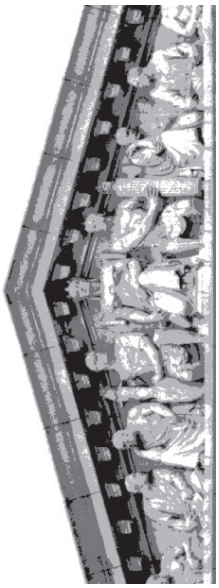

G-2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

Medicare Finalizes 2006 Inpatient Changes

Hospitals Get Incentive For Reporting Quality Data

Inpatient hospitals that submit data on specific quality measures will receive a full 3.7% increase in payment rates beginning October 1, the Centers for Medicare & Medicaid Services (CMS) says in final changes to hospital inpatient payment policies for fiscal 2006.

To receive the full payment for FY 2006, hospitals must correctly abstract and report clinical data on 10 quality measures relating to the treatment of heart attack, heart failure, and pneumonia cases for two consecutive quarters. Many hospitals are already reporting 17 quality measures for these three conditions, according to CMS.

The final rule also reduces the outlier threshold to $23,600 in 2006 from $25,800 in 2005. The outlier threshold is used to determine how much a hospital's costs for a particular case must exceed the DRG payment before extra payments will be made for the case. As a result of the lower threshold, it will be easier for hospitals to qualify for additional payments in 2006, says the agency. ➥ *p. 2*

CMS Proposes Revisions To Part B Policies, Payment

The Centers for Medicare & Medicaid Services (CMS) is proposing to expand the Stark prohibition on self-referrals to include nuclear medicine services, which previously were exempt. The change is contained in the proposed Medicare physician fee schedule (MPFS) for 2006, announced August 1.

CMS says the change is necessary because physician self-referrals for nuclear medicine services create the same risk of abuse and overutilization that occur in other contexts, and it is now easier for such services to be furnished outside of hospital facilities, in freestanding physician-owned facilities. Medicare is now covering PET (positron emission tomography) scans in a far greater range of situations than before, which also has increased the risk of abuse, CMS states. Between 1999 and 2003, nuclear medicine procedures grew 85%—faster than other physician services, and faster than other forms of imaging services.

CMS also states that consultants and others have been encouraging the spread of joint ventures because the nuclear medicine services were not initially covered under the Stark prohibition. Because this change would require many arrangements to be restructured, CMS is soliciting comments on how to minimize the impact on physicians who are currently parties to such arrangements (such as by delaying the effective date of the change or by grandfathering certain arrangements). ➥ *p. 9*

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2006 Inpatient Changes, *from p. 1*

CMS projects that the combined impact of the 3.7% inflation update and other changes adopted in the final rule will yield an average 3.5% increase in payments for operating costs for urban hospitals in 2006, while rural hospitals will see an average increase of 3.3%.

The final rule also:

- **Revises nine cardiovascular surgery DRGs (diagnosis related groups) that account for more than 700,000 Medicare discharges per year.** CMS says it is making these revisions to Medicare's payments to better recognize the severity of illness. The changes will differentiate cardiac surgery patients based on whether they have "major cardiovascular conditions." The agency believes the changes represent a significant improvement in the accuracy of the cardiac DRGs. CMS currently is completing a comprehensive analysis of potential changes in cardiac DRGs as recommended by the Medicare Payment Advisory Commission for implementation by fiscal 2007.

The IPPS final rule was published in the August 12 Federal Register. *The changes take effect October 1.*

- **Expands the number of DRGs that are subject to the postacute care transfer policy.** The policy reduces payment to the hospital when the patient is transferred after a short stay to a post-acute care setting that provides most of the patient's care. The purpose of this policy is to protect Medicare from paying for the same care twice—once as part of the hospital's payment for the DRG, and then as a separate payment to the postacute facility. CMS had proposed to make 231 DRGs subject to this policy. However, in response to public comments, CMS reduced the number of DRGs that would be subject to the postacute transfer policy to 182. CMS estimates the change to the postacute transfer policy will save $780 million.

- **Reduces the share of Medicare's inpatient hospital payments that are attributable to hospital labor costs from 71.1% to 69.7% for hospitals in areas that have labor costs greater than the national average.** The result would be a very small reduction in the rates paid to these hospitals. For all other hospitals, the statute requires the labor-related portion of Medicare's inpatient hospital rates to equal 62%. Any savings associated with the proposed change in the labor-related portion of Medicare's rates will be returned to all hospitals nationally through a higher base rate of payment.

- **Establishes indirect medical education (IME) resident caps for non-IPPS hospitals that convert to the IPPS.** CMS provides that, in such a situation, the fiscal intermediary will determine an IME FTE cap for the hospital, applicable beginning with the hospital's payments under the IPPS, based on the full-time equivalent count of residents during the cost-reporting period(s) used to determine the hospital's direct graduate medical education FTE cap in accordance with existing regulations.

