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Letters to the Editor

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OIG approves cost-sharing arrangement

by Susan A. Marks, Esq., Contributing Editor

The OIG approved a municipal Fire District's proposal for payment of emergency medical services (EMS) because it did not generate prohibited remuneration under the anti-kickback statute. The Fire District is a municipal corporation that has the authority to provide emergency services and is the exclusive provider of these services to its residents. It neither subcontracts for these services nor does it provide routine transportation. It provides EMS 24 hours a day and seven days a week. The funds to provide EMS services comes primarily from real estate taxes. The Fire District adopted an ordinance under which it bills residents or their insurers, including Federal health care program, for EMS. The Fire District accepts the insurance or resident payment as payment in full. Any amount still owing on the service is paid for by revenue from local taxes and the residents have no out-of-pocket costs. The Fire District treats employees of local businesses as "residents" while they are working at the premises of the business. The Fire District delayed implementation of new ordinance until receipt of the OIG's advisory opinion.

Insurance only billing. The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive remuneration to induce or reward referrals of items of services reimbursable by a federal health care program, Soc. Sec. Act. § 1128(B)(b). Remuneration, under the statute, means anything of value and covers any arrangement where a single purpose of the remuneration was to obtain money for the referral of services or to induce further referrals, U.S. v. Kats, 871 F2d. 105 (9th Cir. 1989). Many times "insurance only" billing violates the statue to the extent that it constitutes a waiver of Medicare or other federal health care program cost-sharing amounts. Providers who routinely waive Medicare cost-sharing amounts for reasons unrelated to individualized, good faith assessments of financial hardship may be held liable under the anti-kickback statute. See, Special Fraud Alert, 59 Fed. Reg. 65374 (Dec. 19, 1994).

Special rule. In its analysis the OIG recognized a special rule for providers and suppliers who are owned and operated by a state or municipality. The rule, found at Ch. 16, section 50.3 of the Medicare Benefit and Policy Manual, states that a state or local government facility which reduces or waives its charges for a patient unable to pay, or charges patients only to the extent of their Medicare and other health insurance coverage, is not viewed as furnishing free services. The CMS has interpreted facility to apply to a state or municipal ambulance company that is a Medicare part B supplier. CMS also confirmed that this provision applies

to waivers of cost-sharing amounts for employees of taxpaying businesses who need EMS while working.

Narrow exception. The OIG made clear that the rule applies only to situations where the governmental unit is the ambulance supplier. It does not apply to contracts with outside ambulance companies.Where a municipality contracts for ambulance services from an outside vendor, the municipality cannot require the ambulance vendor to waive out-of-pocket cost-sharing amounts unless the municipality pays the cost-sharing amounts owed or otherwise makes provision for the payment of such cost-sharing amounts. See, OIG Advisory Opinion No. 01-12 (July 20, 2001), ¶500,064. Lump sum or periodic payments by the municipality on behalf of residents is permitted as long as the payments are reasonably calculated to cover the uncollected cost-sharing amounts. There is an important distinction between a municipally-owned ambulance company voluntarily waiving cost-sharing amounts for its own residents and a municipality requiring a private EMS business to bill "insurance only"as a condition of getting the municipality's EMS business, including Medicare business. ■

OIG Advisory Opinion 04-13, October 5, 2004, ¶500,116

Doctor, pharmacists charged in $30 million prescription fraud scheme

by Sharon Sofinski, Contributing Editor

The U.S. Attorney's Office for the Southern District of Texas announced a 127-count indictment charging nine people, including six pharmacists and a physician, with conspiracy and money laundering from the illegal distribution of prescription drugs. Two of the defendants face charges of conspiracy, health care fraud and money laundering in connection with an alleged scheme to defraud Medicare of $30 million.

Illegal prescriptions. According to the indictment, Dr. Callie Hall Herpin, MD, sold prescriptions for hydrocodone and promethazine with codeine for cash to people who had no medical need for the drugs. The doctor also allegedly wrote prescriptions for people who never visited her office.

Two of the other defendants charged in the scheme created a list of names from the telephone directory, and Dr. Herpin allegedly used that list to write the prescriptions. The phony prescriptions were filled by the pharmacists charged in the indictment. Each pharmacist is charged with filling hundreds of illegal prescriptions from Dr. Herpin.

