Health Law Washington Beat: Recent Health Industry News - Issue 8

4/30/2009

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Senate Approves Sebelius to Head HHS

Following a full day of debate, by a vote of 65 to 31, the Senate approved the nomination of Kathleen Sebelius to head the Department of Health and Human Services (HHS) by a vote of 65 to 31. The approval came on the eve of President Obama's 100th day in office and filled the final seat in his Cabinet.

Although Democrats had sought a quick vote in order to move ahead with health care reform, Republicans slowed Sebelius' advancement because of her record in favor of abortion rights and comparative effectiveness research. When Sebelius testified before the Senate Finance Committee on April 2, 2009, eight of the ten Committee Republicans challenged Sebelius' nomination due to concerns about her support of comparative effectiveness research, a tool that supporters believe will increase the use of evidence based medicine and that critics believe will lead to government interference with the doctor-patient relationship. Several Republicans also cited Sebelius' relationship with a Kansas physician who performs late-term abortions and who donated almost $40,000 to Sebelius' campaigns as a reason for challenging the nomination.

Republican objections faded, however, amid the recent outbreak of swine flu and the threat of a global pandemic. Senator Mark Warner (D-VA) noted that having a strong HHS Secretary in place is essential for the health of the nation and to ensure that federal efforts on this potential pandemic are able to coordinate.

Immediately after the Senate vote, Sebelius resigned as governor of Kansas and headed to Washington where she took the oath of office last night.

14 Warning Letters: Old Requirements Applied to a New Medium

On April 2, 2009, the U.S. Food and Drug Administration (FDA) released 14 Warning Letters issued to drug manufacturers in late March regarding their use of sponsored links on various Internet search engines. The most common citations included in these Warning Letters were: (1) failure to use the full established name of the drug in the ad; (2) failure to include risk information about the drug; and (3) inadequate communication of the drug's indication (*i.e.,* the brief statement about the drug's use did not include its limitations).

Given the FDA's detailed requirements for the content of promotional material, and the small number of characters that search engines permit to be included in sponsored links, it is nearly impossible for sponsored-link ads to be both useful and compliant with the law. The manufacturers believed that the ads complied with the law because of the "one-click rule." That is, all of the FDA-required information was only "one click" away — no different, really, than having to turn the page of a magazine to read the risk information. However, as demonstrated by the agency's issuance of these Warning Letters, the FDA has not actually adopted a one-click rule. Instead, the FDA concluded that these sponsored links misbranded the drugs being promoted and requested that the companies immediately cease dissemination of such promotional materials.

In a podcast posted to the Eye on FDA website a few days before the Warning Letters were issued, Dr. Jean Ah Kang, Special Assistant to Tom Abrams at the FDA's Division for Drug Marketing, Advertising and Communications (DDMAC), emphasized that the FDA regulates the message, not the medium. In other words, the regulated entity (the manufacturer) is responsible for compliance; the FDA cannot require Google to have longer sponsored link options. Dr. Kang recognized that social media is here to stay, but would not comment on the FDA's plans (if any) for adapting the current promotional requirements to fit the newer media, which include not only sponsored links on search engines, but also promotional material that may appear on YouTube, Twitter, and other outlets that may arise in the future.

For now, the manufacturers have removed the targeted sponsored links and are working to develop search ads that comply with the Warning Letters, such as ads and web addresses that do not include the product's brand name. It remains to be seen whether the FDA will ultimately take another look at instituting a rule similar to the one-click rule or issue some other form of guidance applicable to Internet marking. In the meantime, the safest method to ensure compliance for companies wishing to take a more innovative approach to marketing is to request advisory comments on draft proposals from DDMAC, which is the process suggested by Dr. Kang in the podcast cited above.

DEA Proposes Regulations Implementing the Online Pharmacy Consumer Protection Law

The Drug Enforcement Administration (DEA) recently promulgated regulations ("Regulations") to implement the Ryan Haight Online Pharmacy Consumer Protection Act ("Ryan Haight Act"),[1] which was enacted on October 15, 2008.[2] The Regulations became effective April 13, 2009, except for a definition of the "practice of telemedicine."

