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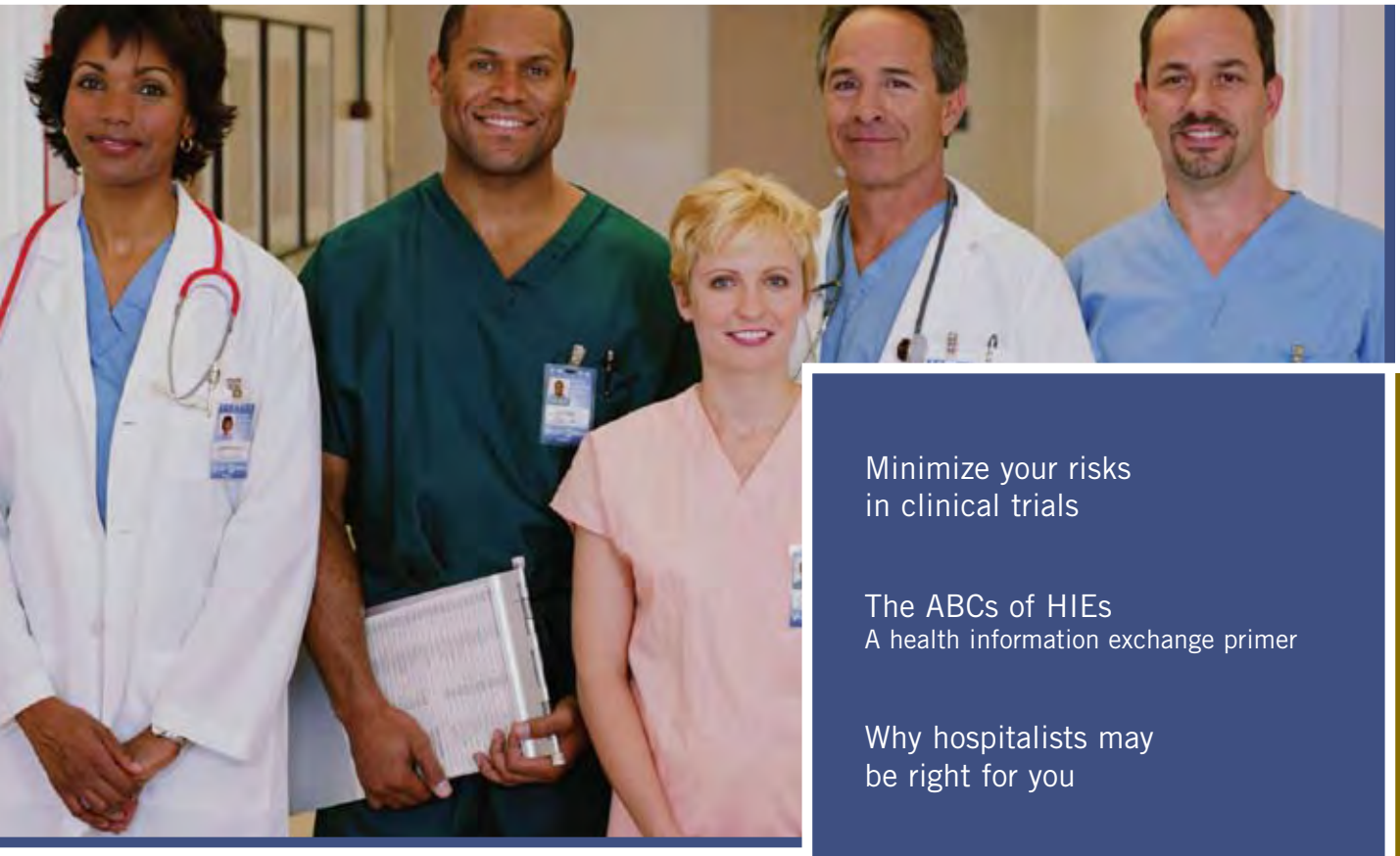

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without implicating EMTALA

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Minimize your risks in clinical trials

If you're one of the many physicians or hospitals that participate in clinical research trials, you're aware that the federal government monitors these trials for various legal violations. Of these violations, allegations under the civil False Claims Act (FCA) carry the most risk for hospitals and physicians, because they can result in large fines and possible exclusion from Medicare participation. What are some of the ways physicians and hospitals can get into trouble under the FCA, and how can they minimize their risks? Let's take a look.

