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Information Technology in Health Care and Medicine

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IN THE NEWS: INFORMATION TECHNOLOGY IN HEALTH CARE AND MEDICINE

Predictive Modeling in Identifying Health Care Providers for Audits

Jacob Harper

Predictive modeling, a technique to predict and prevent wasteful or fraudulent spending before it occurs, is the newest and potentially most versatile fraud enforcement scheme ever implemented by the United States Department of Health and Human Services (HHS). Put into use throughout 2011, predictive modeling is intended to allow HHS to predict and confront potential fraudsters before health care fraud occurs, thereby limiting or eliminating the damages against the United States and its health care program funds. Banks and other financial institutions, as well as advertising and marketing agencies, have been using this technology for years with a great degree of success. HHS anticipates that similar results can be achieved in a health care context. In limited instances, HHS and its contractors have already employed predictive modeling through data mining activities for review of provider billings. If a contractor sees that a provider presents questionable billing data, it will commence an audit to further investigate whether the billing and subsequent payment constitutes fraud, waste, abuse, or some other overpayment. This same activity, under predictive modeling, will be conducted before payment is made to a suspected provider. In abandoning the old “pay-and-chase” model, HHS now hopes to lessen the amount of outstanding overpayments due to it, thereby better protecting the Medicare and Medicaid Trust Funds and helping to reduce the impending gap between costs and funding in federal programs.

EMRs and Hospital-Physician Integration

Jacob Harper

The federal government relies primarily on two powerful tools for health care fraud enforcement: the Stark Law and the Anti-Kickback Statute (AKS), codified at 42 U.S.C. § 1395n and 42 U.S.C. § 1320a-7b(b), respectively. These laws, in combination with increased reimbursement rates, incentivize health care providers and hospitals to integrate their practices, but also

create a complex regulatory scheme with which health care providers often struggle to comply. One method to facilitate the integration between a hospital and its associated physicians is to utilize the hospital’s technological infrastructure, including electronic medical record (EMR) system and physical and technological security measures demanded by HIPAA. Although EMRs may raise other concerns in the eyes of an investigator, meaningful use of such a system will tend to prove that a hospital has sufficiently integrated the practice of the employed physicians and that such arrangement is legitimate and reasonable. Moreover, EMR coordination can increase the quality of patient care delivery; coordinated efforts by the physician, hospital staff, and other providers (such as diagnostic and imaging facilities) will generally result in better information, fewer mistakes, and improved patient outcomes.

Sunshine Act Provides Transparency to Financial Relationships

Jeff Wurzburg

Section 6002 of the Patient Protection and Affordable Care Act, known as the Physician Payment Sunshine Act, increases transparency regarding the financial relationships of physicians and teaching hospitals with the manufacturers of any device, pharmaceutical, biological, or medical supply that are sold to public health care programs, such as the Children’s Health Program, Medicare, or Medicaid. The act requires manufacturers to file an annual report that includes all payments or transfers of value that exceed ten dollars made in the prior calendar year. This encompasses, inter alia, consulting fees, honoraria, gifts, entertainment, food, travel, royalties, investment interests, and education.

The act also mandates the disclosure of any financial ownership interest a physician or their family members have in manufacturing companies or group purchasing organizations, therefore benefiting consumers by illuminating potential conflicts of interest. The secretary of Health and Human Services will publish these disclosures on a website, which will enhance

government and public scrutiny of payments. Manufacturers will need to be vigilant in avoiding violations under the Stark Law, federal and state anti-kickback laws, and the False Claims Act.

The Physician Payment Sunshine Act includes several exclusions from the reporting requirement and explicitly preempts any state statutes or regulation. Civil monetary penalties will be assessed for violations. The penalties range from \$1,000 to \$10,000 for each knowing failure to report, with an annual maximum fine of \$1 million dollars. The first report under this act will be due on March 31, 2013.

