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Health Policy Monitor

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Health Reform and Related Health Policy News

In this Issue:

An executive summary of political, legal and regulatory issues that may impact your business, prepared by Polsinelli Health Care legal and Public Policy professionals.

Top News

CMS Releases Payment Rules for the Medicare Physician Fee Schedule, Hospital Outpatient Prospective Payment System, Renal Dialysis and Home Health

Medicare Physician Fee Schedule: CMS released the Final Rule with Comment Period for the 2014 Medicare Physician Fee Schedule on November 27, 2013. The rule will be published in the Federal Register on December 10, 2013. Comments in response to the rule are due on January 27, 2014. The Final Rule sets payment rates for services provided by physicians, non-physician practitioners, and other suppliers for services paid for under the physician fee schedule.

Services are paid for under the physician fee schedule are based on the service's assigned relative value units (RVUs) for work, practice expenses and malpractice costs, as further adjusted by the geographic practice cost index and multiplied by a fixed dollar amount conversion factor to obtain the final payment rate.

For 2014, the conversion factor is $27.2006 reflecting a 20.1% reduction from 2013 due to the application of the sustainable growth rate (SGR) imposed by law. Congress routinely patches the SGR by enacting temporary delays the SGR's application to allow for modest year-to-year changes to

reimbursement under the physician fee schedule. There are currently two proposals before Congress that would permanently repeal the SGR.

The final rule also updates quality programs including the physician quality reporting system (PQRS), Physician Compare, the value based payment modifier (VBPM) and others. The PQRS program provides incentive payments and downward payment adjustments to incentivize quality reporting by eligible professionals. For 2014, the PQRS program will contain 287 measures and 25 measures groups. CMS also continued to build upon the Physician Compare website, and finalized a proposal that would continue to make more quality reporting data publicly available to consumers. The implementation of the VBPM continues in 2014 to include group practices with more than 10 eligible professionals. CMS is required by law to implement the VBPM so that all eligible professionals are subject to a VBPM adjustment in 2017.

A copy of the Final Rule with Comment Period is available here.

Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System: CMS also released the Medicare Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Final Rule with Comment Period on November 27, 2013. The rule is set for publication in the Federal Register on December 10, 2013, and comments are due on January 27, 2014. Total OPPS payments are expected to increase by $4.4 billion or approximately 9.5% in 2014. Payments for ASCs are expected to increase by $143 million or 5.3% over 2013 levels.

One major change made by the OPPS final rule is that it collapses the previous coding mechanism with five levels of clinical visits into one clinical visit level. Previously, outpatient clinical visits were coded within one of five categories depending on the level of physician work associated with the visit. CMS believes that one code will offer administrative simplicity and better reflect the resources used in providing the service. CMS will continue to pay for outpatient drugs at the average sales price +6% rate.

Four new measures were introduced into the Hospital Outpatient Quality Reporting Program. One measure assesses influenza vaccinations among healthcare personnel, one measure assesses improvement after cataract surgery, and two measures relate to endoscopy and polyp surveillance. A measure related to a transition record for discharged emergency department patients and a cardiac rehabilitation patient referral measure were removed from the program.

The Final Rule with Comment Period is available here.

Renal Dialysis: CMS also issued a final rule that updates Medicare policies and payment rates for 2014 for dialysis facilities paid under the End Stage Renal Disease (ESRD) Prospective Payment System (PPS). CMS received extensive public comment on the proposed rule issued in July. Following review of those comments, it decided to implement a three- to four-year transition for the drug utilization adjustment to the base rate mandated by Congress as part of the American Taxpayer Relief Act.

The Final Rule sets a base reimbursement rate for CY 2014 of $239.02, which reflects the CY 2013 ESRD PPS base rate of $240.36 adjusted by: (i) the ESRDB market basket of 3.2% minus a productivity adjustment of 0.4%; (ii) the application of a wage index budget neutrality factor and a home dialysis training add-on budget neutrality factor; and (iii) reducing this amount by the portion of the CY 2014 drug utilization adjustment that is being transitioned this year

($8.16).

