PRACTICAL*HEALTH*LAW

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Structure your purchased diagnostic tests arrangement for maximum payment

The Centers for Medicare and Medicaid Services (CMS) finalized its rule relating to diagnostic tests, commonly referred to as the "anti-markup rule." Analyzing arrangements that may be subject to the rule's payment limitation can be tricky. Let's take a closer look at the rule and review an example of its application.

WHAT'S THE ANTI-MARKUP RULE?

The rule limits Medicare payment for billed diagnostic tests. If the billing physician/supplier (biller) bills for either the technical component (TC) or professional component (PC) of a diagnostic test of the ordering physician/supplier (orderer), and the test is performed by a physician (performer) who doesn't share a practice with the biller, the payment by Medicare for the TC or PC may not exceed the lowest of:

- The performer's "net charge" (the fixed fee charged by the biller, or the salary and benefits paid to the performer for the PC/TC) to the biller,
- The biller's actual charge, or
- The Medicare Part B fee schedule amount.

The new rule — which took effect Jan. 1, 2009 — clarifies exceptions to the rule.

WHEN DOESN'T THE RULE APPLY?

The rule's payment limitation doesn't apply in two situations.

First, the rule won't apply if the biller doesn't order the test, and there's no common ownership or control between the biller and the orderer. To have common ownership or control, both the biller and the orderer must either possess significant ownership in the same organization or have the power to influence the actions or policies of that organization. So if the biller orders the test or if the orderer has common ownership or control with the biller, the rule will still apply.

Second, the rule won't apply if the performer "shares a practice" with the biller.

HOW DO A BILLER AND PERFORMER "SHARE A PRACTICE"?

The rule provides two ways in which the biller and the performer may "share a practice":

1. 75% of services. Individuals share a practice if the performer furnishes at least 75% of his or her professional services through the biller. The calculation is based on the actual hours that the physician works. So if your hospital or physician group has physicians who provide services only part-time, you'll make the calculation based on their respective hours worked and not on a full-time equivalent or standardized number of hours. And you'll calculate contract or temporary physicians' work as if it were provided by a permanent physician. You must calculate the percentage of professional services either by the previous 12 months or by the next 12 months.

2. Ownership and office of the biller. If the performer is an owner, employee or independent contractor of the biller, *and* the TC or PC is performed in the biller's office, the performer shares a practice with the biller. Any medical office space in which the orderer regularly furnishes patient care is considered to be the office of the biller. This may include space where the biller furnishes diagnostic testing if it's located in the same building in which the orderer regularly furnishes patient care. If the biller is a physician organization, the space in which the

orderer generally provides the majority of his or her patient care services will be the office of the biller.

Satisfying either alternative for a component allows *that component* — the TC or PC — to avoid the rule's payment limitation. But for both components to avoid the payment limitation, each must individually satisfy either alternative.

HOW ABOUT AN EXAMPLE?

A radiologist provides services for three group practices. He provides direct supervision of the TC and performs the PC. Over the past year, he provided a total of 1,000 hours of service: 800 to Group A, 100 to Group B and 100 to Group C. In all cases, the biller either orders the test or has common ownership with the orderer. Group A and Group B each have a central building which houses only the group-owned imaging equipment. Group C's imaging equipment is located in the same building as its office, but on a different floor.

How does the anti-markup rule apply to each arrangement? Let's see:

Group A. The radiologist provided more than 75% of his services to Group A over the previous 12 months. Because the TC and PC both meet the 75% of services requirement, the location of the equipment isn't relevant. Thus, no payment limitation under the rule applies to this arrangement.

Group B. Because the radiologist provides only 10% of his services to Group B, he can't meet the 75% of services requirement. And the centralized building that holds only the imaging equipment doesn't satisfy the location requirement. If the billing physician is the group itself, the location would have to be in the building where a majority of patient care services are provided. And if the biller is a physician, he or she would have to be in the same building where the ordering physician regularly furnishes patient care, which isn't the case. Thus, the payment limitation under the anti-markup rule applies.

Group C. As in the previous analysis, the radiologist doesn't meet the 75% of services requirement. However, he meets the location requirement for both the TC and PC, because the equipment is located in the same building as the orderer — even though the imaging equipment is on a different floor and suite. Thus, no payment limitation under the rule applies to this arrangement.

ARE YOU READY?

