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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

### Congress Passes Omnibus Spending Package

Congress passed a more than \$1 trillion spending package that will fund the government through the end of the FY 2015. The so-called “CRomnibus” combined 11 appropriations bills, including the Department of Health and Human Services (HHS) and a short-term Continuing Resolution for the Department of Homeland Security. Highlights of the CRomnibus include:

- \$5.4 billion of President Obama's \$6.2 billion funding request for U.S. efforts to combat Ebola in the U.S. and abroad
- \$2.7 billion for HHS, including \$1.2 billion for the CDC to help contain Ebola in West Africa and bolster public health systems in countries at risk of an Ebola outbreak.
- A requirement that the Health Resources and Services Administration (HRSA) provide the House and Senate appropriations committees with a report detailing its progress on creating a website that documents prescription drug prices under the 340B program by March 3.
- Direction that prevents CMS from using program management funds for the Affordable Care Act's risk corridor program, which is intended to protect insurers from losses incurred due to inaccurate rate setting in the initial years of the ACA.
- A reduction in the ACA's Independent Payment Advisory Board's budget by \$10 million.



## HRSA Cancels Plan for 340B ‘Mega Reg’; Congress Weighs Options

The Health Resources and Services Administration’s (HRSA) decision not to publish its long-anticipated 340B “Mega Reg” could force Congress to act. When HRSA formally withdrew its 340B Mega-Reg from the rulemaking process, it effectively abandoned its effort to clarify and formalize the existing 340B program.

Commander Krista Pedley, who is also the director of the Office of Pharmacy Affairs in HRSA, indicated that HRSA no longer believes it has sufficient rulemaking authority to proceed with the Mega-Reg. HRSA’s rulemaking authority was called into question by a federal court that ruled against HRSA in a recent orphan drug rule case. The “Mega Reg” was expected to address the definition of a 340B patient, hospital eligibility, compliance requirements for pharmacy contracts, and program eligibility for off-site facilities. A court decision in May 2014, however, limited HRSA’s rulemaking authority over 340B to dispute resolution, ceiling prices and civil monetary penalties. HRSA has signaled that instead of using the rulemaking process it will issue a series of guidance documents but the organization has not yet detailed which subject areas may be addressed. The agency is expected to move forward with rulemaking in the three areas the court determined to be appropriate.

In the meantime, HRSA’s decision and upcoming reports may prompt Congressional action. The HHS Office of Inspector General and the Government Accountability Office are expected to release reports on the program and their findings could result in the House Energy & Commerce Committee scheduling a hearing on the program. Recently, Rep. Joe Pitts (R-PA), chair of the House Energy and Commerce health subcommittee, has suggested possibly scaling back the 340B program and using the savings for drug and medical device development and other research funding. The Affordable Care Act extended 340B program eligibility to critical access hospitals, certain sole community hospitals and rural referral centers for outpatient services.

## Supreme Court to Hear Challenge to ACA Subsidies

The Supreme Court will hear a case this term that challenges the ability of federally run exchanges to offer subsidies to help low- and middle-income Americans pay their health insurance premiums. The Court on November 7 agreed to hear *King v. Burwell* after two appeals courts reached opposite conclusions. Oral arguments could be scheduled as early as January. At issue is a phrase in the ACA that indicates subsidies are available only in “exchanges established by a state” to those with incomes less than 400 percent of the federal poverty level. The Fourth Circuit in Richmond, Va., unanimously found Congress intended for both state and federally run exchanges to offer the subsidies. That same day, a panel of the U.S. Appeals Court for the D.C. Circuit ruled 2-1 in *Halbig v. Burwell* that the Internal Revenue Service lacked the authority to allow subsidies in exchanges not run by the states. The federal government runs the exchanges in 37 states.

