

Bipartisan Budget Act of 2018 Includes Significant Changes in Medicare, Other Federal Health Programs

February 2018

*On February 9, 2018 after a brief shutdown, Congress passed and President Trump signed the **Bipartisan Budget Act of 2018**, a two-year budget agreement that includes funding for the operation of the federal government until March 23, 2018.*

The law includes significant health care policy changes impacting Medicare, Medicaid and other federal health agencies. In addition to raising federal spending caps enacted in the Budget Control Act of 2011, this legislation includes additional spending for health care priorities.

This article offers an overview of the Act's major federal health care program provisions. It is not, however, an exhaustive summary of all the health care provisions in the new law, and we encourage readers to review the law to identify additional provisions that may be of interest to your organization.

Helpful Resources



- Bipartisan Budget Act ([Text](#))



For more information please contact [Eric Zimmerman](#) or [Piper Su](#).

On February 9, 2018, following several continuing resolutions that have kept federal doors open since the previous funding agreement expired on September 30, 2017, the US Congress passed the **Bipartisan Budget Act of 2018** (Act) to enact a two-year federal spending agreement and provide for the operation of the federal government until March 23, 2018. In addition to addressing a number of critical budget questions, the legislation includes significant health care policy changes impacting Medicare, Medicaid and other federal health agencies. The agreement's inclusion of budget provisions for a two-year time period marks a positive departure from the shorter-term spending bills typical of the recent past, and it includes other necessary actions such as the periodic raising of the nation's debt ceiling to ensure continued payment of financial obligations.

The Bipartisan Budget Act addresses a number of key health funding issues. First, it raises the federal spending caps previously enacted in the Budget Control Act of 2011 and increases annual spending authority above sequestration levels for both defense and non-defense spending levels.


The law allocates an additional \$2B for NIH and \$6B to fight opioid abuse


The non-defense spending cap will be higher by \$63 billion and \$68 billion in 2018 and 2019, respectively. It does not alter the separate sequestration reduction of two percent for payments under Medicare and, in fact, extends those reductions through 2027. It also includes significant funding for key health care initiatives, including \$2 billion for the National Institutes for Health (NIH) and \$6 billion in funding to address the opioid epidemic over the next two years. These provisions, in addition to the specific Medicare and Medicaid program policies highlighted below, represent the largest legislative package addressing health issues since passage of the Medicare Access and CHIP Reauthorization Act (MACRA) in 2015.

The federal health care program changes included in the Act cover a wide range of issue areas in addition to the time-sensitive extension of several Medicare programs that expired in 2017. Notably, it also includes an additional four-year extension of the Children's Health Insurance Program (CHIP) to follow the six years already authorized in the HEALTHY KIDS Act of 2018 enacted last month, meaning that the program will not expire again until 2027. It also includes the long-awaited repeal of the Independent Payment Advisory Board (IPAB) established in the Affordable Care Act of 2010 (ACA) to control growth in health care spending. This article offers an overview of the Act's major federal health care program provisions. It is not, however, an exhaustive summary of all the health provisions in the new law and we encourage readers to review the legislation to identify additional provisions that may be of interest to your organization.

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PHYSICIAN AND PRACTITIONER SERVICES

Permanent Repeal of Caps on Outpatient Therapy Services

Under Medicare, outpatient therapy services (physical therapy (PT), occupational therapy (OT), and speech and language pathology (SLP) services) are covered under Part B regardless of where services are delivered. In the Balanced Budget Act of 1997 (BBA 97), Congress enacted two annual limits (or “caps”) per beneficiary: one cap for PT and SLP services combined, and another cap for OT services. Cap limits are updated annually to account for inflation and in 2017 were \$1,980 each. Almost immediately, caps led to concerns that such spending limits would restrict access to medically necessary services. Congress suspended the caps from 2000 to 2005 but reinstated them with an accompanying exceptions process in 2006. The exceptions process allows beneficiaries to use services above the annual spending limit if a provider certifies that additional services are medically necessary. Congress last reauthorized these exceptions through December 31, 2017, and instituted a medical review process for beneficiaries whose annual utilization exceeded \$3,700.

The new law permanently repeals the therapy caps starting in January 2018 but maintains the use of a modifier attesting to medical necessity documented in medical records. The threshold for targeted medical review of claims is lowered to \$3,000 until 2028, after which the threshold will be increased per a specified formula.

