G-2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

Ohio Hospital Does Not Have to Produce Lab Results

A hospital in Ohio does not have to produce laboratory results of a patient accused of transmitting an infectious illness to a hospital roommate, an appeals court ruled in December.

Ohio law does not allow discovery of nonparty medical records without the consent of the party regardless of whether personal information in those records has been redacted, a state appeals court ruled Dec. 4 (*Bednarik v. St. Elizabeth Health Center*).

The Ohio Court of Appeals, Seventh District, said discovery of nonparty laboratory results is prohibited by the physician-patient privilege regardless of alleged need and regardless of whether all personally identifiable information has been redacted. An exception to the privilege would have to be enacted by the Ohio Legislature and it has not done so, the court said. *Continued on page 10*

Bio-Reference Sues Employees Over Company Secrets

Bio-Reference Laboratories Inc. (Elmwood Park, N.J.) has sued two departing employees over company information it says it fears might be used by a competitor.

The company filed suit in U.S. District Court in Newark against Sam Ruta of Yardley, Pa., a departing sales manager, and Matt Carey of Fairfield, Conn., a departing salesman, according to a report on *www.northjersey.com*. Both men were hired in 2003 and recently gave notice.

The suit says Ruta and Carey signed contracts that limit their work competing with Bio-Reference after their departure. Bio-Reference wants the court to order the two men to allow Bio-Reference to remove its business information from their personal computers and BlackBerry phones using a neutral, third-party information technology expert.

Bio-Reference is concerned that Ruta and Carey might have shared, or will share, confidential business information with a competing lab (namely, Orange Regional Pathology in Middletown, N.Y.). Orange recently hired a hematopathologist, Zachary Liu, M.D., from Bio-Reference and is in the process of building a fluorescence in situ hybridization (FISH) laboratory that will compete with Bio-Reference. *Continued on page 2*

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Bio-Reference Sues Employees, *from page 1*

The law firm representing Ruta and Carey, Skoloff & Wolf, says Bio-Reference has no basis for the suit and that the defendants have adhered to their obligations. Steve Kramarsky, Ruta and Carey's attorney, says the two men have offered to return all of Bio-Reference's information from their computers but refused to allow the company to "go on a fishing expedition through their personal computers." He said both men have turned their computers and BlackBerrys over to him and have no access to the information on them.

Anti-Fraud Strike Force Expands; 30 People Charged

Thirty people in three cities were charged Dec. 15 with various fraud charges against the Medicare program, federal officials announced, as they also announced the expansion of a Medicare Strike Force to target fraudulent activity in Brooklyn, N.Y.; Tampa, Fla.; and Baton Rouge, La.

The joint enforcement task force of the Department of Health and Human Services Office of Inspector General (OIG) and the Department of Justice (DOJ) is building on the initial focus in Miami that was launched in March 2007 and then expanded into Los Angeles, Detroit, and Houston, federal officials said.

Five indictments were unsealed Dec. 15 in Miami, Detroit, and Brooklyn, following the arrests of 25 individuals in Miami, four in Detroit, and one in Brooklyn. In addition, Strike Force agents executed four search warrants at businesses and homes in Coconut Creek, Fla., Miami, and Brooklyn.

Beefed-up anti-fraud activities begun during the Bush administration and expanded during the Obama administration "are powerful illustrations of the effectiveness of our interagency Strike Force teams," Inspector General Daniel R. Levinson said. "They demonstrate our commitment to catching criminals who prey on providers and beneficiaries alike."

Since the initial Strike Force operations in Miami and including the current operation, law enforcement agencies have obtained indictments of more than 460 individuals and organizations that have falsely billed the Medicare program for more than $1 billion.

In addition, enforcers said, the Centers for Medicare and Medicaid Services, working with the OIG, is taking steps to increase accountability and decrease the presence of fraudulent providers.

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HHS Secretary Kathleen Sebelius Dec. 15 said expansion of the joint force into three new cities "will allow us to concentrate our agents and resources on the criminal hubs where we know a significant share of fraud occurs."

