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For Hospitals, Laboratories and Physician Practices

CMS Issues Stark II Final Rule

More than three years after it issued the first set of rules addressing physician referrals to entities with which they or their family members have a financial relationship, the Centers for Medicare & Medicaid Services March 25 released an interim final rule addressing additional self-referral issues.

The so-called Phase II rule, which takes effect July 26, addresses issues that remained open after CMS released the Phase I rule on Jan. 4, 2001. According to CMS, the new rule is designed to reduce regulatory burden by broadening exceptions to the self-referral prohibitions and to provide "bright-line" guidance for health care providers. The rule was published in the March 26 *Federal Register*.

"The new regulations will protect Medicare and Medicaid beneficiaries from potentially abusive referrals while accommodating ➥ *p. 10*

CMS Eases Medicare Reassignment Rules *Change A Mixed Bag For Pathologists*

A provision included in the new Medicare reform law enacted in December is expected to make it much easier for medical practices to hire independent contractors—including pathologists—and bill Medicare for their services.

In the past, Medicare prohibited reassignment of benefits, which essentially restricted the ability of a health care provider to bill for the services of a physician unless the provider was a hospital, clinic, or other health care facility, or unless the physician was employed by the health care provider.

As a general matter, this restriction has prohibited medical practices from engaging the services of other physicians as independent contractors (rather than as employees) and submitting claims for the services of the independent contractors to the Medicare program, unless the claims are submitted in the name of the independent contractor physicians, explains Jane Pine Wood, an attorney with McDonald Hopkins Co. (Cleveland).

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (DIMA), however, Medicare must permit an entity to submit Medicare bills and receive payment for services furnished by a physician with whom it has a contract, regardless of where the services are furnished or whether an employer-employee relationship exists. The change is detailed in Transmittal 111, issued by the Centers for Medicare & Medicaid Services (CMS) on February 27. While the implementation date of the change is March 12, it will apply to claims filed on or after Dec. 8, 2003. ➥ *p. 2*

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Jane Pine Wood

Thomas Greeson

Medicare Reassignment Rules, *from p. 1*

According to the transmittal, "A carrier may make payment to an entity (*i.e.*, a person, group, or facility) enrolled in the Medicare program that submits a claim for services provided by a physician or other person under a contractual arrangement with that entity, regardless of where the service is furnished. Thus, the service may be furnished on or off the premises of the entity submitting the bill."

Even though the change was made primarily to authorize reassignment of benefits to staffing companies who provide specialty services —such as emergency department care—it will also more easily permit various contractual arrangements involving pathologists and physician groups, notes Wood.

The potential downside, however, is that medical groups could try to use the global billing arrangement to secure discounts from pathologists on professional services provided to Medicare beneficiaries, she says. "There are fraud and abuse concerns that limit the ability to provide deeply discounted services, but within certain parameters, there could be an expectation that pathologists will discount their Medicare services," explains Wood.

Locum Tenens Services

Liberalization of the reassignment rules also will allow medical groups to contract with nonemployee, independent contractors for extended periods of time, which should help ease the shortage of specialists in some areas and allow the practices to cope with *locum tenens* restrictions, says Thomas Greeson, an attorney with Reed Smith (Falls Church, VA).

The *locum tenens* rules are used to permit reassignment to a group in situations where a regular physician is absent due to reasons such as vacation, disability, or otherwise, notes Greeson. The regular physician must be unavailable, and the physician may not provide his or her services over 60 continuous days as a substitute for that physician.

Under these rules, the group bills using the regular physician number and adds the Q6 modifier after the HCPCS code to indicate that the services were performed by the substitute physician. Medical practices may not use *locum tenens* for purposes of staffing the group, according to CMS.

Under the revised reassignment rules, however, a medical practice may now contract with physicians over a longer period of time, which has clear benefits. "If a group has a staffing problem, it may now enter into relationships with contractors, which should help tremendously," says Greeson.

"This is good for medical groups in terms of their own internal staffing," agrees Wood, "but it's potentially bad for outreach business because they may find their profit margin reduced."

Safeguards

Medical groups that take advantage of the expanded opportunity to enter into contractual arrangements must ensure that their contracts contain certain safeguards identified by CMS. Specifically, the contracts should specify that:

1. Joint and several liability is shared between the entity submitting the claims and the person actually furnishing the service, for any Medicare overpayment relating to such claim.
2. The person furnishing the service has unrestricted access to claims submitted by the entity for the services provided by that person.