Modifications to the Quality Payment Program and Reduction of the Annual Physician Fee Schedule Update in 2019

The law also includes several technical amendments related to the Medicare Physician Fee Schedule and the new Medicare Quality Payment Program (QPP), the Medicare physician quality program that was established through MACRA. Under current law, beginning in 2019, eligible clinicians will be paid for Medicare services under the QPP, and they will elect to either be subject to payment adjustments based upon performance under the Merit-based Incentive Payment System (MIPS) or to participate in the Advanced Alternative Payment Model (APM) track. Many of these technical amendments are related to MIPS transition issues raised by the physician community and other stakeholders.

QPP changes exclude Part B drugs from MIPS adjustment; offer flexibility in MIPS implementation

Reduction in Physician Fee Schedule Update

MACRA established a fee schedule update of 0.5 percent beginning July 1, 2015, and continuing each year through 2019. Section 53106 reduces the 2019 update from 0.50 percent to 0.25 percent.

Repeal of the Application of the MIPS Payment Adjustment to Part B Drugs

In the 2018 QPP Final Rule, the Centers for Medicare and Medicaid Services (CMS) clarified that MIPS payment adjustments (both positive and negative) will be made to payments for both items and services under Medicare Part B, including Part B drugs. This policy was a departure from previous physician quality programs, such as the Physician Quality Reporting System (PQRS), in which adjustments applied only applied to professional services. Under the new law, Congress limits the MIPS payment adjustment only to professional services, thereby excluding reimbursement for drug-related expenses from the MIPS adjustment.

Slowing Down the Implementation of the Cost Performance Category in MIPS

MIPS participants are scored based on their performance in four categories: Quality, Advancing Care Information, Improvement Activities and Cost. MACRA requires the Cost performance category to be weighted at not more than 10 percent for the first year of the program, not more than 15 percent for the second year of the program and 30 percent by the third year of the program. CMS has been challenged in

implementing the Cost performance category, since there is a lack of cost measures ready for adoption. The legislation revises the timeline of the implementation of the Cost performance category so that for the second through fifth years of the program (2020 through 2023), the Cost performance category “shall be not less than 10 percent and not more than 30 percent of the MIPS score.”

Continued Incremental Transition of the MIPS Adjustment

In the first two years of the MIPS program, CMS set the threshold that determines if a clinician will receive a neutral, positive or negative payment adjustment relatively low for the first two years of the program, resulting in a slow and gradual transition to MIPS for clinicians. MACRA requires that, in the third year of the program, CMS set this threshold at the historical mean or median of MIPS scores nationally. The new law continues the gradual transition of the MIPS program by requiring the US Department of Health and Human Services (HHS) Secretary to increase the performance threshold from the third through the fifth years of MIPS, i.e., 2021 through 2023.

Scope of Work of PTAC Established in Statutory Language

In order to promote the development of APMs for physicians, the MACRA statute established the Physician Focused Payment Model Technical Advisory Committee (PTAC). PTAC was tasked with reviewing proposals for physician-focused APMs submitted by the public and making recommendations on their implementation to CMS. The new legislation expands the language from the original MACRA statute describing PTAC’s scope of work and requiring the panel to provide “initial feedback” on models and an “explanation of the basis for the feedback provided.” Since PTAC’s establishment, there has been significant discussion and debate around its processes and the role and impact its recommendations have on CMS, which has authority to establish and implement APMs through the CMS Center for Medicare and Medicaid Innovation Center (Innovation Center).

Updated Eligibility for the Intensive Cardiac Rehabilitation Benefit

Intensive cardiac rehabilitation (ICR) services are covered under Medicare Part B for beneficiaries with specified conditions who meet program guidelines. The new law modifies these guidelines to add coverage of ICR services for patients with “stable, chronic heart failure” and “any additional condition for which the Secretary has determined that a cardiac rehabilitation program should be covered, unless the Secretary determines...that such coverage is not supported by the clinical evidence.” While these patients previously had access to cardiac rehabilitation services, the change now allows them to qualify for the more intensive set of services.