A decision to restrict the subsidies to state exchanges could make insurance unaffordable for millions of people and threaten the viability of the law’s entire health insurance program. Some states are developing plans to ensure that subsidies remain available in the event the court rules in favor of the plaintiffs. In Illinois, Gov. Pat Quinn is working with the state legislature to establish a state-based exchange. Delaware, however, is prepared to argue that it’s partnership exchange should be considered a state-based one. Six states have filed briefs supporting the plaintiffs in arguing that states with federally run exchanges,





including theirs, should not qualify for the subsidies. These states are: Oklahoma, Alabama, Georgia, West Virginia, Nebraska, and South Carolina.

## Congressional Focus

### Republicans Take Senate, Build on House Majority in 114<sup>th</sup> Congress

Republicans will assume control of the Senate and operate with an expanded majority in the House when the 114<sup>th</sup> Congress convenes in January. In the Senate, Republican members will hold 54 seats with Democrats holding 44. Two independents are expected to caucus with Democrats effectively raising the total to 46. Sen. Mitch McConnell (R-KY) will be the majority leader and Sen. Orrin Hatch (R-UT) will chair the Senate Finance Committee. Hatch has indicated that one of his top priorities is expected to be the repeal of the ACA's medical device tax. Sen. Lamar Alexander (R-TN) will also chair the Senate Health, Education, Labor and Pensions Committee, and he is expected to conduct oversight activities regarding the ACA.

In the House, Republicans expanded their majority control to 246 seats with the Democrats holding 234 (one race is still pending). Rep. Paul Ryan (R-WI) will chair the Ways and Means Committee. Subcommittee chairs have not been announced. Rep. Fred Upton (R-MI) will chair the Energy & Commerce Committee and Rep. Joe Pitts (R-PA) will chair its subcommittee on Health.

### Congress Extends Physician Supervision Exemption for Critical Access, Rural Hospitals

President Obama signed into law H.R. 4067, which will require the HHS Secretary to continue to instruct Medicare contractors to not enforce requirements for direct physician supervision of outpatient therapeutic services in critical access and small rural hospitals through 2014. This requirement does not continue beyond the end of the 2014 calendar year. Additional details are available [here](#).

### Brady Unveils Medicare Discussion Draft

Rep. Kevin Brady (R-TX), chair of House Ways and Means Health Subcommittee, released a discussion draft of the Hospital Improvements for Payment (HIP) Act of 2014 on November 19. The bill would alter Medicare's payment for certain hospital stays, payment amounts and RAC audits. In particular, the draft bill targets the "two-midnight rule," which requires a patient stay through two midnights to qualify for coverage. The draft would repeal the 0.2 percent reduction that CMS implemented in its FY 2014 IPPS final rule. The HIP 2014 Act would also establish a site-neutral hospital prospective payment system (HPPS) for Medicare by fiscal year 2020. Brady's draft bill would also reform the Recovery Audit Contractor (RAC) program by reducing the look-back period from four years to three years. Additional details are available [here](#).

## Regulatory Roundup

### CMS Proposes Changes to ACOs in Medicare Shared Savings Program

CMS issued a proposed rule that would amend the Medicare Shared Savings Program (MSSP). The rule proposes changes to several aspects of the program, including beneficiary assignment, data sharing, available performance risk models, eligibility requirements, participation agreement renewals, and compliance and monitoring. Currently, ACOs must opt to participate in either a one-sided or two-sided financial risk model. Those in the one-sided model, known as Track 1, qualify to share in savings but are not responsible for any losses. Regulations





require that those in Track 1 may continue in the MSSP after their initial agreement period of three years only if they enter a two-sided track. The rule proposes to permit ACOs to participate in one additional agreement period under Track 1, but at a lower sharing rate than the previous agreement. The proposed rule would also create an additional risk-based option for ACOs. This new Track 3 model would modify the beneficiary assignment method, sharing rate, minimum savings rate, minimum loss rate, and performance payment. Comments are due February 6. The rule is available [here](#).

