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Voluntary Disclosure Program: OIG Stats

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In May 2007, the OIG announced statistics regarding provider results under the OIG's Self-Disclosure Protocol (SDP). The OIG indicated that it had accepted 321 disclosures since the inception of the program in 1998. Of the total disclosures, a significant number were not resolved under the SDP, but were referred by the OIG to various Medicare contractors, such as fiscal intermediaries and carriers, for resolution. According to the OIG, more than half of the disclosures were treated in this fashion. The OIG also indicated that 137 of the disclosures resulted in the imposition of either single or multiple damages. Only 23 of the settlements involved Corporate Integrity Agreements. To date, we are unaware of any disclosures which resulted in a subsequent investigation or criminal prosecution.

Of particular note, the SDP accepted and resolved a number of matters involving potential violations of both the antikickback statute and the Stark self-referral law. In these cases, the OIG has chosen to impose a "penalty" of a multiple of the financial benefit provided to the physician. The OIG noted that the Stark law prohibits any payment to a health care entity based on services furnished pursuant to a referral which violated the Stark law. However, rather than disallowing the total revenue, a result of which would appear to be significantly out of proportion to the nature of the Stark violation, the OIG agreed to

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From the Chair

As I gather my thoughts regarding this issue of the *Health Law Alert*, I am struck by the fact that there is a presidential campaign underway. I am not surprised that there is a campaign, of course, as that seems to occur approximately every four years. What strikes me, however, is that there appears to be less focus on health care issues than in prior campaigns. Certainly, each candidate talks about the number of uninsured citizens and the need to provide adequate access to high quality health care services. However, the campaign seems to focus more on the economy, the war, and which candidate's "friends" are doing more damage to his or her campaign. A statement often made by my late father-in-law comes to mind. "When is help not helpful?"

In any case, the health care delivery system marches on, the government regulates, investigates, and enforces, and our friends and neighbors worry about whether appropriate health care services will be available when they need them and, if so, whether they will be able to afford them.

This issue of the *Health Law Alert* addresses a number of ongoing issues of import and relevance to our friends and clients. Specifically, we write about the focus on Medicare Part D, device

manufacturers and CMS's decision to deny payment for certain hospital-acquired conditions, commonly referred to as "never events."

The past few months have seen a number of developments relating to HIPAA privacy and employment issues. We also present the second of a two-part article on the response by general acute care hospitals to physician-owned specialty facilities.

With respect to our health law practice group, I would like to congratulate Chris Morse on her election to shareholder status. I would also like to welcome Richard Westling as a principal to our group, Mark Stanley as an associate and John Kirk as a paralegal. Finally, we also welcome the newest future health care lawyer and congratulate Emily and Zack Wein on the birth of their son Paden.

I hope that you are enjoying and benefitting from our *Payment Matters* publication, which recently celebrated its one-year anniversary. If you have not seen it, please let us know and we will put you on the e-mail distribution list. Additionally, we are planning a new publication focused on long term care matters. Look for the first issue in the near future.

Finally, please accept my best wishes for an enjoyable, healthy, and "interesting" summer.

Sandy Teplitzky, Department Chair

Voluntary Disclosure Program… *FROM PAGE 1*

compromise in these matters by imposing a penalty of a multiple of the financial benefit.

Through experience with the SDP, the process has been made more interactive. In other words, rather than simply submitting information and waiting for a decision from the OIG, these matters have involved numerous communications, meetings, and the submission of additional information, and the OIG has resolved numerous matters outside of the normal investigative process. Thus, the OIG has lived up to its word that the settlement of a voluntary disclosure generally results in a payment which is less than that which might have been imposed had the government learned of the activity from someone other than the self-disclosing provider.

> *"The OIG has lived up to its word that the settlement of a voluntary disclosure generally results in a payment which is less than that which might have been imposed had the government learned of the activity from someone other than the self-disclosing provider."*

The OIG recently developed the SDP process even further by expediting resolution of self-disclosures and offering additional incentive for providers to adopt effective compliance measures. In an April 2008 Open Letter, the OIG announced refinements to the SDP that promote a streamlined process through more stringent submission requirements and increased responsiveness on the OIG's part. In addition, the OIG will presume that a self-disclosing provider who has expedited the SDP process (by submitting a complete and informative disclosure, quickly responding to OIG inquiries, and performing an accurate audit) already has effective compliance measures in place. The import of this presumption to the self-disclosing provider will be to avoid the necessity of entering into a Corporate Integrity Agreement or Certification of Compliance Agreement as part of its negotiated resolution with the OIG.

Providers are likely to continue to use the OIG's SDP in those matters in which there is a reasonable belief that a violation of federal law, regulations, or policy has occurred. This is not a decision to be taken lightly. However, it has become a more realistic option in many situations. ■

OIG

Deferred Prosecution Agreements with Device Manufacturers

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The DOJ and the U.S. Attorney's Office for the District of New Jersey announced settlements with the five largest orthopedic device manufacturers to resolve criminal and civil charges of fraud and kickbacks in September 2007. Four of those companies, Zimmer, Inc., Depui Orthopedics, Inc., Biomed, Inc., and Smith & Nephew, Inc., entered into Deferred Prosecution Agreements. Civil payments under those agreements ranged from $26.9 million by Biomed to $169.5 million by Zimmer. The fifth company, Stryker Orthopedics, Inc., entered into a non-prosecution agreement. Although it is not entirely clear why Stryker Orthopedics was treated differently, the DOJ press release indicates that the company voluntarily cooperated with the U.S. Attorney's Office before any of the others.

The DOJ noted in its press release that it was prepared to file criminal complaints against each of these companies. However, the release indicated that there were no allegations that the conduct adversely affected patient health or patient care.

In explaining the basis upon which DOJ agreed to enter into Deferred Prosecution Agreements, the DOJ noted:

- Remedial actions taken to date
- A willingness to take additional remedial action "as necessary"
- Acknowledgement of responsibility for behavior
- Continued cooperation
- Demonstration of good faith and a commitment to compliance

The Deferred Prosecution Agreements have a term of 18 months and require the companies to fully implement a corporate compliance program, adopt the AdvaMed Code of Ethics, and commit to "exemplary corporate citizenship." Additionally, and most importantly, the companies agreed to retain an independent "monitor." The monitors are to be selected by the U.S. Attorney's Office in New Jersey and will report directly to that office. However, the companies will pay all of the costs associated with the monitors' activities.

Under the settlement documents, the monitors are to review and evaluate all policies, practices, and procedures relating to "consultants." The agreements define *consultants* broadly as:

> Any United States-based orthopedic surgeon, PhD, health care professional, non-physician practitioner, medical fellow, resident or student, or any employee or agent of any educational or health care organization the Company retains for any personal or professional services or compensates or remunerates in any way, directly or indirectly, for or in anticipation of personal or professional services relating to hip and knee reconstruction and replacement. The term Consultant shall not include accountants, auditors, attorneys, fair market value specialists, CME providers, reimbursement specialists, any non-physician engineering or marketing consultants, or any other types of non-physician professionals or entities excluded from this definition by the Monitor upon recommendation by the Company.

Deferred Prosecution Agreement 3, Biomet, Inc. (Sept. 2007) at http://www.usdoj.gov/usao/nj/press/files/pdffiles/Deferred%20pros%agreementBiometfinal.pdf. In other words, virtually any agreement pursuant to which a physician or other health care professional provides services to the company would be treated as a consulting agreement.

The Deferred Prosecution Agreements go on to describe the obligations of the monitor, to include:

- Monitor review compliance with the Deferred Prosecution Agreement and all applicable federal health care laws, statutes, regulations and programs, including the antikickback statute, relating to the sale and marketing of hip and knee reconstruction and replacement products
- As requested by the government, full cooperation with the government
- Provide written reports to the government, on at least a quarterly basis, concerning the company's compliance with the Deferred Prosecution Agreement
- Engagement of consultants, accountants, or other professionals, to be paid by the company, that the monitor determines to be reasonably necessary to assist in the execution of the monitor's duties
- Review and approval of "all new or renewed Consulting Agreements"

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- Review of any requests for consulting services
- Review of any payments made to consultants
- Approval of all hourly rates or any payments made to consultants

Of particular note, the agreements provide that if the monitor opposes any consulting agreement, requests for consulting services, or payment under an agreement, the monitor will promptly meet with the company to "discuss his or her concerns." Further, the agreement may not be executed, nor may payment be made "unless and until the Monitor's objections are remedied."

> *"The Deferred Prosecution Agreements represent the largest and most significant intrusion into the ongoing operations of a health care company to date."*

The companies are also required to promptly notify the monitor and the government "in writing of any credible evidence of criminal corporate conduct, as well as of any known criminal investigations of any type of the corporation or of any of its officers or directors that becomes known to the company." Further, the company must notify the monitor and the government of "any credible evidence of criminal conduct or serious wrongdoing relating to federal health care laws by the Company, its officers, employees and agents." This would include any information concerning such allegations, including but not limited to "internal audit reports, letters threatening litigation, 'whistleblower' complaints, civil complaints, and documents produced in civil litigation." Deferred Prosecution Agreement 7, Biomet, Inc. (Sept. 2007).

The Deferred Prosecution Agreements provide detailed requirements for all consulting agreements and specifies the officers within the company who must execute those agreements. Further, the officers "shall attest and certify in writing that, based on their reasonable inquiry and knowledge, all Consulting Agreements and all Consulting Services performed thereunder were bona fide, commercially reasonable, and compliant with all federal health care programs."

In addressing payments to consultants, the settlement documents require a determination of a fair market value hourly rate "of no more than $500 per hour" for time actually expended by a consultant. If the company desires to make payment to a consultant based upon his or her special expertise or the nature of the service, the company must obtain "a fair market value analysis conducted by an independent organization with expertise in valuation as approved or accepted by the Monitor. Any changes to the Hourly Rate or Payments other than at the Hourly Rate must be approved by the Monitor." Deferred Prosecution Agreement 11, Biomet, Inc. (Sept. 2007).

For the first time, to our knowledge, the agreements require each company to "prominently feature on its web site the name, city, and state of residence for each of the company's consultants who were retained at any time in 2007, who provided consulting services to the company at any time in 2007, or who received any payments from the company in 2007." Deferred Prosecution Agreement 13, Biomet, Inc. (Sept. 2007). Further, the companies must disclose, on their web sites, payments made to each consultant in 2007 within $25,000 increments.

Each of the companies to the Deferred Prosecution Agreements also were required to enter into Corporate Integrity Agreements with the OIG. The documents are not clear as to how the activities of the monitors and the provisions of the CIA will interface, if at all.

The Deferred Prosecution Agreements represent the largest and most significant intrusion into the ongoing operations of a health care company to date. As opposed to the CIAs, which generally require ongoing monitoring and annual reporting, the monitors under the Deferred Prosecution Agreement will, by design, play an active role in the day-to-day operations of the companies as they relate, at least, to the engagement of consultants. It has been suggested that payments to the monitors could easily range into the tens of millions of dollars.

It remains to be seen whether the use of Deferred Prosecution Agreements will expand into other areas of health care investigations. However, this is certainly a development worthy of continued review. ■

OIG

OIG Reviews Relationship Between CAH, Radiologists

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OIG Advisory Opinion No. 07-19, posted on the OIG's website on January 3, 2008, responds to an inquiry as to whether a radiology practice can prepare a written report of its interpretation of a radiology procedure for patients of a critical access hospital without charge, without violating the federal antikickback statute (FAS). As discussed below, the OIG's response reflects consideration of two important issues: (1) the relationship of Medicare payment principles to the FAS, and (2) services which hospital-based physicians can be required to provide to hospitals, without payment, consistent with the FAS.

The OIG states that the hospital had asked whether the radiology group's preparation of the written report for the hospital's medical records without charge to the hospital implicated the FAS. A footnote to the opinion indicates that the issue may have surfaced during contract negotiations. The radiologists had requested payment from the hospital for preparing the reports. In all likelihood, they asserted that providing these services for free would violate the FAS. The hospital sought confirmation from the OIG that that would not be the case.

Old Issue Revisited

As discussed most recently in our Spring 2005 *Health Law Alert* ("OIG's Supplemental Hospital CPG Looks at Hospital-based Physicians"), similar issues have been debated by hospitals and hospital-based physicians (e.g., pathologists, radiologists, and anesthesiologists) since the OIG issued a Management Advisory Report in 1991 addressing contract arrangements that potentially violate the FAS. In fact, payment for the cost of radiology report preparation is not a new issue. Approximately 15 years ago, an OIG attorney responded to an inquiry from counsel for the American College of Radiology (ACR) seeking guidance regarding hospital demands that radiologists pay the hospital for transcribing the radiologist's interpretation. The ACR attorney asserted that because the cost of transcription was part of the hospital's operating costs for which it received payment from Medicare, the hospital would be seeking a duplicate payment from the radiologists in violation of the FAS. The OIG attorney agreed, to a point. The OIG attorney indicated that the OIG would not express an opinion on how Medicare and Medicaid paid for hospital transcription costs. However, he concluded that "[i]f a hospital demands payment from a hospital-based physician ostensibly for services that the hospital has already received reimbursement for through the prospective payment system, the [FAS] may be implicated."

OIG Analysis

In contrast to the general response to the ACR's informal inquiry, in the advisory opinion, the OIG specifically determined whether the arrangement violated FAS based on applicable Medicare payment principles. The OIG stated that, according to CMS, in order for a radiologist to receive Medicare payment for an interpretation of a radiology procedure for a hospital patient, the radiologist had to prepare a written report for the hospital's medical records. A critical access hospital was required to maintain medical records satisfying regulatory standards, but it was not required to bear the cost of preparing a report documenting the radiologist's services. Based on these Medicare principles, the OIG concluded that the radiologists' provision of written reports for hospital Medicare patients without charge to the hospital was not "remuneration" paid to the hospital. In fact, if the hospital paid the radiologists for preparing the report, the radiologists would receive double payment for the same service – one time through receipt of Medicare payment for the professional component service, and a second time from the hospital. The OIG's analysis – effectively providing for the entity that received Medicare payment for the service to bear its related cost – makes eminent sense. This is more obvious when the arrangement involves the mirror image of that addressed by the OIG – when the source of referrals or other Medicare business (e.g., hospital) attempts to shift costs for which the hospital receives Medicare payment to the recipient of its Medicare business (e.g., hospital-based physician). In those instances, the cost-shifting may violate the FAS.

The OIG recognized that while the FAS prohibits only remuneration paid for referrals or similar activities related to goods and services payable under a federal health care program, financial arrangements for services furnished to patients whose care is covered under other arrangements can result in payment of prohibited remuneration (just as a contract related to private-pay patients can result in a compensation arrangement under the federal self-referral (Stark) law). Therefore, the OIG separately addressed the issue in connection with radiology reports for hospital patients whose services were not covered by Medicare. The OIG stated that it was uncertain how other payers paid for the cost of preparing radiology reports.

