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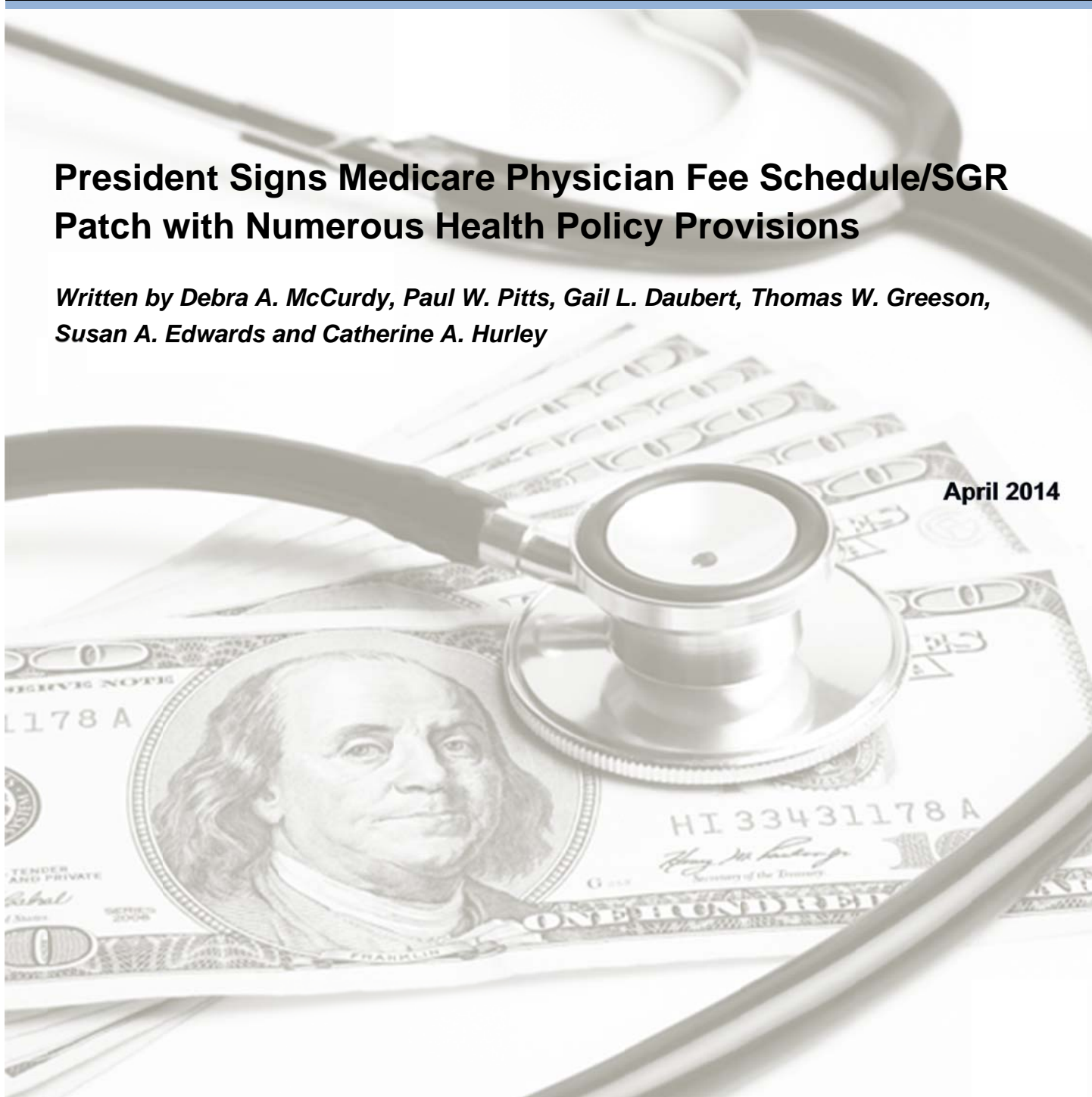
Client Alert

Life Sciences Health Industry Group

President Signs Medicare Physician Fee Schedule/SGR Patch with Numerous Health Policy Provisions

Written by Debra A. McCurdy, Paul W. Pitts, Gail L. Daubert, Thomas W. Greeson, Susan A. Edwards and Catherine A. Hurley