### Final Rule Cuts Medicare Physician Payments by 21.2 Percent

The final 2015 CMS Physician Fee Schedule will cut Medicare physician payments by 21.2 percent after March 2015, unless Congress acts to delay the reduction (as it has done for years) or replaces the current formula. Absent a change in law, the fixed-dollar conversion factor, which is used to calculate physician payments, will drop to \$28.2239 from \$35.8013. The Congressional Budget Office has estimated that a permanent replacement of the Medicare physician payment system, known as the sustainable growth rate (SGR), would cost \$144 billion from 2015 to 2024. A temporary fix that would replace the scheduled cut with a freeze at the current payment rate would cost \$13.6 billion over 10 years. It also would require a 17 percent reimbursement cut in 2016, according to the CBO.

The rule established requirements for the 2017 Physician Quality Reporting System, the pay-for-reporting system that uses payment cuts and incentive payments to encourage physicians to report quality information. The rule added 20 new individual measures and two measure groups to the PQRS. CMS also removed 50 measures from the PQRS reporting requirements. A CMS fact sheet on the rule is available [here](#).

### CMS Finalizes 2014 Hospital Outpatient Rule

CMS's final calendar year (CY) 2015 Hospital Outpatient Prospective Payment (OPPS) rule will increase overall OPPS

payments by an estimated 2.3 percent. The increase is based on the projected hospital market basket increase of 2.9 percent minus both a 0.5 percentage point adjustment for multi-factor productivity and a 0.2 percentage point adjustment required by law and includes other payment changes. The rule also finalized the addition of an outcome-based measure to the Hospital Outpatient Quality Reporting (OQR) and Ambulatory Surgical Center Quality Reporting (ASCQR) Program for CY 2018 payment determination. CMS opted to keep payments for Part B drugs in hospital outpatient departments at the average sales price plus 6 percent for certain drugs and biologicals that CMS pays for separately under the Outpatient Prospective Payment System (OPPS). CMS also finalized a proposal to require physician certification for inpatient hospital stays only for outlier cases and long hospital stays that last 20 days or more. CMS currently requires physician certification, which includes an admission order, for all inpatient admissions. Additional details are available [here](#).

## State Summary

### Maine Expected to Appeal Maintenance of Effort Ruling

The First Circuit Court of Appeals upheld the ACA's maintenance-of-effort provision against a constitutional challenge brought by the Maine Department of Health and Human Services. States participating in Medicaid must agree to cover certain groups of people up to specific income thresholds, but states may choose to expand these groups in various ways. In 2012, Maine sought to stop providing





Medicaid coverage to 19- and 20-year-olds. The ACA, however, requires states participating in Medicaid to maintain their eligibility standards through 2019. Maine argued the provision is unconstitutionally coercive, as the Supreme Court found in *NFIB v. Sebelius* that states could not be required to expand their Medicaid programs as envisioned by the ACA. The First Circuit rejected this argument and said that the maintenance-of-effort provision could not be considered new spending and analogous to the Medicaid expansion. Gov. Paul LePage has indicated the state may appeal. The ruling is available [here](#).

## Federal Register

The proposed rule that changes the Medicare Shared Savings Program is available [here](#).

The FY 2015 final hospital outpatient prospective system is available [here](#).

The FY 2015 final physician fee schedule is available [here](#).



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The Health Care practice comprises one of the largest concentrations of health care attorneys and professionals in the nation. From the strength of its national platform, the firm offers clients a depth of resources that cannot be matched in their dedication to and understanding of the full range of hospital-physician lifecycle and business issues confronting health care providers across the United States.

Recognized as a leader in health care law, Polsinelli is ranked no. 2 by The American Health Lawyers Association<sup>1</sup> and no. 3 by *Modern Healthcare*<sup>2</sup>. Polsinelli's highly trained attorneys work as a fully integrated practice to seamlessly partner with clients on the full gamut of issues. The firm's diverse mix of seasoned attorneys, well known in the health care industry, along with young lawyers with outstanding law school credentials, enables our team to provide counsel that aligns legal strategies with our clients' unique business objectives.

<sup>1</sup> Based on the number of American Health Lawyers Association members in the firm (AHLA Connections, June 2014)

<sup>2</sup> Based on a blended score of health care lawyers employed in 2013 and AHLA membership (June 2014)

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\* Law360, March 2014

\*\* The American Lawyer 2013 and 2014 reports

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