The final rule will also strengthen the ESRD Quality Incentive Program (QIP), which creates incentives for dialysis facilities to improve the quality of care and patient outcomes for beneficiaries diagnosed with ESRD. For the ESRD QIP payment year 2016 program (which will rely on measures of dialysis facility performance during 2014), CMS is finalizing 11 measures addressing infections, anemia management, dialysis adequacy, vascular access, mineral metabolism management, and patient experience of care. CMS is also finalizing the method by which performance scores will be calculated by weighting clinical measures at 75% of the total performance score and weighting the reporting measures at 25%. The ESRD QIP will reduce payments to ESRD facilities that do not meet or exceed certain performance standards.

Additionally, the Final Rule:

- Updates the outlier services fixed dollar loss amounts for adult and pediatric patients and Medicare Allowable Payments for adult patients for CY 2014 using 2012 claims data.
- Finalizes an increase in the amount of the self-dialysis and home dialysis training add-on adjustment for both peritoneal dialysis and home hemodialysis training treatments furnished on or after January 1, 2014.

The Final Rule is available here.

Home Health: CMS released the Home Health Prospective Payment System Final Rule on November 22nd. Medicare pays for home health services prospectively. The 2014 rates represent a 1.05% cut to home health reimbursement, or approximately $200 million. This decrease is attributable to the net effects of the home health update percentage which would have increased reimbursement by $440 million, a decrease to rebasing adjustments mandated by the Affordable Care Act that caused a $520 million decrease, and a decrease due to home health prospective payment grouper refinement causing a $120 million decrease.

Two new quality reporting measures for home health providers were finalized by CMS. One measure tracks re-hospitalization during the first thirty days of a home health stay, and the second tracks emergency department use during the first thirty days of a home health stay without re-hospitalization.

The Final Rule is available here.

President Signs the Drug Quality and Safety Act Reforming the Regulation of Compounding Pharmacies and Establishing a New Voluntary Program for the FDA to Regulate Entities Engaged in Compounding

On November 27, 2013 President Obama signed H.R. 3204, the Drug Quality and Security Act. The Act clarifies the FDA's ability to regulate the practice of compounding pharmaceuticals by reaffirming Section 503A of the Food, Drug and Cosmetic Act (FD&C Act), and creates a new section 503B which creates a new category of regulated facilities, "outsourcing facilit[ies]," which may voluntarily register with the FDA. Additionally, the FD&C Act now requires enhanced communication between state boards of pharmacy to identify certain compounding practices which the FDA deems to be outside the normal scope of pharmacy compounding.

The Drug Quality and Security Act also establishes authority for FDA to develop a national track-and-trace system to secure the pharmaceutical supply chain and minimize opportunities for contamination, adulteration, diversion, or counterfeiting, according to a Statement from the White House.

The Drug Quality and Security Act's inception and approval are likely a direct response to illnesses linked to steroids manufactured at the New England Compounding Center in Framingham, Massachusetts. Several hundred people developed illnesses after receiving steroid injections for neck and back pain which were manufactured by the compounding center. Over 17,000 vials of the steroid were shipped to 23 states before a nationwide recall was issued, and the FDA later discovered unsanitary conditions at the facility.

Full text of the Drug Quality and Security Act is available here.

CMS Declares Healthcare.gov Overhauled and Repair Goals Reached

In mid-October, the Obama administration conducted an assessment of the site HealthCare.gov using experts from across government and private sector. The team determined that HealthCare.gov could be fixed, but only with significant changes to the management approach and a relentless focus on execution.

On December 1, 2013, the Department of Health and Human Services released a report stating that the administration had fixed or improved more than 400 software issues. According to the report, the new management system and instrumentation have helped improve site stability, lowered the error rating below 1%, increased capacity to allow 50,000 concurrent users to simultaneously use the site, and will drive continuous improvement to the site in the future. In the report the administration stated that while it strives to innovate and improve its outreach and systems for reaching consumers, it believe it has met the goal of having a system that will work smoothly for the vast majority of users.

The Progress and Performance Report is available here.

Obama Administration Expands the Marketplace Open Enrollment Period for Coverage Beginning on January 1, 2014; Small Business Enrollment Delayed to 2015

The Obama administration has delayed two key dates related to the implementation of the Affordable Care Act (ACA) due to the deficiencies of HealthCare.gov. Originally, consumers purchasing plans on the health insurance exchanges created by the ACA had until December 15, 2013 to purchase coverage that would go into effect on January 1, 2014, but on November 22 the administration announced it would delay the deadline until December 23. According to Bloomberg a spokesman for America's Health Insurance Plans delaying the deadline to December 23 "makes it more challenging to process enrollments in time for Jan. 1."

