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Health Law Washington Beat: Recent Health Industry News

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Mintz Levin's Health Law Practice has assembled the following overview of recent issues and developments that affect the health industry and that will continue to take center stage during the coming months. Clicking on the titles below will link you to each summary announcement.

In This Issue

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Obama Reiterates His Promise to Revitalize Health Care

In his inaugural address on Tuesday, January 20th, President Barack Obama reiterated his pledge to overhaul America's health care system and to increase the use of health care technology. In his brief reference to health care, Obama stated, "We will restore science to its rightful place, and wield technology's wonders to raise health care's quality and lower its cost."

Obama's health care message is consistent with his campaign promise to revamp America's health care system through new and expanded government programs and widespread use of electronic health record (EHR) technology. Indeed, the proposed economic stimulus package will set aside billions of dollars to support the adoption of health information technology (IT), and thus facilitate Obama's plan to spend $50 billion over five years to ensure that all Americans have EHRs by the year 2014.

Just days before Obama's inauguration, on January 15th, the House Ways and Means Committee released details about a $825 billion economic stimulus bill called the "American Recovery and Reinvestment Act of 2009," which includes $20 billion for health IT and creates incentives for doctors to adopt EHR technology. On January 21st, the House Appropriations Committee voted 35 to 22 to approve $358 billion for health IT and community health centers.

Meanwhile, consumer advocates and some legislators argue that stricter privacy protections must be adopted before the nation can attain Obama's goal of securing EHRs for all Americans. House Ways and Means Committee Chairman Pete Stark (D-CA), for instance, has drafted legislation that would establish a federal breach notification requirement for health IT and allow patients to request an audit trail displaying all electronic disclosures of their health information. Representative Edward Markey (D-MA) and Senators Patrick Leahy (D-VT) and Olympia Snowe (R-ME) are also urging Congress to include medical privacy and safety provisions in the stimulus package. Senator Barbara Mikulski (D-MD) has stated that the Senate Appropriations Committee will likely review the House economic stimulus bill by February, but she has not provided details about funding for health IT.

CMS Issues Interim Final Rule Implementing Required Changes to DMEPOS Bidding Program

The Centers for Medicare & Medicaid Services (CMS) has announced that it will continue to reimburse suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) under the Medicare fee schedule, at least for now, and that it will ease the financial documentation requirements for suppliers participating in the competitive bidding process. CMS issued the interim final rule on January 16, 2009 to implement certain provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) that affect the DMEPOS Competitive Acquisition Program (the "Program"). The rule becomes effective on February 17, 2009, and comments must be received by CMS no later than March 17, 2009.

Under the Program, Medicare sets payment amounts for selected DMEPOS items and services furnished to beneficiaries in competitive bidding areas based on bids submitted by qualified suppliers and accepted by Medicare. The new payment amounts replace the fee schedule methodology. Congress directed CMS to phase in the Program beginning with 10 of the largest metropolitan statistical areas (MSAs) in 2007. The Program was to be expanded into 70 additional MSAs in 2009, and additional areas thereafter. In 2007, CMS began implementing the Program by conducting the first round of competition in ten of the largest MSAs. The bidding window opened on May 15, 2007, and CMS awarded over 329 contracts to qualified suppliers. CMS implemented the Program on July 1, 2008.

On July 15, 2008, just two weeks after CMS implemented the Program, Congress enacted MIPPA. Section 154(a) of MIPPA delayed competition under the Program and terminated the competitive bidding contracts effective June 30, 2008—thus effectively reinstating the fee schedule payment methodology for the competitively bid items and services—and required CMS to conduct a second Round 1 competition (the "Round 1 rebid") in 2009. The Round 1 rebid will include the same items and services and will be conducted in the same areas as the Round 1 competition with certain limited exceptions. For example, Puerto Rico, one of the 10 original MSAs, is excepted from the Round 1 rebid, as are negative pressure wound therapy items and services. Section 154(a) also permanently excluded Group 3 complex rehabilitative wheelchairs from the Program by amending the definition of "items and services."

The interim final rule implements the above MIPPA requirements and also delays competition for Round 2 of the Program from 2009 to 2011 and subsequent competition under the Program from 2009 until after 2011. The interim final rule also implements certain changes to the bidding process required by MIPPA:

- CMS must notify suppliers who submit their bids within a specific time period if their bid submission is missing any of the required financial documents;
- suppliers who are awarded a contract under the Program must disclose information to CMS on each subcontracting relationship, including whether each subcontractor meets applicable accreditation requirements; and
- hospitals are exempted from the Program when they furnish certain types of competitively bid DME, such as crutches, walkers, and canes, to their own patients during an admission or on the date of discharge.