Health care fraud scheme. According to the indictment, Dr. Herpin and her office manager also participated in a scheme authorizing motorized wheelchairs for Medicare beneficiaries for a $200 fee. Dr. Herpin and her office manager signed paperwork authorizing the wheelchairs for individuals who clearly did not qualify for them. In some cases, the individual never visited Dr. Herpin's office, though files were created to make it look like the individual was indeed there.

The indictment seeks to forfeit $12.9 million of the Medicare fraud scheme proceeds from Dr. Herpin and her office manager, and approximately $3.1 million from other defendants from the proceeds of the illegal drug distribution network.

The Department of Health and Human Services (HHS), Office of Inspector General (OIG); the Drug Enforcement Administration; the FBI; and the IRS Criminal Investigation division all participated in the investigation. Timothy Menke, HHS OIG Special Agent in Charge, stressed that "Prescription drug fraud cannot, and under my watch, will not go unpunished. Such crimes result in personal tragedy for the victims—and perpetrators can face very long jail terms and multi-million dollar penalties."

The defendants face a maximum penalty of 10 years in prison and a $250,000 fine for each of the 19 health care fraud counts, and 5 years in prison and a $250,000 fine for the health care conspiracy and drug conspiracy counts. For money laundering, they face a 10- or 20-year maximum prison sentence and up to a $500,000 fine. The U.S. Attorney's press release on the indictment is at http://www.usdoj.gov/usao/txs/releases/October2004/041001-Herpin.htm. ■

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Conflicting privacy measures create burdens for providers, researchers

by Catherine Hubbard, MA, Contributing Editor

Health care providers are burdened by conflicting rules geared to protect the personal health information (PHI) of people who seek treatment while authorizing repository research. "Providers are struggling with some of the bureaucracy that has been imposed on authorizations surrounding repository research work," according to Kristen Rosati, a partner at Coppersmith Gordon Shermer Owens & Nelson, Phoenix, Arizona.

While the National Institutes on Health (NIH) has concluded that health care providers cannot condition treatment obtained in a clinical trial on the patient authorizing the release of his or her PHI to a repository, the HIPAA Privacy Rule states that a covered entity may condition research related to treatment on an authorization for repository research. "I'm not sure that NIH had clear regulatory support for this conclusion," said Rosati. Unfortunately, she said, NIH didn't explain its conclusion. "They've created a real problem because now you can't combine an authorization for a patient to permit the release of their information or tissue to a repository with the authorization that they sign for participation in a clinical trial where they receive treatment," she said.

Unless NIH changes its guidance, if a provider seeks a research participant's permission to allow the release of PHI to a repository and to use that PHI for a specific research project, then it can't use a single authorization form if the specific research project is a clinical trial where the individual is receiving treatment. The Office of Civil Rights (OCR) has not explained whether the authorization forms have to be separate documents or whether the provider can include separate signature lines on one document. "Arguably you could do it either way until we hear otherwise from the OCR," she said. Regardless of how providers handle the separate authorization, the NIH interpretation unnecessarily increases the complexity of participating in research for the patients, she said.

PHI for future research. Another challenge that arises in repository research, one that creates substantial tension between health care providers and research sponsors who are not covered entities, is access to PHI for future unspecified research projects, said Rosati.

HHS says the privacy standards do not permit an authorization to seek permission to use or disclose PHI for future unspecified research. The authorization rule (Privacy Rule, 45 CFR §164.508) requires an authorization form to include a description of each purpose of the requested restricted use or disclosure, Rosati said. "HHS has interpreted this very narrowly and concluded that a covered entity may not seek authorization for future research unless the specific protocol is described in the authorization form," she said. However, she said, "This interpretation conflicts with the Common Rule and poses a real barrier to access for repositories," noting that the National Committee on Vital Health Statistics has urged HHS to change the interpretation.

In contrast to the Privacy Rule as interpreted by HHS, Rosati said, the Common Rule permits an informed consent document to seek consent to use a research participant's information for future research projects even if those research projects are not specifically identified when the participant's informed consent is sought. As long as the internal review board–approved informed consent document adequately describes the research that will happen at a future date, the consent obtained as part of the original informed consent process is sufficient for the future research, she said. In tissue repositories, for example, the specific research project may not have been known when the tissue was donated, but the informed consent document may have given adequate permission under the common rule for future research by having the participant give permission for research concerning cancer or diabetes or other disease states, she said.

