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For Hospitals, Laboratories and Physician Practices

OIG Modifies Self-Disclosure Protocol
Integrity Agreements No Longer Required

Health care providers who resolve fraud matters using the Department of Health and Human Services Office of Inspector General's (HHS OIG) provider self-disclosure protocol generally will no longer be required to enter into corporate integrity agreements (CIAs).

In an open letter to providers released April 15, IG Daniel Levinson said that accurate and complete disclosure, timely responses to OIG requests for additional information, and accurate audits by disclosing providers all indicate "effective compliance measures" that rule out the need for CIAs or certification of compliance agreements in most cases.

"We believe that this presumption in favor of not requiring a compliance agreement appropriately recognizes the provider's commitment to integrity and also advances our goal of expediting the resolution of self-disclosures," Levinson said in the letter, which he released at the Health Care Compliance Association's 2008 Compliance Institute.

Levinson also said that his office seeks to speed the self-disclosure process and told providers they should "be in a position to complete an *Cont. on p. 9*

Court Dismisses Case Against Anti-Markup Rule

A federal district court May 5 vacated a preliminary injunction order blocking the Centers for Medicare & Medicaid Services from enforcing a provision in an anti-markup rule that would have made substantial changes to the way physicians bill for anatomic pathology diagnostic testing services (*Atlantic Urological Associates PA v. Leavitt*).

The U.S. District Court for the District of Columbia dismissed the lawsuit filed by three urology physician groups, a pathologist, and Uropath LLC, a company managing pathology laboratories, after finding they did not have the standing to challenge a final order issued in January 2008 that delayed the anti-markup rule for some providers.

The court determined that the plaintiffs did not demonstrate that the final order caused them an injury likely to be remedied by a final decision. In addition, because Uropath and its director do not participate in Medicare, the district court held that they had no standing to challenge the anti-markup rule. *Cont. on p. 2*

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Anti-Markup Rule, *from page 1*

Even if the plaintiffs had standing, however, the court determined that the physician groups and the managing company must channel their objections to the anti-markup rule, published by the Centers for Medicare & Medicaid Services (CMS) in November 2007, through the administrative process before going to court.

Final Anti-Markup Rule

The Department of Health and Human Services issued the final anti-markup rule, which prohibits physician groups from marking up the technical or professional components of pathology tests performed in their own laboratories if the labs are not in the same building as their practices, in November 2007.

The concern was that the testing services, often delivered through "pod" lab arrangements, used a perceived loophole in the Stark rule to profit from referrals to such labs. In January, a final order was issued to delay for one year the effective date of the anti-markup rule except for anatomic pathology diagnostic testing services furnished in a centralized building.

The district court found that the impact of the anti-markup rule and the final order was the same, even though the exact language was not identical.

"The anti-markup rule that issued in November 2007, after multi-year consideration and a full-blown administrative process, is what changed the Medicare billing landscape for pod laboratories, including those managed by Uropath," Judge Rosemary M. Collyer wrote. "The final order did nothing to alter that new landscape as it affected Uropath and its associated physician practices. Since the final order did not change anything for these plaintiffs, invalidating it would not afford them any relief."

Although the plaintiffs alleged that requiring them to assert an administrative challenge would drive them out of the diagnostic testing business, the court found that they overstated their case. The physician groups are not required to violate a regulation—and thus be subject to termination from participating in Medicare—to challenge the regulation, the court determined.

The plaintiffs can submit their claims for reimbursement, noting their disagreement with the application of the anti-markup rule and then pursue an administrative challenge, the court found. The physician groups' argument that the administrative review would be costly and time-consuming did not transform their claim into one where judicial review is essentially precluded, the court determined.

Accordingly, the court granted the HHS secretary's motion to dismiss and vacate the preliminary injunction. Further, the court denied as moot the secretary's motion for reconsideration of the order granting preliminary injunction.