- **Revises existing regulations concerning direct graduate medical education initial residency period (IRP).** CMS's policy on how IRPs are determined directly affects a hospital's number of FTE residents and, thus, the amount of direct GME payment to the hospital. The IRP is determined as of the time the resident enters the "initial" or first residency-training program and is based on the period of board eligibility associated with that medical specialty. In many cases, medical students simultaneously "match" to both a clinical base-year program and a specialty residency-training program. CMS has become aware, however, of situations where residents match into an advanced program but fail to match into a clinical base-year program. In the final rule, CMS revises regulations to indicate that, when a hospital can prove that a resident matched prior to the start of any training in an advanced residency program in the second residency year, the IRP will be determined based on the period of board eligibility for the specialty associated with the advanced program, even if the resident had not matched for a clinical base-year training program.

Resource

Hospital inpatient prospective payment system final rule for FY 2006: *www.cms.hhs.gov/providerupdate/regs/cms1500f.pdf*

ACLA: Proposed "Correction" Could Hurt Fraud & Abuse Collection Program

The American Clinical Laboratory Association (ACLA) is opposing a proposed "correction" to the requirements under the Health Care Fraud and Abuse Data Collection Program, saying it could lead to needless reporting of minor actions.

The proposed correction, published June 24 in the *Federal Register*, amends the definition of "any other negative action or finding" to include language that clarifies when states are *not* required to report certain actions. This clarifying language was found in the preamble of the final rule when it was originally published Oct. 26, 1999, but apparently was left out of the text of the rule itself.

Currently, the text of the section in question (61.3) provides that "citations, corrective action plans, and personnel actions" need not be reported. The proposed correction narrows these exceptions and now excludes "administrative fines or citations, correction action plans, or other personnel actions," unless they are: "1) connected to the delivery of healthcare services, and 2) taken in conjunction with other licensure or certification action, such as revocation, suspension, censure, reprimand, probation, or surrender."

Exemption Narrowed

This language, says ACLA, would turn the exemption "on its head" and would significantly narrow a much broader exemption. "The fact that this oversight has apparently gone undetected for almost six years also raises questions about how necessary the proposed correction actually is," writes ACLA in comments submitted to the Health and Human Services Office of Inspector General.

ACLA is particularly concerned because this correction may, in fact, require states to report to the data bank a large number of relatively minor actions, a circumstance that may actually interfere with the ability of interested parties to recognize where real problems may exist or that could unfairly prejudice the party about whom or which the report was made.

For example, under the proposed correction, most corrective action plans will have to be reported, states ACLA. "Corrective action plans are routinely used during inspections to highlight any issue, regardless of significance, that the inspectors believe should be corrected," the group writes. "The provider lists how it plans to correct the problem identified, and the inspecting entity may then check back to see if the specified action was in fact taken."

In most cases, notes ACLA, that is the end of the matter. Inclusion of such relatively minor matters will likely overwhelm the data bank with minutiae that is of little significance, the group argues. Further, a minor inspection issue should not be the basis for a person, who sees a report of that nature in the data bank, to draw significant conclusions concerning the provider named in the report.

"If the matter were not subsequently resolved as required by the Corrective Action Plan, it might then be appropriate to report it to the data bank, but not before," writes ACLA. "Ac-

Medicare To Stop Processing Non-Compliant Claims

The Centers for Medicare & Medicaid Services (CMS) will not process electronic claims starting October 1 unless they are compliant with the Health Insurance Portability and Accountability Act (HIPAA), the agency said August 4.

As of October 1, the start of fiscal year 2006, claims not compliant with the standardized transactions and code sets rule (TCS) will be returned to the filer for resubmission."We are firmly committed to an interoperable electronic healthcare system, and the close-to-100% compliance with HIPAA standards for claims shows that the healthcare industry shares this commitment," said CMS Administrator Mark McClellan.

As of June, only about 0.5% of Medicare fee-for-service providers submitted electronic claims that were not HIPAA-compliant, with clinical laboratories having the highest rate (1.72%).

CMS currently is working with providers that are not in compliance, the agency said. A contingency plan had been in effect since the October 2003 compliance deadline, allowing covered entities that requested conditional extensions to transmit noncompliant transactions. The law required all payers to conduct HIPAA-compliant transactions no later than Oct. 16, 2003, but only about 31% of Medicare claims were compliant at that time.

cordingly, [we] suggest that language be included in the revised definition that will exempt such common, easily corrected actions, unless subsequent action is taken against the facility."

