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in the news

Health Policy Monitor

May 2013 Issue 2

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

Tavenner Wins Senate Confirmation to Head CMS

On May 15, 2013, as reported in Medscape, the Senate confirmed Marilyn Tavenner to become the Administrator of the Centers for Medicare & Medicaid Services (CMS), a position she has held in an acting role since November 2011. The 91-7 vote for Tavenner gives CMS its first confirmed Administrator since Mark McClellan resigned from that post in October 2006. The lack of a confirmed CMS appointee has been viewed as a roadblock for the Obama administration as it attempts to implement the Affordable Care Act (ACA). For more information, click here

US Charges 89 in Nationwide Medicare Fraud Crackdown

In a major nationwide healthcare fraud crackdown, 89 people, including 14 doctors and nurses, were charged for their roles in various alleged Medicare scams that cost taxpayers over $223 million in fraudulent charges.

According to a report by NBC News, over 400 federal agents were involved in the arrests and raids, which took

place in Miami, Los Angeles, Houston, Detroit, Chicago, New York City, Tampa, and Baton Rouge. In Miami, where 25 people were charged for their parts in various alleged fraudulent schemes totaling $44 million, federal officials allege that one scheme involved bribing Medicare patients for their identification numbers and then using the numbers to bill the federal government $20 for unnecessary home health care services. US Attorney General Eric Holder claimed that $8 dollars are returned to the US Treasury for every dollar spent on investigations. For full article, click here.

State News

Vermont Becomes Fourth State to Allow Physician-Assisted Suicide

According to the Washington Post, Vermont is poised to join three other states that allow physicians to prescribe lethal doses of medication to terminally ill patients, after the Vermont House approved a bill similar to Oregon's 1997 law. The bill now goes to Governor Peter Shumlin, a strong supporter of the legislation. If Shumlin signs the bill, Vermont will become the fourth state, and the first east of the Mississippi, to allow doctors to assist patients to die by writing a prescription for a lethal dose of medication.

The Vermont law requires that, for the first three years, several safeguards must be followed, including that the patient must state three times, including once in writing, that he or she wishes to die. Other requirements include a concurring finding by a second doctor that the patient has less than six months to live and a finding that the patient is of sound mind. For full article, click here.

Colorado Signs Medicaid Expansion into Law

The San Francisco Chronicle reported that on May 13, 2013, Colorado approved legislation to expand Medicaid eligibility, a move that is expected to add 160,000 adults to public health assistance in Colorado. The expansion will allow single adults earning less than about $15,900 per year to qualify for Medicaid. State analysts believe that more than 750,000 people in Colorado did not have health insurance in 2011.

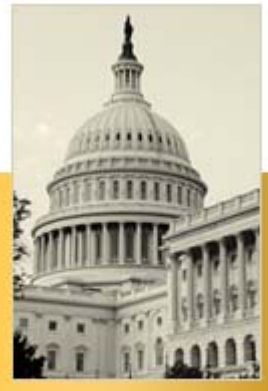
Supporters of the expansion say that it will reduce health care costs in the long run. State Republicans, however, the majority of whom voted against the legislation, argued that the state's cost will increase significantly once the federal government stops assuming the full cost of the expanded coverage under the program. Under the Affordable Care Act, the federal government will cover the entire cost of the expansion for the first three years.

Fourteen states have rejected the Medicaid expansion, which was made operational by the U.S. Supreme Court ruling on the constitutionality of the Affordable Care Act (ACA). For more information, click here.

Regulatory News

OIG Issues Updated Special Advisory Bulletin on Effect of Exclusion from Federal Health Care Programs

On May 8, OIG issued a Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs, which replaces OIG's original



September 1999 Special Advisory Bulletin on the topic. The Bulletin is intended to address several questions that have arisen since the release of the 1999 Bulletin.

The updated Bulletin includes some notable guidance for health care providers. In particular, it suggests that providers should screen employees and contractors against OIG's List of Excluded Individuals and Entities (LEIE) on a monthly basis to minimize the potential that a provider could incur overpayment and civil monetary penalty liability by employing or contracting with excluded individuals. In addition, the OIG recommends that providers screen all persons working under a contract or in a job category that provides items or services that are reimbursable by federal health care programs. The OIG also advises providers to use the LEIE as their primary screening tool, as opposed to the General Services Administration's System for Award Management or other databases. The updated Special Advisory Bulletin can be found here.