Those charged in indictments announced Dec. 15 are accused of various Medicare fraud crimes, enforcers announced, including conspiracy to defraud the Medicare program, conspiracy to launder money, money laundering, criminal false claims, making false statements, and receiving kickbacks.

The charging documents alleged the defendants participated in schemes to submit claims to Medicare for products and services that were medically unnecessary and often not even provided. DOJ and OIG said the defendants in Detroit are alleged to have participated in a scheme to pay kickbacks to individuals who were instructed by clinic owners to feign symptoms to justify expensive testing.

In Brooklyn, prosecutors accused two defendants of fraudulently billing Medicare for durable medical equipment. In Miami, individuals, including doctors and nurses, were charged in connection with fraudulent claims to Medicare for home health services.

More information about the task force is available at *www.stopmedicarefraud.gov/*.

Jane Pine Wood, Esq.

Legal and Practice Issues for In-House Histology Labs

This is the first of two articles. The second article, which will appear in the February issue of GCR, *will address other issues key to setting up in-house histology labs, including the Medicare anti-markup rule, payer issues, and professional interpretations.*

In light of the government scrutiny and regulatory initiatives to limit pod laboratories, many referring physician practices, such as urologists and gastroenterologists, are pursuing the establishment of an in-house histology laboratory.

These practices often contract with their local pathology practices for assistance in establishing the laboratory and providing professional interpretation. Pathologists and practices that enter these arrangements must be aware of a number of legal and business considerations, cautions Jane Pine Wood, an attorney with McDonald Hopkins LLC (Dennis, Mass.).

Speaking at Washington G-2 Reports' annual Lab Institute in September, Wood noted that there are significant financial expenditures involved in the establishment and operations of a histology laboratory. For instance, she said, not only must the referring practice make space available for the laboratory, but it also must invest in equipment, personnel, and supplies. The practice must also invest in education and training for laboratory staff.

The practice must also ensure that its histology laboratory is in full compliance with all applicable federal and state license and certification requirements, including but not limited to Clinical Laboratory Improvement Amendments (CLIA) certification and state laboratory licenses. CMS take the position that CLIA certification is not required for technical component histology processing although CLIA certification is required for other types of technical component services, such as cytology and immunohistochemistry services.

Malpractice Liability

Malpractice liability is a significant issue involved in the establishment of a histology laboratory. Because the practice will be the actual provider of the technical component pathology services, it will have full legal liability for the services. In the event of a malpractice action, the referring practice likely will be held to the standard of care of a hospital or pathology laboratory, which is a high standard of care, explained Wood.

Furthermore, the individual physicians in the referring practice who are responsible for the supervision of the pathology services will bear legal liability for their supervisory services. According to Wood, under the new Medicare anti-markup rules, one of the practice physicians likely will be designated as the "supervising" physician (this is different than the CLIA medical director), which could increase the malpractice exposure for this physician.

It is also possible for the referring practice to contract with the pathology practice as an independent contractor to provide the required supervision of the performance of the technical component services.

In a malpractice action, the plaintiff's legal counsel may argue that the applicable liability standard is the quality of supervision provided by a board-certified pathologist and any supervising physician must be prepared to fulfill this standard of care.

The referring practice also should confirm that its malpractice insurance covers not only the provision of pathology services but also the supervision of the laboratory personnel. This could entail additional insurance premiums and an endorsement or supplement to the policy.

Fraud and Abuse Compliance

In order to refer specimens of its Medicare and Medicaid patients to its own anatomic laboratory, the practice must comply fully with the in-office ancillary services exception of the Stark law. An important requirement of this exception is that the revenues from the practice's technical component services cannot be allocated among the referring doctors based upon referral volume.

The applicable Stark law exception requires that the technical component services be provided by or under the supervision of one of the referring practice's physicians, or an independent contractor of the referring practices. In light of both the location and the supervision requirements of the Stark law prohibition, the most reasonable location for the laboratory is in the practice's offices (i.e., where the practice's physicians see patients). If the practice has more than one office location it is acceptable for the laboratory to be housed in one of the office locations.

