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by Charles I. Artz, Esq. and Michael D. Miscoe, CPC, CHCC, Contributing Editors

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Former HHS Secretary urges Congress to overhaul Medicare

Rather than relying on states to expand health care coverage through pilot programs, the federal government should work to fix the Medicare system, former HHS Secretary Tommy Thompson said at a Senate Finance Committee hearing on May 6, 2008.

"The federal government has got to deal with it," he told the senators, adding that "Medicare absolutely has to be looked at and it's got to be overhauled." Lawmakers should work together. "Forget about partisanship and come up with a nonpartisan solution," he urged.

Committee members' reactions. Senate Finance Committee Chairman Max Baucus (D-Mont.) said Congress needs bipartisanship to get to universal coverage. "We need to do something and more than incremental," he noted.

Senate Finance Committee ranking member Charles Grassley (R-Iowa), however, cautioned against expanding government beyond its reach. "Health reforms should not up-end the system and do harm while trying to help the folks without insurance," he said, adding that "we need to be prudent in taking on new obligations for the federal government."

Building on the private health insurance system "makes the most sense," Grassley said. People are used to their employers providing health benefits and they like that employers find a plan, take care of the billing, and take premiums out of their paychecks. "By and large they are satisfied with their health plans," he explained.

Grassley suggested making the current unlimited income tax exclusion for employer-provided health insurance more equitable, while increasing the tax benefits for taxpayers purchasing nongroup insurance. "We need to look at the tax system and determine whether we can make changes there that would enable more people to buy insurance," he said.

Former Secretaries weigh-in. Thompson suggested formation of a bipartisan commission charged by Congress and the next president to recommend solutions. Noting the obesity epidemic, he also called for action to make prevention a centerpiece of America's health care system, beginning with Medicare and Medicaid.

Another former HHS Secretary, Donna Shalala, said that the time has come for universal health care. According to Shalala, "[o]nly with the successful implementation of a universal health care strategy will the United States have the potential to extend quality coverage to the millions of Americans currently uninsured and the opportunity to save billions of dollars in the process." ■

CCH Washington Bureau, May 6, 2008.

Wolters Kluwer Law & Business

Court finds no initial duty to disclose physician impairment

A hospital and physician group that wrote referral letters on behalf of an anesthesiologist had no duty to disclose to a future employer their investigation into the anesthesiologist's on-duty use of narcotics, according to a recent decision by the fifth circuit court of appeals. The court found, however, that the hospital and physician group had a duty to avoid affirmative misrepresentations in the referral letters.

Background. The anesthesiologist, Dr. Robert Berry, was employed Lakeview Anesthesia Associates (LAA), a physician group that was the exclusive provider of anesthesia services to Lakeview Medical Center (Lakeview). Dr. Berry was fired by LAA when it was discovered that he had been making excessive and undocumented withdrawals of narcotics from the hospital pharmacy for personal use. Referral letters written by Lakeview and LAA, and relied on by Kadlec Medical Center (Kadlec), Dr. Berry's future employer, did not disclose LAA's termination of Dr. Berry, his on-duty drug use, or the investigation into Dr. Berry's undocumented withdrawals of narcotics.

While under the influence of narcotics at Kadlec, Dr. Berry made mistakes that caused several patients to suffer adverse effects from not being properly anesthetized. On one occasion, Dr. Berry failed to resuscitate a patient who stopped breathing during a routine surgical procedure, and the patient lapsed into a permanent vegetative state. The patient's family sued Dr. Berry and Kadlec, whose insurers settled the claims against them.

Following the settlement of the patient's claims, Kadlec sued Lakeview and LAA, alleging that misrepresentations in, and omissions from, their referral letters led to Kadlec's hiring of Dr. Berry and the resulting expenditure of millions of dollars to settle the lawsuit brought by the patient.

Affirmative misrepresentations. On appeal from a jury verdict in favor of Kadlec on its negligent and intentional misrepresentation claims, Lakeview and LAA argued that any representations in, or omissions from, the referral letters could not establish liability. Once they volunteered information in the referral letters, however, Lakeview and LAA had a duty under the Health Care Quality Improvement Act and state regulations to avoid affirmative misrepresentations, the court said.

