies the premises it covers if the lease lasts for at least one year; the space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the DHS entity when being used by the DHS entity (and is not shared with or used by the physician's practice except for prorated common areas such as waiting rooms); the rent is set in advance and is consistent with fair market value and does not take into account the volume or value of any referrals or other business generated between the parties; and the agreement would be commercially reasonable even if no referrals were made between the DHS entity and the physician.

Anti-Kickback Statute/OIG Bulletin

The Anti-Kickback Statute (AKS) is broader than Stark since it applies to all services covered by Medicare, Medicaid or other government programs. In 2000, the Office of Inspector General published a comprehensive analysis of rental arrangements with physicians that included a formula for prorating part-time lease costs (http://oig.hhs.gov/fraud/docs/alertsandbulletins/office%20space.htm). I strongly recommend that leases spell out exactly how the rent was calculated using the OIG's formula. Note that under the optional OIG Safe Harbor, if an agreement is intended to provide access to the physician's premises for periodic intervals of time rather than on a full-time basis for the term of the rental agreement, the rental agreement must specify exactly the schedule of such intervals, their precise length and the exact rent for such intervals. This is often difficult to predict in advance, but is critical if safe harbor protection is desired. Failure to meet a safe harbor (unlike a Stark exception) does not mean the deal is prohibited, but does require the parties to defend it if it is challenged.

IDTF Rules

For independent diagnostic testing facilities (IDTFs), just meeting the Stark and AKS exceptions isn't good enough. Under CMS regulations, with the exception of hospital-based and mobile IDTFs, a fixed-base IDTF is prohibited from (1) sharing a practice location with another Medicare-enrolled individual or organization; (2) leasing or subleasing its operations or its practice location to another Medicare-enrolled individual or organization; or (3) sharing diagnostic testing equipment used in the initial diagnostic test with another Medicare-enrolled individual or organization.

Accordingly, a mobile IDTF such as a mobile x-ray, ultrasound, EMG or similar provider can share space with another provider, but a fixed IDTF such as an imaging center cannot lease space to other providers. This restriction may have been intended to curb the controversial practice of imaging centers leasing blocks of time to their busiest referring practices as a way to meet the Stark in-office ancillary rules.

The physician is not at risk under these payment rules, but the IDTF may not qualify for Medicare payments. If the IDTF is willing to forego such payments and has sufficient non-Medicare business to justify the lease, it may be possible to proceed, but keep in mind the Stark requirement of "commercial reasonableness." If a reasonable business would not rent the space under such restrictions from a landlord that was not a referral source, and the physician refers Medicare patients to the IDTF's other sites, the deal will be suspect.

DMEPOS Supplier Rules and "Consignment Closets"

A once-common arrangement under which durable medical equipment, prosthetics, orthotics and orthotic supplies (DMEPOS) companies rent small storage spaces in physician offices will no longer

work as of March 1, 2010, unless CMS withdraws new payment rules that quietly appeared in an August 2009 transmittal. Such deals, referred to as "consignment closets" or "stock-and-bill arrangements," let the DMEPOS entity dispense the devices from the physicians' offices and bill Medicare directly. Instead of prohibiting the lease relationship, CMS will only reimburse the physician, not the DMEPOS company, for such items when the transmittal takes effect. This requires the physician practice to get a DMEPOS supplier number and runs directly afoul of Stark restrictions for most DME other than ambulatory aids (canes, crutches, walkers, non-motorized wheelchairs). Stay tuned to see if this change is implemented as planned, and if you have this kind of arrangement in place, be prepared to alter or terminate it.

Medical Assistance Regulations

A relatively obscure Pennsylvania Medical Assistance regulation states:

> A participating provider may not lease or rent space, shelves or equipment within a provider's office to another provider or allow the placement of paid or unpaid staff of another provider in a provider's office. This does not preclude a provider from owning or investing in a building in which space is leased for adequate and fair consideration to other providers nor does it prohibit an ophthalmologist or optometrist from providing space to an optician in his office. 55 Pa. Code 101.51(c)(3).