Expanded Access to Telehealth Stroke Services

The new law expands, beginning in 2019, the ability of patients presenting with stroke symptoms at hospitals or mobile stroke units to receive a timely telehealth consultation with a neurologist in order to determine the best course of treatment. The provision eliminates the current geographic restriction that limits originating sites to rural areas, meaning distant site providers delivering telestroke services could receive a professional fee for delivering the consultation to patients located anywhere in the United States, provided that the other Medicare telehealth coverage requirements are satisfied (e.g., type of provider, type of technology).

Transition Period Payment for Medicare Home Infusion Services

Medicare reimbursement for home infusion services was recently updated in the 21st Century Cures Act to implement a revised payment methodology under the current benefit beginning in 2017, and to add a new benefit for home infusion education and services beginning in 2021. Due to the time lag between the effective date of the revised payment policy and the new benefit, Congress grew concerned that some beneficiaries may experience difficulty accessing home infusion services during this period. This new law establishes a temporary transition payment for education and services beginning in 2019, and establishes specific payment rates in three categories based upon existing HCPCS codes during the transition period.

Payment Rate for Services Furnished by Physical Therapy and Occupational Therapy Assistants

The new law requires that PT and OT services furnished by PT or OT assistants will be paid at 85 percent of current rates after January 1, 2022. The Act directs the Secretary to develop the appropriate modifier to identify claims for services performed by PT and OT assistants by January 1, 2019, and to put the codes in use by January 1, 2020.

Extension of the Geographic Practice Cost Index (GPCI) Payment Adjustment

Medicare payments to physicians are geographically adjusted to reflect the varying cost of delivering physician services across areas. The adjustments are made by indices, known as the Geographic Practice Cost Indices (GPCI), that reflect how each geographic area compares to the national average.

In 2003, Congress established that for three years there would be a “floor” of 1.0 on the “work” component of the formula used to determine physician payments, which meant that physician payments would not be reduced in a geographic area just because the relative cost of physician work in that area fell below the national average. Congress has extended the work GPCI floor several times, but the most recent extension expired December 31, 2017. The new law now extends the work GPCI floor of 1.0 for an additional two years, through 2019.

Transition Payment for Certain Radiation Therapy Services

In 2015, the Patient Access and Medicare Protection Act (PAMPA) put a freeze on Medicare reimbursement rates in 2017 and 2018 for freestanding radiation therapy centers at the 2016 Medicare payment levels. It was intended to be transitional as the industry was to be moving to an episodic alternative payment model. While the CMMI is in the process of developing a radiation therapy APM, it will not be operational by 2019, prior to the expiration of the freeze on payment rates. As such, the Act extends the payment freeze through 2019.

HOSPITAL SERVICES

Meaningful Use Flexibility

The new law removes the requirement enacted in the Health Information Technology for Economic and Clinical Health (HITECH) Act that requires HHS to make the requirements of the Meaningful Use electronic health record incentive program more stringent over time. Removal of this so-called escalator clause gives the administration significant additional flexibility in administering the program. Providers have struggled to meet program requirements, and Congress has had to step in and afford providers expanded hardship exceptions from various program requirements and penalties.

Delay of 2018 and 2019 Medicaid DSH Payment Reductions

The ACA reduced the amount paid under Medicaid disproportionate share hospital (DSH) payments based on the expectation that expanded access to coverage included in the other portions of that law would reduce the need to reimburse hospitals for uncompensated care. As a result of shifting market dynamics and policies, however, Congress has revised and delayed those reductions in subsequent legislation. The law furthers this trend by removing the \$5 billion DSH payment cuts scheduled for both 2018 and 2019 under current law but adding additional DSH reductions of \$4 billion in 2020 and \$8 billion each year in 2021 through 2025.

Extension of the Medicare Dependent Hospital (MDH) Program

Under the Medicare Hospital Inpatient Prospective Payment System (IPPS), hospitals that are located in rural areas and treat a high percentage of Medicare beneficiaries are eligible for enhanced payments,

including payments on a cost basis. Although the MDH program was established in 1990, Congress has periodically reauthorized it only for limited periods, and the most recent reauthorization expired September 30, 2017. The new law reauthorizes this program for five more years through FY 2022. The new law also expands program eligibility slightly, making it available to hospitals in all-urban states (i.e., states that do not have rural areas) that would qualify for urban-to-rural reclassification. This change benefits hospitals in three all-urban States: Delaware, New Jersey and Rhode Island.

