Health Law Washington Beat: Recent Health Industry News - Issue 13

8/3/2009

In This Issue

* * *

House and Senate Miss August Recess Goal for Health Reform Vote

Tensions ran high in the House last month as lawmakers scrambled to meet President Obama's deadline for passing health care reform legislation. House Majority Leader Steny Hoyer (D-MD) stated on July 27th that a floor vote on health care reform "clearly will not be possible" by July 31st—the date the House was scheduled to adjourn for its August recess—but had not ruled out keeping the House in session past the scheduled July 31st adjournment date.

House Democrats officially introduced H.R. 3200, their long-awaited tri-committee health care reform bill, on July 14th, and the three House committees—Energy & Commerce, Education & Labor, and Ways & Means—immediately began working on their mark-ups. By July 20th, only the Energy & Commerce Committee had yet to complete its mark-up of the bill. After failing to meet its self-imposed deadline of July 22nd, the Energy & Commerce Committee postponed all other business to focus on health care reform. However, as the Committee continued working on its mark-up, disagreements between supporters of Chairman Henry Waxman's (D-CA) plan and the Blue Dogs—a group of fiscally conservative Democrats led by Representative Mike Ross (D-AR)—heightened, culminating in a breakdown in negotiations on July 24th. Both sides appeared agitated when speaking with the press afterwards, and Waxman indicated that he was prepared to bypass his own Committee and bring the bill to a full floor vote. Waxman quickly apologized for the comment and negotiations resumed on July 27th, but ideological differences between the Blue Dogs and the party's most liberal members threatened to drag negotiations into September. Undaunted by the tension brewing within her party, House Speaker Nancy Pelosi (D-CA) promised, "When I take this bill to the floor, it will win."

On July 29th, Speaker Pelosi and Majority Leader Hoyer announced that the Energy & Commerce Committee had reached an agreement, and would pass its version of the health care bill by the end of the week. On July 31st, the Committee passed its version of the bill by a vote of 31–28, with five Democrats joining the 23 Republican Committee members in opposition. The Energy & Commerce Committee's version of the bill will be merged with the versions passed by the Education & Labor and Ways & Means Committees during the August recess, and the full House will debate the final version when they return in September.

The Senate ended any suspense regarding its ability to meet President Obama's deadline on July 23rd, when Majority Leader Harry Reid (D-NV) confirmed that the Senate will not vote on their health care reform proposals until after their August recess. The Senate Finance Committee is the only committee yet to produce a bill and is attempting to forge a bipartisan compromise. Recent reports indicate that the Senate Finance Committee is close to a deal and that the deal may not include the government-run insurance program backed by President Obama and liberal Democrats.

CMS Proposes Significant Policy Changes in CY 2010 OPPS Proposed Rule

The Centers for Medicare & Medicaid Services (CMS) included several notable policy changes in its proposed rule for the outpatient prospective payment system (OPPS) for the 2010 calendar year. The CY 2010 OPPS proposed rule (*see* 74 Fed. Reg. 35,232, published July 20, 2009), includes a 2.1% market basket update for OPPS services, which corresponds to $31.5 billion in projected outpatient services payments to hospitals in 2010. This proposed market basket update effectively adopts a March 2009 Medicare Payment Advisory Commission recommendation to increase outpatient services payment rates.

Other significant developments in the CY 2010 OPPS proposed rule include clarification of CMS's policies for the physician supervision of outpatient services, Part B coverage for cardiac and pulmonary rehabilitation services, and payment to rural providers for kidney disease education services.

Physician Supervision. Beginning in 2010, CMS proposes that certain non-physician practitioners (physician assistants, nurse practitioners, certified nurse specialists, and certified nurse-midwives) may directly supervise hospital outpatient therapeutic services that they are able to personally perform within their state's scope of practice and hospital-granted privileges. Under current CMS policy, only physicians and clinical psychologists are allowed to provide direct supervision of these services. This policy change is particularly significant for hospitals in rural areas, because it increases the number of people who can provide direct supervision for such services.

In addition to the expansion of supervising practitioner classes, CMS also is proposing to revise the definition of "direct supervision" in the hospital or in an on-campus provider-based department (PBD) to eliminate the requirement that the supervising physician be physically present in the department when services are furnished. Under the proposed revision, the

physician or non-physician practitioner must be present in the hospital or in an on-campus PBD of the hospital, and be immediately available to furnish assistance and direction throughout the performance of the procedure. CMS clarified that the supervising practitioner cannot be occupied with any other procedure that he or she cannot leave in order to adequately supervise other services. Failure to meet such requirements would raise quality concerns, according to CMS. Services rendered in an off-campus PBD would still require the physician or non-physician practitioner to be present in the off-campus PBD at all times services are furnished.

The proposed rule also clarifies the definition of "in the hospital" as used in the context of direct physician supervision. CMS proposes to change "in the hospital" to mean areas in the main building(s) of the hospital that are under the ownership, financial, and administrative control of the hospital; that are operated as part of the hospital; and for which the hospital bills the services furnished under the hospital's CMS Certification Number.