If the physician participates in Medicaid, most sublease arrangements with other Medicaid providers would technically violate this rule. It is not clear whether restricting the subtenant from servicing Medicaid beneficiaries while using the subleased space is sufficient to cure the violation. DPW has historically not enforced this rule aggressively, but it needs to be considered when structuring a sublease.

Private Insurer Issues

Finally, both the practice and its subtenant need to review the policies of the private insurers and managed care companies with which they participate. In Western Pennsylvania, that means Highmark first and foremost. Highmark has adopted provider privileging requirements for diagnostic imaging service, including bone densitometry, ultrasound, CT and MRI, echocardiography, fluoroscopy, mammography, nuclear cardiology, plain films positron emission tomography (PET), urological imaging and women's health. Among other criteria, this policy states that Highmark will only reimburse providers for diagnostic imaging services if the services are provided on imaging equipment owned by the provider and used by that provider on a full-time basis or leased by the provider on a full-time basis. Full-time basis is defined as: "the provider has possession of the equipment on the provider's property and the equipment is under the provider's direct control, and the provider has exclusive use of the equipment, such that the provider, and only the provider, uses the equipment."

This policy has been interpreted to mean that a single piece of imaging equipment may only be used by one practice but a mobile unit may be moved and used at multiple sites of a single practice entity.

Do It Right

There are enough pitfalls in these rules to trip up even careful physicians and suppliers. Before entering into a lease or sublease with another provider, seek help from experienced health care counsel. Although it's hard to argue with his choice of targets, remember where Willie Sutton wound up.

For more information about this topic, contact William H. Maruca at 412.394.5575 or wmaruca@foxrothschild.com.

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It's Final! Reviewing the Current Medicare Appeals Process

By: Anne E. Jorgensen

During the last decade, the Centers for Medicare and Medicaid Services (CMS) underwent significant changes in an attempt to improve output, reduce waste and streamline processes. As part of this overhaul, the Medicare Appeals Process was revised. Both the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) and the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) required significant changes to the then current Medicare Appeals Process. After more than five years of delays "due to the need to allow an opportunity for full consideration of issues of law and policy raised in the regulation," on December 9, 2009, the final rule addressing the changes to the Medicare Appeals Process was issued, to be effective on January 8, 2010.[1] Now that the final rule has been issued, all participants should again reacquaint themselves with the revised Medicare Appeals Process, which unites Part A and Part B under one appeals system.

First Level of Appeal – The Redetermination

The first step in the Medicare process is the provision of Medicare covered services to a Medicare beneficiary. Following the provision of this covered service, the provider would file the appropriate claim forms with the Medicare claims processor for the region. After reviewing the claim, Medicare would issue an initial determination letter (the Medicare Summary Notice or the Remittance Advice) to the parties involved. Upon receipt of that initial determination letter,[2]

1 See 74 Fed. Reg. 65296 (December 9, 2009).

2 The initial determination letter is deemed received five days from the date of the notice unless there is evidence to the contrary.

if a party disagrees with the determination, the party has the right to request a "redetermination" from the applicable claims processor (fiscal intermediary, carrier or Medicare Administrative Contractor).[3] The request for redetermination must be filed in writing within 120 days of the receipt of the Medicare demand letter and may (and should) include any supporting documentation. The claims processor must then have the determination reviewed by new personnel and issue a decision regarding the redetermination generally within 60 days of receipt of the request for redetermination. Notably, if additional supporting documentation is submitted after filing the request for redetermination, the claims processor is granted an additional 14 days to review the request. In the event of a repeated denial, the Medicare Redetermination Notice (MRN) will explain the basis for such denial as well as the recipient's right to appeal further.

