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MedPAC Examines Part B Drug Payment Policy



Congressional Medicare advisers met last week to discuss policy alternatives to the controversial payment model currently in place for Part B drugs.

The Commission specifically focused on the consolidation of payment codes and bundling, while continuing its discussion on the link between the payment rate of Part B drugs – those administered in doctors offices, such as oncology medications – to comparative clinical evidence.

The current “Average Sales Price (ASP) Plus 6%” payment model was discussed, during which time some commissioners expressed concern that the policy creates a “perverse incentive” for doctors to prescribe more expensive medications. While the Commission ultimately stressed the need for further progress in devising comprehensive reform, members discussed three primary alternatives.

First, they introduced a payment model in which CMS would compensate based on the average price of two treatment options plus six percent. Commissioners cautioned against the approach, however, as patients would not be able to pay out of pocket if they wanted the more expensive drug, or, if they were allowed to pick up the cost difference themselves, lower income beneficiaries wouldn't be able to afford it.

Next, the commission presented the idea of flat fee compensation. While they lacked significant evidence that a flat fee may benefit patients, they would research bringing up the flat fee medication management option for further discussion at a future meeting.

Third, the commissioners discussed the idea of bundling. Commissioner Kathy Buto recommended that the Commission explore the benefits of granting Accountable Care Organizations (ACOs) new authority to set up episode bundling. Some members dissented, however, supporting a consolidated payment code approach initially before bundling payments. Others also warned that ACOs have a number of inherent limitations – especially involved with configuring an effective cost-savings model with oncologists.

Commissioner Hackbarth ultimately concluded that the best solution might be a temporary proposal, serving as a holdover until lasting policy could be formulated. While payment reform would require significant legislation, he said, MedPAC must actively develop recommendations on the subject.

According to the MedPAC presentation, “linking payment to clinical evidence better ensures that beneficiaries are getting the best value for their health care dollar.”

To view the MedPAC presentation on payment policy reforms based on clinical evidence, [click here](#).

HRSA Pulls Back 340B 'Mega Rule'



The Health Resources and Services Administration (HRSA) announced last week that it has decided to withdraw a proposed "mega rule" for the 340B Drug Discount Program and instead plans to issue guidance on key policy issues beginning in 2015. According to the HRSA announcement, stakeholders will have opportunity to comment on the 340B guidance HRSA issues next year.

Stakeholders had previously expected the 'mega rule' following a series of legal and regulatory battles including a lawsuit filed by the Pharmaceutical Research and Manufacturers of America (PhRMA) against the Department of Health and Human Services, alleging the agency overstepped its authority when it allowed 340B-covered entities to purchase orphan drugs – expensive medications developed to treat rare diseases – at 340B discount prices.

Leaders in the community cancer community have advocated for reforming and strengthening the 340B Drug Discount Program because its current structure favors hospital providers by creating financial advantages for hospital systems delivering cancer care, which ultimately harm the delivery of community-based cancer care and lead to negative consequences for the uninsured indigent patients the program was designed to serve.

The 340B Program offers eligible safety net providers discounts for medications and is intended to make care more accessible and affordable for America's most vulnerable patient populations.

Supreme Court to Hear Affordable Care Act Subsidies Case

The Supreme Court will hear *King v. Burwell*, a lawsuit challenging the use of healthcare subsidies in states without their own healthcare insurance exchanges, raising questions about the Affordable Care Act's future.

Specifically, the court will consider the legality of the federal government's decision to distribute tax subsidies in the 34 states that did not construct their own insurance exchanges. Currently, 87 percent of Americans purchasing plans through the Affordable Care Act receive subsidies.

If the court rules against the Obama administration, the decision would rescind one of the law's most vital components. More than four million Americans have already received premium credits. That number is expected to rise to 7.3 million by 2016, according to a Robert Wood Foundation study. The rollback would equate to \$36 billion in lost subsidies.