Rosati noted that combining HIPAA authorization with informed

continued on page 7

2005 OIG Work Plan: Integrity in action

by Gené Stephens Connolly, JD

In this article, writer/analyst Gené Stephens Connolly discusses the highlights of the OIG Work Plan for 2005.

While many of the elements of the Office of Inspector General's (OIG) Work Plan are a continuation of the agency's ongoing evaluation and detection efforts to prevent health care fraud and abuse, the 2005 Plan incorporates existing evaluation and assessment processes with the latest Medicare discount drug card legislation under the provisions of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) and highlights future health care fraud prevention initiatives. Of particular interest for compliance professionals, providers, and prescription drug and equipment suppliers is the Plan's emphasis on creating additional anti-kickback safe harbors, the close monitoring of drug market pricing to federal health care beneficiaries, and a renewed commitment to reviewing and implementing the exclusion of several thousand providers from program participation.

Added to the OIG's standard annual evaluations, such as the review of Medicare error payment rates estimates for fee-for-service claims and corporate integrity agreements, are assessments of university hospital adherence to the HIPAA privacy rights of beneficiaries who utilize university hospital services and a determination of the effectiveness of state and Medicare contractor coordination of payments for when beneficiaries are dually eligible for both Medicare and Medicaid. The 2005 Work Plan, which was issued on October 12, 2004, also contains both standard and new programmatic evaluations that health care fiscal intermediaries and carriers will find helpful. Finally, the OIG is in the process of examining both state- and health care-related taxes imposed on various Medicaid providers to determine if the tax levels comply with federal regulations, as well as whether the imposed taxes are being used for the stated purposes.

"Of particular interest for compliance professionals, providers, and prescription drug and equipment suppliers is the Plan's emphasis on creating additional anti-kickback safe harbors ..."

Below is a list of some of the Work Plan highlights:

- **Anti-Kickback Safe Harbors.** In 2005, the OIG will begin publishing regulations for several new safe harbor exemptions from the Anti-Kickback Statute, including safe harbors to the new MMA. OIG will continue to evaluate comments solicited from the public concerning additional safe harbors.
- **Detecting and Investigating Fraud and Abuse in SCHIP.** OIG will continue to determine the extent to which separate state child health insurance programs (SCHIP) are in compliance with federal regulations for detecting and investigating fraud and abuse, as well as state experiences with SCHIP fraud and abuse. The evaluation will only include states' compliance with federal regulations. The study will, however, establish a benchmark for SCHIP fraud and abuse activities for future OIG work in this area.
- **Diagnosis-Related Group Coding.** OIG plans to examine coding payment error rates and incorporate the results of a recent review by quality improvement organizations.
- **Rebates Paid to Hospitals.** OIG will begin visiting several large vendors to determine the amount of rebates paid to hospitals in a given year.
- **Effect of Prospective Payment System on Quality of Home Health Care.** OIG will assess whether any changes have occurred in the number of hospital readmissions or emergency room admissions.
- **Use of Additional Funds Provided to Skilled Nursing Facilities.** In 2003, CMS published a skilled nursing facility (SNF) payment rule that incorporated a cumulative market basket forecast error correction rule. The OIG will review the ways in which the funds for the forecast error correction have been utilized and determine whether the SNFs have used the funds to improve patient care.
- **Monitoring of Market Prices for Part B Drugs.** The OIG will begin monitoring the market prices of Medicare Part B drugs. The MMA mandates that OIG conduct studies, including market surveys, to determine market prices for Part B drugs, which are then compared to drug average sales prices.
- **Beneficiary Understanding of the Drug Discount Card Program.** In light of the MMA's prescription drug discount card program, OIG plans to assess beneficiary understanding of the program and materials that CMS provides. OIG will also determine whether the program materials comply with MMA requirements.