Second Level of Appeal – The Reconsideration

The second level in the appeals process is a "reconsideration" by the qualified independent contractor (QIC). The reconsideration is a record review of all documentation submitted. If a party is unhappy with the result of the redetermination, the party would file in writing for a reconsideration within 180 days of the receipt of the MRN. Upon filing for reconsideration, the party is again offered the opportunity to submit additional supporting documentation. Further, the party is expected to submit a copy of the MRN and clearly explain why the party disagrees with the MRN. Importantly, evidence and documentation not submitted at the reconsideration level may be excluded from consideration at subsequent levels of appeal unless good cause is shown. Therefore, it is important for the party to submit any and all documentation and supporting evidence that may be necessary at the very latest during the appeal at this level.[4]

In addition to reviewing the documentation presented, the QIC must also consider any applicable local coverage determinations (LCD), local medical review policy (LMRP) and CMS program guidance. To the extent applicable, the QIC should defer to those policies, as "the use of consistent review criteria will serve several important purposes, including the identification of recurrent problems with CMS policies, fostering consistency in appeal decisions, and potentially reducing both ALJ appeals volume and the ALJ reversal rate." However, to the extent the QIC finds such policies do not apply to the facts of the case, the QIC may use its discretion to not apply such policies.[5] Furthermore, if necessary, the QIC is permitted to contact the appellant to obtain any additional necessary information by phone or other means.

The QIC will issue a decision regarding the reconsideration generally within 60 days of receipt of the request. Again, to the extent evidence or documentation is submitted after the initial submission of the reconsideration, the QIC is granted an additional 14 days to review the reconsideration. If the reconsideration does not fully favor the appellant, the appellant would be informed of its right to appeal further. Should the QIC fail to issue a decision within the specified time frames, the QIC will inform the appellant of its inability to make a determination using an escalation option letter and advise the appellant of its right to submit the appeal to the administrative law judge (ALJ), the next step in the appeals process, without having received a determination.

Third Level of Appeal – The ALJ Hearing

The third level of appeal is the first opportunity for the appellant to have the appeal considered in a hearing. Within 60 days of the appellant's receipt of the reconsideration notice or escalation option letter, the appellant has the opportunity to file a request for a hearing by an ALJ. In addition to being within the specified time frame, only those claims with amounts in controversy above the requisite threshold may be submitted for an ALJ hearing. The requisite threshold is adjusted each year. Beginning in 2010, to request an ALJ hearing, the amount in controversy must be at least $130.

The ALJ performs the role of an independent evaluator of the facts presented. The ALJ hearing may be heard via telephone, video-teleconference or in person. However, an in-person hearing will only be granted upon a showing of good cause as to why an in-person hearing is necessary. In certain cases, the appellant may request that the ALJ hearing be "on-the-record" and based upon submitted documents only. At the ALJ level, upon notifying all parties to the hearing, CMS or its contractors may elect to become a party to or participate in the hearing. Contractor means "an entity that contracts with the Federal government to review and/or adjudicate claims, determinations, and/or decisions, including fiscal intermediaries, carriers, and Medicare administrative contractors."[6] As this is the first time CMS or its contractors may enter the appeals process, CMS or its contractors are permitted to submit evidence into the administrative record for consideration.[7]

The decision of the ALJ is expected within 90 days of the receipt of the hearing request. During such review, the ALJ, like the QIC, must also give deference to CMS rules, regulations, LMRPs and LCDs if such policies are applicable to the facts of the case. This time frame may be extended in instances of additional submission of evidence, the request for an in-person hearing, CMS' intervention into the proceeding or the escalation to an ALJ hearing without a QIC reconsideration finding. As with the QIC, in the event the ALJ is unable to issue a decision within the requisite time period, the ALJ will notify the appellant of the right to escalate the case to the next appellate level, the Medicare Appeals Council.