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IF YOU HAVE QUESTIONS OR WOULD LIKE ADDITIONAL INFORMATION ON THE MATERIAL COVERED IN THIS ALERT, PLEASE CONTACT ONE OF THE AUTHORS:

Debra A. McCurdy
Senior Health Policy Analyst,
Falls Church
+1 703 641 4283
dmccurdy@reedsmith.com

Paul W. Pitts
Partner, San Francisco
+1 415 659 5971
ppitts@reedsmith.com

Gail L. Daubert
Partner, Washington, D.C.
+1 202 414 9241
gdaubert@reedsmith.com

Thomas W. Greeson
Partner, Falls Church
+1 703 641 4242
tgreeson@reedsmith.com

Susan A. Edwards
Associate, Washington, D.C.
+1 202 414 9261
saedwards@reedsmith.com

Catherine A. Hurley
Associate, Washington, D.C.
+1 202 414 9229
churley@reedsmith.com

...OR THE CHAIR OF THE LIFE SCIENCES HEALTH INDUSTRY GROUP

Carol C. Loepere
Partner, Washington, D.C.
+1 202 414 9216
cloepere@reedsmith.com

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President Signs Medicare Physician Fee Schedule/SGR Patch with Numerous Health Policy Provisions

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On April 1, 2014, President Obama signed into law H.R. 4302, the “Protecting Access to Medicare Act of 2014” (“the Act”).¹ The Act includes a one-year Medicare physician fee schedule (MPFS) fix that averts a nearly 24 percent payment cut set for April 1, 2014, but which falls far short of earlier hopes for full repeal of the current sustainable growth rate (SGR) formula. The Act also includes numerous other Medicare payment and policy changes, including skilled nursing facility (SNF) value-based purchasing provisions, reforms to the physician fee schedule relative valuation process, a new framework for clinical laboratory payments, a variety of changes impacting imaging services, changes in the exceptions for long term care hospitals (LTCHs), and extension of certain expiring provisions. In other areas, the bill includes a one-year delay in the transition to ICD-10, changes to the timetable for Medicaid disproportionate share hospital (DSH) cuts, and “front-loading” of the 2024 Medicare sequestration reduction. A summary of major provisions of the Act follows.

One-Year Medicare Physician Fee Schedule Fix

The final Medicare physician fee schedule rule for 2014, which was published on December 10, 2013, called for a significant reduction in the MPFS update for 2014, largely as a result of the statutory SGR formula. The Congressional Budget Office (CBO) estimates that if implemented, the final rule would result in a 23.7 percent cut in physician payments for 2014. The Bipartisan Budget Act of 2013 temporarily blocked the SGR cut and replaced it with a 0.5 percent increase for services provided through March 31, 2014.

The Act extends the 0.5 percent update through December 31, 2014. CMS has confirmed that the conversion factor for the remainder of the year continues to be \$35.8228. Moreover, the Act provides a 0 percent update from January 1, 2015 through March 31, 2015 – likely reverting to the 2013 conversion factor for three months (although the January-March 2015 Medicare conversion factor could see some slight change as a result of budget neutrality adjustments that occur annually through the rulemaking process). The conversion factor for the remainder of 2015 and subsequent years would be computed as if the 0 percent update had not applied, so physicians would again face a steep SGR cut yet again beginning April 1, 2015. Note that Medicare sequestration cuts applicable to payments under the MPFS and other Medicare payment systems also continue under the Act, as described below.

¹ Public Law No: 113-93.

Valuation of Services Under the Physician Fee Schedule

The Act seeks to improve the accuracy of relative values for physician services under the MPFS, while achieving savings by addressing payment for “misvalued” procedures. In short, the Act allows the Secretary to use new sources of data to set relative values, including (1) surveys of physicians, other suppliers, providers, manufacturers, and vendors; (2) surgical logs, billing systems, or other practice records; and (3) electronic health records. These sources would be announced through notice and comment rulemaking. The Act provides up to \$2 million annually to compensate eligible professionals who submit information under this provision. The Act also expands the criteria the Secretary must use for identifying potentially misvalued codes to include, among others, codes that have experienced the fastest growth or substantial changes in practice expense, new technologies, codes that account for the majority of spending under the physician fee schedule, codes for services that have experienced a substantial change in the hospital length of stay or procedure time, codes with high-cost supplies, and codes for which there is a significant difference in payment for the same service between different sites of service.

