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in the news

Health Policy Monitor

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Health Reform and Related Health Policy News

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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

Judge Orders $237.4 Million Penalty Against Tuomey for Stark Law and False Claims Act Violations

On October 1, 2013, federal United States District Court Judge Margaret Seymour reduced her prior order against Tuomey Healthcare System ("Tuomey") by nearly $40 million. Federal prosecutors filed a motion to reduce a previous judgment of $277 million because of a clerical error.

On September 30, 2013, Judge Seymour had ordered Tuomey to pay $277 million in Stark penalties and for violations of the False Claims Act after a jury found Tuomey violated the federal ban on compensating doctors based on the volume and value of referrals.

The case originated in 2005 with a lawsuit filed by whistleblower physician Michael Drakeford, M.D. The United States intervened in that lawsuit and alleged Tuomey violated the Stark Law by entering into improper financial agreements with 19 specialist physicians. A federal jury found that more than 21,000 Medicare claims, valued at $39.3 million, violated the Stark law and False Claims Act.

The damage amount is believed to be the largest of its kind against a community hospital in the history of the United States. Tuomey has

vowed to appeal the decision. To read the full order and opinion, click here.

Glitches and Demand Lead to Marketplace Frustration

Despite the government shutdown, on the first day the health insurance marketplaces opened for enrollment, Marilyn Tavenner, current Administrator for the Centers for Medicare and Medicaid Services ("CMS"), told reporters that there were more than 2.8 million visits to healthcare.gov. The website is handling exchanges for 36 states that defaulted to the federal government in the individual health insurance market. Fourteen states and the District of Columbia are operating their own exchanges.

On the first few days of the website's operation, users reported delays and failures, which the Obama administration attributed to high volume. However, analysts suggest software design may be the bigger culprit. Nevertheless, at least three insurance companies confirmed they enrolled individuals through the federal online marketplace.

Current numbers released by CMS indicate there have been more than 8.6 million visits to the website. The Department of Health and Human Services did not release the number of individuals who actually enrolled in coverage through healthcare.gov. Read more about the start of the federal online marketplaces at here.

HHS Delays Small Business Marketplaces Enrollment by One Month

On September 26, 2013, the Obama administration announced that small businesses will not be able to enroll in the Small Business Health Options Program ("SHOP") marketplaces until November 1, 2013. SHOP is designed for small employers with 50 or fewer full-time employees. Small businesses were able to begin participating in SHOP on October 1st to evaluate their coverage options, but must wait until November 1st to enroll in coverage options. Open enrollment for SHOP marketplaces is year-round.

To read the news release issued by the Department of Health and Human Services, click here.

Consumers Have Option to Choose From Average of 53 Health Plans, with Lower-Than-Projected Premiums

According to data released by the Department of Health and Human Services ("HHS"), individuals will have an average of 53 qualified health plan choices in states where HHS will fully or partially run the marketplace. In addition, premiums before tax credits, will be more than 16 percent lower than initially projected.

Approximately 95 percent of eligible uninsured individuals live in states with lower-than-expected premiums. The result is that nearly 60 percent of uninsured individuals could purchase insurance for $100 or less each month, with financial assistance and expanded access to Medicaid.

To read the news release issued by HHS, click here. To read the Office of the Assistant Secretary for Planning and Evaluation Issue Brief, click here.

State News

CMS Approves Arkansas Private-Option Medicaid Expansion Plan; Several States Still Grappling With Expansion Decision

On September 27, 2013, CMS approved Arkansas' proposal to use the so-called "private option" to expand Medicaid. Under the new program, rather than covering low-income individuals through the traditional Medicaid program, Arkansas will use Medicaid funds to provide premium assistance for individuals to purchase qualified health plans (QHPs) on the state's health insurance exchange. The federal government will fund 100 percent of the program for the first three years and 90 percent thereafter. Medicaid coverage will now be available to 200,000 additional Arkansans between ages 19-65 with incomes at or below 138 percent of the federal poverty level who are not enrolled in Medicare or incarcerated. Additional information regarding the Arkansas private option and the CMS approval is available here and here.

Approval of the Arkansas Medicaid expansion plan may open the door for other states that are on the fence with respect to expansion. Several states, including Iowa and Pennsylvania, are considering similar private options while other states, such as Ohio, New Hampshire and Missouri are still weighing their options. In total, the country remains divided, with 25 states (including the District of Columbia) moving forward and 26 states not moving forward at this time.

California Expands Pharmacist Scope of Practice

As of January 1, 2014, pharmacists in California will enjoy a much broader scope of practice thanks to the passage of Senate Bill No. 493 on October 1. The new legislation authorizes pharmacists to administer drugs and biologicals pursuant to a prescriber's order, to fit a patient for certain medical devices, and, in coordination with the patient's primary care provider, to order and interpret tests for the purpose of monitoring and managing drug therapies, among other things. The law also establishes board recognition for an "advanced practice pharmacist," a designation that will allow such pharmacists to perform patient assessments, to initiate, adjust, or discontinue drug therapy, and to order and interpret drug-therapy related tests, provided the patient's primary care provider is notified of any changes. To review the text of the new legislation, please click here.