The rule requires you to consider the TC and PC components individually. Based on your arrangement's characteristics, either or both may be subject to the payment limitation. If your practice involves purchasing diagnostic tests, make sure to structure the arrangements so they either fall outside of the rule or meet the "shares a practice" requirement. ❙

Compliance guidance

Don't forget the U.S. Sentencing Commission

Ethics and compliance programs are essential components of health care organizations. Generally, to establish their compliance programs, organizations rely on the Health and Human Services' Office of Inspector General (OIG) and its published guidance documents. In addition, a program must satisfy the U.S. Sentencing Commission (USSC) manual. But there are some inconsistencies between the two as they relate to the seven basic elements of a compliance program that you should be aware of.

A LITTLE BACKGROUND

The USSC developed its manual in part to encourage health care organizations to develop compliance programs. The seven basic elements originated in the manual. The OIG then took the elements, added details and other information, and created guidance documents. Since then, the USSC has

amended its manual, modifying the elements. But the OIG's guidance hasn't incorporated these changes.

Thus, health care organizations are left with two documents: the OIG guidance that provides greater depth to the elements and the USSC manual that includes modifications to the elements. Each lacks certain details of the other and contains additional requirements the other doesn't. So for now, you'll have to rely on both when developing or amending your compliance program.

THE 7 ELEMENTS OF COMPLIANCE

A successful compliance program includes:

1. Policies and procedures. The USSC manual simply requires an organization to "have" compliance policies and procedures. OIG guidance goes one step further, saying that the organization should put the policies and procedures into a written set of documents.

2. A compliance officer and committee. OIG guidance recommends that organizations establish a compliance committee and suggests that it consist of representatives from relevant departments and senior management. Additionally, it suggests that committee functions include recommending and monitoring the compliance program's development.

The USSC manual requires more. It specifically delegates oversight of the compliance program's implementation and effectiveness to the organization's governing authority, and it requires that high-level personnel be assigned oversight responsibility for the program. Additionally, it establishes a duty for those high-level individuals to actively promote a culture of ethical and legal conduct.

Example of a compliance committee policy and procedures

One of the first of the seven compliance program elements under both the Office of Inspector General (OIG) guidance and the U.S. Sentencing Commission (USSC) manual requires that organizations have a compliance committee. Here's a basic compliance committee policy, which brings together the OIG guidance and USSC manual requirements:

Policy. The compliance committee has authority over issues and processes that relate to the organization's compliance program, subject to limitations implemented by the board of directors. The board will implement safeguards to ensure that the committee's authority doesn't exceed what is necessary for overseeing the program. The committee also has overall responsibility for the continual improvement of the program, including evaluation of organizational values, culture and areas of compliance risk.

The committee has direct access and will report to the board of directors on all significant compliance laws, regulations and policies and the organization's code of conduct. The compliance committee will include members from various departments and levels, including both senior managers and knowledgeable individuals from billing and coding, human resources, finance, discharge planning and others deemed appropriate by the board.

Procedures for implementation. To evaluate and ensure the efficacy of the program, the compliance committee will analyze the legal and regulatory requirements relevant to the organization, identifying specific risk areas. It will develop, review and update the program's code of conduct. It also must promote an organizational culture that encourages adherence to the compliance policies and procedures and provide guidance to executives and managers on how to promote compliance in the work environment.

