G2 Compliance Report

G2 INTELLIGENCE

For Hospitals, Laboratories and Physician Practices

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Palmetto Implements New Limitations on Prostate Biopsies; Change Directed by CMS, Could Go Nationwide

Palmetto GBA, one of the largest Medicare Part B contractors, has implemented a new policy limiting the number of prostate biopsies that may be reported using CPT code 88305 to four services. Under the policy, announced in August, labs and pathologists would have to use HCPCS code G0416 (one unit) for five or more prostate biopsies.

This change is expected to result in a significant reduction in Medicare reimbursement for clinical laboratories and pathologists. The current national payment amount for 88305 is $105.86 (professional component, $36.08; technical component, $69.78) while the national payment amount for G0416 is $670.88. It is not uncommon for pathologists to take 10 or more specimens when performing a prostate biopsy. The difference in Medicare payment for 10 units of 88305 versus one unit of G0416 is $387.72. In a case where there are 20 specimens, the difference in payment would be $1,446.32.

Given that 88305 is the most commonly used pathology procedure code, accounting for almost $1.3 billion in allowed charges in 2010, a limitation of four units of service for prostate biopsies is likely to result in a significant decline in Medicare reimbursement for labs and pathologists.

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OIG Urged to Suspend 60-Day Repayment Rule For Self-Disclosed Overpayments

The Department of Health and Human Services Office of Inspector General (OIG) should suspend an obligation to report and return overpayments within 60 days for Medicare providers who voluntarily enter into the provider self-disclosure protocol, according to comment letters from industry stakeholders.

The letters were in response to a notice the OIG published in the June 18 *Federal Register* soliciting comments and recommendations on how to revise the provider self-disclosure protocol.

In a letter dated Aug. 17, James Madera, executive vice president and chief executive officer of the American Medical Association, said suspending the 60-day repayment obligation would make the OIG's self-disclosure protocol consistent with the Centers for Medicare and Medicaid Services (CMS) Self-Referral Disclosure Protocol. Madera also said that failing to suspend the 60-day obligation could discourage providers from self-disclosing overpayments.

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Palmetto Implements New Limitations on Prostate Biopsies, *from page 1*

Palmetto officials have said the new policy was based on correct coding initiative (CCI) edits that went into effect Jan. 1, 2012. That policy, contained in Chapter 10 of the CCI Policy Manual, states:

"HCPCS codes G0416-G0419 describe surgical pathology, including gross and microscopic examination, of prostate needle biopsies from a saturation biopsy sampling procedure. CMS requires that these codes rather than CPT code 88305 be utilized to report surgical pathology on prostate needle biopsy specimens only if the number of separately identified needle biopsy specimens is five or more. Surgical pathology on four or fewer prostate needle biopsy specimens should be reported with CPT code 88305 with the unit of service corresponding to the number of separately identified biopsy specimens."

According to Lale White, chief executive officer of XIFIN, a revenue management company based in San Diego, a Palmetto official told her that the Centers for Medicare and Medicaid Services (CMS) recently sent a memo to all Medicare contractors directing them to implement this policy. It appears that the change incorporated into the CCI edits was missed by the Medicare administrative contractors (MACs).

Further, since it is recognized and previously incorporated into the nonpublished medically unlikely edits that a collection of 12 samples is not unusual to calculate a Gleason Score, the policy does not appear to be focused on medical necessity but rather on capping the reimbursement for prostate biopsies at a multiple that represents slightly over six specimens, White tells G2 Intelligence.

According to the publication of the directive on the Palmetto GBA Web site, providers who submitted more than four units of 88305 for prostate biopsies after Jan. 1, 2012, are at risk for overpayment collection. Any provider that received more than $670.88 for seven or more prostate biopsies is at risk for recoupment by the MAC or through an audit by a recovery audit contractor, explains White.

Economics of Prostate Biopsy

A report published earlier this year by Georgetown University on urologists' self-referral for pathology of prostate cancer details the economics of prostate biopsy. A common practice is to extract cores from the right and left sides of the apex, midzone, and base regions of the prostate, writes Jean Mitchell, Ph.D., the lead researcher.