It is permissible for the referring practice to contract with a pathology practice to provide consulting services with respect to the establishment and management of the ongoing operations of the referring practice's laboratory, provided that (1) the consulting and management arrangements comply with the Stark law exception for personal service contracts or the Stark law exception for fair market value compensation, (2) the arrangements comply with the safe harbor under the Medicare and Medicaid anti-kickback law for personal services contracts, and (3) the referring practice remains responsible for its supervision obligations under the in-office ancillary services exception.

It is also possible for the referring practice to contract with the pathology practice as an independent contractor to provide the required supervision of the performance of the technical component services. Both Stark law exceptions and the anti-kickback safe harbor require that the compensation paid to the pathology practice for the consulting and management services, as well as the supervision services, reflect fair market value, and the compensation cannot vary based upon the value or volume or referrals between the parties.

COMPLIANCE PERSPECTIVES

Electronic Health Record Donations: Best Practices to Minimize Liability

Theresa C. Carnegie and Karen S. Lovitch are health care attorneys with Mintz Levin Cohn Ferris Glovsky and Popeo PC in Washington, D.C.

In 2006, the government made its first real effort to promote the adoption and use of electronic health records (EHR) through the promulgation of rules that allow entities to provide nonmonetary assistance to physicians installing EHR systems without running afoul of the federal physician self-referral law (the Stark law)[1] or the federal health care anti-kickback statute.[2] At the time, the government's stated purpose was to "lower perceived barriers to the adoption of health information technology" by promoting "the adoption of open, interconnected, interoperable electronic record systems."[3]

Today, the push for EHR adoption has taken on greater urgency as part of the wider health reform effort. While there are divergent views on the need for health reform, both sides of the aisle generally agree on the benefits associated with EHR adoption and the potential it holds to reduce medical errors, increase quality of care, improve efficiency, and enhance coordination and information management among providers. Both parties want to reduce the redundancy, errors, and administrative overhead created by paper records, making the national goal of fully interoperable health records by 2014 a real possibility.

The EHR initiative gained additional momentum on Feb. 17, 2009 when President Obama signed into law the $787 billion American Recovery and Reinvestment Act of 2009 (ARRA).[4] The ARRA established $19 billion in incentives for hospitals and physicians to replace manual patient record systems with EHR systems. The government hopes that these incentives, in combination with the existing Stark law exception and anti-kickback statute safe harbor, will contribute to widespread EHR adoption and use.

Notwithstanding the many benefits associated with EHR use, there are a number of legal risks involved in implementing, managing, and maintaining EHR systems. Among other things, providers must ensure the privacy and security of patient information under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[5] This obligation recently became even more complex with the passage of the ARRA, which strengthened HIPAA's privacy and security standards, including the penalties for noncompliance and the requirements associated with breach notifications. This article will focus on the legal risks associated with EHR adoption under the Stark law and anti-kickback statute, offer best practices to avoid liability, and consider the future utility of such provisions in light of the ARRA.

EHR Exception and Safe Harbor

In 2006, the Centers for Medicare and Medicaid Services (CMS) and the Office of Inspector General (OIG) for the Department of Health and Human Services simultaneously published final rules intended to promote physician adoption of EHR technology.[6] Before promulgation of these rules, CMS and OIG viewed a donation

[1] *42 U.S.C. § 1395nn.*
[2] *42 U.S.C. § 1320a-7b(b).*
[3] *Statement of Lewis Morris, chief counsel to the inspector general, U.S. Department of Health and Human Services, testimony before the Subcommittee on Health of the House Committee on Ways and Means, April 6, 2006.*
[4] *Pub. L. No. 111-5.*
[5] *42 U.S.C. § 1320d through d-8.*
[6] *See 42 C.F.R. §§ 411.357(w), 1001.952(y).*

of EHR technology to a potential or actual referral source as a possible inducement prohibited by the anti-kickback statute, and also as a likely violation of the Stark law.[7] However, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)[8] required the creation of exceptions and safe harbors that would allow entities to provide nonmonetary assistance to physicians to encourage the adoption of EHRs, thereby promoting the government's ultimate goal of achieving fully interoperable EHRs for all patients.