The EARLY Act Targets Breast Cancer in Women

Jeff Wurzburg

According to the American Cancer Society, that ten thousand women under the age of forty are diagnosed with breast cancer each year. These women confront challenges in addition to the cancer diagnosis, including possible negative impact upon reproductive health. In 2009, Congresswoman Debbie Wasserman Schultz (D-FL), a breast cancer survivor, sponsored the Young Women's Breast Health and Awareness Requires Learning Young Act of 2009 (EARLY Act), (section 10413 of the Patient Protection and Affordable Care Act). This act includes several ambitious targeted objectives to increase awareness of breast cancer among young women.

Section 399NN(a) of the EARLY Act requires the Centers for Disease Control and Prevention (CDC) to create an evidence-based education campaign to increase awareness of breast cancer among women. The act specifies several subjects on which the campaign should focus, including risk factors in women who are "at high risk for breast cancer based on familial, racial, ethnic, and cultural backgrounds."

As a result of the act, the CDC created the Advisory Committee on Breast Cancer in Young Women. This committee is comprised of fifteen members, consisting of medical professionals, researchers, breast cancer survivors, and advocates. The committee already met twice, in January and September of 2011.

Further, to increase knowledge and awareness, the act mandates that the CDC issue grants to create a media campaign oriented to young women and an education campaign directed to health care professionals. In addition, the directors of the CDC and NIH are required to conduct research regarding the prevention of breast cancer in women. The EARLY Act provides an annual appropriation of \$9 million between 2010 and 2014.

New Policy Clarifies Antitrust Enforcement for Accountable Care Organizations

Thomas Kirby

On October 20, 2011, the U.S. Department of Justice and the Federal Trade Commission issued a joint policy statement, the "Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings

Program." An accountable care organization is made of health care providers who jointly offer services to decrease costs and enhance the quality of patient care. The Patient Protection Affordable Care Act encouraged such collaborations between health care providers to innovate and improve care for U.S. consumers, but critics are concerned about the potential for reduced competition resulting from these collaborations, which may actually result in higher prices or lower quality care.

Previously, health care providers faced uncertainty and lack of guidance from antitrust regulators in connection with potential anti-competitive consideration. On the one hand, antitrust law treats any agreement among competitors to allocate markets or fix prices as per se illegal, even if the agreement sets a maximum price. However, U.S. antitrust regulators have explained that joint pricing agreements among health care competitors will be analyzed under the more lenient rule of reason. Under a rule of reason approach, any harm to competition is considered alongside benefits to consumers, and a significant benefit may outweigh a relatively insignificant harm. The antitrust agencies also carved out an antitrust safety zone within which collaborations between competitors are highly unlikely to raise significant antitrust concerns.

This new policy statement clarifies the regulatory environment and provides predictability for health care providers who participate in the new system. U.S. antitrust regulators will continue to protect competition in the markets served by accountable care organizations by using market data compiled by the Centers for Medicare & Medicaid Services while also vigilantly monitoring complaints. Collaborations are covered by this policy irrespective of when they were created, and newly formed accountable care organizations are eligible for a voluntary expedited ninety-day review.

Electronic Medicine

Achieng Rosa Ragwar

As a sign of the times, it is commonplace to see people walking with, talking on, and playing with their smartphones. In an age where electronics are taking our country by storm, we are becoming more digitally interactive. This phenomenon is even going global, as video chat and instant messaging have allowed us to communicate with people all over the world. It is no surprise, then, that the digital world is extending to the realm of health care and may soon be central to the provision of health care services.

The iPhone has brought us revolutionary features such as applications (apps) that enable easier, faster, and more interactive usage. Apps are already being used to track nutrition and fitness and to measure workout regimens. Additionally, "labs on a chip," computer chips that instantly test for bacterial infections and the safety of new drugs, have made their debut. iPhone apps that will allow users to check in with their doctors remotely are currently under development.

Both health care providers and consumers share a mutual interest in digitalized health care. A recent study by the Consumer Electronics

Association revealed that consumers want to communicate with their physicians through wireless devices. This would include sending medical information to their doctor electronically, managing health information online, and consulting with a physician through online video.