FCA BASICS

A person violates the FCA if he or she knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval, or uses a false record or statement to get a false or fraudulent claim paid or approved by the federal government. Because it's a civil — not criminal — statute, the government doesn't have to prove that the violator *intended* to defraud the government. But, it does have to prove that the person had actual knowledge of the information, deliberately remained ignorant about the truth or falsity of the information, or acted in reckless disregard of the truth or falsity of the information.

The government can impose financial sanctions of up to $11,000 per claim and treble damages. In addition, providers may be excluded from Medicare, Medicaid, the National Institutes of Health (NIH) and any other federal program that makes health care related grants. Because the potential outcomes are so drastic, those who find themselves the subject of an investigation often enter into settlement agreements with the government. These settlements can be in the millions of dollars.

INCREASED OVERSIGHT OF CLINICAL TRIALS

Hospitals and physicians conducting clinical trials will begin to face increased scrutiny by federal agencies, in part because agencies such as the FDA are under attack from consumer groups and government agencies for failing to monitor clinical trials adequately, resulting in patient injuries and deaths. The Office of Inspector General 2009 Work Plan includes reviewing financial conflicts of interest in NIH-funded research, colleges' and universities' compliance with cost principles, and the use of data and safety monitoring boards in clinical trials.

Those conducting clinical trials also face potential allegations of FCA violations from whistleblowers. The FCA rewards whistleblowers for bringing cases on behalf of the federal government. If the government decides to enter the case, the person who brought the claim can receive between 15% and 25% of any resulting judgment or settlement.

AREAS OF RISK

Hospitals and physicians participating in clinical trials must comply with federal guidelines and carefully document how they use federal grant funds. If you fail to adequately document how you use these

funds, it can result in an FCA violation. (See "Beware of what you do with federal grant funds!" at right for examples.) For example, the government may consider misstatements on grant applications an FCA violation.

FCA violations can also result from mistakes in submitting Medicare claims for payment of certain clinical trial-related expenses. Medicare pays for routine costs of qualified clinical trials, including items and services generally covered by Medicare Parts A and B, and not excluded by statute or under a national coverage decision. Routine costs don't include items and services provided to collect and analyze data and not used in the clinical management of subjects, or items and services provided by the research sponsors for free.

In addition, CMS has special rules for "coverage with evidence," in which it pays for items or services used in clinical trials that look promising, but don't meet CMS' threshhold standard of "reasonable and necessary." CMS can ask the researcher to collect additional data, which it will use in its final coverage determination. To avoid FCA violation allegations, make sure you comply with all CMS conditions.

Beware of what you do with federal grant funds!

Several recent cases of universities and their researchers involved in False Claims Act (FCA) inquiries represent the seriousness of possible violations.

In *U.S. ex rel. Long v. Mayo Foundation* (2005), the complaint alleged that the Mayo Foundation had fraudulently mismanaged research funds from the NIH. The complaint alleged that Mayo had participated in spending down grant accounts at the end of a year to avoid returning used funds to NIH; shifting costs from one grant to another without adequate documentation; and retroactively altering effort reports to coincide with the cost shifts. They entered into a $6.5 million settlement with the federal government.

Yale University settled FCA and other claims for $7.6 million in December 2008. The complaint alleged that Yale researchers had transferred funds to inappropriate accounts rather than returning the funds to the government. Researchers were also accused of charging 100% of their time and effort on the grant when they were actually working on other projects.

As you can see, misrepresentations of time spent working on a grant and "creative" efforts to reassign grant funds without sufficient authority and supporting documentation are actions that the government won't tolerate.