Both the EHR safe harbor and the EHR exception expire on Dec. 31, 2013. The OIG and CMS chose this date because it is consistent with the government's goal of full adoption of EHR technology by 2014 and because the agencies expect that the need for donations of EHR technology will diminish over time. Considering that the OIG and CMS declined to limit the value of donated technology and also allowed remuneration to be linked to some degree to volume or value of referrals, the sunset provision offers an additional safeguard against potentially abusive arrangements.

Since promulgation of the EHR safe harbor and exception, neither the OIG nor CMS has provided any significant guidance regarding best practices for EHR donations. In the preamble to the final EHR safe harbor, the OIG expressed concerns about inappropriate cost-shifting, abusive schemes involving free or deeply discounted goods, and abuse of the safe harbor by ancillary providers, but noted throughout that the totality of the safe harbor's conditions, such as the cost-sharing and sunset provisions, should address these issues.[9] The OIG further indicated that the benefit from interoperable EHRs is so significant that safe harbor protection is warranted for a limited period of time despite its concerns regarding abusive arrangements. In light of this lack of guidance, donors and recipients must carefully review their covered arrangements to ensure compliance.

Protected Donors and Recipients

The potential class of donors and recipients for EHR technology is very broad. Under the EHR safe harbor, "any individual or entity that provides covered services and submits claims or requests for payment, either directly or through reassignment, to any federal health care program, and health plans" may qualify as a protected donor or recipient.[10] With this definition, the OIG intended to focus on those individuals and entities that participate directly in the provision of health care to patients and are therefore in the best position to advance the implementation of EHR adoption through participation in interoperable EHR systems.

The OIG chose not to include pharmaceutical, device, and durable medical equipment manufacturers as protected donors. In doing so, the OIG noted its concern that such manufacturers' primary interest in offering technology to potential referral sources would be to market their products.[11] Under the EHR exception, "any entity that furnishes designated health services to any physician" may qualify as a protected donor and "any physician" may qualify as a protected recipient.[12]

When selecting a recipient, the donor cannot consider the volume or value of referrals or other business generated between the parties. Notwithstanding the foregoing, the following six selection criteria are considered proper: (1) the size of the physician's practice, (2) the total number of prescriptions written by the physician, (3) the total number of hours that the physician practices medicine, (4) the physician's overall use of automated technology, (5) the amount of uncompensated care, or (6) whether the recipient is a member of the donor's medical staff.[13] It is therefore permissible for a donor to make a donation to a recipient from whom it receives a significant

[7] *The OIG enforces the anti-kickback statute while CMS is charged with enforcing the Stark law. Although the terms of the EHR safe harbor and the EHR exception are almost identical, the two applicable statutory schemes differ significantly. The anti-kickback statute is a criminal statute that requires proof of criminal intent. In contrast, the Stark law is a civil statute that has no intent requirement.*

[8] *Pub. L. 108-173.*

[9] *See e.g., 71 Fed. Reg. 45,110, 45,129 (Aug. 8, 2006).*

[10] *42 C.F.R. § 1001.952(y)(1)(i).*

[11] *71 Fed. Reg. 45,128.*

[12] *42 C.F.R. § 411.351.*

[13] *Id. §§ 411.357(w)(6), 1001.952(y)(5).*

volume of business. This approach is a deliberate departure from other safe harbors under the anti-kickback statute and Stark law based on the unique public policy considerations surrounding EHR technology.

Neither the OIG nor CMS has provided guidance on the standard for determining whether technology the recipient already possesses is "equivalent" to the proposed donation.