Committee Recommends Additional Oversight of Genetic Tests

In its final report on gaps in the oversight of genetic testing, the Health and Human Services Secretary's Advisory Committee on Genetics, Health & Safety (SACGHS) has urged the Centers for Medicare & Medicaid Services (CMS) to increase proficiency testing in this rapidly expanding market. The panel also recommended that the Food & Drug Administration (FDA) expand its regulation to all lab tests, including lab-developed tests (LDTs).

In its main FDA recommendation related to clinical validity, SACGHS said the agency should "address all laboratory tests in a manner that takes advantage of its current experience in evaluating lab tests." In comments on the previous draft, lab and pathology groups argued

that the CMS CLIA (Clinical Laboratory Improvement Amendments) program should have the lead oversight role for genetic testing, in particular over LDTs, while the FDA should have a consultative role.

But SACGHS said the FDA should exercise this expanded role by consulting "with a multi-stakeholder public and private sector group to determine the criteria for risk stratification and for systematically applying them." The effort should involve, the commission said, a look at various regulatory models and data sources (for example, New York State, which has the most stringent genetic testing requirements among the states).

For CMS, the advisory commission recommended requiring proficiency testing (PT) for an expanded list of regulated analyses. For tests without PT products, labs should use alternative assessment methods, as required under current CLIA rules. The agency also was advised to develop training for inspectors of genetic testing labs. To pay for these initiatives, the CLIA program should be exempt from hiring constraints imposed by or on HHS, the panel noted.

"We chose to apply a number of our recommendations to laboratory tests generally. Nonetheless, we recognize that implementing an expansion of federal oversight of laboratory tests will require incremental steps and that, in this context, genetic tests should have the highest priority."
—SACGHS

The committee also recommended that HHS appoint and fund a lead agency to develop and maintain a mandatory, publicly available, Web-based registry for laboratory tests and support efforts to identify education or training deficiencies in each of these groups and support research and development of effective clinical support systems. In addition, FDA should prepare a guidance document articulating the scope of its regulation of clinical decision support systems, it advised.

"Although SACGHS was tasked to look at the oversight of genetic tests specifically, we concluded that the concerns associated with genetic testing generally do not differ from other complex laboratory tests," the committee wrote in a letter accompanying the report. "For this reason, and because it will be increasingly difficult to distinguish between genetic and other complex laboratory tests, we chose to apply a number of our recommendations to laboratory tests generally. Nonetheless, we recognize that implementing an expansion of federal oversight of laboratory tests will require incremental steps and that, in this context, genetic tests should have the highest priority."

ACLA Responds

The American Clinical Laboratory Association (ACLA) says it shares the committee's overarching goal to ensure that genetic technologies and test methodologies continue to keep pace with innovation and remain accessible to enhance and benefit individual personal health care. However, ACLA is concerned that the recommendations for regulatory oversight could have unintended consequences if interpreted to mean that FDA's Food Drug and Cosmetic Act requirements should be applied to all laboratory diagnostic tests.

"Any change in the regulatory oversight of these critically important tests has to be fully informed by the laboratory community to ensure interagency coordination, elimination of regulatory redundancies and duplications," said Alan Mertz, ACLA president, in a statement. "Although there are many similarities between FDA's and CLIA's regulatory requirements, there are clear redundancies and duplications that, if not coordinated, harmonized, and streamlined, will stifle innovation in this area."

ACLA has proposed a regulatory model that it says builds on interagency coordination, is consistent with principles of least burdensome, fills all the identified "regulatory gaps," avoids overlapping

and potentially conflicting requirements, and allows for a participatory approach that draws on the expertise of industry stakeholders, CMS, and FDA. The model also invokes public-private partnerships, thus avoiding significant new costs for the agencies, says ACLA.

A key aspect of the model is "an interagency Memorandum of Understanding defining a significant consultative role for the FDA while maintaining CMS and CLIA as the exclusive regulatory authority for lab test services." The FDA role would include defining a risk classification for in-vitro diagnostic multivariate index assays (IVDMIAs) and validity criteria.

The model also includes CLIA enhancements to identify any gaps in CLIA-quality programs and to resolve overlaps between CLIA-quality control rules and the FDA's quality system requirements, a mandatory IVDMIA test registry to standard data maintained by CMS or a public-private entity and accessible by the public, and independent review of clinical validity and use claims by CMS/FDA or by a third-party review funded through user fees.