BEST PRACTICES TO MINIMIZE FCA RISKS

It's critical that you take potential FCA violations seriously, especially with the government's stepped-up oversight. Some actions that can minimize risk include:

- Reviewing and updating your clinical trial policies and procedures,
- Putting mechanisms in place to make sure researchers actually spend the time on the grant that they represented on the grant application and subsequent reports,
- Maintaining accurate and complete records regarding transfer of government funds between grant accounts,
- Reviewing clinical trial protocols to determine which services you can and can't bill, and
- Tracking items and services provided by sponsors of clinical trials as accurately as possible.

To make sure you're complying with Medicare billing requirements, review the Medicare Claims Processing Manual and the National Coverage Determinations Manual. You can find these on the Internet at www.cms.hhs.gov/Manuals/IOM/list.asp.

STAY OUT OF TROUBLE

Losing your ability to participate in Medicare because of a mistake in a clinical trial is a high cost to bear. By following the above steps, you stand a better chance of avoiding FCA violations and will have the proper documentation to defend against any possible allegations.

The ABCs of HIEs

A health information exchange primer

The American Recovery and Reinvestment Act of 2009 (ARRA) provided substantial funding for health information exchanges (HIEs), which will play a large role in the federal push to develop a nationwide health information network. HIEs are organizations that support the exchange of electronic health information (EHI) among diverse stakeholders such as hospitals, providers, laboratories, pharmacies and insurers.

UNDERSTANDING HIEs

The purpose of HIEs is to coordinate patient health care by making data available to professionals involved in a patient's care in different locations. By doing that, providers can avoid duplicating tests, obtain a more complete medical history and have access to a patient's current prescriptions to avoid potential drug interactions.

With greater access to relevant clinical data, HIEs can improve health care quality and potentially lower costs of care. The goal is to extend the use of HIEs beyond clinical applications to include improvements in public health and health care research.

Of course, patients are often concerned about how their health information may be used and the measures taken to ensure privacy of this information. Some patients may worry that you or other organizations may use their health care information in discriminatory or inappropriate ways, such as by employers in their hiring and promotion decisions, and by insurers denying health care, disability or life insurance coverage and benefits.

To alleviate such concerns, make sure you build in necessary safeguards in your electronic health data management system, and reassure your patients about their EHI's security.

PARTICIPATING IN HIEs

Hospitals and physician practices will have little choice but to participate in these exchanges. So what should you do when deciding how to participate in an HIE?

Familiarize yourself with the Department of Health and Human Services' (HHS's) framework for the electronic exchange of individually identifiable health information (IIHI). Although these principles are meant to be dynamic and open to revision, they reveal a common vision that will direct future efforts. These principles are:

Individual access. Give individuals simple and timely means to access their IIHI.

Correction. Provide individuals a way to dispute the accuracy of their IIHI, and have it corrected or a dispute documented.

Openness and transparency. Implement open and transparent policies, procedures and technologies for activities that directly affect an individual's IIHI.

Individual choice. Give individuals a reasonable opportunity to make informed decisions about the collection, use and disclosure of their IIHI.

Collection, use and disclosure limitation. Collect, use and disclose IIHI only to the extent necessary to accomplish a specified, nondiscriminatory purpose.

Data quality and integrity. Take reasonable steps to ensure that IIHI is complete and accurate, and that it hasn't been altered or destroyed in an unauthorized manner.

Safeguards. Protect IIHI with reasonable administrative, technical and physical safeguards to ensure its confidentiality, integrity and availability, and to prevent unauthorized access, use or disclosure.

Accountability. Monitor adherence to these principles and report nonadherence and breaches.

Also, require that other entities involved in your HIE use "fair information practices." These practices include:

Openness. Give consumers and other organizations notice of your entity's information practices before you collect any personal information from them.

Disclosure. For all entities involved in the HIE, give consumers options as to how their IIHI may be used.

Secondary use. Provide a way for individuals to prevent information obtained for one purpose from being used or made available for other purposes without his or her consent.