CMS has also stated that it will require only one year of requested financial documentation rather than the three years requested under the initial Round 1 bidding process.

CMS Issues Proposed Rules for CLIA and Cytology Proficiency Testing

On January 16, 2009, CMS published a proposed rule ("Proposed Rule") changing the cytology proficiency testing requirements under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The proficiency tests apply to laboratory technicians who screen results of Papanicolaou tests, a common test for cervical cancer.

The Proposed Rule includes a number of significant changes. First, CMS would reduce the frequency of proficiency testing and require a test every two years, rather than every year. Second, the Proposed Rule would require technicians to screen 20 slides during each challenge, an increase from the current 1-slide requirement. Third, proficiency tests could utilize new technologies, such as digital images.

CMS is accepting comments on the Proposed Rule until 5:00 pm on March 17, 2009.

OHRP Published New Registration Requirements for IRBs

The Office for Human Research Protections published new registration requirements for institutional review boards (IRBs) and expanded the amount of information to be collected from the registering IRBs. For more information, see Mintz Levin's Health Law Alert.

CMS Finalizes Medicare Part D Negotiated Pricing Regulation and Additional Remaining Provisions to Medicare Advantage and Part D Programs

CMS recently published a final rule with comment period that includes significant changes to the regulations governing the Medicare Advantage and Prescription Drug Benefit Programs. For more information, see Mintz Levin's Health Law Alert.

HHS Published Final Rule Revising and Adding HIPAA Electronic Transaction Standards

On January 16, 2009, the U.S. Department of Health and Human Services (HHS) published a rule (the "Final Rule") finalizing certain modifications and additions to the electronic transactions standards (the "Transaction Standards") originally adopted under the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA.)[1] Among other things, this Final Rule made two notable changes. First, the Final Rule updated the current Transaction Standards. Second, the Final Rule added new standards for certain electronic transactions related to pharmacy services.

By way of background, the HIPAA Transaction Standards apply to administrative transactions conducted electronically between certain entities, including HHS, health plans, health care clearinghouses, and certain health care providers. The original Transaction Standards (Version 4010, published on August 17, 2000) adopted standards for eight core electronic transactions and for code sets to be used for the following transaction types:

- health care claims or equivalent encounter information;
- health care payment and remittance advice;
- coordination of benefits;
- eligibility for a health plan;
- health care claims status;
- enrollment and disenrollment in a health plan;
- referral certification and authorization; and
- health plan premium payments.

The updated Transaction Standards (Version 5010) modify and replace the current standards. HHS adopted Version 5010 in response to repeated comments from the industry regarding technical issues with previous standards.

The Final Rule also added several new Transaction Standards for certain electronic transactions related to pharmacy services. HHS added a new subpart S to 45 C.F.R. part 162 regarding the subrogation of pharmacy claims paid by the Medicaid program. The new standard, the NCPDP Batch Standard Medicaid Subrogation Implementation Guide Version 3.0, applies to Medicaid agencies in their role as health plans, and to other health plans that are covered entities under HIPAA, but *not to* providers, which do not utilize this transaction type.

The Final Rule also modified the current Transaction Standards for certain retail pharmacy drug transactions (*i.e.*, health care claims or equivalent encounter information; eligibility for health plan; referral certification and authorization; and coordination of benefits). More specifically, the Final Rule adopted either the NCPDP Telecommunication Standard Implementation Guide Version D Release 0 (D.0) and Equivalent Batch Standard Implementation Guide, Version 1, Release 2 (1.2) for certain retail pharmacy drug transactions. In addition, the Final Rule updated the Transaction Standards for billing retail pharmacy supplies and services by permitting entities to adopt either the Version D.0 standard, referenced immediately above, or the 837 Health Care Claim; Professional ASC x12 Technical Report Type 3 standard. HHS noted in the preamble to the Final Rule that the use of either standard would be determined by trading partner agreements between health plans and providers.

With the exception of the new Medicaid pharmacy subrogation standards, which require compliance by January 1, 2013, entities must comply with the revised Transaction Standards by January 1, 2012. The text of the Final Rule, along with HHS's discussion, can be found at 74 Fed. Reg. 3296 (Jan. 16, 2009).

