TABLE OF CONTENTS
Between a Rock and a Hard Place: Trying to Balance the Privacy Requirements of HIPAA and FERPA
Catherine Greaves, Esquire

Letter from the Chair
Melissa Markey, Esquire

Guidance from the Garden State: What Legal Counsel Should Learn from University of Medicine and Dentistry of New Jersey
Lisa Taylor, Esquire

FDA Clarifies Emergency Research and the Exception to Informed Consent
Thomas Shrack, Esquire

Accepting the Inevitable: Trends, Expected Outcomes, and What to Look for as Electronic Health Records
Implementation Goes Forward
Rupasri Lloyd, Esquire

Teaching Hospital Updates

Continued on page 2

Between a Rock and a Hard Place:
Trying to Balance the Privacy Requirements of HIPAA and FERPA
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For healthcare providers, trying to comply with the multiple privacy requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as well as multiple state confidentiality laws and regulations, is difficult enough. However, for academic medical centers and other educational institutions, this task is made even more complicated by the requirements of the Family Educational Rights and Privacy Act of 1974 (FERPA). FERPA provides privacy protection for an individual’s educational records, including some medical records, held by an educational institution that receives specified federal funding. However, the application of FERPA to treatment records has created an artificial distinction between the medical records of students and those of other patients. Further, the privacy protections offered by FERPA are not identical to those under HIPAA. Thus, many academic medical centers are in the unenviable position of having to craft and comply with confidentiality policies based on a convoluted combination of federal and state laws and regulations.

FERPA was adopted to protect the privacy interests of students and parents in educational records, and it prevents an institution from having a policy or practice of disclosing the records, or any personally identifiable information contained in the records, without appropriate consent or authorization. The term “educational records” is defined to mean all records, files, documents, and other materials that contain information directly related to a student and are maintained by an educational agency or institution or by a person acting for such agency or institution. There are several important exceptions to FERPA’s definition of an educational record, including an exception relating to treatment records. Specifically, FERPA excludes:

Records of a student who is eighteen years of age or older, or is attending an institution of postsecondary education, which are made or maintained by a physician, psychiatrist, psychologist, or other recognized professional or paraprofessional acting in his professional or paraprofessional capacity, or assisting in that capacity, and which are made, maintained, or used only in connection with the provision of treatment to the student, and are not available to anyone other than persons providing such treatment, except that such records can be personally reviewed by a physician, or other appropriate professional of the student’s choice.

At first blush, this exception appears to exclude many treatment records from the requirements of FERPA. However, upon closer review it is clear that this is not the case. The release of information to an insurance company, state health department, Medicaid agency, or even the student receiving the treatment will disqualify a record from the exception and result in the application of FERPA requirements to that record. This has the rather odd outcome of providing differing privacy protections based solely on the location of treatment rather than more logical factors such as the privacy needs of a class of patients or the sensitivity of a particular diagnosis. Thus, if a student receives medical treatment at a university health center, his records are governed by HIPAA, but if that same student receives the same care at a private physician’s office, the medical records are governed by HIPAA.

While the confidentiality provisions of both FERPA and HIPAA are triggered by the provider of services, the commonalities of the two laws end there; FERPA deals with student medical records in an educational setting, while HIPAA protects the medical records of everyone else if they are for...
services provided, utilized, or maintained by a healthcare provider (physician, hospital, etc.) or other specified entities. HIPAA confidentiality provisions apply only to protected health information or PHI, which is defined as individually identifiable health information transmitted by electronic means, maintained in electronic media, or transmitted or maintained in any form or medium. While similar, the confidentiality requirements provided by FERPA are not aligned with the confidentiality provisions of HIPAA even though treatment may be provided by the same types of entities (i.e., health centers) and individuals (i.e., physicians) that under any other circumstance would be governed by HIPAA, and therein lies the problem. In drafting the final privacy regulations, the Department of Health and Human Services (DHHS) recognized the potential confusion that could arise between HIPAA and FERPA. In its preamble to these regulations, DHHS states:

While we strongly believe every individual should have the same level of privacy protection for his/her individually identifiable health information, Congress did not provide us with authority to disturb the scheme it had devised for records maintained by educational institutions and agencies under FERPA. We do not believe Congress intended to amend or preempt FERPA when it enacted HIPAA.

The preamble continued and attempted to provide further clarification on the relationship between the two statutes:

With regard to the records described at 20 U.S.C. § 1232g(a)(4)(B)(iv), we considered requiring healthcare providers engaged in HIPAA transactions to comply with the privacy regulation up to the point these records were used or disclosed for purposes other than treatment. At that point, the records would be converted from protected health information into education records. This conversion would occur any time a student sought to exercise his/her access rights. The provider, then, would need to treat the record in accordance with FERPA’s requirements and be relieved from its obligations under the privacy regulation. We chose not to adopt this approach because it would be unduly burdensome to require providers to comply with two different, yet similar, sets of regulations and inconsistent with the policy in FERPA that these records be exempt from regulation to the extent the records were used only to treat the student.

Thus, in the final HIPAA privacy regulations the definition of PHI excludes both individually identifiable information in education records covered by FERPA and records described at 20 U.S.C. § 1232g(a)(4)(B)(iv), the FERPA exception related to student medical records maintained by academic institutions. However, the question must be raised as to whether it truly the intent of DHHS that student medical records be covered by FERPA even when their disclosure is allowed without consent under exceptions not contained within HIPAA. For example, student education records may be released to school officials, including teachers, within the agency or institution whom the agency or institution has determined have a legitimate educational interest. Yet there is no regulatory definition of a “legitimate educational interest” and such determinations are left to the discretion of the institution. Additionally, the agency or institution is not required to maintain documentation regarding release of records under these circumstances. Further guidance on this issue is likely to come only if there is a complaint made or enough interest is generated by students or institutions. Until that time, academic medical centers should ensure that their policies and procedures address student medical records define and apply the term “legitimate educational interest” narrowly enough to protect sensitive medical information contained within student treatment records.

Not all academic medical centers will be subject to HIPAA privacy regulations because not all will conduct the types of electronic transactions that potentially subject them to HIPAA. However, many will, and because of the complicated interplay of the multiple statutes and regulations governing patient privacy, academic medical centers have been forced to stitch together confidentiality policies based on a convoluted combination of federal and state requirements. For student records accessed only by specified healthcare providers, state law confidentiality requirements will prevail. If those same records are released for other reasons, FERPA will govern the disclosure. The records of non-students, such as faculty members, employees, and visitors, will be governed by HIPAA if these records contain PHI or state law if the particular institution does not engage in any of the activities that subject those records to HIPAA. This dysfunctional overlap of regulatory schemes, based on distinctions unrelated to the actual privacy needs of the individuals involved, has created an overly cumbersome system for medical record privacy. Unfortunately, there is no easy fix for this situation, and while not the easiest, the most effective solution may be to change the definitions contained in both the HIPAA privacy regulations and the FERPA regulations to bring them into alignment. Including medical records maintained by institutions of higher education within the definition of PHI and expanding the exclusion of education records under FERPA to include medical records released outside of the provider/patient relationship will place all student medical records under the protections of HIPAA. This will grant students the same privacy protections afforded other healthcare patients and ease the regulatory burdens currently imposed on educational institutions.

Endnotes

2 20 U.S.C. § 1232g.
3 20 U.S.C. § 1232g(b).
Dear Teaching Hospital and Academic Medical Centers (TH/AMC) Practice Group (PG) Members:

I am pleased to write my first Letter From the Chair. I would like to first thank our immediate past Chair, Lisa Vandecaveye, for her great leadership and dedication. All of you who know Lisa will not be at all surprised to hear that she remains a fantastic supporter and inspiration. I would also like to thank my Vice Chairs who, as any chair knows, are really the most important members of the team. Not only do Holley Thames Lutz, Andy Lemons, Veronica Marsich, and Neil O‘Flaherty have great ideas, they are wonderful to work with. Please feel free to let any of us know how we can best serve you.

TH/AMC PG has several projects in the works. First, we are going to have some great teleconferences in the coming year; stay tuned for more details. Teaching Hospital Update continues as an almost-weekly recap of some of the most noteworthy (to the editors’ minds, at least) events impacting teaching hospitals, and the listserve provides a valuable resource for PG members. We are planning other initiatives as well. TH/AMC PG is pleased to establish an affinity group for clinical research issues, and we are very pleased to welcome Rachel Nosowsky to that leadership role. TH/AMC PG is also working with several other practice groups to develop an emergency preparedness toolkit. We invite you to please share your policies, contracts, or other tools regarding emergency preparedness. If you would like to become more involved in the practice group, please let us know. Your energy and ideas are always valued and welcome!

I would also like to remind you of the upcoming TH/AMC PG Luncheon at the Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions, which will be held January 25-26, 2007, at the Ritz-Carlton Hotel in Washington, D.C. It promises to be a great program! The luncheon is on Thursday, January 26, and will feature a collegial debate regarding whether patents on genetic sequences and medical methods should be granted. It has been said that patents may be issued on “everything under the sun that is made by man.” Controversy exists regarding the proper scope of patent protection for biological and genetic discoveries. Are science and medicine advanced or limited by grants of patents such as these? We are pleased to have Lin Sun-Hoffman, PhD, JD, of the Applied Biosystems and Celera Genomics Group, and Maximilian Grant, a partner at Latham & Watkins LLP, join us to present a vigorous discussion regarding the issues surrounding biological and genetics patents and the impact of the answers on U.S. health and public policy, moderated by Mike Dansky, a Managing Director in Huron Consulting Group’s Financial and Economic Consulting practice with many years of experience in the area of intellectual property issues.

Finally, I would like to thank each of you for your membership with TH/AMC PG. It is truly in our members that the value lies. The leaders of TH/AMC PG extend to each of you our best wishes for you and your families.

7 45 C.F.R. § 160.103.
9 Id.
10 45 C.F.R. § 160.103.
11 34 C.F.R. § 99.31(a)(1).
12 34 C.F.R. § 99.32(d)(2).
Guidance from the Garden State: What Legal Counsel Should Learn from the University of Medicine and Dentistry of New Jersey

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In late December 2005, Christopher J. Christie, the U.S. Attorney for the District of New Jersey, appeared unannounced and uninvited, at a meeting of the Board of Trustees of the University of Medicine and Dentistry of New Jersey (UMDNJ) and issued an ultimatum—UMDNJ would agree to oversight by a federal monitor and enter into an agreement consenting to deferred prosecution in the event of non-compliance with a series of corrective directives. The alternative was criminal prosecution of the state-owned and operated university for Medicaid fraud, which aside from the risks and consequences associated with any criminal prosecution, would mean suspension from the Medicare and Medicaid programs.

For any institution, criminal prosecution would be catastrophic, but for UMDNJ, it would be fatal—the majority of the $1.6 billion annual budget of the health sciences university’s budget comes from government sources. The university’s 15,000 faculty and staff members would become unemployed. The university’s eight schools, including three medical schools and a dental school, would close, leaving the training of 10,000 students and faculty members’ research in limbo. The university’s hospital, trauma center, and outpatient clinics would close, leaving some of New Jersey’s most vulnerable residents, many of them living in or around the urban areas of Newark and Camden, without access to healthcare. Indeed, UMDNJ’s role as a healthcare provider in the Garden State is so significant that it represents 2.2 million patient visits per year.