"Under Medicare billing rules, the 'unit of service' for surgical pathology services (HCPCS codes 88300-09) is the 'specimen'. . . . Medicare reimburses each provider for the number of specimens or 'jars,' containing tissue cores that are reviewed by a pathologist. The number of jars may differ from the number of tissue cores extracted because multiple cores can be combined into one jar prior to referral for pathology services.

"If six jars containing twelve tissue cores are submitted, the reimbursement will be six times the Medicare global allowable payment for HCPCS code 88305 (level IV surgical pathology, gross and microscopic examination). However, if each core is in a separate jar, the reimbursement will be twelve times the payment."

Will Other MACs Follow?

Although Palmetto is believed to be the first Medicare contractor to officially implement the limitations on prostate biopsy, G2 Intelligence expects this policy is likely to be adopted by other contractors.

Given that the directive to implement the policy came from CMS, it's probably just a matter of time until other MACs adopt similar restrictions on billing for prostate biopsies. Any further effort likely will have to be directed at challenging the CCI edit.

Pathologists Avoid Meaningful Use Penalties—For Now

Under the final Stage 2 Meaningful Use (MU) rules released in late August, pathologists will automatically qualify—and therefore do not have to apply—for the significant hardship exception to payment adjustments based on their Medicare provider status, according to the College of American Pathologists (CAP). Beginning in 2015, these penalties are applied to providers and hospitals who fail to meet the requirements of the MU program.

This hardship exception applies to anesthesiology and radiology, in addition to pathology, although it's unclear how the Centers for Medicare and Medicaid Services (CMS) will apply the relief under the agency's Provider Enrollment, Chain and Ownership System (PECOS), as all three specialties have several codes. CAP is working with the agency to clarify this issue.

The Three Stages of Meaningful Use

- CMS issued the final rule on Stage 1 in July 2010; implementation began in 2011.
- Stage 2 takes effect beginning in 2014.
- Stage 3 is expected to begin in 2016.
- Penalties begin in 2015 at 1 percent of a physician's Medicare payments and could rise to as much as 5 percent of Medicare payments in 2017 and beyond.

CAP had urged the agency to grant this exception, as these three specialties lack face-to-face interactions with patients and rarely need to follow up with patients. Indeed, the program's eligible physician (EP) requirements have focused on office-based physicians, not reflecting pathologists' scope of practice, usual interaction with patients, and type of IT system used in laboratories and practices (an APIS/LIS rather than an electronic health record (EHR)).

However, in the final rule, CMS indicates that this exception is not permanent, as it will be up for an annual review.

To make this exception permanent, CAP is urging lawmakers to support the Health Information Technology Reform Act (H.R. 4066). Introduced by Rep. Tom Price, M.D. (R-Ga.), this bill exempts pathologists from eligibility for both MU penalties and incentives. To date, CAP has secured 43 co-sponsors and continues to lobby for its enactment.

Rule Specifics

The final rule delayed implementation of Stage 2 from 2013 to 2014 to provide adequate time for vendor and provider compliance. Other pathology-related details in this rule include requiring hospitals and EPs to enter 30 percent of laboratory orders through computerized provider order entry.

There are several other new requirements of specific interest to pathologists, among other changes:

- EPs and eligible hospitals must incorporate more than 55 percent of all laboratory test results into certified EHR technology as structured data. The tests must be ordered by the EP or by authorized providers of the eligible hospital for patients admitted as inpatients or to the emergency department during the reporting period. The results must be either in a positive or negative affirmation or in numerical format. This structured reporting was a "menu" objective in Stage 1 and is now a "core" required objective.
- Eligible hospitals must provide structured electronic laboratory results to ambulatory ordering providers for more than 20 percent of electronic laboratory orders received.
- A new menu objective for cancer reporting requires EPs to report case information from certified EHR technology to a public health cancer registry for the entire EHR reporting period in accordance with applicable law and practice.