The Act establishes a 0.5 percent target for relative value adjustments for misvalued codes under the MPFS, applicable annually from 2017 through 2020. If the estimated net reduction in expenditures for the year is equal to or greater than the 0.5 percent target, reduced expenditures attributable to the adjustments will be redistributed in a budget-neutral manner within the physician fee schedule. If the estimated net reduction in expenditures for the year is less than the 0.5 percent target, fee schedule payments will be reduced by the difference. Beginning in 2017, if the RVU reduction for a code would be more than 20 percent compared to the previous year, the reduction will be phased in over two years. The CBO estimates that the relative value provision will save \$600 million over five years and \$4 billion over 10 years.

The Secretary is authorized to “smooth” minor differences in relative values for families or groups of procedures. The Act also directs the Government Accountability Office (GAO) to assess the processes used by Relative Value Scale Update Committee to provide recommendations to the Secretary regarding the relative values for specific services under the physician fee schedule.

ICD-10 Delay

CMS previously scheduled implementation of the International Classification of Diseases, 10th Revision (ICD-10) code sets for October 1, 2014. The Act delays this schedule, however, and prohibits the HHS Secretary from adopting the ICD-10 code sets as the Medicare standard prior to October 1, 2015. The Act does not address CMS’s current limitation on updates to the ICD-9 and ICD-10 code sets that had been imposed in anticipation of an October 1, 2014 transition.

LTCH Moratorium to Become Effective Immediately

The Act advances the effective date of a new moratorium on the establishment and classification of new LTCHs, LTCH satellite facilities, and LTCH beds in existing LTCHs or satellite facilities. A moratorium was previously in place for a five-year period before expiring on December 28, 2012. The Bipartisan Budget Act reinstated the moratorium beginning January 1, 2015 through September 30, 2017. Now, as a result of enactment of the Act, the new moratorium will be effective on April 1, 2014 and continue through September 30, 2017.

The Act includes exceptions to the moratorium that are applicable to LTCHs currently under development. These exceptions are the same as the exceptions to the original five-year moratorium enacted in the Medicare, Medicaid, and SCHIP Extension Act of 2007. Notably, the new moratorium will not apply to LTCHs that:

- 1) began their qualifying period to become an LTCH before April 1, 2014;
- 2) have a binding written agreement as of April 1, 2014 with an unrelated party for construction, renovation, or lease for an LTCH and have expended at least 10 percent of the estimated cost of the project (or, if less, \$2,500,000); or
- 3) have obtained a certificate of need on or before April 1, 2014.

Skilled Nursing Facility (SNF) “Value-Based Purchasing”

The Act requires the Secretary to establish two hospital readmission-related measures that will apply to SNFs: (1) a SNF “all-cause all-condition” hospital readmission measure; and (2) a measure to reflect an “all-condition risk-adjusted potentially preventable hospital readmission rate” for SNFs. In specifying such measures, the Secretary must develop a methodology that leads to reliable and valid results, particularly for SNFs with few admissions, and the Secretary may work with a consensus-based entity, such as the National Quality Forum, to develop the measures. Beginning October 1, 2016, the Secretary will provide confidential reports, on a quarterly basis, giving SNFs feedback with respect to the two measures. No later than October 1, 2017, SNFs’ performance with respect to the two measures will be posted on [Nursing Home Compare](#) (or a successor website). However, pursuant to the Act, SNFs will have the opportunity to review and submit corrections to the hospital readmission information before it is made publically available. In addition, Nursing Home Compare will include information regarding an individual SNF’s readmission performance score and ranking under the SNF “value-based purchasing program” (SNF VBP), as discussed further below, and certain aggregate information, including the range of SNF readmission performance scores in the SNF VBP.

The Act also requires the Secretary to establish a SNF VBP, which will apply to payments for services furnished by SNFs on or after October 1, 2018 (i.e., FY 2019). Under the SNF VBP, the Secretary must develop a

methodology for assessing the readmission performance of SNFs (based on performance standards that include levels of improvement or achievement in one of the aforementioned readmission measures). After developing performance scores for each SNF during each performance period, the Secretary must rank SNF performance scores from high to low. A SNF's adjusted federal per diem rate will be multiplied by the applicable value-based incentive payment percentage, which is determined based on a particular SNF's readmission performance score. The lowest 40 percent of SNFs—as ranked with respect to readmission performance score—will face reduced adjusted federal per diem rates.