Resources

- OIG *Federal Register* notice, June 24, 2005: *www.oig.hhs.gov*.
- ACLA: 202-637-9466

California Hospital Settles Upcoding Charges

Simi Valley Hospital and Health Care Services in Los Angeles has paid the federal government more than $3.6 million to resolve allegations that it routinely "upcoded" Medicare claims for treatment of pneumonia cases from 1993 through 1998, according to Debra Yang, U.S. Attorney for the Central District of California.

The hospital did not admit any wrongdoing as part of the settlement, but entered into a corporate integrity agreement with the Department of Health and Human Services (HHS) that is designed "to ensure continuing compliance by the hospital with Medicare and other federal health programs' rules and regulations," said Yang in a statement.

HHS undertook a nationwide review in 2000 of compliance with pneumonia billing practices. As a result of that review, federal investigators found evidence that from 1993 through 1998, Simi Valley submitted claims for more intensive or sophisticated levels of service than what had actually been documented by the hospital in patients' medical records. The government also alleged that the questionable billing extended beyond Simi Valley's classification of pneumonia cases and included billing for septicemia, a life-threatening form of blood poisoning, rather than less serious forms of infection and for classifying less serious respiratory problems as services provided to patients who are on mechanical ventilators.

Simi Valley Hospital and Health Care Services also has entered into a corporate integrity agreement with the Department of Health and Human Services.

Resources

- U.S. Attorney Debra Wong Yang: 213-894-6947

GAO Faults CMS Plan On Contracting Reform

The Government Accountability Office (GAO) is recommending that the Centers for Medicare & Medicaid Services (CMS) extend its implementation schedule on Medicare contracting reform from 2009 to 2011.

The GAO also believes that CMS's estimates of costs and savings are too uncertain to support decisions on contracting reform implementation.

In a new report released in August, the GAO concluded that CMS has provided an appropriate framework to implement contracting reform in some critical areas but not in others. For example, says GAO, the plan indicates the rationale for reform but lacks a detailed schedule to coordinate reform activities with other initiatives CMS plans to implement at the Medicare administrative contractors (MAC) during the same period.

Further, CMS's plan does not comprehensively detail steps to address potential risks during the transitions of the claims workload from the current contractors, such as failing to pay providers or paying them improperly. "These transitions will be complex to manage because they require moving multiple claims workloads from current contractors to a single MAC with new jurisdictional lines," writes GAO in the report. CMS has accelerated its schedule to transfer the current contractor claims workload to MACs by 2009, more than two years ahead of the time frame mandated by law, it adds. "This schedule leaves little time for CMS to adjust for any problems encountered."

The Medicare Modernization Act of 2003 reformed contracting for the administration of claims for Medicare Parts A and B. The MMA required CMS to conduct competition for its claims administration contracts and to transfer the work to MACs by October 2011.

Resource

GAO report, "Medicare Contracting Reform: CMS Plan Has Gaps and Its Anticipated Savings Are Uncertain," *www.gao.gov/cgi-bin/getrpt?GAO-05-873*.

COMPLIANCE PERSPECTIVES

Justice Department Limits Prosecution Under HIPAA

David Marshall, JD, and Rebecca Williams, RN, JD, are partners with the law firm of Davis Wright Tremain

The U.S. Department of Justice (DOJ) recently issued an internal opinion (DOJ opinion) that limits DOJ criminal prosecutions under the "Administrative Simplification" provisions of the Health Insurance Portability and Accountability Act (HIPAA).[1] The DOJ opinion was leaked to the Internet (*see www.worldprivacyforum.org/pdf/hipaa_opinion_06_01_2005.pdf*).

In sum, the DOJ opinion limits prosecutions to:

- "Covered entities" – that is, healthcare providers who engage in electronic transactions (such as most hospitals, medical centers, and physicians), health plans (including insurers and employee benefit plans), healthcare clearinghouses, and sponsors of Medicare prescription drug cards;
- Certain directors, officers, and employees of such covered entities who may be criminally liable "directly . . . in accordance with general principles of corporate criminal liability" (which, regrettably, is little explained in the DOJ opinion); and
- Those third parties who cause, aid or abet, counsel, command, induce, procure, or conspire with a covered entity to act (through employee conduct imputed to the entity in certain circumstances) in violation of HIPAA, liable under "principles of aiding and abetting liability and of conspiracy . . . ."[2]

The DOJ opinion leaves much unsaid. Although federal prosecutors likely will act with caution in applying its guidance, prosecutors retain the ability to prosecute parties outside of covered entities, depending on the applicable facts.