ACLA Continues to Press for Extension of TC Grandfather, Elimination of Stark 'Loophole'

Despite the June 30 expiration of the pathology grandfather protection, the American Clinical Laboratory Association (ACLA) is continuing to urge the Centers for Medicare and Medicaid Services (CMS) to use its authority to extend the protection.

For years the grandfather protection allowed certain independent laboratories to bill Medicare directly for the technical component (TC) of pathology services provided to hospital patients. It applied to hospital-lab arrangements in effect as of July 22, 1999, the date when Medicare officials first proposed to eliminate the direct billing, saying hospitals already receive payment for the TC as part of their diagnosis-related group payments.

The protection was eliminated as part of the Middle Class Tax Relief and Job Creation Act of 2012. Effective July 1, 2012, all independent labs must bill the hospital for the pathology TC.

> ***"ACLA is disappointed that CMS once again has failed to act to curb the proliferation of anatomic pathology services furnished pursuant to the Physician Self-Referral Law in-office ancillary services exception."***
>
> ***—The American Clinical Laboratory Association***

In commenting on the proposed 2013 physician fee schedule, ACLA said it "once again requests that CMS implement administratively the TC grandfather clause, which Congress extended legislatively for several years and which recently expired, so that laboratories will continue to be permitted to bill Medicare for the technical component of a service furnished to a hospital patient when a hospital has a prior arrangement with the independent laboratory for such service."

Physician Self-Referral

ACLA also continues to urge CMS to eliminate the in-office ancillary services exception to Stark statute, which prohibits physician self-referral. Laboratory and pathology groups have pressed CMS to close the loophole, arguing that it provides perverse incentives to perform unnecessary procedures.

Physician specialists increasingly are taking advantage of gaps in the anti-markup and self-referral rules and entering into business arrangements that permit them to order, bill, and be paid the full fee schedule rate for anatomic pathology services, even though the services are furnished by physicians who have little or no relationship with the ordering physicians, notes ACLA in its Sept. 4 comments. In past rulemakings, CMS has expressed concern about such arrangements, but it has not taken concrete steps to address them.

"ACLA is disappointed that CMS once again has failed to act to curb the proliferation of anatomic pathology services furnished pursuant to the Physician Self-Referral Law in-office ancillary services exception," writes ACLA in its comments. "Each year that CMS does not address this abusive practice is a tacit signal that the agency will not stop those who engage in it, and it places patients and the Medicare program at risk."

The final physician fee schedule rule is expected to be released on or around Nov. 1.

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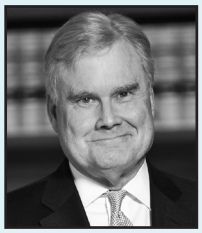
COMPLIANCE PERSPECTIVES



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Medicare's Three-Day Window Is Fully in Effect: Are You in Compliance?

In Section 102 of the Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010, Congress expanded Medicare's three-day payment window policy to apply to certain therapeutic services furnished by physician practices and other Part B entities that previously had not been subject to the rule. Subsequently, in the 2012 Medicare Physician Fee Schedule Final Rule, published Nov. 28, 2011, CMS detailed its policies regarding the three-day payment window's application and then issued implementing manual instructions, which were published on Dec. 21, 2011. Finally, in mid-June of 2012, CMS issued frequently asked questions to address common questions regarding the application of the three-day window payment policy. As a consequence, providers should now be aware of the policy and the need to conform to the policy.

Background

Medicare has long required that most preadmission services furnished prior to a beneficiary's inpatient admission to a hospital be "bundled" into the hospital's inpatient prospective payment (IPPS) rate if both (1) the entity furnishing the preadmission services is wholly owned or wholly operated by the admitting hospital and (2) the service is furnished within three days of the inpatient admission (or one day in the case of hospitals excluded from IPPS). The "bundled" services subject to the three-day window include all preadmission diagnostic services and most nondiagnostic services.

As a practical matter, until recently, Medicare excluded from the "bundling" requirement those preadmission nondiagnostic services furnished by non-provider-based wholly owned or wholly operated physician clinics or practices. Congress, however, has now included those services within the payment window's ambit.