CMS Mandates Switch to Single Medicare ABN by Sept. 1

The Centers for Medicare & Medicaid Services (CMS) has issued a revised Advanced Beneficiary Notice (ABN) that clinical laboratories and other providers billing Part B must use by no later than September 1 of this year.

The ABN alerts beneficiaries that Medicare is not likely to cover a particular item or service and they are financially liable if the claim is denied.

The revised single-page ABN (Form CMS-R-131) replaces the general-use ABN-G (CMS-R-131G) and the lab-specific ABN-L (CMS-R-131L) that CMS has required since 2003. CMS last year proposed combining the two into a single all-provider form.

Lab organizations have responded that the time period to make the switch to the new form is too short and want CMS to grant a longer extension—at least one year from the date that CMS issues final instructions to Medicare contractors on use of the revised ABN and what is required to make it valid.

Industry sources say there appears to be some "wiggle room" with CMS on the issue of allowing more time, but the agency is not likely to budge on one big change in the revised ABN: a new requirement that to be valid, the form must provide an estimated cost for the particular item/service in question.

CMS has said, in preliminary instructions accompanying the revised ABN, that "there is flexibility in listing individual or total cost. The revised ABN will not be considered valid absent a good-faith attempt to estimate cost. CMS will be flexible in defining what a good-faith estimate is, particularly in consideration of cases where the ordering and rendering providers may be different."

In a letter to CMS, the American Clinical Laboratory Association (ACLA) said its members "find this type of flexibility to be extremely problematic . . . particularly for clinical labs that are often the rendering provider and are forced to rely on the physician, or other ordering provider, to complete the ABN form appropriately.

Therefore, contractors need to be instructed clearly that an ABN is not invalidated merely because it does not contain the estimated cost . . . It is very important that there be clear standards for what is and what is not permissible, particularly with respect to cost. Otherwise, there will be repeated disputes about whether or not the lab or other provider can bill for the service."

COMPLIANCE PERSPECTIVES

[Editor's Note: This is the first of two articles on non-waived physician office labs.]

Where Have All the Non-Waived POLs Gone?

Dr. Sheila Dunn heads Quality America, Inc., an Asheville, North Carolina-based consulting firm that assists manufacturers and POLs in complying with regulatory requirements.

Before the Clinical Laboratory Improvement Amendments of 1988 (CLIA) took effect in 1992, significant numbers of primary care physician office laboratories (POLs) performed tests that are now classified as moderate and high complexity. At that time, no quality requirements existed for POLs and reimbursement for lab tests was generous in comparison to today, since managed care was virtually nonexistent and Medicare fee cuts and freezes had not yet begun.

Then, the CLIA regulation categorized all labs into four types, depending on the complexity of tests performed. CLIA requirements range from onerous for very complicated tests (termed high complexity) to virtually nonexistent for the simplest tests (CLIA-waived, see chart).

The only quality requirement for waived tests is to "follow the manufacturer's instructions," and anyone that can fog a mirror can run a CLIA-waived test or facility. POLs that hold a certificate of waiver pay only $150 every two years and are not routinely inspected by CMS.

Contrast this with non-waived labs, which are subject to stringent quality requirements, routine inspections, and proficiency testing. Moderate and high complexity labs also pay volume-dependent fees every two years that range from several hundred to several thousand dollars.

During the first few years of the CLIA program, the number of moderate and high complexity POLs numbered about 40,000[1] out of a total of 90,000 POLs.