UMDNJ’s Board unanimously accepted the U.S. Attorney’s proposal. If the conditions of the arrangement, as memorialized in a Deferred Prosecution Agreement (DPA) between UMDNJ and the U.S. Attorney’s Office, were met, as determined by the U.S. Attorney over a period of two to three years, the university would avoid criminal prosecution. However, individuals involved in the wrongdoing would not.

Full financial restitution to the state and federal governments, a condition of the arrangement, was made. Two university attorneys and two university compliance officers were terminated, as mandated by the U.S. Attorney.

A former federal judge, who had also previously served as U.S. Attorney for the District of New Jersey, was appointed as federal monitor of the university. Pursuant to the DPA, the federal monitor was afforded “unfettered access to all documents and information” the monitor determined would be necessary to carry out his duties and was provided “the authority to meet with, and require reports on any subject from, any officer or employee” of the University. The federal monitor was directed to conduct a comprehensive review and evaluation of policies, practices, and procedures concerning a wide range of subjects and issue written reports and recommendations regarding such matters. The monitor was also granted “authority to require UMDNJ to take any steps” he believed would be necessary to carry out the terms of the DPA and directed to make regular reports to the U.S. Attorney on UMDNJ’s compliance with the DPA and federal and state laws.

The prospect of indicting such a large and state-owned and operated institution was stunning. At first glance, the penalties and remedies imposed on UMDNJ, as a condition of avoiding criminal prosecution, might be perceived as extreme. Given the severity of the allegations though, the penalties and remedies were not at all draconian. The solution to allow the University to continue to operate, while righting itself, was eminently pragmatic.

The Criminal Complaint alleged that the University billed for physician services via the hospital’s cost reports at the same time the faculty practice plan billed for such services but that this was no mistake. The complaint also alleged that, despite an awareness of the situation, at no time did senior management, including legal counsel, instruct the university to stop billing or notify Medicaid of the double-billing.

Counsel for teaching hospitals and academic medical centers should view the UMDNJ situation as a cautionary tale. They should reflect on the great challenges inherent in counseling such complex institutions and organizations. They should reaffirm the standards that should be followed in the course of providing legal representation.

The first standard is to acknowledge the competition for resources and attention that so many different constituencies in a teaching hospital or academic medical center—faculty, administration, staff, students, and patients—demand of the institution, and of counsel. The multiple missions of education, research, and clinical service also pull in different directions.

It is important to try to achieve a balance of interests. It is necessary to accept that everyone and everything cannot take precedence every time.

It is also necessary to accept that everyone will not be happy because of choices that have to be made by institutions and sometimes by counsel. Indeed sometimes no one will be happy.

The second standard is to acknowledge the vast number of legal mandates faced by institutions and recognize that applicability and requirements will impact teaching hospitals and academic medical centers and their organizational components in many different ways. Both the obvious and the obscure have to be considered.

Many counsel are by necessity jacks of all trades, but masters of none. Other counsel are masters of a narrow domain, and assistance should be sought when necessary.

Regardless, it is essential to critically evaluate both the pieces...
and the whole on a regular basis. Consider each project both in the context of that project and in the context of the broad array of decisions and transactions made and undertaken in a complex and multifaceted organization.

Try to enlist assistance, in the form of help or guidance, or in the form of education, when necessary. No one can be all things all of the time.

The third standard is to acknowledge that sometimes a solution to a problem does not exist and at other times there is no answer, or at least no clear path to resolution. Still at other times, the answer may be obvious, but not pleasantly so. Counsel’s role is to analyze and advise. Counsel’s role is not, and must not be, to facilitate an institutional preference in every instance.

The fourth standard, which is related, is to bear the bad news when it must be borne. It will be hard. It may even be painful. It may not be fair, but ignoring problems or potential problems will not make them disappear and may make them worse.

The fifth standard is to avoid being caught up in politics. Every organization has politics, and teaching hospitals and academic medical centers may have more than their share. Decisions are often made for political reasons. Doing so though often has far reaching and unpredictable ramifications. Remember that sometimes, doing something to control things for political reasons renders a situation most uncontrollable.

Serving as counsel has never been easy. Operating a teaching hospital or academic medical center may never have been harder. In order to best serve, counsel for teaching hospitals and academic medical centers should step back and reflect. They need to recognize their roles, resources, limitations, and responsibilities and endeavor to serve within the confines of those parameters.

* Copyright 2006 by Lisa D. Taylor, Esq. All Rights Reserved.
** Lisa D. Taylor is a partner with the firm of Stern & Kilcullen LLC in Roseland, New Jersey, where she serves as counsel for the Federal Monitor of the University of Medicine and Dentistry of New Jersey. She commenced her career working in the legal department of a major university medical center. The views expressed in this article do not reflect the views of the Federal Monitor or any other individual, agency, or organization.

Endnotes

1 The Deferred Prosecution Agreement and the Criminal Complaint referenced hereinafter are available on the website of the U.S. Attorney for the District of New Jersey. www.usdoj.gov/asao/nj/.
FDA Clarifies Emergency Research and the Exception to Informed Consent

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The Food and Drug Administration (FDA), in an effort to clarify the requirements for performing emergency research studies without subject consent, recently issued a draft guidance document entitled “Guidance for Institutional Review Boards (IRBs), Clinical Investigators, and Sponsors; Exception from Informed Consent Requirements for Emergency Research,” which can be found at www.fda.gov/OHRMS/DOCKETS/98fr/06d-0331-gdl0001.pdf.

This new guidance is an update of previous guidance issued for clinical emergency research when informed consent cannot be obtained, and is part of the FDA’s Human Subject Protection and Bioresearch Monitoring Program (HSP-BIMO Program), which is a series of new policy and regulatory developments aimed at strengthening FDA’s oversight and protection of patients in clinical trials and the integrity of resulting data.

In this new document, the FDA has expanded on its previous guidance addressing 21 C.F.R. § 50.24, which allows emergency research studies an exception to informed consent if certain requirements are met. The updated guidance is intended to further address the roles and responsibilities of Institutional Review Boards (IRBs), clinical investigators, and sponsors in emergency research, to clarify terminology used in regulations that have been difficult to interpret and to broaden the discussion of community consultation and public disclosure.

Under 21 C.F.R. § 50.24 and the conforming amendments contained in 21 C.F.R. Parts 56, 312, 314, 601, 812, and 814, the FDA allows the conduct of research studies to test emergency treatments on patients with specific life-threatening medical conditions (head trauma, cardiac arrest, stroke) when patients cannot give informed consent because of their conditions, family is not available to provide consent either, and where, to be effective, the intervention must be administered before informed consent from the subjects’ legally authorized representative is feasible. Studies involving an exception from the informed consent requirements may proceed only after a sponsor has received prior written authorization from the FDA, and the reviewing IRB has found and documented that specific conditions have been met.

Among these conditions are consultation with representatives of the community in which the research will take place and from which the subjects will be drawn, public disclosure of information before and after performance of the study, and documentation of the investigator’s efforts to contact a family member to offer an opportunity for the family to object to the subject’s participation. The FDA has determined these requirements are necessary because emergency research performed without informed consent, while it can offer potential for subjects to benefit from new therapies, involves a very vulnerable population: persons with life-threatening conditions who can neither give informed consent nor actively refuse enrollment. As a result, it is especially necessary for the FDA, sponsors, IRBs, and clinical investigators to work closely together to protect the interests of these vulnerable subjects.

This guidance addresses the exception from informed consent in emergency research regulations in studies involving investigational new drug applications (IND) and investigational device exemptions applications (IDE). The guidance clarified that this includes studies such as those in which diagnosis of a life-threatening condition cannot be confirmed by an approved product or well-established procedure. The example provided in the guidance is research involving an investigational test for a neurotoxin that when inhaled or in contact with skin, can cause patients to become sick within minutes and at high doses, to lose consciousness, develop seizures and die. The FDA notes in the guidance that the reason for this is because the administration of therapy in a life-threatening situation can depend upon a diagnostic intervention.

To begin, the guidance restates the requirement under 21 C.F.R. § 50.24(a)(3) that the IRB must find and document that participation in emergency research studies holds out the prospect of direct benefit to proposed subjects because they are in a life-threatening situation and require intervention, that support exists, through animal and other preclinical studies, for the potential of direct benefit to the subject through the proposed intervention, and that the risks to the subjects are reasonable given their medical condition and the risks and benefits of standard therapy. The guidance points out that trials that have morbidity endpoints rather than mortality endpoints can also meet the requirements of 21 C.F.R. § 50.24(a)(3) if subjects are at risk of death from the condition and the risks and benefits of standard therapy. The guidance points out that trials that have morbidity endpoints rather than mortality endpoints can also meet the requirements of 21 C.F.R. § 50.24(a)(3) if subjects are at risk of death from the condition and severe morbidity that is closely associated with mortality is being evaluated. Patients with stroke or head injury are at risk of both death and severe disability, and a study of an intervention to improve stroke outcome would always consider survival, but would also closely examine functional status, which might be the primary endpoint of the trial.

Study designers will also need to demonstrate that the trial could not be practicably carried out without the waiver from informed consent requirements. The guidance explains that the FDA considers “practicable” to mean either that results obtained in consenting subjects would be expected to apply to subjects who are unable to provide consent, or that the research would not be unduly delayed by restricting it to consenting subjects. The FDA also notes that it may be advisable to describe in study protocols situations in which emergency care personnel can reasonably infer that some incapacitated individuals would not agree to participate in a research study,
even if they meet the inclusion criteria. The guidance states that placebo-controlled trials may be conducted under this emergency research provision, when appropriate, but that sponsors designing trials that include subjects who receive neither some aspect of the standard treatment nor a test article should provide a sound rationale for this type of study design. Consultation with the FDA is recommended for sponsors interested in designing and conducting such studies. Finally, the FDA states that its regulations do not limit study designs for conducting emergency research, and that the focus of study design should be whether the study will be adequate to the task of evaluating whether the investigational drug or device has the hypothesized effect.

Once such an emergency research study that contemplates enrolling subjects without their informed consent is designed, it must be submitted to the FDA for approval, and thereafter must be reviewed by an IRB. The FDA anticipates that a study in which informed consent is not obtained for all subjects is by its very nature controversial. Therefore IRBs must summarize their discussions and decisions regarding the required elements for these studies in the IRB’s written meeting minutes. In addition to reviewing the previously identified requirements, IRBs are also expected to review plans for community consultation and public disclosure, which are also required for emergency research seeking an exception to the informed consent requirement.

Community consultation, according to the guidance, is a dialogue between the community and the researchers, and incorporates discussions with and by a wide group of community members and representatives. It also includes the IRB’s consideration of such discussions before the IRB has made a decision as to whether the research should go forward. Community consultation activities are designed to help ensure that the communities in which the emergency research will be conducted are adequately informed about the risks and expected benefits of the research and are given the opportunity to ask questions about it. The guidance states that standing meetings, such as local civic public forums, may be more effective methods of community consultation and may be better attended because such meetings are already on community members’ calendars. However, it is also noted that organizing special meetings specifically to discuss the research may be valuable in that such meetings may draw participation from individuals with strong interest in the research. It is advised in the guidance document that selecting a variety of community consultation activities will broaden the opportunity for community involvement, and that several factors, such as community size, languages spoken in the community, and the targeted research population and its heterogeneity, should be considered when determining the number of meetings to be held and the number of community members to be consulted. The FDA also recognizes that other community consultation methods may be appropriate, such as the use of local call-in television or radio programs.