The "bundled" services subject to the three-day window include all preadmission diagnostic services and most nondiagnostic services.

Thus, as a result of the statutory change, all diagnostic services and all therapeutic services that are clinically related to the reason for the patient's inpatient admission are to be bundled into the hospital's diagnosis-related groups (DRG) if furnished by a wholly owned or wholly operated entity within three days of the patient's admission. The payment window is three days—not 72 hours. Thus, it applies to services provided on the date of admission and during the preceding three calendar days, which could be longer than 72 hours.

Application of the Three-Day Window

In order for the payment window provisions to apply, the hospital must wholly own or wholly operate the outpatient entity. For an entity to be wholly owned by a hospital, the hospital must be the sole owner of the entity. For the entity to be wholly operated by the hospital, the hospital must have exclusive responsibility for conducting and overseeing the entity's routine operations, regardless of whether

the hospital has, as well, policymaking authority over the entity. Notably, if the hospital and the third-party entity, including a physician office or other Part B entity, are "siblings," both owned by a common third party such as a health system, the three-day window does not apply.

Determining whether the three-day window applies is not always easy. Because of the multitude of possible business and financial arrangements that may exist between hospitals and physician practices and other Part B entities, CMS does not make individual determinations as to whether specific physician practices or Part B entities are wholly owned or wholly operated by an admitting hospital. Rather, CMS states the hospital and its owned or operated physician practices or other Part B entities are collectively responsible for making this determination.

For diagnostic services, the wholly operated or wholly owned physician practice or the Part B entity should bill only for the professional component of the diagnostic service and append modifier -26 and modifier PD to the diagnostic code for the service.

If the matter remains unclear, even after review by an entity's legal counsel, CMS's advice is that the entity essentially make the best determination possible and, if the determination is that the entity is not wholly owned or wholly operated and not subject to the payment window, that the entity maintain documentation to support that determination.

The payment effect of the three-day window is as follows. First, if the CPT or HCPCS codes at issue have a professional component (PC) and a technical component (TC) split, CMS will pay only the professional component. The agency will assume that the technical component expense is incurred by the hospital and reimbursed through the DRG payment.

Second, for codes without a TC-PC split, CMS will pay for the service at the "facility rate" to reflect, again, that the expense of technical resources associated with the preadmission services have been incurred by the hospital. These reductions in the physician payment amount will apply to all diagnostic and related nondiagnostic services provided within the window, including drug therapies and imaging services. In some instances, as well, services furnished within a global surgical package might overlap with the payment window and be subject to the rule's application.

Operationally, the physician practices or other Part B entities should use a modifier PD to identify codes for services subject to the payment window period, with that modifier being required for services furnished on or after July 1, 2012. Only if the hospital determines that nondiagnostic preadmission (therapeutic) services furnished within the payment window are not clinically related to the inpatient admission, and thus not subject to the three-day window, would the physician practice or other Part B entity not apply a modifier PD. The absence of the modifier will then serve to attest that the hospital believes that the nondiagnostic services were unrelated to the hospital admission.

For diagnostic services, the wholly operated or wholly owned physician practice or the Part B entity should bill only for the professional component of the diagnostic service and append modifier -26 and modifier PD to the diagnostic code for the service.

Not all services are subject to the three-day window. The payment window does not apply to services furnished in rural health clinics or federally qualified health centers. Also, outpatient maintenance dialysis services and ambulance services

are exempt or excluded from the window. Further, the payment window has limited application to critical-access hospitals (CAHs). If the admitting hospital is a CAH, the payment window policy does not apply. If, however, the admitting hospital is a short-stay acute-care hospital paid under IPPS, and the CAH is wholly owned or wholly operated by that hospital, the outpatient's CAH services are subject to the window.

Similarly, if the CAH is wholly owned or wholly operated by a psychiatric hospital and patient rehabilitation hospital, children's hospital, cancer hospital, or long-term care hospital, outpatient CAH services furnished within one day of the patient's admission to such a hospital are bundled.