Background

HIPAA establishes: (1) civil penalties for enforcement of regulations promulgated under HIPAA, including the agency regulations respectively entitled Standards for Privacy of Individually Identifiable Health Information, Security Standards for the Protection of Electronic Protected Health Information, Standards for Electronic Transactions, and General Administrative Requirements Including Civil Money Penalties, Procedures for Investigations, Imposition of Penalties and Hearing[3] (HIPAA Regulations); and (2) criminal penalties available to enforce statutory prohibitions. The DOJ opinion applies to only the criminal aspects of HIPAA. The DOJ opinion will not affect the investigation of complaints or the imposition of civil money penalties by the government agencies responsible for HIPAA enforcement (the Office for Civil Rights for the HIPAA privacy regulations and the Centers for Medicare and Medicaid Services for the security and transaction regulations).

Under HIPAA, a person may face criminal penalties if he or she "knowingly and in violation" of HIPAA:

- "Uses or causes to be used a unique health identifier," such as a National Provider Identification Number;
- "Obtains individually identifiable health information relating to an individual," which generally is information related to an individual's health or condition, healthcare services, and payment for such healthcare services, including demographic information and patient lists; or
- "Discloses individually identifiable health information to another person."

If convicted, a person faces the following criminal penalties:

- A fine of not more than $50,000, imprisonment of not more than one year, or both for an offense committed without certain aggravating factors (discussed next);

[1] *This opinion was issued on June 1, 2005, by Steven G. Bradbury, Principal Deputy Assistant Attorney General.*

[2] *DOJ opinion, p. 1.*

[3] *42 CFR Parts 160, 162, and 164.*

- A fine of up to $100,000, jail time of up to five years, or both if the offense is committed through the use of false pretenses; and
- A fine of not more than $250,000, imprisonment of not more than 10 years, or both if the offense is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm.[4]

The Administrative Simplification provisions of HIPAA thus created three new crimes (HIPAA crimes):

- A federal misdemeanor for "knowing" violations of the administrative simplification provisions. The DOJ opinion says this crime "requires only proof of knowledge of the facts that constitute the offense" not "proof of knowledge that the conduct was contrary" to law;
- A five-year felony if a knowing violation involved false pretenses (such as misrepresentation of identity); and
- A 10-year felony if a knowing violation involved intent to transfer or use "protected health information" (PHI) for gain or to cause harm.

United States v. Gibson, resolved by plea agreement in Seattle, Washington, in late 2004, has been the only HIPAA privacy prosecution so far. While an employee at a Seattle cancer center, Mr. Gibson obtained "demographic" health information for a leukemia patient treated at his employer's facility. Thereafter, Gibson obtained credit cards in the patient's name, used for cash advances and items worth more than $9,000, such as video games, jewelry, groceries, and porcelain figurines. He was sentenced to 16 months in jail.

DOJ June 1, 2005, Opinion

According to the DOJ opinion, the department was asked by the General Counsel of the U.S. Department of Health and Human Services (HHS) whether only "covered entities" could be directly liable under the HIPAA criminal provisions or whether other persons could also be liable, particularly those whose actions cause a covered entity to violate HIPAA.[5] In response, DOJ opined that the parties "directly" liable included the "covered entities" and, "depending on the facts of a given case,"

> [C]ertain directors, officers, and employees of these entities may be liable directly under . . . [HIPAA], in accordance with general principles of corporate criminal liability, as these principles are developed in the course of particular prosecutions. Other persons may not be liable directly under this provision. The liability of persons for conduct that may not be prosecuted directly under section 1320d-6 will be determined by principles of aiding and abetting liability and of conspiracy liability.[6]

DOJ stressed that any analysis of liability for a HIPAA crime:

> ***must begin with covered entities, the only persons to whom the standards apply***. If the covered entity is not an individual, general principles of corporate criminal liability will determine the entity's liability and that of individuals within the entity, including directors, officers, and employees. Finally, certain conduct of these individuals and that of other persons outside the covered entity, including of recipients of protected information, may be prosecuted in accordance with principles of aiding and abetting liability and of conspiracy liability. *(Emphasis added).*[7]

The DOJ opinion concluded that for covered entities that are not individuals, "principles of corporate criminal liability" will determine the liability of the covered entity itself as well as any individuals who are acting for the covered entity. Accordingly, the conduct of agents of a covered entity (*e.g.*, those who act on behalf of the covered entity):

> . . . may be imputed to the entity when the agents act within the scope of their employment, and the criminal intent of agents may be imputed to the entity when the agents act on its behalf. *See* Kathleen F. Brickley [sic, Brickey], *Corporate Criminal Liability* §§ 3-4 (2d ed. 1992) [hereafter Professor *Brickey*]. In addition, we recognize that, at least in limited cir-

[4] *42 U.S.C. § 1320d-6.*

[5] *DOJ opinion, p. 1.*

[6] *Id.*

[7] *DOJ opinion, pp. 4-5.*

> cumstances, the criminal liability of the entity has been attributed to individuals in managerial roles . . . .[8]

The DOJ opinion declined to discuss further these general corporate and aiding and abetting liability principles, noting the law varies in different jurisdictions and will be applied on a case-by-case basis.