LAA's referral letters stated that Dr. Berry was "an excellent clinician" who would be "an asset to any anesthesia service." One of the letters also "recommended [Dr. Berry] highly as an anesthesiologist." According to the court, these letters were materially misleading, therefore, LAA incurred a duty to cure the misleading statements by disclosing to Kadlec that Dr. Berry had been fired for on-the-job drug use.

Duty to disclose. Lakeview's referral letter, however, was not misleading, the court concluded. The letter did not comment on Dr. Berry's proficiency, nor did it recommend him as an anesthesiologist. Therefore, the court said, Lakeview could not be held liable for negligent or intentional misrepresentation.

Although the court recognized that imposing a duty on health care providers to disclose physician impairments that could affect patient safety would promote important policy goals, the court declined to impose an affirmative duty based on Lakeview's mere nondisclosure. Absent misleading statements, Lakeview did not have a fiduciary or contractual duty to disclose what it knew about Dr. Berry, the court said.

Causation. LAA argued that even if it breached a legal duty to Kadlec, Kadlec's claims failed nonetheless because Dr. Berry's and its own negligence precluded a finding that LAA was a legal cause of Kadlec's injuries. The court found, however, that those intervening acts were "easily associated with" the risk of harm brought about by the misleading nature of LAA's referral letters. As the court explained, "[Dr. Berry] had used narcotics while on-duty in the past, and [LAA] could foresee that he would do so again if [it] misled [Kadlec] about his drug problem." The harm to the patient and Kadlec, therefore, was a foreseeable consequence of LAA's conduct, the court concluded.

Accordingly, the appellate court upheld the district court's finding of liability against LAA and reversed the judgment against Lakeview. ■

Kadlec Medical Center v. Lakeview Anesthesia Associates, 5th Cir., May 8, 2008, Health Care Compliance Reporter ¶800,503.

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Legal health records' accuracy, authenticity crucial, experts say

When creating, correcting, and adding to a patient's health record, it is crucial for legal purposes to make sure the information is accurate and authentic and that the original record is maintained, according to experts who spoke during a recent American Health Information Management Association webinar on defining and maintaining the legal health record.

Victoria Barcena-Weaver, Director of the Shared Services Division, Health Information Management, at Hospital Corporation of America, Nashville, Tennessee, said the legal health record supports the decisions made in a patient's care, supports the revenue sought from third-party payers, and documents the services provided as legal testimony regarding the patient's illness or injury, response to treatment, and caregiver decisions.

Defining the record. According to Barcena-Weaver, when defining the record it is important to confer with outside legal counsel. "At the end of the day you have to consult your individual facility's legal counsel to make sure you're covering special considerations for your facility as well as state and local laws," she said.

Authenticity. Under CMS' interpretive guidelines for hospitals, all entries into the record must be legible, complete, and authenticated and dated promptly by the person (identified by name and discipline) who is responsible for ordering, providing, or evaluating the service furnished, according to Keith Olenik, Principal, The Olenik Consulting Group, Kansas City, Missouri. "We really need to make sure that the identity of the individuals who authenticated or created that information also appears—their name and their discipline—otherwise we're looking at possibly not being compliant," he emphasized.

Accuracy. To ensure accuracy, facilities should validate record identity, Barcena-Weaver said, adding that each entry should be linked to a specific record identifier. "Chronology must be apparent in the [electronic health record (EHR)]." She noted that the people who may make entries in the EHR should be defined by organizational policy. Organizations must follow standards and policies for level of documentation based on licensure, certification, and professional practice standards, she added.

Retention of original record. Olenik advised organizations to retain the original records. "Follow the basic tenet of never obliterating or altering an original entry," he said. Changes to the original can include corrections, clarifications, addenda, late entries, and patient amendments, he explained, noting that policies and procedures should address each type of action and when it is appropriate.

Consider what the original record is, Barcena-Weaver recommended. For instance, the original could be could be an electronic document or it could be a paper document that was scanned. The integrity of the information must be maintained through sound information management principles, and it should be clear who the author of that information is, she noted. Olenik added that organizations should document images and anything else that can be transported electronically.