Conclusion

Hospitals should have, by now, become familiar with the three-day window's application to wholly owned or wholly operated physician practices and related entities. All hospitals should have implemented changes to their billing practices to ensure compliance. In instances where questions remain, hospitals should consult with counsel to engage in a detailed analysis of whether the particular ownership or control structure might fall within the window.

Hospitals should be aware that these requirements apply not only to wholly owned or wholly operated physician practices. Other Part B entities that are wholly owned or wholly operated also fall within the ambit of the statute. Thus, for example, when a patient is seen in a wholly owned or wholly operated ambulatory surgical center (ASC), the ASC would be required to use the modifier PD to identify the outpatient physician or practitioner services subject to the window.

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Frequently Asked Questions

The following are excerpts from the Centers for Medicare and Medicaid Services frequently asked questions on the three-day payment rule. The full FAQ is available at *www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/CR7502-FAQ.pdf.*

Q. What is the 3-day payment window?

A. Medicare's 3-day (or 1-day) payment window applies to outpatient services furnished by hospitals and hospitals' wholly owned or wholly operated Part B entities. The statute requires that hospitals bundle the technical component of all outpatient diagnostic services and related non-diagnostic services (e.g. therapeutic) with the claim for an inpatient stay when services are furnished to a Medicare beneficiary in the 3 days (or, in the case of a hospital that is not a subsection (d) hospital, during the 1-day) preceding an inpatient admission in compliance with §1886 of the Social Security Act.

Q. Which services are considered diagnostic services?

A. As discussed in the Medicare Benefit Policy Manual (Publication 100-02, chapter 6, section 20.4.1) a service is "diagnostic" if it is an examination or procedure to which the patient is subjected, or which is performed on materials derived from a hospital outpatient, to obtain information to aid in the assessment of a medical condition or the identification of a disease. Among these examinations and tests are diagnostic laboratory services such as hematology and chemistry, diagnostic x-rays, isotope studies, EKGs, pulmonary function studies, thyroid function tests, psychological tests, and other tests given to determine the nature and severity of an ailment or injury.

Q. What type of hospital inpatient admissions would be subject to a 1-day payment window?

A. The hospital and hospital units subject to the 1-day payment window policy (instead of the 3-day payment window) are psychiatric hospitals and units, inpatient rehabilitation hospitals and units, long-term care hospitals, children's hospitals and cancer hospitals. A wholly owned or wholly operated physician practice (or other Part B entity) of the aforementioned hospitals would also be subject to a 1-day payment window when furnishing diagnostic services and related non-diagnostic services within 1 calendar day preceding an inpatient admission.

Frequently Asked Questions - *continued*

Q. Are Critical Access Hospitals (CAHs) subject to the payment window?

A. If the admitting hospital is a CAH, the payment window policy does not apply. However, if the admitting hospital is a short stay acute hospital paid under the inpatient prospective payment system (IPPS) hospital and the wholly owned or wholly operated outpatient entity is a CAH, the outpatient CAH services are subject to the payment window. The CAH services are also subject to the payment window if the admitting hospital is a psychiatric hospital, inpatient rehabilitation hospital, long-term care hospital, children's hospital, or cancer hospital.

Q. Does the 3-day window (or 1-day window) include the 72 hours (or 24 hours) directly preceding the inpatient hospital admission?

A. The 3-day payment window applies to services provided on the date of admission and the 3 calendar days preceding the date of admission that will include the 72 hour time period that immediately precedes the time of admission but may be a longer than 72 hours because it is a calendar day policy. The 1-day payment window applies to the date of admission and the entire calendar day preceding the date of admission and will include the 24 hour period that immediately preceded the time of admission but may be longer than 24 hours.

Q. How do I know if my physician practice, or other Part B entity, meets the statutory requirements of hospital wholly owned or hospital wholly operated?

A. Wholly owned or wholly operated entities are defined in 42 CFR §412.2. "An entity is wholly owned by the hospital if the hospital is the *sole owner* of the entity," and "an entity is wholly operated by a hospital if the hospital has *exclusive* responsibility for conducting and overseeing the entities routine operations, regardless of whether the hospital also has policy making authority over the entity." [Emphasis added] The hospital and associated physician practice or other Part B entity must determine whether the entity is wholly owned or wholly operated.

