McDermott Will & Emery

Significant Proposed Changes for Federal Health Care Programs in President's Fiscal Year 2014 Budget Plan

April 19, 2013

Boston Brussels Chicago Düsseldorf Frankfurt Houston London Los Angeles Miami Milan Munich New York Paris Orange County Rome Seoul Silicon Valley Washington, D.C.

Strategic alliance with MWE China Law Offices (Shanghai)

On April 10, 2013, President Obama released his budget proposal for fiscal year (FY) 2014 (the Budget). The President reiterated his long-standing goal of reducing the deficit by $4.3 trillion over 10 years and his willingness to do so in part by saving $400 billion from changes to federal health programs, including Medicare and Medicaid. According to the President's budget document, these savings would be enough to cancel the sequestration required by the Budget Control Act of 2011, which went into effect in March 2013.

The President's Budget contains a number of notable proposals affecting Medicare payment to hospitals, post-acute providers, labs, pharmaceutical companies and others. This *White Paper* identifies and summarizes some of the more noteworthy proposed changes.

Hospitals

GRADUATE MEDICAL EDUCATION

Graduate medical education add-on payments reimburse teaching hospitals for additional costs associated with training residents. For FY 2013, the Medicare Program will pay teaching hospitals an additional 5.5 percent per Medicare stay for every 10 percent increase in the hospital's ratio of medical residents to beds. The President now recommends reducing the indirect medical education adjustment by 10 percent beginning in 2014. Additionally, the President would like to give the U.S. Centers for Medicare & Medicaid Services (CMS) authority to set standards for teaching hospitals receiving graduate medical education payments, to encourage training of primary care residents and emphasize skills that promote high-quality and high-value health care delivery.

CRITICAL ACCESS HOSPITALS

The critical access hospital (CAH) program reimburses hospitals located in rural communities that provide essential access to care for Medicare beneficiaries in these areas. In the Budget, the President reintroduces the proposal from his 2013 budget to reduce payment to CAHs from 101 percent of reasonable costs to 100 percent, and to revoke CAH status from facilities within 10 miles of another hospital effective in 2014.

DISPROPORTIONATE SHARE HOSPITAL PAYMENTS

Disproportionate share hospital (DSH) payments reimburse hospitals that treat a higher number of low-income patients. From a policy perspective, these payments help account for increased costs for patients that may need special services as well as for those are who are under- or uninsured. The Patient Protection and Affordable Care Act (ACA) reduced State Medicaid DSH allotments from 2014 through 2020 to reflect the reduced need to reimburse hospitals for uncompensated care as a result of increased coverage in the ACA, and these reductions were extended through 2022 by the American Taxpayer Relief Act of 2012.

The Budget provides one benefit to hospitals by proposing "to begin the reductions in 2015, instead of 2014, and to determine future State DSH allotments based on States' actual DSH allotments as reduced by the Affordable Care Act." Essentially, this measure will provide more time for hospitals to develop procedures and protocols to implement the new Medicaid eligibility criteria, thus reducing the number of uninsured patients that they treat.

Physicians

PHYSICIAN PAYMENTS

The Medicare statute requires that the Medicare physician fee schedule be revised upward or downward every year depending on the results of a complex formula known as the sustainable growth rate (SGR). Since 2003, Congress has intervened 16 times with legislation overriding reductions required by the SGR, including most recently in the American Taxpayer Relief Act of 2012. However, each time Congress delays implementation of the reductions, the reductions commanded by the formula the next year are compounded.

Although the President addressed his support for reform only cursorily in his 2013 budget, the President now announces his support for an SGR reform that provides "a period of payment stability lasting several years to allow time for the continued

development of scalable accountable payment models," and framed the issue as one essential to avoid access to care issues for Medicare beneficiaries.