While this is a potentially promising development, health care providers who employ physicians should not rush to convert these relationships to independent contractor arrangements, cautions Woods. IRS regulations require that many of these arrangements be structured as employment relationships rather than independent contractor arrangements, she says. What's more, malpractice insurers and health plans may also place limitations on use of contract workers.

"I would look carefully at all your contracts and consult with a tax advisor before converting any employees," Wood advises.

Resources

- Transmittal 111 (Feb. 27, 2004): *www.cms.hhs.gov/manuals/pm_trans/R111CP.pdf*
- Jane Pine Wood: 508-385-5227
- Thomas Greeson: 703-641-4242

Deadline For HIPAA Business Associate Agreements Near

Check For "Stragglers," Gaps In Contracts

Reece Hirsch

With less than a month to go before all covered entities are required to have HIPAA-compliant business associates contracts in place, experts advise conducting a final review of agreements to ensure full compliance.

Although the compliance date for the privacy standards under HIPAA (the Health Insurance Portability & Accountability Act) was April 14, 2003, the Department of Health and Human Services (HHS) gave covered entities an extra year to bring existing contracts with their business associates (BA) into compliance with the privacy rule. That means all BA agreements must reflect HIPAA requirements by April 14, 2004. In addition, small health plans – which also received an extra year to implement privacy safeguards—must be in compliance by April 14.

> ***"If you're getting new contracts in place, it's a good idea to begin addressing requirements of the security rule now"***
>
> ***—Reece Hirsch, Esq. Sonnenschein Nath & Rosenthal***

Under HIPAA, BA agreements are required between covered entities (providers, payers, and clearinghouses) and companies that assist those entities with activities that involve the use or disclosure of individually identifiable information, such as firms furnishing legal, accounting, and consulting services. BA contracts typically are not required with people or organizations whose functions do not involve protected health information (PHI) use or disclosure, such as janitors, plumbers, electricians, and photocopy repair technicians.

"Most covered entities performed an inventory of their business associate relationships before the April deadline last year, so this is a good time to go back to that inventory and see if there are any remaining gaps," suggests Reece Hirsch, a partner in the San Francisco office of Sonnenschein Nath & Rosenthal.

"Most covered entities, as they approached the deadline last year, put agreements in place with their major relationships, but often there are stragglers—small vendors, for example—and now is the time to make sure you've followed up on those."

Determining whether you need a BA agreement with a vendor involves careful analysis, notes Hirsch. For example, a vendor who provides software to your organization might not be considered a business associate for purposes of the privacy rule. However, if that vendor supplies personnel who perform testing or maintenance and potentially could have access to protected health information, you might need to have a BA agreement.

"The basic questions are: Is the vendor performing a function on behalf of the covered entity, and is the vendor getting PHI in the course of the service?" he explains.

Link To Security Rule

This is also a good time to start thinking about how contracts need to be modified to be in compliance with the HIPAA security rule, which takes effect April 21, 2005 (small health plans have an extra year to comply),

Business Associate Requirements

Under HIPAA, every business associate agreement must contain certain provisions to ensure that adequate privacy protections are in place. BAs must agree to:

- Ensure that protected health information (PHI) will not be used or disclosed except in accordance with the exceptions specified in the contract;
- Ensure that appropriate safeguards are in place to protect the confidentiality of PHI;
- Report privacy breaches to the covered entity;
- Require their agents and subcontractors to comply with the same requirements that apply to business associates;
- Make PHI available to satisfy patients' rights;
- Make PHI available to satisfy HHS's right to investigate and enforce HIPAA; and
- Return or destroy all PHI upon termination of the agreement, if feasible.

Hirsch says. The security regulations, published in the *Federal Register* Feb. 20, 2003, adopt the privacy rule's definitions of business associate and echo its requirements on protection of PHI (*GCR, March 2003*).

In every case in which the security rule would require a business associate contract, the privacy rule would, too, which helps covered entities address requirements of both rules in one contract.

"If you're getting new contracts in place, it's a good idea to begin addressing requirements of the security rule now," recommends Hirsch.

However, he advises caution when including provisions relating to reporting of security incidents. Under the security rule, business associates are required to report to the covered entity "any security incident" of which it becomes aware—a standard that many consider to be overly broad.

"For the security incident reporting provision, I would advise putting it in a contract, but I would specify that it doesn't become effective until the compliance date of the security rule," says Hirsch. "I suspect by the time that rolls around, we'll have some additional guidance on this issue."