Q. When would the 3-day (or 1-day) payment window not apply?

A. The 3-day (or 1 day) payment window does not apply in the circumstances described below:

- If the hospital and the physician office or other Part B entity are both owned by a third party, such as a health system; and
- If the hospital is not the sole or 100 percent owner of the entity, for example, if the hospital has a financial or administrative partner, or if physicians or other practitioners have an ownership interest in the \hospital, physician practice or Part B entity.

Q. How does the 3-day payment window affect wholly owned or wholly operated physician practices (or other Part B entities)?

A. The technical component for all diagnostic services and those direct expenses that otherwise would be paid through non-facility practice expense relative value units for non-diagnostic services related to the inpatient admission, provided by a wholly owned or wholly operated entity within the payment window, are considered hospital costs and must be included on the hospital's bill for the inpatient stay.

Medicare will pay the wholly owned or wholly operated entity through the Physician Fee Schedule for the professional component (PC) for service codes with a Technical/ Professional Component (TC/PC) split that are provided within the payment window, and at the facility rate (i.e., exclusive of those direct practice expenses that are included in the hospital's charges) for service codes without a TC/PC split.

Q. What if a diagnostic service is unrelated to the inpatient hospital admission?

A. The technical component (TC) of all diagnostic services furnished by a wholly owned or wholly operated entity to a Medicare beneficiary who is admitted as an inpatient within 3 calendar days are subject to the 3-day payment window policy (or 1-day if applicable).

Q. How should a wholly owned or wholly operated physician practice bill for diagnostic services subject to the payment window?

A. The wholly owned or wholly operated physician practice (or other Part B entity) should only bill for the professional component of a diagnostic service subject to the 3-day (or 1-day) payment window. The modifier -26 and modifier PD must be appended to the diagnostic HCPCS code for the service. Please note that this policy has been longstanding and is unchanged since 1998.

Q. Should the wholly owned or wholly operated physician practice bill for the technical component of a diagnostic service?

A. No, the wholly owned or wholly operated physician practice (or other Part B entity) should not bill for the technical component (TC) of a diagnostic service subject to the payment window. The modifier PD does not apply to the TC of a diagnostic service. The TC of a diagnostic service (e.g. taking the x-ray) subject to the payment window is considered part of the admitting hospitals' costs and therefore, included on the bill for the inpatient stay.

OIG Urged to Suspend 60-Day Repayment Rule, *from page 1*

"Suspending the statutory obligation to report and return overpayments within 60 days would allow the submitting provider, and other providers who may be implicated in the disclosure, an opportunity to engage with the OIG protocol staff without running up against the 60-day due date for repayment," Madera said.

The 60-day obligation should remain suspended until a provider reaches a settlement agreement with the OIG or is removed or withdraws from the self-disclosure protocol, Madera said.

Clarifying Appropriate Disclosures

In an Aug. 16 letter, Charles N. Kahn III, president and CEO of the Federation of American Hospitals, also supported suspending the 60-day rule, urging the OIG "to supplement its standard letter to providers with additional language reflecting this approach to tolling the overpayment refund timeframe."

Kahn also said the OIG should clarify whether settling a potential Stark law violation through the CMS self-disclosure protocol resolves all Stark issues. The Stark law prohibits physician referrals of Medicare or Medicaid patients to facilities with which the physicians have a financial relationship. In 2009, the OIG said it no longer would accept self-disclosures focused solely on Stark law issues unless the disclosure also involved a "colorable anti-kickback statute violation."

"Our overarching concern is that hospitals not be unreasonably burdened when disclosing a situation that implicates both the Stark statute and the CMP [civil monetary penalties] Statute," Kahn said in his letter. "We believe strongly that where similar facts and parties are involved, a single disclosure should be appropriate, even if one of the arrangements does not have a colorable anti-kickback issue."