Late entries and amendments. Olenik cautioned providers to review how they handle late entries—information entered after the fact—and patient amendments. These additional entries should be supported by policies, he said. "You don't want to write a policy that cannot be supported by your practice," he warned. Managing amendments is critical if the information will be used to support clinical decisions, Olenik said. "You want to look at the [EHR] that you have, how you perform these functions, and then document your policies appropriately," he emphasized.

Preserving integrity of records. Olenik added that there should be a clear indication of the various versions and links among the versions. "Amendments that intentionally change the content or character of health information in the EHR for less than honorable purposes [would be considered] tampering... Document that this type of activity is not appropriate," he advised. "We need to make sure that we're assuring that the electronic information has not been altered," Barcena-Weaver added.

Finally, organizations should be able to lock down the record when it is considered complete so that people cannot change it, Olenik advised. "Each organization will have to determine what's best for [its] facility," he said. ■

CCH Washington Bureau, May 5, 2008.

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Medicare mark-up prohibition on diagnostic tests: Navigating compliance and coding implications

by Charles I. Artz, Esq. and Michael D. Miscoe, CPC, CHCC, Contributing Editors

Medicare providers have long been able to report comprehensive diagnostic services when either the technical or professional component of the service was "purchased" from an outside provider or entity. An issue, however, has arisen regarding the circumstances in which this is permissible and the fee that Medicare may be charged for the purchased component of the test. CMS recently published new rules related to purchased diagnostic services.

The rules regarding purchased diagnostic services frequently are implicated in situations involving radiology services. Consider the following hypothetical: A recent audit revealed that an imaging center in one state was performing the technical component of services on-site. The images were interpreted by a physician who was physically located in another state but had a license to practice medicine in the state where the imaging center was located. The interpreting physician was not an employee, but rather an independent contractor for the imaging facility. Such a situation falls squarely within the new rules and, therefore, a review of these rules is necessary to determine whether this approach is permissible.

Published rule changes

On November 27, 2007, CMS published an expanded diagnostic test mark-up prohibition (MUP) rule, which is applicable to both the technical and professional components of diagnostic tests.[1] The original regulation was slated to go into effect January 1, 2008.

A few weeks later, on January 3, 2008, CMS published a notice delaying certain provisions of the MUP until January 1, 2009.[2]

The MUP, as revised pursuant to 42 C.F.R. §414.50, contained the following elements:

- The new MUP rules apply to both the technical and professional components of diagnostic tests.
- The new MUP rules do not apply to clinical laboratory tests, which already have their own MUP.
- If a physician or supplier (or related party) bills for the technical component (modifier TC) or professional component (modifier 26) of a diagnostic test that was ordered by the physician or supplier and the diagnostic test is either purchased from an outside supplier or performed at a site other than the office of the billing physician or supplier, the payment (less any applicable deductible and coinsurance) for either component cannot exceed the lowest of the net charge, actual charge, or applicable fee schedule amount for the performing provider (*i.e.*, the provider who "sells" one part of the test).
- The phrase "office of the billing physician" is defined as: (1) the medical office space where the physician or supplier regularly furnishes patient care; or (2) in the case of a group practice, the space in which the physician organization provides substantially the full range of patient care services generally provided by the physician organization.

CMS received several comments expressing concern about the ambiguity created in the MUP rules with respect to the "office of the billing physician" definition. Over the next several months, CMS is accepting comments and proposals about how to create a clearer definition of "office of the billing physician." Physicians should not expect this issue to go away.

There also were concerns that compliance with the Stark II Phase III "same building" test would create noncompliance under the new MUP rule. In other words, compliance with the complicated Stark II rule would not constitute compliance with the MUP; accordingly, any mark-up or profit would be precluded even though the physician group may be structured lawfully under the stringent Stark II rules.

CMS conceded that it was concerned that its definition of "office of the billing physician" in the MUP rule "may not be entirely clear and could have unintended consequences,"[3] although it did not identify what "unintended consequences" it was specifically concerned about. Nonetheless, to study the issues further, CMS delayed the applicability of the revised MUP until January 1, 2009, with two exceptions.