Pursuant to the Act, beginning with FY 2019, the Secretary will reduce all SNF adjusted federal per diem rates by 2 percent. This reduction will fund the value-based incentive payments made to SNFs with certain readmission performance score rankings. Notably, however, the total amount of value-based incentive payments will not be greater than 70 percent of the total amount of the aforementioned 2 percent reduction.

The Secretary must inform a SNF about the payment adjustments that will be made under the SNF VBP no later than 60 days prior to the fiscal year involved. The Act includes a provision that limits administrative and judicial review of the methodology used to determine the value-based incentive payment percentage and the amount of value-based incentive payments, among other aspects of the SNF VBP. Finally, the Act requires that the Medicare Payment Advisory Commission (MedPAC) review the progress of the SNF VBP and report to Congress with recommendations, as appropriate, no later than June 30, 2021.

Medicare Policies for Clinical Diagnostic Laboratory Tests

The Act substantially changes the way clinical laboratories will be paid for diagnostic testing beginning in 2017. Instead of a fee schedule approach, Medicare will pay laboratories using a market approach, at rates that are based on what private payers pay for the test. Specifically, beginning in 2016, laboratories will report to the Secretary the rates that each private payer, as defined, paid for each test (reflecting all discounts, rebates or other price concessions), and the volume of tests that were billed to the payer, during the applicable reporting period. Using this information, Medicare will calculate Medicare reimbursement rates for each test equal to the median of the rates private payers paid, weighted by volume. If the rates calculated pursuant to the new methodology are lower than existing rates, the reductions in payment will be phased in over time.

New tests and new “advanced diagnostic laboratory tests,” (defined as tests that analyze multiple DNA, RNA, or protein biomarkers, or are approved by the FDA, and are furnished by a single laboratory that developed the test), will be subject to separate reimbursement policies. New tests that are not “advanced diagnostic laboratory tests” will initially be paid by either the crosswalking or the gapfilling process that is currently used to establish reimbursement rates for new diagnostic tests. See 42 C.F.R. § 414.508. New advanced diagnostic laboratory tests will initially be paid based on the laboratory's actual list charge for the test. If it turns out that such list

charge exceeds the market rate that would have been paid under the new methodology by 30 percent, the Secretary must recoup the difference.

Finally, the Act requires Medicare Administrative Contractors (MACs) to follow the local coverage determination process when issuing coverage policies with respect to clinical diagnostic laboratory tests and allows the Secretary to designate up to four MACs to establish coverage policies and process claims for clinical laboratory tests.

Computed Tomography Policy

In an effort to minimize patient exposure to ionizing radiation from computed tomography (CT) scans, beginning January 1, 2016, the Act reduces Medicare payment for the technical component of CT services when the services are performed on equipment that does not meet the requirements of the National Electrical Manufacturers Association, or NEMA, Standard XR-29-2013, or such other standard as CMS may adopt in future rules. According to industry reports, slightly more than one-third of CT scanners operating in the United States currently do not meet the NEMA dose standards. The payment reduction is only applicable to the technical component of CT services billed under the MPFS and the Hospital Outpatient Prospective Payment System (HOPPS). It does not apply to hospital inpatient services billed under the Medicare Inpatient Prospective Payment System.

For CT services performed on scanners that do not meet the NEMA standard and are subject to the payment reduction, the technical component payment will be reduced by 5 percent in 2016 and 15 percent in 2017 and in subsequent years.

The following HCPCS codes are subject to the new payment policy: 70450–70498; 71250–71275; 72125–72133; 72191–72194; 73200–73206; 73700–73706; 74150–74178; 74261–74263; 75571–75574. In future years CMS may apply the payment policy to any codes that succeed these initial codes.

CMS will verify whether a CT meets the NEMA standard through a modifier to the claim form or another form of attestation by the imaging provider. Verifications may also be made through the existing process for accreditation of advanced diagnostic imaging services required for Medicare outpatient imaging services.