Maryland Waiver Plan Would Overhaul Existing All-Payer Hospital Reimbursement System

Under an existing Medicare waiver, the Maryland Department of Health and Mental Hygiene (DHMH) is permitted to set universal hospital reimbursement rates, which are the same for all patients, whether they have Medicare, Medicaid, private insurance, or pay out of pocket. On September 27, 2013, DHMH released a new version of a proposal to overhaul this hospital reimbursement scheme, which would shift from a fee-for-service approach to a focus on global payment rates and quality of care. If approved by CMS, the new program would operate as a five-year pilot program. The full text of the Maryland Medicare waiver proposal is available here.

Regulatory News

CMS Issues Guidance on Implementation of Hospital Two-Midnight Rule; Implements 90-Day 'Education' Period

On September 26, 2013, CMS issued a set of Frequently Asked Questions (FAQs) to clarify its new inpatient admission payment policy known as the "two midnight" rule. As explained in a prior Polsinelli Health Care E-Newsletter, available here, the two-midnight rule was finalized as part of the 2014 Inpatient Prospective Payment System (IPPS), and it generally establishes a two-tiered set of guidelines for hospitals and for claim reviewers to determine if a particular patient is (or was) appropriately admitted as an inpatient: (1) the two-midnight benchmark, which provides that an inpatient stay is generally appropriate if the physician or other admitting practitioner expects the patient to require a stay that spans at least two midnights and admits the patient on that basis; and (2) the two-midnight presumption, which allows CMS and its reviewers to presume that inpatient claims spanning two or more midnights are appropriate for Part A payment.

Under the CMS FAQs, Recovery Auditors are not permitted to review inpatient admissions of one midnight or less during the period between October 1 and December 31, 2013. During this 90-day period, however, Medicare Administrative Contractors (MACs) will conduct a prepayment probe audit of 10-25 claims for inpatient admissions spanning less than two midnights. The probe is intended to allow MACs to educate hospitals, and if errors turn up, the MAC may return the claims to the hospital to rebill as outpatient services. To review the CMS FAQs, please click here.

Congress Moves Closer to Bill To Give FDA More Regulatory Oversight of Compounding Pharmacies

A bipartisan group of lawmakers announced on September 25, 2013, that it had reached a compromise on legislation designed to further regulate compounding pharmacies. As proposed by the Senate Health, Education, Labor & Pensions (HELP) Committee, the legislation distinguishes those engaged in traditional pharmacy practice and those compounding larger quantities of drugs without individual prescriptions, defines the oversight role of the Food & Drug Administration (FDA), requires FDA to track outsourcing facilities, and clarifies federal law regarding pharmacy compounding. A summary of the proposed law is available here.

Additional Reading

- CMS published the 2014 list of teaching hospitals for use by applicable manufacturers and group purchasing organizations in compliance with the Open Payments rule (also known as the Physician Sunshine Act). See the list here.
- According to the OIG, Medicare overpaid $7.7 million dollars to hospitals for ventilator services. Read the OIG report here.
- As reported by Kaiser Health News, federal health insurance exchanges will be unable to communicate with state Medicaid offices to verify beneficiary eligibility until November 1. Read the full article here.
- Due to the government shutdown, the District of Columbia Medicaid program is unable to pay health

care providers for the foreseeable future. Read the full article from Kaiser Health News here.

- On October 3, 2013, the Tenth Circuit Court of Appeals ruled a Catholic-owned company is temporarily exempt from the Affordable Care Act's birth control coverage mandate. Read the full article here and the opinion of the Tenth Circuit United States Court of Appeals decision here.

Federal Register

On September 24, 2013, the Food and Drug Administration (FDA) published notice of new guidance applicable to mobile medical applications (Mobile Apps). The guidance outlines the criteria that FDA intends to use in regulating Mobile Apps, indicating that such regulation will focus on applications that intend to be used as an accessory to a regulated medical device or intend to transform a mobile platform into a regulated device. The Federal Register notice is available here, and the guidance document is available here.

CMS published notice announcing the annual adjustment in the amount in controversy threshold amounts for Administrative Law Judge (ALJ) hearings and judicial review under the Medicare appeals process. Effective January 1, 2014, the threshold amount for ALJ hearings remains the same at $140 and the threshold amount for judicial review is increased from $1,400 to $1,430. The notice is available here and appeared in the September 27 *Federal Register*.

On September 27, 2013, CMS published notice that laboratories located in and licensed by the State of Washington that possess a valid state lab license are exempt from the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) for six years. Federal statute permits CMS to exempt labs in states that enact legal requirements that are equal to or more stringent than CLIA's statutory and regulatory requirements. Currently, Washington and New York are the only states that qualify.

The federal Office of Personnel Management (OPM) published a final rule on October 2, 2013, to implement Section 1312 of the Affordable Care Act, which requires all members of Congress and Congressional staff to purchase health insurance through an exchange. As of January 1, 2014, these individuals will no longer be eligible to participate in the Federal Employees Health Benefits (FEHB) program and, in order to receive a contribution from the federal government, must enroll in a plan offered by the District of Columbia Small Business Health Options (SHOP) exchange. The final rule is available here.

CMS published an interim final rule revising uncompensated care payments under the Medicare Disproportionate Share Hospital (DSH) program for hospitals with cost-reporting periods that span more than one federal fiscal year. The rule clarifies operational concerns and revises the methodology for uncompensated care payments to insure Indian Health Services hospitals are included. Comments will be accepted through November 29, 2013. The interim final rule is available here and appeared in the October 3 *Federal Register*.

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About Polsinelli

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