Cardiac and Pulmonary Rehabilitation Services. Beginning January 1, 2010 and in accordance with legislative changes included in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, Public Law No. 110-275), CMS will establish a new benefit and OPPS payment for pulmonary and cardiac rehabilitation services, including intensive cardiac rehabilitation services, that are provided to beneficiaries with chronic obstructive pulmonary disease, cardiovascular disease, and related conditions. Unlike other outpatient therapeutic services that can be furnished under the direct supervision of physician and non-physician practitioners discussed above, CMS will require direct physician supervision of cardiac and pulmonary rehabilitation services.

Kidney Disease Education Services. MIPPA also created a new Medicare Part B benefit for kidney disease education services furnished to beneficiaries diagnosed with stage IV chronic kidney disease. In the CY 2010 OPPS proposed rule, CMS includes a proposed payment for kidney disease education services furnished by rural providers, including hospitals, critical access hospitals, skilled nursing facilities, home health agencies, comprehensive outpatient rehabilitation facilities, and hospices. For kidney disease education services provided in non-rural facilities, CMS proposes to make payment under the Medicare Physician Fee Schedule (MPFS) in accordance with the Social Security Act as amended by MIPPA. MIPPA, however, did not specifically address how such services should be paid when furnished by providers located in rural areas. Consequently, in the CY 2010 OPPS proposed rule, CMS recommends to employ a single payment methodology under the MPFS for all qualified persons who furnish kidney disease education services in an outpatient facility, regardless of location.

Comment Period and Effective Date

Comments on the CY 2010 OPPS proposed rule are due to CMS by August 31, 2009. CMS expects to issue its final CY 2010 OPPS rule on November 1, 2009, which will be applicable to services furnished on or after January 1, 2010.

OIG Concludes that Arrangement To Provide Select Drugs to Indigent Patients Through a Bulk Replacement Program May Proceed

In a recent Advisory Opinion, the Department of Health and Human Services Office of Inspector General (OIG) concluded that a free prescription drug restocking arrangement between a pharmaceutical company and certain participating disproportionate share hospitals (Proposed Arrangement) would not constitute grounds for the imposition of civil money penalties. The OIG further concluded that while the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute[1] if the requisite intent to induce or reward referrals were present, the OIG would not impose sanctions[2] in connection with the Proposed Arrangement. To read the OIG's Advisory Opinion 09-08, please click here.

The Proposed Arrangement

A pharmaceutical and health care company that develops, manufactures, and markets pharmaceutical products (Pharma Company) intends to create an Institutional Patient Assistance Program (Program) that will make available, at no charge, selected drug products (Program Drugs) to indigent patients without prescription drug coverage. Through the Proposed Arrangement, Pharma Company will provide bulk replacement of Program Drugs to outpatient pharmacies at participating hospitals (Participating Hospitals) on a quarterly basis. The bulk replacement drugs provided under the Program will replace drugs that Participating Hospitals dispensed to eligible patients during the preceding quarter. Participation in the Program will be limited to patients who meet specified criteria (Qualified Patients).

The Possible Fraud and Abuse Implications of the Proposed Arrangement

The OIG scrutinized the Program under the anti-kickback statute to determine if it may be a vehicle through which Pharma Company could offer or pay remuneration to induce Participating Hospitals to purchase or order Pharma Company's federally reimbursed products, or to influence the prescribing patterns of physicians at Participating Hospitals with respect to such products. The OIG decided that certain safeguards of the Program limited this risk. The OIG favorably discussed the following aspects of the Program, among others:

- ***Participation not based on utilization.*** The Program will ensure that Participating Hospitals' overall utilization of Pharma Company's products is decoupled from participation.
- ***Participating hospital as pass through.*** The Program is structured so that Program Drugs merely pass through Participating Hospitals, which safeguards against the risk that Participating Hospitals might obtain excess stocks of drugs from which they could benefit.
- ***No fees.*** Participating Hospitals will receive no administration, dispensing, or other fees in connection with the Program.

- ***No opportunity for remuneration.*** Participating Hospitals will be prohibited from selling Program Drugs or from ordering Program Drugs to replace drugs they have sold.
- ***Program structure.*** The Program contains no mechanism to reward physicians for prescribing Program Drugs.
- ***Program transparency.***
    - The terms of the Program will be documented in a written, signed agreement between Pharma Company and each Participating Hospital.
    - An independent program administrator (Program Administrator) will manage the Program and scrutinize its operations.
    - Each Participating Hospital will provide the Program Administrator with utilization reports signed by its Medical Director or Pharmacy Director certifying that Program Drugs are only replacing drugs provided to Qualified Patients.
    - Each Participating Hospital will be audited regularly.
- ***Program targets needy patients.*** The Program Drugs will be provided only to vulnerable, needy patients. Hospitals typically lack the time and resources to individually enroll large numbers of indigent patients into patient assistance programs, and the Program will help ensure the availability of drug products for otherwise underserved patients.

The OIG also scrutinized the arrangement under the Civil Monetary Penalties (CMP) provision[3] but determined that the CMP did not apply.