CMS is also allowing consumers in Texas, Ohio, and Florida the opportunity to bypass HealthCare.gov and enroll directly with their health insurer of choice, as part of a direct enrollment pilot program.

A Politico article detailed the Administration's delay of the online small business enrollment through HealthCare.gov for federally facilitated health insurance exchanges through 2014. Small Business Health Option

Program (SHOP) exchanges are health insurance exchanges that allow small businesses to select coverage for their employees. The administration stated that it will offer alternative ways for small businesses to enroll their employees for 2014, and small businesses have been able to apply through paper application since open enrollment began on October 1. Online enrollment through HealthCare.gov is expected to be available in 2015.

Supreme Court to Hear Arguments on Women's Preventive Services Mandate

On November 26, 2013 the Supreme Court announced it will hear arguments on the validity of one of the Affordable Care Act's most controversial provisions: the women's preventive services mandate. The mandate requires employers of a certain size to offer insurance coverage for birth control and other reproductive health services without a co-pay. Almost 50 cases have been filed in Federal Court challenging the mandate; three federal appeals courts struck down the mandate, while two other appeals courts have upheld it.

Likely prompted in part by the circuit split, the United Stated Supreme Court granted review in two cases. In *Hobby Lobby v. Sebelius*, the U.S. Court of Appeals for the Tenth Circuit held that two corporations and their owners were likely to succeed on their claims that the Department of Health and Human Services regulation under the Affordable Care Act violates the Religious Freedom Restoration Act (RFRA) by requiring the corporations to provide insurance coverage for contraceptives in violation of their religious beliefs or pay hefty fines. Conversely, in *Conestoga Wood Specialties v. Sebelius*, the U.S. Court of Appeals for the Third Circuit held that the plaintiffs were unlikely to succeed on the merits of their RFRA and free exercise claims, given that "for-profit, secular corporations cannot engage in religious exercise."

Oral arguments are likely to be held in March, with a decision expected sometime in June. The Supreme Court's response to petitions for writs of certiorari is available here.

State News

States Wrestle with Medicare Expansion

The Washington Post reports that Alaska Governor Scott Parnell rejected expansion due to $200 million in costs to the state over seven years.

In Missouri, the St. Louis Post Dispatch detailed Democratic Governor Jay Nixon's continued efforts to expand Medicaid. Nixon, who supports Medicaid expansion, cancelled a meeting with members of the Republican controlled legislature on expansion discussions due to a disagreement over the meeting's format. Governor Nixon accused the GOP of politicizing the meeting after they attempted to convene it as a joint hearing of the state's interim Medicaid committees, where the Governor would have been the sole witness. The Kansas City Star reported on the impasse November 29, detailing the political roadblocks and an alternative Republican expansion proposal.

The White House has applied pressure to both Nebraska and Maine in an attempt to spur action on Medicaid expansion in those states. The Lincoln Journal Star reports that White House Deputy Press Secretary Josh Earnest participated in a press call with Nebraska media and stated that Republican governors in other states have already allowed Medicaid expansion and that expansion would reduce the rate of uninsured while saving Nebraska

money. Expanding Medicaid in Nebraska would extend the program to an estimated additional 48,000 Nebraska citizens.

Josh Earnest also made comments in reference to Medicaid expansion efforts in Maine, which were reported by Politico. "They can score short-term political points by attacking the Affordable Care Act and blocking Medicaid expansion," Earnest stated. "Or on the other hand, they can actually save taxpayer dollars and ensure that thousands of their residents … would have access to quality, affordable health care."

Wisconsin has delayed its plans to shift low-income residents from BadgerCare, the state's Medicaid program, to the federally-facilitated exchange at HealthCare.gov. The Washington Post reports the state refused to expand Medicaid eligibility under the ACA, and its biennial budget required adults with incomes above the federal poverty level to move into the federal exchange. Due to the problems with HealthCare.gov, Republican Governor Scott Walker called a special session of the state legislature to delay the requirement by three months stating that it would be "irresponsible to force some Wisconsinites to pay the price for the federal government's failure." The Post Crescent reports that Joint Budget Committee within the Wisconsin state legislature voted 11-2 to advance the measure.