The sponsor and clinical investigator have the primary responsibility for planning and conducting the process of community consulta-

tion, hearing the concerns, and making appropriate changes in the plans for the research. A sponsor may provide to an IRB a model plan and information for use in consultation with the community, but it is the responsibility of the IRB to ensure the adequacy of the community consultation. As a result, it is very important that IRBs that review research under this rule be knowledgeable about local conditions in order to evaluate the plans for community consultation and public disclosure. IRB members may wish to attend and/or actively participate in various community consultation activities to hear firsthand the views of these communities. It is also recommended that the IRB document its discussion of issues raised during community consultation activities, particularly discussions of community opposition to, or concern about, the emergency research study, and how such concerns were resolved.

Unlike community consultation, public disclosure is a one-way transfer of information from the researchers to the community. The FDA regulations require public disclosure of plans for emergency research that may be conducted without obtaining prior informed consent to the communities in which such research is to be performed prior to the start of any such study. The guidance advises that appropriate disclosure includes a clear statement that informed consent will not be obtained for most research subjects, a balanced description of the risks and expected benefits, a short summary of the research protocol and study design, how potential study subjects will be identified, institutions participating in the research, and a description of the attempts that will be made to contact a legally authorized representative or family member before the investigational treatment is administered. Disclosure should also include suggestions as to how individuals who do not want to participate in the research can communicate this, such as with medical identification bracelets or necklaces. The IRB may determine that it is appropriate to require additional disclosure thereafter, such as when new information becomes available.

The FDA recommends that multiple forums and media resources be used to widely disseminate information about the study, and can include newspaper advertisements and articles, posted information on websites, presentation or distribution of information at local government, civic, or patient advocacy group meetings, letters to community leaders and to hospitals, police and paramedic departments, public service announcements, and interviews or discussions on talk radio or television programs. The FDA does not consider a legal notice, or informing physician specialists or the staff at the hospital where the study will take place, to be sufficient public disclosure, since these activities do not effectively inform the public.

In addition, following completion of the study, sufficient information about the study results must be disclosed to the community and to other researchers, and must include the demographic characteristics (age, gender, and race) of the research population. Disclosure of sufficient information for researchers may be accom-
plished through publication of the results, both positive and negative, of the completed investigation in a scientific journal. Disclosure of sufficient information for the community may require additional efforts to publicize the study results. The FDA anticipates that the sponsor would normally bear the costs because consultation is a requirement for conducting the research.

Finally, the guidance notes that, under 21 C.F.R. § 50.24(b), the IRB must ensure that there are appropriate procedures in place to inform, at the earliest feasible opportunity, subjects or their legally authorized representatives, or family members, of the subjects’ inclusion in the investigation, details about the investigation, and a subject’s right to discontinue participation in the research. For each subject unable to provide informed consent in emergency research, the clinical investigator must attempt to seek written informed consent or objection to enrollment from the subject’s legally authorized representative or family member before treating the subject with the investigative drug or device. The IRB, therefore, must find and document that procedures are in place for contacting and providing information to a subject’s legally authorized representative or family member within the window of time available to diagnose and treat the subject using the investigational drug or device, or at the earliest feasible opportunity.

The FDA states that the term “feasible” incorporates the idea of “practicability” and recognizes that in some instances it may not be feasible to provide information to the subject, such as when the subject does not survive or is mentally incompetent, or the subject’s legal representative or family member cannot be informed, such as when the identity of the subject is never determined. The IRB must also ensure that there are procedures in place to provide information about the study to the legally authorized representative or family member in the event of the subject’s death, if feasible. The regulations do not contain a time limit for providing this information, in order to allow consideration of the emotional condition of the family members who have just learned of the death.

In addition, the clinical investigator is required to summarize efforts made within the window of time available to diagnose and treat the subject, using the investigational drug or device, to contact legally authorized representatives for consent, or in the event that a legally authorized representative is unavailable, the subject’s family members to provide an opportunity to object to the subject’s participation in the study. The clinical investigator must make the information available to the IRB at the time of continuing review. The FDA recommends that clinical investigators record this information in the subject’s medical or study records so that it may be easily retrieved, analyzed, and reported to the IRB, and so that it is accessible if FDA conducts an inspection.

This new FDA guidance provides a great deal of information, but should prove very helpful by clarifying researchers’ various responsibilities when designing and conducting emergency research studies, and should help researchers continue to conduct their studies in the most ethical way, and with an emphasis on protecting human subjects.

* Mr. Shrack focuses his practice in the areas of health law and hospital-based clinical research law, including clinical trial agreements, institutional review boards, regulatory audits, research strategic planning, and scientific misconduct. Mr. Shrack was a vascular ultrasonographer and participated in clinical research in that capacity prior to attending law school. He earned his undergraduate degree from Miami University, Oxford, Ohio, in 1987, and his law degree, cum laude, from Indiana University-Indianapolis Law School in 2003. Mr. Shrack is admitted to the bar in Indiana.
Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions
January 25-26, 2007
Ritz-Carlton Hotel • Washington, DC

and plan to attend the

Teaching Hospitals and Academic Medical Centers Practice Group Luncheon:
Thursday, January 25

Title: Patenting Life: Issues in Protection of Biological Materials

Description:

It has been said that patents may be issued on “everything under the sun that is made by man...” Today controversy exists regarding the proper scope of patent protection for biological and genetic discoveries. Should scientists who discover the relationship between certain genetic mutations and disease processes be granted a patent based on that relationship? Are patents which encompass correlations between the values of certain chemicals in the blood and diagnosis consistent with the policy underlying the patent system? Are science and medicine advanced or limited by grants of patents such as these? We are pleased to have Dr. Lin Sun-Hoffman, PhD, JD, of the Applied Biosystems and Celera Genomics Group, and Maximilian Grant, a partner at Latham & Watkins LLP, join us to present a vigorous discussion regarding the issues surrounding biological and genetics patents and the impact of the answers on U.S. health and public policy, moderated by Mike Dansky, a Managing Director in Huron Consulting Group's Financial and Economic Consulting practice with many years of experience in the area of intellectual property issues.

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Accepting the Inevitable: Trends, Expected Outcomes, and What to Look for as Electronic Health Record Implementation Goes Forward

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I. Introduction

Earlier predictions that information technology will play a critical role in curing the crisis that is the nation’s fragmented healthcare delivery system1 are quickly becoming validated.2 Implemented correctly, the modernization of the healthcare industry through the current national health information technology (NHIT) initiative has the potential to have a profoundly positive impact on the cost, access, and quality of healthcare in the U.S.3 Ramped up efforts to fine-tune existing and develop new electronic health record (EHR) technologies, coupled with demonstrated cost-saving efficiencies and significant quality improvements,4 are now resulting in rising pressures upon the healthcare industry to move toward a higher standard of care.5

As technology for EHR becomes more readily available, patients will begin to demand and expect it. Personal testimonials of how the implementation of EHR has the potential to improve upon the state of healthcare in the U.S. can be found on the website end-theimplementationofEHR.gov.6 As improvements in patient safety and reduction in medical errors become increasingly well-documented, the availability of EHR technology will result in an environment where the errors of yesterday are no longer tolerated. Implementation of information technology on a nationwide level will essentially redefine the medical standard of care as we know it today. Healthcare professionals will find themselves unable to meet this higher standard of care, absent moving forward with EHR implementation. As a consequence, doubt with regard to expectations on return on investment (ROI) may no longer be looked to as a basis for not going forward with adoption of EHR.

The difficulty is that while it is quickly becoming apparent that the transition to a NHIT framework is inevitable, there remain many uncertainties in adoption of EHR, which account in large part for the continued resistance of many healthcare professionals in moving forward with implementation. Fortunately, many big name technology companies have recognized the need to assist healthcare professionals in this endeavor and are working to develop the capabilities to be able to roll this out for healthcare professionals. This leaves us at a critical juncture where healthcare professionals need to carefully establish equal footing with such technological vendors to set an equitable stage for future dealings.

Information technology alone cannot cure all the ills of the nation’s healthcare system, but it will go far in filling in existing gaps. The concerns that come associated with EHR are also very real, but can be surmounted with careful planning. “If not done properly, computerizing medical care can frustrate doctors and threaten the confidentiality of patients’ records. But in health-care systems that have adopted the technology, these are occasional problems, while improved safety, quality and efficiency are a daily reality.”7

II. Understanding the Full Extent of the Crisis

The National Academy of Sciences released a report entitled To Err is Human: Building a Safer Health System in 1999, and another report entitled Crossing the Quality Chasm: A New Health System for the 21st Century in 2001, in which the Institute of Medicine makes some telling observations regarding the crisis condition of the nation’s healthcare delivery system at that time, and recommends innovation and technology as a means to improving upon that system. The reports put forth eye-opening numbers on how many people die in hospitals each year as a consequence of medical errors that could have been prevented, and identify the nation’s healthcare system as being decentralized to the point of being a “non-system.”8 Although we appear to be on the verge of improvements with NHIT and pay-for-performance initiatives, many of the concerns identified in these reports remain unaddressed in the nation’s current healthcare delivery system.9 The nation’s healthcare system remains highly fragmented and difficult to access as a consequence of continued record storage in a variety of locations, and in paper-based forms. Providers are still hampered by a lack of comprehensive information about the patient at the point of care.10

Reading the reports of the National Academy of Sciences in full, or at least the summary report briefs (which are available on-line), is highly recommended. The quality chasm identified by the Institute of Medicine can be linked to the convergence of two key factors:

1. The scope of scientific knowledge has expanded exponentially in the past half-century; and

2. Healthcare has become increasingly complex. This is a consequence of patients living longer, suffering from combinations of conditions, and seeking more care, in concert with the availability of more procedures, equipment, technologies, and medications to prevent and treat the many more conditions about which we now know.

The move from paper-based to electronic recordkeeping systems will help to alleviate this crisis by allowing for the implementation of information technologies that can be utilized to translate the existing knowledge base into practice, thereby making healthcare more scientific (evidence-based), more effective, and less costly. The current system is poorly organized, overly complex, and not coordinated with healthcare organizations, hospitals, and physician groups typically operating independently of each other, where no one has the full pic-
ture of a patient’s medical condition and history. Information technology needs to be implemented to provide effective access to information so that evidence-based evaluation methods can be developed, extracting best practices from the expanse of scientific knowledge, and widely disseminated to benefit both providers and consumers.

It is ironic that when our lives and the lives of our loved ones are at stake, the nation continues to rely on an antiquated healthcare delivery system, where the memory of the provider and the risks of human error remain at the core of the quality of our care. This is in stark contrast to matters where finances are at stake. In that arena, the nation has at its fingertips, and expects financial professionals to have at their fingertips, sophisticated systems of coordinated data funneling up-to-the-minute investment advice and research tools into user-friendly sites, as well as real-time tracking of the status of our financial investments (e.g., stock tickers).