April 14, 2003	Privacy - all covered entities except small health plans.
April 16, 2003	Electronic Health Care Transactions and Code Sets - all covered entities must have started software and systems testing.
October 16, 2003	Electronic Health Care Transactions and Code Sets - all covered entities that filed for an extension and small health plans.
October 16, 2003	Medicare will only accept paper claims under limited circumstances. Contingency plan in place.
April 14, 2004	Privacy - small health plans. Existing business associate contracts.
July 30, 2004	Employer Identifier Standard - all covered entities except small health plans.
April 21, 2005	Security Standards - all covered entities except small health plans.
August 1, 2005	Employer Identifier Standard - small health plans.
April 21, 2006	Security Standards - small health plans.
May 23, 2007	National Provider Identifier - all covered entities except small health plans.
May 23, 2008	National Provider Identifier - small health plans.

Source: Centers for Medicare & Medicaid Services

Resources

- Reece Hirsch: 415-882-5040
- HIPAA privacy rule (Dec. 28, 2000, and Aug. 14, 2002): *www.cms.hhs.gov/hipaa/hipaa2/regulations/privacy/default.asp*
- HIPAA security rule (Feb. 20, 2003): *www.cms.hhs.gov/hipaa/hipaa2/regulations/security/default.asp*

Noncompliant HIPAA Claims Face Delay

Beginning July 6, claims received by the Medicare program that are not compliant with federal transactions and code sets (TCS) rules will not be eligible for payment as quickly as compliant claims, the Centers for Medicare & Medicaid Services (CMS) said February 27.

Claims not compliant with the TCS rule issued under the Health Insurance Portability & Accountability Act (HIPAA) will not be paid earlier than 27 days after receipt. Compliant claims can be paid as early as 14 days after receipt by CMS.

CMS is introducing this disincentive to noncompliance to spur entities covered under the TCS rule—providers, payers, and clearinghouses—to begin using standard transactions when submitting Medicare claims, CMS said in Transmittal 114. The effective date of the change is July 1; the implementation date is July 6.

COMPLIANCE PERSPECTIVES

Quality Assessment of CLIA Equivalent QC: What's Wrong Here?

James O. Westgard, Ph.D., is a professor in the Department of Pathology and Laboratory Medicine, University of Wisconsin Medical School, and president of Westgard QC Inc., both in Madison, WI.

One of the biggest changes in the CLIA (Clinical Laboratory Improvement Amendments) quality control (QC) regulation that became effective April 24, 2003, is not in the rule itself but is found in the Interpretative Guidelines issued this January in the form of recommendations for *Equivalent QC Procedures*.

These equivalent QC procedures, established by the Centers for Medicare & Medicaid Services (CMS), allow further reductions from daily QC to weekly or even monthly QC for certain analytic systems that contain internal procedural controls. Given that QC is still one of the major deficiencies identified in laboratory inspections, it is difficult to understand the rationale for reducing QC from the already low minimum of two levels of control per day.

CMS uses the term "internal procedural control" to identify a monitoring check or system that the manufacturer builds into an instrument. The most common is an electronic check on the instrument readout, which is often referred to as Electronic QC (EQC). CMS also uses the same abbreviation for Equivalent QC procedures, which may reveal the underlying purpose of the QC guidelines.

As part of those guidelines, CMS provides three EQC options and evaluation protocols by which a laboratory can qualify an instrument for reduced QC:

- **EQC Option 1** is for instruments with procedural controls that test the whole analytic process and requires running two levels of external controls daily for a period of ***10 days***; if no rejections are observed for both the external and internal controls, the external QC can then be reduced to ***once a month***.
- **EQC Option 2** is for instruments with procedural controls that test part of the analytic process and requires running two levels of controls daily for a period of ***30 days***; if no rejections are observed for both the external and internal controls, the external QC can then be reduced to ***once a week***.
- **EQC Option 3** is for instruments without procedural controls and requires running external controls daily for ***60 days***; if no rejections are observed, the external QC can be reduced to ***once a week***.

It seems contradictory to utilize a QC protocol to qualify for reductions in QC, given that deficiencies in QC are known to be the most common problem in the testing sites for which the EQC options are intended. If these testing sites can't, don't, or won't perform QC properly, then the evaluation protocols recommended by CMS are inherently limited, and the validity of EQC options seems questionable. One might also wonder how the lack of out-of-control signals provides evidence for quality – it's the same illogic that assumes the lack of customer complaints means everything is okay. How do we know the complaint system itself is working or that customers could even identify a technical problem in order to complain about it? And then there's the lack of out-of-control signals for a 10-day period that somehow justifies the reduction of daily QC to ***monthly*** QC. Just how does that work? [For more discussion of the CMS EQC evaluation protocols, go to *www.westgard.com/cliafinalrule10.htm*.]