According to the Budget, "such models can take different forms, but all will have several common attributes such as encouraging care coordination, rewarding practitioners who provide high-quality, efficient care, and holding practitioners accountable through the application of financial risk for consistently providing low quality care at excessive costs." While short on details, the President's comments are strikingly similar to an SGR reform proposal unveiled earlier in April 2013 by Republican leaders of the House Ways and Means and Energy and Commerce Committees that proposed to repeal SGR and replace the formula with a multi-phase alternative. Under the congressional Republican proposal, in phase one, physicians would receive undefined "stable" updates for a "period of time." In phase two, payments would be more comprehensively linked to quality performance. In phase three, payments would be linked to both quality and efficiency. Under the proposal, defining quality and efficiency would be left to CMS.

PHYSICIAN SELF-REFERRAL

CMS and the Medicare Payment Advisory Commission (MedPAC) have had growing concern about the potential overutilization of certain services performed by a physician in his or her own office. Under the Ethics in Patient Referrals Act (the Stark Law), there is currently an exception that physicians may meet in order to furnish these services within their offices. Effective calendar year 2015, the President would exclude radiation therapy, therapy services and advanced imaging from the in-office ancillary services exception under the Stark Law, except in cases where a practice meets certain accountability standards defined by the Secretary. The President's Budget does not define the term "advanced imaging," but based on other legislation and regulations, this term likely includes magnetic resonance imaging, computed tomography and nuclear medicine imaging.

Other Providers

POST-ACUTE CARE

Following an acute inpatient stay, some Medicare beneficiaries are discharged for post-acute care and treatment at inpatient rehabilitation facilities (IRFs), long-term care hospitals (LTCHs), skilled nursing facilities (SNFs) and home health agencies. These services can constitute a large portion of expenses for the Medicare Program (*e.g.*, an estimated 5 percent of Medicare payments are for skilled nursing fees). Recently, there has been an increasing focus on coordination of acute and post-acute care through accountable care organizations and bundled payment initiatives. Nevertheless, the President is making a number of recommendations, many of which align with recommendations made by MedPAC in March 2013.

Specifically, the President proposes to do the following:

- Reduce market basket updates for IRFs, LTCHs, SNFs and home health agencies by 1.1 percentage points beginning in 2014 through 2023
- Reinstitute the 75 percent standard for classifying a facility as an IRF, whereby 75 percent of a facility's cases would be required to be in one or more of 13 designated severity conditions
- Cap payments to IRFs for three conditions involving hips and knees, pulmonary conditions and other conditions selected by the Secretary at SNF payment amounts
- Implement a readmissions payment penalty program for SNFs
- Beginning in 2018, implement a bundled payment for post-acute care services furnished by LTCHs, IRFs, SNFs and home health providers

DURABLE MEDICAL EQUIPMENT

The President proposes to "limit Medicaid Reimbursement of Durable Medical Equipment (DME) Based on Medicare Rates," a phrase that was also used in both the FY 2012 and FY 2013 budgets. According to the Budget, "This proposal, starting in 2014, would limit Federal reimbursement for a State's Medicaid spending on certain DME services to what Medicare would have paid

in the same State for the same services." The Budget estimates that this proposal would save $4.5 billion over 10 years, an estimate that is up from the $3 billion estimate in the President's FY 2013 budget (likely a result of the new lower single payment amounts announced in January 2013 and the American Taxpayer Relief Act of 2012 provision on changing reimbursement for diabetes test supplies).

LABORATORIES

Outpatient clinical laboratory services are currently reimbursed under the Clinical Laboratory Fee Schedule (CLFS). In 2012, CMS's Center for Strategic Planning issued a report calling the current Medicare payment policy for these services "outdated." Consistent with CMS's recommendations to reform payments for these services, the President proposes to lower payment rates under the CLFS. Specifically, he seeks a reduction in the payment rate by 1.75 percent every year from 2016 through 2023, and the granting of authority to the Secretary to adjust payment rates under the CLFS in a budget-neutral manner, precluding administrative or judicial review of these adjustments. In addition, the Budget encourages electronic reporting of laboratory results.

Pharmaceuticals

PART B PAYMENTS

Under current law, drugs and biologicals covered under Part B of Medicare are reimbursed at Average Sales Price plus 6 percent. Now, the President proposes to "reduce payment of physician administered Part B drugs from 106 percent of average sales price to 103 percent of average sales price." According to the administration, "These proposals would save approximately $20 billion over 10 years."