3 Please note that claims processors are no longer permitted to utilize the appeals process to correct minor omissions or errors on claims. In the event a claim is denied due to an error or omission, the provider may simply request to re-open the claim to correct the error or omission.

4 See 42 C.F.R. §§ 405.966, 405.1018 and 405.1028.

5 74 Fed. Reg. 65310-65311 (December 9, 2009).

6 74 Fed. Reg. 65298 (December 9, 2009).

7 74 Fed. Reg. 65317 (December 9, 2009).

Fourth Level of Appeal – Medicare Appeals Council

The fourth level of appeal is a review by the Medicare Appeals Council (MAC). The MAC is a part of the U.S. Department of Health and Human Services. The request for a de novo review by the MAC must be submitted within 60 days of receipt of the determination or notice of escalation from the ALJ. Any party may submit a MAC request, if applicable, including CMS or a contractor. CMS or a contractor may request a MAC review if it believes the determination contains an error of law that is material to the outcome, contains broad policy or procedural issues that may affect the public interest or is not supported by a preponderance of the evidence or includes an abuse of discretion by the ALJ.

Upon submitting the request for review, the appellant must specifically state the issues and findings that are being challenged. The MAC review is not a hearing process, but in certain cases, the MAC may grant a request for oral argument if the issues raised involve an important question of law, policy or fact that cannot be determined based upon written submissions. The parties may submit briefs in support of their positions, but only evidence already on the record or approved for submission by the MAC due to good cause will be considered by the MAC.

The MAC decision is typically issued within 90 days of the receipt of the request for review. Similar to the ALJ, that time period may be extended in certain circumstances, including the escalation of the appeal from the ALJ without a decision. Should the MAC fail to issue a decision in the provided timeframe, the parties may request the appeal be escalated to the final appeal stage, federal district court. Following such request, the MAC must issue either a decision, dismissal, remand or notice of receipt of the request.

Fifth Level of Appeal – Federal District Court

Typically, to escalate a Medicare appeals claim to the federal district court, each administrative level of the Medicare appeals process must be exhausted. The request for review by the federal district court may only be filed if the amount in controversy exceeds a certain threshold amount. The threshold amount for 2010 is $1,220. If the amount in controversy is met, the complaint must be filed within 60 days of the receipt of the MAC decision or determination. The defendant for the complaint shall be the Secretary of the Department of Health and Human Services and the complaint must be filed in the federal district court where the beneficiary resides.

Dismissals of Actions

CMS has also included special provisions when dealing with a dismissal of a claim. A dismissal at any level of the appeals process may be appealed to the next level. However, upon the approval of the dismissal of the claim at that subsequent level, the dismissal is binding and not subject to further review. For example, an appeal that is dismissed at the redetermination level by the claims processor may be reviewed by the QIC at the reconsideration level. Should the QIC affirm the dismissal, the dismissal would be final and binding and not subject to further review.[8] Notably, despite the affirmation of a dismissal, a party may still request that the dismissal be vacated in accordance with the regulations.[9]

With the final rule issued, the BIPA and MMA sections addressing the revised Medicare appeals process have become fully realized. While additional changes may arise in the future, as health care reform continues to loom on the horizon, it is important for all parties to be aware of the basic changes in the Medicare appeals process so as to protect their rights now.

For more information about this topic, contact Anne E. Jorgensen at 610.458.4950 or ajorgensen@foxrothschild.com.

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8 See 74 Fed. Reg. 65311 (December 9, 2009); see also 42 C.F.R. §§ 405.972 and 405.1004.

9 See 42 C.F.R. §§ 405.952, 405.972, 405.1052, and 405.1108.

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Practice Co-Chair
David S. Sokolow
215.299.2712 or 609.895.3308
dsokolow@foxrothschild.com

Practice Co-Chair
Todd A. Rodriguez
610.458.4978
trodriguez@foxrothschild.com

Newsletter Editor
William H. Maruca
412.394.5575
wmaruca@foxrothschild.com

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