If quality assessment is truly the interest and intent of the CLIA Final Rule[1] then it is important to develop an objective approach for the quality assessment of QC systems. There are objective planning approaches for selection of appropriate QC procedures[2], but CMS seems reluctant to implement a rigorous approach for quality assessment of QC itself. To understand the difficulties, remember that

the regulations use the term "equivalent quality testing," and CMS converts that to "equivalent QC procedures" in the Interpretative Guidelines[3]. And that's where things start to go wrong!

What's "Equivalent Quality"?

Let's go back to the language in the final rule and consider how to evaluate equivalent quality. It turns out to be rather simple. It might even make use of the evaluation data that is recommended in the original CMS guidelines, but that data needs to be analyzed in a different way to properly characterize the performance of the method in the laboratory.

To understand the problem and its solution, we must begin by understanding the meaning of the words "equivalent" and "quality."

- Equivalent implies equal. According to one dictionary, it means "to have equal power, equal in force, amount, or value, like equal in signification or import, corresponding to or virtually identical, esp. in effect or function, or equal in might or authority."
- Quality is more difficult to define, but one well-accepted definition is that quality is the "totality of features and characteristics of a product or service that bear on its ability to satisfy given needs." This definition comes from the American Society for Quality—the professionals in the field of quality. We might refine the last part of this definition—the phrase "to satisfy given needs"—to mean "to conform to the stated or implied requirements of users and customers." That will make the definition easier to apply with existing recommendations on laboratory performance.

How Do We Measure "Unquality"?

The difficulty with quality is how to measure it. However, as laboratory scientists who regularly deal with characteristics such as accuracy and precision, we recognize that the measures of certain characteristics are related to the "lack of" the characteristics, e.g., inaccuracy and imprecision.

- Accuracy is determined by experiments that measure the inaccuracy, as described by the bias between a method and the correct or true values (ideally obtained from a reference quality method but also by comparison with existing field methods).
- Precision is determined by experiments that measure the imprecision, as described by the SD or CV of a method.

Likewise, we should understand that the measure of quality is unquality, *i.e.*, *the lack of conformance to requirements, which is universally described by defectives, defects, or defect rates*.

Imprecision, inaccuracy, and unquality! They're all determined by measuring the lack of agreement or the lack of conformance.

How Do We Define Good Quality?

The next step in making quality a quantitative characteristic is to define "good quality," *i.e.*, what is needed, required, or desired. We can speak of quality in quantitative terms only when we define how good something has to be. Whether the characteristic is turnaround time or accuracy, an essential step is to define the goal or requirement, e.g., an allowable time period of 60 minutes and an allowable error of 10 mg/dL.

- A test was reported in 47 minutes. Acceptable or defective?
- A test is correct within 12.4 mg/dL? Acceptable or defective?

To manage quality, to assess it, improve it, and ultimately assure that customer needs are satisfied, it is absolutely essential to define the requirement for good quality. Otherwise, quality is only a concept, does not have any practical meaning, and will not have any impact on operations and production.

What's Wrong With CMS's Equivalent QC?

Equivalent quality testing must have something to do with "testing that satisfies a defined requirement for quality." To assess

[1] U.S. Centers for Medicare & Medicaid Services (CMS). Medicare, Medicaid, and CLIA Programs: Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications. Final Rule. Fed Reg Jan. 24, 2003; 16:3640-3714. 714 (available at *http://www.phppo.cdc.gov/clia/pdf/CMS-2226-F.pdf*)

[2] Westgard, J.O. Internal Quality Control: Planning and Implementation. Ann Clin Biochem 2003; 40:593-611. Available on the Internet at *www.westgard.com/iqcpaper2003.html*.

[3] CMS State Operations Manual—Interpretative Guidelines: Appendix C. (*www.cms.gov/clia/appendc.asp*).