More Changes to the HIT "Meaningful Use" Definition

After receiving nearly 800 public comments, a Department of Health and Human Services (HHS) advisory group responded to commentators' concerns by proposing revisions to the definition of "meaningful use" that will be used to demonstrate meaningful use of electronic health records by hospitals and physicians in order to qualify for Medicare and Medicaid incentive payments.[4] On July 16, 2009, the Meaningful Use Workgroup of the HIT Policy Committee (Committee) submitted its recommendations for revisions to the Office of the National Coordinator for Health Information Technology and other HHS units. The proposed revisions include the following:

- ***Computerized physician order entry systems.*** Only 10% of hospital physicians will need to use computerized physician order entries in 2011.
- ***Timing.*** The timeline for using clinical decision support will be moved up, requiring a provider to implement clinical decision support for the treatment of at least one high clinical priority in the provider's community in 2011.
- ***New "adoption year" framework for awarding incentive payments.*** Under the early draft proposals, a provider submitting an initial application for incentive payments in 2013 would need to meet 2013 standards in that year. But under the Committee's revised recommendations, a provider submitting an initial application in 2013 would only need to meet 2011 standards.

- ***Patient access.*** Providers will be required to offer patients access to electronic health information and an electronic copy of such information. Providers must make real time access to patient information available to patients in the form of a public health record by 2013.
- ***Privacy and security violations.*** CMS and state Medicaid administrators will withhold meaningful use incentive payments from entities with *confirmed* HIPAA or state privacy and security violations until such violations are corrected.

HHS currently is considering the Committee's proposals, and a notice of proposed rulemaking regarding the implementation of the meaningful use standards is expected in the fall. The interim final rule is scheduled to go into effect January 1, 2010.

National Governors Association and eHealth Initiative Highlight HIT Progress

E-prescribing practices and health information exchanges (HIEs) are the subject of recent reports by the National Governors Association Center for Best Practices (NGA) and the eHealth Initiative.

The NGA published an issue brief on July 27, 2009 acknowledging increased use of e-prescribing in many states and recommending that states take additional steps to encourage practitioners to adopt e-prescribing practices. In this brief, the NGA explained that more providers would use e-prescribing if states included funding for e-prescribing initiatives in public health budgets, and created financial incentives for providers to use e-prescribing more regularly. The NGA also asserted that developing, incorporating, and implementing e-prescribing would accomplish some of the primary goals of health reform set forth in the American Recovery and Reinvestment Act (ARRA), such as the enhanced delivery of health care services, administrative efficiencies, and ultimately, a reduction in health care costs.

While encouraging the creation of strong e-prescribing infrastructures, the NGA acknowledged that barriers still exist that inhibit the use of e-prescribing by many providers, including limited access to e-prescribing in states with large numbers of independent pharmacies and rural pharmacies, and federal laws prohibiting e-prescribing for controlled substances. But despite these barriers, many states—including Florida, Massachusetts, Nevada, Rhode Island, and Tennessee—have been successful in promoting and incorporating e-prescribing practices. The full NGA report may be viewed here.

On July 22, 2009, eHealth Initiative released "Migrating Toward Meaningful Use: The State of Health Information Exchange," a report based on its Sixth Annual Survey of Health Information Exchange. This report showed that the number of fully operational HIEs utilized to send electronic medical information between health care entities has grown from 42 in 2008, to 57 to date in 2009, with the largest numbers of HIEs in New York, California, and Michigan. The report also indicates that the use of HIEs has been growing steadily since 2005, with many initiatives reporting that enrollees are experiencing a reduction in overall health care costs, spending less time on administrative functions, and decreasing the amount of money spent on redundant testing. Since ARRA will designate $300 million for investment in HIEs and require

providers to exchange information via HIEs to qualify for financial incentives, the number of HIEs will likely continue to grow at a rapid pace in the coming years. The full text of the survey and the accompanying report are available here.

Endnotes

[1] Section 1128B(b) of the Social Security Act.

[2] Administrative sanctions may be imposed under Sections 1128(b)(7) or 1128A(a)(7) of the Social Security Act.

[3] Section 1128A(a)(5) of the Social Security Act.

[4] Published on the HIT Policy Committee website: http://healthit.hhs.gov; *see also* Health Information Technology Policy Committee; Notice of Meeting, 74 Fed. Reg. 28,937 (June 16, 2009).

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

MEMBERS

Karen S. Lovitch
Managing Member, Health Law Practice
KSLovitch@mintz.com

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

Hope S. Foster
Chair, Health Care
Enforcement Defense Practice Group
HSFoster@mintz.com

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

Robert D. Clark
RDClark@mintz.com

Thomas S. Crane
TSCrane@mintz.com

Stephen C. Curley
SCCurley@mintz.com

Deborah A. Daccord
DADaccord@mintz.com

Ellen L. Janos
EJanos@mintz.com

M. Daria Niewenhous
DNiewenhous@mintz.com

Andrew B. Roth
ARoth@mintz.com

OF COUNSEL

Michael D. Bell
MDBell@mintz.com

ASSOCIATES

Stephen R. Bentfield
SRBentfield@mintz.com

Dianne J. Bourque
DBourque@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

Carrie A. Roll
CARoll@mintz.com

Tara E. Swenson
TESwenson@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