Principles Of Corporate Criminal Liability

Professor Brickey's analysis of these general corporate liability issues provides some guidance. As the DOJ opinion observed, generally corporations are held criminally responsible for the acts of their employees if the employees (1) act within the scope of their employment; and (2) with intent to benefit the corporation. Professor Brickey notes that:

> [In] the context of corporate criminal prosecutions, "within the scope of employment" is a term of art signifying little more than that the employee's crime must be committed in connection with his performance of some job-related activity . . . .[9]

Professor Brickey also has observed that the "clear weight of federal authority" holds a corporation bound by the acts of its agent even though the agent acts contrary to actual instructions or policy.

According to Professor Brickey, it is accepted doctrine that an agent "must intend to benefit the corporation if the entity is to share responsibility,"[10] with the agent intending to produce "some benefit to [the] corporation or some benefit to himself and secondarily to [the] corporation."[11] Where a "rogue" employee clearly acts with no intent to benefit a covered entity and acts solely for personal gain, prosecutors may be unable to impute that employee's conduct to his or her employer, and thus to show a covered entity was "in violation of HIPAA." Proof that a covered entity was involved and that the covered entity was "in violation of HIPAA" are essential elements of any HIPAA criminal violation, according to the DOJ opinion, even a criminal case brought only against an individual. In other words, the government must prove a covered entity was in violation, though a covered entity may not have been charged in the particular case against an individual.

The DOJ opinion notes that certain directors, officers, and employees of covered entities may be liable directly under HIPAA, "depending on the facts of a given case." Again, the DOJ opinion contains little explanation, but references *Brickey*. Professor Brickey's treatise explains that there is liability for corporate entity managers and employees for offenses committed by the corporate entity, including:

- liability for "direct" participants, whose conduct results in entity liability;
- liability for managers with duties to control illegal conduct based on responsibilities within the organization (commonly called "responsible corporate officers" under the Supreme Court cases[12]); and
- liability under the federal aiding and abetting statute.[13]

Under the aiding and abetting statute, a person who "aids, abets, counsels, commands, induces or procures" the commission of an offense against the United States may be punished as if he or she were the principal (*e.g.*, the one committing the underlying offense). Moreover, a person who "willfully causes an act to be done, which if directly performed by him ***or another*** would be an offense against the United States, is punishable as a principal."[14] *(Emphasis added.)* Professor Brickey's treatise has observed, now particularly relevant to this recent DOJ opinion and its interpretation of HIPAA, that:

> [T]he legislative history [of the aiding and abetting statute] . . . contains an explicit statement of congressional purpose "to clarify and make certain the intent to punish aiders and abettors regardless of the fact that they may be incapable of committing the specific violation which they are charged to have aided and abetted."[15]

By way of illustration, the court in *U.S. v. Scannapieco* upheld the conviction of a firearms dealer's ***salesman*** under the aiding and abetting statute for causing a violation of a statute that prohibits a ***dealer*** from selling and delivering firearms to a buyer while knowing the buyer does not reside in the state of the sale, despite the fact the ***dealer*** was not

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[8] *DOJ opinion, pp. 4-5.*

[9] *Brickey, Corporate Criminal Liability, § 3.01, p. 90 (1992).*

[10] *Brickey, at § 3.08, p.111, cases collected at p.111 - 114 (and in 2004 pocket part, citing U.S. v. Beusch, 596 F.2d 871, 877-88 (9th Cir. 1979)); see also, cases collected in Note, Corporate Criminal Liability for Acts in Violation of Company Policy, 50 Georgetown Law Journal 547 (1962).*

[11] *Brickey, at 4.02, p. 131.*

[12] *U.S. v. Dotterweich, 320 U.S. 277 (1943) and U.S. v. Park, 421 U.S. 658 (1975)).*

[13] *18 U.S.C. § 2.*

[14] *Id.*

[15] *Brickey, id., at § 5.11, p. 169, and n.92.*

present at the time of the illegal sale and not convicted of the sale. In *Scannapieco*, the court held the aiding and abetting statute permits conviction as a "causer" even though the accused was himself not capable of committing the act forbidden by federal statute (he was not a ***dealer,*** and the statute prohibited only acts by a ***dealer***).[16]

Professor Brickey's treatise noted that "an aider and abettor may be held accountable as a principal even though the perpetrator has not first been tried and convicted or even identified, so long as the government proves the crime was actually committed."[17] In other words, DOJ prosecutors may charge that an employee caused an entity to act "in violation of" HIPAA and that the employee is therefore liable, without charging the entity.

Finally, the DOJ opinion states that the conspiracy statute prescribes punishment "if two or more persons conspire . . . to commit any offense against the United States . . . and one or more of such persons do any act to effect the object of the conspiracy." Federal conspiracy liability is broad and poses risk to third parties who affiliate with covered entity employees who "cause" an entity to violate HIPAA.