Appropriate Use Criteria for Outpatient Advanced Diagnostic Imaging Services

The Act requires CMS to develop appropriate use criteria for outpatient advanced diagnostic imaging services by November 15, 2015. Slightly more than one year later, beginning January 1, 2017, physicians and practitioners ordering outpatient advanced diagnostic imaging services on behalf of a Medicare beneficiary must consult with a

qualified decision support system and provide the furnishing professional with information confirming that a clinical decision support system was consulted.

The Medicare program will only pay for advanced diagnostic imaging services billed under the MPFS, the HOPPS, or the Ambulatory Surgery Center payment system after January 1, 2017 if the claim for such services provide the NPI of the ordering physician or practitioner and information about which clinical decision support mechanism was consulted. The information must include whether the service: (1) adheres to the appropriate use criteria; (2) does not adhere to the appropriate use criteria; or (3) the appropriate use criteria is not applicable to the service ordered.

The requirements to consult with appropriate use criteria do not apply to patients with an emergency medical condition or inpatients. In addition, the Act permits CMS to exempt ordering physicians and practitioners from consulting with appropriate use criteria (and furnishing suppliers from reporting on such consultations) on a case-by-case basis if such consultations would result in a significant hardship. What constitutes a significant hardship is subject to CMS's determination on an annual basis; however, the Act provides the example of an ordering physician located in a rural area without sufficient Internet access.

Beginning January 1, 2020, prior authorizations will be required for outpatient advanced diagnostic imaging services ordered by a physician or practitioner who is determined to be an "outlier" in utilizing appropriate use criteria. CMS will identify these outliers by identifying on an annual basis those physicians and practitioners who have a low adherence to appropriate use criteria compared to other ordering physicians or practitioners during a two-year period. No more than 5 percent of the total number of ordering physicians and practitioners may be deemed outliers in any one year.

In developing the appropriate use criteria, CMS is required to consult with physicians, practitioners, and other stakeholders on criteria that has been endorsed by professional medical specialty societies, such as the ACR, or other provider-led entities. The criteria must be scientifically valid and evidence based as demonstrated through studies published and reviewed by stakeholders. The criteria is subject to review and update through annual rulemaking. The Act specifically prohibits CMS from independently developing or initiating the development of appropriate use criteria or clinical practice guidelines.

The Act requires CMS to specify by April 1, 2016 the mechanisms that ordering physicians or practitioners may use to consult with appropriate use criteria, which may include (1) clinical decision support modules in certified EHR technology, (2) clinical decision support mechanisms developed by the private sector that are independent from certified EHR technology, and/or (3) clinical decision support mechanisms established by CMS.

The Act also requires the Comptroller General to report to Congress within 18 months on the extent to which appropriate use criteria could be used for other Medicare Part B services, such as radiation therapy and clinical laboratory services.

Disclosure of Data Used to Establish the Multiple Procedure Payment Reduction Policy

The Act requires CMS to provide the public with the data the agency used to justify the 25 percent multiple procedure payment reduction, or “MRRP,” applied to certain imaging procedures provided to the same patient, on the same day, in the same session.

Limitation on “Two-Midnight Rule” Enforcement

The Act places limits on enforcement of new Medicare inpatient hospital admission and medical review criteria commonly known as the Two-Midnight Rule. Specifically, recovery audit contractors (RACs) are prohibited from conducting post-payment patient status reviews related to this policy for inpatient claims with dates of admission on October 1, 2013 through March 31, 2015 “unless there is evidence of systematic gaming, fraud, abuse, or delays in the provision of care.” The Act specifies that the Secretary may continue previously-announced “probe and educate” medical review activities through March 31, 2015 for additional hospital claims as appropriate.

Extension of Medicare Expiring Provisions

The Act extends for one year certain Medicare policies set to expire March 31, 2014, including: the Medicare physician work Geographic Cost Price Index (GPCI) floor; the outpatient therapy cap exceptions process; certain ambulance add-on payments; the Medicare low-volume hospital payment adjustment; and the Medicare-dependent Hospital program. In addition, the Act extends for one year the authority for Medicare Advantage Special Needs Plans and certain Medicare reasonable cost contracts.