Protected Technology and Services

In practice, the permissible scope of donated EHR technology is often the most difficult piece of the safe harbor and exception for providers to navigate. Any software, information technology and training services that are "necessary and used predominantly to create, maintain, transmit, or receive electronic health records" may qualify for protection.[14] Donated software must be interoperable and must include e-prescribing capability, either as an electronic prescribing component or through the ability to interface with the recipient's existing e-prescribing system.[15]

❖ ***The "Necessary" Requirement.*** The "necessary" requirement of the exception and safe harbor means that the recipient may not already possess equivalent software or services, and the donor may not have any actual knowledge, or act in reckless disregard or deliberate ignorance of, a recipient's possession of EHR technology that is functionally or technically equivalent to that being donated.[16] From the government's perspective, the provision of equivalent items or services poses a heightened risk of abuse because such arrangements potentially confer independent value on the recipient unrelated to the need for electronic health records technology. For this reason, donors should make reasonable inquiries to potential recipients regarding their existing technology systems and document these communications. However, neither the OIG nor CMS has provided guidance on the standard for determining whether technology the recipient already possesses is "equivalent" to the proposed donation. For example, is the equivalence determination based on a comparison of features and functions, the technology platform, or specific system architecture? These questions remain unanswered and often make it difficult for donors to assess whether this requirement is met.

Although the safe harbor and exception do not include a separate requirement addressing divestiture of technology, the government remains concerned about the risk of recipients intentionally divesting themselves of technically or functionally equivalent technology that they already possess, or have previously obtained, in order to shift costs to the donor.[17] The government has indicated that such cost-shifting may occur in connection with ongoing maintenance and help desk support for EHR systems previously purchased by the recipient or the movement of previously purchased technology to other uses and replacement of such technology with equivalent new technology obtained from a donor.[18] As noted below, maintenance services may be included as part of a permissible EHR donation, but a donor may not offer to pay for maintenance services associated with EHR technology previously purchased by the recipient. The necessary requirement does not, however, preclude the donation of upgrades to EHR technology that enhance functionality, including upgrades that make software more user-friendly or current, or items and services that result in standardization of systems among donors and recipients.[19]

❖ ***The "Used Predominantly" Requirement.*** The EHR functions of any donated software must be predominant. In other words, the core functionality of the technology must be the creation, maintenance, transmission, or receipt of individual patients' EHRs. The safe harbor and exception do protect software packages that include other functionality related to the care and treatment of individual patients,

[14] *Id. §§ 411.357(w), 1001.952(y)(5).*
[15] *Id. §§ 411.357(2), 1001.952(y)(2).*
[16] *Id. §§ 411.357(w)(8), 1001.952(y)(7).*
[17] *See 71 Fed. Reg. 45,124.*
[18] *See id.*
[19] *See 71 Fed. Reg. 45,123.*

such as patient administration, scheduling functions, billing, and clinical support that is commonly integrated with EHR software,[20] as long as those features are secondary to the EHR function.

Cost-Sharing Requirement

An arrangement between a donor and a recipient for EHR technology is only protected where the recipient pays for at least 15 percent of the cost of the donated technology,[21] and this cost-sharing requirement also applies to the technology as well as the related services, such as training, help-desk, and maintenance services. In addition, any updates, upgrades, or modifications to the donated technology that are not covered under the initial purchase price are subject to a separate cost-sharing obligation by the recipient if the donor incurs additional costs. This 15 percent cost-sharing must be paid at the time of, or prior to, receipt of the EHR technology. The donor may not finance the recipient's cost-sharing obligation or loan funds to the recipient to pay for the recipient's portion of the donated technology. There is no cap on the amount of protected technology that can be donated.

Documentation Requirement

Each EHR donation arrangement must be set forth in a written agreement between the donor and recipient.[22] The parties must enter into the written agreement prior to the donation, and the agreement must describe all of the donated technology, the donor's costs, and the amount of the recipient's contribution. The parties also should include in the agreement specific representations regarding their compliance with the safe harbor and exception. For example, the agreement should contain representations by the parties that:

- the donor has not restricted the software's interoperability;
- the donation is not a condition of doing business between the parties;
- the donation is not based on the volume or value of referrals between the parties;
- the recipient does not possess equivalent software or services; and
- the recipient has not received any loans from the donor to finance the recipient's cost-sharing obligation.