Extension of the Medicare Low-Volume Hospital Program

Under the IPPS, rural hospitals with low inpatient volumes are eligible for a percentage increase to each payment. The ACA substantially broadened the eligibility criteria, enabling many more hospitals to qualify for these additional payments, and revised the percentage increase methodology, but set these changes to expire after two years. Subsequent legislation, most recently MACRA, extended these changes for additional time, but these provisions expired on September 30, 2017. The new law extends the eligibility expansion and ACA methodology for calculating such payments through 2022. Notably, the legislation also would make the low-volume adjustments available to more hospitals by increasing the eligibility threshold from the ACA maximum 1,600 Medicare discharges (currently at 800 discharges, since the ACA provision expired on October 1, 2017) to a new maximum of 3,800 discharges. The new law makes corresponding changes to apply the adjustment to hospitals with between 500 and 3,800 discharges.

Outpatient Therapy Supervision for Critical Access Hospitals (CAHs) and Rural Hospitals

In 2009, CMS changed the supervision requirements for outpatient therapy services at all hospitals (except CAHs and small rural hospitals) requiring that a supervising physician be physically present in the department at all times when Medicare beneficiaries are receiving outpatient therapy. CMS announced that it would apply the supervision requirement to CAHs and small rural hospitals beginning in 2014, but Congress approved legislation barring enforcement of the supervision requirement for 2014, 2015 and 2016. The policy went into effect for CAHs and small rural hospitals in 2017. CMS on its own volition recently announced that it would suspend enforcement for 2018 and 2019, but left 2017 unaddressed. The new law fills that gap by suspending enforcement of this supervision requirement for CAHs and small rural hospitals in 2017 as well.

POST-ACUTE SERVICES

Revisions to Home Health Payment Methodology

The new law requires CMS to implement changes to the Home Health Prospective Payment System consistent with the Home Health Groupings Model changes proposed, but not implemented, by CMS in 2017. Specifically, beginning in 2020, CMS must begin using a 30-day episode as the unit of service for determining payment for home health services. The new legislation requires CMS to implement these changes in a budget-neutral manner (when CMS proposed to make similar changes in a non-budget neutral manner in 2017, effective in 2019, the agency estimated that doing so would reduce payments by as much as 4.3 percent), but it does permit the agency to make payment adjustments to offset anticipated behavior changes that could result from the changed methodology.

Home Health payments will be reformed beginning in 2020

Extension of the Home Health Rural Add-on Payment

Legislation enacted in 2000 provided a temporary 10 percent increase for home health services furnished in rural areas. The payment increase has been periodically and temporarily extended, but the amount of the adjustment was lowered, first to 5 percent and then to 3 percent. The new legislation extends the 3

percent add-on for all home health services furnished in rural areas for one year, through calendar year 2018. After that, the amount of the adjustment is 3 percent for 2019, 2 percent for 2020 and 1 percent for 2021, unless the home health service is furnished in a rural area described below, in which case an alternative adjustment (as specified) applies:

- For services furnished in areas that are within the highest quartile of service frequency based on the number of Medicare home health episodes furnished per 100 individuals, the adjustment is 1.5 percent in 2019 and 0.5 percent in 2020, but discontinued thereafter; and
- For low population density areas (*i.e.*, six individuals or fewer per square mile of land area), the adjustment is 4 percent in 2019, 3 percent in 2020, 2 percent in 2021 and 1 percent in 2022, but discontinued thereafter.

Updated Home Health Documentation Requirements

The new law relaxes the documentation standards necessary to qualify a home health service for payment by allowing the medical records of the home health agency to demonstrate home-bound and medical necessity status, in addition to the medical records of the certifying physician.

Payment Reduction for Early Discharge to Hospice

The Act adds hospice facilities to the existing Medicare post-acute care transfer policy effective October 1, 2018. These transfers include discharges by prospective payment system hospitals to one of several specific settings. Under this change, hospitals will be paid less when the hospital transfers a patient to hospice if that patient had a short length of stay in the hospital. The policy applies only in those cases where the patient falls into one of the top-ten reimbursed hospital stays.

Reduction in Home Health Payment Update

The new law continues a policy of restricting inflation-based payment increases for home health services to a statutorily specified amount. Under the new law, payments for home health services will be inflated by the home health market-based index (recently around 2.5 percent) for 2019, but set at only 1.4 percent for 2020. The payment increase will not be subject to the otherwise-required productivity adjustment in 2020.