Compare the financial tools available electronically to those available in the healthcare arena. "Google takes about 0.12 seconds to return 184 million pages on diabetes . . . one hundredth of second longer to offer 163 million results for heart disease . . . Like a parched traveler offered a drink from a fire hose, consumers face a flood of healthcare information that has morphed into 'mess information,' in the past five years. Payors and physicians are among the groups that have started winnowing that information down for consumer use, driven by the advent of consumer-driven healthcare."12

Patients no longer show up at the doctor’s office looking to the physician to explain the ABC’s of a particular diagnosis. Rather, many patients come armed with a plethora of information from the internet and his/her own theories and explanations for whatever symptoms he/she is experiencing. Patients sometimes challenge the decisions of medical professionals based on conflicting information on the internet, which may or may not be based on sound science. The information is out there, but none of the players in this industry, neither the consumers, nor the providers, nor the payors, know how to navigate it. The healthcare industry needs to catch-up with implementation of available technologies into the healthcare delivery system, thereby enabling the nation to utilize “mess-information” to come up with the most effective approaches for treating illnesses and preventing medical errors, and deaths.

III. Key Definitions

Although the terms Electronic Health Record (EHR) and Electronic Medical Record (EMR) are often used interchangeably, there is an important distinction between the two terms. While the use of EMR has experienced increases over the last five years,13 adoption of EHR is not as widespread. Implementation of the NHIT initiative requires adoption of both EMR and EHR and careful coordination between the two.

A. Electronic Medical Record

An EMR (electronic medical record) is generally defined as the set of databases (or repositories) that contains the health information for patients within a given institution or organization. Thus, an EMR contains the aggregated datasets gathered from a variety of clinical service delivery processes, including laboratory data, pharmacy data, patient registration data, radiology data, surgical procedures, clinic and inpatient notes, preventive care delivery, emergency department visits, billing information, etc.

Furthermore, an EMR contains clinical applications that can act on the data contained within this repository—for example, a clinical decision support system (CDSS), a computerized provider order entry system (CPOE), a controlled medical vocabulary, a results-reporting system, etc. In general terms, EMRs are clinician-focused in that they enhance or augment the workflow of clinicians or administrators. EMRs are said to be interoperable if they are able to exchange (transmit and receive) data using standardized data transmission (coding and messaging) formats.14

B. Electronic Health Record

An EHR (electronic health record) extends the notion of an EMR to include the concept of cross-institutional data sharing. Thus an EHR contains data from a subset of each institution’s EMR (that is agreed upon by the institution). An EHR may also reside “entirely within one institution” and link the various affiliated practice sites together. The EHR is generally patient-focused and spans episodes of care rather than a single encounter. An EHR can only be present if the participating sites all have an EMR in place that is interoperable.15

IV. Trends and Expected Outcomes

A. AMC Study

In April 2006, the National Institutes of Health (NIH), National Center for Research Resources (NCRR), in conjunction with the MITRE Corporation, issued a report summarizing the features and functions of major commercial EHRs and reviewing the use of these EHRs in the academic medical center (AMC) setting (AMC Study).16 The report found that many modern-day EHRs are based on the pioneering work done in AMCs and for government clinical care organizations,17 but that those systems have serious shortcomings, i.e. non-standard vocabularies and system interfaces. The focus of the AMC Study is that commercial off-the-shelf (COTS) systems may be an attractive and cost-effective solution for AMCs, based on the following findings [portions excerpted]:

[1.] The ability of clinical systems to interoperate through the use of standard clinical vocabularies and structured data organization enhances the use of EHR data for purposes of clinical trials management and scientific discovery.18

[2.] COTS systems introduce new capabilities which were nonexistent with paper-based systems, e.g., interactive alerts to clinicians, interactive flow sheets, and tailored order sets.19

[3.] An AMC is actually multiple organizations within one. Many AMCs have multiple healthcare facilities, such as affiliated hos-
pitals and clinics, numerous specialty diagnostic and treatment centers, laboratories associated with training and research, and complex business operations to manage all of these components. Because AMCs providing tertiary medical care and are doing research, they often have more complex and more niche information systems to support new diagnostic and treatment modalities than a community hospital would have.20

[4.] The major value of integrated clinical systems is that they enable the capture of clinical data as a part of the overall workflow. An EHR enables the administrator to obtain data for billing, the physician to see trends in the effectiveness of treatments, a nurse to report an adverse reaction, and a researcher to analyze the efficacy of medications in patients with co-morbidities. If each of these professionals works from a data silo, each will have an incomplete picture of the patient’s condition. An EHR integrates data to serve different needs. The goal is to collect data once, then use it multiple times.21

[5.] Most commercial EHRs are designed to combine data from the large ancillary services, such as pharmacy, laboratory, and radiology, with various clinical care components (such as nursing plans, medication administration records [MAR], and physician orders). The number of integrated components and features involved in any given AMC is dependent upon the data structures and systems implemented by the technical teams.22

The AMC Study highlights the immediate rewards, intervening pain, and successes AMCs can expect to go through in engaging a COTS vendor, as was reported by the Medical Records Institute [excerpted]:

[1.] Rewards: Virtually any current EHR application can support more efficient and accurate collection, storage, analysis, and distribution of data than current manual operations. Eliminating the need for managing paper files provides immediate efficiency benefits.23

[2.] Pain: At present, available EHR applications rarely allow a seamless flow of data to a common database where multiple users—physicians, researchers, administrators, patients, and nursing stations—can convert data to information using a shared set of tools. As more EHR systems are implemented, chief information officers’ departments will be forced to find ways to interface existing ancillary systems (such as pharmacy) to respond to pressing needs for integrated data views and analyses. Some have investigated buying all components of their clinical automation tools from one vendor, but have discovered that these vendors have recently bought series of smaller vendors and have not yet had a chance to integrate disparate applications themselves. Also, specialty physicians often resist using the solution provided by a “mega-vendor,” preferring to use a more specialized vendor that they consider “best of breed.”24

[3.] Success: Discussion of EHRs at the national level begins to impose expectations that any new technology must be compatible with a data-driven medical enterprise. New data, communication, and visual technologies (e.g., “endo-cams,” digital camera views of the intestine uploaded to a hip-mounted data collection device), for example, will need to be integrated into the automated clinical records systems. More systems will be designed to allow data collection to become a by-product of the process—administration of a medication to a patient could be integrated with billing, inventory, and MAR systems. This improvement will come as the systems mature and as the clinical users become more involved in the design of systems and associated process changes.25

Overall, the AMC Study came to the following conclusions regarding EHR Implementation [excerpted].26

[1.] Pros: Clinicians in environments with EHRs spend less time updating static data, such as demographic and prior health history, because these data are populated throughout the record and generally remain constant. Clinicians also have much greater access to other automated information (regarding diseases, etc.), improved organization tools, and alert screens. Alerts are a significant capacity of EHRs because they identify medication allergies and other needed reminders. For clinical researchers, alerts can be established to assist with recruitment efforts by identifying eligible research participants.27

[2.] Cons: Challenges that EHRs may present to workflow processes include: increased documentation time (slow system response, system crashes, multiple screens, etc.), decreased interdiscipli-

nary communication, and impaired critical thinking through the overuse of checkboxes and other automated documentation. System crashes are particularly problematic because clinicians, particularly at in-patient facilities, will not know what treatments are needed or if medications are due.28

B. Governmental Activity

1. Initiatives at the Federal Level

In April 2004, President George W. Bush called for widespread adoption of interoperable electronic health records within 10 years and issued an executive order that established the position of the National Coordinator for Health Information Technology. A National Coordinator within the Department of Health and Human Services (DHHS) was appointed in May 2004 who released a framework for strategic action two months later.

In late 2005, to help define the future direction of a national strategy, DHHS awarded several health IT contracts and formed the American Health Information Community, a federal advisory committee made up of healthcare stakeholders from both the public and private sectors. Through the work of these contracts and the professional community, DHHS and its Office of the
National Coordinator for Health IT (ONC) have made progress in five major areas associated with the President’s goal of nationwide implementation of health IT.

The five major areas are:

a. Advancing use of electronic health records;
b. Establishing interoperability standards for a health information exchange;
c. Developing prototypes of a nationwide health information network;
d. Addressing privacy and security issues associated with the nationwide exchange of health information; and
e. Integrating public health systems into a national network.²⁹

On August 22, 2006, President George W. Bush issued an Executive Order that directs federal agencies to share with beneficiaries information on the quality of services provided by doctors, hospitals, and other healthcare providers as well as on prices paid to healthcare providers for procedures.³⁰

On September 1, 2006, the Government Accountability Office (GAO) released a report summarizing DHHS’ progress so far, but also expressing concern in the lack of detailed plans, milestones, and performance measures for meeting the President’s goals.³¹

On September 20, 2006, Robert M. Kolodner, MD, joined DHHS as the Interim National Coordinator for Health Information Technology.

2. Initiatives at the State Level

The recently published findings of the Third Annual Survey of the eHealth Initiative reflect significant increases in policy activity and leadership at the state level. Thirty-six bills were passed in 24 states during 2005 and 2006, calling for the use of health information technology to improve health and healthcare, and ten state governors have passed executive orders related to the same.³²

The objectives of improving quality and safety, and eliminating or reducing inefficiencies in the nation’s healthcare system, were identified as driving forces behind state activities. Ninety-two percent of respondents cited “improving quality” as a significant driver of their Health Information Exchange efforts, while 82% cited “improving safety.” Additionally, 70% cited “inefficiencies experienced by providers who need information to support patient care” as a significant driver, while 56% cited “rising healthcare costs”.³³

DHHS has contracted with the National Governors Association’s (NGA’s) Center for Best Practices to establish the State Alliance for e-Health. The State Alliance creates a vehicle through which states may come together to evaluate and possibly resolve:

a. State-level privacy and security issues;
b. State-law practice of medicine barriers; and
c. State-level health information organization issues in governance, sustainable financial models, and the role of payors and integration of public health and benefit programs.³⁴

C. Technology Vendors

The AMC Study makes an interesting observation on consolidation as a “standard phase in the life cycle of software in a cash-rich industry.” The phases identified are [excerpted]:

[1.] Initiation: Small, entrepreneurial ventures, responding to recognized “pain” within an industry, focus on a specific niche (e.g., patient records, billing, etc.) and serve it with proprietary software. They attempt to respond to unique language, structure, and processes associated with an industry. As awareness of their products and their credibility grows, they leverage the knowledge they have gained serving their installed base of customers and apply increasing revenues to further the development of their “flagship” product and attempt to expand into other arenas of the industry.³⁵

[2.] Acquisition: As their sales begin to validate the presence of a real need, entrepreneurs attract acquirers—larger companies that seek to exploit an emerging market and build upon their own capabilities and products (such as “compatible” software, data collection devices such as barcode readers, etc.). Acquirers’ difficulty comes when they try to integrate disparate software that was created using different terminology, operating systems, and hardware platforms. It can take several years to establish a stable suite of products.³⁶

[3.] Consolidation: The final stage is consolidation, in which larger companies make decisions about remaining in the market or departing it, and in which a few surviving companies become “standards” for the industry.³⁷

The AMC Study comes to the conclusion that EHR vendors are in the acquisition phase, but are quickly moving towards consolidation, with companies like GE, Siemens, and McKesson buying smaller vendors and bundling them with their own products. There also are companies such as IBM, Intel, Microsoft, and Accenture that lack established clinical record product lines and are investing in the development of EHR-related technology.³⁸

V. What to Look for as EHR Implementation Goes Forward

Until recently, the EMR and EHR vendor community has created proprietary database systems that make it difficult for them to send and receive data from other (potentially competing) products. Fortunately the need for interoperability is now well-recognized and the medical informatics community has created standards for data coding and communication. The ONC has also announced several major initiatives to harmonize standards and create a certification process for information technology vendors so that different products can interoperate better and be easily and objectively compared.³⁹

Continued on page 14
Due to the excessive costs of adopting traditional information technology options (that is hosted within the practice) many providers are evaluating ASP (application service provider) models. These are ‘subscription-based’ models for information technology, whereby the application runs on the computer system (server) of an ASP provider (a company that hosts the EMR and/or EHR). This approach substantially reduces the cost for the practice. In addition, the risks associated with security and privacy protection are undertaken by the host company and not the practice. Some practitioners dislike this approach because their data then reside with the host company.40

The limitations of the final EHR fraud and abuse rules, published by the Centers for Medicare and Medicaid Services (CMS), effective October 10, 2006, (providing that donations of EHR technology will not violate the physician self-referral law (Stark) or the Anti-Kickback Statute) also support implementation through the ASP approach. While the final EHR rules do not permit the donation of hardware, including modems, wireless routers, and storage devices, donations of certain software information technology and training services, such as connectivity, maintenance services, and help desk support, are protected under the EHR rules.