CLIA Allowable Total Errors For Common POC tests

- Blood gas pH should be correct within ±0.04 pH Units
- Blood gas pCO2 should be correct within ±5 mm Hg
- Calcium, total, should be correct within ± 1.0 mg/dL, which would be approximately ±10% for a normal calcium value or for an ionized calcium measurement
- Chloride should be correct within ± 5%
- Creatinine should be correct within ± 0.3 mg/dL or ± 15%, whichever is greater
- Glucose should be correct within ±6 mg/dL or ±10%, whichever is greater
- Hematrocrit should be correct within ± 6%
- Potassium should be correct within ±0.5 mmol/L
- Sodium should be correct within ±4 mmol/L
- Urea nitrogen should be correct within ± 2 mg/dL or ± 9%, whichever is greater

equivalency, the quality required must be defined. Equivalent to what? Equal to what?

For analytical performance, a quality requirement can be defined in terms of an "allowable total error," such as specified in the CLIA proficiency testing criteria for acceptable performance. CLIA itself defines allowable total errors for some 80 or so tests, therefore, the CLIA regulations include minimum requirements for quality for many of the commonly performed laboratory tests. Some examples are shown above for tests where EQC procedures are of most interest for POC applications, as discussed recently in *Clinical Laboratory News*[4].

One might think that CMS would make use of these PT criteria for defining equivalency, but it doesn't. How can you draw any conclusion about defective results and equivalent quality if you have never defined how good a test should be? How could you detect medically important errors if you haven't defined the requirement for good quality and designed the QC procedures to detect runs with bad quality? Can you assume that simply running controls will detect any and all errors? NOT TRUE! Running controls is not the same as assessing conformance to a defined quality requirement. *That requires doing the right QC right, but the CMS recommended evaluation processes don't.*

What's Wrong With Current Thinking?

Something is missing in current thinking about quality in health care today. Fundamental to the organization and operation of any business or service is the knowledge of the goals to be achieved and the requirements to be satisfied. For example, for test turnaround time, we may focus on providing 95% of our STAT testing results within one hour. For analytical quality, we may focus on providing 90% assurance that test results are correct within the CLIA allowable total errors. These goals will not be achieved without conscious efforts to plan the processes carefully, monitor performance objectively, and make improvements when necessary.

A problem in health care today is that quality goals are seldom defined or even acknowledged. Many quality programs, policies, and procedures are put in place that make it look like quality is being assessed and assured, even though the goals for good quality are never defined. How can we manage quality if we don't define how good it needs to be?

Health care organizations often attempt to get around this shortcoming by benchmarking performance against peer institutions. None of them have defined what good quality should be, only that they want to be as good as their competition. The result is that we often consider error rates up to 10% to be okay, 5% to be good, 1% to be excellent, and anything better than that to be fantastic.

Here's where current thinking is wrong. On the Sigma scale, six sigma performance is considered the goal for world-class quality and three sigma performance is considered the minimum acceptable for routine operation and production. A 10% error rate corresponds to 2.8 sigma performance, 5% to 3.2 sigma, and 1% to 3.8 sigma. Instead of error rates of 10% to 1%, we need to aim for 0.1% to 0.01% to 0.001% (4.6 sigma, 5.3 sigma, and 5.9 sigma, respectively). *We're off by orders of magnitude in our current thinking about acceptable error rates because we haven't defined objective quality goals and can only assess our performance against other organizations that are doing just as badly as ourselves.*

[4] Auxter-Parham, S. CLIA Interpretive Guidelines Debut on CMS Web Site: EQC Options Now Applicable to Broader Spectrum of Laboratory Testing. *Clin Lab News* 2004; 30:1, 8, 10.

Editor's note:
This discussion is adapted from Chapters 14 and 15 of the book CLIA Final Rules for Quality Systems: Quality Assessment Issues and Answers, by James O. Westgard, Sharon S. Ehrmeyer, and Teresa P. Darcy, published by Westgard QC Inc., Madison, WI, and available at the CLIA Final Rules workshop to be presented June 14, 2004, in Madison. For further information about the book and workshop, see www.westgard.com/workshops.htm.

Why Not Use Sigma Metrics To Evaluate Quality?

Six Sigma Quality Management[5] is slowly making inroads in health care organizations and offers a real hope for improving quality management thinking and processes. The reason is that Six Sigma focuses on defects, which in turn requires that goals for good quality be defined.

Six Sigma provides a universal methodology for measuring quality by counting the defects, determining the defect rate as "defects per million" (DPM) and then converting DPM to a sigma-metric (by use of standard tables available in any Six Sigma text). Benchmarking can be done using the sigma-metrics, which first account for quality goals and secondarily allow universal comparisons across processes, services, organizations, and industries.