The first exception applies to anatomic pathology diagnostic testing services furnished in space that: (a) is utilized by a physician group practice as a "centralized building" under the Stark II regulations; and (b) does not qualify as a "same building" under the Stark II rules. For this kind of testing, the MUP went into effect January 1, 2008, and will remain in effect. CMS stated that anatomic pathology diagnostic testing arrangements precipitated the revised MUP rules and remain

its "core concern." Continued application of this provision of the MUP rule eliminates physicians' opportunity to generate any profit from arrangements that are structured such that the technical and professional components are performed in a location that technically complies with the "centralized building" rule but does not comply with the "same building" rule under Stark II.

The second exception applies to purchased technical components of diagnostic tests. CMS has not delayed the MUP with respect to the technical component of any purchased diagnostic test given that "[t]he anti-markup prohibition with respect to the technical component of purchased diagnostic tests is long-standing and was incorporated into the expanded and revised provision of §414.50."[4] Accordingly, the MUP will remain applicable to the technical component of any purchased diagnostic test.

Reprieve for certain arrangements

At a minimum, the delayed implementation of the MUP rule eliminates the potential conundrum in which one or both components of a diagnostic test were performed in the "same building" but not in the same office space. For example, a practice with an imaging component could have an MRI on the first floor of an office building and the physicians' offices on the second floor of the same building. This arrangement satisfies the Stark II regulations, but it would violate the MUP.

Additionally, when interpretations of tests are performed off-site pursuant to a contract, purchase of the professional component of such tests arguably may be allowed without being restricted by the MUP. There appears to be a reprieve for both of these kinds of arrangements until at least January 1, 2009. When the MUP is implemented, however, these arrangements may have to be restructured or eliminated.

Pod labs and imaging restrictions

Pod labs (labs that meet the centralized building test under Stark) and specialists billing for imaging appear to have been CMS' main targets. The Office of Inspector General (OIG) believes these arrangements are inherently abusive. Under these arrangements, pod labs rent space and technology services to the physicians. The pod labs also provide a physician to interpret the tests, creating the appearance that the pod labs are selling both the professional and technical components of the tests to the physicians.

According to the OIG, the difference between the amount the physician makes over the lease/purchase prices constitutes something of value: the opportunity to bill and make a profit. Pod lab arrangements are arguably lawful structures pursuant to Stark II, but physicians cannot make a penny above what they pay under these contracts, rendering them largely ineffectual from a business perspective with respect to Medicare claims.

Further, some commenters requested that CMS impose imaging restrictions similar to those imposed by a large Pennsylvania Blues plan, Highmark Blue Shield, allowing only radiologists to bill for certain imaging studies. CMS rejected this request, indicating it had no legal authority to impose such restrictions.

The full employee rule

CMS did not adopt the full employee rule as it had proposed. Implementation of the full employee rule would have limited performance of the technical or professional component of the test to full-time employees only. Under this standard, the MUP would not apply if a full-time employee performed the service. Rather than implement a full-time employment standard when the physician (or technician) performing the service (the professional or technical component as the case may be) is required to be a full-time employee, the failure to implement this provision allows performance by a full-time employee, part-time employee, or independent contractor.

CMS' failure to impose a full-time employment requirement is additionally significant because it makes employment status irrelevant for determining applicability of the MUP rule. Instead, the determining factor is the location where the professional or technical component of the service is performed. If the professional or technical component of the service is not performed at the location where substantially all of the practice's medical services are provided, the practice billing the service cannot mark it up beyond what the practice paid for it (*i.e.*, the lowest of the actual charge, net charge, or fee schedule amount).

Coding implications

If the professional or technical component of the service is performed at the office site consistent with the regulations, the MUP does not apply, and the practice may bill the full global fee. When the MUP applies, the coding and fee implications are significant and a number or possible scenarios emerge.

Generally, the billing entity must identify that a purchased test was performed, as well as the price paid for the service, in field locator 20 of the Form CMS-1500. Moreover, the billing entity may not charge Medicare any more than the amount paid. In the short term, this billing requirement applies only when the technical component of the test is performed externally. Alternatively, the entity performing the test can simply report the service directly and append modifier TC to reflect only the technical portion of the service. When the physician purchases the technical component of the service, the service is performed at a different location, and the

physician is billing for the global service (no modifier), then the physician must alter his or her fee to reflect the actual amount of the purchased technical component when that amount is less than the CMS allowance.