As providers select vendors to assist in the EHR implementations, they are likely to receive contracts crafted by the vendor’s sophisticated legal resources (whether in-house or outside counsel) to maximize the vendor’s profits and minimize vendor risk. The end result is that the brunt of the costs and risk will fall on providers, unless equitable terms are carefully negotiated. Providers need to be proactive in ensuring a standard is not established early on in the transition period that unduly burdens providers with technological responsibilities that could consume and cripple their ability to focus on patient care.

The following is a brief overview of some key issues to address in contract discussions with information technology vendors.

A. Ancillary legal considerations: “Implementation of an EHR raises many legal issues related to cross-institutional data sharing, security and privacy of shared records over potentially insecure network lines, and patient access to and augmenting their own data in electronic format (using the web, for example).”41 Even for some big name vendors, this NHIT initiative is their first foray into working with the provider community within the healthcare industry.

1. Do not assume the vendor knows or understands the myriad of federal and state laws, regulations, and requirements applicable to healthcare.
2. Require key vendor representatives who will have frequent contact with the provider to undergo the same training as provider’s workforce, including compliance, privacy, and security.

3. Have key vendor representatives sign off on the same confidentiality statements required of provider’s workforce.
4. Consider entering into a Business Associate Agreement that addresses in detail the regulatory requirements, especially setting forth timeframes for response, rather than merely citing to the statute that the vendor may never take the time to fully understand.

B. Quality improvement and reporting functionalities: Verify that the vendor has expanded capabilities to be able to support quality improvement and reporting activities. “It is estimated that only about 20% of current health information exchange efforts have incorporated functionalities such as providing disease or chronic care management services and 10% quality performance reporting capabilities.”42

C. Customization and Pricing: Each provider’s unique needs will drive pricing from the vendor. Each practice has distinct requirements, and systems often need to be custom tailored. Many EHR systems are based on templates that are initially general in scope, with the intention of customization in cooperation with the vendor to fit specified needs of a particular provider. There are EHR systems available that do not use templates.43

Under the ASP framework two common pricing frameworks are often presented for “usage” charges: (1) based upon the number of patients or providers using the system, or (2) based upon the amount of storage and bandwidth used by the system. The latter may prove the better approach where new technologies are likely to cause some data/exchanges to occupy less storage space/bandwidth, thereby creating a cost-saving which is built into the contract terms. Separate fees may also be assessed for deployment, subscription, and implementation and support services.

D. Governing Law: Many vendors are national companies providing these services for clients in states across the United States. While it is likely these vendors have designed their services and processes to comply with federal laws, providers must confirm that vendors are aware of the nuances in the law that are specific to each state. At a minimum, providers must seek to have a clause subjecting the contract to governance by the state laws under which the provider client is licensed. A more proactive approach is to add a rider to the vendor’s boilerplate, providing citations to key state requirements, and expanding upon any areas where the state laws present unique challenges.

E. Record Retention: Make sure the vendor’s policy to retain medical records matches up with the provider’s policies and state law requirements.

F. Mobility: The provider will need to invest a considerable amount of time and energy in moving paper records to electronic form. Clearly address in the contract what happens if the provider decides to terminate and choose another vendor to ensure the vendor is required to return the provider’s records in a compatible electronic form if another vendor is chosen.
1. Service Level Guarantee: The responsibility to guarantee and warrant the system will be up and running 98% of the time or more must fall on the vendor. The vendor needs to be careful to specify in the contract when scheduled maintenance can occur without disrupting the provider’s practice of medicine. Ensure the vendor has an incentive to minimize down-time by including a pro-rata deduction of fees for any down-time, including the right to terminate, and recoup all fees paid if down-time exceeds agreed to limits.

2. Successful installation, implementation, support, and maintenance services must also fall on the vendor, including training, workflow analysis, configuration support, account management, monthly utilization reporting, upgrades, and educational materials for patients, providers, and other stakeholders.

3. The vendor shall perform and assume all costs for set-up, training, maintenance, and updates to the system.

4. The vendor must provide a grant of license.

5. System configuration and accessibility must fall on the vendor.

6. Responsibility for back-ups and restoration of user data lies entirely with vendor.

7. The vendor must guarantee against software defects.

8. The vendor must guarantee current and continued compatibility.

9. The vendor must provide technical desktop and system support. Make sure there is a local or 1-800 help-line providers can call if they have difficulty. Require resolution in one business day or less.

10. If EHR is hosted on vendor’s server, the vendor should be responsible for safeguarding confidentiality and integrity of data and communications, daily data back-up, and restoration of service.

11. The vendor must protect confidential information and not just PHI. The vendor will also have provider’s identification information and other sensitive data.

12. For purposes of registration, the vendor is responsible for setting forth pre-load data requirements, and assisting provider in collecting and transferring this information into electronic form compatible with vendor’s functionalities.

13. Responsibility for authentication of users should also fall on the vendor.

14. Provider will need to be responsible for notifying vendor when a user (either provider or patient) should not longer have access, but responsibility for de-activation of rights must fall on the vendor. Deactivation should be immediate, upon notice from the provider.

H. Miscellaneous Vendor Responsibilities: Responsibility and assumption of risk for the following obligations belong with the vendor, as the entity with the technological expertise, control, and ownership of the process:

1. G. Hook & Bait: Vendors are aware of the investment providers will need to make on the front end and may offer lucrative deals in the initial years with plans to ramp up rates once the provider is hooked. To avoid the risks of later price gouging, cap the amount all fees can increase for any renewal term.

J. Testing periods: EHR systems generally are not fully functional or adequately customized to the providers’ needs in the first-run implementation. Include in the contract terms the right for the provider client to inspect, review, test, and validate data and report functionalities during a testing period.

K. Termination: Providers will be in a serious bind if the vendor is able to terminate without sufficient notice for the provider to transition to another vendor. Qualify the vendor’s right to terminate upon the provider having had the opportunity to either make this transition or cure the breach that may be the basis for the vendor’s desire to terminate. The provider should have an unrestricted right to terminate with a reasonable number of days prior notice to the vendor.

In any contract negotiation, compromises will need to be made. By focusing on redirecting certain areas of risk and responsibility which are inextricably tied to the vendors’ technological expertise, a more equitable share of the stresses that come with this transition will be placed on the vendor, instead of falling upon the already overwhelmed provider community.

VI. Conclusion

Where the biggest value lies in NHIT is not in the reduction of paper, but in electronic data that can be readily shared, searched, measured, and analyzed to determine what the most effective approaches to healthcare are, and at what cost. The mobilization of clinical information electronically supports interoperability and facilitates access to and retrieval of clinical data, privately and securely, among different entities involved in the healthcare delivery system, to provide safer, more timely, efficient, effective, equitable, and patient-centered care.”44

In moving forward with EHR implementation, and in anticipating the many headaches that are likely to come with that transition, one should keep in mind lessons of Hurricane Katrina and the difference an established EHR system could have made in the lives and well-being of so many in that disaster. Thousands of people in those disaster-ravaged areas no longer had access to their healthcare providers and their paper medical records were lost. Having such a system well established and running would also make an

Continued on page 16
immeasurable difference in the unthinkable event this country should ever be subject to bioterrorism.45

* The statements expressed herein are those of the writer and do not necessarily reflect the policies, practices, or opinions of her employer, its management, trustees, or affiliates.

Endnotes


4 See GAO, Information Technology: Benefits Realized for Selected Healthcare Functions, GAO-04-224 (Washington, D.C., Oct. 31, 2003) (stating “a 1,951-bed teaching hospital reported that it realized about $8.6 million in annual savings by replacing outpatient paper medical charts with electronic medical records. This hospital also reported saving more than $2.8 million annually by replacing its manual process for managing medical records with an electronic process to provide access to laboratory results and reports. Healthcare organizations also reported that IT contributed other benefits, such as shorter hospital stays, faster communication of test results, improved management of chronic diseases, and improved accuracy in capturing charges associated with diagnostic and procedure codes.”)


7 Bates, David W., M.D. and Komaroff, Anthony L., MSNBC.COM Newsweek (Oct. 16, 2006), Next: Paperless Medicine, available at www.msnbc.msn.com/id/15173075/site/newsweek/print/l/displaymode/1098/ (last visited Oct. 22, 2006) (stating “Computerizing medical care will be expensive, but there should be a huge return on investment. An authoritative study from the Center for IT Leadership estimates savings at a staggering $78 billion a year just from better information exchange. If not done properly, computerizing medical care can frustrate doctors and threaten the confidentiality of patient records. But in health-care systems that have adopted the technology, these are occasional problems, while improved safety, quality and efficiency are a daily reality.”)


12 Molpus, supra note 9.


15 Id.


17 Id. at p. 2, stating
Notable early projects include:

COSTAR (the Computer Stored Ambulatory Record), Barnett, et al., developed Harvard, placed in the public domain in 1975 and implemented in hundreds of sites worldwide.

HELP (Health Evaluation through Logical Processing), Warner, et al., developed at Latter-Day Saints Hospital at the University of Utah (brought to market by the 3M Corporation). HELP is notable for its pioneering decision support features.

TMR (The Medical Record), Stead and Hammond, Duke University Medical Center.

THERESA, Walker, at Grady Memorial Hospital, Emory University, notable for its success in encouraging direct physician data entry.4

CHCS (Composite Healthcare System), the Department of Defense’s (DoD) clinical care patient record system used worldwide.

DHCP (De-Centralized Hospital Computer Program), developed by the Veteran’s Administration and used nationwide.

TDS, developed by Lockheed in the 1960s and 1970s.

18 Id. at p.9.

19 Id. at p.1.

20 Id. at p.2.

21 Id. at p.3.

22 Id. at p.6.

23 Id. at p.12.

24 Id.


26 Id. at p.13.

27 Id. at p. 13

28 Id. at p.13

29 See GAO, supra note 5, at p. 2.

30 eHealth Initiative, supra note 10, at p. 5.