Results Mixed for State-Based Health Insurance Exchanges

State health insurance exchanges have reported varying levels of success since open enrollment began on October 1.

- The Washington Post reports that the total number of enrollments in state based exchanges increased in November to approximately 150,000. California, New York and Washington all report enrollment numbers in the tens of thousands, with California reporting that the numbers were larger than expected.

- Oregonlive.com reports the Oregon exchange continues to experience significant problems with its exchange, as the exchange website continues to malfunction and be largely unavailable for enrollment. On December 2, the exchange announced that exchange director Rocky King would be stepping down and taking a medical leave of absence.

- The Washington Post reports weak enrollment for the Maryland health insurance exchange due to problems with its website. The state reports that it enrolled 1,278 people in private plans in October and 465 through the first week of November.

- Providers in Washington are reporting significant errors in the provider directory on the state exchange website that is used by consumers to examine which professionals and facilities are within a plan's network according to the Seattle Times.

State Governments Weigh Options in Deciding Whether to Embrace Obama's Fix for Cancelled Plans

Responding to a rash of cancelled plans, President Obama advanced a fix to reinstate plans for 2014 that were cancelled due to the Affordable Care Act, by allowing insurers to offer cancelled plans in 2014 subject to approval at the state level. Thus far states are split on whether they will move forward with implementing the President's fix. Concerns have been cited that the plan could destabilize the

state insurance markets and keep healthy individuals out of the new exchange plans.

Bloomberg reports that California is the most notable state to forgo the President's proposal, and is doing so in order "focus in the coming months on the enrollment we need" according to Covered California's executive director Peter V. Lee. The Wall Street Journal reports that New York, Washington, Massachusetts, Minnesota and Rhode Island are among the states that have also rejected the President's fix. While the St. Louis Post Dispatch reports that Missouri has indicated that it is among the states that will allow plan renewals.

Regulatory News

Florida Court Finds Stark Law Referral Prohibitions Apply to Medicaid, Allows FCA Suit to Proceed

On November 15, 2013, the U.S. District Court for the Middle District of Florida denied a motion to dismiss a *qui tam* lawsuit alleging that All Children's Health System Inc. compensated its physicians above the market rate in order to induce Medicare and Medicaid referrals. The *qui tam* relator, Barbara Schubert, was tasked with establishing a compensation plan for physicians employed by All Children's. Using several national compensation surveys, Schubert developed a compensation plan that would pay all physicians between the 25th and 75th percentiles of national compensation rates. Schubert alleged in the complaint that All Children's executives ignored her proposal and instead paid physicians at above the 75th percentile, resulting in operating losses at the hospital.

All Children's argued that the Stark Law does not apply to Medicaid claims, that. Schubert's allegations were not sufficiently particular under the False Claims Act's heightened pleading standards, and that the physician compensation plan approved by hospital executives did not violate the Stark Law.

The Court found that the Stark referral prohibitions do apply to Medicaid, refuting All Children's claim that a 1998 Proposed Rule indicates Stark does not apply to Medicaid. The Court concluded the commentary of the Proposed Rule clearly states that "referral limitations apply with equal force to Medicaid." The Court also found that Schubert adequately alleged both False Claims Act liability and that fixed compensation rates paid to All Children's physicians may violate the Stark Law.

Full text of the Court's denial of the motion to dismiss is published by Bloomberg and available here.

Hospital RAC records requests increased 13% between first and third quarters of 2013

According to a survey released by the American Hospital Association (AHA) on November 21, 2013, during the first through third quarters of 2013 hospitals experienced a 13% increase in Recovery Audit Contractor (RAC) records requests. According to the report, hospitals also reported that the number of cumulative complex audit denials reported by respondents has increased by 28% since the first quarter of 2013. The report stated that such RAC requests and associated appeals place financial burdens on hospitals that can impact patient care.