Senate Finance Committee Seeks Input on Reforming Physician Payment Formula

Senator Max Baucus (D-Mont.), the Chairman of the Senate Finance Committee, and Orrin Hatch (R-Utah), the Committee's Ranking Member, released a letter on May 10 asking physicians and other health care providers to submit ideas on how to permanently fix the sustainable growth rate (SGR) formula, which threatens physicians with drastically reduced Medicare payments unless Congress acts each year to temporarily avert the cuts.

The letter, which is available here, asks stakeholders in the health care industry to provide input on topics such as how to reform the SGR formula to "ensure that physician services are valued appropriately" and how Medicare can "incentivize physician practices" to make "changes needed to participate in alternative payment models." Comments and responses should be submitted to sgrcomments@finance.senate.gov no later than May 31, 2013.

Congress Considers Drug Supply Chain Legislation

On May 15, the House Energy and Commerce Committee approved legislation aimed at securing the nation's pharmaceutical supply chain. The legislation, the "Safeguarding America's Pharmaceuticals Act of 2013" (H.R. 1919), calls for lot-level tracking of pharmaceuticals and for the Food & Drug Administration to propose regulations for unit-level tracking by 2027. In addition, the bill would establish national wholesaler licensing standards and would preempt state drug pedigree laws.

The Committee voted down several proposed amendments, including an amendment that would have required unit-level tracking within 10 years and an amendment that would have allowed states to enact more stringent wholesaler licensing standards than those found in the bill. The legislation will next go to the House floor for debate. The full text of the House bill can be found here.

The Senate Health, Education, Labor and Pensions (HELP) Committee introduced a similar bill on May 15, called the Drug Supply Chain Security Act. The Senate version of the legislation calls for unit-level tracking of pharmaceuticals within 10 years. It was marked up by the HELP Committee on May 22.

Senate Committee Considers Compounding Bill

The Senate Health, Education, Labor and Pensions (HELP) Committee held a hearing on May 9 regarding draft drug compounding legislation that had been released by a bipartisan group of senators in April. Days later, members of the HELP Committee introduced a bill based upon the draft legislation, the "Pharmaceutical Compounding Quality and Accountability Act" (S. 959).

According to a HELP Committee summary of the legislation, which can be found here, the bill would create a new category, compounding manufacturers, for those entities that "make sterile products without or in advance of a prescription and sell those products across state lines." Compounding manufacturers would be subject to FDA regulation, while traditional compounders would continue to be subject to state regulation. Under the bill, compounding manufacturers would be subject to many of the Good Manufacturing Practices of the Federal Food, Drug, and Cosmetic Act (FFDCA), and the FDA would be able to promulgate regulations designating drugs that may not be compounded due to safety concerns. The HELP Committee marked up the bill on May 22.

DOL Publishes Guidance on Notifying Employees of Health Insurance Exchanges

The Department of Labor published guidance on May 8 concerning a provision of the Affordable Care Act (ACA) requiring employers to give notice to their employees regarding health insurance exchanges established under the ACA.

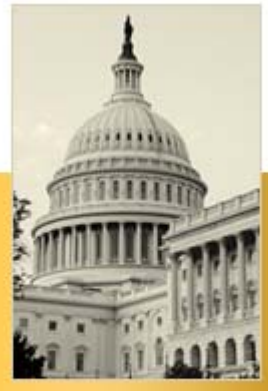
The guidance, which can be found here, states that employers must provide the notice to all current employees on or before October 1, 2013, and all employees hired after October 1 must be notified at the time of hiring. The guidance also refers to model notice language that employers can use to comply with this requirement, which can be found here.

CMS Issues Proposed Rule on Reduced Medicaid Payments to Disproportionate Share Hospitals

On May 13, CMS issued a proposed rule regarding reductions to Medicaid disproportionate share hospital (DSH) payments. The reductions are required by the Affordable Care Act (ACA) because Congress had assumed that the health insurance exchanges and expanded Medicaid coverage established under the ACA would significantly reduce the number of uninsured individuals that previously received care from DSHs.

The rule sets forth a reduction methodology only for fiscal years 2014 and 2015, after which CMS will refine the methodologies used to calculate reductions to DSH allotments for FY 2016 and beyond, which is when the bulk of the ACA's reductions are scheduled to take effect. The proposed reductions will become effective on October 1, 2013 unless Congress approves President Obama's budget proposal to delay the reductions until FY 2015.

