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Health Law Washington Beat: Recent Health Industry News

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HHS Selects Boston Physician as National Coordinator for Health Information Technology

The Department of Health and Human Services (HHS) announced on March 20, 2009 that David Blumenthal, M.D., M.P.P. is the Obama Administration's choice for National Coordinator for Health Information Technology. As the National Coordinator, Dr. Blumenthal will lead implementation of the American Recovery and Reinvestment Act's mandate for a national interoperable, privacy-protected health information technology infrastructure. He will head the Administration's efforts to build health IT, using nearly $20 billion from the economic stimulus package.

Dr. Blumenthal's qualifications for the post include years of national and state leadership positions in the fields of health policy and health information technology. Most recently, Dr. Blumenthal served as a physician and director of the Institute for Health Policy at The Massachusetts General Hospital/Partners HealthCare System and as a professor of medicine and health policy and management at Harvard Medical School. Dr. Blumenthal also gained recent experience with national health issues while serving as a senior health adviser to the Obama for America campaign. In that capacity, he focused on, among other things, the dissemination of health information technology, quality management in health care, and access to health services.

Federal Coordinating Council for Comparative Effectiveness Research Named

HHS has announced fifteen members of the new Council for Comparative Effectiveness Research (the "Council"). As part of the American Recovery and Reinvestment Act of 2009[1] (the

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"Act"), Congress provided $1.1 billion for comparative effectiveness research and authorized the development of the Council "to conduct or support research to evaluate and compare the clinical outcomes, effectiveness, risk, and benefits of two or more medical treatments and services that address a particular medical condition." Comparative effectiveness research evaluates various medical interventions to determine their relative strengths and weaknesses in order to allow clinicians and patients to make informed decisions that will improve the performance of the U.S. health care system.

The Council will assist the federal government to coordinate comparative effectiveness and related health services research. HHS has said that the Council will not recommend clinical guidelines for payment, coverage, or treatment, but instead will consider the needs of those served by federal programs and opportunities to expand on current investments and priorities.

Twelve of the fifteen Council members are from HHS; the remaining three members come from the Veterans Administration, the Department of Defense, and the Office of Management of Budget. The Council will hold a public listening session on April 14, 2009, and it is required by the Act to submit a report to Congress no later than June 30, 2009 that describes the current federal activities on comparative effectiveness research and makes recommendations for research conducted or supported from federal funds dedicated to such research.

Nominees for Key Posts Indicate Commitment of Administration to Food and Drug Safety

On March 14, 2009, President Obama nominated Dr. Margaret Hamburg to lead the United States Food and Drug Administration (FDA) and Dr. Joshua Sharfstein to be her deputy. Dr. Hamburg is a physician and a bioterrorism expert who led the New York City Health Department when the city was battling an outbreak of drug-resistant tuberculosis. She also served as an assistant health secretary under President Clinton in the late 1990s. Dr. Sharfstein, currently health commissioner for the city of Baltimore, is a pediatrician who pushed the FDA for new labeling requirements to restrict the use of over-the-counter cold medicines for young children. The nominations have been well-received by individuals, consumer groups, industry groups, and others across the political spectrum.

The selection of Drs. Hamburg and Sharfstein demonstrates President Obama's commitment to improving food and drug safety in the United States. The FDA has faced harsh criticism in the wake of recent food poisoning outbreaks and questions surrounding drug safety. In furtherance of the goal of revamping the FDA and its mission, the president has pledged to request $1 billion in increased funding to help modernize the food safety system and to hire new inspectors. President Obama also announced his intention to assign the new HHS Secretary and Agriculture Secretary to lead a food safety working group in an effort to upgrade the nation's food safety laws.

OIG Issues Guidance on Free Local Transportation

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On March 13, 2009, the HHS Office of Inspector General (OIG) issued an advisory opinion (Advisory Opinion No. 09-01) analyzing the propriety of a complimentary local transportation program for friends and family of the residents of a skilled nursing facility. The OIG concluded that the program would not constitute grounds for civil monetary penalties (CMP) or result in administrative sanctions even though the Anti-kickback Statute may be implicated.

According to the Requestor, a nonprofit skilled nursing facility (SNF), its facility is not easily accessible by public transportation and requires visitors to cross a $9.00 toll bridge. The free transportation program proposed by the SNF will use a company-owned, employee-driven van to bring friends and family of its residents to the facility and drop them off only at designated public locations within the SNF's primary service area. The program will be offered uniformly to all residents' friends and family and without regard to the residents' income, source of payment, or level of care received. Neither passengers nor third party payors will be charged for the transportation, which is estimated to cost more than $50 annually per household, and the costs related to the program will not be claimed directly or indirectly on any federal health care program cost report or otherwise shifted to a federal health care program. Finally, the program will be advertised only in local newspapers and in written materials distributed to patients by discharge planners at hospitals located in the SNF's primary service area.

In analyzing the program, the OIG first set forth some "general observations" relevant to an analysis of free transportation programs offered by providers to potential referral sources of federal health care program business (including beneficiaries who self-refer). While recognizing that free transportation can be beneficial to patient care when narrowly tailored to address financial need, limited transportation availability, or safety, the OIG indicated that such programs can also lead to fraudulent schemes involving inappropriate patient steering, overutilization, or the provision of medically unnecessary services. Factors indicative of a potentially abusive arrangement include:

- transportation related to referrals, such as selecting passengers based upon their treatment or condition;
- transportation to or from locations outside of the facility's geographic area or to or from locations other than the facility;
- availability of other means of transportation;
- luxury transportation;
- marketing or advertising of the service; and
- treatment of the costs of the free transportation in a manner that shifts the costs to a federal healthcare program.

The OIG concluded that although the Anti-kickback Statute and CMP law were potentially implicated because the value of the transportation per household may exceed $50 annually,[2] the program poses a low risk of fraud and abuse. The OIG noted the following factors: (i) the transportation will not be provided to residents in exchange for federal health care program business or for the benefit of the SNF's referral sources; (ii) federal health care program beneficiaries will not be targeted; (iii) the transportation will be reasonable and only offered and marketed locally; (iv) the program is consistent with the SNF's mission to provide facility access to residents' friends and family; and (v) no costs will be shifted to a federal health care program.

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Advisory Opinion 09-01 provides helpful guidance on the topic of complimentary transportation, which the OIG had previously addressed in Advisory Opinion 00-07 (November 17, 2000) and in a December 10, 2002 letter, in which the OIG offered protection from administrative sanctions to those free transportation programs that were in existence prior to August 30, 2002 and met certain requirements. That letter also indicated that the OIG was considering developing a regulatory exception under the CMP law for certain complimentary local transportation of higher value offered to beneficiaries residing in a provider's primary service area, but no such exception has since been implemented or proposed.

Endnotes

[1] Pub. L. No. 111-5.

[2] The OIG found that the likelihood that the program might induce a passenger to choose the SNF as his provider in the future is too remote to constitute an impermissible inducement here. Thus, the OIG focused on the aggregate value of the program as the factor that can potentially implicate the Anti-kickback Statute and the CMP law. The OIG has previously taken the position that "incentives that are only nominal in value are not prohibited by the statute" and has interpreted "nominal value to be no more than $10 per item, or $50 in the aggregate on an annual basis." 65 F.R. 24400 (April 26, 2000).

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