G-2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

Lab Groups Support Additional Efforts to End Incentives for Ordering Tests

Groups representing pathologists and clinical laboratories are urging the Centers for Medicare and Medicaid Services (CMS) to do more to limit the ability of physician groups to bill for pathology services under the auspices of an exception to the Stark law.

In comments on the 2009 Medicare physician fee schedule (MPFS) proposed rule, submitted August 28, the American Clinical Laboratory Association (ACLA) notes that despite efforts to stop physicians from profiting from their referrals, abusive arrangements have continued to proliferate.

In November 2007, CMS finalized an anti-markup rule, essentially prohibiting 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. 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 2008, CMS issued an order delaying for one year the effective date of the anti-markup rule except for anatomic pathology diagnostic testing services furnished in a centralized building.

Continued on page 9

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Inside this issue

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Beware of Proficiency Testing Referral, Labs Warned

Clinical laboratories will face severe consequences if they refer proficiency testing (PT) specimens to other laboratories, Judy Yost, director of the Division of Laboratory Services at the Centers for Medicare and Medicaid Services (CMS), warned attendees of Washington G-2 Reports' 26th Annual Lab Institute, held in Arlington, Va., September 17-19.

There have been a number of recent cases where labs have referred PT specimens to other labs in violation of the Clinical Laboratory Improvement Amendments (CLIA), Yost explained. Although referrals are sometimes unintentional, the penalties are just as severe, she said.

The penalties for PT referral include loss of the CLIA certificate for one year, exclusion from Medicare and Medicaid, and the potential loss of a lab director's

Continued on page 2

Judy Yost

Proficiency Testing Referral, *from page 1*

authority for two years. CMS has prevailed in all appeals to date, Yost noted.

The CLIA regulations specifically state that a laboratory cannot refer any PT material for testing to another laboratory. If your lab typically performs patient sample testing to a certain point and then sends out some of the sample for additional testing, you must not do so with PT samples. An example of this, according to the College of American Pathologists (CAP), is a lab that does Gram stains under one CLIA number and then sends out the sample for culturing to a laboratory with a different CLIA number.

Yost warned labs not to communicate with another lab about PT results until after the PT program deadline and results are received. She advises labs to have robust policies and procedures regarding proficiency testing to avoid the perception of cheating.

Scenarios Resulting in Sanctions

The College of American Pathologists (CAP) provides examples of several scenarios involving PT referrals that have resulted in sanctions for labs.

Scenario One

Sister Labs with Different CLIA Numbers

A laboratory director works with two laboratories, one a hospital (Lab A) and the other an esoteric lab (Lab B). Both are under the same ownership and operations between the two are standardized. However, the labs have different CLIA numbers. Component tests are performed at different labs. For example, total serum protein is performed at Lab A, protein electrophoresis is performed at Lab B.

How to Treat a Patient Sample

Both results may be used to quantify each protein factor.

How to Treat a PT Sample

Laboratory A would need to be enrolled in a proficiency testing product for total protein as that is the testing the laboratory performs. Laboratory B would need to identify a cost-effective means to perform a total protein if needed for reporting out the electrophoresis results.

PT samples cannot be shared between Laboratory A and Laboratory B. Each site must be enrolled separately based on location.

Scenario Two

Reflex and Confirmatory Testing

How to Treat a Patient Sample

If a laboratory does not perform the confirmatory or reflex portion of a test battery or other testing, the sample would typically be sent to a different lab for that testing.

How to Treat a PT Sample

A laboratory should report PT results for the testing that is done in that laboratory. If the lab does not do the confirmatory or reflex testing, then the lab should refer to the PT providers' kit instructions on how to record a result for a test not performed in this laboratory as appropriate. The laboratory is prohibited from sending the proficiency testing sample outside of the participating laboratory.

All results and signatures must be confined to the site with the same CLIA number in which the PT sample was received. That lab must complete the PT results forms using "not on test menu."

New ABN Mandatory as of March 1, 2009
Reasonable Cost Estimate Required

Tony Culotta

Clinical laboratories must provide a reasonable cost estimate of services to be provided when completing the new single-page Advance Beneficiary Notice (ABN) that will be required beginning March 1, 2009, Tony Culotta, director of the Medicare Enrollment and Appeals Group at the Centers for Medicare and Medicaid Services (CMS), told Lab Institute participants September 18.