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Radiology Relationship Reviewed… FROM PAGE 5

Therefore, unlike in the case of reports for Medicare patients, the OIG was unable to conclude that the radiologists' provision of reports for non-Medicare patients would not result in payment of remuneration to the hospital.

The OIG analyzed application of the FAS to those arrangements based on the Supplemental Compliance Guidance (SCG) for hospitals which it had published in January 2005. *See* 70 Fed. Reg. 4858 (Jan. 31, 2005). The OIG had then stated that if an exclusive contract arrangement between a hospital and hospital-based physicians was consistent with fair market value, taking into account the value of the exclusivity to the physicians, then "in an appropriate context," requiring hospital-based physicians to perform "*reasonable* administrative or *limited* clinical duties *directly related* to the hospital-based professional services at no or a reduced charge" would not violate the FAS. 70 Fed. Reg. at 4867. The OIG concluded that the radiologists' preparation of reports appeared to be a reasonable and limited service directly related to their professional services that were furnished under their exclusive relationship with the hospital.

In further support of its decision that it would not impose sanctions as a result of this arrangement, the OIG made several statements that would apply arguably to many, if not most, arrangements between hospitals and hospital-based physicians. The OIG stated that the arrangement was unlikely to lead to overutilization of federally payable services or increased cost to federal programs. Additionally, the radiologists' ability to generate additional Medicare Part B billings in order to recover the cost of preparing reports for non-Medicare beneficiaries was limited by the nature of their hospital-based specialty.

Conclusion

Although the OIG expressed no opinion regarding arrangements that did not involve critical access hospitals, the analytical approach used by the OIG to determine whether the hospital or radiologists should bear the cost of report preparation should be useful to hospitals and hospital-based physicians (and potentially other physicians negotiating payment arrangements with hospitals). However, reliance on the entity that received related Medicare payments will not always lead to a clear result. The OIG had the benefit of specific advice from CMS regarding Medicare payment for the particular cost at issue. In the absence of such advice, it is sometimes difficult or impossible to determine how a particular cost – which is a component of a reimbursable health care service – is paid by Medicare.

The OIG also made clear that because other payers may use different payment principles, an analysis limited to Medicare payment principles may not be adequate. Application of the FAS to the cost of services provided to individuals who are not Medicare beneficiaries may need to be made on a different basis. The OIG relied on the supplemental CPG for hospitals. CPG statements relating to uncompensated services provided by hospital-based physicians have been subject to varying interpretation since its publication. Unfortunately, the OIG's determination sheds little light on when services can be provided by hospital-based physicians without charge, including what services will be considered "reasonable" or "limited," and "directly related" to the physicians' professional services, and what is an "appropriate context" in which such services might be provided by hospital-based physicians on an uncompensated basis. ■

Guide to Terms

The following guide to frequently used acronyms may assist you in reading this issue of the *Health Law Alert*.

ALF	Assisted Living Facility
BIPA	Benefits Improvement and Protection Act of 2000
BBA	Balanced Budget Act of 1997
BBRA	Balanced Budget Refinement Act of 1999
CMP	Civil Money Penalty
CMS	Centers for Medicare and Medicaid Services
DME	Durable Medical Equipment
DOJ	U.S. Department of Justice
DRA	Deficit Reduction Act of 2005
EHR	Electronic Health Records
EMTALA	Emergency Medical Treatment and Active Labor Act
FCA	Federal False Claims Act
GAO	Government Accountability Office
HHA	Home Health Agency
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
HMO	Health Maintenance Organization
MCO	Managed Care Organization
MMA	Medicare Prescription Drug, Improvement and Modernization Act of 2003
OIG	Office of Inspector General of the Department of Health and Human Services
PAP	Patient Assistance Program
PPS	Prospective Payment System
SNF	Skilled Nursing Facility

OIG

OIG Advisory Opinions

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No. 08-01: OIG Approves Bulk Replacement PAP

The OIG's first advisory opinion for 2008, issued January 28, 2008, addresses whether a proposed "bulk replacement" PAP violates either the antikickback statute or CMP prohibition against inducements to beneficiaries. Bulk replacement PAPs provide free drugs in bulk quantities – typically on a monthly or quarterly basis – to hospitals, clinics, and other safety net providers to replace drugs dispensed to patients who meet established PAP criteria. The OIG concluded that the proposal potentially implicates the antikickback statute and the CMP. Nevertheless, based on a combination of safeguards certified by the requestor, the OIG approved the program and determined that the imposition of sanctions would not be warranted.

The requestor of this opinion (the Partnership) is a non-profit corporation that serves as a liaison between the pharmaceutical industry and its affiliated free clinics and federally qualified health centers (FQHCs) (collectively, clinics), for the clinics' low-income patients, i.e., those whose incomes are less than 200 percent of the Federal Poverty Level (FPL) and who do not have any outpatient prescription drug insurance coverage. The Partnership is funded by state appropriations, contributions from individuals and foundations, and fees paid by the participating clinics. The Partnership aims to make it easier for participating drug manufacturers to offer their bulk replacement PAPs to the Partnership's affiliated clinics by imposing a number of uniform PAP operating standards on the clinics, including the requirements that they:

- Maintain separate, auditable records of all donated drugs received as the Partnership's affiliate
- Maintain systems for separating PAP inventory from other purchased drugs
- Implement a computerized dispensing system that has the capacity to generate reports necessary for auditing and monitoring for compliance
- Agree to submit to annual on-site compliance audits
- Check and document patient eligibility before dispensing the PAP drugs

Participating drug companies enter into written contracts with the Partnership that specify these terms and conditions pursuant to which the clinics receive free prescription drugs.

The OIG first considered application of the safe harbor for certain FQHC arrangements. 42 C.F.R. § 1001.952(w). While noting that the arrangement shares many features of the safe harbor, it does not meet all of the requirements. For example, the requirements that the FQHCs make the requisite determinations regarding benefit to underserviced populations, and that the free drugs offered by PAP sponsors be offered to all FQHC patients, regardless of payer status, are not met.

> *"The OIG notes that the donation of drugs by pharmaceutical companies to free clinics and FQHCs, whether through PAPs or directly, play an important role in ensuring that these clinics continue to provide a safety net for medically underserved patients."*

The OIG next analyzed application of the antikickback statute and CMP prohibition against inducement to beneficiaries. Although the Partnership limits utilization of the PAP drugs to uninsured patients with incomes below 200 percent of FPL, the OIG expressed concern that the arrangement (i) potentially raises compliance risks because it might induce the affiliate clinics to purchase the sponsors' other pharmaceutical products which are payable by federal health care programs, or (ii) acts as an improper influence on the prescribing patterns of physicians who work at the clinics. The OIG nevertheless approved the proposed arrangement, citing the following safeguards:

1. The agreement prohibits the stockpiling of surplus drugs that might be diverted to other uses by requiring sponsors to ship drugs monthly based on consumption by eligible patients in the previous months.
2. The arrangement is transparent. Its terms are documented, signed by the Partnership and each PAP sponsor, and requires the clinics to maintain auditable records so that compliance can be monitored.

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3. The arrangement prevents PAP sponsors from "cherry picking" clinics for participation based on their use of other program-reimbursable products. The Partnership has the sole discretion to decide which clinics meet the criteria to become Partnership affiliates, and PAP sponsors are required to provide PAP drugs uniformly to all affiliates. Additionally, the Partnership certified that the availability of drugs under the PAPs is not conditioned on the volume or value of program business or the inclusion of sponsors' other non-PAP products on the clinics' formulary.
4. The agreement protects the independent professional judgment of the clinics' prescribing physicians by ensuring that they do not receive any compensation that takes into account their prescribing patterns for PAP drugs, and by not tracking any physician's prescribing patterns of PAP drugs.
5. In its liaison capacity, the Partnership insulates the FQHCs from potentially inappropriate influence by the PAP sponsors on the FQHCs formulary decision-making process.
6. Although providing remuneration on the basis of payer status or ability to pay can be problematic in the case of the FQHCs, this arrangement does not involve the kind of "cherry picking" of such patients that raises concerns in other contexts. The PAP drugs are dispensed solely to the type of vulnerable, financially needy patients without any outpatient prescription drug coverage that the FQHCs are commissioned to serve.

Finally, the OIG notes that the donation of drugs by pharmaceutical companies to clinics such as these, whether through PAPs or directly, play an important role in ensuring that these clinics continue to provide a safety net for medically underserved patients.

Advisory Opinion 08-01 follows a number of other advisory opinions dealing with PAPs. In analyzing PAPs, the OIG has recognized that these programs provide significant community benefit with limited risk to federal health care programs. Nevertheless, the OIG has refused to approve these programs across the board. Health care entities wishing to participate in or sponsor PAPs need to examine them on a case-by-case basis in light of the various guidance from the OIG.

No. 08-02: OIG Allows Honorary Charitable Donations

Advisory Opinion 08-02, issued on January 29, 2008, is one of a short list of advisory opinions in which the OIG has concluded that the antikickback statute is not implicated. The proposed arrangement involves a marketing and research company's idea to encourage physicians to complete online surveys by making a donation to a public charity in honor of the physician. The OIG concluded that the antikickback statute was not implicated because the proposed arrangement did not generate any remuneration for the physician.

The requestor is a company that works with pharmaceutical and medical products manufacturers and the entities that distribute and market their products. The requestor helps its clients develop clinical, marketing, and other data about how physicians diagnose and treat certain illnesses. The requestor is not a health care provider or supplier and does not participate in any federal health care programs.

> *"Advisory Opinion 08-02 confirms a common belief that a charitable donation in the name of a physician generally does not implicate the antikickback law so long as the physician is not entitled to a tax deduction or other monetary benefit from the donation."*

Physicians who participate in the requestor's web-based surveys are permitted to designate a public charity to receive donations "in the name of" the physician. The entity receiving the donation must be organized as a 501(c)(3), qualify as a public charity under 509(a), and meet the public support test under section 509(a). Donations may not be made to private foundations. The amount of the donation might vary between surveys, but would be uniform for all participants in a given survey. The charity's use of the donated funds would be without any earmarks or restrictions. The physician in whose name the donation is made is not entitled to a tax deduction or to otherwise receive any monetary benefit from the donation. In addition, neither the physician in whose name the donation is made nor any of the physician's family may hold a position on the board of the designated charity, be employed by the charity, or have any other financial relationship with the charity.

The OIG began its analysis with a discussion of the important role of charitable donations from health care providers and suppliers in strengthening the health care system. The OIG also recognized its "need to exercise caution in undertaking any enforcement action in this area." In something of a departure from its normal pattern, the OIG went beyond the specific facts of the proposed arrangement to

warn that some charitable donations are nothing more than disguised kickbacks intended to induce referrals. The OIG then described several examples of potentially abusive arrangements.

In the end, the OIG concluded that no funds would be transmitted to the physician and the physician would not be entitled to any tax deduction or other economic benefit from the donation. The benefit to the physician would be "wholly intangible in the form of potential personal satisfaction." There would be "no actual or expected economic or other actionable benefit" to the physician. Despite the fact that the antikickback statute was not implicated by the proposed arrangement, the OIG also noted that the requestor had included several additional safeguards against potential abuse.

Advisory Opinion 08-02 is important because it confirms a common belief that a charitable donation in the name of a physician generally does not implicate the antikickback law so long as the physician is not entitled to a tax deduction or other monetary benefit from the donation. However, the OIG warned that it is aware of situations where charitable donations are nothing more than disguised kickbacks intended to induce referrals.

No. 08-03: OIG Approves Prompt-pay Discounts

The OIG issued Advisory Opinion 08-03 on January 30, 2008, analyzing whether a proposed arrangement pursuant to which a health care system would provide prompt-pay discounts to inpatients and outpatients, including those covered by Medicare, Medicaid and other federal health care programs, violates either the CMP prohibition against inducements to beneficiaries or the antikickback law. The OIG concluded that the proposed arrangement (1) would not constitute grounds for imposing CMPs; and (2) could implicate the antikickback statute if the requisite intent to induce or reward referrals of federal health care program business were present, but would not result in administrative sanctions under the antikickback statute or the CMP against inducements to beneficiaries.

The three-hospital health care system requesting the opinion proposes providing discounts to inpatients and outpatients, including federal health care program beneficiaries and other insured patients, regardless of their ability to pay, for promptly paying their cost-sharing amounts and amounts owed for noncovered services for which they received an advance beneficiary notice. The rational for this discount, as certified by the requestor, is to reduce the health care system's accounts receivables and cost of debt collection, and to boost its cash flow.

The requestor certified that it would not claim the waived amounts as bad debt or otherwise shift the burden to the Medicare or Medicaid programs or other third-party payers or individuals. The discount would not be part of a price reduction agreement with third-party payers. The discount would be offered for both inpatient and outpatient services without regard to the reason for the patient's admission, length of stay, diagnostic-related group, or ambulatory payment classification. The costs associated with administering the prompt-pay discount program would be borne solely by the health care system. The discount (5 percent to 15 percent of the amount of the bill, depending on the timing of the payment and size of the remaining balance owed by the patient) would bear a reasonable relationship to the avoided collection costs. The prompt-pay discount program would not be advertised. Instead, patients would be notified of its availability only when they register for outpatient services and pay their cost-saving amounts, when written statements are sent to the patients by mail, when financial arrangements are made between the health care system and patients, or after their admission for inpatient services. All payers would be notified of the discount.

> *"One interesting point about Advisory Opinion 08-03 is that it seems to suggest that prompt pay discounts may not be advertised. Whether this should be a requirement when a discount is designed to encourage prompt payment is not clear."*

In analyzing the arrangement, the OIG first concluded that the prompt-pay discount, as it applies to inpatient services, satisfies all the requirements of the safe harbor for waivers of beneficiary coinsurance and deductible amounts owed by patients. 42 C.F.R. § 1001.952(k). The health care system certified that it would not claim waived amounts as bad debt or otherwise shift the burden to the Medicare and Medicaid programs or other third-party payers or individuals. The health care system would make the waiver without regard to the patient's reason for admission, length of stay, or diagnostic related group. The waiver would not be part of a price reduction agreement with any third-party payer.

With respect to outpatient services, the OIG noted that the safe harbor was inapplicable because it applies only to inpatient services. The OIG nevertheless cited to language in the preamble to the 1991 final safe harbor regulations which provides that, although outpatients are not covered by this safe harbor, discounts which are not used ▸ PAGE 10

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to induce patient referrals but are, instead, implemented for the purpose of more successful bill collection, would not likely violate the antikickback law. The OIG pointed to the specific features of the discount program which, in its opinion, indicate that the program is being implemented for successful bill collection rather than as a disguised payment for referrals. First, the discount would not be advertised and the patient would be informed of the discount only during the billing process. Second, third-party payers would be notified of the discount program. Third, the costs of the discount program would be borne solely by the health care system. Fourth, the amount of discounted fees would bear a reasonable relationship to the amount of avoided collection costs.

For these same reasons, the OIG also concluded that no grounds would exist for the imposition of CMPs against the health care system.