When CMS says equivalent quality testing, is it asking for three sigma performance or six sigma performance? Will the CMS evaluation process allow laboratories to provide less than three sigma performance? No one knows, but it would be easy to find out. Just apply Six Sigma concepts to "equivalent quality testing," and evaluate method performance and the need for QC by calculating the sigma-metric for test performance. The evaluation protocols would then focus on estimating the precision (SD or CV) and accuracy (bias) of the method, rather than assessing control status. The protocols calling for 30-to-60 day evaluation would be sufficient to provide these estimates if control materials had known correct values or available peer values. It would even be okay to initially assume a bias of zero and just estimate the precision achieved within the laboratory.

The QC recommendation could then be related to the demonstrated performance of the method relative to a stated quality requirement for the test. At least six sigma performance should be required for all three options that allow reduction from daily to weekly or monthly QC. Any process with only three sigma performance needs controls at least every shift (and methods with less than three sigma performance should be replaced by better methods). Methods in-between might use daily controls. [For more details about the QC procedures that are appropriate for methods with different sigma performance metrics, see *www.westgard.com/cliafinalrule9.htm.*]

What Could Be Simpler?

If the goal is to provide equivalent quality testing, then CMS should modify the evaluation methodology to determine the sigma performance of the methods and relate the QC that is needed to the performance that is demonstrated. For instruments with procedural controls, only one testing protocol is needed to obtain 30 days of routine control data on two different materials. For methods without procedural controls, the 60-day protocol could be used. The CLIA criteria for acceptable performance in proficiency testing would be used as the quality goals. Sigma could be calculated for a bias of zero to make things as simple as possible. Then the recommendation for frequency of running QC could be related to the sigma-metric determined on the basis of the minimum quality required by CLIA and the actual performance observed in the laboratory.

Why Not Try It?

At the time of this writing, CMS is on record as saying it will evaluate data being collected in the field to assess the performance of certain instruments and methods. Let's hope it also applies the Sigma calculations as part of its evaluation before letting the State Operations Manual guidance on equivalent QC procedures loose in the field.

If CMS doesn't evaluate the use of Sigma metrics to assess equivalent quality, then laboratories must take responsibility to do this themselves before making any reductions in QC. Let's see if the methods are really world class and good enough to assure the safety of our patients. Let's make sure we have the data to prove our assumptions and the evidence to support our practices. ***Let's walk the talk about evidence-based medicine!***

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[5]Westgard, J.O. Six Sigma Quality Design and Control: Desirable Precision and Requisite QC for Laboratory Measurement Processes. Madison, WI: Westgard QC, Inc., 2001.

Quest To Pay $11.35 Million To Settle Fraud Allegations

Quest Diagnostics Inc. (Teterboro, NJ) will pay the federal government $11.35 million to settle allegations that one of its subsidiaries and two of its predecessor companies improperly billed Medicare for blood tests that weren't necessary.

The settlement, announced March 3, resolves allegations of a civil complaint brought against Quest and its subsidiary, Unilab Corp., by Kevin Spear, a former sales representative of Unilab. Under the False Claims Act whistleblower provisions, Spear will receive a 21% share of the settlement, or nearly $2.4 million, according to U.S. Attorney Christopher Christie.

The complaint alleged that between 1990 and 1997, labs owned by Unilab and Quest's predecessors—Damon Inc. and Metpath Inc.—submitted claims to Medicare for several medically unnecessary tests:

- apolipoproteins, included in test profiles and panels designed to test for coronary conditions;
- urine microscopy examinations; and
- calcium and parathormone tests, when calcium test results were elevated.

Spears also alleged that the labs automatically calculated free thyroxine indices (thyroid tests panel or T7 index) when those tests should have been included as part of defined organ disease test panels, and billed for unlisted test panels when more specific tests existed and could have been used for billing.

Quest, as successor to Metpath and Damon, and on behalf of Unilab, has denied any wrongdoing. Quest spokesman Gary Samuels maintains the labs did nothing wrong by putting the apolipoprotein test on a panel.

"We strongly disagree with the government's position and do not acknowledge any wrongdoing by the predecessor companies," he says. "However, we are settling this case to put behind us a historical matter that involved industry practices that were common in the early to mid-1990s."

CMS Issues Guidance For Exceptions To Specialty Hospital Moratorium

The Centers for Medicare & Medicaid Services (CMS) March 19 released long-awaited definitions and criteria governing referrals of patients to specialty hospitals under the new Medicare prescription drug law.