The cost estimate must be within $100 or 25 percent of the actual cost, whichever is greater, said Culotta. Labs may also use a range, bundle multiple items/services that are routinely grouped, or enter average daily cost. For example, a single cost estimate can be given for a group of laboratory tests, such as a basic metabolic panel (BMP).

The revised ABN includes a new beneficiary option under which an individual may choose to receive an item or services and pay for it out of pocket, rather than have a claim submitted to Medicare. Previously, providers had just two options: get the service and pay if Medicare denies it or don't get the service.

Providers may also preprint a menu of items or services in Blank (D) and include a cost estimate alongside each item or service. If a situation involves the possibility of additional tests or procedures (such as in reflex testing) and the costs associated with such tests cannot be reasonably estimated, the lab may enter the initial cost estimate and indicate the possibility of further testing.

On a case-specific basis (that is, not as a routine practice), it is permissible to exclude the cost of follow-up testing or note in Blank (F) that a cost estimate is not available.

While CMS recognizes that providing cost estimates can sometimes be difficult, Culotta noted that it is only fair to the beneficiaries. "If it were your mother getting the test, you would want her to know how much she might have to pay," he said. At the same time, Culotta explained that CMS would try to be as flexible as possible in implementing this provision.

The new ABN (CMS-R-131) combined the general ABN (ABN-G) and the laboratory ABN (ABN-L) into a single notice, although CMS has approved a lab-customized version that has a slightly different layout. Instead of the headers running across the top of the page, the lab-customized version has them stacked in a column running down the left side of the page.

The ABN alerts beneficiaries that Medicare is not likely to cover a particular item or service and that they are financially liable if a claim is denied. Without a valid ABN, the provider cannot bill the beneficiary when a claim is denied. CMS had intended to make use of the new ABN mandatory as of September 1 of this year, but final instructions were not completed in time.

The revised ABN includes a new beneficiary option under which an individual may choose to receive an item or services and pay for it out of pocket, rather than have a claim submitted to Medicare. Previously, providers had just two options: get the service and pay if Medicare denies it or don't get the service.

Clinical laboratories may tailor the new single-page Advance Beneficiary Notice (ABN) to promote efficiency and ensure clarity for beneficiaries. As long as the required language and general formatting of the ABN are not altered, labs may add preprinted company logos with the name, address, and telephone number at the top of the notice.

More information on the revised ABN is available online at *www.cms/hhs.gov/bni*.

HHS Proposes Adoption of ICD-10 Code Sets, Updated Election Transaction Standards

The Department of Health and Human Services (HHS) on August 15 announced a long-awaited proposed regulation that would replace the ICD-9-CM code sets now used to report health care diagnoses and procedures with greatly expanded ICD-10 code sets, effective Oct. 1, 2011.

In a separate regulation, HHS has proposed adopting the updated X12 standard, Version 5010, and the National Council for Prescription Drug Programs standard, Version D.0, for electronic transactions, such as health care claims. Version 5010 is essential to use of the ICD-10 codes.

In 2000, the ICD-9-CM code sets were adopted for use in the administrative transactions by both the public and private sectors to report diagnoses and inpatient hospital procedures. Covered entities required to use the ICD-9-CM code sets include health plans, health care clearinghouses, and health care providers who transmit any electronic health information in connection with a transaction for which a standard has been adopted by HHS.

Comments on both proposals are due by 5 p.m. Eastern time Oct. 21, 2008.

Developed almost 30 years ago, ICD-9 is now widely viewed as outdated because of its limited ability to accommodate new procedures and diagnoses. ICD-9 contains only 17,000 codes and is expected to start running out of available codes next year. By contrast, the ICD-10 code sets contain more than 155,000 codes and accommodate a host of new diagnoses and procedures. The additional codes will help to enable the implementation of electronic health records because they will provide more detail in the electronic transactions. This granularity will also improve efficiencies by helping to identify specific health conditions such as Methicillin-resistant Staphylococcus aureus (MRSA) and other conditions.

Updated versions of current HIPAA electronic transaction standards require the use of the ICD-10 code sets for claims, remittance advice, eligibility inquiries, referral authorization, and other widely used transactions. The currently adopted standard, Version 4010/4010A1 of the Accredited Standards Committee (ASC) X12 group, cannot accommodate the much larger ICD-10 code sets.

