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Health Law and Policy in the News

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The Looming Crisis of Health Care

Jake Harper, First Year JD Candidate

Medicare represents the most critical revenue stream for doctors and hospitals throughout the United States. Medicare funding in 2008 was 20% of all federal spending, or \$599 billion. Because the program is so heavily funded, it has attracted its fair share of abusers of the system.

The federal government has taken many reactive steps to address the surge of fraud and abuse in the Medicare system, reinforced by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA, while enacted to help protect private health information, also was designed to combat health care fraud. HIPAA allocated substantial funds to the Department of Health and Human Services (HHS) through the Health Care Fraud and Abuse Program to implement more effective anti-fraud measures. Currently, hundreds of millions of dollars are used to fight Medicare fraud. HHS has created special entities designed solely to address fraud over the past few years, including Recovery Audit Contractors, Program Safeguard Contractors and Zone Program Integrity Contractors and, as well, strengthened FBI and HHS fraud investigative units.

Why, then, is there still a crisis looming for our health care system? Simply put, these anti-fraud programs have also swept up many well-meaning providers during their reviews, driving legitimate doctors, clinics and hospitals out of business. Medicare contractors utilize data mining, where they review claims data to identify outliers. With a myriad of ways to review the data, nearly every provider can become an outlier in some respect. Once selected for review, a health care provider then undergoes the extremely difficult audit process, which may result in massive penalties and overpayments, or even complete exclusion from the Medicare program by the HHS Office of Inspector General. Many doctors fear these audits, and others are simply choosing to opt out of Medicare, thereby rejecting Medicare patients altogether. This trend is not only rising, but accelerating. With the federal government taking an even greater role in health care in the coming years, substantial reform in identifying and prosecuting fraudulent activities is warranted.

Electronic Medical Records: Too Much Too Soon?

Jake Harper, First Year JD Candidate

Electronic medical records (EMR) are the future of health care and undoubtedly will someday help improve the quality of care for patients. But before backing the full implementation of EMR, it is important to consider some of its shortcomings and inadequacies.

The most startling concern for both patients and providers is the potential breach of security and privacy to which EMR is susceptible. Americans have long feared the unapproved use of their personal health information, a sentiment embodied in the HIPAA. Additionally, the widespread use of the Internet in recent years has led to a sharp increase in identity theft, particularly of medical information. With EMR emerging as the preferred choice for medical documentation, those involved must first be sure that the system is adequately secure. This becomes especially problematic when attempting to integrate the security and compatibility of numerous independently-developed software platforms. While the HHS Office of the National Coordinator for Health Information Technology is expected to remedy this problem, EMR is currently easy for unauthorized individuals to access. Moreover, EMR multiplies the number of people with access to a patient's records (providers, clinics, hospitals, billers, insurers and auditors) from about 120 interventions with paper records to over 600,000 through EMR. Until these privacy problems are addressed, patients and doctors alike should remain cautious about the use of EMR.

Aside from the privacy issue, the cost-benefit of EMR has not been affirmatively established, especially for individual doctors and clinics. While billions of dollars in savings have been projected through the implementation of EMR, the costs of purchasing, training and beginning "meaningful use" of EMR are generally too high for individual providers. Though the government has incentivized the program to some extent through the HITECH Act, part of the ARRA (the stimulus law), the current rewards and penalties are insufficient for doctors to justify the cost, even from a purely economic standpoint. Until standard

programs and procedures for EMR are established, with little to no upfront cost to those mandated to use it, it is unlikely that the implementation of EMR will be as successful as proponents have forecasted.

The Children's Health Insurance Battle

Krista Maier, Third Year JD Candidate

The battle over children's health insurance coverage is in full swing. It began in September, when major health insurers, including WellPoint, CIGNA and CoventryOne, announced that they will no longer offer child-only plans. This announcement came days before the start of the Patient Protection and Affordable Care Act's (PPACA) prohibition against denying health coverage for people with pre-existing medical conditions. The insurance companies stated that uncertainty in the market and fear that parents will wait until their children get sick before buying health insurance led to the decision to drop these plans. Advocacy groups and the HHS believed, however, that the move was a way to avoid providing new policies for sick children.

In October, HHS Secretary Kathleen Sebelius struck back. In a letter to the National Association of Insurance Commissioners (NAIC), Sebelius criticized the arguments that the insurance companies are relying on to deny coverage to children, stating that they are "legally infirm" and inconsistent with the language of PPACA. Sebelius outlined other ways to counter potential adverse selection: the premise that, if only sick people buy health insurance, an insurance company's costs will increase greatly. Most of Sebelius' suggestions are temporary fixes until the state health insurance exchanges are up and running in 2014—including the suggestion that insurers may adjust rates for children's plans based on health status, a policy which will be prohibited by PPACA for new plans starting in 2014. Sebelius also urged states to continue to regulate "discrimination against children" with pre-existing conditions.

So now, the proverbial ball is back in the insurance industry's court. Time will tell whether they accept Sebelius's suggestions, or develop their own solution to the children's health insurance issue.

Controlled Substance Prescriptions Now Allowed in Take-Back Programs

Krista Maier, Third Year JD Candidate

According to a 2009 Department of Justice report, crimes associated with controlled prescription drugs have increased nationwide over the past five years. In addition, the Office of National Drug Control Policy reported that, in 2008, one-third of all new prescription drug abusers were between ages 12 and 17. In an effort to limit access to prescription drugs, many states have implemented their own drug disposal programs, also called "take-back" programs. Through these programs, the state collects and destroys unused or expired medications, limiting teens' access to these medications in their homes.