Extension of Other Expiring Health Policy Provisions

The Act provides funding for the National Quality Forum (NQF) for certain health care performance measurement activities through March 31, 2015. The Act also extends for one year funding for the Qualified Individual program (which reimburses states for certain Part B premiums); the Transitional Medical Assistance program; the Medicaid and CHIP Express Lane Eligibility option; the Special Diabetes Program for type 1 diabetes and for Indians; abstinence education programs; the Personal Responsibility Education Program (PREP); Family-to-Family Health Information Centers; the health workforce demonstration project for low income individuals; the Maternal, Infant, and Early Childhood Home Visiting program; and outreach and assistance funding for certain low-income programs (including the State Health Insurance Programs, Area Agencies on Aging, Aging and Disability

Resource Centers, and the National Center for Benefits). In addition, the Act continues funding for development of pediatric quality measures.

Revisions to the Medicare ESRD PPS

The Act makes a series of changes to the Medicare end stage renal disease (ESRD) prospective payment system (PPS). Among other things, the Act mitigates the effect of an American Taxpayer Relief Act of 2012 provision that requires a reduction in ESRD PPS payments to account for decreased utilization of ESRD-related drugs and biologicals. The Act provides that in lieu of the reduction schedule set forth in a [December 2, 2013 final rule](#), the payment reduction will be accomplished through a market basket freeze for 2015, a 1.25 percentage point reduction to the market basket update in 2016 and 2017, and a 1.0 percentage point reduction to the market basket update in 2018.

In addition, the Act delays inclusion of “oral-only” drugs in the ESRD bundled payment until 2024 (instead of 2016), requires the adoption of quality measures specific to conditions created with oral-only drugs; and requires the Secretary to establish a process for (1) determining when a product is no longer an oral-only drug and (2) including new injectable and intravenous products into the ESRD PPS.

Medicaid DSH Payments

The Act restructures planned reductions in Medicaid disproportionate share hospital (DSH) payments by delaying FY 2016 cuts until FY 2017 but increasing the overall level of reductions and extending cuts through FY 2024. The provision has the effect of boosting payments by \$2.9 billion during the period of 2014-2019, but decreasing payments by a total of \$4.4 billion over the 2014-2024 budget window. The Act also requires the Medicaid and CHIP Payment and Access Commission (MACPAC) to submit an annual report to Congress on DSH payments, including data related to the amount and sources of hospitals’ uncompensated care costs and their provision of essential community services to targeted populations, among other things.

2024 Medicare Sequestration Cuts

Under the Budget Control Act of 2011, as subsequently amended by additional legislation, Medicare provider and plan payments are subject to [2 percent across-the-board cuts known as sequestration](#). Medicare sequestration cuts currently are scheduled to last through 2024 (although Congress could repeal or revise the sequestration provisions at any time). The Act “realigns” the Medicare sequestration amounts for FY 2024 to capture more of the sequestration savings during the first half of FY 2024, which falls in the legislation’s 10-year budget window. Specifically, the current 2 percent cap on Medicare provider payment cuts will be raised to 4 percent for the first six months of FY 2024, and then drop to 0 percent for the second half of FY 2024. This change “scores” as \$4.9 billion in savings in FY 2024 as a whole.

Delay of Medicaid Third-Party Liability Reforms

The Act delays implementation of a provision in the Bipartisan Budget Act that is intended to strengthen Medicaid third-party liability. Among other things, that provision reinforces Medicaid's standing as the payer of last resort by letting states delay paying certain prenatal and preventive pediatric care claims, to the extent that doing so is cost-effective and will not adversely affect access to care. It also allows Medicaid to recover costs from beneficiary liability settlements. While these provisions were scheduled to take effect on October 1, 2014, the Act delays the effective date for two years, until October 1, 2016.

Elimination of Limitation on Deductibles for Employer-Sponsored Health Plans

The Act repeals Section 1302(c)(2) of the Patient Protection and Affordable Care Act (PPACA), thereby eliminating the deductible limitations on small group plans.

Mental Health Provisions

The Act directs the Secretary to establish a pilot project in up to eight states to improve access to and quality of outpatient mental health treatment through the use of certified community behavioral health clinics. The Act also authorizes \$15 million for each of FYs 2015 through 2018 to provide grants to states to implement assisted outpatient treatment programs for individuals with serious mental illness.

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