Under the updated transaction standards proposed rule, compliance with Version 5010 (health care transactions) and Version D.0 (pharmacy claims) would be required by April 1, 2010. Both regulations may be viewed at *www.cms.hhs.gov/TransactionCodeSetsStands/02_TransactionsandCodeSetsRegulations.asp#TopOfPage*.

PQRI Not Ready for Public Reporting, Says CAP

It is premature to report performance data from the Physician Quality Reporting Initiative (PQRI) in a public reporting system, the College of American Pathologists (CAP) said in recent comments to the Centers for Medicare and Medicaid Services (CMS).

In its 2009 proposed Medicare Physician Fee Schedule (MPFS) rule, published in July, CMS requested feedback on how PQRI data may be used by physicians, consumers, and other stakeholders in a public reporting system.

In comments submitted August 28, CAP said it is premature to report PQRI data for several reasons, including the inability of independent laboratories to participate until at least 2010.

Further, pathologists employed by independent laboratories have been told by carriers that their computer systems cannot accept the necessary quality data from the labs required for reporting, a glitch which CMS reports was not a policy decision, but an oversight. CAP is working with CMS to resolve this issue.

COMPLIANCE PERSPECTIVES

CMS Finalizes Changes to Stark Rules

Editor's Note: This is the second of two articles on final changes to the Stark rules.

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The Centers for Medicare and Medicaid Services (CMS) on August 19 announced a number of revisions to the Stark rules prohibiting physician self-referrals. In last month's issue of *G-2 Compliance Report*, we discussed changes to percentage-based compensation, per-click leasing arrangements, and "under arrangements." In this month's issue, we continue the discussion of other significant changes.

'Stand in the Shoes'

In the 2009 final Hospital Inpatient Prospective Payment Systems (IPPS) rule, CMS simplifies the "stand in the shoes" (SITS) doctrine for physicians and their physician organizations and addresses concerns that academic medical centers (AMCs) and integrated, tax-exempt health care delivery systems (IDSs) have raised.[1] Under the current SITS doctrine, a physician is deemed to stand in the shoes of his or her physician organization, which means any compensation arrangement between the physician organization and an entity offering designated health services (DHS) must satisfy a Stark exception for direct compensation arrangements.[2]

The new SITS rules provide that only a physician who has an ownership or investment interest in his or her physician organization is deemed to stand in the shoes of the organization. Other physicians (i.e., employees, independent contractors, and physicians whose ownership or investment interest is titular only) are permitted to stand in the shoes of their physician organizations but are not required to do so.

CMS highlights in the preamble that it is providing nonowner physicians this option, but since it is more difficult to comply with the Stark exceptions for direct compensation arrangements than it is to comply with the indirect compensation exception, in most cases a physician would not choose to stand in the shoes of his or her physician organization.[3] As a result, the flexibility afforded by this option is of little practical benefit.

[1] *In the 2009 final IPPS rule, CMS does not finalize the "entity" version of SITS that would have considered a DHS entity to stand in the shoes of an organization in which it had a 100 percent ownership interest, commenting that "a measured approach to the overall 'stand in the shoes' regulatory scheme is warranted and appropriate." CMS nonetheless warns that "arrangements that attempt to evade restrictions on payments for referrals by using interposed organizations are highly suspect under the fraud and abuse laws" and "could violate the physician self-referral law, constitute unlawful circumvention schemes, or violate the anti-kickback statute."*

[2] *Prior to SITS, the relationship between a DHS entity and a physician who contracted with the DHS entity through his or her practice was analyzed as an indirect compensation arrangement under Stark. Many of these arrangements either fell outside of Stark's indirect compensation arrangement definition (and did not need to fit within a Stark exception at all) or could easily be structured to fit within the Stark exception for indirect compensation arrangements (which imposes fewer requirements than most of the direct compensation exceptions).*

[3] *Rather than rely on an arrangement falling outside the definition of an indirect compensation arrangement, a more conservative physician may elect to stand in the shoes of his or her physician organization for the added certainty that compliance with a direct compensation exception affords.*

The requirement in the new SITS rules that an owner-physician be deemed to stand in the shoes of his or her physician organization does not apply:

- to an arrangement that satisfies the requirements of the Stark exception for AMCs;
- to a physician whose ownership or investment is titular only (i.e., if the interest excludes the ability or right to receive any of the financial benefits of ownership or investment); or
- during the original term or the then-current renewal term of an arrangement that satisfied the requirements of the indirect compensation arrangements exception as of Sept. 5, 2007 (i.e., indirect compensation arrangements that are currently grandfathered under the Stark II Phase III final rule's SITS provisions).