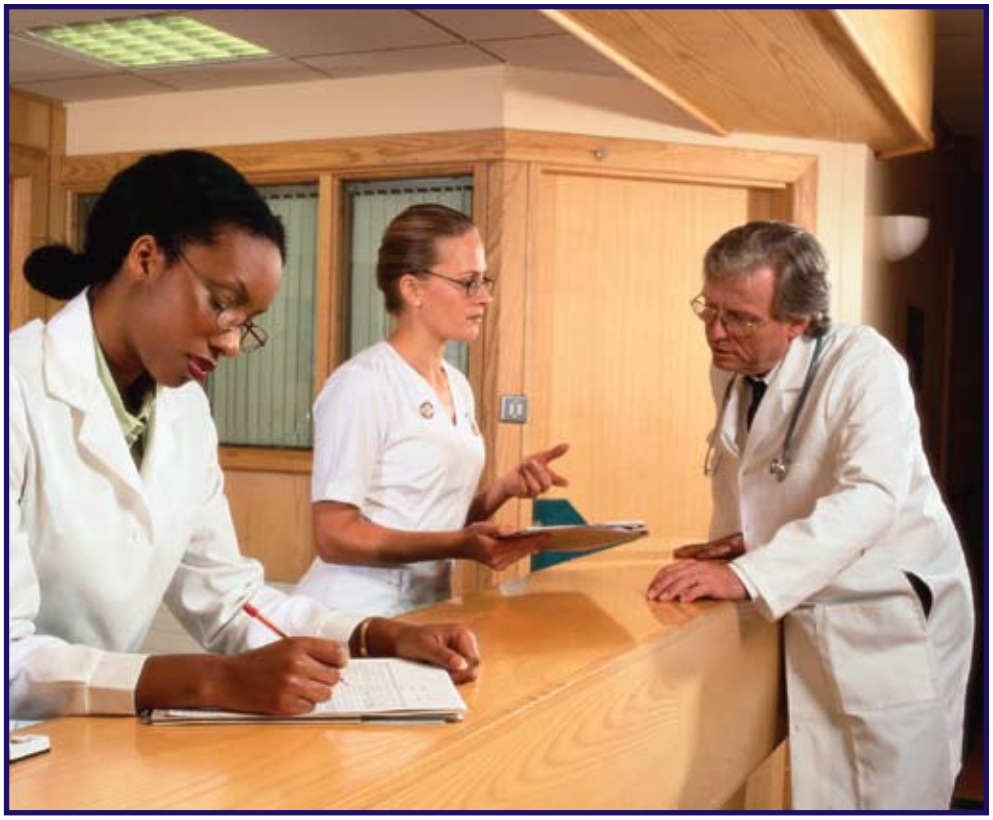
The compliance committee will monitor and review the compliance education and training program. It must also review the need for and oversee the development of remedial actions and program improvements designed to ensure that violations aren't repeated. The committee will oversee uniform enforcement of remedial action taken in response to violations and coordinate disclosures to governmental entities when necessary.

Remember this is just a brief example of a compliance committee policy and procedures. Contact your health care attorney to develop policies and procedures that suit your organization.

3. Education and training. OIG guidance strongly suggests an informal compliance education quota for employees. It suggests approximately one to three hours per year for nonspecialty fields.

The USSC manual excludes these details.

4. Open communication and reporting. Relating this element to whistleblower protections, OIG guidance stresses the importance of providing multiple paths, including anonymous methods, for accessing the compliance officer or committee and encourages employees to do so without fear of retaliation.



The USSC manual doesn't require a compliance program to offer a way to report issues anonymously. It does, however, require organizations to establish a system for employees or their agents to seek guidance or file a report without fear of retaliation.

5. Auditing and monitoring. OIG guidance stresses the use of auditing and monitoring as tools to evaluate the specifics of a compliance program to help verify conformance with, identify deficiencies in, and develop changes for the program.

> *The USSC manual and OIG guidance parallel each other in requiring consistently applied and enforced disciplinary standards.*

Conversely, while the USSC manual broadly establishes a duty for an organization to ensure the program is followed and to periodically evaluate its effectiveness, the use of auditing and monitoring is seen as more of a separate method for detecting criminal conduct.

To comply with this element, therefore, health care organizations must use auditing and monitoring both as an independent method for discovering criminal conduct and as an inward-looking tool for evaluating and developing the program.

6. Enforcement standards and disciplinary guidelines. The USSC manual and OIG guidance parallel each other in requiring consistently applied and enforced disciplinary standards. However, the manual also requires that an organization provide incentives to act appropriately; the guidance doesn't mention positive incentives.

To be safe, include both consistently applied enforcement and incentives for performing in accordance with your program.

7. Responding to and preventing issues. The USSC manual focuses on the organization's internal efforts in responding appropriately to identified problems. It requires taking reasonable steps to address the problem, blocking any similar conduct and modifying the program if necessary. OIG's guidance expands an organization's necessary efforts to include external actions and even provides an outline of its program for voluntary disclosure.

IT'S ELEMENTARY

Although these two documents don't echo each other, both contain vital direction for establishing a compliance program. And remember, you can't simply rely on one document — you'll have to integrate both into your compliance program.

Authentication issues with electronic physician orders and protocols

Digital and electronic methods of providing care continue to replace physical, or paper, methods. In some situations, new rules are implemented before these new methods have achieved standardization. And in a worst-case scenario, these new rules fail to grasp the fundamental differences between an electronic process and a paper process.