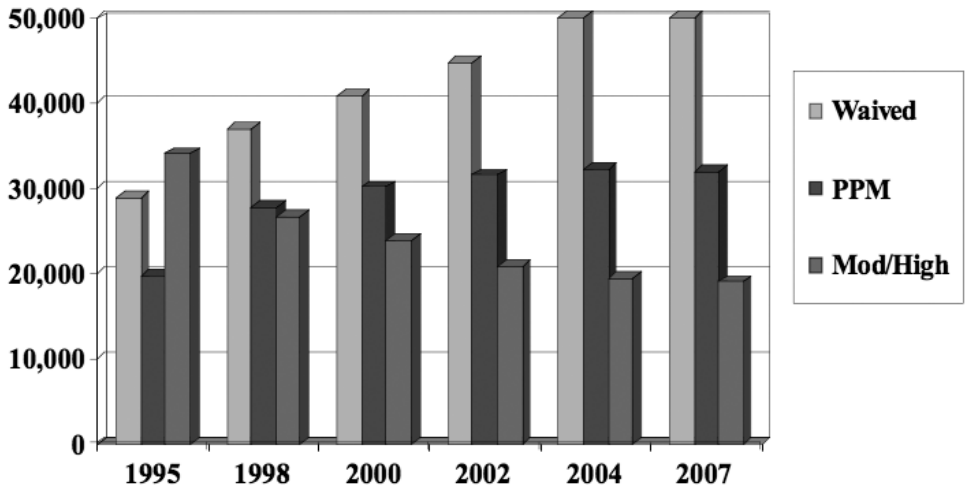
CLIA Requirements by Test Complexity

CLIA Category	*Test Examples*	*Fees**	*Routine Inspections*	*PT** QA****
Waived	Urine dip strips; fecal occult blood; kits for strep A, influenza, H. pylori, RSV, HIV, Gardnerella vaginalis, trichomonas and mono; urine pregnancy tests; urinalysis; blood chemistry; A1c; hematocrit and prothrombin time instruments	$150	No	No
PPMP***	Microscopic: wet preps, urine sediment exam, KOH preps, pinworm preps, semen detection	$200	No	No
Moderate Complexity	CBC, large chemistry, immunoassay analyzers	Varies by test volume	Yes	Yes
High Complexity	Cultures and sensitivities, esoteric chemistry tests, pathology, histology	Varies by test volume	Yes	Yes

*Assessed every other year; **Proficiency Testing; ***Provider Performed Microscopy Procedures; **** Quality Assessment

In the decade and a half since that time, and despite a 17 percent growth in total POLs to about 108,000, more than half of medical practices limit their testing menu to CLIA-waived tests and almost 80 percent do not undergo routine biennial CLIA inspections because they perform only waived or provider performed microscopy procedures (PPMP).

POLs By CLIA Complexity



POLs that continue to perform moderate and high complexity tests range from single-practitioner offices performing incubator-dependent throat cultures to 100+ provider group practices that use sophisticated instruments and employ a staff of medical technologists. But the trend toward simpler testing in POLs continues to accelerate, despite a general consensus that rapid, in-office test results often equate to better patient outcomes.

Why does the largest group of testing facilities in the United States eschew non-waived CLIA tests and limit their in-office testing capabilities to CLIA waived or PPMP tests?

Judy Yost, director, Division of Laboratory Services, Survey & Certification Group, CMS, maintains that the decline is primarily attributable to the growing number and types of waived tests: "If you look back historically at the most frequently performed tests in POLs, you'll see all are waived or PPMP except the CBC, and some of the components of a CBC are waived." Yost also cited the fact that third-party payment has decreased and that the marketplace is changing due to the competitive pricing of the giant reference labs.

But there is another equally important reason that moderately complex POLs are jumping ship, and so far, government agencies don't acknowledge it. But, the ever more onerous CLIA-quality requirements for moderate complexity tests may be the most significant factor.

The remainder of this article examines three reasons why POLs are increasingly becoming CLIA-waived laboratories:

1 CLIA fees combined with lab payment cuts make it impractical for all but the largest POLs to perform moderate or high complexity tests in their offices,

2 An increasing number of tests that physicians need to diagnose and manage outpatients are available in CLIA-waived versions, and

3 CMS's enforcement of additional CLIA-quality requirements causes financial hardship.

Financial Impact on Non-Waived POLs

CLIA Fees

CLIA fees are tolerable for large facilities, averaging a few cents per test, and they haven't increased significantly since the program's inception over 15 years ago. Since CLIA fees are based on the number of non-waived tests performed, though,

they have a huge impact on smaller volume labs, such as POLs. Granted, CLIA fees that average about $.25 per test are easier to swallow for POLs that perform mostly expensive tests, such as DNA probes for sexually transmitted diseases, which average about $20 per test.