31 GAO, supra note 10.

32 eHealth Initiative, supra note 10, at p. 2.

33 Id.


35 NIH, NCRR, and The, MITRE Corporation, Center for Enterprise Modernization, supra note 16, at p. 17.

36 Id.

37 Id.

38 Id. See also Lohr, supra note 2 (stating “Major Technology corporations like I.B.M., General Electric, and Microsoft, as well as a crowd of specialist companies including Cerner, Epic Systems, and Eclipsys, are all chasing what they see as a fast-growing multibillion-dollar opportunity to sell health information technology to hospitals.”)


40 Id.

41 eHealth Initiative, supra note 10, at p.2.

42 Id.

43 See NIH, NCRR and The, MITRE Corporation, Center for Enterprise Modernization, supra note 16, at p.18-19. (Summarizing the tradeoffs between completely customized systems as opposed to COTS).

44 eHealth Initiative, supra note 10, at p. 5-6.

It has been an eventful, inaugural year for AHLA’s Teaching Hospital Update. We are so pleased with the positive comments regarding the weekly e-newsletter. With many of the comments, a common thread has emerged—that in the busy, fast-paced, and information-overloaded field of health law, it is nice to have a resource that provides updates in a condensed, easy-to-read format. It has been our pleasure to bring you such a useful resource, and we look forward continuing this new tradition of the Teaching Hospitals and Academic Medical Centers Practice Group. The following are some of the highlights (that we’ve further edited) published in July through October of this year:

July 10-14, 2006 issue:

**FDA Regulators to Alter Guidelines to Create More Flexible Clinical Trials**

Hoping to encourage “adaptive” clinical trials that do periodic evaluations and are able to change course based on interim findings, the FDA is preparing guidelines that tell drug makers how they can streamline the testing of experimental medicines. These changes balance an effort to promote “trial designs that tell us more about safety and benefits” with the reality that such new trial designs require “complicated decisions and uncertainty about the best approach for data analysis.” This is a radical departure from the current “blinding” processes employed to prevent doctors, patients, and companies from learning results before the completion of a given drug study.

For more information, please go to www.medicalnewstoday.com/medicalnews.php?newsid=46943.

**FDA Criticized for Lack of Post-Marketing Follow-Up**

The FDA from time to time requires post-marketing studies of approved drugs, but it often fails to ensure that these post approval studies actually occur. Current procedures leave the follow-up studies to the drug makers themselves. A recent review of reports due in 2004 found 8% not filed at all, with another 27% labeled as incomplete. The study, done by the HHS, prompted the FDA to respond that new regulations would be required to allow it to require and pursue additional or even complete reporting.

For more information, please go to www.medscape.com/viewarticle/540351. (Note: free registration is required to view this content.)

July 17-21, 2006 issue:

**“Parking” ER Patients May Violate EMTALA**

As overcrowded emergency departments struggle to cope with increased volumes of sicker patients, and “boarding” of patients in the emergency department (ED) becomes more common, some EDs have reportedly been refusing to permit emergency medical services (EMS) personnel to off-load patients from ambulance stretchers to ED beds, in an attempt to delay the assumption of patient care responsibilities by ED staff. This is commonly referred to as the “parking” of emergency patients, and multiple-hour delays have been reported in some areas.

In response, the CMS and State Operations/Survey and Certification Group recently issued guidance to State Survey Agency Directors stating that the parking of emergency patients may violate EMTALA and/or the Conditions of Participation for Hospitals for Emergency Services, as well as cause quality of care problems. Noting that the obligation of a hospital to provide a screening examination and stabilizing treatment attaches when an individual presents and requests care (or has such a request made on his or her behalf), CMS states that “[a] patient who arrives via EMS meets this requirement when EMS personnel request treatment from hospital staff . . . .” EMTALA may also be violated if a patient “appropriately transferred” from another hospital arrives and care is delayed. Although CMS acknowledges the “enormous strain and crowding many hospital emergency departments face[,]” the use of parking is not permitted because “parking” patients in hospitals and refusing to release EMS equipment or personnel jeopardizes patient health and impacts the ability of the EMS personnel to provide emergency services to the rest of the community.


**President Bush Vetoes Embryonic Stem-Cell Research Legislation**

On July 19th, 2006, President Bush followed through for his conservative base by vetoing legislation passed by the House and Senate that would have expanded federally funded embryonic stem-cell research. This decision puts him at odds with scientists, most Americans, and a large portion of the Republican Party. Surrounded by children born from donated embryos, President Bush defended his decision to the media, stating that “[i]t crosses a moral boundary.” Neither chamber was able to garner the necessary 2/3 majority vote to override the veto.

**Physician and Two Nurses Arrested in Hurricane Katrina Hospital Deaths**

A physician and two nurses were arrested in connection with the deaths of four patients at Memorial Medical Center in New Orleans. The Louisiana Attorney General has been investigating allegations that medical personnel euthanized suffering patients after Hurricane Katrina struck last August. Memorial physician Anna Pou and nurses Cheri Landray and Lori Budo were each charged as principals with four counts of second-degree murder for allegedly administering lethal doses of morphine to patients. Each was released on a $100,000 personal recognizance bond.

As of September 24th, the New Orleans District Attorney still had not brought these charges before a grand jury. Morley Safer interviewed Dr.

The state’s near-universal healthcare plan. As part of the plan, the finance a Medicaid expansion in Massachusetts—a key element of coverage of the uninsured. The additional federal funds will help remain eligible for continued funding, the state needed to expand Medicaid waiver that established a free-care pool, but in order to Massachusetts has been receiving the additional money as part of a funds each year for the next two years to help finance the plan.

CMS approved a Massachusetts’ plan to extend healthcare coverage to most of its uninsured population, stating that it will continue to provide the state an additional $385 million in federal Medicaid funds each year for the next two years to help finance the plan. Massachusetts has been receiving the additional money as part of a Medicaid waiver that established a free-care pool, but in order to remain eligible for continued funding, the state needed to expand coverage of the uninsured. The additional federal funds will help finance a Medicaid expansion in Massachusetts—a key element of the state’s near-universal healthcare plan. As part of the plan, the state will require that uninsured individuals buy health insurance or face a tax penalty; that low-income individuals will receive subsidies; and that the state will create low-cost insurance options for affected individuals.

Since reporting this story, the State of Massachusetts’s Commonwealth Health Insurance Connector Authority has entered contracts with four “affordable” health insurance providers: Boston Medical Center Health Net, Fallon Community Health Plan, Network Health, and Neighborhood Health Plan. Enrollment in Commonwealth Care began on October 1st.


For information on the program, including enrollment, access the Commonwealth Health Insurance Connector Authority website at www.mass.gov/?pageID=hichomepage&L=1&LD=Home&sid=Qhic.

July 31-August 4, 2006 issue:

CMS and OIG Establish New Stark Exceptions and Anti-Kickback Safe Harbors

HHS announced final regulations establishing new Stark law exceptions and Anti-kickback safe harbors for electronic prescribing and electronic health records arrangements with physicians. These regulations are intended to improve the quality and efficiency of health care through the increased use of electronic prescribing and electronic health records technology. In general, the rules set forth the circumstances under which hospitals, group practices, prescription drug-plan sponsors, and Medicare Advantage organizations may provide hardware, software, or information technology and training services to physicians and other healthcare providers without violating the Stark law or Anti-kickback statute. The regulations became effective on October 10, 2006.


Access the final OIG rule at http://oig.hhs.gov/authorities/docs/06/OIG%20E-Prescribing%20Final%20Rule%20080806.pdf.


Custom-Built Viruses Raise Bioterrorism Concerns

Four years ago, Eckard Wimmer, a molecular geneticist at the State University of New York, created the first live, fully artificial virus in

Continued on page 20
Continued from page 19

the lab—a variation of the virus that causes polio and yet is different from any natural virus. He made it wholly from nonliving parts, and he obtained the genetic code for free from the Internet. While this was intended to sound a warning regarding the ease in which viruses can be created, some argue it could also open the door to improper use and regulations that could restrict scientific freedom. The Bush administration has acknowledged the growing threat, and last year, it appointed a panel of scientists to study the problem, but the CDC has declined to police the booming gene-synthesis industry. The risks are increased by the fact that our $8 billion annual bioterrorism defense budget largely goes to developing and stockpiling new drugs primarily tied to a single, well-known threat—anthrax.


Employers Sending Workers Overseas for Surgery

This week, the Los Angeles Times reported that some employers, which fund their own health insurance plans, are looking into the costs that could be saved by sending employees overseas for surgeries. For instance, an employee of Blue Ridge Paper Products of Canton, North Carolina will fly to New Delhi in September for surgeries to remove gallstones and fix a rotator cuff. The employer’s plan will cover the costs of the surgeries, including airfare for the employee and his fiancée, and will share with him a portion of the expected savings up to $10,000. Blue Ridge began researching the overseas idea out of frustration with rising rates at local hospitals.

After we reported this story, the United Steelworkers union stepped in, halting Blue Ridge from sending its employee to New Delhi. The union argued that workers should not be sent to low-cost countries just to cut healthcare costs. The employees will receive alternative treatment in the U.S., and Blue Ridge will only offer the overseas option to salaried employees.


August 7-11, 2006 issue:

FDA Calls for Universal ID Systems for Medical Devices

As reported by The New York Times, the FDA is moving toward requiring the medical device industry and hospitals to adopt a universal system for using bar codes and other technology to identify individual devices. The FDA has been criticized for its inability to gather reliable data on the role of certain medical devices in patient injuries and deaths. The FDA’s concerns and proposed strategy for medical-device identification rules were published today in the Federal Register, beginning the 90-day comment period. When finalized, the rules will supplement the identification requirements adopted in 2004 by the FDA for drugs and biological agents like vaccines. A proposal to include medical devices in the 2004 rule was defeated under industry pressure.


Interim Guidance Regarding Recognition of Certification Bodies for Health IT

On August 4th, 2006, the Office of the National Coordinator for Health Information Technology (ONC) published in the Federal Register notice of the availability of a Certification Guidance Document (CGD). The CGD will serve as a guide for ONC in evaluating applications for Recognized Certification Body (RCB) status, and it explains the factors that the ONC will use in determining whether to recommend to the Secretary of the HHS that he recognize a body for certification.

The RCB status is a component of the two final rules issued by CMS and the OIG earlier this month creating an exception to the Stark law and creating an Anti-kickback statute safe harbor for the donation of interoperable electronic health records (EHR) technology to physicians and other healthcare practitioners or entities. The exception and safe harbor provide that EHR software will be “deemed to be interoperable if a certifying body recognized by the Secretary [of HHS] has certified the software no more than 12 months prior to the date it is provided to [the physician or recipient].”

Since originally reporting this article, HHS has designated the Certification Commission for Healthcare Information Technology (CCHITSM) as a Recognized Certification Body (RCB). EHR software will be deemed interoperable under both the new rules above if it has been certified within 12 months prior to the donation by a certification body recognized by the HHS.


August 14-18, 2006 issue:

Percentage of Physicians Treating Medicaid Patients Falls

The Center for Studying Health System Change reports that the proportion of U.S. physicians treating Medicaid patients decreased over the past decade by about 1.7%. In 2004 and 2005, 21% of
physicians declined to accept new Medicaid patients—five times higher than physicians who declined new patients covered by private insurance. Of the physicians declining to treat Medicaid patients, 84% stated that it was because of inadequate reimbursement. Because of this trend, larger practices, hospitals, academic medical centers, and community health centers have seen an increase in Medicaid patients.