This last exception continues the grandfathering of certain indirect compensation arrangements and lets those agreements continue to avoid SITS altogether until the expiration of their current term (assuming that term has been in effect since at least Sept. 5, 2007). Grandfathered agreements that were to be renewed prior to Oct. 1, 2008, will need to comply with the current SITS rules, in which all physicians in a physician organization stand in the shoes of the physician organization, while agreements that are to be renewed after that date will need to comply with the new, more flexible SITS rules.

The new SITS rules should be welcome news for AMCs and IDSs. Arrangements that comply with the AMC exception now are explicitly exempted from the rules. Furthermore, the many AMCs and IDSs that currently rely on the indirect compensation arrangements provisions in the Phase II regulations will be able to continue to do so under the new rules because their physicians will not be required to stand in the shoes of their faculty practice plans or other physician organizations.

For other physician organizations that are not owned by referring physicians, the news is also good. These organizations will not be required to have any physicians stand in their shoes, which means their arrangements with DHS entities can be structured either to fall outside the definition of an indirect compensation arrangement under Stark or to satisfy the requirements of the indirect compensation arrangements exception. As a result, these arrangements will not be required to comply with the one-year term or "set-in-advance" requirements found in many direct compensation exceptions and will regain the flexibility they had under the Stark II Phase II regulations.

Amendments to Agreements

In response to a comment in the discussion of the stand in the shoes doctrine, CMS indicates that it has reconsidered its position, taken in the Stark II Phase III final rule, that a multiyear agreement for rental of office space or a personal service arrangement may not be amended during its term without violating the Stark exceptions' requirement that the compensation under the arrangement be "set in advance" for the term of the agreement. This position was widely criticized as exalting form over substance and imposing additional transaction costs on the parties to these agreements by requiring them to terminate an existing agreement and enter into a new agreement on modified terms rather than simply amending the agreement.

In a welcome change, CMS states that in light of the revisions it is finalizing with respect to percentage-based and per-click compensation formulae, it believes that it is able to interpret the "set in advance" requirement to permit an agreement to be amended as long as the following criteria are met:

- All of the requirements of an applicable exception are satisfied;
- The amended rental charges or compensation (or the compensation for-

mula) is determined before the amendment is implemented, and the formula is sufficiently detailed that it can be verified objectively;

- The formula for amended rental charges does not take into account the volume or value of referrals or other business generated by the referring physician; and
- The amended rental charges or compensation (or the compensation formula) remain in place for at least one year from the date of the amendment.[4]

CMS also states that this rule applies to all of the Stark exceptions for compensation arrangements that include a one-year term requirement for satisfying the exception. Note that this change is not a regulation; rather, it is CMS's current interpretation of Stark's "set in advance" requirement.

'Period of Disallowance'

Earlier this year, CMS proposed rules to address the period for which a physician may not refer DHS to an entity and for which the entity may not bill Medicare because the financial relationship between the referring physician and the entity fails to satisfy all of the requirements of a Stark exception (referred to as the "period of disallowance"). These rules have now been finalized, largely in the form of the proposal, and essentially provide that from the time that the financial relationship fails to satisfy a Stark exception to a period no later than the date that the financial relationship satisfies all of the requirements of a Stark exception,[5] a physician may not refer DHS to the entity and the entity may not bill Medicare.

CMS was careful to point out that the rule creates an "outside date" and that parties are free to take the position (presumably if questioned in the context of an enforcement action) that the period of disallowance ended sooner on the theory that the financial relationship ended earlier. However, CMS cautioned that the beginning and end dates of the financial relationship for purposes of the disallowance period do not necessarily coincide with the term of the parties' written agreement.

In practice, CMS provided the following example to illustrate how the period of disallowance would apply: Where a party (e.g., a physician) has paid rent in an amount below the fair market value for each of the months one through six under a lease, unless and until the lessee has paid the lessor (e.g., a hospital) the compensation to bring the rental payments for months one through six up to fair market value, the period of disallowance would apply. In other words, the physician lessee may not refer DHS to the hospital and the hospital may not bill Medicare until the physician pays the hospital the amounts owed for months one through six, even if the lease expires prior to such payment.