The parties may also wish to include provisions regarding ownership of the EHR technology and termination of the donation arrangement. In particular, the parties should consider what, if any, effect termination of the donation arrangement may have on the ownership of the EHR technology.

Future of the EHR Safe Harbor and Exception

As discussed above, the ARRA provided for $19 billion in grants to promote the adoption of health information technology. Physicians and hospitals participating in the Medicare and Medicaid programs may qualify for grants to purchase certified EHR technology if they engage in "meaningful use" of EHR. Physicians may receive up to $44,000 over a five-year period beginning in 2011, and hospitals may receive a $2 million base amount, plus additional amounts beginning in 2011. In addition, physicians and hospitals that do not engage in meaningful use of EHR technology will be subject to reimbursement reductions beginning in 2015. Even though CMS has not yet published final regulations implementing this grant program, the OIG already has indicated that it will make scrutiny and enforcement in this area a top priority so providers should proceed with caution.

In light of the incentives available under the ARRA, some trade associations have called for the repeal of the anti-kickback statute safe harbor and Stark law exception for EHR donations.[23] In a letter to the OIG, the American Clinical Laboratory Association (ACLA) noted that the financial incentives available under the ARRA

[20] *See id. at 45,125.*
[21] *42 C.F.R. §§ 411.357(w)(4), 1001.952(y)(11).*
[22] *Id. §§ 411.357(w)(7), 1001.952(y)(6).*
[23] *See Letter from American Clinical Laboratory Association to Daniel R. Levinson, inspector general, Office of Inspector General, Department of Health and Human Services, March 19, 2009. Available at www.clinical-labs.org/documents/ACLAOIG-LetterreEHRSafeHarbor_1.PDF. See also Letter from College of American Pathologists to Daniel R. Levinson, inspector general, Office of Inspector General, Department of Health and Human Services, Feb. 17, 2009. Available at www.cap.org/apps/docs/advocacy/comments/comments_levinson.pdf.*

PROTECTED	NOT PROTECTED
❑ Software with core functionality of creating, maintaining, transmitting, or receiving EHR	❑ Money
❑ Software with other functionality directly related to individual patient care and treatment (e.g., registration, scheduling, billing, clinical support software)	❑ Reimbursement for previously purchased technology
❑ Interface and translation software	❑ Software with core functionality other than EHR (e.g., human resources or payroll software)
❑ Rights, licenses, and intellectual property related to EHR software	❑ Hardware
❑ Information technology services	❑ Hardware support
❑ Connectivity services (including broadband and wireless Internet services)	❑ Technology that is duplicative of technology currently possessed by the recipient
❑ Maintenance services	❑ Items or services used by a recipient primarily to conduct business unrelated to the recipient's clinical practice or clinical operations
❑ Training and support services	❑ The provision of staff to recipients or their offices
❑ Help desk services (and other similar support)	❑ Support and information services unrelated to EHR or patient care (e.g., research or marketing support services)
❑ Clinical support and information services related to patient care (but not separate research or marketing support services)	
❑ Secure messaging (e.g., permitting physicians to communicate with patients through electronic messaging)	
❑ Data migration services (but not through the provision of staff to the recipient)	
❑ Upgrades and enhancements to existing technology to enhance functionality or to make the technology more current or user-friendly	
❑ Items and services needed to standardize systems among donors and recipients (if standardization enhances the EHR functionality)	

"make it possible for any physician or hospital that needs an EHR system to obtain it" and called into question the OIG's "ultimate justification for adopting the EHR safe harbor."[24] In light of the potential windfall available to physicians and hospitals, ACLA recommended either repeal of the safe harbor or the removal of laboratories from the list of permitted donors.

However, the ARRA contains no indication that providers who have already availed themselves of an EHR donation under the Stark law or anti-kickback statute may not also take advantage of the incentives available under the ARRA. In addition, repeal of the safe harbor or exception is unlikely because both already contain safeguards against fraud and abuse, such as the sunset provision, and because the Obama administration is prioritizing adoption of EHR technology.