- **Benefit Stabilization Fund under the MMA.** The Benefit Stabilization Fund acts like a savings account for managed care organizations (MCO) by allowing the MCO to withdraw monies from the fund in future years when capitation payments from Medicare fall short of the MCO's estimates costs of serving Medicare enrollees. In 2001, the benefit stabilization fund contained $100 million. The passing of the MMA, however, established a new $10 billion "regional plan stabilization fund" that will be used for either one year national bonus payments or multi-year adjustments.
- **Accuracy of the Fraud Investigation Database.** OIG will follow up on specific complaints regarding the Fraud Investigation Database and identify ways to correct any problems identified.
- **Independent Diagnostic Testing Facilities.** OIG will review the medical necessity of service provided by independent diagnostic testing facilities, which were formerly known as independent physiological laboratories. Specifically, the OIG will determine whether: (1) the individual facilities provided services for which they received prior approval; (2) the designated level of physician supervision provided; and (3) non-physician personnel were properly licensed.
- **Smart Card Technology.** OIG will assess the use of "smart card" technology in Medicare demonstration projects and review any risk or program integrity concerns.
- **Graduate Medical Education.** OIG will study the appropriateness of alternative payment methodologies for graduate medical education involving the costs of training residents in non-hospital settings. The study is required under the guidelines of the MMA.
- **Ryan White Grant Programs.** OIG will review the use of Ryan White grant programs as a payer of last resort for HIV and AIDS patients.
- **Privacy of Medical Records.** OIG will conduct an early assessment of colleges' and universities' polices and procedures for protecting the privacy of medical records of person participating in National Institute of Health (NIH) funded clinical trials and other research in response to the provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).
- **Nursing Home Resident and Care Planning.** OIG plans to update its work in this area by examining the compliance issues and methods that state survey agencies use to identify and deal with assessments and care plans that do not address all the needs of residents. OIG also plans to examine the frequency, type and severity of deficiencies related to the care planning of nursing home residents.

"OIG plans to examine coding payment error rates and incorporate the results of a recent review by quality improvement organizations."

- **Provider-based Entities and Long Distance Physician Claims.** Reiterating that beneficiaries may seek progressional services for specialized medical consultations during vacation or leisure travel, the OIG will review claims for face-to-face physician consultations where the practice setting and the beneficiary's location were separated by a significant distance. OIG plans to recommend, if necessary, enhancements to existing program integrity controls in this area. Separately, OIG will consider whether providers designated as "provider based" are in compliance with the requirements for receiving this designation. The provider-based entity study coincides with OIG's prior work in which it found that hospital ownership of physician practices was widespread and that fiscal intermediaries were frequently unaware of whether these hospitals were provider-based or freestanding.
- **Bioterrorist and Terrorist Activities.** In response to the events of September 11, 2001, OIG is working with the Centers for Disease Control and Prevention (CDC), the FBI and the Department of Agriculture to establish a protocol for the investigation of potential criminal violations of statutes governing the registration, storage and transfer of toxins and agents.
- **Other Financial Related and Contractor Items.** At the request of CMS, the OIG has begun to conduct pre-award reviews of the cost proposals for bidders of Medicare contracts. The pre-award review will assist CMS in its selection of Medicare contractors.

Separately, the audited 2005 fiscal year consolidated HHS financial statements are due to the Office of Management and Budget (OMB) by November 15, 2005. During the 2006 fiscal year, a consolidated HHS audit will be performed at all operating divisions, including those that will receive separate audit reports and those that will not. A list of the operating divisions that will and will not receive the audit reports is provided in the Work Plan.

In addition, OIG will initiate audits of certain contracts awarded by public health agencies to review the materiality of the contracts and any significant modifications since the original award. Ongoing audits include the non-federal auditing of state and local governments, colleges and universities, and nonprofit organizations that receive federal awards. Attention will be given to the quality of the audits of these agencies by non-federal auditors to ensure that the work meets applicable standards. Finally, OIG will continue to provide upfront technical assistance to non-federal auditors to ensure their understanding of federal audit requirements.

Gené Stephens Connolly is a writer/analyst in CCH Incorporated's Health Law Group, and is currently working on her LL.M. at DePaul University College of Law.

Lack of funding, interoperability standards are obstacles to e-health records system

by Catherine Hubbard, MA, Contributing Editor

The government and the private sector both want to move toward an electronic health information sharing, but neither has established a funding scheme, set up a workable regulatory structure, created standards of interoperability, or ensured the health information would be protected in complex electronic networks. Even the comprehensive health information privacy and security rules under HIPAA may not be fully effective for a national electronic health information infrastructure.

One of the main concerns about electronic information sharing is the broad array of participants that HIPAA permits--not only covered entities, but non-covered entities regulated by business associate contracts, according to Paul Smith, a partner with Davis Wright Tremaine, San Francisco, who spoke at an October 23 session of the Health Information Technology Summit in Washington, D.C. Covered entities that participate in the system would need a business associate contract with the non-covered entity and would need to adopt reasonable and appropriate measures to safeguard the information. "The responsibility for compliance rests with each of the covered entities," he said.