Advisory Opinion 08-03 confirms a widely held view that prompt-pay discounts do not violate the antikickback statute. This position was based on language from a 1991 preamble that stated that by definition prompt-pay discounts are designed to induce prompt payment. One interesting point about this advisory opinion is that it seems to suggest that prompt pay discounts may not be advertised. Whether this should be a requirement when a discount is designed to encourage prompt payment is not clear.

No. 08-04: OIG Approves Free Trial Prescription Program

In Advisory Opinion 08-04, issued February 5, 2008, the OIG addressed a proposed agreement pursuant to which a pharmaceutical manufacturer proposed offering a free trial prescription program to hemophilia A patients, including federal health care program beneficiaries. The OIG was asked to opine on whether this proposed arrangement would violate the antikickback statute. Based on the facts certified by the requestor, the OIG concluded that while the proposed arrangement could potentially generate prohibited remuneration under the antikickback statute if the requisite intent to induce or reward referrals of federal health care program business were present, it would not impose administrative sanctions based on the facts of the particular arrangement.

The pharmaceutical manufacturer requesting the opinion manufactures health care products and pharmaceuticals, including a recombinant antihemophilic factor VIII product indicated for the prevention and control of hemorrhagic episodes and surgical and short-term routine prophylaxis in patients with hemophilia A. The medication is reimbursed by Medicare Part B under the average sales price methodology, and the Medicare beneficiary is responsible for paying the 20 percent cost share of the allowable Medicare benefit.

Patients with hemophilia A have a choice of medications for the disease. They can choose between other recombinant factor VIII products that are also manufactured by competitors of the requestor, or they can choose plasma-derived products. While the costs of the latter are generally less expensive than the recombinant products, there is greater risk of transferring blood-borne pathogens. Patients can switch between the two kinds of products with no adverse effects.

> *"Advisory Opinion 08-04 is consistent with a number of prior advisory opinions in which the OIG has recognized that arrangements that are beneficial to certain at-risk patient populations may be approved through the advisory opinion process, even though they potentially implicate the antikickback statute."*

Under the proposed agreement, the requestor will offer a limited number of program enrollment forms to hemophiliac treatment centers and hemophilia/oncology physician practices (collectively, physicians). The numbers of enrollment forms will be based on ten percent of the U.S. hemophiliac A patients served by that practice, with a further limitation that no physician could receive more than 20 enrollment forms per year, per location). Furthermore, patients already on the medication would be ineligible to participate in the trial program, and patients would not be allowed to enroll in the program more than once.

Physicians who elect to participate in the trial would identify patients who could benefit from the medication. The physician and patient would complete an enrollment form and this, together with the physician's prescription for the Medication, would be forwarded to the program administrator.

The program administrator, a licensed pharmacy under contract with the requestor, does not distribute hemophiliac products commercially. After filling the prescription, the

program administrator would ship the medication directly to the patient as a safeguard to ensure that the physician would neither bill for, nor resell, the Medication. At no time would physicians have possession of the medication. The requestor certified that the program would comply with the Prescription Drug Marketing Act of 1987 (PDMA).

The requestor would not compensate any physician, directly or indirectly, for participating in the program. Neither the requestor nor the program administrator would charge the patient or any other third party (including federal health care programs) for the medication provided under the program.

The amount of medication each patient would be eligible to receive is based upon 10 doses for the average patient size for three age ranges. These amounts approximate the minimum amount necessary to permit a fair trial of the medication's efficacy. Physicians could not prescribe more than the trial quantity established for each age tier. There would be sufficient medication for approximately one to ten weeks depending on several factors, such as the patient's weight, severity of the illness, and level of activity. The total value of free medication provided to any one patient would range from $5,000 to $20,000.

Under the program, the medication would be offered free of charge. No third-party payer would be billed for the medication. Physicians would be required to sign a statement on the program enrollment form acknowledging that the medication is complimentary and may not be billed to third-party payers or resold. Patients would sign a similar statement which includes the fact that there is no obligation to purchase the medication after the trial as a precondition to participating in the program. Similarly, the program administrator would contractually acknowledge that the medication is provided at no cost to patients or health care providers, and that it would not resell the medication or bill any third-party payer.

In analyzing the proposed agreement, the OIG first directed attention to its Compliance Program Guidance for Pharmaceutical Manufacturers (CPG) which highlights the risks involved when manufacturers provide free samples to recipients (e.g., physicians) treating federal health care program beneficiaries. While noting that physicians would not take possession of the Medication under the program, and that the program appeared to address the risks raised by the CPG, the OIG stated that this was not dispositive with regard to the fraud and abuse concerns related to the proposed arrangement, citing two potential kickback concerns: (i) kickbacks to participating physicians; and (ii) remuneration in the form of cost-sharing relief on the free drugs to induce participating patients to self-refer the medication in the future.

As to the first concern, the OIG concluded that the proposed arrangement does not appear to create any benefit, direct or indirect, monetary or economic, or any other kind of benefit for the participating physicians that would warrant imposing administrative sanctions. There are safeguards to ensure that no physician could take possession of the medication and then bill for it or sell it by virtue of the fact that the program administrator ships the medication directly to the patients. This addresses the specific risk outlined in the OIG's CPG concerning improper resale or billing of samples. Additionally, physicians would be required to certify on their enrollment forms that the medication is to be provided free of charge to the patient and is not to be billed to any third-party payer.

As to the second concern, the OIG concluded that the risk of patients being induced to self-refer the medication at the end of the trial creates a low level of risk of fraud and abuse and is readily distinguishable from riskier consumer-based programs for the following reasons:

1. The program creates no cost to federal health care programs and has safeguards to prevent billing for the samples.
2. Any risk of steerage associated with the program is offset by (a) the cost-sharing obligations that would apply to any future medication; (b) no substantial barriers to prevent patients switching between competing treatments; and (c) the inability of patients to self-enroll in the program.
3. Any risk of overutilization associated with the program is reduced by the cost-sharing obligations, the nature of the medication, and the limitations placed on enrollment, namely patients cannot enroll more than once, and cannot enroll if they are already on the medication.
4. The program includes additional safeguards, including (a) the physicians do not take possession of the medication; (b) hemophelia treatment centers and physician practices will receive only a limited number of enrollment forms; (c) patients would not be obligated to purchase the medication in the future; and (d) the program would be structured to comply with the Prescription Drug Marketing Act of 1987.

In a footnote, the OIG noted that the CMP provisions that relate to inducements to a beneficiary to choose a particular provider would not apply because the requestor, as a manufacturer that does not bill Medicare or Medicaid, would not meet the definition of a *particular provider, practitioner, or supplier* under the act.

Finally, the OIG notes that the result may have been different had different facts been presented, or if the sampling program was non-PDMA compliant.

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OIG Advisory Opinions... FROM PAGE 11

Advisory Opinion 08-04 is consistent with a number of prior advisory opinions in which the OIG has recognized that arrangements that are beneficial to certain at-risk patient populations may be approved through the advisory opinion process, even though they potentially implicate the antikickback statute. Here, the OIG has recognized a number of safeguards that limit the potential fraud and abuse risk posed by the program for offering free trial prescriptions to hemophilia patients.

No. 08-05: OIG Approves Pharmaceutical Kiosks in Physician Offices

In an Advisory Opinion issued February 15, 2008, the OIG responded to a request by a pharmaceutical company to determine whether or not its proposal to place electronic kiosks in certain physicians' waiting rooms that offered free disease state screening questionnaires implicates either the antikickback statute or the CMP prohibition against inducements to beneficiaries. The OIG concluded that the proposed arrangement would not implicate the antikickback statute because the kiosks had no independent value to either the physicians or their patients, and, as such, could not generate any prohibited remuneration. For these same reasons, the OIG concluded that the proposed arrangement would not subject the requestor to CMPs for inducements to beneficiaries.

The pharmaceutical and health care company requesting the opinion develops, manufactures and markets pharmaceuticals for a number of diseases and conditions reimbursable by federal health care programs. The company proposes placing freestanding electronic kiosks in physicians' waiting rooms at no charge to participating physicians. The kiosks would contain a touch screen, keyboard, printer and software, and display interactive questionnaires involving one of four specific disease states. Physicians that would be targeted for placement of the kiosks include those who treat a large number of patients with these disease states. These physicians would be identified based on whether they have prescribed drugs in therapeutic classes commonly used to treat these disease states in the past. The prescribed drugs do not necessarily have to be those manufactured by the requestor. Physicians would not be required to prescribe these drugs as a precondition to hosting the kiosks.

Patients may, but are not required to, complete questionnaires that may point to their having one of these disease states, but which would not draw any conclusions about the patient's condition or recommended therapeutic regime, or contain any message directed to their physician. Patients are simply advised to talk to their physicians as appropriate. Patients may print out their responses and share the results with their physicians.

Neither the kiosks nor questionnaires would mention the requestor's drug products; nor would they contain advertisements or incentives for using the kiosks, such as coupons, or offers of free items. The kiosks would carry a small image of the requestor's logo, a "brought-to-you-by" statement. The requestor's logo and a copyright notice would be included in a footer at the bottom of the questionnaires and printouts.

> *"The OIG determined that the kiosks amounted to 'little more than high-tech interactive brochures' with no independent value to the physicians."*

Patients would not be required to enter their names when participating in the questionnaires. Questionnaires would include a screen with a privacy statement notifying patients that the requestor, and companies working with the requestor, would capture only general information such as the number of patients who complete questionnaires, the number of incomplete ones and the number of results printed out. No individual identifying information would be captured. The requestor certified that it would meet all applicable privacy laws and that the information captured would not be available to its sales representatives.

Participating physicians would not pay the requestor to provide the kiosks; nor would they be paid for hosting them. Kiosks would be installed in the waiting rooms for up to a one-year term, after which the requestor could either remove them or renew the term for an additional period of time. Physicians could request to have the kiosks removed at any time. At all time, the kiosks would remain the property of the requestor.

Based on these facts, the OIG first concluded that the proposal did not present a potential kickback from the requestor to the patient users. Nothing would induce them to self-refer to the requestor's drugs because the kiosks contained nothing of value for the patients. Significantly, patients would not be offered any incentives, such as coupons or free items, for participating.

The OIG cautioned, however, that while this proposed arrangement does not implicate the antikickback statute, this does not necessarily mean that it does not implicate other laws, such as federal and state consumer protection laws or Food and Drug Administration or Federal Trade

Commission regulations. The OIG noted that its conclusion would likely be different if the kiosks were used to communicate offers of remuneration to patients such as coupons, gifts, or free services. The OIG pointed out, however, that it is apparent that the kiosks are designed to direct patient inquiries regarding these four disease states for which the requestor's drugs are indicated, and that they are therefore a type of "direct-to-consumer" advertising often used by pharmaceutical manufacturers, which results in overutilization and the steering of patients to brand-name drugs instead of their cheaper generic equivalents.

The OIG next concluded that the proposed arrangement does not present a potential kickback from the requestor to participating physicians. In the OIG's view, the kiosks would not generate prohibited remuneration for purposes of inducing physicians to prescribe the requestor's drugs for the following reasons: (i) the kiosks would remain the requestor's property; (ii) the participating physicians would not receive any space rental, utility fees, or other compensation for hosting the kiosks; (iii) the kiosks would not increase the attractiveness of the physicians to prospective patients; and (iv) the kiosks were not viewed as saving the physicians or their staff any appreciable time. The OIG determined that the kiosks amounted to "little more than high-tech interactive brochures" with no independent value to the physicians. The OIG distinguished them from other multi-functional computers or fax machines that have independent value to physicians and which may otherwise act as inducements.

The OIG also emphasized the importance of the fact that the requestor had included sufficient safeguards to protect patient privacy and noted that the requestor had certified that it would comply with all applicable privacy laws. Based on the totality of the facts, the OIG concluded that the proposed arrangement would not subject the requestor to administrative sanctions under the antikickback law or the CMP against inducements to beneficiaries.

Advisory Opinion 08-05 is interesting in that it permits a drug manufacturer to place a computer kiosk in a physician's office without implicating the antikickback statute. Essentially, the OIG take the position that the kiosk in this situation was no more than a high-tech brochure. The OIG recognized that it is common practice for drug manufacturers to leave their brochures in physician waiting rooms. It seems unlikely that Advisory Opinion 08-05 will open the flood gates to additional marketing activities by drug companies. As normal, the Advisory Opinion is limited to the specific facts presented in the request.

No. 08-06: OIG Rejects Free Labeling of Test Tubes, Collection Containers for Dialysis Facilities

In Advisory Opinion 08-06, issued May 2, 2008, the OIG considered a laboratory's proposal to provide selected dialysis facilities with free labeling of test tubes and specimen collection containers used by the facilities to send specimens to that laboratory for testing under the antikickback statute. The OIG concluded that the proposed arrangement could potentially generate prohibited remuneration under the antikickback statute. A careful reading of this opinion suggests that the laboratory requesting the opinion may have been seeking a negative opinion.

> *"The question is whether laboratories will modify their existing arrangements or simply rely on the advisory opinion as the justification for not providing the labeling service anymore."*

Under the proposed arrangement, the laboratory requesting the advisory opinion would offer the free labeling of test tubes and specimen collection containers to dialysis facility customers, but only as necessary to retain their business. Absent the proposed arrangement, the dialysis facilities would incur the costs of labeling the test tubes and containers that they use for both composite rate tests (which are included in the composite rate that Medicare pays the dialysis facilities and are not separately billable), and for noncomposite rate tests (which the laboratory bills directly to Medicare and other payors). If the dialysis facilities receive the labeling services for free, they would reduce their costs for the composite rate tests and realize a greater portion the composite rate reimbursed by Medicare.

First, the OIG considered whether the proposed labeling arrangement could satisfy the personal services and management contracts safe harbor. The OIG concluded that the safe harbor was unavailable because the dialysis facilities would not pay any compensation to the laboratory for the labeling services. Given the lack of safe harbor protection, the OIG considered the proposed arrangement on its facts.

The OIG determined that the proposed arrangement had all of the hallmarks of certain disfavored arrangements described in prior guidance on the provision of free or below-market goods or services to actual or

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OIG 2008 Work Plan

Ober\Kaler attorneys have developed a comprehensive listing of the most important projects identified in the OIG's Work Plan for fiscal year 2008. ***The article is available at www.ober.com. Click Health, then Publications, then*** **Health Law Alert** ***Summer 2008.***

HOSPITALS

Certain "Never Events" No Longer Payable

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In the fiscal year (FY) 2008 final Hospital Inpatient Prospective Payment Rule (IPPS), to avoid paying hospitals for the higher-paying diagnosis related group (DRG) attributable to reasonably avoidable secondary conditions acquired by patients during hospital stays, CMS has identified eight such conditions that will no longer be reimbursed by Medicare or Medicaid unless they are present on admission (POA), beginning October 1, 2008. In other words, CMS will reimburse the hospital at the lower DRG rate, as if the patient had not acquired one of these identified conditions during a hospital stay. Hospitals are prohibited from billing affected beneficiaries for any charges associated with these conditions.