But a POL performing mostly inexpensive tests, such as serum HCG or fecal occult blood tests, feels the sting of CLIA fees, especially when reimbursement barely covers the cost of the test. Add to this the occasional test where Medicare coverage doesn't apply or when the test is not separately payable from a managed health plan, and in these instances, POLs consume the CLIA fee and the cost per test.

Another factor contributing to the viability of non-waived POLs is the fiscal health of the overall practice.

Even if CLIA fees aren't a significant expense for some moderate and high complexity POLs, add on the cost for proficiency testing (PT), quality control (QC) materials, calibrators, and any nonreimbursed tests performed for QC and PT, and CLIA quickly becomes cost prohibitive for all but the largest POLs. Small practices that perform only two or three tests per day can't afford to perform non-waived tests in their offices.

POL Pay Cuts

Physicians that once maintained a profitable POL are now squeezed between rising costs for lab tests and stagnant Medicare reimbursements. Physician offices that see mostly Medicare patients can still eke out a profit from their POLs . . . if they're high-volume testers.

In order to achieve the economies of scale needed to profit from Medicare reimbursement for common moderate complexity tests such as CBCs, thyroid, and PSA assays on instruments typically sold into POLs, physicians must order five to 10 tests per day, and this volume is usually only achievable for physicians in groups of five or more. As recently as 2005, there were only about 5,000 group practices with more than six physicians,[2] and the movement toward larger groups isn't accelerating to the extent needed to achieve the test volume to perform moderate and high complexity testing. In fact, about one-third of all practicing physicians do so in solo and two-physician practices.[3]

Another factor contributing to the viability of non-waived POLs is the fiscal health of the overall practice. The average physician's net income has been declining by about 7 percent per year. To make matters worse, over the last several years, the general inflation rate was 21 percent, but Medicare payments rose only 13 percent and payments from private insurers rose even more slowly.[4]

This year, physicians earned a 0.5 percent increase in Medicare fees, but only through June 30, at which time, they're slated for a 10 percent fee cut . . . unless Congress steps in to save them.

Unlike internists and cardiologists that derive much of their revenue from the federal Medicare program, specialists such as OB/GYNs and pediatricians that rely primarily on managed health plans for reimbursement, typically perform fewer tests and rarely have a moderate or high complexity POL. Why? Because they risk not getting paid for various tests, since many managed care plans contractually require physicians to send some or all tests to mega-labs with who they've negotiated rock-bottom pricing.

In these cases, physicians can:

1. Perform the test and forego reimbursement, or
2. Send the test to the specified referral lab, or

1. *Centers for Medicaid and Medicare Services—CLIA Database Information—As of December 2007.*
2. Medical Economics, *Small practice evolution: New models go mainstream. May 2, 2008, medicaleconomics.modernmedicine.com/memag/article/articleDetail.jsp?id=512297.*
3. *ibid.*
4. *Center for Studying Health System Change, Washington, DC, April 24, 2008.*

3 Negotiate the managed care contract to include fair payment for tests performed in their POL.

Physician groups large enough to control local market share or with significant bargaining power can successfully negotiate to keep testing in-house, but many don't. After months of haggling with managed care executives who often display a "take it or leave it" attitude, physicians may secure test payments that barely allow them to break even. Several more rounds of negotiations are often needed to achieve a fee increase needed to make a profit.

For physician practices where lab testing is a small part of their business and those with a myriad maze of plans, this is all too much effort, but for those specialties that rely on real-time data to manage and treat patients, such as hematology, oncology, and endocrinology specialties, relinquishing their non-waived POL isn't an option. For the foreseeable future, these practices will continue to test, regardless of their bottom line, because first-rate patient care depends on it.