However, providers, even those with identical types of data and identical security risks, will have different security measures, in part because they have varying amounts of resources to spend on their systems, Smith said. This variance, allowed under the HIPAA Security Rule, could make providers and the public uncomfortable with electronic data exchange, he said.

Smith suggested business associates prescribe security standards for covered entities. "You have to have a top-down approach where the system is to some extent prescribing security standards," he said, adding that there also should be a method of monitoring and enforcing the standards.

Moreover, training will be an important factor in security, Smith said. "You may have the best technical implementation in the world, but if people are not trained to use the system properly, it's not going to be any good." The network, possibly a system similar to Napster, ought to develop an education curriculum and provide materials to help further security compliance, he suggested.

Funding the infrastructure. Obstacles to funding creation of a health information infrastructure have led to slower than predicted adoption of electronic health records, Smith said during a recent interview. "These systems are expensive to implement," he said.

"An added barrier to the implementation of an electronic health records system is the lack of interoperability standards in the public and private sectors."

How the systems are funded is important; legal problems could arise if hospitals, rather than physicians, pay for setting up the infrastructure. By funding the infrastructure, hospitals could be conferring a potential economic benefit to the physicians, giving rise to anti-kickback and Stark issues, Smith cautioned. "If the physicians don't pay for it themselves, then somebody else is paying for it and that creates potentially financial relationships of the kind that health care attorneys are worried about," he cautioned.

Federal law and the law in most states have prohibitions against referrals among providers that have tainted financial relationships, prohibitions that include federal and state anti-kickback statutes, the federal Stark Law and state equivalents and the federal False Claims Act. "These are notoriously difficult laws," Smith said.

Under Stark, if a physician has a financial relationship with a hospital, unless it falls within an exception, then the physician cannot refer Medicare patients to the hospital, Smith explained. The recent Stark II regulations provide a new exception for information technology for providers who participate in a communitywide network if the technology is needed by the physician to participate, is used principally for participation in the network, is available to all willing providers and residents without regard to referrals. and if it is not intended to induce referrals.

But this exception will be hard to implement, Smith predicted. "It's a difficult exception to comply with," he said. In addition, he said, "Simply having an exception under Stark doesn't take care of other regulatory issues under the anti-kickback statutes," adding that an anti-kickback safe harbor may be needed as well.

"There's a broad array of regulatory barriers that still need to be addressed," Smith said. "The regulatory issues are being tackled on a piecemeal basis, but a great deal more needs to be done to sweep away the regulatory underbrush, particularly so that these health information infrastructures can be funded by people other than physicians," he said.

Interoperability. An added barrier to the implementation of an electronic health records system is the lack of interoperability standards in the public and private sectors. While HIPAA mandates standards for sharing of PHI, it does not mandate interoperability standards, nor does it mandate standards for health information exchange outside of a few financial transactions, Smith said.

The system would not function properly without standards for interoperability, Smith said. "The only way you can share health information is to have standards both for the content of health records and for the way in which information is exchanged among

health records," he said. "There's got to be tight interoperability, if this is going to work."

Lacking standards for interoperability, the private sector needs to avoid designing multiple systems that do not mesh. "Making them interface will require time and skill," Smith said. "There's such a huge array of different products that the task of pulling them together into a set of standards that will actually allow communications is daunting," he said.

Nevertheless, moving toward an electronic system would provide many benefits to the health care community, Smith said. "The great advantage of working off of a computer, rather than paper is the ability to share information among providers so that they have access to the full set of information," he said. Such a system, many providers, patients and administration officials argue, would improve health care quality, improve the public health infrastructure and bolster national security and research. ■

CCH Washington Bureau, October 26, 2004

$139M granted for health info technology

by Suzanne Szymonik, JD

Approximately $139 million in grants and contracts to promote the use of health information technology was awarded recently by HHS' Agency for Healthcare Research and Quality to states, communities, and a national research center. The recipients must use the money to build health information technologies that improve patient safety by: reducing medication errors; increasing shared health information between providers, laboratories, pharmacies and patients; helping to insure safer patient transitions between hospitals, doctors' offices, and nursing homes; and reducing duplicative and unnecessary testing.