Implications For Healthcare Providers

The DOJ opinion represents both good news and bad news for healthcare providers. In this environment where many, if not most, providers feel under the gun, with fears of government investigations and prosecutions, it is a relief to hear that the government's ability to prosecute HIPAA crimes is limited (though the extent of such limitation will only become clear as prosecutors develop a history of applying the DOJ guidance). Regrettably, this limitation, to the extent it truly exists, does not provide comfort to individual providers, such as physicians and other independent practitioners, who have been and continue to be directly liable under HIPAA as covered entities.

With respect to institutional providers, on one hand, the DOJ opinion may soothe some anxieties of workforce members. Of course, such perceived comfort may be unwarranted because prosecutors may turn to the aiding and abetting statute, conspiracy theories, and other criminal laws (such as identity theft laws) to prosecute employees, directors, officers, and other agents of HIPAA crimes. On the other hand, institutional providers remain on the hook for compliance with HIPAA.

Compliant providers will have appropriate policies and procedures in place to promote HIPAA compliance. Workforce members are required to comply with such policies and procedures. But with widespread knowledge (and probable misunderstanding) of the DOJ opinion, institutional providers now may face difficulty in encouraging workforce compliance. Institutional compliance officers often note that it helps to get the attention of a roomful of employees by stating that certain actions are both prohibited by policy and could result in criminal penalties, imprisonment, and fines. The DOJ opinion potentially undermines this motivational tool.

Conclusion

Analysis of the risk of criminal prosecution under HIPAA has become very fact-specific. Federal prosecutors may conclude there is no employee or third-party liability without a nexus between the particular individual and a covered entity acting in violation of HIPAA. When there *is* a nexus with a covered entity, when protected health information came from a provider and the third party dealt directly with a healthcare provider through one of its employees, then there is greater risk a prosecutor might bring a case. Arguably, based on the corporate liability doctrines referenced in the DOJ opinion, such a prosecution should fail absent proof the employee acted with some intent to benefit the employer entity.

Because the DOJ opinion has left to the DOJ Criminal Division and local U.S. Attorneys application of the opinion to real-world cases, we will have to await those cases to know for certain how line-level prosecutors will follow the DOJ guidance. Healthcare providers should continue to make good-faith efforts to comply with HIPAA and show prudence in encouraging compliance by employees.

Rebecca Williams *can be reached at Davis Wright Tremain, 600 Century Square, 1501 Fourth Ave., Seattle, WA 98101-1688. Phone: 206-628-7769. E-mail: beckywilliams@dwt.com.* ***David Wallace*** *can be reached at DWT, 777 108th Ave., NE, Suite 2300, Bellevue, WA 98004-5149. Phone: 425-646-6199.*

[16] *U.S. v. Scannapieco, 611 F.2d 619 (5th Cir. 1980).*

[17] *Brickey, § 5.11, p. 169 and n.92.*

Part B Policy & Payment, *from p. 1*

Payment Cuts

Medicare payment rates to physicians would fall by 4.3% under the proposed rule. The cut is required under a Congressionally-mandated formula tied to overall Medicare spending growth. Unless Congress acts to avert the projected cuts or redesigns the spending formula, the reduction will go into effect on Jan. 1, 2006.

"The payment reduction shows the need for more effective ways to pay physicians that help them improve quality and avoid unnecessary costs," said CMS Administrator Mark McClellan in a statement. "CMS is working with members of Congress, physician organizations, and other healthcare stakeholders on ways to improve physician payment without adding to overall Medicare costs, if at all possible."

Outpatient Drugs & Biologicals

A final rule is expected by November 1.

Hemophilia and homecare companies that supply items and services associated with furnishing blood-clotting factors have received a furnishing fee since 2005 of $0.14 per unit. CMS is proposing to update the fee in 2006 by the percentage increase in the consumer price index (CPI) for medical care for the 12-month period ending with June 2005 (last year's CPI-M was 5.1%). The 2006 update percentage is not yet available and will be included in the final rule.

Since 2005, reimbursements for intravenous immune globulin (IVIG) administered in a physician's office have been pegged to the average sales price (ASP), rather than the average wholesale price (AWP), and reductions have resulted (the per-gram dollar reduction for powdered brands was $25; for liquid brands, $10). Average IVIG treatments include about 30 to 50 grams. Despite calls for an increase in physician reimbursement for IVIG, the proposed rule does not include any commitment to change the current payment structure.