Reduction in Long-Term Care Hospital (LTCH) Payment

Congress implemented site neutral payment reforms using specified LTCH patient criteria in 2016, to be phased in over several years. In FY 2016 and FY 2017, LTCH cases that do not meet the specified patient criteria receive a blended rate that consists of one-half the standard LTCH payment and one-half the site neutral payment. This section would extend the 50/50 payment blend for two additional years, through FY 2018 and FY 2019. This section also reduces the LTCH market basket update for FY 2018 through FY 2026 by 4.6 percent.

AMBULANCE SERVICES

Ground Ambulance Add-On Payments and Reforms

The new law extends several ambulance service payment add-ons for five years through calendar year 2022, including the 3 percent increase for ground ambulance trips originating in rural areas, the 2 percent increase for ground ambulance trips originating in urban areas, and a “super rural” add-on of 22.6 percent for ambulance services in the “lowest population density” areas.

CMS must collect ambulance cost and utilization data beginning in 2020

Additionally, the new legislation sets the stage for substantial changes to how Medicare will pay for ambulance services in the future. First, beginning in 2020, CMS will be required to collect certain cost, revenue and utilization information from a representative sample of providers and suppliers of ground ambulance services. Beginning in 2022, ambulance providers and suppliers failing to submit

this information will have payments reduced by 10 percent. Notably, these requirements do not apply to suppliers of air ambulance services. These requirements are decidedly less onerous than provisions previously approved by the House of Representatives, which would have required all providers and suppliers of ground ambulance services to submit hospital-like cost reports. The information provided by these surveys could lead to substantial recalibration of payments for ambulance service providers in future years.

MEDICARE ADVANTAGE (MA) PROGRAM

Permanent Authorization of Special Needs Plans (SNPs)

As part of the MA program, Medicare offers SNPs that are specifically designed to provide care and restrict enrollment to individuals who qualify for three different types of plans: Chronic Care SNPs (C-SNPs), Dual Eligible SNPs (D-SNPs) and Institutional SNPs (I-SNPs). SNPs are exempt from certain beneficiary enrollment requirements and tailor their benefits, provider choices and drug formularies to meet the specific needs of the relevant population. Current law authorizes these plans through December 31, 2018. The new law permanently reauthorizes this program and implements a number of reforms for C-SNPs and D-SNPs, including (but not limited to) improved integration with state Medicaid programs for D-SNPs and improving care management for C-SNPs. Specifically for the D-SNPs, the new law requires improved integration with the state Medicaid program by establishing requirements for a unified grievance and appeals process, improving information sharing between these plans and the state Medicaid agencies, and tighter integration of benefits between D-SNPs and the Medicaid plans. For C-SNPs, the new law requires improves in care management including (but not limited to) an initial and annual face-to-face assessment with documentation in the medical record. The law gives the Secretary the authority to require quality data reporting at the plan level for all SNP types. A GAO report evaluating the integration of the State Medicaid agencies and D-SNPs must be completed within two years of this law's enactment.

Expansion of the Value-Based Insurance Design (VBID) Pilot

Under current program requirements, MA plans are required to offer the same benefits package to all of their enrollees. In 2017, the Innovation Center launched a pilot program that allows plans in seven states greater flexibility in the benefit design for their plans so that they can better address the needs of certain beneficiaries with chronic illness. The initial period of the pilot has been positively received and in 2018, CMS extended it to plans in three additional states. CMS recently announced it would again expand the pilot to 15 additional states in 2019. The Act expands the pilot even further, offering plans in any state the opportunity to participate in the model by 2020.

Expansion of MA Supplemental Benefits for Beneficiaries with Chronic Illness

MA plans are allowed to offer supplemental benefits as part of their plan design as long as the benefits meet certain conditions under the current program. CMS recently released a proposed rule potentially allowing plans greater flexibility in the types of supplemental benefits they can offer, and this law permits plans to offer an even broader range of supplemental benefits to certain beneficiaries with chronic illness beginning in 2020. In order to qualify under this provision, a benefit must offer a reasonable expectation of improving or maintaining a beneficiary's health or overall function, and the broader range of acceptable benefits may include services that are not primarily health care services.