Hospitals are reminded to submit secondary diagnoses information that is POA when reporting payment information for discharges.

Background

Efforts to improve patient safety and quality of care resulted in certain advocacy groups such as the National Quality Forum and The Leapfrog Group designating certain adverse, reasonably preventable, hospital-acquired conditions as "never events." These groups questioned why Medicare and Medicaid were paying for such events.

Starting in 2002, the National Quality Forum, a nonprofit membership organization geared toward developing a national strategy for health care quality measurement, published a report listing 27 of such never events. The stated purpose of the list was to bring order to adverse event reporting in the United States. In 2006, the National Quality Forum added another never event to its list, bringing the total to 28.

The Leapfrog Group, a health care purchasing coalition, endorsed the National Quality Forum's list to promote standardized patient safety and quality. Going further than merely endorsing the never events list, Leapfrog gives public recognition to hospitals that take responsibility for a never event. To receive public recognition through Leapfrog, facilities must agree to (1) apologize to the patient/family affected by the event, (2) report the event to at least one reporting agency such as the Joint Commission, (3) perform a root cause analysis, and (4) waive all costs directly related to the event.

In section 5001(e) of the DRA, Congress directed the Secretary of HHS, by October 1, 2007, to select diagnosis codes associated with at least two adverse conditions for which hospitals will not receive additional reimbursement unless the condition was POA. Each code must (a) have a high cost or high volume, or both; (b) result in the assignment of a case to a DRG that has a higher payment when the code is present as a secondary diagnosis; and (c) reasonably have been preventable through the application of evidence-based guidelines.

> *"Effective for discharges occurring on or after October 1, 2008, hospitals will not receive additional Medicare or Medicaid reimbursement for eight 'reasonably preventable' conditions unless they are present on admission."*

In response to Congress' directive, CMS finalized the "hospital-acquired condition" rule as part of its rulemaking updating the hospital IPPS for FY 2008. 72 Fed. Reg. 47,130, 47,201 (Aug. 22, 2007). Effective for discharges occurring on or after October 1, 2008, hospitals will not receive additional Medicare or Medicaid reimbursement for the following eight "reasonably preventable" conditions unless they are POA:

- Serious Preventable Event – Foreign Object Retained After Surgery
- Serious Preventable Event – Air Embolism
- Serious Preventable Event – Blood Incompatibility
- Catheter-Associated Urinary Tract Infection
- Pressure Ulcers
- Vascular Catheter-associated Infection
- Surgical Site Infection – Mediastinitis After Coronary Artery Bypass Graft Surgery
- Hospital-acquired Injuries – Fractures, Dislocations, Intracranial Injury, Crushing Injury, Burn, and all other unspecified effects of external causes

Absent its existence on admission, the presence of one of these conditions results in no Medicare or Medicaid payment to the hospital for any costs related to treating such conditions. The rule also prohibits hospitals from billing the affected patient for any charges related to these hospital-acquired conditions.

Finally, this rule requires hospitals to submit secondary diagnosis information that is POA when reporting payment information for discharges. Such "Present on Admission Indicators" will allow CMS to determine which secondary conditions were present on admission, and which occurred only after the patient was admitted to the hospital.

CMS's rationale for this new payment rule is to try to ensure that Medicare payments to hospitals are more accurate, better reflect the severity of the patient's condition, and force hospitals to pay more attention than they ever have before to the issue of preventable errors, injuries, and other conditions.

In the IPPS proposed rule for FY 2009, CMS proposed to revise, from eight to seventeen, the number of conditions that would not be assigned to a higher-paying DRG unless present on admission. These additional conditions include many of those that were initially proposed for inclusion in the FY 2008 final rule, but which were not included because CMS determined that additional investigation and information was needed before subjecting these conditions to a new policy. The additional nine conditions which may be added to the list for FY 2009 IPPS are:

- Surgical site infections following certain elective procedures
- Legionnaire's disease
- Extreme blood sugar derangement
- Delirium
- Ventilator-associated pneumonia
- Deep vein thrombosis
- Staphylococcus aureus
- Clostridium difficele

73 Fed. Reg. 23,528, 23,552–58 (Apr. 30, 2008). CMS will make its decision on whether some or all of these should be included based upon public comments.

Recently, several insurers and hospital associations have followed CMS's lead by announcing their plans to discontinue paying or billing for never events. Vermont hospitals, through their trade group, The Vermont Association of Hospital and Health Systems, followed the lead of Minnesota and Massachusetts hospitals in announcing that their members will not bill patients or their patients' insurance companies for defined never events. Though the exact list of never events that the Association identified may not match CMS's list precisely, it is a significant step toward addressing the payment effects of care provided as a result of adverse events.

Three of the country's bigger insurers and some states have taken similar steps. Blue Cross and Blue Shield plans, Aetna, and Cigna have announced plans to include provisions in their contracts with hospitals that would exclude never events from payment. These insurers have indicated their plans to implement these new contract provisions incrementally over the next several years, affirmatively indicating their intention to begin phasing out payments for never events. Pennsylvania, Minnesota, and Massachusetts have set up no-pay polices through their Medicaid programs, refusing to reimburse hospitals for never events.

While payment for never events continues to be based on a payer-by-payer determination for most hospitals, hospitals must pay particular attention to reporting never events. While a particular insurer may not have implemented its refusal to pay for defined adverse events, it nevertheless may have implemented requirements for reporting never events in order to obtain information to make decisions on payment going forward. Depending on the current contracts that hospitals have with insurers, a hospital's failure to report a never event as required by a payer may trigger financial or payment consequences that could be as significant as the failure to pay for the never event itself.

Additionally, while nothing in CMS's rules describes never events as creating a health care version of strict liability or as setting any specific standard of care, by designating certain hospital-acquired conditions for nonpayment on the basis that they are, by definition, preventable, CMS inadvertently may have handed the plaintiff's bar a distinct advantage and may well result in increased litigation with higher dollar verdicts. ■

Congratulations

Chris Morse *became a principal of the firm, effective January 1, 2008. Chris focuses on general health care law and regulatory matters, with particular focus on fraud and abuse issues, reimbursement issues, corporate compliance, long-term care, and Medicare Part B. She also has developed significant legal and operational experience relating to institutional and specialty pharmacies, including licensure, Medicaid reimbursement and Medicare Part D issues.*

Ober|Kaler's ***Payment Group*** *marks the one-year anniversary of its email newsletter* Payment Matters, *a publication focused on Medicare and Medicaid payment issues for health care professionals and entities. To subscribe, send an email to Gina Eliadis at gmeliadis@ober.com or visit www.ober.com/subscribe.*

PRIVACY

HIPAA Security Assessments

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In 2007, the OIG attracted the attention of the national health care provider community when it initiated audits of several health systems' compliance with the HIPAA Security Rule. Apart from the general fact of the audits, little was publically known about these audits, including their scope and the process for selecting facilities to be subject to audit. It was thought that these audits were designed, in part, to lay the groundwork for HIPAA security audits on a broader scale.

Earlier this year, CMS dropped the other shoe, albeit softly, when it announced its intention to conduct "assessments" of ten to twenty health care entities nationwide in calendar year 2008. These assessments are separate from the OIG audits, which apparently will continue on their own track based on the OIG's separate mission. The entities to be subject to CMS assessments are to be selected from among those against which security related complaints have been filed. CMS has engaged PriceWaterhouseCoopers to conduct these "assessments" and the results of the assessments (except for the identity of the health care entity assessed) will be made public for educational purposes.

CMS stated that the focus of the assessments will be remote access of electronic protected health information. This dovetails nicely with the "HIPAA Security Guidance For Remote Use Of and Access To Electronic Protected Health Information" published by CMS over a year ago. *See* http://www.cms.hhs.gov/SecurityStandard/Downloads/SecurityGuidanceforRemoteUseFinal122806.pdf. That Guidance encourages covered entities to be "extremely cautious" about allowing the offsite access or use of ePHI but recognizes that such access or use is sometimes necessary. When necessity is shown, CMS urges covered entities to employ "great rigor" to ensure that "policies, procedures and workforce training have been effectively deployed." In the Guidance, CMS lays out the analysis that it will follow in determining whether or not the actions of a covered entity are "reasonable and appropriate" for determining whether a covered entity has adequately safeguarded ePHI that is used or accessed remotely. The Guidance goes on to provide specific strategies for assessing risks and taking appropriate protective actions when ePHI must be accessed, stored, and transmitted remotely.

Risks	*Possible Risk Management Strategies*
Log-on/password information is lost or stolen resulting in potential unauthorized or improper access to or inappropriate viewing or modification of ePHI.	Implement two-factor authentication for granting remote access to systems that contain ePHI. This process requires factors beyond general usernames and passwords to gain access to systems (e.g., requiring users to answer a security question such as "Favorite Pet's Name"); Implement a technical process for creating unique user names and performing authentication when granting remote access to a workforce member. This may be done using Remote Authentication Dial-In User Service (RADIUS) or other similar tools.
Employees access ePHI when not authorized to do so while working offsite.	Develop and employ proper clearance procedures and verify training of workforce members prior to granting remote access. Establish remote access roles specific to applications and business requirements. Different remote users may require different levels of access based on job function. Ensure that the issue of unauthorized access of ePHI is appropriately addressed in the required sanction policy.
Home or other offsite workstations left unattended risking improper access to ePHI.	Establish appropriate procedures for session termination (time-out) on inactive portable or remote devices. Covered entities can work with vendors to deliver systems or applications with appropriate defaults.
Contamination of systems by a virus introduced from an infected external device used to gain remote access to systems that contain ePHI.	Install personal firewall software on all laptops that store or access ePHI or connect to networks on which ePHI is accessible. Install, use and regularly update virus-protection software on all portable or remote devices that access ePHI.

In addition, the Office of E-Health Standards and Services recently published a "Sample — Interview and Document Request for HIPAA Security Onsite Investigations and Compliance Reviews," which is significantly broader than the Guidance. Two key sections of the Sample identify documents and other information that may be requested for investigations/reviews:

1. **Policies and Procedures and other Evidence that Address:**

   - Prevention, detection, containment, and correction of security violations

- Employee background checks and confidentiality agreements
- Establishing user access for new and existing employees
- List of authentication methods used to identify users authorized to access ePHI
- List of individuals and contractors with access to ePHI, to include copies of pertinent business associate agreements
- List of software used to manage and control access to the Internet
- Detecting, reporting, and responding to security incidents (if not in the security plan)
- Physical security
- Encryption and decryption of ePHI
- Mechanisms to ensure integrity of data during transmission — including portable media transmission (i.e., laptops, cell phones, blackberries, thumb drives)
- Monitoring systems use — authorized and unauthorized
- Use of wireless networks
- Granting, approving, and monitoring systems access (for example, by level, role, and job function)
- Sanctions for workforce members in violation of policies and procedures governing ePHI access or use
- Termination of systems access
- Session termination policies and procedures for inactive computer systems
- Policies and procedures for emergency access to electronic information systems
- Password management policies and procedures
- Secure workstation use (documentation of specific guidelines for each class of workstation (i.e., on-site, laptop, and home system usage)
- Disposal of media and devices containing ePHI

2. Other Documents:

- Entity-wide Security Plan
- Risk Analysis (most recent)
- Risk Management Plan (addressing risks identified in the Risk Analysis)
- Security violation monitoring reports
- Vulnerability scanning plans
- Results from most recent vulnerability scan
- Network penetration testing policy and procedure
- Results from most recent network penetration test
- List of all user accounts with access to systems which store, transmit, or access ePHI (for active and terminated employees)
- Configuration standards to include patch management for systems which store, transmit, or access ePHI (including workstations)
- Encryption or equivalent measures implemented on systems that store, transmit, or access ePHI
- Organization chart to include staff members responsible for general HIPAA compliance to include the protection of ePHI
- Examples of training courses or communications delivered to staff members to ensure awareness and understanding of ePHI policies and procedures (security awareness training)
- Policies and procedures governing the use of virus protection software
- Data backup procedures
- Disaster recovery plan
- Disaster recovery test plans and results
- Analysis of information systems, applications, and data groups according to their criticality and sensitivity
- Inventory of all information systems to include network diagrams listing hardware and software used to store, transmit or maintain ePHI
- List of all Primary Domain Controllers (PDC) and servers
- Inventory log recording the owner and movement media and devices that contain ePHI

While the focus of the 2008 CMS assessments will be on entities against which security-related complaints have been filed, CMS's announcement clearly indicates a need for all covered entities to review their HIPAA security procedures, especially those involving remote access. ■

Save-the-Date

Craig Holden *will speak at Physician Hospitals of America's Eighth Annual Conference & Exhibits on October 2-4 in Palm Springs, California.*

PRIVACY

Notifying Patients of Medical Information Security Incidents

California Mandate Leads Way; Will Other States Follow?

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Health care organizations are well aware of the fact that, led by California, a growing number of states have enacted laws designed to protect state residents from identity theft. These laws are of general application, i.e., they are consumer protection laws not directed specifically at health care providers. In general, these consumer protection laws specifically require a holder of an individual's social security number, driver's license number, or other personal identifiers to notify individuals if their information is lost, stolen, or improperly accessed.

Generally, these laws have the following common features:

- They apply to holders of social security numbers, drivers license numbers and other identifying data that might support identity theft of a citizen of the state, whether or not the holder is organized under, or maintains an office within, the state.
- The statute may be limited to electronic personal information. If the personal information is encrypted, notification may not be required.
- Covered information is typically the individual's name together with any of the following: social security number; driver's license number; or financial account numbers, such as bank accounts, credit or debit card numbers, and PIN numbers.
- Specific time limits may apply or the notification may be required without unreasonable delay. Some states, such as California, specifically require notice "in the most expedient time possible and without unreasonable delay" but allow consideration of the needs of law enforcement and/or the need to adequately investigate the circumstances in determining what is expedient and reasonable. Other states, such as Florida, generally require notification within a set time (45 days after determination of the security breach, in Florida).
- Notice invariably must be in writing; some statutes state that regular mail is sufficient. States often provide for alternative methods of notification in specified circumstances. California, for example, permits "substitute notice" by email to the individual and conspicuous posting on the holder's web site, and notification of statewide media if the number of individuals affected or the costs of notice exceed certain high thresholds or if the holder has insufficient information about the individuals to send a written notice.
- Significant penalties may apply for failure to make timely notification. In Florida, for example, civil penalties up to a whopping $500,000 may be levied if notice is not given for six months or longer after the determination of the loss.

California amended its consumer notification law, effective January 1, 2008, to include "medical information" in the definition of personal information that is subject to the notification law. Medical information is defined as "any information regarding an individual's medical history, mental or physician condition, medical treatment or diagnosis by a health care professional." Thus, under the California law, any person or business conducting business in California that owns or licenses computerized data that includes medical information is required to disclose any breach of the security of the computer system in which the data resides following discovery of the security breach to each resident of California whose unencrypted medical information was, or is reasonably believed to have been, acquired by an unauthorized person.