In the proposed rule, CMS does not specify a particular dispensing fee amount for inhalation drugs administered via a nebulizer. Instead, the agency seeks comments on an appropriate dispensing fee payment rate for such drugs in 2006. For 2005, CMS established an interim dispensing fee of $57 for a 30-day supply and $80 for a 90-day supply of these inhalation drugs. However, in establishing these fees, CMS indicated its intent to study the services delivered and the associated costs in order to set an appropriate dispensing fee for 2006.

Other Changes

The proposed rule makes adjustments to the resource-based relative value units (RVUs) that underlie fee schedule amounts for physicians' services by modifying calculations for malpractice RVUs and practice expense RVUs. Among other proposed modifications:

- **Telehealth services.** CMS proposes to add individual medical nutrition therapy (MNT, HCPCS codes G0270, 97802, and 97803) to the list of Medicare telehealth services. As required by law, only a registered dietitian or other nutrition professional may furnish and receive payment for this service. CMS proposes not to add group MNT (G0271 and 97804) and diabetes outpatient self-management training (G0108 and G0109) to the list of Medicare telehealth services.
- **National coverage decision time frames.** CMS proposes to revise the time frames for national coverage decisions (NCDs) to reflect the time frames mandated by the Medicare Modernization Act. CMS proposes to amend its regulations to provide that if CMS informs the Departmental Appeals Board (DAB) that a revision or reconsideration was or will be initiated, the DAB will stay the proceedings and set appropriate time frames for the revision to be completed. CMS would eliminate the 90-day reconsideration period for NCD appeals and, instead, the DAB would be able to establish sufficient time frames to reflect the time for the publication of the proposed decision, a 30-day comment period, and time for CMS to prepare its final determination in response to public comments. This proposed change will not apply to local coverage determinations.

Resource

Proposed changes to Medicare physician fee schedule for 2006: *www.cms.hhs.gov/providerupdate/regs/cms1502P.pdf*

Renal Care Group Under Investigation

Renal Care Group (Nashville, TN), which provides care to patients with kidney disease, is the latest dialysis company to be targeted in an investigation by the U.S. Attorney for the Eastern District of Missouri.

Company officials announced August 9 that they had received subpoenas related to Renal Care Group's compensation arrangements with physicians and medical directors, as well as information about the company's pharmaceutical and supply services to patients.

President and CEO Gary Brukardt said the company would cooperate with the investigation, noting that other dialysis companies have been subpoenaed as well. In March, U.S. Attorney James Martin made a similar request for information from DaVita Inc., another dialysis services company.

Fresenius Medical Care also has been subpoenaed. That company is expected to acquire Renal Care Group by the end of 2005, and Brukardt says the two firms had already anticipated that the federal investigation would include the Renal Care Group, and that the subpoena would not affect Fresenius's acquisition.

Renal Care Group is also one of several dialysis firms being investigated by U.S. Attorney for the Eastern District of New York Roslynn Mauskopf, in what appears to be a broad-ranging investigation into parathyroid hormone testing and vitamin D therapies at kidney dialysis centers.

Resource
David Dill: 615-345-5514

Judge Approves Tenet Settlement

A California judge has approved settlement of a nationwide class-action lawsuit brought against Tenet Healthcare Corp. over prices that uninsured and some underinsured patients were charged for prescription drugs and other medical products and services at hospitals owned and operated by the company and its subsidiaries.

The settlement, approved by Wendell Mortimer Jr. of the California Superior Court for Los Angeles County, directly resolves 13 cases that all involved disputes over amounts charged to uninsured patients, regardless of whether they were indigent. The cases were brought primarily on behalf of uninsured patients, who were billed at the hospitals' undiscounted gross charge rates, according to Tenet's recent 10-K filing with the Securities & Exchange Commission. While the specific allegations and relief sought vary from case to case, the plaintiffs generally allege violations of state consumer protection statutes, breach of contract, and other state law claims.

The settlement covers charges assessed by Tenet during the class period—between June 15, 1999, and Dec. 31, 2004—and obligates the company to refund amounts paid in excess of certain thresholds. The specific percentage of reimbursement varies, depending on the year the patient was treated as set forth in a table included in the proposed settlement.

CMS Gives Nod To Stock Ownership In New Stark Opinion

In its first general Stark advisory opinion issued since 1998, the Centers for Medicare & Medicaid Services (CMS) has concluded that stock held by physician shareholders of a medical practice does not constitute an ownership or investment interest that would trigger the prohibition on physician self-referrals, commonly known as the Stark law.

The opinion was requested by a large, independent, nonprofit group medical practice that

owns and operates outpatient clinical, educational and research sites in 34 communities. The practice employs more than 700 physicians, representing 86 different medical specialties. Physicians in the practice are eligible for stock ownership after two years of full-time employment, and when they leave the practice, the $1,000 purchase price is returned, without interest.