Correction. Allow individuals to correct or amend his or her personal information.

Security. For all organizations involved in the HIE that maintain, use or disseminate IIHI records, assure the data's reliability for their intended use and take precautions to prevent the data's misuse.

USING HIE INFORMATION

Organizations in an HIE will share information and not all of it will be in an identifiable form. Different processes apply to health information that's "de-identified." If an HIE wants to de-identify information and provide health data to another party for the purposes of research, public health or health care initiatives, it must enter into a data use agreement (DUA) with the other party. These agreements specify allowable use of the data and who's permitted to use or receive it.

> *With greater access to relevant clinical data, HIEs can improve health care quality and potentially lower costs of care.*

DUAs also provide that the recipient of the data won't use the information in ways that are inconsistent with the DUA. The agreement must have safeguards to make sure unauthorized uses don't occur and require that a report be made to the covered entity if uses outside the DUA do occur. Make sure your DUA covers subcontracted parties. They should abide by the same conditions regarding the data, and not identify the information or contact the individuals.

REASSURING YOUR PATIENTS

When exchanging IIHI with other entities, make sure they adhere to the same standards of privacy and security, and follow fair information practices and the principles identified in the HHS framework. Use these principles in your HIE participation agreements, as well as business associate agreements required for all covered entities under HIPAA. Moreover, be aware of uses of de-identified health information — and make sure your patients understand them as well.

Although these uses shouldn't lead to discrimination, transparency is the best way to avoid a loss of trust in the provider, the hospital and the HIE.

Why hospitalists may be right for you

Primary care physicians (PCPs) who maintain busy office-based practices are often unable to see their hospitalized patients during the day. They often try to "squeeze in" a trip to the hospital, which may include significant travel time. Both patients and their PCPs enjoy these visits, but the PCP's cramped schedule can take its toll, both on the physician's energy level and on the activities of giving orders, talking with families and speaking with medical specialists. For some PCPs, hospitalists can provide the answer.

WHAT ARE HOSPITALISTS?

Hospitalists are physicians, or in rare instances advance practice nurses, who provide care to hospital inpatients. According to a 2005–2006 Society of Hospital Medicine (SHM) survey, in the mid-1990s there were approximately 800 practicing hospitalists. By 2007, there were 20,000. Industry analysts expect the number to reach 30,000 by 2010.

Hospitalists provide care at times when it's impossible or inconvenient for patients' own PCPs or surgeons to see them. They can coordinate admissions and discharges, manage consultations with specialists, and order laboratory tests and procedures. Because they're in the hospital around the clock, they're typically available on short notice to meet with patients and family members, and to consult with nurses involved in the patients' care.

SHOULD YOUR HOSPITAL EMPLOY A HOSPITALIST GROUP?

Hospitals employ 54% of all hospitalists. Generally, hospitalists have been shown to reduce average length of stay and are associated with higher hospital survival rates. Hospitals can also rely on hospitalists to help with quality improvement activities, such as reducing postoperative infections. This is increasingly important as both government and private insurers implement initiatives to decrease or

refuse payment where preventable injuries and other hospital-acquired conditions occur in the hospital.

Hospitalists can help save hospitals money by reducing costs and increasing the amount of reimbursable care provided. For example, to the extent that a hospitalist can improve outcomes and prevent accidents or hospital-acquired conditions, hospitals can often receive pay-for-performance payments or avoid penalties or payment denials.

When devising compensation arrangements with hospitalists, be prepared to employ and pay hospitalists a competitive salary. You may want to offer productivity-based payments. But first work with your health care attorney to draft agreements that can help you avoid inadvertent violations of federal fraud and abuse laws.

SHOULD PHYSICIAN GROUPS USE HOSPITALISTS?

Although some PCPs enjoy maintaining their hospital care skills, others are content to allow other qualified providers to step in who can provide greater availability to patients, family members and other members of the health care team. If your physician group chooses to employ a hospitalist directly or use a hospitalist employed by a hospital, you'll

need to consider any financial and compliance implications.