Even with such programs in place, abuse of controlled prescription drugs continues to increase in the U.S. This is due in part because these programs generally do not accept controlled substances, such as amphetamine, morphine and codeine, as federal law requires special permission from the Drug Enforcement Administration and full-time police officers to receive the medication. To address this, President Obama signed into law the Secure and Responsible Drug Disposal Act of 2010 (S.3397). This law modifies existing controlled substances law, allowing people who have legally obtained a controlled prescription drug to bring that drug to a disposal program without advance permission. The law requires the Attorney General to provide regulations for controlled substance take-back programs, considering both public health and safety, and also the costs of implementing such programs.

In addition, the law allows long-term care facilities to dispose of their residents' controlled substances on their behalf, subject to guidelines from the Attorney General. Finally, the law also allows people who are authorized to dispose of a decedent's property to bring the decedent's controlled prescription drugs to a take-back program.

The “Stem Cell Age”

Kirsten Tullia, Second Year JD Candidate

With the first FDA license to use cell-based treatment in hand, Geron, a pharmaceutical and biologics manufacturer, began treatment on the first patient to receive human embryonic stem cells on October 11, 2010. Although Geron has not released many details concerning the procedure, the basic premise is that patients with spinal cord injuries will be injected with oligodendrocyte precursor cells, grown from human embryonic stem cells, in the hope that these new cells will regenerate damaged tissue. In this early phase of stem cell treatment, the aim is to determine the safety of the procedure rather than its efficacy.

This procedure is not without its risks, however. Embryonic stem cells are undifferentiated “master cells,” leaving them capable of becoming any of the hundred of cell types in the human body –including cancer cells. Early tests using embryonic stem cells to treat Parkinson’s disease met a grisly end when the cells reproduced at an uncontrolled rate and actually worsened the patients’ muscle control problems. In order to lower the risk of unmitigated growth, Geron’s researchers first ensured that the cells were differentiated into normal tissue before giving them to patients.

There are also important policy implications in embryonic stem cell implantation. Critics of embryonic stem cell research believe it is wrong to use an embryo to obtain the cells. President George W. Bush placed strict limitations on their use during his presidency. President Barack Obama loosened these limitations just weeks after he took office, allowing researchers to use embryonic stem cells from human embryos left over from fertility treatments.

Despite the controversial nature of the treatment, embryonic stem cell treatment is a huge step forward for those who suffer from degenerative diseases such as Parkinson’s and muscular dystrophy. As Professor Pete Coffey of University College London said, “There are still many years of rigorous testing ahead and there will be setbacks and failures before we have safe and effective cell-based therapies. But this first in man study marks the dawn of the ‘Stem Cell Age’.”

Privacy in Hospital Rooms

Kirsten Tullia, Second Year JD Candidate

In response to a growing patient demand for private rooms, a number of local Washington, DC, area hospitals have already converted or are in the process of converting their facilities to all private rooms. One notable entity pushing for private patient rooms is Inova Fairfax Hospital, the largest hospital in Northern Virginia and the only Level 1 trauma unit in the Northern Virginia area. Inova Fairfax’s expansion calls for a new general hospital tower comprised of private rooms and a new women’s hospital. These renovations will cost approximately \$161 million dollars, which Inova Fairfax plans to fund through debt and some use of cash reserves. Interestingly, however, this building expansion will not drastically increase the capacity of these already large hospitals. Inova Fairfax’s construction plan, for example, will cost approximately \$161 million dollars but only will produce about 174 new private rooms.

Hospital officials presented many different reasons for these changes, including fewer cases of infection and more space for medical equipment. Roger Ulrich from Texas A&M University has a different opinion: “The attitude of viewing patients as objects has shifted. Hospitals are now in the consumer service business.” With the passage of the Patient Protection and Affordable Care Act last winter and its first provisions coming to life just a few months ago, the American public is quickly becoming more versed in health issues, and is demanding more from its providers as a direct result of this knowledge. While the push for private rooms predates the Affordable Care Act, we can expect to see more action on the part of health care providers as they rise to the challenge of the new American health care consumer.

A Provision of Health Care Reform: Positive or Negative For People with Disabilities?

Gary C. Norman, Esq., LLM Candidate

The Patient Protection and Affordable Care Act of 2010 (PPACA) spurs the federal government into action by requiring a rulemaking on health care service delivery for people with disabilities by The Architectural and Transportation Barriers Compliance Board (commonly known as The U.S. Access Board). Section 4203 of the PPACA requires the promulgation of a new subsection of the Rehabilitation Act of 1973 to address the barrier of inaccessible diagnostic medical equipment.

The Board must promulgate standards on medical diagnostic equipment within twenty-four months after enactment, in consultation with the Food and Drug Administration and in accordance with the Administrative Procedures Act. Under the new standards, to the maximum extent possible, people with disabilities should be able to independently utilize—transfer to and from, enter and exit from—an array of examination chairs and tables in medical settings such as hospital emergency rooms. Mammography equipment is an example of the type of equipment specifically mentioned in the provision. Women with

disabilities, especially mobility impairments, have also historically been victims of inaccessible gynecological exam equipment.

The requirements under section 4203 of the PPACA help to reveal a gap in current health care service delivery to more than fifty-four million citizens. Once these standards are enacted it will not a priori mean that providers will comply. Currently, the PPACA contains insufficient enforcement authority. Lacking is a clear indication of who has enforcement authority; as well, the PPACA does not provide sufficient appropriations for training on the standards. Since the PPACA designates the U.S. Access Board to formulate accessibility standards, many presume that the Board will also have enforcement authority on such standards. However, the Board is not an agency, and is best described as an advisory body or an information clearinghouse on accessibility issues. If the Board does not become the enforcement authority the next logical choice is the Office of Civil Rights at the United States Department of Health and Human Services.

Only time will tell if these standards constitute a valuable mechanism for improving the quality of health care for people with disabilities.