In the course of describing this new final rule, CMS clarifies its view that simply correcting a financial relationship that falls outside the applicable Stark exception due to technical noncompliance is not adequate. CMS clearly states in the commentary that parties shall not have the right to "cure" defects and that "all of the requirements of the [Stark] exception must be met at the time the referral is made … The statute does not contemplate that parties have the right to back-date arrangements, return compensation, or otherwise attempt to turn back the clock so as to bring arrangements into compliance retroactively."

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[4] *By this language, CMS presumably means that the amended compensation may not be changed again for at least one year from the date of amendment rather than requiring that the compensation (and the agreement itself) remain in place for at least a year after the amendment date.*

[5] *When the noncompliance is due to the payment of excess or insufficient compensation, in addition to satisfying all of the requirements of an exception, a party that has received excess compensation must return all of the excess and the party that has underpaid compensation must pay all of the additional compensation required.*

Additionally, while describing the strict compliance that is expected of providers, CMS noted that the financial impact of the nonconformance is irrelevant and emphasized that since Stark is a strict liability statute, CMS is concerned with any violation by (i) a physician referring DHS to an entity, or (ii) an entity billing Medicare for DHS when the financial relationship between the physician and the entity does not comply with a Stark exception.

Alternative Method for Compliance

Following a discussion regarding the period of disallowance in which CMS was careful to emphasize the inflexibility of the Stark law and its limited authority to make exceptions and avoid extreme results, CMS adopted a limited amendment to existing exceptions. The amendment permits payments to an entity that fully complied with an applicable Stark exception, except with respect to a signature requirement, if (i) the failure to comply with the signature requirement was inadvertent and the entity rectifies the failure to comply within 90 days after the commencement of the financial relationship (without regard to whether referrals have occurred or compensation paid), or (ii) the failure to comply with the signature requirement was not inadvertent and the entity rectifies the failure within 30 days after the commencement of the financial relationship. This exception may be used by an entity only once every three years with respect to the same referring physician.

Disclosure of Financial Relationships Report

The *Disclosure of Financial Relationships Report (DFRR)* will require up to 500 general and specialty hospitals to provide CMS detailed information about their financial relationships with physicians and copies of relevant documents. Originally proposed in a Paperwork Reduction Act (PRA) filing in 2007, the *DFRR* was withdrawn, revised, and resubmitted to the Office of Management and Budget for review and approval. It will then be published in the *Federal Register* and will be subject to a 30-day comment period. Hospitals that receive the *DFRR* will have 60 days to respond.

In the 2009 IPPS final rule, CMS provides some updated information about the *DFRR*:

- CMS's estimate of the average number of hours to complete the *DFRR* has been increased from 31 to 100 hours, and the projected costs per hospital to complete the *DFRR* have increased from $1,550 to $4,080.
- CMS may decide to decrease (but not increase) the number of hospitals that will receive the *DFRR*.
- CMS notes that although it has the authority to impose civil monetary penalties of up to $10,000 per day for late submissions, it is using the 2009 Final Rule to inform the public that it will issue a letter to any hospital that does not return a completed *DFRR*, inquiring as to why the hospital failed to do so, before imposing such penalties.
- CMS reiterated that it will give hospitals extensions of time to complete the *DFRR* submission "upon a demonstration of good cause."
- The *DFRR* will be a one-time collection effort. CMS may propose future rulemaking to use the *DFRR* or some other instrument as a periodic collection instrument.
- CMS will allow hospitals that have uniform rental, recruitment, or personal services agreements to submit only one copy of each such agreement, instead of having to provide signed copies of each individual agreement. To be "uniform," all of the material contract terms must be the same.

We continue to believe that for most hospitals, responding to the *DFRR* will take much longer than CMS estimates.

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Incentives, *from page 1*

In this year's proposed MPFS rule for 2009, issued in July, CMS proposes to modify the anti-markup provisions announced last year, to clarify them, and to avoid unintended consequences.

CMS has offered two alternative approaches for revising the current anti-markup provisions.

Under the "single group approach," the anti-markup provision would apply in all cases where the professional component (PC) and the technical component (TC) of diagnostic testing services were purchased from an outside supplier or where the services were performed or supervised by a physician who does not share a practice with the billing physician or physician organization.

CMS would consider a physician employed by or under contract with a single physician or physician organization to share a practice for the purpose of determining whether anti-markup provisions would apply.

The second option proposed by CMS is to maintain the current regulation text and its "site-of-service" approach. Under this alternative, CMS will continue to apply the anti-markup provisions to the TC and PC of nonpurchased tests that are performed outside the "office of the billing physician or other supplier." As part of this approach, CMS proposes to clarify some of the key terms that arise in this area.