**Fines Levied by OCR for HIPAA Violations = $0**

Since the effective date of HIPAA’s privacy rule through July 31st, there have been 21,434 complaints alleging HIPAA violations filed with the HHS Office of Civil Rights (OCR). Over the same time frame, the OCR has levied zero fines. The OCR noted that the complaint-resolution process it has adopted, which emphasizes education, coaching, and “voluntary compliance” over penalties, has proven to be an effective approach.


*August 21-25, 2006 issue:*

**CMS Publishes Proposed Rule to Revise Physician Fee Schedule**

On August 22nd, 2006, CMS published in the Federal Register its proposed rule to “revise payment rates and policies under the Medicare Physician Fee Schedule.” The Physicians Organization Practice Group of the AHLA reported in an email alert that in addition to changes to the Physician Fee Schedule, including the implementation of a minus 5.1% update in physician payment rates, the Proposed Rule also changes the definitions of “centralized office building” and “physician in a group practice” under Stark II. The proposed rule also addresses reassignment rules as well as rules regarding Independent Diagnostic Testing Facilities (IDTFs).

**CDC Releases Genetic Blueprints for 650 Viruses**

The CDC, in collaboration with the Association of Public Health Laboratories, has deposited genetic blueprints of more than 650 flu viruses into public databases in Genbank, a public-access library for virus sequences managed by the NIH and in a database housed at Los Alamos National Laboratories. The information contains data only for naturally circulating viruses isolated in the U.S., including data from the annual flu season, animal flu viruses that infect humans, as well as new strains that may emerge in the U.S., such as the bird-flu virus. The CDC hopes that easy access to the blueprints for viruses will encourage timely and transparent research, and it also hopes that some developing countries adopt similar approaches.


**Health IT Legislation Across U.S. Examined**

The eHealth Initiative, a consortium of health plans, healthcare IT vendors, providers, laboratories, pharmaceutical and medical-device companies, and others, published a report detailing health IT legislation across the U.S. In 2005 and 2006, 38 state legislatures introduced 121 bills to promote healthcare information technology, including 36 bills in 24 states that were signed into law. Eight bills that passed in seven states contained state appropriations to fund these IT efforts. Also, 10 governors signed IT-related executive orders to develop IT planning and advisory programs.


*September 11-17, 2006 issue:*

**Stanford University Medical Center to Issue a Policy of “No Gifts” from Pharmaceutical Sales Representatives**

Under a new policy effective this fall, physicians at Stanford University Medical Center will no longer be able to accept gifts from pharmaceutical sales representatives. It prohibits free drug samples, de minimis gifts, underwriting of journal articles, and free meals from drug companies. Sales reps will be barred from areas of the hospital dedicated to patient treatment and physician education.

This policy could cost the institution millions of dollars each year, but Stanford representatives state the policy is important to secure the public trust in academic medicine. Pharmaceutical manufacturers argue that it will have a negative effect on the industry and patient care by suppressing information on drug products.

“Three days after Stanford announced the policy shift, the drug industry came out swinging. Industry lobbyist Pharmaceutical Research and Manufacturers of America (PhRMA) defended drug representatives, arguing that they are integral cogs in the medical industry.”


Continued on page 22
Senate Finance Committee Investigated Not-for-Profit Practices, To Issue Proposals for Community-Benefit Standards

A Senate Finance Committee investigation found that not-for-profit hospitals routinely overcharge or deny care to low-income, uninsured patients. The investigators reviewed the charitable activities and billing practices of ten not-for-profit hospitals across the nation and concluded that some hospitals take advantage of their IRS tax-exempt status by offering some no-cost services but providing little support for low-income patients. Some hospitals failed to inform patients that no-cost services were available.

Following the release of the study, the Senate Finance Committee will now work to develop proposals for oversight of charity care and community benefits at not-for-profit hospitals. Part of the Committee’s discussion paper will include community-benefit standards issued by the Catholic Health Association this past summer. Committee Chairman Charles Grassley did not set a deadline for completion of the Committee’s discussion paper.

As many of you are aware, the Catholic Health Association has published a guidance tool to assist hospitals in calculating and reporting their community benefits. The American Hospital Association has also published similar guidance. Richard Umstenstock, COO of the AHA, states that the AHA still embraces the CHA guidance, but with the additional reporting of bad debt and Medicare underpayment at cost.


The Catholic Health Association community benefit guide can be accessed at www.chausa.org/Pub/MainNav/ourcommitments/CommunityBenefits/Resources/ResourceTools.htm.

The American Hospital Association community benefit guide can be accessed at www.aha.org/aha/content/2004/pdf/guidelinesfinalweb.pdf. August 28-September 1, 2006 issue:

U.S. Supreme Court to Review Partial-Birth Abortion Ban

The U.S. Supreme Court has recently heard oral argument regarding federal ban on partial-birth abortions ruled unconstitutional by two federal appeals courts. In Planned Parenthood Federation of America, Inc. v. Gonzales, 435 F.3d 1163 (9th Cir. 2006), the Ninth Circuit found the federal law unconstitutional because it did not contain an exception allowing an abortion when necessary to preserve a woman’s health. In Carhart v. Gonzales, 413 F.3d 791 (8th Cir. 2005), the Eighth Circuit ruled the same. Government attorneys claim the appeals courts erred in finding the law invalid “on its face” and in declining to defer to Congressional findings that an abortion “is never necessary to preserve a woman’s life.” Also at issue is whether the judiciary is entitled to second-guess the Congressional finding that there is a consensus in the medical community that an abortion is never necessary to protect a woman’s health.

Peyton Sturges, U.S. Supreme Court Challenge to Partial-Birth Abortion Ban Tops High Court’s 2006 Health Care Docket, 15 BNAHealth L. Rep’t, No. 35, 999 (Aug. 31, 2006) (containing summaries of all healthcare cases on the Supreme Court’s docket this term), available by subscription at www.bna.com/products/.

OIG Publishes Guidelines for Evaluating State FCA Claims

The OIG issued a notice in the August 21st Federal Register announcing the publication of the OIG’s guidelines for evaluating state False Claims Act (FCA) cases. According to the Deficit Reduction Act of 2005, under Section 1909 of the Social Security Act, if a state enacts legislation that meets certain criteria in establishing liability to the state for individuals or entities that submit false claims to the state Medicaid program, then the state’s share of any amounts recovered from an action brought under the qualifying law increases by 10%. The OIG notice sets forth the guidelines for evaluating whether such a law meets the requirements of Section 1909.

Among the criteria that a state law must meet to qualify for the incentive is that it must create liability to the state for false or fraudulent claims with respect to Medicaid program expenditures, including: (1) knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the Medicaid program, and (2) conspiring to defraud the Medicaid program by getting a false or fraudulent claim allowed or paid. The state law must have qui tam provisions and seal provisions that meeting certain criteria. Also, a qualifying state law must contain a civil penalty that is not less than the amount of the civil penalty authorized under 31 U.S.C. § 3729.


Alabama’s High Court Upholds Order for Scrushy to Repay Bonuses

Alabama’s Supreme Court upheld a lower court ruling requiring Richard Scrushy, former CEO of HealthSouth Corp., to repay $52 million in bonuses that were realized due to overstated earnings. Scrushy appealed the decision by a state circuit court in Birmingham ordering the repayment. He could appeal the high court’s ruling or file for a rehearing with the state court, but his attorney, Art Leach, is still evaluating the state court opinion and assessing the legal options. Last summer, Scrushy was acquitted on criminal charges alleging knowledge of the accounting fraud at HealthSouth; how-
ever, in a separate case, he was found guilty of bribing Alabama’s
governor to obtain a seat on the state’s certificate-of-need board.
The high court denied Scrushy’s motion to reconsider its order.
Joseph Mantone, Court Upholds Order for Scrushy to Repay Bonus,

September 4-8, 2006 issue:

**CMS Administrator McClellan Resigns**

This week, CMS Administrator, Mark McClellan, announced his
resignation from CMS, effective in early October. McClellan was
often considered the name and face behind many controversial
CMS initiatives, including Medicare Part D and pay-for-performance
programs. He stated that “It’s a good time for a transition
because we’re in such a fundamentally good position, with momentum
in all our major programs.” A successor has not been named.

**FDA Issues Draft Guidance for Oversight of Group of Laboratory Tests**

The FDA published in the Federal Register its draft regulatory guid-
ance for industry and clinical laboratories for multivariate index
assays, which use complex mathematical formulas to interpret large
amounts of gene and protein data to produce results that can help
guide medical decision making. The FDA already requires approval
of diagnostic test kits, which are sold to laboratories, hospitals, and
physicians. However, the multivariate index assays are generally
developed and performed by a single laboratory (known as home-
brew tests)—they are considered lab “services” and are currently
outside the purview of the FDA. The FDA states that requiring
approval before these tests can be marketed could better ensure the
tests are valid; however, critics contend that the requirement could
also discourage the development of diagnostic tests by raising the
costs and time to introduce them to the market.

Andrew Pollack, F.D.A. Seeks to Regulate New Types of Diagnostic
business/06drug.html?ex=1315195200&en=e5191cee43bungf36&ei=5088
&partner=rssnyt&emc=rss.

For more information, view the FDA news release at www.fda.gov/
bbs/topics/NEWS/2006/NEW01445.html, and the draft guidance at

**Drug Enforcement Agency Issues a Proposed Rule Regarding Dispensing Controlled Substances for the Treatment of Pain**

In a move intended to ease the pain and concern of physicians
who prescribe controlled substances for pain relief, the DEA issued
a proposed rule regarding Dispensing Controlled Substances for
the Treatment of Pain. Noting that “[o]ne of the chief purposes of
this document is to make clear that fear of enforcement should in
no way interfere with the legitimate practice of medicine to cause
any physician to be reluctant to provide legitimate pain treatment.
. . .” The DEA also stated that it “wished to dispel the mistaken
notion . . . that the agency has embarked on a campaign to ‘target’
physicians who prescribe controlled substances for the treatment of
pain, or that physicians must curb their legitimate prescribing of
pain medications to avoid legal liability.” However, no clear consen-
sus exists among physicians regarding when it is appropriate to pre-
scribe opioids for pain control.

The DEA declined to issue guidelines regarding the appropriate
use of controlled substances for pain relief, noting that it is impossible
to fully address situations which might arise and emphasizing
that the DEA recognizes that use of controlled substances for pain
relief is legitimate so long as the substance is prescribed for legiti-
mate medical purposes in the usual course of professional practice.
Actions against physicians for prescription of controlled substances
are quite rare, but most involve typical patterns of abusive behav-
ior, including prescribing of excessive quantities, prescribing with-
out a physical examination, or prescribing knowing the patient was
diverting the drug.