Given the public sensitivity to the security of medical information, other states are likely to expand their consumer notification laws to include medical information. ■

A Growing List

While not an exhaustive list, the following states have enacted notification laws, many of which are closely modeled after the California law:

Arizona	Kansas	North Dakota
Arkansas	Louisiana	Ohio
Colorado	Maine	Oklahoma
Connecticut	Maryland	Pennsylvania
Delaware	Michigan	Rhode Island
the District of Columbia	Minnesota	Tennessee
Florida	Montana	Texas
Georgia	Nebraska	Utah
Hawaii	Nevada	Vermont
Idaho	New Hampshire	Wisconsin
Illinois	New Jersey	Washington
Indiana	New York	
	North Carolina	

REIMBURSEMENT

No Longer Final: CMS Proposes Review of Some DAB Decisions

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In December 2007, CMS proposed regulations governing administrative review by the Department Appeals Board (DAB or Board). 72 Fed. Reg. 73,708 (Dec. 28, 2007). The proposed rules would amend DAB procedural regulations relating to review of grant disputes, challenges to civil money penalties, exclusions and assessments involving health care fraud and abuse, and appeals of adverse determinations affecting providers' and suppliers' participation in the Medicare and Medicaid programs. Specifically, the amendments add provisions to require that the DAB follow published CMS guidance where such guidance is not inconsistent with existing statutes and regulations, and also change appeal procedures to allow for Secretarial review of DAB decisions. These amendments, if implemented, represent a drastic departure from current CMS regulations relating to DAB review. Under current rules, the DAB speaks for the Secretary and issues decisions that, if adverse to the Secretary, are no longer reviewable.

Current procedural regulations for the DAB provide that the Board is bound by all applicable laws and regulations. The proposed rule further limits DAB discretion by adding a provision to require the Board to follow published guidance issued by the Secretary of HHS or any agency component delegated responsibility for the interpretation and administration of the provision at issue. Published guidance is defined as publically disseminated guidance, including, for example, manual provisions, Medicaid director letters, and postings on the CMS website.

According to CMS, these provisions clarify the proper role of the DAB as an adjudicatory entity, and not as a policy-maker that weighs the relative strengths of previously adopted interpretations. CMS clarifies that the DAB is not authorized to develop new interpretive policies.

In addition to limiting the Board's discretion, the proposed rules further incorporate new provisions to allow for Secretarial review of DAB decisions and, in some cases, Administrative Law Judge (ALJ) determinations. CMS explains in the preamble that the original DAB rules provided for review by a relevant CMS component prior to becoming a final agency determination; however, in 1978, the rules were amended to provide that DAB decisions were final administrative decisions. Now, almost 30 years later, CMS is proposing to authorize Secretarial review of DAB decisions to, according to CMS, "ensure consistency in decision making and to ensure that the Secretary's policies are correctly implemented."

Under the proposed provisions, the Secretary would have 30 days to determine whether to undertake a review of a DAB determination. The proposal includes no time limit for the Secretary to render a decision, although CMS anticipates that review should be completed within 45 days. In most circumstances, the Secretary would be authorized to affirm or reverse the DAB decision, or to remand the case back to the Board for further consideration in accordance with the Secretary's instructions. However, for appeals involving the Temporary Assistance for Needy Families program, the Secretary is limited under the proposed rules to either affirming or remanding the Board's decision because, by statute, the decision of the Board is appealable to federal court. CMS has not proposed any regulatory text relating to briefing or other procedures for Secretarial review, but is accepting comments as to whether such procedures should be adopted. In each case reviewed, it is proposed that the Secretary issue a written opinion summarizing the basis for his or her conclusions. The proposed rules also incorporate provisions that will allow the Secretary to directly review ALJ determinations, when the DAB declines review of an ALJ decision.

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SELF-REFERRAL

Deal Revised Post-recruitment Falls Out of Stark Exception

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In September 2007, CMS issued an advisory opinion regarding a physician recruitment arrangement. The recruitment arrangement was originally between a hospital and a physician for the purpose of inducing the physician to relocate to the hospital's service area to provide professional medical services as part of a physician-owned professional group. The financial assistance provided by the hospital to the physician included an income guarantee loan. Under the terms of the recruitment arrangement, the hospital guaranteed the physician a minimum monthly revenue plus a capped amount of expenses attributable to the physician's medical practice, less the physician's monthly collections for services rendered as part of the group. The income guarantee loan also included an "excess receipts" provision, which specified that the physician was obligated to pay the hospital any portion of his collections that exceeded the sum of the guaranteed revenue and expenses, up to the amount of the outstanding portion of the income guarantee loan.

The Stark Phase II rule amended the regulations addressing recruitment arrangements, at 42 C.F.R. § 413.357(e), to require that an income guarantee offered as part of a recruitment arrangement only include amounts for practice expenses that are the "actual additional incremental costs attributable to the recruited physician." To conform to these changes, the hospital and physician modified the recruitment arrangement to add the group as a party and reduce the maximum amount allowable for the physician's practice expenses under the income guarantee. As a result, the maximum allowable monthly payment the group was entitled to receive under the amended recruitment arrangement was significantly less than what the hospital was liable to pay the physician directly for practice expenses under the original recruitment arrangement. The amended recruitment arrangement also had the effect of increasing the amount for which the physician could potentially be liable to pay the hospital if the physician received excess receipts.

The requestor sought clarification on two issues. First, whether the original recruitment arrangement, without the excess receipts provision, would have complied with the Stark regulatory exception for recruitment arrangements. Second, whether the parties to the amended recruitment arrangement may remove the excess receipts provision and remain in compliance with the law.

CMS declined to address the first query on the basis that hypothetical situations are not eligible for consideration under the advisory opinion process. With regard to the second query, CMS did not address the merits of the excess receipts provision and, in fact, noted that such provision is not required for compliance with the recruitment exception. Instead, CMS took issue with any change to a recruitment arrangement that could potentially provide the recruited physician with additional compensation and that would occur after the physician was already successfully recruited. CMS reasoned that the purpose of the recruitment exception is to permit compensation arrangements to induce physicians to relocate their medical practices. In the situation at issue, CMS found that, because the physician had already relocated, the additional compensation that would be potentially available to the physician as a result of removing the excess receipts provision would not be part of an inducement to relocate and could directly or indirectly reflect the volume or value of the physician's actual or potential referrals. Overall, CMS concluded that if the parties deleted the excess receipts provision, the amended recruitment arrangement would not meet the criteria of the Stark regulatory exception for recruitment arrangements.

While this advisory opinion describes in detail the income guarantee and the excess receipts provision within the guarantee, it does not provide additional guidance on CMS's view of income guarantees as CMS's analysis within the opinion does not turn on the substance of the income guarantee. Rather, CMS's conclusion that the amendment to the recruitment arrangement would take the arrangement out of compliance with the exception turns on the fact that the amendment potentially provides additional compensation to the physician after the goal of the arrangement has been reached, i.e., the physician's relocation, and therefore the additional compensation could not be protected under the recruitment exception. ■

Congratulations

Nightingale's Healthcare News *has named two OberlKaler attorneys in recent rankings of the nation's most prominent health lawyers.*

Tom Pedroni *was selected for the 2008 "Outstanding Physician Practice Lawyers" list, and* ***Bill Mathias*** *was named to the 2008 "Outstanding Fraud & Compliance Lawyers" list.*

LITIGATION/ADR

In-house Counsel and Compliance Director Faces FCA Action

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In a complaint filed September 18, 2007, under the federal False Claims Act, the U.S. Attorney's Office for the Southern District of Florida alleged that Christi R. Sulzbach, as Corporate Integrity Program Director for Tenet Healthcare Corporation, fraudulently signed a certification under the Tenet Corporate Integrity Agreement stating that the company was in material compliance with all applicable federal laws. *United States v. Sulzbach*, No. 07-61329 (S.D. Fla. filed Sept. 18, 2007).

The complaint details Ms. Sulzbach's professional history with National Medical Enterprises (NME), a company which entered into a settlement with the federal government in 1994 to resolve an investigation of physician relationships. That case also included a $33 million criminal fine and a five-year CIA. As part of the settlement, the government required outside counsel review of contracts involving payments to physicians.

At some subsequent date, NME merged with a company to form Tenet. The original CIA continued to apply to the new entity. Ms. Sulzbach became the Associate General Counsel and Corporate Integrity Program Director for Tenet.

The complaint notes that Tenet negotiated certain physician employment agreements in 1993 and 1994. At some later time, and presumably based on an allegation regarding the propriety, or legality of those agreements, Ms. Sulzbach retained an outside law firm to review the agreements. The law firm, according to the complaint, issued letters to Ms. Sulzbach concluding that over one-half of the arrangements reviewed included "violations of the law." The alleged violations included payments in excess of fair market value, payments which were not commercially reasonable, and payments which were tied to the volume or value of referrals from the physicians. The complaint notes that the physicians were paid under the employment agreements more than they earned before they became employees, with no expectation of additional patient visits or services to be provided by the physicians. Rather, according to the complaint, internal documents specified the exact value of expected referrals from the physicians (e.g., lab referrals) and noted that these revenues would offset the projected losses from physician fees. Moreover, the complaint alleges an immediate switch in the referral patterns of the physicians.

According to the complaint, four days after receiving the letters from the outside firm, Ms. Sulzbach executed a sworn certification under the CIA indicating that the company was in "material compliance to the best of my knowledge and belief" with all applicable federal laws.

The complaint goes on to identify how this information came to the attention of the government. Specifically, a federal investigation focused on the exact physician employment agreements reviewed by the outside law firm, in addition to other financial relationships between that Tenet hospital and certain physicians. As part of that investigation a privilege log of over 1,000 pages was created. When Tenet entered into a settlement agreement to resolve that investigation, pursuant to which it paid $920 million, Tenet also agreed to cooperate and to turn over documents, including the privileged documents. Of particular note, the settlement agreement did not release any civil or criminal claims against individuals. Further, the obligation of continued cooperation contained in the settlement agreement required Tenet to turn over privileged documents. ■

Welcome...

With this issue of the Health Law Alert, *we welcome three new faces to Ober|Kaler's Health Law Group.*

Richard W. Westling *joins us as a principal. He brings over twenty years of experience, both as a government attorney and in private practice, particularly in matters involving fraud, compliance and related litigation. Richard holds degrees from Sewanee – The University of the South (B.A., 1985) and Tulane Law School (J.D.,* cum laude, *1988).*

Mark A. Stanley *is a second year associate who started in the firm's Finance Group and now practices health law. He handles Medicare and Medicaid regulatory and payment issues, and brings to the Group experience in various financing matters. Mark is a graduate of the University of Maryland at College Park (B.A., 2004), where he was named a Howard Hughes Medical Institute Research Fellow. He earned his law degree from the University of Maryland School of Law (J.D.,* cum laude, *2006).*

John Kirk *joins us as a paralegal. Working in two practices, John will assist our Health Law Group's Payment attorneys while continuing to work in the firm's Intellectual Property practice, which he joined in 2006.*

LITIGATION/ADR

Caremark Settles with 28 States and District of Columbia

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On February 14, 2008, Caremark Rx, LLC entered into settlement agreements with 28 states and the District of Columbia to resolve the civil litigation addressing the following issues:

- Caremark's Drug Interchange program
- Practices regarding the placement of certain drugs on, and operations involving, Caremark's Performance Drug List and Preferred Primary Drug List
- The disclosure and retention of rebates and other payments received from manufacturers
- Disclosures of potential cost savings to Plan Participants and Client Plans
- Issues regarding whether the conduct of its pharmacist violated consumer protection statutes by failing to comply with pharmaceutical ethical principles and guidelines

As part of the settlements, Caremark denied all of the allegations.

The actions were generally filed under the state consumer protection statutes. This settlement tracks the settlement entered into by Caremark on behalf of Advance PCS in the Eastern District of Pennsylvania on September 7, 2005.

In each settlement, Caremark agreed to take certain actions, and to provide certain information, in the context of its operations and relationships with client plans, plan participants, and pharmacists and physicians. In large part, the settlement agreement provides the parameters for drug interchanges, including the circumstances under which such drug interchanges may occur, information which must be provided to plan participants and prescribers, and the ability of plan participants and providers to reject certain suggested drug interchanges. Under the settlement, Caremark also agreed to pay up to $2.5 million to reimburse plan participants up to $25 each for out-of-pocket expenses, including copayments and other health care services incurred as a result of the drug interchange. A portion of the total settlement payment was also directed to cover attorneys fees and investigative costs, consumer education, litigation, public protection, and consumer protection purposes to be used at the sole discretion of each state's Attorney General.

Caremark previously agreed to abide by the terms of a CIA entered into by Advance PCS with the OIG addressing many of the same issues. Thus, the state settlements do not contain any additional reporting or monitoring requirements. ■

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This proposed regulation has been met with significant opposition by both industry stakeholders and Congress. Comments on the proposed rule were due by January 28, 2007. Significantly, many commenters, including attorneys representing as many as 17 states and the American Health Care Association, have urged CMS to withdraw the rule immediately. This has led to congressional action in the form of two bills that would impose a moratorium on implementation of the rule. Senator Amy Klobuchar (D-Minn.) and Representative Keith Ellison (D-Minn.) introduced a bill (S. 2849, H.R. 5763) that calls for a one-year moratorium on any action with respect to the proposed rule. Senator John D. Rockefeller, I.V. (D.-W.Va.) also included a moratorium provision relating to the proposed DAB rules as part of the Economic Recovery in Health Care Act (S. 2819), which would impose moratoriums on several controversial rules.

The proposed regulation represents a drastic change in the CMS administrative appeals process. The DAB hears disputes involving a wide range of issues and the proposed changes will limit the DAB's authority to effectively adjudicate such issues. This change, if implemented, would mark a sharp reversal of current policy, under which the Board speaks for the Secretary and issues decisions that, if adverse to the Secretary, are no longer reviewable. The proposed regulations would create a process similar to that presented in Provider Reimbursement Review Board (PRRB) matters, under which PRRB rulings are subject to review by the CMS Administrator. Experience shows that PRRB rulings, if favorable to the provider, are reversed by the CMS Administrator, thus forcing the providers to seek further court review. ■

TAX

Economic Stimulus Act Creates Bonus Depreciation, Increases Expensing Limits

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The Economic Stimulus Act of 2008 (the "Act") contains two key provisions benefiting businesses that purchase and place into service various types of machinery, equipment, aircraft and other depreciable property during 2008.

50 Percent Bonus Depreciation

The first of these provisions creates a 50 percent "bonus" depreciation deduction for purchases of certain depreciable property in 2008 and, in limited circumstances, 2009. The bonus depreciation deduction is equal to 50 percent of the cost, plus normal accelerated depreciation on the balance of the cost, of qualified property purchased and placed into service in 2008. Qualified property includes tangible personal property eligible for accelerated depreciation with a recovery period of 20 years or less, depreciable computer software, and certain leasehold improvements.