"The only way you can share health information is to have standards both for the content of health records and for the way in which information is exchanged among health records."

The $139 million will be used for: (1) grants spread across 38 states, focusing on small hospitals, rural hospitals, and rural communities, with first year funding of $41 million and total funding of $96 million over three years; (2) five-year contracts of $1 million each, totaling $25 million over the course of the contracts, to Colorado, Indiana, Rhode Island, Tennessee and Utah, to help these states develop statewide networks that are secure, ensure privacy of health information, and make individuals' health information more available to health care providers; and (3) the creation of the National Health Information Technology Resource Center at NORC, a national organization for research at the University of Chicago, to aid grantees by providing technical assistance, through a two-year contract, renewable for up to three years, with first year funding of $4 million and $18.5 million over the course of the contract. ■

CCH Chicago Bureau, October 13, 2004

consent that seeks consent to use the participant's information in the future is not permitted. Providers must have separate documents or at least separate signature lines.

Moreover, this conflict between the HIPAA Privacy Rule and the Common Rule about whether a provider can get patient permission for future research creates tension between providers and research sponsors when they're negotiating the terms of an informed consent document, Rosati concluded. The research sponsor, a holder of the repository that generally is not a covered entity, is bound only by the terms of the informed consent document, she noted.

Tug of war. Finding a balance between research and privacy has been challenging, Rosati said. Sponsors generally want an informed consent document that's as broad as possible regarding their ability to access their repository for future research purposes, while providers have an investment in making sure the HIPAA authorization is valid so they don't commit a HIPAA violation in disclosing the patient's PHI. "This tug of war

Antitrust

Physicians entitled to class certification against HMOs

by Sonali Kolhatkar, Contributing Editor

Health care providers were entitled to class certification in their Racketeer Influenced and Corrupt Organizations Act (RICO) action against health maintenance organizations (HMOs) that allegedly made material misrepresentations regarding insurance coverage because the organizations met throughout the country via trade associations and joint health plan providers organizations to discuss and develop common plans regarding the processing of providers' claims, the U.S. Court of Appeals in Atlanta has held, affirming the district court's decision.

The health care providers contended that the HMOs conspired to program their computer systems to systematically underpay physicians for their services. The class included physicians who were reimbursed by one or more of the HMOs for treating patients covered by the HMOs. The HMOs' reimbursement system allegedly was based not on medical necessity but on covertly denying payments to physicians using financially expedient cost and actuarial criteria, on processing physicians' bills using automated programs that manipulated the standard coding practices to artificially reduce the amount they were paid, and on systematically delaying payments to gain increased use of the physicians' funds.

Because the providers used uniform documents and programs to create reimbursement schedules in submitting claims, a common scheme to misrepresent health care coverage existed. Common issues--medical necessity requirements, actuarial guidelines, automated claim systems, and reimbursements systems--of the proposed class also would predominate over individual issues. In addition, the providers demonstrated that their claims, even if factually different, arose out of the same legal theories, in the court's opinion. (*Klay*, 11th Cir.) ■

CCH Chicago Bureau, October 13, 2004

HIPAA (cont.)

regarding the scope of the informed consent and the HIPAA authorization has sometimes been quite difficult to resolve," she said.

Unless HHS changes its interpretation that a HIPAA authorization can seek permission for future unspecified research consistent with the Common Rule, Rosati said, "There's always going to be this tug of war between health care providers that have to comply with HIPAA and research sponsors and the holders of repositories that don't have to comply with HIPAA."

One way to resolve this conflict is to separate the informed consent document and the HIPAA authorization form, Rosati said. "Generally, you can combine a HIPAA authorization and informed consent document for research purposes as long as the internal review board (IRB) approves the HIPAA authorization," she said. She noted that the existence of a separate HIPAA authorization limited to a specific research protocol seems to meet the technical requirements of the HIPAA rules, adding that the HIPAA authorization itself would not be seeking authorization to use or disclose the PHI for future unspecified research projects. "HHS seems to have approved this approach," she said.

Yet combining an informed consent document and a HIPAA authorization into one document could confuse research participants, Rosati cautioned. "It increases the likelihood that this information will be viewed by the participant as inconsistent." She advised, "The IRB may have a duty to make sure the research information given to the research participants is consistent and understandable." ■

CCH Washington Bureau, October 22, 2004