In a press release, CMS said it is implementing a moratorium on physician investment in and referrals to certain specialty hospitals. Under the moratorium, a doctor may not refer a patient to a specialty hospital in which he/she has an ownership or investment interest, and the hospital may not bill Medicare or any other entity for services provided as a result of a prohibited referral, the agency release said.

The definitions and criteria are contained in a program transmittal (Change Request 3036) to Medicare contractors. They cover the types of services provided by specialty hospitals; a list of hospitals not covered under the law; how to determine if a hospital is grandfathered under the specialty hospital provision; and information on seeking an advisory opinion on the issue from the Department of Health and Human Services Office of the Inspector General.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 included an 18-month moratorium on the "whole hospital exception" to the Stark physician self-referral law, which would allow a physician to refer patients to a specialty hospital in which he or she has an ownership interest, if the referring physician is authorized to perform services at the hospital and the ownership is in the hospital itself and not its subdivision.

However, a grandfathering clause provides an exception to the moratorium, which excludes physicians having an ownership in specialty hospitals for those hospitals existing or under development as of Nov. 18, 2003. The notice is available at *www.cms.hhs.gov/manuals/pm_trans/R620TN.pdf*.

Stark II Rule, *from p. 1*

legitimate business and financial arrangements, including those that enhance the emerging national health information infrastructure," said CMS Acting Administrator in releasing the rule. "Overall, there shouldn't be any additional burden on physicians trying to structure their business arrangements to comply with the law, and the regulations will not prevent doctors from continuing to provide high-quality health care services to their patients."

Peter Kazon

Peter Kazon, an attorney with Mintz Levin Cohn (Washington, D.C.) believes CMS has made a good attempt to clarify the self-referral prohibitions and to reduce, rather than increase, the regulatory burden. In particular, the agency's modifications to exceptions for percentage compensation arrangements should alleviate a lot of concerns, he tells *G-2 Compliance Report*.

The Phase I rule had excepted percentage compensation methodologies that use "fluctuating and indeterminate measures" and generally result in physician compensation that varies from one payment to the next. Difficulty in defining this type of payment caused CMS to postpone the effective date of that provision four times.

Under the Phase II rule, a percentage compensation arrangement may qualify for a physician compensation exception if the formula for calculating compensation is established with specificity before the services for which payment is being made are rendered, is objectively verifiable, and is not changed over the course of the agreement.

While CMS has made a good effort to address or clarify previous areas of confusion, the sheer size and complexity of the rule makes this a difficult task, notes Kazon. "The line may be bright in some places, but it's still pretty fuzzy in others," he says.

New Exceptions, Sanctions

Phase II of the self-referral prohibition addresses comments CMS received on Phase I, covers remaining statutory exceptions, and creates several new regulatory exceptions. Specifically, Phase II covers:

- general exceptions related to ownership or investment in publicly traded securities and mutual funds;
- additional exceptions pertinent only to ownership or investment prohibitions (hospitals in Puerto Rico, physician ownership of whole hospitals, and rural providers);
- exceptions related to other compensation arrangements (rental of space and equipment, bona fide employment relationships, personal services arrangements, remuneration unrelated to the provision of designated health services (DHS), physician recruitment, isolated transactions, certain group practice arrangements with hospitals, and payments physicians make for items and services).

Phase II also covers reporting requirements (changing periodic reporting to a requirement that entities that provide DHS make information about their financial relationships with physicians available upon the request of the Department of Health and Human Services), and sanctions.

Exception For Pap Tests

Phase I of the Stark rule created a regulatory exception for certain preventive screening tests, immunizations, and vaccines. In responding to comments on those exceptions, CMS noted that groups representing pathologists inquired about the treatment of Pap tests under the final regulations. One association was concerned that only screening Pap tests, but not diagnostic Pap tests, could qualify for the preventive screening tests exception.

Another association urged CMS not to except screening Pap tests because physicians would

CMS will consider comments on this interim final rule if they are received by June 24

then have financial incentives to send all screening tests to clinical laboratories with which they have financial relationships and to send all diagnostic tests to different laboratories, which might endanger continuity of care and the ability to compare the findings of screening and diagnostic Pap tests.

CMS says it can discern no reason to expand the exception to protect referrals for diagnostic Pap tests, saying it was not persuaded that diagnostic Paps are any different from other diagnostic clinical laboratory tests to which the statutory prohibition applies.