The plaintiffs will argue that residents of such states cannot receive subsidies. Their case rests largely on the law's ambiguous wording, which limits the distribution of subsidies to those purchasing plans on "an exchange established by the state."

Proponents believe that the law intends for federal exchanges to fill the void in states that opted against creating their own health insurance marketplace. The White House has promised to defend the law, affirming that they "have high confidence in the legal arguments" and "expect a vigorous defense."

Yet, the plaintiff's argument has traction and widespread Republican support. A Washington, D.C. district court ruled against the Obama Administration on the issue earlier this year. Since then, however, the same panel has said that it would re-hear the case in December.

Researchers at the Robert Wood Foundation suggested a denunciation of subsidies from the nation's highest court could trigger a "domino effect" impacting other parts of the law. Without subsidies, they cautioned that the government might be forced to reconsider its policies on the individual mandate, regulatory reforms and state exchanges.

Many economists also suggested the individual market could break down entirely. Prices, they suggested, could spiral out of control as healthier, younger Americans that acquired insurance because of the individual mandate leave the pool of those currently insured.

"Without the subsidies, prices would jump sharply and many people simply could not afford to enroll," said Christine Eibner, an economist who led the Robert Wood Foundation study, which was sponsored by the U.S. Department of Health and Human Services.

The Affordable Care Act now faces four separate lawsuits including a separate, but similar, *Halbig v. Burwell* case. The King case will, in all likelihood, be heard in February or March, with a decision coming in June 2015.

Lawmakers, Physician Groups Seek SGR Reform in Lame Duck Session



As Congress enters a "lame duck" session following this month's elections, lawmakers in Congress as well as leading physician groups are calling for permanent replacement of the Sustainable Growth Rate (SGR) formula.

On November 3, the GOP Doctors Caucus sent a [letter](#) to House Speaker John Boehner (R-OH) and Majority Leader Kevin McCarthy (R-CA) urging Congress to reach an agreement that will allow passage of [H.R. 4015](#), the SGR Repeal and Medicare Provider Payment Modernization Act. In a letter to House leadership, the

GOP doctors write, “We appreciate the tremendous effort that Republican leadership and committees have put into SGR reform this year – but our work is not done. We have a unique opportunity to bring much needed stability to the Medicare program that will benefit seniors and physicians alike. With bipartisan, bicameral support for the policies contained in H.R. 4015, and one of the lowest cost estimates for fixing SGR in recent memory, the time to act is now.”

Another letter, signed by 110 bipartisan members of the U.S. House and led by Reps. Kurt Schrader (D-OR) and Reid Ribble (R-WI), asks House leaders to immediately move forward with the SGR deal.

Recent news reporters indicate that a handful of leading Republicans may be open to replacing Medicare’s SGR physician payment formula this year without a budgetary offset, with the tax extender package noted as a potential vehicle.

The American Medical Association is [urging Congress](#) to make repealing Medicare’s SGR formula a priority for the lame duck session. If there’s no temporary or permanent fix, physicians will face a 21.2 percent reduction in pay at the end of March 2015. In a November 10 [blog post](#), AMA President Robert M. Wah, MD, wrote, “If Congress does not seize the moment to act now during the lame duck session all of the hard bipartisan, bicameral work that went into building that framework will be for naught, and the process of negotiating a solution will start all over again. The current legislation is a remedy to improve care for patients through new health care delivery and payment systems that promise to create the stable environment that is needed for physicians to innovate.”

On Friday, the Congressional Budget Office (CBO) revised its cost [estimate](#) for legislation to replace the Medicare physician payment system (H.R. 4015/S. 2000) from \$144 billion over 10 years to \$138 billion from the estimate CBO released in February when the legislation was introduced.

CBO also lowered its 10-year estimate of the cost of freezing physician payments under Medicare by \$5 billion to just under \$119 billion. CBO further estimates that the cost of giving physicians a pay bump of 0.5 percent annually increases the costs slightly to \$140.2 billion over the next decade. CBO also estimates the price tag for another temporary “doc-fix” would total \$13.6 billion.