Ultimately, if the proposed rule takes effect in its current form, when the professional component of the service is purchased and performed externally, this fact and the price paid for the service must be identified in field locator 20 of the Form CMS-1500 form. When this is the case, the billing entity is assumed to have performed the technical component of the service and the global service is billed (*i.e.*, without a modifier). Again, the alternative is to have the entity performing the technical component of service bill just that component with modifier TC, while the physician performing the professional component bills the service with modifier 26.

It should be noted that not all diagnostic studies have professional and technical components. As an example, consider a range of motion study (Current Procedure Terminology (CPT®) code 95851) or a physical performance test (CPT® code 97750). When these tests, which are purely technical and have no professional/technical split, are purchased and performed externally, the MUP applies and the information in field locator 20 of the CMS Form-1500 must include that the test was purchased and the amount paid for the test. Because of this possibility, be certain to check the Medicare Physician Fee Schedule to determine if the service at issue has a professional/technical split.

Conclusion

Returning to the hypothetical above, because the purchased component of the test is the professional component, there currently is no issue given the delay in implementation of the related provisions of the MUP rule. Nonetheless, this scenario will fall within the new provisions when implemented on January 1, 2009.

Compliance with the MUP is imperative. Physicians involved with the purchase of diagnostic or lab services should evaluate their exposure under the MUP now. False Claims Act (FCA) and Civil Money Penalties (CMP) case law is clear in establishing that knowing noncompliance with a regulation that establishes a condition of reimbursement creates either FCA or CMP liability. A "knowing" violation occurs if there is actual knowledge, deliberate ignorance, or reckless disregard of the applicable billing rules. FCA/CMP sanctions can be enormous, including a fine of up to $11,000 for each improperly submitted claim, triple damages, and exclusion from federal health care programs. Physicians are advised to scrutinize their billing carefully when any portion of a diagnostic service is performed externally. Even those who are only purchasing the professional component of a service should plan for implementation of the new MUP rules.

Recent developments

On March 31, 2008, a federal district court in Washington, D.C., issued an injunction preventing the MUP from going into effect.[5] While it was anticipated that this injunction would be temporary, it was not anticipated that the injunction would last only a few weeks.

In *Atlantic Urological Associates v. Leavitt*,[6] three urology groups, one pathologist, UroPath, and the clinic director of UroPath sought and obtained a temporary injunction, arguing that if the anatomic pathology prohibition was not enjoined, UroPath's existing business would be destroyed almost immediately, and the physician group labs would have to be dismantled. Tissue samples then would have to be sent to outside labs, and the outside labs, instead of the physician groups, would bill for those services anyway.

In response to UroPath's request for an injunction, the court held that CMS violated the Federal Administrative Procedure Act by issuing an arbitrary and capricious regulation. The court found that the MUP was arbitrary because it failed to consider relevant data from the public or provide any explanation or rational connection between the final MUP rule and the public's input.

The court also found that the physician practices proved the MUP rule would cause irreparable harm because they would lose a substantial portion of their business inasmuch as their clinical labs would have to close. The government's regulations would completely destroy UroPath's business model, the court concluded.

On May 5, 2008, despite having granted the preliminary injunction just weeks earlier, the district court dissolved the injunction and dismissed the UroPath case in its entirety.[7] The court, in its reasoning, held that physicians submitting claims in the context of UroPath-type models would have to go through the five-step internal Medicare appeal process before filing a suit in federal court. Accordingly, the court concluded that it had no jurisdiction to hear the case until that administrative process was complete.

Unless the federal court of appeals reverses this decision, which is unlikely, the UroPath model and every similar pod lab arrangement has been effectively destroyed by the government, inasmuch as it is impossible for physician pod labs to submit claims and then challenge the regulation through the administrative appeal process without violating the MUP rule and exposing themselves to FCA liability. In suggesting that providers could include a narrative statement in field locator 24D of the Form CMS-1500, the court failed to recognize that this field is for submission of CPT® modifiers and only permits entry of eight characters. It is unclear what type of administrative challenge could be made in eight characters that would, in the words of the court, "demonstrate that a physician group lacked intent to defraud the program, [thereby] removing any potential liability the group might have otherwise incurred by filing the claims."[8]

Nonetheless, in light of the dissolution of the injunction and dismissal of the litigation, the January 2008 final MUP rule will be effective with the following implications:

1. The MUP is now in effect as it relates to purchased professional components and nonpurchased technical components of anatomic pathology diagnostic testing

services. This means neither the professional nor the technical component of any anatomical pathology test can be marked up.