2,452 hospitals have participated in AHA's RAC*Trac* data collection and survey program since data collection began in January of 2010. 1,269 hospitals participated in the third quarter of 2013. The report identifies several other statistics of note related to RAC requests:

- 58% of medical records reviewed by RACs did not contain an overpayment.
- 67% of hospitals indicated medical necessity denials were the most costly complex denials.
- 64% of short-stay denials for medical necessity were because the care was provided in the wrong setting, not because the care was medically unnecessary.
- Hospitals reported appealing 47% of all RAC denials, with a 67% success rate in the appeals process. The appeals overturn rate may be impacted by appeals withdrawn by hospitals for rebilling.
- 43% of participating hospitals reported having a RAC denial reversed through utilization of the discussion period.
- 70% of all hospitals filing a RAC appeal during the 3rd quarter of 2013 reported appealing short stay medically unnecessary denials.
- 71% of all appealed claims are still sitting in the appeals process.
- 68% of all hospitals reported spending more than $10,000 managing the RAC process during the third quarter of 2013, 49% spent more than $25,000 and 12% spent over $100,000.

The full report is available here.

HHS issues Proposed Rule Related to Premium Credits, Other Payment Parameters and Oversight Provisions

On November 25, 2013 the U.S. Department of Health and Human Services (HHS) released a proposed rule which would establish the 2015 payment parameters for cost-sharing reductions, advance premium tax credits, reinsurance, and risk adjustment programs under the Affordable Care Act.

The proposed rule sets forth payment parameters and oversight provisions related to the risk adjustment, reinsurance, and risk corridors programs; cost-sharing parameters and cost-sharing reductions; and user fees for Federally-facilitated Exchanges. It also proposes additional standards with respect to composite rating, privacy and security of personally identifiable information, the annual open enrollment period for 2015, the actuarial value calculator, the annual limitation in cost sharing for stand-alone dental plans, the meaningful difference standard for qualified health plans offered through a Federally-facilitated Exchange, patient safety standards for issuers of qualified health plans, and the Small Business Health Options Program.

A copy of the Proposed Rule with Comment Period is available here.

Four Next-Generation Gene Sequencing Devices Approved by FDA

Illumina, Inc. received approval for four "next-generation" gene sequencing devices that are intended to be used in the diagnosis and treatment of cystic fibrosis and certain genetic cancers according to the Wall Street Journal. The WSJ also reported that FDA Commissioner Dr. Margaret Hamburg and NIH Director Dr. Francis Collins published an article in the New England Journal of Medicine that called the approvals "a significant step forward in the ability to generate genomic information that will ultimately improve patient care."

FDA Does Not Support Congressional Action to Regulate Mobile Medical Devices

FDA Director of the Center for Devices and Radiological Health Jeffrey Shuren testified before the House Energy and Commerce Subcommittee on Health on Tuesday November 19. Shuren's testimony argued that the FDA's final guidance document on regulation of mobile devices released in September is a "balanced approach to mobile apps that supports continued innovation while ensuring appropriate patient protections." The defense of the guidance is at odds with HR 3303, a bill introduced by Congresswoman Blackburn (R TN-7) that would statutorily define categories of regulated mobile devices. In the bill's introductory press release Blackburn argues that her bill would provide the clarity that is needed by manufacturers to spur innovation in the area by clearly defining the types of mobile devices that would be regulated.

In September 2013, the FDA released a guidance document on the regulation of mobile medical devices available here.

A copy of Shuren's written testimony is available here.

Additional Reading

- The OIG released its Strategic Plan for 2014-2018, which outlines the vision, goals and priorities guiding the office in the coming years. These goals drive OIG's work, including, for example, the planned audits and evaluations contained in OIG's annual Work Plan. The Strategic Plan is available here.
- The OIG released a report entitled "State and CMS Oversight of the Medicaid Managed Care Credentialing Process." The Report is available here.
- CMS posted its Hospital Value-Based Purchasing Incentive Payment Adjustment Factors for FY 2014, which are available here.

Federal Register

Patient Protection and Affordable Care Act; Exchanges and Qualified Health Plans, Quality Rating System (QRS), Framework Measures and Methodology, 78 Fed. Reg. 69418.

- This notice with comment is to solicit comments on the proposed list of Quality Rating System measures for Qualified Health Plans offered through health insurance exchanges. It is available here.

Renewal of the Advisory Committee on the Maternal, Infant and Early Childhood Home Visiting Program Evaluation, 78 Fed. Reg. 70565.

- The Children with Families Association and Health Resources Services Administration announce the renewal of the Advisory Committee on the Maternal, Infant and Early Childhood Home Visiting Program Evaluation to provide advice to the Secretary of Health and Human Services on the design, plan, progress, and findings of the evaluation required under the Affordable Care Act. It is available here.

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