According to the August 5 opinion, the physicians would not be considered under the Stark law as owners or having financial interest in the practice since the doctors did not earn interest on the single $1,000 practice shares, and the doctors were not directly or indirectly paid dividends. In addition, the agency found no financial relationship because the physician shareholders had no right to distribution of net practice income, assets, or profits.

"Accordingly, the physician-shareholders lack the pecuniary incentive to enhance their investment interests normally held by purchasers of stock in for-profit corporations," CMS stated in the opinion. The agency cautioned, however, that similar arrangements with substantially the same facts by larger share prices or amounts of investment could trigger different analysis and results.

The advisory opinion is available at *www.cms.hhs.gov/physicians/aop/CMS-AO-2005-08-01.pdf*.

For the Record

Medicare Proposes Changes To Outpatient Pathology APCs

The Centers for Medicare & Medicaid Services (CMS) is proposing to reconfigure three ambulatory payment classification (APC) groupings for pathology and add a fourth. The changes are contained in proposed revisions to the hospital outpatient prospective payment system (HOPPS) for 2006, published July 25 in the *Federal Register*.

The proposed changes would increase outpatient payments to hospitals for 32 of the 47 services in the main pathology APCs, according to the College of American Pathology. These include a 36% rate hike for CPT codes reassigned to a revised pathology level IV APC group. Payment to hospitals for each would rise from $34.82 to $47.24. This includes the following codes:

88182 .... Cell marker study
88307 .... Tissue exam by pathologist
88325 .... Comprehensive review of data
88358 .... Analysis, tumor
88361 .... Tumor immunohistochem/comput
88365 .... Fluorescent in situ hybridization (FISH)
88368 .... In situ hybridization, manual
88184 ..... Flow cytometry/tc, 1 marker
88309 ..... Tissue exam by pathologist
88356 ..... Analysis, nerve
88360 ..... Tumor immunohistochem/manual
88362 ..... Nerve teasing preparations
88367 ..... In situ hybridization, auto

The proposed rule regroups the three existing pathology APCs – 342, 343, and 344 – and adds a fourth, 433, which will fall between 342 and 343 in terms of payment level. Under the proposal, a dozen existing APC 342 services would move to a new classification, 433, and receive 29% payment increases – from $11.78 to $15.25 each. According to CAP, the new scheme would also result in a 36% payment rate increase for 11 codes that join 88307 and 88361 in the reconfigured APC 344. The payment rate for APC 343 also would rise, from $24.67 to $28.27, or about 15%.

Some codes would experience decreases in payment. For example, CPT 88161 (Cytopathology smears, any other source; preparation, screening, and interpretation) would move from APC 343 to APC 342, and its payment rate would fall from $24.67 to $9.22.

The complete rule is available at *http://www.cms.hhs.gov/providers/hopps/fr2006.asp*.

Lab Co-Pay: Pennsylvania lawmakers have declined to include in final budget legislation a proposal to institute laboratory test co-payments under Medicaid, but gave the state's welfare agency broad power to establish co-payment and make other program changes. The state legislature in July passed a 2006 budget without the co-payment language that Gov. Ed Rendell (D) included in his original proposed budget for Medicaid. Rendell's proposal called for lab test co-pays of up to $3 for adult Medicaid and $6 for General Assistance Packages. But the legislature kept the issue alive by giving the state Department of Public Welfare (DPW) free rein to require co-payments and make other rate and benefit changes. Further, the final budget bill allows the DPW to make changes without regulatory review by the legislature through the end of this year.

Patient Safety: President Bush has signed the Patient Safety and Quality Improvement Act of 2005 into law, saying the legislation "is a critical step toward our goal of ensuring top-quality, patient-driven healthcare for all Americans." The bill (S. 544) creates a system for voluntary reporting by healthcare providers of medical errors and makes these reports confidential, shielding them from use in civil and criminal proceedings. The House approved the measure July 27; the Senate, July 21.

Medicaid Fraud: New York Gov. George Pataki (R) has launched a plan to fight fraud and abuse in the Medicaid programs, including the creation of an inspector general for Medicaid. Other elements of the five-point plan include the appointment of former federal prosecutor Paul Shechtman to recommend long-term reform of the state's current fraud efforts, a push for approval by the federal government of the state's pending request to join an existing federal Medicaid fraud-detection program, and measures that will expand the use of existing state resources and agencies to combat fraud.

HHS IG To Keynote Lab Institute

Daniel Levinson, the new Inspector General of the Department of Health and Human Services, will discuss his top priorities for the healthcare sector, including labs, at G-2 Report's 23rd annual Lab Institute: *Transformational Forces Reshaping Labs*.

Lab Institute will be held October 19-22 in Arlington, VA. G2 subscribers pay just $875. For more information, go to *www.g2reports.com*.

There are four easy ways to register:
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2. CALL: 1-800-401-5937, ext. 2
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