2. The professional component of other diagnostic tests (not involving anatomic pathology) can be marked up consistent with existing regulations. (Notably, CMS' interpretive guidelines have precluded this mark-up for a significant amount of time, and there is ongoing debate about which rules apply.)
3. The technical component of any diagnostic test cannot be marked up and, therefore, is subject to the MUP.
4. UroPath-type pod labs no longer may leverage any profit for physicians, despite that such arrangements may remain technically compliant with the Stark II "centralized building" requirement. ■

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1 *Final rule*, 72 FR 66221, Nov. 27, 2007.
2 *Final rule*, 73 FR 404, Jan. 3, 2008.
3 *Id.* at 405.
4 *Id.*
5 *Atlantic Urological Associates v. Leavitt*, No. 08-141, D.D.C., March 31, 2008.
6 *Id.*
7 *Atlantic Urological Associates v. Leavitt*, No. 08-141, D.D.C., May 5, 2008.
8 *Id.*

HIPAA

Senators agree to strengthen health IT bill privacy provisions

Senators working to protect the privacy and security of personal health information have reached an agreement that will advance negotiations over provisions in the Wired for Health Care Quality Act ("Wired Act"), a bill sponsored by Senators Edward Kennedy (D-Mass.) and Michael Enzi (R-Wyo.) to help establish a national health information technology system.

Senator Patrick Leahy (D-Vt.) has been working with Kennedy, Enzi, and other members of the Senate to strengthen the privacy and security protections in the legislation, and Leahy's privacy provisions will be incorporated into a version of the bill that Kennedy and Enzi are expected to offer this month.

Last year, Leahy and Kennedy introduced the Health Information Privacy and Security Act, which would create new privacy safeguards to better protect patients' personal health information and impose criminal and civil penalties for unauthorized disclosures. During negotiations over the provisions in the Wired Act, Kennedy committed to work with Leahy on a Judiciary Committee hearing on health information privacy to be held in June.

Wired Act privacy provisions. The language drafted by Leahy for inclusion in the Wired Act would:

- strengthen privacy by eliminating the loophole in the bill that would have allowed operators of personal health information databases to provide health records to virtually anyone under the Health Information Portability and Accountability Act (HIPAA) privacy rule;
- eliminate loopholes in the HIPAA privacy rule that allow certain health care providers to use or disclose patient health records for marketing purposes;
- direct the HHS Secretary to submit a report to Congress containing recommendations for privacy and security protections for personal health records;
- provide a broad right of access to inspect records retained in electronic form and receive an electronic copy of the record;
- strengthen congressional oversight over HIPAA privacy compliance and enforcement;
- direct the HHS Secretary to ensure transparency and stronger privacy obligations on health care providers that contract and outsource patient health records to third-party providers; and
- direct the HHS Secretary to provide for the development of standards and protections to ensure that consumers are notified when their personal health information has been compromised.

"We have worked for months to secure stronger privacy protections in the Wired Act," Leahy said. "I thank Senator Kennedy and Senator Enzi for their willingness to address these important issues. No information is more personal than an individual's health records. In the information age, it is essential to protect the privacy and security of Americans' most sensitive personal data from unauthorized disclosure online and through commercial databases." He added, "Today's agreement is an important first step in accomplishing this goal, and I look forward to continuing to work with Senator Kennedy to examine ways to better protect Americans' health privacy." ■

U.S. Senator Patrick Leahy Press Release, May 14, 2008.

Anti-Kickback

OIG rejects free labeling services arrangement

The Office of Inspector General (OIG) has declined to approve a laboratory's proposal to provide certain services at no cost to dialysis facilities because the arrangement could potentially generate prohibited remuneration and subject the laboratory to administrative sanctions under the anti-kickback statute, according to a recent advisory opinion.