Additional information is available in the Federal Register at
http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access

September 18-22, 2006 issue:

**Senate Committee Approves Nomination of FDA’s Head**

On September 20th, the Senate Health, Education, Labor and
Pensions Committee approved President Bush’s nomination of act-
ing Commissioner Andrew von Eschenbach to permanently head
the FDA; however, the nomination remains controversial. Some
senators have threatened to place a “hold” on the final nomination
until the FDA removes the medical abortion drug, Mifeprax or RU-
486, which would prevent full Senate consideration of the nomina-
tion. Last month, Senators Hillary Rodham Clinton and Patty
Murray held up Dr. von Eschenbach’s nomination in protest over
his agency’s delay in approving over-the-counter sales of the emer-
gency contraception Plan B. The FDA approved the Plan B applica-
tion, but it is not expected to suspend the sales of RU-486 in the
near future.

Gardiner Harris, F.D.A. Nominee Advances; Hurdles Linger, New York
washington/21fda.html?_r=2&ref=health&oref=slogin&oref=slogin.
(Nota registration is required to view this content.)
September 25-29, 2006 issue:

**House and Senate Committees Approve Bill To Allow U.S. Residents to Purchase Prescription Drugs from Canada**

On September 25th, House and Senate committees voted unanimously to approve a bill that would allow U.S. residents to purchase lower-cost prescription drugs from Canada. This provision is part of the larger fiscal year 2007 Homeland Security appropriations bill. While committees of both houses approved Canadian importation, the Senate committee refused to allow an amendment that would have paved the way for U.S. residents to purchase prescription drugs from Mexico. The full House and Senate are expected to approve the bill late this week or next. If approved, the law will allow U.S. residents to transport as much as a 90-day supply of FDA-approved prescription drugs from Canada. The law would exclude controlled substances and some biological products.


**Deputy CMS Administrator Norwalk to Serve as Acting Administrator**

Earlier this month, CMS administrator, Mark McClellan, announced his resignation effective October 15. CMS announced Deputy Administrator, Leslie Norwalk, will fill McClellan’s role as acting agency administrator. Herb Kuhn, director of the Center for Medicare Management at CMS, will replace Norwalk. Ms. Norwalk has been with the agency for five years where she has served as the chief operating officer and acting director of its Center for Beneficiary Choices. Before joining CMS, Ms. Norwalk practiced law at the Washington, DC office of Epstein, Becker and Green, and she worked in the White House Office of Presidential Personnel during the administration of George H.W. Bush. Ms. Norwalk will serve as acting administrator until President Bush nominates a permanent administrator and Congress confirms his/her appointment.


**CDC Report Finds U.S. Emergency Departments Unprepared to Deal with Natural Disasters, Disease Outbreaks, Terrorist Attacks**

The CDC announced that between 40% and 50% of United States emergency departments are unable to handle large surges of patients in the event of a disaster because many are “overcrowded” based on ambulance diversion; wait times more than one hour for patients in need of immediate care; and because of the proportion of patients that leave without receiving care.

The Institute of Medicine (IOM) has issued a similar report, which concludes “a national crisis in emergency care has been brewing, and is now beginning to come into full view.” The IOM report also addresses the fragmentation among the different agencies in the emergency health field, a shortage of on-call specialists, and an overall lack of emergency preparedness. Funding is a major focus of the IOM report and the IOM recommends a significant increase in federal resources and attention be directed towards the many problems facing emergency medicine.


October 2-6, 2006 issue:

**Supreme Court Declines to Hear Privacy Suit Involving Electronic Health Records**

When the Supreme Court opened its new term, it rejected a lawsuit by privacy advocates who challenged the sufficiency of the HIPAA regulations. Ten groups filed the suit on behalf of 750,000 consumers, healthcare providers, and patients.


October 9-13, 2006 issue:

**Hospitals Need Translation Services, Medicare Coverage Recommended**

In a recent survey of more than 800 hospitals, the National Health Law Program and the Health Research & Educational Trust found that about 80% of hospitals encounter patients with limited English proficiency (LEP), but only 3% receive direct reimbursement for language services, primarily through the Medicaid program. Approximately the same percentage of hospitals reported that staff interpreters are their most frequently used language resources, and the most common languages encountered are Spanish, Chinese, and Vietnamese.

In a separate report on financing language services in healthcare, the Center for Budget & Policy Priorities, suggests a flexible system for Medicare coverage of hospital-based language services and also suggests using grants to finance the training of interpreters and using federal government contracts with companies for telephone-based interpretation.

Under Title VI of the Civil Rights Act, recipients of federal financial assistance must take reasonable steps to ensure meaningful access to their programs and activities by LEP persons. For hosp-
Few Physicians Have Implemented Electronic Health Records

In a study funded by the Robert Wood Johnson Foundation (RWJF) and the Office of the National Coordinator (ONC) for Health Information Technology, researchers found that only about one in four physicians use some type of electronic health records (EHR), and fewer than one in ten use a comprehensive EHR system. In non-hospital settings, approximately one-quarter of physicians use some form of EHR, while about 9% use "fully operational" systems to collect patient information, display test results, order medications, and assist in treatment decisions. Notably, physicians who treat large numbers of Medicaid beneficiaries are half as likely as other physicians to have adopted EHRs. Likewise, physicians in private practice or in practices with one other physician were much less likely to use this type of record system. Approximately one-half of U.S. physicians practice in small, private settings.

No reliable data exist on the percentage of hospitals that have adopted EHRs. Nevertheless, researchers found that about 5% of hospitals use computerized physician order entry systems.


October 20, 2006 issue:

CDC Issues Guidelines—Wash Your Hands!

On October 19th, the CDC issued new guidelines for hospitals to prevent infections with drug-resistant “superbugs.” These bacteria have evolved to evade use of antibiotics, including later-generation types of antibiotics such as methicillin. According to the CDC, each year hospital infections claim the lives of 90,000 people and cost $4.5 billion in healthcare costs. In light of these statistics, the CDC advised hospitals, nursing homes, and long-term care facilities to track infection rates, ensure that staff use standard infection control practices, and follow guidelines regarding the correct use of antibiotics. The CDC noted that simple hand-washing is still a problem in some facilities, and the main mode of transmission is through human hands.


FDA Plans To Expedite Reviews of Generic Drugs

On October 18th, the FDA’s director of the Center for Drug Evaluation and Research announced that the agency will accelerate its review for certain generic medications that no longer have patent protections. The agency will also accelerate review for generic medications that would assist in public health emergencies or shortages. According to the Generic Pharmaceuticals Manufacturers Association, the accelerated reviews will save the United States health system millions of dollars. Over the past five years, applications for generic medications have more than doubled, and currently, the FDA has a backlog of more than 800 generic medications, in large part because of a lack of staff and funds. The FDA plans to charge generic pharmaceutical companies user fees to accelerate reviews for their medications that it already charges brand-name manufacturers.


U.S. Medical School Enrollment Up 2.2%

According to the Association of American Medical Colleges (AAMC), first-year enrollment in U.S. medical schools increased by 2.2% in 2006, reaching an all-time high of 17,340 students. In addition, medical school enrollment shows greater student diversity. The AAMC notes that this is an important step toward resolving the expected future shortage of physicians. The AAMC represents all of the nation’s 125 accredited medical schools and has called for a 30% increase in medical school enrollment by 2015.


October 23-27, 2006 issue:

Hospitals Provide Preventive Care for Uninsured Patients to Avoid Costly Emergency Care

On October 25th, the New York Times examined efforts by hospitals and healthcare systems to prevent the large costs associated with emergency care for chronic diseases. According to the Times, some hospital officials have determined that it is less expensive to provide free preventive care for uninsured patients with chronic diseases rather than absorb the costs of repeated emergency room visits. For example, New York City’s public Health and Hospital Corporation has assigned about 240,000 uninsured patients to primary care physicians. Although some industry members applaud these efforts, others warn that it is not a long-term solution to the problems of the United States’ fragmented healthcare system.
Continued from page 25


October 30-November 3, 2006 issue:

New NIH Ethics Rules Lead Scientists to Consider New Employment

According to an internal survey at the NIH, nearly 40% of tenure and tenure-track scientists have considered new employment because of the agency’s new ethics rules. NIH implemented the changes last year after a review found that scientists had violated existing restrictions on private consulting deals. The new ethics rules would curtail opportunities to earn outside income. Specifically, NIH employees cannot accept consulting fees from pharmaceutical, biotech or medical device companies, healthcare providers, health insurers, or research institutions sponsored by the agency. In addition, the top 200 NIH officials must maintain holdings at or less than $15,000 in individual pharmaceutical and biotechnology companies, and they must limit investments in healthcare sector funds to $50,000 or less.


Congress Likely to Consider FDA Post-Market Safety Surveillance in 2007

Reform of the FDA is likely to be on the Congressional agenda in 2007. According to a GAO report issued in April, the FDA “lacks a clear and effective process” for tracking safety issues related to approved drugs. Under the current system, drug makers are required to report serious adverse events to the FDA within fifteen days of discovery. Manufacturers must also report other problems quarterly for the first three years after market arrival and annually thereafter. Hospitals, physicians, and individuals also can submit reports. According to an FDA representative, reported events represent only about 10% of the serious side effects that occur annually and only about 1% of total side effects.


New York City to Go “Trans-Fat-Free”?

This week, the New York City Health Board held a public hearing to consider whether the nation’s largest city will go “trans-fat-free.” Under this proposal, the Board could force fast-food restaurants to ban use of fat and require the restaurants to list the calories in their products. Trans fat is made by adding hydrogen to vegetable oil—a process invented in the late 19th century to help lengthen the shelf life of food products. However, the process has negative health effects. In particular, partially hydrogenated oil raises bad blood cholesterol (LDL), while lowering levels of the good cholesterol (HDL).

Although New York would be the first American city to adopt the trans fat ban, Chicago is considering a similar plan to do so.


* Teaching Hospital Updates were compiled by Dana L. Cilla, Esquire, and Leah Romano, Esquire, of Hall Render Killian Heath & Lyman PLLC, Troy, MI.

Role of Attorneys

As I write this, temperatures are dropping and precipitation is becoming more common. We are approaching the holiday season, and the end of the year madness is beginning. I have just read a story regarding allegations that a hospital discharged a homeless patient back to the streets wearing a hospital gown and socks, and a story from the New England Journal of Medicine that discusses the importance of teaching medical students and residents to internalize professionalism. These stories led to a contemplation of the role of the lawyer in organizational culture and accomplishment of mission.

We represent institutional providers of healthcare, which, whether charitable or not, play a significant role in the communities they serve. What is our responsibility, as attorneys, to assist in the fulfillment of the mission and values of the organization? Does the fact that the patient has indeed been stabilized, or did not have an emergency medical condition in the first place, excuse our client’s failure to discharge appropriately? When our clients decide to replace LDR rooms with upscale, private birthing rooms, while failing to address an emergency department which is chronically overburdened, frequently on diversion, and suffering from long “boarding” times, should the attorney speak out? Do we have an obligation which transcends the obligation to give legal advice? I cannot pretend to have the answers, but as we approach winter, when the burdens of homelessness typically become greater, and the holidays, during which we tend to reflect on blessings granted and the coming year, I encourage each of you to consider the questions raised.

Melissa Markey, Esquire
Chair, Teaching Hospitals and Academic Medical Centers
LEGAL ISSUES IN HEALTHCARE FRAUD AND ABUSE, THIRD EDITION!

Legal Issues in Healthcare Fraud and Abuse: 
Navigating the Uncertainties  Third Edition

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- Provides an overview of state counterparts to the federal laws addressing self-referrals, anti-kickback issues, false claims, other statutory authorities, and private initiatives

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