If Congress is unable to advance a permanent or temporary fix by March 31, physicians will face a pay cut of 21.2 percent on April 1.

CMS Proposed Lung Cancer Screening Coverage for High-Risk Beneficiaries

The Centers for Medicare and Medicaid Services issued a National Coverage Determination (NCD) last week, which proposes Medicare payment for a yearly, low-dose CT scan for lung cancer among current smokers as well as those who have already quit, but have a significant smoking history.

To be eligible, beneficiaries must fit the criteria of the [National Lung Screening Trial \(NLST\)](#):

- Ages 55 to 74
- At least a 30 pack-year history of smoking
- A current smoker or one who quit in the prior 15 years

The proposal by the CMS — based on the results of a national trial that showed that low-dose CT screening can find lung cancer in its early stage — will be open for public comment for 30 days and will not become final until February 2015.

Lung cancer is the third most common cancer diagnosed in the U.S., behind breast and prostate cancers. The National Cancer Institute estimated last year that the number of new lung cancer cases for that year was more than 220,000, with a median age at diagnosis of 70.

The Lung Cancer Alliance (LCA), a leading organization dedicated to saving lives and advancing research by empowering those living with and at risk for lung cancer, praised the NCD proposal declaring that CMS “got it right” in a [press statement](#). LCA’s President & CEO Laurie Fenton Ambrose stated, “Tens of thousands of lives will be saved by providing America’s seniors with fair and equitable access to the same lifesaving lung cancer screening that is now being offered to those with private insurance. Now, we will focus our attention on making sure those who would benefit most from this screening actually get screened.”

The American College of Radiology also commended CMS in a [statement](#). “CT lung cancer screening is the first and only cost-effective test proven to significantly reduce lung cancer deaths. Medicare coverage provides access to care for seniors and will help physicians save thousands of lives each year from the nation’s leading cancer killer,” said Ella Kazerooni, M.D., FACR, chair of the American College of Radiology Lung Cancer Screening Committee and American College of Radiology Thoracic Imaging Panel.

To view the CMS proposed National Coverage Determination, [click here](#).

VA Reimbursement Rule Has Providers Fearing Slow Payment

A proposed Veteran Affairs Department rule intended to expand care delivery for Veterans is now facing criticism, as providers express concern over vague reimbursement guidelines and potentially pernicious payment policies.

President Obama signed a bill this summer providing the agency \$10 billion to contract care for veterans who lived more than 40 miles away from a VA care facility or those that could not receive an appointment within 30 days. However, the American Hospital Association has cautioned against the policy, citing delayed reimbursements and an overly simplistic compensation model.

The VA released an [interim rule](#) earlier this month that established and reiterated guidelines for covered services, eligibility requirements, reimbursement rates and criteria that non-VA providers must meet to participate. The updated regulation, however, did not quell fears from providers.

“We had hoped to see a more detailed plan to ensure that care provided to veterans is reimbursed in a timely manner,” Richard Umbdenstock, CEO of the American Hospital Association, said in a statement.

The rule does not specifically address when providers will receive compensation from the VA for services provided to Veterans. The VA is notorious for slow payment, though, sometimes taking more than a year to reimburse for a claim, and even then, paying less than expected.

Despite ambiguity regarding when reimbursement will take place, the rule clearly establishes what they can expect to be paid, which will not exceed applicable Medicare rates. However, some hospitals believe the decision will, in fact, fail to expand access to care for Veterans because it does not provide resources for investment in the new people, technologies and facilities needed to meet growing demand.”

Still, some hospitals have stated publically that they will treat Veterans, regardless of reimbursement. The proposed rule also stresses that it will pay more to providers in highly rural areas, as well as those that do not have current Medicare rates, like OB-GYNs.

The proposed rule was issued on November 5 and CMS will accept comments through March 5, 2015.