Growth opportunities for non-waived POLs also exist with the small but growing segment of medical practitioners who have opted out of all third-party payer programs, including Medicare, Medicaid, and managed care plan participation, preferring to instead provide medical care and POL services to those willing to pay out of pocket. Emulating the retail health care concept, these entrepreneurial physicians are including customized wellness programs and disease management programs, which rely heavily on testing.

CLIA-Waived Test Proliferation

The second factor causing physicians to flee from moderate and high complexity testing is an explosion in the amount and types of CLIA-waived tests.

Manufacturers are taking note of the diminishing number of POLs willing to invest in non-waived instruments and tests and are concentrating their product-development efforts for outpatient testing on tests that can achieve a CLIA-waived status. The market is now flooded with CLIA-waived tests which help caregivers better diagnose and manage patients with both chronic and acute conditions in the office setting.

The CLIA-waived test list is comprehensive enough now to enable physician practices to meet government screening guidelines for detecting and managing common chronic diseases such as diabetes using glucose, A1c, microalbumin, and creatinine, and heart disease using lipid and liver function panels, BNP, and INR. Several new compact chemistry instruments even include CLIA-waived basic and comprehensive metabolic chemistry panels.

CLIA-waived diagnostics also abound for detecting the most common infectious diseases likely to be seen in primary care settings, such as influenza, strep throat, H. pylori, mononucleosis, RSV, and HIV.

CLIA-waived POLs can also screen patients for drug abuse, using one of several types of simple test kits. Finally, in response to consumer and physician pressure, test kits for thyroid and menopause hormones recently gained the coveted CLIA-waived status.

One important test that physicians would like to perform in-house to meet Medicare's prostate cancer screening recommendations is PSA, which is not CLIA-waived. Complete blood counts (CBC), another key test for most physicians, is also not CLIA-waived, and the major reason for POLs to fall into the moderate complexity CLIA category.

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See the July-August issue of* G-2 Compliance Report *for a discussion of how CLIA-quality requirements present an emerging barrier for non-waived POLs.

Self-Disclosure Protocol, *from page 1*

investigation and damages assessment" within three months of the OIG accepting self-reported cases of fraud.

OIG Chief Counsel Lewis Morris said his staff also has made internal improvements to streamline the self-disclosure protocol and that the new time frame not only speeds the process but discourages providers from entering the self-disclosure protocol with too little information or with no intent to actually resolve the matter.

Since its release in 1998, the OIG's self-disclosure protocol has provided an avenue for health care providers and suppliers to report identified misconduct proactively. Assuming the written disclosure is accepted by the OIG as sufficient to meet the requirements of the protocol, the process allows resolution with the OIG, usually by means of a monetary settlement and often accompanied by a CIA.

"Although the 2008 open letter offers some favorable prospects to providers and suppliers to encourage use of the protocol, caution (and legal counsel) is still advised with respect to all disclosure of misconduct to avoid prejudicing future options."
—Foley & Lardner

Downsides of the protocol, says the law firm of Foley & Lardner, have included concerns by providers and suppliers about the extent of information required to secure acceptance under the protocol, the cautionary advice by the OIG that the matter may not end with the disclosure but may require referral to or involvement with the U.S. Department of Justice (DOJ), and an aversion by providers and suppliers to incur the costs and other burdens associated with a CIA.

IG Daniel Levinson, like his predecessors, has placed the protocol clearly at the center of the OIG's compliance and fraud enforcement activities, notes Foley & Lardner in a recent legal news alert. Since 1998, 379 disclosures have been accepted into the protocol, and 165 of those were resolved with monetary settlements totaling $118 million. There were 53 disclosures submitted during calendar year 2007.

"It must be underscored that the OIG does not accept all self-disclosures for processing under the protocol," says F&L. "Among other factors, the OIG must be convinced that the disclosure is offered in good faith, and the OIG generally will not accept a matter for the protocol already under investigation by the government."

Initial Submission Requirements

The open letter also addresses the OIG's expectations for providers' initial submissions, saying that such submissions should include sufficient details about the conduct being disclosed, a description of the providers' internal investigation, an estimate of damages to the federal government, and a statement of the laws violated.