The bonus depreciation deduction is allowed for both regular tax and alternative minimum tax purposes for the taxable year in which the property is placed in service. The original use of the property must commence with the taxpayer after December 31, 2007, and before January 1, 2009 (extended to January 1, 2010, for certain aircraft, transportation property, and property with a production period exceeding one year). Special rules with respect to the original use requirement (generally identical to the prior bonus depreciation rules) apply in the case of certain sale/leasebacks and syndications (in each case, within three months of original use). For sellers of fractional interests in property to unrelated third parties, the original use of such property begins with the first user of each fractional interest (i.e., each fractional owner is considered the original user of its proportionate share of the property).

One very important requirement is that bonus depreciation is not available if the original user of the property (or a related party) had a binding contract to acquire the property that was in effect on or before December 31, 2007. Furthermore, taxpayers should not assume that bonus depreciation is automatically available for state income tax purposes. Instead, they should determine which state may help generate maximum deduction recognition for the year in which the asset is placed into service. As was the case with the prior bonus depreciation rules, it is unlikely that all 50 states will recognize the new 50 percent bonus depreciation rules in their entirety. Therefore, from a practical level, a taxpayer will need to maintain separate records for federal and state tax law purposes.

Increased Expensing for Qualified Small Business Taxpayers

The Act increases the maximum expense deduction (in lieu of depreciation) for 2008 to $250,000 for capital purchases of personal property and depreciable computer software used in the active conduct of a business. The full amount of the increased deduction is available to taxpayers who invest up to $800,000 in such eligible property in 2008.

> *"While these opportunities appear to be "pro" business development, the benefits of the new rules may be limited by the application of the well-established and highly restrictive passive activity loss limitation rules, at-risk loss limitation rules and entertainment use deduction limitations."*

The increased deduction is reduced on a "dollar-for-dollar" basis to the extent that capital purchases of eligible property made in 2008 exceed $800,000, until it is completely phased out if total purchases equal or exceed $1,050,000. The increased deduction is calculated before depreciation, with any non-expensed portion subject to normal depreciation rules. The deduction is also limited to the amount of combined taxable income from the taxpayer's active trades or businesses, which includes the amount of wages paid to a taxpayer. The income limitation is calculated before the deduction is taken and

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LEGISLATION

Patent Law Reform and the Health Care Lobby

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Last April 18, 2007, Congressman Howard Berman introduced bill H.R. 1908 into the House of Representatives while Senator Patrick Leahy introduced its counterpart into the Senate. The bills reflect the most dramatic changes to the patent laws in the last half century. Fundamentally, the changes harmonize our U.S. patent laws with those of most foreign countries. Specifically, we will move from a "First to Invent" system to a "First to File" system under which patents are awarded to whoever files the first patent application, as opposed to the first to invent. Despite an outcry from independent inventors, most of corporate America considers harmonization a good and necessary thing and this much will eventually become law. However, certain Fortune 500 technology companies have long been lobbying for additional reforms against exorbitant litigation expenses, patent trolls and other impediments to their bottom line. For example, Microsoft wants to make it easier to challenge patents after they have been granted, claiming that they spend more than $100 million a year defending against 30 to 40 patent lawsuits pending at any given time. Hewlett Packard spends about the same. They would like to make patent litigation an uphill battle and reduce the potential gain for plaintiffs. As a result, a mixed bag of bundled provisions were included in the original bills to do just that, including:

1. Make it easier to file patent applications without the inventor's cooperation. This will help corporations file despite recalcitrant ex-employees.
2. Damage recovery limited to the economic value of the patented improvement as compared to the prior-art, and punitive damages for willful infringement reduced.
3. Issued patents could be challenged any time in "post-grant opposition proceedings."
4. There would be interlocutory appeals from district court Markman hearings (claims construction) to the federal circuit, which appeals stay the district court action. This would disrupt District Court litigation and interpose the burden of defending an appeal on the plaintiff.

The House voted last September and passed its bill 220 to 175, with 37 abstaining. On the Senate side, the result of the bundled reform measures has been anything but harmonious. Smaller technology companies have begun lobbying in earnest, arguing that reform would tip the scales in favor of big technology. The health care industry also reacted strongly. Both pharmaceutical and biotechnology companies are fighting hard against the current bill, arguing that unlimited patent challenges and damage limitations would seriously disrupt their business. Johnson & Johnson spends over $7 billion annually on its research and wants patents with teeth to protect its investment. Health care associations have also taken up the cause for their members. For example, the Biotechnology Industry Organization (BIO) accepts the change to first-to-file, but not the post-grant opposition proceedings or damage limitations. BIO argues that most of its members are small research businesses with no products to sell. They are funded through private investment and need strong and predictable patents to lure investors. The Pharmaceutical Research and Manufacturers of America (the largest pharmaceutical lobby) is lobbying against the post-grant review for the same reasons.

And so the current debate pits the technology hardware and software giants against the pharmaceutical and biotechnology industry. The stakes are high. Apple spent $720,000 just in the first half of 2007 to push the reform. The Business Software Alliance (BSA), which includes members such as Microsoft, IBM, Adobe, Cisco, HP, Intel, and Apple, has been funding the efforts aggressively. Verizon Communications Inc. spent nearly $3.9 million in 2007 to lobby on issues including patent reform, while RIM devoted $890,000 on the heels of its widely publicized patent ordeal. On the other side of the field, Millennium Pharmaceuticals spent $1.3 million in 2007 opposing the current reform bill, while Genentech spent $1.8 million. Novartis has a $6 million yearly lobbying budget and is actively voicing its opposition. Medtronic spent $760,000 in just the first half of 2007 to lobby against the bill, and Amgen invested as well. The Coalition for Patent Fairness contributed about $500,000, and the Coalition for 21st Century Patent Reform (including members 3M, Caterpillar, Eli Lilly, General Electric, Johnson & Johnson, and Proctor & Gamble) is spending to prune the bill.

The White House recently sided with the health care community, announcing that it strongly opposes the current version of the bill because the damages limitations "would likely lead to less than adequate compensation for many patent holders and could promote infringement." Ober|Kaler attorneys recently visited with aides from the offices of U.S. Senators Ben Cardin (D-MD) and Barbara Mikulski (D-MD) and learned that the Senate version of the bill is currently undergoing emergency liposuction, and "micro-entity" exemptions are being put in place for independent inventors. The Senate was expected to vote on a revamped bill in April. At that point someone might get hurt. It certainly won't be the lobbyists. ■

ANTITRUST

General Hospitals' Responses to Specialty Facilities: Competition or Exclusion?

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This is part two of a two-part article. Part One appeared in the Fall/Winter 2007 Health Law Alert and is available at www.ober.com. Click Health, then Publications, then Health Law Alert *Fall/Winter 2007.*

General hospitals have responded in a variety of ways to the continuing expansion of physician-owned facilities (POFs) and the perceived threat that such competing facilities present. Part One of this article discussed these reactions, the antitrust claims filed by physician-investors in response to general hospitals' actions, and empirical and economic studies addressing the purported benefits and harm to general hospitals from POFs. In this second part, the article reviews the United States Department of Justice Antitrust Division's guidance in this area, and the legal, economic, and empirical justifications for general hospital responses, and examines whether such justifications constitute a legally cognizable defense as legitimate business justifications under the antitrust laws.

U.S. Department of Justice's Views on Physician-owned Facilities and Hospital Actions in Response

Although neither the Federal Trade Commission nor the Antitrust Division have initiated any enforcement actions in this area, the Antitrust Division has recently issued several public statements commenting and providing some guidance on the POF issue. The Antitrust Division submitted written testimony to the Georgia legislature on February 23, 2007, and a competition advocacy letter to the South Carolina State Health Planning Committee on December 8, 2006, focusing on the imposition or use of certificate of need laws or regulations (CONs) to bar the entry of new competitors, including single-specialty or limited-specialty hospitals (SSHs) and other free-standing facilities. The South Carolina letter addressed a draft plan to specifically ban all new SSHs from obtaining a CON. Both statements cited to the joint hearings and Joint Report on competition in the health care industry published by the Antitrust Division and Federal Trade Commission in July 2004. *See* Competition in Healthcare and Certificates of Need: Before a J. Sess. of the Health and Human Servs. Comm. of the State S. and the CON Spec. Comm. of the State H.R. of the Gen. Assemb. of the State of Ga. (2007) (statement of Mark J. Botti, Chief, Litigation I Section, U.S. Dep't of Justice, Antitrust, Div.) (Georgia testimony); letter from Mark J. Botti to South Carolina State Health Planning Committee, December 8, 2006 (South Carolina letter).

In both the Georgia and South Carolina statements, the Antitrust Division amplified several views initially expressed in the Joint Report. First, the Antitrust Division reiterated that it is opposed to CON laws in general because they create barriers to entry and expansion by competitors, and is opposed to their specific use as a device to forestall entry by potentially efficient and innovative competitors such as SSHs, ASCs, and free-standing diagnostic imaging facilities. At the same time, however, the Georgia testimony and the Joint Report acknowledge that although a general hospital may use the CON process to hinder the entry of competing POFs, "much of this conduct, even if exclusionary and anticompetitive, is unlikely to be subject to legal challenge as a violation of the antitrust laws because it involves petitioning of the state government by the existing competitor" under the Noerr-Penington doctrine. Of course, this is why the Antitrust Division submitted these statements to the Georgia and South Carolina governments in the first place – to caution the states about what it sees as the potential anticompetitive effects from implementing CON laws that otherwise likely cannot be challenged.

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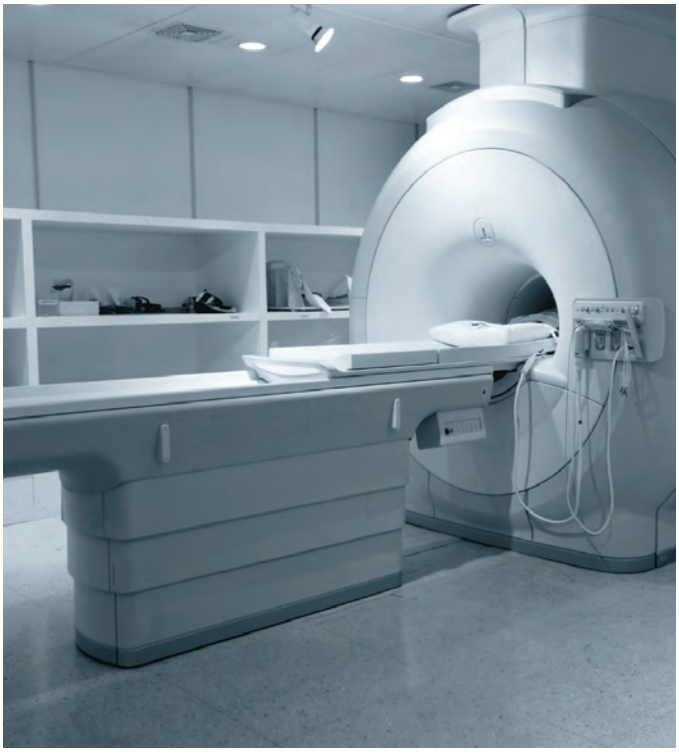

Competition or Exclusion?… FROM PAGE 25

Second, the statements appear to assume that these types of POFs are "higher-quality, low cost providers" whose entry "would put competitive pressure on incumbent providers" – i.e., that the entry of these types of POFs have procompetitive effects. Georgia testimony at 6. The Division stated that it based its comments on evidence from the agencies' joint hearings that SSHs may "achieve better outcomes through increased volume, better disease management, and better clinical standards," and thus increase the efficiency of physician services. South Carolina letter at 2 (citing Joint Report, Executive Summary at 15). And both the Georgia testimony and S. Carolina letter, citing the 2006 MedPAC report, stated that general hospitals responded to the entry of SSHs by improving efficiency, adjusting pricing, and expanding profitable lines of business. As a result, the Antitrust Division concluded that the "evidence to date" indicates that general hospitals have maintained profit margins consistent with national averages.

> *"One of the most prominent business justifications that have been articulated for general hospitals' responses to POFs is that they are necessary to protect the general hospital's ability to cross-subsidize its unprofitable patients or services."*

Third, both statements specifically reject one of the most prominent justifications asserted by general hospitals for opposing CON applications – that competition from SSHs impair their ability to cross-subsidize unprofitable patients and services lines with the profitable services, such as cardiac programs, and the profitable patients who are being referred away from the general hospital to the SSH by the physician-investors. Factually, the Antitrust Division took issue with the underlying premise for this rationale, stating that the "evidence to date" indicates that SSHs do not undercut general hospitals' financial viability and thus ability to perform their charitable missions because, as noted above, general hospitals maintained profit margins consistent with national averages. And the Division also criticized the cross-subsidization justification in principle, going as far as to state that cross-subsidization rationale "turns [the CON] laws on their head" by stifling competition and keeping prices high. Georgia testimony at 6. Again, the Division appears to base this view on the assumptions that SSHs are lower cost, more efficient providers, and that on balance, the entry of SSHs results in procompetitive benefits that outweigh their harm. The Antitrust Division concluded that there are more efficient ways to achieve the goal of ensuring that general hospitals can maintain the ability to provide indigent care and unprofitable but necessary services than using CON laws to protect general hospitals from competition by SSHs.

While the Georgia and South Carolina statements address the limited issue of using the CON process to respond to the entry of SSHs and ASCs (and to be clear, the statements address any free-standing facility and SSH regardless of whether or not it was physician-owned), the Joint Report more broadly addresses the entire range of possible hospital responses to POFs, but offers little specific guidance. The Joint Report concludes that, in general, the antitrust laws permit unilateral responses to competition, stating that hospitals generally can unilaterally respond to the entry and expansion of SSHs by terminating the physician-investors' staff privileges or, as discussed above, by engaging in Noerr-protected CON opposition. The Joint Report warns, however, that the agencies will "aggressively pursue" general hospitals' responses where there is "specific evidence of anticompetitive conduct by individual providers" or of "hospitals colluding together against efforts to open a SSH or ASC." Joint Report, Executive Summary at 28, Ch. 3 at 27.

Unfortunately, the Joint Report does not elaborate on what types of unilateral conduct might be considered predatory conduct supporting a Section 2 claim, or under what circumstances, if any, conflict-of-interest credentialing could violate Section 2. It also does not discuss the parameters of joint activity that might constitute collusion under Section 1. Interestingly, although the Joint Report briefly mentions that hospitals enter into exclusive or preferred contracts with health plans as one response to SSHs, it does not address those vertical agreements in the section on competitive evaluation of hospital responses. As discussed above, those hospital-health plan agreements are one of the hospital responses to POFs most commonly challenged by plaintiffs. Finally, the Georgia and South Carolina statements shed no additional light on these questions.

Business Justifications – Can General Hospitals "Level the Playing Field?"

The final step in a rule of reason analysis of an antitrust claim under Section 1 is determining whether there are legitimate business justifications for the general hospitals' conduct in response to the POF. Some courts hold that once a defendant establishes a legitimate business justification, the burden then shifts back to the plaintiff to show that these benefits could have been achieved through a less restrictive alternative means or that the restraint is not

reasonably necessary to achieve the stated objective. Similarly, under Section 2, conduct generally is not predatory if the defendant has a legitimate (non-pretextual) business justification or "valid business reasons" for engaging in it.