CHANGES TO THE PART D PROGRAM

A recent study by the Office of Inspector General suggests the Part D Program has significantly lower rebates for brand name and prescription drugs than rebates under the Medicaid Program. In addition, there has been a rise in the cost of prescription drug coverage since the Part D program began in 2006. For example, MedPAC estimated in 2012 that average spending per prescription for non-high-cost Part D enrollees was $42 in 2009. As a result, the President proposes to "allow Medicare to benefit from the same rebates that Medicaid receives for brand name and generic drugs provided to beneficiaries who receive the Part D Low-Income Subsidy beginning in 2014." The administration estimates this change would "save $123 billion over 10 years," which is a decrease from the estimate of $156 billion contained in the FY 2013 budget.

In addition, the President seeks to increase utilization of generic drugs by lowering copayments for these drugs by more than 15 percent, to $0.90 for beneficiaries with income below 100 percent of the federal poverty level, and $1.80 for beneficiaries with incomes below 135 percent of the federal poverty level. Copayments for brand name drugs would increase to twice the level required under current law.

GENERIC DRUGS AND FOLLOW-ON BIOLOGICS

Brand name drug manufacturers may currently enter into agreements with generic drug makers to delay introduction of generic equivalents onto the market. In his Budget, the President re-introduces his proposal from his FY 2013 budget that would authorize the Federal Trade Commission to prohibit these agreements. This issue is the subject of a pending Supreme Court of the United States case (*Federal Trade Commission v. Actavis Inc.*).

Section 7002 of the ACA created a pathway for pharmaceutical manufacturers to seek licensure of biological products as biosimilar or interchangeable. Through this legislation, Congress created an exclusivity period of 12 years for the reference product. The President now seeks to hasten generic biological development and competition by reducing the period of exclusivity for brand biologics from 12 years to seven years.

Medicare Advantage Plans

Starting in 2015, the President would change the yearly increase to the minimum coding intensity adjustment from 0.25 percentage points to 0.67 percentage points until the minimum adjustment plateaus at 7.59 percent in 2018 and thereafter. Beginning in 2015, the President also would establish payment amounts for Employer Group Waiver Plans based on the average Medicare Advantage plan bid in each individual market.

Changes Affecting Beneficiaries

In an effort to protect funding for the Medicare trust funds, the President would increase the lowest income-related Part B and D premiums five percentage points, from 35 percent to 40 percent, and also would increase other income brackets until capping the highest tier at 90 percent. The proposal would maintain the income thresholds associated with these premiums until 25 percent of beneficiaries under Parts B and D are subject to these premiums. In addition, the President would gradually increase the deductibles applicable to new beneficiaries under Part B by $75 beginning in 2017. Beginning in 2017, for any new beneficiaries a $100 beneficiary copayment for home health services would be required for episodes with five or more visits not preceded by a hospital or inpatient post-acute stay.

Currently, many Medicare beneficiaries purchase Medigap policies that decrease or eliminate their cost-sharing obligations. The President now articulates the U.S. Department of Health and Human Services' (HHS's) concern that beneficiaries may be increasing costs to the Medicare Program when they have no incentive to consider the financial costs of such care. As such, beginning in 2017 the President proposes to introduce a Part B premium surcharge of approximately 15 percent of the average Medigap premium (or about 30 percent of the Part B premium, according to HHS documents) for new beneficiaries who purchase Medigap policies with particularly low cost-sharing requirements.

All Providers

BAD DEBT REIMBURSEMENT

Medicare pays certain providers a portion of beneficiaries' unpaid coinsurance and deductible amounts. Prior to FY 2013, hospitals were paid 70 percent of these bad debts, while CAHs, rural health clinics, federally qualified health clinics, community mental health clinics and health maintenance organizations were reimbursed on a cost basis, and competitive medical plans, health care prepayment plans and end-stage renal disease facilities were paid 100 percent of uncollected amounts. Medicare paid SNFs 100 percent of bad debts for Medicare beneficiaries who are eligible for Medicaid (dual eligibles) and 70 percent of the uncollected allowable costs for other beneficiaries. In 2012, the Middle Class Tax Relief and Job Creation Act reduced Medicare's bad debt payment to 65 percent for all eligible providers. In the Budget, the President now reiterates his support for further reducing Medicare bad debt payments to 25 percent for all eligible providers over three years starting in 2014. According to the administration, this proposal will save approximately $25 billion over 10 years.