In the past, a provider had two avenues for self-disclosure. First, it could disclose at the beginning of its own internal investigation by including only certain "basic information" in the submission. Second, the provider could disclose after it had completed its internal investigation and self-assessment by submitting more detailed information as part of its submission.

The 2008 open letter no longer permits providers to submit bare-bones disclosures limited to the basic information. "This heightened requirement appears to be driven by the OIG's concerns about disclosures not being made in good faith or not containing enough information for the OIG to determine whether to admit a provider or supplier to the protocol," says F&L.

Not for Simple Overpayments

The open letter clearly restates the OIG's long-standing policy that the self-disclosure protocol is not intended to resolve billing errors or overpayments. Such matters should be resolved directly by providers to "the appropriate claims-processing entity" such as a Medicare

payment contractor, Levinson said.

According to Morris, examples of matters providers should consider self-disclosing include systemic evaluation and management upcoding, Stark law violations, and alteration of medical records. The benefits of self-disclosing include the possibility of reduced damages and, generally, assurance that the OIG would not seek to exclude a provider from federal health programs, Morris said during the compliance conference.

However, he cautioned that the OIG still would seek some damages and could not shield providers from action by private entities or the DOJ. Levinson and Morris added, though, that they believe that self-disclosing could protect providers in many instances against qui tam actions.

Morris also said that the OIG did not seek to use the self-disclosure protocol as an avenue to investigate matters unrelated to those raised by providers, but noted that if obvious cases of fraud were brought to light during a disclosure, the OIG would not ignore them.

Cautions Remain

Although the protocol may offer significant comfort given possible alternatives, the decision whether to self-disclose (and where—to the OIG, the Medicare contractor, Medicaid, or the DOJ) has always been a decision that has required careful consideration, notes Foley & Lardner. The primary concerns with the protocol have been the lack of significant incentives to those self-disclosing, inconsistent or disparate treatment of self-disclosers, and the time often required to resolve a self-disclosure with the OIG.

"It should also be noted that recent positions taken by the DOJ suggest that the protocol may not be viewed as a "public disclosure" that would bar a qui tam recovery under the False Claims Act," says F&L in its alert. "Although the 2008 open letter offers some favorable prospects to providers and suppliers to encourage use of the protocol, caution (and legal counsel) is still advised with respect to all disclosure of misconduct to avoid prejudicing future options."

CMS Revisits Controversial Stark Provision

The Centers for Medicare & Medicaid Services (CMS) is revisiting a controversial provision it finalized in the Phase III Stark rule in 2007 that requires doctors with financial interests in physician organizations to "stand in the shoes" of those organizations for the purpose of complying with the physician self-referral law.

CMS has proposed new ways of analyzing physician arrangements to determine whether it is necessary for doctors to "stand in the shoes" of their physician organizations when determining Stark compliance. In cases where physicians meet three existing Stark exceptions—for employment services, personal services arrangements, or fair market value compensation—they would not be required to "stand in the shoes" of their physician organizations to determine compliance with the statute.

The physician self-referral provisions were included in the 1,200-page inpatient hospital prospective payment system proposed rule for fiscal year 2009, released April 14 by CMS. The hallmark of the rule was a proposed $4 billion increase in Medicare funding for hospitals next year. CMS will accept comments on the proposed rule until June 13, and the final rule is expected to be published by August 1.

The "stand in the shoes" provision appeared in the final Phase III Stark rule in September 2007 and stated that physicians referring designated health services (DHS) to an entity would be treated as "standing in the shoes" of their physician organizations when applying the Stark rules regarding direct and indirect compensation arrangements.

In November 2007, CMS delayed the provision for certain arrangements between academic medical centers and nonprofit integrated health systems, citing comments that commonly paid support payments and other financial arrangements between academic medical centers and integrated health systems to physician groups had not triggered Stark law application in the past and were not tied to specific items and services covered by the statute. The provision remained effective, though, for all other arrangements.