In light of this fact, donors may wish to reconsider the scope and format of their donations. For example, a donor may require that the recipient apply for ARRA funds and reimburse the donor if it receives such funds. Either way, EHR technology undoubtedly will continue to play a central role in the health care delivery system.

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[24] *Id.*

Ohio Hospital, *from page 1*

The appeals court rejected efforts by plaintiff Carol Bednarik to require St. Elizabeth Health Center to produce lab results of a patient with whom she shared a hospital room and who was allegedly diagnosed with the infectious disease methicillin resistant staph aureus (MRSA). Bednarik, who at the time she shared the room was recovering from back surgery, also contracted the disease and sought to use the documents to show hospital negligence.

A state trial court called for the hospital to release the results with all personal information redacted but the appeals court reversed, citing *Roe v. Planned Parenthood of Southwest Ohio Region*, a July decision in which the Ohio Supreme Court held state law does not create a right to discover confidential medical records of nonparties in a private lawsuit.

The appeals court noted that the trial court hearing Bednarik's claims had relied on *Biddle v. Warren General Hospital*, 715 N.E.2d 518 (Ohio 1999). The trial court, however, issued its decision months before the Roe court ruled that the balancing test it created in Biddle applied only as a defense to claims of unauthorized disclosure of confidential medical information.

The Roe court had also said that whether the public policy issues advanced by the party seeking the records are sufficient to overcome the nonparties' privacy rights is a matter better addressed to the Ohio General Assembly than the judiciary, the appeals court noted.

The appeals court also noted a more recent action by the state supreme court summarily reversing a May 2008 decision by a state appeals court in *Cepeda v. Lutheran Hosp*. The Eighth District Appeals Court in that case ruled that billing records of a doctor accused of performing unnecessary surgeries were discoverable, despite the fact that the documents were covered by the patient-physician privilege and that requiring production of the patient information pursuant to a court order did not violate the Health Insurance Portability and Accountability Act.

"The case before us indisputably revolves around the application of the Biddle exception to discovery," the appeals court said.

"Since Roe has now held that Biddle does not create the right to discover confidential medical records and that such records cannot be disclosed in the absence of legislative enactment, the Supreme Court has precluded appellee from forcing discovery of a non-party patient's privileged medical records (redacted or not). As such, we are forced to reverse the trial court's decision on the basis of Roe," the appeals court concluded.

Kentucky High Court Holds Ohio Peer Review Records Discoverable in Malpractice Action

Kentucky's judge-made rule that otherwise-privileged peer review records are discoverable in medical malpractice actions against health care providers applied in a case alleging that an Ohio laboratory technician misread a test for cervical cancer, Kentucky's highest court held Nov. 25 (*Saleba v. Schrand*).

The Kentucky Supreme Court, in an opinion by Justice Lisabeth Hughes Abramson, affirmed an appeals court ruling that under Kentucky's choice of

law rules, documents that would have been protected by Ohio's peer review privilege were discoverable in a medical malpractice action brought by the estate of a woman who died from cervical cancer after cytotechnologist Karen Saleba read her Pap smear as negative.

The issue arose out of a Pap smear performed on Kentucky resident Norma Luann Soard in her gynecologist's Kentucky office in 2000. The gynecologist sent the specimens to a medical laboratory located in Covington, Ky., which sent the specimens to Good Samaritan Hospital in Cincinnati, where Saleba reviewed them. Five years later, Soard was diagnosed with cervical cancer and died shortly thereafter.

Soard's estate brought a medical malpractice action in Kentucky state court against several defendants, including Good Samaritan and Saleba. During discovery, the estate requested production of all documents related to the slides interpreted by Saleba, all documents regarding Saleba's quality assurance reviews, documents related to Saleba's monthly proficiency tests, and copies of any incident reports regarding Saleba's interpretation of Soard's Pap smear.

Saleba and Good Samaritan objected to these requests, arguing that the requested documents were protected from discovery under Ohio's peer review privilege statute, Ohio Rev. Code §2305.252. Judge James Schrand, of the Kentucky Circuit Court for Boone County, ordered defendants to produce the documents. Schrand held that Kentucky law, which permits discovery of peer review documents in medical malpractice lawsuits against health care providers, applied.