Some are crediting President Obama's economic stimulus package for initiating these changes in health care. According to these proponents, the American Recovery and Reinvestment Act, which President Obama signed into law in 2009, allocated \$19 billion to hospitals and physicians to use electronic medical records. The projected move to new age electronics health care is expected to save the country billions of dollars in health care costs over time. Soon, we will see exactly where more advances in technology will move health care innovation.

ACP Releases Position Paper: "Health Information Technology and Privacy"

Julie Dabrowski

The American College of Physicians (ACP), a national organization representing 132,000 internists, recently published a position paper on the ethical use of patient information entitled, "Health Information Technology & Privacy." The ACP paper expresses the

concerns of physicians over the reuse of personal and research data and proposes a rule that would strengthen protections for research subjects while allowing researchers to achieve scientific advances without compromising their ethical obligations. ACP recommends expanding regulations on institutional review board practices to consider the preferences of research subjects whose tissue has been stored. ACP recognizes that further study is required to resolve issues of informed consent related to protected health information and individually identifiable health information associated with existing data and suggests that informed consent documents should clearly disclose whether law enforcement agencies would have access to patients' biobank data. The ACP paper states that various groups—including providers, governmental bodies, consumers, payers, and researchers—should be brought together to draft appropriate data-sharing practices and define consent requirements for research activities. Challenges come with the health care industry's shift from paper to electronic data records, and the ACP strongly suggests that clinical enterprises and clinicians adopt policies and procedures that allow health information to be shared safely and in accordance with patients' preferences. Despite the challenges of moving to a digital health care system, ACP expresses its conviction that widespread adoption of health information technology will significantly improve the quality of health care in America.

INAUGURAL CONFERENCE ON GLOBAL HEALTH, GENDER, AND HUMAN RIGHTS

Presented by

*The Program on Law and Government, American University Washington College of Law;
Pan American Health Organization/World Health Organization (PAHO/WHO); and the
Royal Norwegian Embassy in Guatemala*

*In cooperation with AU Center on Health, Risk and Society; WCL Health Law and Policy Brief; WCL
Health Law and Justice Initiative; WCL Women and the Law Program; WCL Center for Human
Rights and Humanitarian Law; and the AU Center for Latin American and Latino Studies*

SAVE THE DATE

March 21, 2012: 3:30 pm -- 9:00 pm (includes dinner)

March 22, 2012: 8:30 am -- 5:30 pm

American University Washington College of Law
4801 Massachusetts Avenue, NW, Room 603, Washington, DC

- Forum for international experts in global health, gender, and human rights.
- Opening plenary remarks by *Dr. Anand Grover*, the UN Special Rapporteur on the Right to Health.
- Welcome remarks by *Claudio Grossman*, Dean, American University Washington College of Law
- Working groups will produce recommendations on: disabilities/mental health; women/adolescent girls' health; maternal mortality and morbidity; gender identities, expressions and sexual orientation; older persons; neglected diseases; access to medicines; and tobacco control and smoke free environments.
- Working groups will provide an overview with situation analysis by region; share information across international borders within comparative frameworks; review current trends; and highlight public health actions needed in a manner consistent with international human rights treaties and standards.
- Opportunities for networking with participants at dinner, luncheon with keynote speaker.

A full agenda will be available shortly.

Registration is free but required. To register, please go to www.wcl.american.edu/secleregistration
For further information, contact: Office of Special Events & Continuing Legal Education, 202.274.4075 or
seclereg@wcl.american.edu.

*We have arranged for a block of rooms at the special conference rate of \$209 plus taxes at the Courtyard
Marriott Hotel, Chevy Chase. Please make your reservation by going on line to*

[http://www.marriott.com/hotels/travel/wasvy-courtyard-chevy-
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The block of rooms will be held until February 20, 2012.

Health Law and Policy

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