Various business justifications have been articulated for general hospitals' responses to POFs. As noted above, one of the most prominent justifications is that such responses are necessary to protect the general hospital's ability to cross-subsidize its unprofitable patients or services. There are several variations of this rationale. One argument is that such responses are necessary to maintain lower prices, provide access to health care (particularly for the uninsured and indigent), and provide ER services and other necessary but less profitable services to the community. A related economic justification is that conflict-of-interest credentialing is necessary to preserve the full range of services at a community hospital, resulting in economies of scale and scope. Because of the large fixed costs involved with operating a hospital, it is typically more efficient to share among multiple hospital services a single hospital physical plant, administration, dietary and housekeeping services, laboratory facilities, and even operating rooms and expensive equipment like diagnostic imaging machines, as well as other similar inputs.

Whether or not these cross-subsidization rationales are sufficient to constitute a legitimate business justification under the antitrust laws is unclear. On one hand, these justifications fundamentally amount to an argument that terminating privileges or taking some other action against the specialty hospital or its physician investors is necessary simply because they are competing and taking business away from the hospital. This, of course, is just the type of conduct that the antitrust laws are intended to promote, not prohibit. As discussed above, the Antitrust Division has made clear that it does not accept this as a justification for general hospitals' responses that otherwise inhibit competition from POFs. See Georgia testimony at 6–8; S. Carolina letter at 2–3. (The real problem underlying this issue is a market failure, which requires general acute care hospitals to cross-subsidize unprofitable but necessary, and in many cases statutorily-required, services with other more profitable services and better-paying patients. The Antitrust Division stated that there are more efficient ways to address this failure than allowing general hospitals to hinder the entry of SSHs through using the CON process, or presumably, other actions.) And this view is consistent with the Antitrust Division's stance in prior cases. In addition, the Joint Report and additional cases support the argument that "leveling the playing field" is not a legitimate justification for otherwise anticompetitive conduct in this or other circumstances.

On the other hand, several courts have specifically stated that competition for patients and protecting a hospital's ability to provide community services is a legitimate procompetitive justification. In *Williamson v. Sacred Heart Hospital of Pensacola*, one of the reasons the court granted the defendants' motion for summary judgment was that the plaintiff's status as a competitor provided the hospital with a legitimate business justification for rejecting her application for privileges. 1993 WL 543002 (N.D. Fla. 1993), *aff'd per curiam without published opinion*, 41 F.3d 667 (11th Cir. 1995) (opinion reprinted in 1995-1 Trade Cas. (CCH) ¶ 70,905). The court rejected the plaintiff's claim that the hospital's reason for denying her privileges was pretextual, and held that the hospital's denying privileges based, in part, on her directly competing with the hospital for patients constitutes a "rational economic reason" and procompetitive business justification under Section 1 for terminating privileges.

> *"Determining the overall competitive effect from POFs and general hospitals' responses to them is not simply answered by an instinctive view that any entry by a new competing POF is an unalloyed procompetitive development, and that any response that hinders that entry is thus anticompetitive."*

The court went on to note that by granting the physician privileges, the hospital would be supporting its main rival, and concluded: "We find nothing in the antitrust laws mandating such assistance to a competitor." The Eleventh Circuit agreed, explaining that "[w]e find nothing in the antitrust law mandating such assistance to a competitor" and that "nothing in the antitrust laws requires assisting a competitor." Lending support to this view is the Supreme Court's *Trinko* decision that even a monopolist only very rarely has any duty to assist its competitors. *Verizon Communications, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004). The "rare" circumstances under which such a duty still exists, however, remain unclear.

In addition, courts addressing non-antitrust claims also have specifically recognized hospitals' cross-subsidization of services essential to the community as a legitimate business justification. In *Mahan v. Avera St. Luke's*, where plaintiff physician-investors alleged breach of

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medical staff bylaws based on the established hospital's refusal to grant privileges to new surgeons who were affiliated with a competing SSH, the court stated that the hospital "cannot continue to offer unprofitable, yet essential services including the maternity ward, emergency room, pediatrics and critical care units, without the offsetting financial benefits of more profitable areas such as neurosurgery." Mahan v. Avera St. Luke's, 621 N.W.2d 150 (S. D. 2000). The court added that the effect the SSH hospital would have on the "economic viability" of the general acute-care hospital, the cost of care, and the health care needs of the entire community is a "legitimate concern" of the hospital board.

A second justification articulated by general hospitals for their responses to SSHs is to prevent "cream-skimming" or "patient dumping." The underlying concern for this justification is the same as for the cross-subsidization rationale: physician-investors who also have admitting privileges at the hospital have the incentive and ability to steer more profitable patients to their own facility and costlier patients to the hospital. The physicians-investors thus "free ride" on the general hospital's inability to turn away patients and its investments in the services needed to treat those patients — ER services, charitable care to the uninsured, and other services that SSHs and other POFs do not provide but require in order to operate. This can lead to the hospital investing less in those services, and in turn, reduced consumer access to care and diminished consumer welfare. Another variation of the "free-rider" justification in this context states that the physician-investors benefit from the general hospital's reputation or "seal of approval," or more specifically its marketing and advertising, because it attracts patients who the physicians are then able to steer to their own SSH. Similarly, general hospitals may contend that physician-investors free-ride by using their "insider" position on the general hospital's staff to poach not patients, but other staff physicians, nurses, or other valuable employees away from the general hospital to the SSH.

Numerous courts have recognized that conduct undertaken to prevent free-riding can be a legitimate business justification in a variety of contexts. In addition, in the SSH context, commentators have stated that preventing free riding can economically justify conflict of interest credentialing and exclusive or preferred contracting with payors. Not all general hospital responses, however, may be justified on the basis of the free-riding rationale. For example, the court in *Rome Ambulatory Surgery Center v. Rome Memorial Hospital* stated that it was "difficult to see" how exclusive contracting would be "an appropriate response" to defend against cream-skimming. *Rome Ambulatory Surgery Center v. Rome Memorial Hospital*, 339 F. Supp. 2d 389 (N.D. N.Y. 2004). The court stated that, instead, revoking the physician-investors' privileges would have been a "more appropriate response," and thus apparently a less-restrictive alternative, although it did not analyze the justification in those terms. Id. at 411. Economic commentators also have recognized the distinction between conflict of interest credentialing and managed care contracting in this context, noting that "exclusive or bundled discount contracts, may, but do not necessarily address the free-rider market imperfection" and are not restricted to POFs.

In *Surgical Care Center of Hammond v. Hospital Service District No. 1*, however, the court found that the general hospital's discount for exclusivity contracts with managed care plans had legitimate business justifications and were not exclusionary conduct under Section 2. *Surgical Care Center of Hammond v. Hospital Service District No. 1*, 2001-1 Trade Cas. (CCH) ¶ 73,215 (E.D. La. 2001), aff'd, 309 F.3d 836 (5th Cir. 2002). The court noted that the plaintiff's own expert testified that the hospitals' managed care contracts were a reasonable competitive response to the fact that the physician-investor plaintiffs had a financial incentive to refer patients to their own SSH. In addition, not uncommonly a general hospital's managed care contracts predate the development of the POF, and thus were implemented for reasons unrelated or only partially related to excluding physician-investors, but are nonetheless challenged as part of the bundle of conduct underlying a plaintiff's claims. In these circumstances, the typical rationales for the exclusive provisions, such as providing a discount for greater patient volume, would seem to justify the contracts.

In the final analysis, and as recognized in economic research, determining the overall competitive effect from POFs and general hospitals' responses to them is not simply answered by an instinctive view that any entry by a new competing POF is an unalloyed procompetitive development, and that any response that hinders that entry is thus anticompetitive. Instead, the antitrust analysis of this issue is complicated by the physicians' financial incentive to recommend more procedures and to refer to their own facility, which itself may diminish overall market output by reducing access to care and decreasing quality, and increase health care costs to all consumers across all services provided by general hospitals and POFs. ■

Mr. Berlin is a principal in Ober|Kaler's antitrust practice and is resident in the firm's Washington, D.C. office. *He wishes to thank his partner, John Steren, and Jon Jacobs, an attorney with the DOJ Antitrust Division's Litigation I section, for their input and assistance in preparing this article.*

EMPLOYMENT

A Wake Up Call: The SSA "No-Match" Letter and the Safe Harbor Rule

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Information provided by employees in their Wage and Earnings Report (W-2) must match the information stored in the Social Security Administration (SSA) database. Yet, the SSA says approximately 18 million employee records contain mistakes – this, the agency admits, is mostly due to typographical errors, misspellings of foreign names, employee failure to report a name change or to provide fully completed W-2 forms. To rectify the problem, the SSA sends requests for corrections to employers who have more than 10 discrepancies in the W-2 forms they submit, provided also that each employer's number of unmatched W-2 forms represents more than 0.5 percent (one-half of one percent) of its total W-2 forms.

Since the inception in 1994 of the SSA Employer Correction Request or Educational Correspondence, or "No-Match" letters, the agency has not focused on the possibility that W-2 discrepancies might point to employment authorization or immigration status problems. It was in 1986 that Congress addressed that issue with the passage of the Immigration Reform and Control Act and the Immigration Act of 1990 (collectively, IRCA), which imposed a greater responsibility on employers by requiring they fill out an Employment Eligibility Verification or I-9 form. 8 U.S.C. §§ 1324a, 1324b, 1324c. Along with reporting obligations, IRCA provides that *actual* and *constructive* knowledge can be imputed to the employer who possesses information indicating an employee is ineligible to work in the United States. Heavy civil and criminal penalties can accrue to the employer who *knowingly* employs such an individual.

The Safe Harbor Rule

As a collector of W-2 information for the Internal Revenue Service (IRS), the SSA is forbidden from sharing employee tax information with other agencies. However, opponents of the "Safe-Harbor Procedures for Employers Who Receive a No-Match Letter" (Safe Harbor rule) say this new regulation, promulgated by the Department of Homeland Security (DHS) in August 2007, would cause the SSA to become a source of questionable information for the implementation of immigration enforcement aimed at teasing out unauthorized workers on the basis of unresolved No-Match letters. 72 Fed. Reg. 45,611 (Aug. 15, 2007).

A strategic component of the Safe Harbor rule is a "guidance" letter from DHS's Immigration and Customs Enforcement (ICE), to be sent together with the SSA mailing, that would tell employers how to respond to the No-Match letter to avoid IRCA sanctions. In summary, employers must check their own records within 30 days of receipt of the No-Match letter to determine if there was a clerical error in the employee's records or in employer communication with the SSA; follow the I-9 re-verification requirements; correct any existing clerical error and notify the relevant agencies; if no employer clerical error exists, notify the employee regarding the discrepancy and inform the employee that he must contact the appropriate agency to correct the problem within 90 days of receipt of the No-match letter; and, follow up with SSA or DHS to verify the discrepancy has been resolved.

> *"Labor groups and businesses that regard the DHS enactment as the biggest anti-employment regulation in 20 years have argued that the Safe Harbor rule impermissibly expands the definition of knowingly beyond Congress' intent in IRCA; and that it violates federal law by treating receipt of a No-Match letter as a high-probability indicator that discrepancies relate to unauthorized work."*

The Safe Harbor rule places additional legal burdens on the employers: if the employer fails to respond to the SSA notification, receipt of the No-Match and ICE letters would be used as evidence of the employer's *constructive knowledge* that the employee was working without authorization in violation of section 274A (a)(2) of the Immigration and Nationality Act; or, if the discrepancy remained unresolved after the allotted time, the employer might be required to fire the employee.

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EMPLOYMENT

Employee Personal Protective Equipment—Who Pays?

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The Occupational Safety and Health Administration (OSHA) recently published a final rule which resolved an important issue related to personal protective equipment (PPE). 72 Fed. Reg. 64,341 (Nov. 15, 2007). A host of OSHA health, safety, maritime and construction standards obligate employers to provide protective equipment for their employees, if necessary to protect them from job-related injuries and exposure to harmful chemicals. Standard PPE would include hard hats and helmets, safety gloves, goggles, and chemical gear. But who pays the costs for the PPE? That issue was largely unresolved because the regulations were silent on that particular point.

In its final rule, OSHA declared that employers are now responsible for paying for costs for PPE provided to employees, with very limited exceptions. However, it is important to note that the OSHA final rule does not obligate employers to provide PPE where a requirement to do so had not existed before.

All employers must be conscious of their OSHA compliance obligations and the new final rule amounts to a potential additional cost factor to consider. Also, a consequence of the final rule is the fact that it might have an impact on previously negotiated collective bargaining agreements, since the issue of PPE payment and/or reimbursement is frequently negotiated between employers and labor unions.

This final rule became effective on February 13, 2008, and employers are required to implement these policies no later than May 15, 2008.

Employers whose employees utilize PPE would be well-served to consider the application of OSHA's rulemaking to their businesses, particularly with respect to the following issues:

- What exceptions exist to the PPE cost payment requirement;
- Whether an employer is obligated to reimburse an employee who already owns his/her own PPE; or
- Whether an employer can retain ownership of PPE after an employee leaves the job. ■

EMPLOYMENT

WellPoint Sued for Alleged FLSA Violations

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WellPoint, a leading health benefits provider, was recently hit with a putative class action lawsuit brought by several nurses who claim that for the last three years the company failed to pay them overtime pay in violation of the Federal Labor Standards Act (FLSA) and New York labor law. The three named plaintiffs, current and former employees of WellPoint, allege they each routinely work or worked more than 40 hours a week without being compensated for doing so.

While the plaintiffs had different job titles, they each contend they all worked in "a call center environment." According to the complaint, the plaintiffs spent most of the work day on the telephone with providers and others, then inputting into a computer the data they collected from the calls. Other duties allegedly included following guidelines in performing pre-certifications and/or concurrent reviews of medical procedures. The plaintiffs contend that other nurses with different job titles but substantially similar job duties as the named plaintiffs were also denied overtime compensation. The plaintiffs seek to represent a class of all such persons.

The complaint does not state whether the plaintiffs were registered nurses or licensed practical nurses (LPNs). But from the plaintiffs' perspective, such titles do not ▸ PAGE 31

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matter. According to the U.S. Department of Labor, registered nurses in some cases may be classified as "professionals" under FLSA and exempt from the statute's overtime provisions, because, among other things, such nurses often have acquired a prolonged course of specialized intellectual instruction. LPNs are generally not exempt from FLSA largely because an advanced academic degree is not a standard prerequisite for the job. According to plaintiffs' counsel, however, determination of whether an exemption under FLSA applies requires an examination of the plaintiffs' actual job duties, not whether they have a nursing degree. Plaintiffs contend that WellPoint knew they performed work that required overtime pay, but developed a scheme to deprive them of such pay.