Saleba filed a petition for a writ of prohibition in the Kentucky Court of Appeals in order to prevent the production of these documents. The appeals court denied the writ, and Saleba appealed.

Conflict of Law Rules Clear

The Kentucky high court was presented with the question of whether Ohio or Kentucky law applied to these documents. Under Ohio law, peer review materials are protected from discovery; under Kentucky law, specifically the court's ruling in *Sisters of Charity Health Systems Inc. v. Raikes*, otherwise-privileged peer review materials are discoverable in medical malpractice actions.

Saleba argued that the trial judge failed to follow Kentucky's choice of law rules, which required him to apply the law of the state having the "most significant relationship" to the case. The Kentucky high court found, however, that state courts applied the most significant relationship test only in contract cases. In tort cases, like the present lawsuit, state courts applied the "any significant relationship" test—and this case certainly had a significant relationship with Kentucky, it said.

The court concluded that even if Ohio had the most significant relationship to this case, there was no special reason to ignore Kentucky's policy of permitting discovery of peer review documents in medical malpractice cases. Therefore, it said, the court of appeals correctly denied Saleba's petition for a writ of prohibition.

OIG Has Unbundling in Its Crosshairs

Once again, the U.S. Department of Health and Human Services' Office of the Inspector General (OIG) will be investigating clinical laboratories that may be inappropriately unbundling laboratory tests to maximize Medicare payments, warned Hope Foster, an attorney with Mintz Levin Cohn Ferris Glovsky and Popeo in Washington, D.C., at the 2010 Washington G-2 Reports' Lab Compete meeting.

According to the OIG's 2010 work plan, the agency will determine whether labs have unbundled tests by submitting claims for multiple dates of service or by drawing specimens on sequential days, as well as determine the controls that Medicare carriers have in place to detect and prevent inappropriate payments for laboratory tests.

"The OIG really believes that labs have gotten complacent about bundling, and they are ready to investigate," said Foster.

News-At-A-Glance

HEALTH CARE FRAUD RECOVERIES INCREASE: Of the $2.4 billion in False Claims Act (FCA) settlements and judgments in fiscal year 2009, health care fraud recoveries accounted for two-thirds, or $1.6 billion, Assistant Attorney General Tony West, head of the Department of Justice (DOJ) Civil Division, said Nov. 19. West said the $2.4 billion recovery of civil fraud claims represents the second-largest annual recovery in history and brings total recoveries since 1986 to more than $24 billion. The Department of Health and Human Services recovered almost $16 billion of the $24 billion, DOJ said. DOJ expects to see another record year of recoveries in fiscal 2010.

EXECUTIVE ORDER TARGETS IMPROPER PAYMENTS: The White House Nov. 23 announced an executive order aimed at preventing improper payments by federal departments and agencies, essentially by publicizing the information on the Internet and naming names. Under the executive order signed by President Obama Nov. 20, within 90 days the director of the Office of Management and Budget (OMB) must identify federal programs in which the highest dollar value or majority of governmentwide improper payments occur. The order also requires the secretary of the Treasury, in coordination with the attorney general and director of the OMB, to publish certain information about improper payments under high-priority programs on the Internet and to establish an Internet-based method to collect information from the public regarding suspected incidents of fraud, waste, and abuse within 180 days of the order.

MEDICARE ERROR RATE DOUBLES: The percentage of Medicare fee-for-service payment errors more than doubled in fiscal year 2009 compared with 2008, ending several years of downward trends in error rates, the Centers for Medicare and Medicaid Services (CMS) announced late Nov. 17. CMS explained the sharp increase in the Medicare payment error rate as the result of changes in how the fee-for-service error rate was calculated in 2009, calling the new methodology a "more complete accounting of Medicare's improper payments than in past years." Medicare errantly paid 7.8 percent of fee-for-service claims in 2009, translating into $24.1 billion in inappropriate Medicare payments, CMS said. That compares to a 3.6 percent Medicare fee-for-service error rate in 2008.

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