The Regulations closely track the Ryan Haight Act, and impose two central requirements: (i) online pharmacies must modify their registration with DEA, and (ii) no controlled substance may be delivered, distributed, or dispensed by means of the Internet without a valid prescription — which includes an in-person medical evaluation. The Regulations include several noteworthy provisions:

- **Online pharmacy registration and reporting:** In addition to requiring "online pharmacies" to modify their DEA pharmacy registration, the Regulations also impose several reporting and disclosure requirements upon online pharmacies.
- **Online pharmacy defined:** The definition of an "online pharmacy" is very broad. It means "a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet."
- **Valid prescriptions require in-person medical evaluation:** A "valid prescription" means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by (i) a practitioner who has conducted at least one in-person medical evaluation of the patient, or (ii) a covering practitioner.
- **Telemedicine exception:** The requirement of an in-person medical evaluation does not apply to the "practice of telemedicine." The Regulations provide both temporary and permanent definitions of the "practice of telemedicine."
    - The temporary definition largely incorporates current law and applies until DEA (with the concurrence of the Secretary of HHS) promulgates regulations providing for special registration to practice telemedicine, or until January 15, 2010, whichever comes first.
    - The permanent definition defines seven categories of practice that constitute the practice of telemedicine, including a category for special registration to practice telemedicine. The additional regulations providing for special registration with be forthcoming from DEA.

DEA will accept comments on the Regulations postmarked on or before June 5, 2009.

CMS Proposes Lowering Reimbursement Amounts and Increasing Certification Responsibilities for Hospices

The Centers for Medicare & Medicaid Services (CMS) has proposed to decrease reimbursements to hospices by 1.1 percent in fiscal year 2010. The cuts result from the phase-out of the budget neutrality adjustment factor (BNAF) used in calculating the Medicare Hospice Wage Index. CMS believes that eliminating this adjustment will result in more accurate payments and will save Medicare $2.9 billion over five years.

Last August, CMS finalized a rule to phase out the BNAF over a three-year period, with a 25 percent reduction in 2009, an additional 50 percent reduction in 2010, and a complete phase-out of the BNAF in FY 2011.[3] Although the American Recovery and Reinvestment Act of 2009 (ARRA) eliminated the BNAF phase-out for 2009, it did not change the cumulative 75 percent reduction achieved in the BNAF for 2010, nor its entire elimination for 2011. CMS suggests that the ARRA "provided the hospice industry additional time to prepare for" the impending reduction in payments. CMS invites comments on the BNAF reductions for 2010.

In addition, as recommended by the Medicare Payment Advisory Committee (MedPAC), CMS proposes to require physicians to write a "short narrative" describing the patient's clinical condition for every certification or recertification for hospice care in order to receive Medicare reimbursement. Currently, physicians must only certify that patients have a life expectancy of six months or less to receive Medicare payments under the hospice benefit. CMS seeks comments on this proposal and other proposed changes, such as requiring a physician or nurse practitioner to visit every hospice patient after 180 days, and every benefit period thereafter.

CMS will accept comments on the proposed rule until June 22nd.

FTC Publishes Proposed Breach Notification Rules for Personal Health Record Vendors

On April 17, 2009, the Federal Trade Commission (FTC) proposed new rules implementing Section 12407 of ARRA. The rules apply to vendors of personal health records (PHRs) and providers of online applications that interact with PHRs or offer services through the website of a PHR vendor ("PHR-related entities"). Examples of PHR-related entities include web-based applications that help consumers to manage medications or websites offering online personalized health checklists. The rules also apply to third parties providing services to PHRs and PHR-related entities.

The rules require vendors of PHRs and PHR-related entities to notify consumers when the security of their electronic health information is breached. The rules also require third party service providers to notify PHR vendors or PHR-related entities of breaches, so that they may in turn notify consumers.

The proposed rules contain requirements governing the standard for what triggers the notice, as well as the timing, method, and content of the notice. The rules also require PHR vendors and PHR-related entities to notify the FTC of any breaches. The FTC will post information about breaches on its own web site, and will also notify the Secretary of HHS.

The rules do not apply to HIPAA covered entities or to organizations serving in the role of a business associate of a HIPAA covered entity. These organizations are subject to similar breach notification requirements under ARRA, but they will be subject to HHS rather than FTC enforcement.