Both ACLA and the College of American Pathologists (CAP) support the first option, although they caution that the rule should be drafted in a way that does not have detrimental effect on longstanding and legitimate pathology groups and other physician organizations.

Specifically, CAP says it is concerned that by "defining a physician who does not share a practice as the dividing line, a pathologist who provides 99 percent of the pathologist services to a pathology practice and 1 percent of the pathologist's services to an outside practice may be subject to the anti-markup provisions in all settings.

"While pathologists in general do not make referrals for the lab tests that they perform, they do occasionally make a determination on the need for a special stain or other detail in the performance of a test that ultimately is ordered by an outside physician."

Both ACLA and the College of American Pathologists support the first option, although they caution that the rule should be drafted in a way that does not have detrimental effect on longstanding and legitimate pathology groups and other physician organizations.

To address this concern, CAP urges CMS to clarify that the anti-markup rule does not apply to a pathology practice where the initial order for the underlying tests is made by a physician not affiliated with the pathology practice, without regard to any determinations that the pathology group might make for special stains or other professional judgments on how to best perform a test that was ordered by an outside physician.

CAP also urges CMS to provide an exception for single specialty pathology physician groups and independent laboratories, which generally do not order tests and utilize pathology/laboratory CPT codes for at least 75 percent of their billings. In addition, CAP asks CMS to exclude anatomic pathology from the in-office services exception to the physician self-referral regulations.

DOJ Issues New Policy on Privilege Waivers, Guidance on Corporate Compliance Programs

Mark Filip

The Department of Justice August 28 announced revisions to its corporate charging guidelines that will have particular relevance for health care organizations being investigated by federal prosecutors.

The hallmark of the revised guidance is a new DOJ policy that prosecutors are no longer to consider whether corporations waived attorney-client privilege or work product protection when granting credit for cooperating in an investigation.

The guidance also discusses the importance of corporate compliance programs in investigators' decisions to prosecute cases. The revisions attempt to address complaints that its previous policy unfairly forced corporations to waive the attorney-client privilege.

The new guidance and policy, issued by Deputy Attorney General Mark R. Filip, replaces guidance issued in 2006 by then-Deputy AG Paul J. McNulty. The DOJ also said that the revised guidance and policies on federal prosecution of business organizations would for the first time be incorporated into the *United States Attorneys Manual*, "which is binding on all federal prosecutors in the Department of Justice."

Corporate Compliance Programs

Filip noted in the guidance that the DOJ encourages corporations to develop compliance programs intended to detect wrongdoing and provide an avenue for reporting criminal activity to the government. However, the guidance is clear that the DOJ does not consider the mere presence of a corporate compliance program sufficient for freeing an organization from criminal liability.

Nevertheless, the guidance directs prosecutors to evaluate whether a corporation's compliance program is effective in preventing and detecting criminal activity and whether corporate leaders are enforcing the program or, rather, undermining compliance efforts by encouraging misconduct by employees in order to achieve business objectives.

Filip said in the guidance that the DOJ has no "formulaic requirements" for an effective corporate compliance program. As such, the guidance noted that the Department of Health and Human Services and other federal agencies have "considerable experience" with compliance programs and that prosecutors could seek assistance from HHS and others in evaluating whether compliance programs are indeed effective.

Attorney-Client Privilege

The new guidance requires that federal prosecutors no longer consider whether a corporation waives confidential privileges when deciding whether to provide leniency in criminal charging decisions, Filip said in outlining the new policy at a press conference.

Instead, prosecutors will be instructed to measure a corporation's cooperation by the extent to which the corporation voluntarily discloses "relevant facts and evidence," Filip said, speaking at the New York Stock Exchange.

"Corporations that timely disclose relevant facts may receive due credit for cooperation, regardless of whether they waive attorney-client or work product protection," Filip said. "Corporations that do not disclose relevant facts typically may not receive such credit, just like any other defendant."

Voluntary Disclosure

Filip acknowledged that some federal agencies have self-disclosure policies that grant reduced sanctions and even amnesty in some cases where criminal

actions are voluntarily disclosed and said that the DOJ encouraged organizations to develop compliance program policies for conducting internal investigations and disclosing relevant facts to authorities.