> *"According to plaintiffs' counsel, however, determination of whether an exemption under FLSA applies requires an examination of the plaintiffs' actual job duties, not whether they have a nursing degree."*

The plaintiffs earned salaries. However, under FLSA, had the nurses been paid by the hour instead of by salary, they would have been eligible to earn overtime at a rate of 1.5 times their regular hourly rate of pay for every hour worked over a 40-hour threshold.

The complaint also alleges that in addition to failing to pay overtime, WellPoint violated FLSA by failing to preserve records of the hours the nurses actually worked. If that allegation proves true and plaintiffs prevail, WellPoint's failure to maintain records could be problematic in terms of determining and/or mitigating damages.

The plaintiffs seek various forms of relief, including monetary damages, a declaratory judgment that the actions complained of are unlawful, equitable relief and attorneys' fees. The suit, *Ruggles v. WellPoint, Inc.*, was filed in the U.S. District Court for the Northern District of New York. ■

Mr. Oppel would like to thank Matthew W. Green, Jr., a former associate in Ober|Kaler's Employment & Labor Group, for his assistance with this article.

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In a legal action to stop implementation of the No-Match and "guidance" letters, *American Federation of Labor v. Chertoff* (N.D. Cal. Oct. 10, 2007), labor groups and businesses that regard the DHS enactment as the biggest anti-employment regulation in 20 years argued that the Safe Harbor rule impermissibly expands the definition of *knowingly* beyond Congress' intent in IRCA; and that it violates federal law by treating receipt of a No-Match letter as a high-probability indicator that discrepancies relate to unauthorized work. The complaint further argues that without congressional consent, SSA's confidential tax information processing system cannot be used as a tool for immigration enforcement purposes and that the DHS rule would increase due-process violations, with lawfully employed native-born and foreign workers facing termination on account of ethnicity or foreign accent, or because their name and social security number could not be matched with the SSA database.

Stating that these legal challenges "raised serious questions," a federal judge issued a temporary restraining order on August 31, 2007. Concerned that "irreparable harm to innocent workers and employers" would result from the ICE "guidance" insert, the U.S. District Court for the Northern District of California granted plaintiffs' request for a preliminary injunction on October 10, 2007. Two months later, the same court granted DHS its motion to stay, thus blocking implementation of the Safe Harbor rule indefinitely.

In the wake of these judicial decisions, the SSA cancelled plans to send out nearly 140,000 pending No-Match letters that would have affected eight million workers. DHS Secretary Michael Chertoff said, however, that the agency would not abandon the rule. In fact, while still pursuing an appeal, DHS issued a supplemental proposed rule March 21, 2008, that outlines clear steps an employer may take in response to an SSA No-Match letter to rectify errors within 90 days and, thus, enjoy safe harbor from enforcement action on the basis of the No-Match letter.

Employers should heed this wake-up call, remembering that undocumented foreign workers are a top priority for the DHS. The bottom line: Take appropriate steps to ensure observance of the I-9 requirements; document actions taken to resolve mismatch issues; and, before taking any drastic measures when in doubt regarding a work authorization, consult with legal counsel. ■

Ober|Kaler in Print

- Twenty-one **Ober|Kaler** attorneys appear in the *Maryland Super Lawyers 2008 issue*, which was published and distributed with January's *Baltimore* magazine and in *Maryland Super Lawyers* magazine. Ober|Kaler once again dominated the Health Care category with four slots, including **Craig Holden**, **Len Homer**, **Howard Sollins**, and **Sandy Teplitzky**. *Super Lawyers* names the top five percent of Maryland lawyers, as chosen by their peers and through the independent research of Law & Politics. It is based on a survey of more than 21,000 attorneys across the state.

- *Baltimore Business Journal* lauded **Ober|Kaler's** national reputation in health care law in "A Legal Prescription: Ober Kaler Finds Niche in Health Care Law," a February 22, 2008, article discussing the expansion of health care law and the reputation that Ober|Kaler has built for its representation of health care firms over the past 30 years.

- **Craig Holden** has joined the Editorial Advisory Board of *Washington G2 Reports*, a website offering topical and analytical reports for providers of diagnostic testing and related medical services.

- **Rob Mazer's** article, "OIG Reviews Relationship Between Critical Access Hospital and Hospital-based Radiologists," appeared in the February 22, 2008, issue of American Health Lawyers Association's *Health Lawyers Weekly*.

- **Howard Sollins** was quoted by *Long Term Care Wire* in the March 12, 2008, article, "Beware – Media Coverage can Spark Press, Survey Woes for All Facilities," regarding the tendency of surveyors to incorporate health care issues that have been sensationalized by the media into their surveys of long term care facilities.

- **Tom Hyatt** is the co-author of the Third Edition of the *Law of Tax-Exempt Healthcare Organizations*, part of the Wiley Nonprofit Law, Finance and Management Series.

- BNA's *Health Care Fraud Report* quoted **Sandy Teplitzky** in "Medicaid, Physician Compliance top 2008 Enforcement Agenda," a January 2, 2008, article in which Sandy discusses the expected growth in the number of qui tam suits filed as a result of state false claims laws, and the burden that will place on the DOJ as it diverts valuable resources to investigate such claims.

- **Jeff Miles** was quoted by *Modern Healthcare Online* in the December 17, 2007 article, "Nurses Wage War," in which Jeff comments on lawsuits filed by nurses in a handful of states alleging that hospital executives conspired to hold down wages amid a national nursing shortage that would have been expected to push pay upward. Jeff's podcast interview on the subject was posted with the March 24, 2008, issue of Modern Healthcare's *Daily Dose*.

- **Rob Mazer** was quoted by *Laboratory Compliance Insider* in "Set Processes Now to Handle Release of New ABN Form," a May 2008 article in which Rob discusses CMS's transition to its new Advance Beneficiary Notice of Noncoverage and the basic process for completing the form.

- **Tom Hyatt's** article, "New Form 990 Will Follow Your Functions," appeared in the January/February 2008 issue of AGB *Trusteeship*. In it, Tom discusses the heightened disclosure requirements of the newly revised information return filed by tax-exempt organizations, and the resulting need for increased board involvement in completing the form.

- BNA's *Health Law Reporter* quoted **Sandy Teplitzky** in "History Behind On-Call Advisory Opinion Reveals Much About Politics of Compliance," a December 6, 2007, article in which Sandy discusses an OIG advisory opinion approving a hospital's payments to specialty physicians for on-call coverage in its emergency department, and the model that the payment arrangement offers to hospitals looking to structure their on-call payments to avoid risk.

- In "FTC Paves Unclear Path," an article posted May 5, 2008, to *Modern Healthcare Online*, **Jeff Miles** was quoted regarding the rationale behind and the possible impact of the unusual outcome of the FTC's antitrust challenge to Evanston Northwestern Healthcare's acquisition of Highland Park Hospital.

- **Rob Mazer** was quoted by *Laboratory Compliance Insider* in "Anti-markup Delayed, Some Rules Remain for Laboratories," a March 2008 article in which Rob discusses the application to laboratories of those portions of the antimarkup provisions from the 2008 Medicare Physician Fee Schedule final rule that were not delayed by CMS.

- **Sandy Teplitzky** was quoted by *BNA's Health Law Reporter* in "Health Care Quality, Fraud and Abuse Top List of Health Law Issues for 2008," a January 3, 2008, article in which Sandy and other members of the newsletters editorial advisory board discuss their picks for the top 10 health law issues for 2008.

- *Modern Healthcare* quoted **Bill Mathias** in the January 21, 2008, article, "More Gainsharing Guidance," in which Bill discusses the OIG's approval of specific gainsharing arrangements through the advisory opinion process.

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Ober|Kaler in Print (cont'd)

- **Julie Kass** and **Bill Mathias'** article, "Big Changes to Physician Diagnostic Testing Under 2008 Medicare Physician Fee Schedule," appeared in the January 2008 Washington G-2 Reports *G-2 Compliance Report*.
- *Laboratory Compliance Insider* quoted **Rob Mazer** in the January 2008 article, "MPFS 2008 Final Rule: The Ins and Outs of Stark Law," in which Rob comments on CMS's delay of reassignment rule changes in its 2008 Medicare Physician Fee Schedule.
- **Howard Sollins** was quoted by Eli Research's *Part B Insider* in "Take a Fresh Look at Your Beneficiary Gift-Giving," a December 7, 2007, article discussing possible fraud and abuse repercussions of offering gifts to beneficiaries of federal health care programs, even charitable gifts to patients in need.
- **Donna Senft's** article, "OIG Provides Further Guidance Related to Nursing Facility Compliance Programs," appeared in the Spring 2008 *VHCA Legal Quarterly*. In the article, Donna offers an overview many of the issues raised under key topic areas identified in the Draft OIG Supplemental Compliance Program Guidance for Nursing Facilities released in April 2008.
- **Sandy Teplitzky's** article, "Payments for Providing Services Outside of the Country," appeared in the April 2008 *AUA News* (the official newsmagazine of the American Urological Association). The article discusses the expanding use of high intensity focused ultrasound (HIFU) as an alternative to radiation and surgery for treating prostate cancer. ■

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potential referral sources. See Special Fraud Alert, "Arrangements for the Provision of Clinical Lab Services." 59 Fed. Reg. 65,372, 65,377 (Dec. 19, 1994). In the Clinical Laboratory Fraud Alert, the OIG indicated that the provision of free items or services from a laboratory to a referral source creates "an inference… that the item or service is offered to induce referrals." The OIG also cautioned against "swapping" arrangements between laboratories and dialysis facilities in which the laboratory offers discounts on the facility's composite rate tests in exchange for the facility's referrals for noncomposite rate tests billable by the lab directly to Medicare or other federal health care programs.

The OIG noted two key features of the proposed labeling arrangement that resembled the disfavored arrangements described in the Clinical Laboratory Fraud Alert. First, the offering of labeling services at no charge gave rise to an inference that such services are intended to influence the dialysis facilities' choice of laboratory. This was clear from the requestor's representation that the free services would be offered to dialysis facilities only when necessary to obtain or retain their business. Second, the free labeling services would operate in effect as a price reduction or nonmonetary discount on the amount the dialysis facilities would pay the laboratory for composite rate tests. The risk is that the discounts would be offered in exchange for the dialysis facilities' referral of noncomposite rate tests to the laboratory as in a swapping arrangement. The OIG found an improper nexus between the free labeling services and the referral of other federal health care program business (e.g., the noncomposite rate tests). Consequently, the OIG found that the proposed arrangement posed a significant risk of improper swapping that could potentially generate prohibited remuneration under the antikickback statute.

The facts of Advisory Opinion 08-06 leave one with the suspicion that the laboratory requesting it may have been seeking a negative opinion. It is difficult to imagine how the OIG could approve an arrangement in which the requestor acknowledges that its action is based on whether it "would be necessary to obtain or retain the business from a particular Dialysis Facility." Although this opinion suggests that the provision of free labeling services is suspect, there may be ways in which the arrangement might be modified to be consistent with the antikickback statute. ■

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without regard to net operating loss carrybacks/carryforwards or suspended losses. Any amount suspended due to this limitation is carried forward indefinitely.

Additional Considerations

While these opportunities appear to be "pro" business development, the benefits of the new rules may be limited by the application of the well-established and highly restrictive passive activity loss limitation rules, at-risk loss limitation rules and entertainment use deduction limitations. Therefore, it is imperative that business owners/operators ascertain whether the bonus depreciation and/or increased expensing incentives will apply to such purchase and whether the owner/operator may be prohibited from taking full advantage of these incentives due to one or more of the limitations on the deductibility of such amounts contained in the Internal Revenue Code. ■

Ober|Kaler Speeches & Presentations

- **Craig Holden** spoke at the American Bar Association's 18th Annual National Institute on Health Care Fraud.
- **Howard Sollins**, **Sharon Snyder** and **Alan Arville** were among the presenters at LifeSpan's Transitioning Residents Among Levels of Care Under the Federal Fair Housing Act.
- **Christi Braun** presented a discussion on the Robinson-Patman Act and the Nonprofit Institutions Act at the Annual Meeting of the Minnesota Multi-State Contracting Alliance for Pharmacy.
- **Tom Hyatt** spoke at Introduction to Key Antitrust and Tax Issues in Health Law, a program hosted by the District of Columbia Bar.
- **Jeff Miles** was among the presenters at Clinical Integration in Health Care: A Check-Up, hosted by the Federal Trade Commission.
- **Bill Mathias** presented "Quality of Care Initiatives Gaining Momentum," a teleconference hosted by the Health Care Compliance Association.
- **Jim Wieland** served on a panel discussion of HIPAA compliance titled "HIPAA Privacy and Security: Prepare for New CMS and OIG Reviews."
- **Tom Coons**, **Craig Holden** and **Leslie Goldsmith** presented discussions on payment matters at the Institute on Medicare and Medicaid Payment Issues, a program sponsored by the American Health Lawyers Association.
- **Steve Smith** was a presenter at 2008 Outlook on Healthcare: Where Are the Opportunities & Will an Ambulance Be Needed? a program of the Chesapeake Chapter of the Turnaround Management Association.
- Several of Ober|Kaler's Health Law Group attorneys spoke at LifeSpan's 27th Annual Conference & Exposition: Passport to Excellence in Senior Care Services. **Howard Sollins** co-presented "Maryland Legislative & Regulatory Update"; **Jim Wieland** presented "Making the Right Choice: Assessing Electronic Medical Records Systems"; **Donna Senft** presented "Passport to Full-Service, Coordinated Care: Strategies for the Delivery of Ancillary Services in LTC";
- **Alan Arville** co-presented "What Not-for-Profits Need to Know about IRS Form 990 to Avoid Disaster."
- **Donna Senft** and **Howard Sollins** spoke at the "Quality Assurance, Risk Management and Corporate Compliance" session at the annual conference of the Association of Jewish Aging Services.
- **Tom Hyatt** presented "Legal Issues of Not for Profits" at the 2008 Government & Not For Profit Conference hosted by the Maryland Association of CPAs. He also spoke at Commonfund Institute's Fiduciary Responsibilities of Trustees program, and he presented "Health Care Tax Update" at the Washington Non-Profit Legal and Tax Conference.
- **Susan Turner** co-presented "Introduction to Medicare," part of the "Introduction to Health Law Series" hosted by the District of Columbia Bar.
- **Julie Kass** and **Bill Mathias** co-presented "How New Stark & Medicare Payment Rule Changes Affect Your Business," an audio conference sponsored by Washington G-2 Reports.
- **Sandy Teplitzky** and **Howard Sollins** spoke at the Long Term Care and the Law program hosted by the American Health Lawyers Association.
- **Julie Kass** co-presented "Who Moved My Same Building? The Practical Implications of the New Purchased Diagnostic Rule" in this teleconference hosted by the American Health Lawyers Association.
- **Julie Kass** and **Bill Mathias** spoke at the Physicians and Physician Organizations Law Institute, a program hosted by the American Health Lawyers Association.
- **Julie Kass** and **Steve Smith** spoke at the 9th Annual Emerging Issues in Healthcare Law Conference, hosted by the American Bar Association. ■

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