Sources say the proposals are a fresh look at "stand in the shoes" that, if finalized, could have important consequences for hospitals and physicians.

CMS said at the time of the delay that it would evaluate the provision as it applied to academic medical centers and integrated health systems. However, the IPPS proposed rule would apply beyond the initial concerns about the effect of the "stand in the shoes" provisions on academic medical centers and integrated health systems.

Sources say the proposals are a fresh look at "stand in the shoes" that, if finalized, could have important consequences for hospitals and physicians.

CMS said in the proposed IPPS rule that for compensation arrangements not covered by one of the three existing exceptions expressly cited, the physicians would "stand in the shoes" of their physician organizations for purposes of Stark analysis, even if the arrangements met other exceptions.

CMS said that the "stand in the shoes" analysis was necessary to address concerns that certain arrangements between DHS entities and physician organizations not covered by one of the three exceptions could be "particularly prone to abuse."

For example, CMS said that if a physician-employee of a group practice was compensated above fair market value for services and the physician's and the group practice's DHS referrals were covered by the in-office ancillary services exception, there remained risk to the Medicare program that the physician's above-fair market value compensation could reflect the volume or value of referrals.

CMS also said it was considering an approach under which only owners of physician organizations would "stand in the shoes" of the organization if they did not meet one of the three exceptions, even if the other physicians employed by the group did not meet one of the three exceptions.

Period of Disallowance

Among other Stark-related matters addressed in the proposed IPPS rule, CMS said it sought to clarify when the period of noncompliance ended for physician financial relationships that violated the Stark law.

For arrangements that were out of compliance for reasons not related to compensation (such as a missing signature on a contract), CMS proposed that the period of disallowance (defined as the period during which services could not be reimbursed by Medicare) would end when the arrangement was brought into compliance.

In cases where arrangements were not compliant for compensation-related reasons, CMS said the period of disallowance would end only when the excess compensation was returned and all other requirements in the exception on which the arrangement relied were met.

The proposed rule is available on the CMS Web site at *www.cms.hhs.gov/AcuteInpatientPPS/downloads/CMS-1390-P.pdf*.

Genetic Anti-Discrimination Bill: President Bush is expected to sign into law legislation protecting patients from discrimination based on their genetic information. The legislation, H.R. 493 as amended, cleared Congress May 1. The measure bars employers from using genetic information in decisions on hiring, firing, job placement, or promotion. It prohibits group health plans and other health insurers in both the group and the individual market from using genetic information to deny coverage or set premium rates and from requiring individuals to undergo genetic testing.

Pathology Direct Billing: Under a new law effective Oct. 1, 2008, the state of Maryland will require direct billing for anatomic pathology services, with limited exceptions. Generally, a clinical laboratory or physician practice that performed the service must bill the patient or responsible insurer or third-party payer for it directly. The lab or practice may bill for the service only if it performed or directly supervised the service and satisfied other stated requirements. The new law applies to any anatomic pathology service provided to a Maryland patient, even if the service is provided by a lab, physician, or group practice located in another state. Maryland is the 14th state to enact a direct billing statute applicable to anatomic pathology.

Appeals Decisions: A proposed rule to let the Health and Human Services (HHS) secretary overrule decisions by the HHS Departmental Appeals Board (DAB) has drawn opposition from stakeholders calling for withdrawal and prompted bills in Congress to delay any implementation of the rule. The HHS proposal, issued Dec. 28, 2007, would amend DAB regulations to permit the HHS secretary to modify or overturn DAB decisions and to revise all current Medicare administrative appeals processes handled by the DAB "to ensure that the final administrative decision of the Department reflects the considered opinion of the Secretary." Sen. Amy Klobuchar (D-Minn.) and Rep. Keith Ellision (D-Minn.) introduced legislation April 10 calling for a one-year moratorium on implementation of the "controversial" proposed rule. A moratorium provision for the proposed rule was also included in a bill introduced April 7 by Sen. John D. Rockefeller IV (D-W.Va.), the Economic Recovery in Health Care Act (S. 2819).

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