The laboratory provides testing services to dialysis patients pursuant to service contracts with dialysis facilities. The laboratory provides: (1) composite rate tests, which are included in the composite rate that Medicare pays the dialysis facilities and, therefore, are not separately billable; and (2) noncomposite rate tests that are not covered by the Medicare composite rate reimbursement and are separately billable.

Under the proposed arrangement, the laboratory would provide some of the dialysis facilities with services consisting of labeling test tubes and specimen collection containers that are used by the dialysis facilities to send specimens to the laboratory for testing. The laboratory would not charge the dialysis facilities for these services. According to the laboratory, selection of dialysis facilities to receive the free services would be based on whether offering such services would be necessary to obtain or retain a facility's business.

The proposed arrangement would run afoul of the OIG's position on the provision of free or below-market goods or services to actual or potential referral sources. First, the arrangement would provide a financial benefit to the selected dialysis facilities: the receipt of free labeling services that they otherwise would be obligated to provide at their own expense and for which they would receive reimbursement through their composite rate payments. Second, the free labeling services may be viewed as a discount on the amount the selected dialysis facilities pay the laboratory for composite rate tests in exchange for the referral of noncomposite rate tests to the laboratory. Accordingly, the OIG could impose sanctions on the laboratory in connection with the proposed arrangement. ■

OIG Advisory Opinion, No. 08-06, May 2, 2008, Health Care Compliance Reporter ¶500,185.

In the News

Enforcement data added to HIPAA privacy Web site

The HHS Office of Civil Rights (OCR) has added new enforcement data to its Web site on Health Insurance Portability and Accountability Act (HIPAA) privacy compliance. The enhanced information about the OCR's health information enforcement program includes: (1) charts showing enforcement results by year; (2) state-specific case investigation results; (2) charts showing the number of complaints received each year; and (4) the top five HIPAA privacy compliance issues in investigated cases resolved through corrective action each year. The new OCR data section may be accessed at http://www.hhs.gov/ocr/privacy/enforcement/data.html.

HHS Release, May 9, 2008.

Former employee pleads guilty to HIPAA violations

A former employee of a counseling center pled guilty to violating the Health Insurance Portability and Accountability Act by allowing two individuals to take patient files from the counseling center with the intent to obtain personal gain. The individuals who took the files pled guilty to fraudulently obtaining credit cards and aggravated identity theft. Each was sentenced to serve over 100 months in federal prison and pay more than $100,000 in restitution to their victims. At sentencing, the former counseling center employee faces up to ten years in prison and a fine of up to $250,000 for her role in allowing access to the medical files.

DOJ Press Release, May 8, 2008.

Drug distributor settles reporting violation claims

McKesson Corporation, a national distributor of branded and generic prescription medications, has agreed to pay $13.25 million to resolve allegations that it violated federal reporting provisions related to the sale of certain prescription medications regulated by the Drug Enforcement Administration (DEA), the Department of Justice announced. The settlement alleges that from January 2005 through February 2007, McKesson sold large quantities of certain prescription medications to pharmacies and failed to report these sales to the DEA as suspicious orders, as required by the Controlled Substances Act. The Act requires that distributors registered with the DEA to sell controlled substances to retail pharmacies report suspicious orders of controlled substances, including orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. The Act authorizes a civil penalty of up to $10,000 for each violation of the reporting requirement.

DOJ Press Release, May 2, 2008.

Dermatologist found guilty of Medicare fraud

A federal jury in Miami convicted a dermatologist of conspiracy to defraud the U.S. government, conspiracy to cause the submission of false claims to Medicare, conspiracy to solicit and receive kickbacks, and conspiracy to commit health care fraud, the U.S. Attorney for the Southern District of Florida announced. At trial, the dermatologist's patients testified that she wrote prescriptions for medications that they did not want or need, solely for the purpose of billing Medicare for the medications. As part of these conspiracies, the dermatologist wrote unnecessary prescriptions for medications for more than 40 patients, and Medicare was billed $620,000 by complicit pharmacies for unnecessary prescriptions; by complicit durable medical equipment suppliers for equipment used with the prescribed medications; and for visits to the dermatologist. The dermatologist faces a maximum of 15 years in prison for her role in the fraud scheme.

U.S. Attorney, Southern District of Florida Press Release, April 30, 2008.