A fact sheet providing additional details on the proposed rule can be found here. Comments on the proposed rule must be received by CMS no later than July 12.



Additional Reading

- *Bloomberg:* UnitedHealth, Humana May See Surge in Medicare Advantage
- *Sacramento Business Journal*: Adventist Health to Pay $14.1M in Settlement Over Referrals, Kickbacks
- *USA Today:* Hospitals Lose $8.3 Billion Using Old Technology
- *Kaiser Health News:* Hospitals, Testing Companies Face Questions About Value of Community Screenings
- *The Hill:* CRS: Sebelius Can Take Place of Controversial Medical Board
- *Kaiser Health News:* Doctors Transform How They Practice Medicine
- *The Hill:* HHS Launches $1B Healthcare Innovation Effort

Federal Register

In a notice published in the May 6 Federal Register, CMS asked interested persons to submit comments regarding the burdens that may result from the reporting payments under the Physician Payment Sunshine Act. The Sunshine Act, which requires applicable manufacturers of drugs, devices, and supplies to report payments or transfers of value to physicians and teaching hospitals, mandates that payment information be collected beginning August 1, 2013, with the first reports to be made to CMS no later than March 31, 2014. CMS' notice invites comments on, among other things, "ways to enhance the quality, utility, and clarity of the information to be collected" and "the use of automated collection techniques or other forms of information technology to minimize the information collection burden." Comments should be submitted to CMS no later than June 3, 2013. A copy of the notice is available here.

OIG finalized a rule amending certain HHS regulations that prohibit State Medicaid Fraud Control Units (MFCU) from using Federal matching funds to detect fraud through data mining of state Medicaid data. The rule allows for federal financial participation for MFCU data mining activities under certain circumstances, and requires reporting of MFCU costs and results of approved data mining activities to OIG on an annual basis. The final rule was published in the May 10 Federal Register and can be found here.

CMS issued a proposed rule to update the FY 2014 prospective payment rates for inpatient rehabilitation facilities (IRF), which would result in a nearly 2% increase to IRF payments. The proposed rule would also modify the list of ICD-9-CM diagnosis codes that are used to determine presumptive compliance with the "60-percent rule" for IRFs and make various other changes to current IRF regulations. The proposed rule, which was published in the May 8 Federal Register, is available here. Comments to the proposed rule must be received by CMS no later than July 1, 2013.

CMS published a notice seeking additional organizations to participate in Model 1 of the Bundled Payments for Care Improvement initiative. Eligible organizations for the initiative include acute care hospitals paid under the inpatient prospective payment system and organizations that wish to convene acute care hospitals in a facilitator convener role. The notice was published in the May 17 Federal Register, and is

available here. Organizations that wish to participate in the initiative must submit a Model 1 Open Period Information Intake form by July 31, 2013, which can be found here.

CMS published an interim final rule setting payment rates for services rendered to individuals enrolled in the federally-administered Pre-Existing Condition Insurance Plan (PCIP). Under the rule, payment rates for most services rendered on or after June 15, 2013 will be equivalent to Medicare rates. In addition, the rule prohibits facilities and providers from "balance billing" an enrollee for any amount that exceeds the enrollee's out-of-pocket cost for a service as calculated in accordance with the plan. The interim final rule will have a 60-day comment period. A copy of the rule can be found here.

The IRS issued a proposed regulation specifying how Blue Cross and Blue Shield organizations and certain other health care organizations should compute and apply the medical loss ratio (MLR) provisions that were added to the Internal Revenue Code by the Affordable Care Act. Notably, the proposed regulations would not allow these organizations to count "activities that improve health care quality" in computing the amount of the MLR numerator, which, under the proposed rule, would include only amounts expended for reimbursement of clinical services provided to enrollees. The proposed regulations, which were published in the May 13 Federal Register, can be found here. Comments to the proposed regulations must be received by August 12, 2013.

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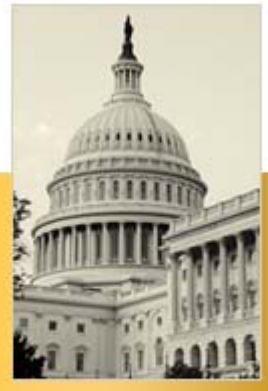

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