FAH's letter included several additional recommendations, including asking the OIG to:

- Do away with imposing penalties on providers in cases where no violations have been found;
- Allow providers to consult with OIG staff on any potential self-disclosure settlement; and
- Clarify whether hospitals that are operating under a corporate integrity agreement can enter into the self-disclosure protocol.

Consolidated Self-Disclosure Protocol

James G. Sheehan, chief integrity officer for the New York City Human Resources Administration (HRA), said the OIG should consolidate its provider self-disclosure protocol into one document.

"In order to simplify the SDP and make instructions clear, OIG should consolidate all documents into one comprehensive guide," he said in an Aug. 16 letter. "Consolidation will be especially helpful for those entities considering disclosure that have yet to retain knowledgeable players."

Sheehan, a former federal prosecutor and inspector general for the New York Medicaid program, said information on the OIG's self-disclosure protocol is spread out over three letters as well as a link to the *Federal Register*.

Sheehan also recommended suspending the 60-day repayment obligation, saying it would encourage more providers to enter into the protocol. HRA also recommended publishing all disclosures after a settlement has been reached, as well as committing to a time frame for handling a provider's self-disclosure.

Survey: Burden of Compliance Audits Falls Heavily on Nonprofit Providers

Outside compliance audits create significant demands on health care providers, and the burden "appears to be falling disproportionately" on nonprofits, concludes a recent survey by the Health Care Compliance Association (HCCA).

The survey, Auditing the Auditors, conducted in April and released in August, noted that a large range of organizations—primarily state and federal agencies, but also third-party payers—were requiring the audits, leading to greater complexity and the need for staff dedicated to audits.

Large organizations were subjected to more audits than small ones, a finding that did not surprise HCCA. But the compliance group noted that it was surprised "that financial structure would have such a significant impact."

Of the greater burden on nonprofits, HCCA said, "It is difficult to know whether this is a conscious policy or an accidental one."

RAC Audits Common

Medicare Recovery Audit Contractor (RAC) audits were common for all organizations, with 47 percent of entities reporting at least one such audit, the survey results said. Again, these audits were most common among larger entities, with 76 percent of those with 5,000 or more employees reporting at least one RAC audit and 30 percent of organizations with fewer than 250 employees reporting one.

Audits conducted by two separate agencies looking at the same issue were reported by 47 percent of nonprofit groups and 25 percent of for-profit groups, the survey said.

Comprehensive Error Rate Testing audits were also common, with 53 percent of nonprofits and 46 percent of for-profit groups reporting them. Again, this type of audit was much more likely to be done at larger institutions: Sixty-seven percent of those reported such audits.

The survey included 397 organizations, 60 percent of which were nonprofit groups. They ranged in size from groups with fewer than 250 employees to those with more than 15,000 employees. About a third of the organizations had between 1,000 and 5,000 employees.

Staffing Varies

Organizations with fewer than 1,000 employees were more likely to have only half of one full-time position dedicated to compliance audits, while those with 5,000 or more tended to have at least three people working in this area. For-profit groups were more likely to have dedicated staff, despite having fewer audits.

Seventy-one percent of organizations reported at least one audit from the Health and Human Services Department Office of Inspector General. Audits by the Centers for Medicare and Medicaid Services were reported by 41 percent, and state Medicaid agency audits were reported by 33 percent of the agencies.

Forty-four percent of the health care organizations reported audits by third-party providers. A few reported audits by organizations not directly related to health care, including the Environmental Protection Agency, the U.S. Department of Labor, the Equal Employment Opportunity Commission, and the Federal Bureau of Investigation.

The survey findings are available at *www.hcca-info.org/Resources/View/ArticleId/817/Auditing-the-Auditors.aspx*.

NIH, FDA Issue Rulemakings to Create New Record Systems, Privacy Exemptions

New systems of records on research misconduct proceedings to be implemented at both the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) would be exempt from certain disclosure provisions of the Privacy Act to protect both the integrity of the research proceedings as well as any possible whistleblowers, under rulemakings published in the Aug. 28 *Federal Register*.