It is also important to note that the rules apply to breaches of "unsecured" health information or information that is not protected in accordance with guidance issued by HHS under ARRA. HHS is proposing that health information be secured by encryption if it is in use. If the information is no longer needed, HHS proposes that it be destroyed in one of the following ways:

- paper, film or other hard copy media must be shredded or otherwise processed so that the health information cannot be read or reconstructed; and
- electronic media must be cleared, purged or destroyed consistent with National Institute of Standards and Technology *Guidelines for Media Sanitization*.

HHS's proposed guidance is available here.

Public comments on the rules regarding unsecured health information are being accepted through June 1, 2009, and comments on the security guidance are being accepted until May 21, 2009.

GAO Announces Appointments to Health Information Technology Policy Committee

Fulfilling its obligations under ARRA, the U.S. Government Accountability Office (GAO) announced on April 3, 2009, the appointment of 13 members to the Health Information Technology Policy Committee ("HIT Policy Committee"), a new advisory board established under ARRA. The HIT Policy Committee will be responsible for making policy recommendations to David Blumenthal, the newly appointed National Coordinator for the Office of National Coordinator for Health Information Technology (ONCHIT), relating to the adoption and implementation of a nationwide health information technology infrastructure that permits the electronic exchange and use of health information.

ARRA directed the Comptroller General to appoint 13 members to the HIT Policy Committee for terms of three years, although the members first appointed have staggered terms, as listed below. An additional seven members will be appointed by the Secretary of HHS, the Majority and Minority Leaders of the Senate, and the Speaker and Minority Leaders of the House of Representatives. The President can appoint other members as representatives of relevant federal agencies.

The 13 members the Comptroller General has appointed across 10 different categories are:

Advocates for Patients or Consumers

1. Christine Bechtel, Washington, D.C. (3-year term) – Vice President, National Partnership for Women & Families

2. Arthur Davidson, M.D., Denver, Colorado (2-year term) – Denver Public Health Department; Director, Public Health Informatics; Director, Denver Center for Public Health Preparedness; medical epidemiologist; Director, HIV/AIDS Surveillance, City and County of Denver

3. Adam Clark, Ph.D., Austin, Texas (1-year term) – Director of Research and Policy, Lance Armstrong Foundation

Representatives of Health Care Providers, including one physician

4. Marc Probst, Salt Lake City, Utah (3-year term) – Chief Information Officer, Intermountain Healthcare

5. Paul Tang, M.D., Mountain View, California (2-year term) – Vice President and Chief Medical Information Officer, Palo Alto Medical Foundation

Labor Organization Representing Health Care Workers

6. Scott White, New York City, New York (1-year term) – Assistant Director, Technology Project Director, 1199 SEIU Training and Employment Fund

Expert in Health Information Privacy & Security

7. LaTanya Sweeney, Ph.D., Pittsburgh, Pennsylvania (3-year term) – Director, Data Privacy Lab, Associate Professor of Computer Science, Technology and Policy, Carnegie Mellon University

Expert in Improving the Health of Vulnerable Populations

8. Neil Calman, M.D., New York, New York (2-year term) – President and CEO, The Institute for Family Health, Inc.

Research Community

9. Connie Delaney, R.N., Ph.D., Minneapolis, Minnesota (1-year term) – Dean, School of Nursing, University of Minnesota

Representative of Health Plans or Other Third-Party Payers

10. Charles Kennedy, M.D., Camarillo, California (3-year term) – Vice President, Health Information Technology, Wellpoint, Inc.

Representative of Information Technology Vendors

11. Judith Faulkner, Verona, Wisconsin (2-year term) – Founder, CEO, President, and Chairman of the Board, Epic Systems Corporation

Representative of Purchasers or Employers

12. David Lansky, Ph.D., San Francisco, California (1-year term) – President and CEO, Pacific Business Group on Health

Expert in Health Care Quality Measurement and Reporting

13. David Bates, M.D., Boston, Massachusetts (3-year term) – Medical Director for Clinical and Quality Analysis, Chief of General Internal Medicine, Partners HealthCare/Brigham & Women's Hospital

Endnotes

[1] The Ryan Haight Act amended two existing laws regulating controlled substances: the Controlled Substances Act and Controlled Substances Import and Export Act.

[2] Implementation of the Ryan Haight Online Pharmacy Protection Act of 2008, 74 Fed. Reg. 15,596 (Apr. 6, 2009).

[3] 73 Fed. Reg. 46,464 (Aug. 8, 2008).

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