PCPs who use a hospitalist to care for their hospitalized patients lose a significant stream of income. One way PCPs may try to recoup this loss is by scheduling additional office visits. And remember: You can still visit your patients in the hospital to provide support to patients and their families.

If your physician group decides to employ hospitalists, keep the lines of communication open between your group's PCPs and hospitalists. Failing to communicate complete and accurate information at points of transferring care can result in poor or redundant care — both of which have financial and legal implications.

WHAT ARE YOU WAITING FOR?

Hospitalists provide a good option for improving care and making hospital-based care run smoothly. If you're thinking about entering into an arrangement with hospitalists, talk to an attorney to make sure it doesn't run afoul of fraud and abuse laws. And be sure to have timely and accurate communication between providers.

RESPONDING TO E.D. OVERCROWDING WITHOUT IMPLICATING EMTALA

Numerous hospital emergency departments (EDs) face serious overcrowding issues, often compromising patient care by increasing the amount of time patients wait before seeing a physician or causing physicians to rush through patient visits. But if your ED administrators and physicians reasonably believe it's in the patient's best interest, can they direct an individual to a different ED or urgent care center?

Under the Emergency Medical Treatment and Active Labor Act (EMTALA), EDs must provide a medical screening exam to patients by a qualified medical professional, and stabilize an emergency medical condition before transferring or discharging the patient. EMTALA penalties include civil monetary penalties and can lead to the termination of a hospital's Medicare agreement.

Overcrowding in EDs across the nation has raised questions about when and how hospitals can refer patients to other facilities. If a hospital employee discusses alternative sites of care with an individual in the ED and that person leaves the ED, it may be considered an impermissible transfer under EMTALA.

The OIG and CMS have stated that, even if an individual chooses, without any direction, to leave the ED before receiving a medical screening exam, the hospital should offer to examine and treat the patient and should inform him or her of the benefits of the examination and treatment, as well as the risks of leaving the ED without such an examination. Plus, the hospital should try to get the patient's written informed consent to refuse such examination and treatment.

If a patient leaves the ED without notifying any hospital personnel, hospital staff should document as much about the patient's departure as possible. And the hospital must show that it tried to discourage the individual from leaving. In another twist, CMS has indicated that it might be able to cite hospitals with an EMTALA violation if patients wait so long that they routinely leave without being seen.

If your staff suggests that patients visit alternative sites of care, make sure they communicate that information *before* patients come to the ED. This will help your facility avoid EMTALA violations.

A message to our clients and friends:

Hall Render is pleased to provide you with this issue of ***Practical Health Law***. This newsletter will be sent to you bi-monthly compliments of our health law attorneys; each issue will also be housed in the **Articles and Newsletters** section of **www.HallRender.com**.

We understand the value of good information when making sound business decisions. ***Practical Health Law*** is written by Hall Render's health law attorneys, each with extensive experience handling the legal issues of health care providers. We trust the information in each issue will be a valuable resource. Our attorneys stand ready to respond promptly to your questions and needs; please contact us if there are specific topics you would like to see addressed.

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IN Downtown Office: Suite 2000, Box 82064, One American Square, Indianapolis, IN 46282 Ph: 317-633-4884 Fax: 317-633-4878
IN North Office: Suite 820, 8402 Harcourt Road, Indianapolis, IN 46260 Ph: 317-871-6222 Fax: 317-338-3946
KY Office: 614 West Main Street, Suite 4000, Louisville, KY 40202 Ph: 502-568-1890 Fax: 502-568-4878
MI Okemos Office: 2369 Woodlake Drive, Suite 280, Okemos, MI 48864 Ph: 517-706-0920 Fax: 517-347-7855
MI Troy Office: Columbia Center, Suite 315, 201 W. Big Beaver Road, Troy, MI 48084 Ph: 248-740-7505 Fax: 248-740-7501
WI Office: 111 East Kilbourn Avenue, Suite 1300, Milwaukee, WI 53202 Ph: 414-721-0442 Fax: 414-721-0491