"We are unclear as to how the potential use of two different laboratories for two different clinical laboratory tests will compromise continuity of patient care," notes the agency. "Moreover, it is our understanding that screening and diagnostic Pap test results are not typically compared. We continue to believe that the exception as set forth in Phase I is sufficiently limited to pose no risk of program or patient abuse. Accordingly, we are not removing the codes for screening Pap tests from the list of codes identifying those services that may qualify for the exception."

Waived Tests

One commenter to the Phase I rules urged CMS to exclude from the definition of "clinical laboratory services" all lab tests for which the requirements of CLIA (Clinical Laboratory Improvement Amendments) have been waived. The commenter reasoned that CLIA-waived tests should not be consider designated health services under the Stark self-referral prohibitions because they are an integral part of patient care furnished in the physician office setting.

In response, CMS says it sees no reason to exclude CLIA-waived tests, noting that none of the criteria for defining waived tests reduce the risk of overutilization or other abuse. "To the extent waived tests are an integral part of patient care and are furnished during an office visit, they will likely fit in the in-office ancillary services exception," the agency writes.

Resources

- Stark II interim final rule (March 26, 2004): *www.gpoaccess.gov/fr/index.html*
- Peter Kazon: 202-661-8739

Credit Card Transactions Under HIPAA

Are credit card transactions covered under HIPAA (the Health Insurance Portability & Accountability Act)? If an individual (*i.e.*, a subscriber or patient) uses his or her credit or debit card to pay for premiums, deductibles, or co-payments, is that transaction covered by HIPAA, and must it be in a HIPAA compliant format?

According to the Centers for Medicare & Medicaid Services, the HIPAA standards must be used by "covered entities," which are health plans, health care clearinghouses, and health care providers who conduct any of the standard transactions electronically. The HIPAA standards do not apply to individuals, unless they are acting in some capacity on behalf of a covered entity, and not on behalf of themselves.

An individual, acting on behalf of himself or herself, is not a covered entity and is therefore not subject to the HIPAA standards. Transactions conducted between subscribers or patients and health plans or health care providers are not transactions for which the Department of Health and Human Services has adopted standards.

Therefore, if an individual uses a personal credit card or debit card to pay either a premium, copayment, or deductible to a health plan or health care provider, the individuals are not covered entities, they are not conducting covered transactions, and the transactions being conducted need not be in the standard format.

For more questions and answers about HIPPA administrative simplification regulations, go to *www.questions.cms.hhs.gov*.

CMS Commissioner Confirmed: The Senate early March 12 confirmed the nomination of Mark McClellan, M.D., Ph.D., as the new head of the Centers for Medicare & Medicaid Services. The Senate approval followed a March 11 hearing during which lawmakers grilled McClellan, the former head of the Food & Drug Administration, about his position on drug reimportation and the new Medicare law. At the hearing before the Senate Commerce, Science, and Transportation Committee, McClellan defended his opposition to drug reimportation, saying the FDA currently lacks the authority and resources to ensure the safety of drugs entering the country from Canada and other foreign sources. McClellan promised, however, to work with Congress on addressing the issue of how to safely import drugs.

GME Settlement: Montefiore Medical Center has agreed to pay $12 million to settle charges that it failed to repay Medicare for graduate medical education expenses. The federal government alleged that Medicare overpaid Montefiore by $5.6 million for GME in 1988. Although Montefiore was obligated to repay the funds once the reconciliation process for 1988 was complete, it improperly retained the funds and removed the outstanding $5.6 million liability from its internal books and records, thus effectively writing off the debt, according to the U.S. Attorney's Office for the Southern District of New York. The complaint also alleged that in 1997 and 1998, Montefiore failed to repay two installment payments of $2.1 million each owed to Medicare in connection with an overpayment received for the 1990 cost year.

TCS Struggle: Less than half of covered health care entities surveyed during the winter said they were compliant with the federal transaction and code sets rules, according to a new report by HIMSS/Phoenix Health Systems. Tom Grove, vice president of Phoenix, a consulting firm based in Montgomery Village, Md., told attendees at the Eighth Annual HIPAA Summit March 8 that the different groups surveyed—providers, payers, vendors, and clearinghouses—tend to blame each other for the failure to comply. Despite the blame game, most respondents have made progress, Grove said, with the percentage of providers who say they are compliant jumping from 18% in the fall survey to about 45% in the winter study. The TCS compliance date was Oct. 16, 2003, although lack of preparedness prompted CMS to launch a contingency plan to accept noncompliant claims.

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