One area where this is apparent is with authenticating electronically communicated orders or protocols from physicians. This can affect whether a hospital meets its conditions of participation (CoP) with these orders.

ORDER AUTHENTICATION

The Centers for Medicare and Medicaid Services (CMS) develops CoPs that health care organizations must meet to begin and continue participating in the Medicare and Medicaid programs. These minimum health and safety standards are the foundation for improving quality and protecting the health and safety of beneficiaries.

One such CoP requires authentication of all physician orders. CMS has clarified that this includes standing orders and protocols. Standing orders and protocols establish standard treatments that a physician orders before, or without the physician repeatedly having to identify, the event that triggers their administration.

In the past, hospitals would receive a faxed copy of an order with the physician's signature, or another, similarly accepted form of authentication. But hospitals are increasingly receiving orders from physicians through various electronic health records (EHR) systems. EHR systems may automatically generate an electronic order for one or more hospitals for use over a period of time, such as a year.

ELECTRONIC AUTHENTICATION

An EHR-generated order differs from the old method in that it's not a physical copy of a physical original. Instead, the original version is digital and

may be stored on an EHR company's server. And because it's only in electronic form, it cannot have a physical signature, and thus it isn't authenticated in the traditional sense.

Hospitals have a duty to ensure that the order originated from the physician. To fulfill this duty, a hospital must be able to immediately show surveyors how it ensures the order came from the physician. CMS now allows authentication through a "computer key or code." An example of a computer key would be a unique password a physician may use when submitting an order on an EHR system.

This authentication with a computer key isn't a problem for physicians on staff at the hospital because they use the same EHR system. And some physicians may use the same EHR company as the hospital. In this situation, authentication may be possible because the EHR company can integrate the two systems.

But in all other situations, there are currently no realistic options for a hospital to meet its duty

through a computer key or code. Thus, hospitals and physicians who lack this integration have to use an old method, which typically is less efficient and increases cost.

FUTURE CONSIDERATIONS

As you can see, an EHR-generated order vs. a paper fax order from the physician makes a difference. Transferring a process from physical to digital isn't always easy or smooth — it's a highly regulated process with additional hurdles to overcome. Electronic standing orders and protocols can run afoul of CMS's authentication rules, potentially causing a health care provider to lose its ability to participate in Medicare and Medicaid programs. So physician groups and hospitals need to carefully consider how their current interactions will change, and what steps they'll need to take to stay compliant as the industry increasingly moves elements of care into the electronic world.

A BETTER WAY: MEDICAL ERRORS AND PATIENT SAFETY ORGANIZATIONS

The U.S. Department of Health and Human Services' patient safety and quality improvement final rule, which became effective in January, provides a privileged and confidential avenue for physicians, hospitals and other providers in the health care industry to voluntarily report medical errors and benefit from analysis of the aggregated data. So how does the rule benefit as well as protect these providers? And what steps can you implement to take advantage of the rule's protections? Here's a brief summary.

The final rule encourages the development of patient safety organizations (PSOs), which collect reported information from multiple providers for analysis. These new entities may be an independent entity or a component part of an entity, such as a hospital or health care system. Certain entities, such as health insurers and licensing and accrediting organizations, may not become PSOs. Becoming a PSO requires certification, which includes establishing specific protections for submitted information, in addition to other requirements.

The new rule protects what is known as "patient safety work product" (PSWP). When the provider begins collecting data related to a reportable event, each piece becomes protected PSWP when it's placed in a "patient safety evaluation system." A patient safety evaluation system is "the collection, management, or analysis of information for reporting to or by a PSO." However, the rule is carefully crafted so that providers can't simply avoid liability by protecting all information. For example, taking a patient's medical history would not be PSWP, but if an adverse event occurred as a result of incorrectly taking the history, the organization's interview of the individual who performed the history would be PSWP.

The provider can list data as PSWP even before it makes a final error determination. If a provider determines that parts of the data need no protection or there was no error, it can delist the information.

As a provider, you must have a contractual arrangement with at least one PSO for the rule's privilege and confidentiality protections to apply. Without a PSO arrangement, the protection of medical error and patient safety data is limited to existing peer review laws.

The rule's intent is to stimulate a multisystem, multiprovider culture of safety through the use of PSOs. The new confidentiality and privilege protections for providers should encourage participation, increasing the quantity, accuracy and diversity of data collected. The result of this participation will be better analysis for reducing errors and improving quality.

A message to our clients and friends:

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