INDEPENDENT PAYMENT ADVISORY BOARD

The Independent Payment Advisory Board (IPAB) is a 15-member board created by the ACA that is required—beginning in 2014—to submit proposals to reduce spending under the Medicare Program *unless* it is determined that projected per capita spending will not exceed the target growth rate for that year. In the Budget, the President demonstrates his interest in enhancing the authority of the IPAB to squeeze more savings from Medicare. Specifically, the President would "lower the target rate from the GDP per capita growth rate plus one percentage point to plus 0.5 percentage point." This proposal is almost verbatim from the text of the President's 2013 budget. The practical effect of this change is that it would require a lower threshold in order for the IPAB to make recommendations for reductions in spending.

FRAUD AND ABUSE ENFORCEMENT

As a result of increased enforcement provisions in the ACA, the Office of Inspector General developed a fraud and abuse identification and enforcement plan in its FY 2013 Work Plan. Mirroring this initiative, the President's Budget includes 17 legislative proposals to further strengthen program integrity for Medicare, Medicaid and the Children's Health Insurance Program. The measures include requiring prepayment review or prior authorization for power mobility devices and advanced imaging services, and allowing civil monetary penalties for providers and suppliers that fail to update enrollment records.

Conclusion

The President's Budget would require legislative changes, and therefore Congress' support, to implement the proposals included therein. While the President's Budget is not likely to advance *in toto*, many individual provisions may move forward if Congress and the President can come to terms on a broad framework for deficit reduction.

Congressional Republicans and the President share a desire to advance deficit reduction legislation, but they differ in how deficit reduction should be achieved. The President and Senate Democrats (as demonstrated by the budget resolution approved earlier in March 2013 by the Senate) prefer a "balanced approach," which achieves deficit reduction through a near equal mix of revenue increases and spending reductions. House Republicans, on the other hand, insist on spending reductions alone, and no further tax increases.

While this difference creates a large ideological divide to overcome, the imperative to reduce the debt and deficit may drive the two parties together. If so, there is considerable agreement between the President and congressional Republicans over how to reduce Medicare to achieve certain savings targets. Many of the proposals contained in the President's Budget have previously been supported by congressional Republicans and so could find their way into a deficit reduction agreement.

For these reasons, the President's Budget is instructive for all health care industry stakeholders that would benefit from a glimpse into potential future Medicare legislation. Interested stakeholders should take note of these proposed changes and find opportunities to help shape these payment policies in the coming months.

For more information, please contact your regular McDermott lawyer, or:

Eric Zimmerman: +1 202 756 8148 ezimmerman@mwe.com

Elizabeth Isbey: +1 202 756 8283 eisbey@mwe.com

For more information about McDermott Will & Emery visit www.mwe.com

The material in this publication may not be reproduced, in whole or part without acknowledgement of its source and copyright. *White Paper* is intended to provide information of general interest in a summary manner and should not be construed as individual legal advice. Readers should consult with their McDermott Will & Emery lawyer or other professional counsel before acting on the information contained in this publication.
© 2013 McDermott Will & Emery. The following legal entities are collectively referred to as "McDermott Will & Emery," "McDermott" or "the Firm": McDermott Will & Emery LLP, McDermott Will & Emery AARPI, McDermott Will & Emery Belgium LLP, McDermott Will & Emery Rechtsanwälte Steuerberater LLP, McDermott Will & Emery Studio Legale Associato and McDermott Will & Emery UK LLP. These entities coordinate their activities through service agreements. McDermott has a strategic alliance with MWE China Law Offices, a separate law firm. This communication may be considered attorney advertising. Prior results do not guarantee a similar outcome.