Compliance Date for ICD-10 Code Sets Pushed Back to October 1, 2013

Concurrent with its publication of the final rule regarding the Transaction Standards mentioned above, HHS has issued a final rule extending the compliance date for transitioning from the ICD-9 to the ICD-10 code sets for two years to October 1, 2013 (the ICD-10 Final Rule). HHS's rationale for the extension was based upon, among other considerations, the need to update claims processing and other related IT systems and the need for coder and provider education. According to HHS, ICD-10 will facilitate the implementation of EHR by allowing for the provision of more detail, thus making the EHR more useful.

While the International Classification of Diseases (ICD) has been managed by the World Health Organization since 1948 and was initially developed in order to classify mortality, its use has been expanded to include morbidity as well. Both the U.S. Centers for Disease Control and Prevention and CMS use clinical modifications of the classification system. ICD-10 is already in use in much of the world, so its adoption will allow the United States to compare its data to international disease and treatment data.

CMS currently uses ICD-9-CM (Clinical Modification) for diagnosis coding and ICD-9-PCS (Procedure Coding System) for inpatient hospital procedure coding. The ICD is organized in chapters by body system, and some of the ICD-9 chapters are currently full, requiring the placement of new codes into inapplicable chapters. For example, CMS had begun to assign codes for heart procedures into the eye chapter. The ICD-9-CM code set has approximately 16,000 procedure and diagnosis codes, and the hospital inpatient procedure code set has been running out of available space within the clinical hierarchy for several years; ICD-10-CM and ICD-10-PCS have approximately 155,000 codes, ranging from three to seven alpha-numeric characters, whereas ICD-9 codes are from three to five digits long.

As ICD-10 is a much more robust coding system, the commentary to the ICD-10 Final Rule sets forth an expectation that it will support an increased level of detail necessary to support emerging needs, including bio-surveillance and pay-for-performance programs. More detail about socioeconomics, ambulatory care conditions, problems related to lifestyle, and screening test results will be captured when ICD-10 is implemented. In its press release, HHS explained that bio-surveillance is the automated monitoring of information sources that may help to detect an emerging epidemic—whether it is one that is naturally occurring or one that is the result of bioterrorism.

October 1, 2013 is designated as the compliance date, which corresponds to annual changes to the Medicare payment system. The text of the Final Rule can be found at 74 Fed. Reg. 3328; additional detailed discussion of the reasons for the need to change from ICD-9 to ICD-10 can be found in the August 22, 2008 proposed rule at 73 Fed. Reg. 49796.

Endnotes

[1] *See generally* 45 C.F.R. part 162.

For assistance in this area, please contact one of the attorneys listed below or any member of your Mintz Levin client service team.

MEMBERS

Robert D. Clark
Chairman, Health Law Practice
RDClark@mintz.com

Stephen M. Weiner
Chairman, Health Law Practice
SWeiner@mintz.com

Susan W. Berson
Managing Member,
Washington, D.C. Office
SBerson@mintz.com

Thomas S. Crane
TSCrane@mintz.com

Stephen C. Curley
SCCurley@mintz.com

Deborah A. Daccord
DADaccord@mintz.com

Hope S. Foster
HSFoster@mintz.com

Ellen L. Janos
EJanos@mintz.com

Karen S. Lovitch
KSLovitch@mintz.com

M. Daria Niewenhous
DNiewenhous@mintz.com

Andrew B. Roth
ARoth@mintz.com

OF COUNSEL

Michael D. Bell
MDBell@mintz.com

Margaret D. Kranz
MKranz@mintz.com

ASSOCIATES

Stephen R. Bentfield
SRBentfield@mintz.com

Dianne J. Bourque
DBourque@mintz.com

Shawneequa L. Callier
SLCallier@mintz.com

Theresa C. Carnegie
TCCarnegie@mintz.com

Brian P. Dunphy
BDunphy@mintz.com

Garrett G. Gillespie
GGGillespie@mintz.com

Lauren N. Haley
LNHaley@mintz.com

Rachel M. Irving
RMIrving@mintz.com

Krietta Bowens Jones
KBowensJones@mintz.com

Sarah A. Kaput
SAKaput@mintz.com

Katina W. Lee
KLee@mintz.com

Andrea P. Testa
ATesta@mintz.com

Melissa O'Neill Thatcher
MOThatcher@mintz.com

Heather L. Westphal
HLWestphal@mintz.com

Jennifer E. Williams
JEWilliams@mintz.com

Nili S. Yolin
NSYolin@mintz.com