The HHS OIG has a self-disclosure policy that generally exempts health care providers from corporate integrity agreements, but not necessarily monetary penalties, for misconduct that is voluntarily disclosed to the agency.

The guidance directs prosecutors to evaluate whether a corporation's compliance program is effective in preventing and detecting criminal activity and whether corporate leaders are enforcing the program or, rather, undermining compliance efforts by encouraging misconduct by employees in order to achieve business objectives.

While the guidance states that prosecutors can consider a corporation's voluntary disclosure—even in the absence of a formal compliance program—when evaluating an organization's and its management's compliance efforts, it also noted that prosecution and economic policies might still require federal prosecution even if a company has cooperated with DOJ investigators.

"Moreover, amnesty, immunity, or reduced sanctions may not be appropriate where the corporation's business is permeated with fraud or other crimes," Filip said in the guidance.

Filip said the policy revisions will take effect immediately and that placing the new guidelines in the U.S. Attorneys Manual "is a big deal within the prosecutorial community." He noted that doing so would help to reinforce the fact that the guidelines are binding on prosecutors.

The policy, which until now has been issued in memorandum form, originated in 2003 following the Enron and WorldCom accounting scandals. The initial policy was issued by then-Deputy Attorney General Larry D. Thompson in the so-called Thompson Memo and was revised by Thompson's successor, McNulty, in 2006, who, in turn, was followed by Filip.

Legislative Activity

The policy revisions come amid increasing pressure from lawmakers on Capitol Hill who have threatened to take legislative action in response to complaints from business groups, bar associations, and civil liberties advocates.

Pending before the Senate Judiciary Committee is a bill (S. 3217) sponsored by Sen. Arlen Specter (R-Pa.), the committee's ranking member, that would bar federal prosecutors—as well as agency attorneys—from demanding that corporations waive the attorney-client and work product privileges in return for more lenient treatment in charging decisions and investigations. The bill has 12 cosponsors, including eight Democrats. The House has approved similar legislation, passing the bill (H.R. 3013) by voice vote in November 2007.

Specter called the new guidelines "a step in the right direction," but said they leave many problems unresolved and that legislation is necessary. He noted that Justice Department guidelines do not bind other federal agencies, many of which have policies similar to those of the DOJ that were objected to.

"The new guidelines expressly encourage corporations to comply with the waiver and disclosure programs of other agencies, including the Securities and Exchange Commission and the Environmental Protection Agency," Specter said in a statement. He added, "Legislation, of course, would bind all federal agencies and could not be changed except by an Act of Congress."

The guidance is available at *www.usdoj.gov/opa/documents/corp-charging-guidelines.pdf*.

'Red Flag' Deadline Approaches: Health care providers may be dangerously unaware that they have a looming deadline for compliance with complex new federal regulations called the Red Flag rules. These rules require the adoption and implementation of a broad identity theft prevention system by Nov. 1, 2008. Under the rules, creditors (including health care providers) must develop and implement a written program that has reasonable policies and procedures for detecting, preventing, and mitigating identity theft. More information is available online at *www.ftc.gov/bcp/edu/pubs/business/alerts/alt050.shtm.*

OIG Nixes Joint-Venture Proposals: Proposed joint ventures between a cancer treatment facility and urology groups could mask an effort to pay improper remuneration to urology groups that already refer patients to the facility and could result in federal penalties for the provider groups that are parties to the arrangements, the Department of Health and Human Services Office of Inspector General (OIG) said August 26 in an advisory opinion (No. 08-10). The proposal specifically called for a cancer treatment center—owned and operated by a physician group practice—to lease out space, equipment, and personnel to local urologist group practices to provide intensity-modulated radiation therapy (IMRT) for prostate cancer patients. The urologist groups, in turn, would contract with the facility to provide the IMRT services, including the professional services. The advisory opinion is available at *www.oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-10A.pdf.*

Travel Allowance Increase: The Centers for Medicare and Medicaid Services (CMS) has announced an increase of 80 cents in the per-mile travel allowance when collecting specimens from nursing home and homebound Medicare beneficiaries. Effective July 1, payment on a per-mile basis (billing code P9603) rises to $1.035. This includes the federal mileage rate of $0.585 per mile, plus an additional $0.45 per-mile to cover personnel time and travel costs. Payment on a flat-rate basis (P9604) remains unchanged at a minimum of $9.55. CMS announced the per-mile update in Change Request 6195 (Sept. 5, 2008). The implementation date is October 6.

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