NIH, through the Department of Health and Human Services (HHS), and FDA issued nearly identical final rules about their new record systems and the Privacy Act exemptions. The agencies also published companion proposed rules and notices about the new record systems and exemptions.

Under Public Health Service (PHS) regulations on research misconduct, a "research record" refers to "the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to HHS or an institutional official by a respondent in the course of the research misconduct proceeding."

PHS policies on research misconduct provide for a number of HHS administrative actions that can be taken in response to a research misconduct proceeding, such as the suspension of a contract, debarment, or an adverse personnel action against a federal employee.

Applying NIH, FDA Systems

The NIH recordkeeping system would apply to misconduct investigations related to research that took place in NIH facilities, was funded by the NIH Intramural Research Program, or, regardless of location, was undertaken by an NIH employee or trainee as official NIH duties or training activities.

According to the FDA notice, that agency's system would cover individuals who are agents of, or affiliated by contract or agreement with, FDA, or an FDA employee involved in intramural research.

Both agencies' new record systems would contain personally identifiable information (PII) and non-PII about respondents, complainants, witnesses, and other individuals affiliated with entities that are contacted by or provide information to those agencies.

Privacy Act Exemptions

The NIH and FDA rules also detail how the systems would be exempt from the accounting, access, and notification requirements of the Privacy Act. The NIH and FDA both note that such exemption is necessary while a research misconduct proceeding is pending in order to protect the investigation and avoid revealing the identify of any source who had been promised confidentiality.

In addition, notifying individuals that there is some sort of research misconduct case about them as required under the Privacy Act—whether it is an assessment, inquiry, or formal investigation—possibly could result in alteration or destruction of evidence, improper influence of witnesses, or other actions that could compromise the research misconduct case.

The agencies therefore said they would exempt research misconduct records from these provisions, which require that each agency that maintains a system of records publish a notice in the *Federal Register* when it creates or revises such a system. The notice should include, according to the Privacy Act, agency procedures for notifying individuals at their request if the system contains a record pertaining to them and, if so, how individuals can gain access to those records and contest their content.

News-At-A-Glance

RADIOLOGIST SETTLES KICKBACK CASE: A Houston radiologist has agreed to pay the federal government $650,000 to settle whistleblower litigation alleging that he paid illegal compensation to doctors to induce them to refer patients to a diagnostic imaging center he owned and operated, U.S. Attorney for the Southern District of Texas Kenneth Magidson said Aug. 14 (*United States ex rel. Blum v. Baker*, S.D. Tex., No. 4:10-cv-2595). The allegations in the qui tam lawsuit alleged that defendant Jack L. Baker violated the federal False Claims Act, the anti-kickback statute, the Stark law on self-referral, and the Texas Medicaid Fraud Prevention Act by entering into improper financial relationships with up to 17 physicians in seven different medical practices between 2002 and 2010. Baker allegedly induced the physicians to refer patients to Fairmont Diagnostic Center and Open MRI Inc. for a variety of imaging studies, including magnetic resonance imaging, computed tomography, X-rays, and sonograms. These prohibited financial relationships included sham medical directorship contracts that took into account the value of referrals from the medical directors and contracts to pay the salaries of employees in physicians' offices, which also took into account the value of referrals from those physicians, Magidson said in a statement. The settlement prohibits Baker from participating in the Medicare and Medicaid programs for six years.

ICD-10 DEADLINE MOVED TO OCTOBER 2014: It's official: The compliance date for health care providers, health plans, and clearinghouses to use the International Classification of Diseases, 10th Edition (ICD-10) diagnosis and procedure codes has been extended from Oct. 1, 2013, to Oct. 1, 2014. The new date was announced by the Centers for Medicare and Medicaid Services (CMS) in a final rule released Aug. 24. The agency had previously proposed the one-year delay to give providers more time to prepare for the transition from the ICD-9 code sets, including thorough testing. In granting the delay, CMS said "some provider groups have expressed strong concern about their ability to meet the Oct. 1, 2013, compliance date and the serious claims payment issues that might then ensue.

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