Expanded Telehealth Services for Chronically Ill MA Enrollees

The new law allows MA plans to offer expanded telehealth services as supplemental benefits to chronically ill enrollees beginning in plan year 2020. HHS is required to solicit public comment before November 30, 2018, with respect to the types of additional telehealth services that should be considered and the requirements for providing those services. MA enrollees would have the option to receive such additional benefits through telehealth or in person. Including telehealth services and technologies in the package of benefits would not change the requirement that MA plans meet network adequacy requirements. This means that a plan that failed to provide in person access to a certain type of physician specialist could not meet network adequacy requirements by providing solely telehealth access to such providers.

MEDICARE SHARED SAVINGS PROGRAM (MSSP)

Expanded Telehealth Opportunities for Accountable Care Organizations (ACOs)

This new law provides additional ACOs the opportunity to expand telehealth services by removing various barriers to the provision of telehealth services. The changes (1) allow beneficiaries assigned to an ACO to receive telehealth services in the patient's home, (2) eliminate the geographic component of the originating site requirement, and (3) allow providers to furnish telehealth services as currently specified under Medicare's physician fee schedule, with limited exceptions. Reimbursement under Medicare is contingent upon the telehealth services being delivered to a beneficiary at an approved originating site, such as a hospital, or at the beneficiary's place of residence. Not surprisingly, the provision does require that Medicare provide a separate payment for the originating site fee if the service is furnished in the patient's home. This additional telehealth flexibility is available now for Next Generation ACOs and for additional ACOs, including MSSP Track II (if the ACO remains at two-sided risk and chooses prospective assignment), MSSP Track III, and two-sided risk ACO models with prospective assignment tested or expanded through the Innovation Center.

The Secretary is directed to study the implementation of this provision and report to Congress before January 1, 2026 with an analysis of the utilization of and expenditures for telehealth services under this section and recommendations for any appropriate legislation and administrative action.

Expanded Beneficiary Attribution Options for ACOs

In the previous MSSP program, Medicare beneficiaries were attributed to ACOs retroactively using encounter data based upon visits for primary care services. This provision, originally included in the CHRONIC Act, allows ACOs to elect to have beneficiaries assigned to their organization prospectively as well as allowing beneficiaries the option of choosing to align with an ACO in which his or her main primary care provider participates. As before, the beneficiary retains the choice to receive services from any provider participating in Medicare even if he or she elects to align with a specific ACO.

Prospective attribution will
be an ACO option in 2020

Beneficiary Incentive Option for ACOs

Addressing the desire to offer greater incentives to beneficiaries to utilize effective primary care services, this section allows ACOs participating in Tracks 2, 3 and future two-sided risk models to offer beneficiaries a payment of up to \$20 per service for receiving select primary care services. While the ACOs are not reimbursed by the Medicare program for these payments, this option allows them to better manage the care of patients attributed to the ACO and encourage patients to keep up with beneficial services such as preventive screenings. The Secretary is responsible for designing the program

parameters, and ACOs seeking to offer payment to beneficiaries must apply for and be approved to participate by the Secretary of HHS.

PUBLIC HEALTH PROGRAMS

Reauthorization of Community Health Center Funding and Teaching Health Centers Graduate Medical Education Program.

Community Health Centers (CHCs) serve over 25 million people and rely on federal discretionary funds of about \$3.6 billion annually (roughly 70 percent of their grant funds). The ACA provided a significant increase in funding for CHCs through 2015; Congress subsequently extended that funding through September 30, 2017. The new law authorizes CHC funding at \$3.8 billion in 2018 and \$4 billion in 2019 to fund new sites and expanded services. The new law also appropriates \$25 million in 2018 for CHCs to participate in the NIH Precision Medicine study, *All of Us*.

Community Health Centers
are funded through 2019

The Health Resources and Services Administration operates Teaching Health Centers Graduate Medical Education (THC-GME) programs focused on primary care in medically underserved communities. Most of the 57 training programs currently operating are conducted in CHCs but funding for the THC-GME program expired in 2017. The Act authorizes a significant increase in funding, including \$126.5 million each year to continue the program in 2018 and 2019.

Reduction in Prevention and Public Health Fund Funding

The Prevention and Public Health Fund (PPHF) was established by the ACA to increase funding for wellness and public health activities related to prevention at the clinical and community level. Funding for the PPHF account was initially authorized at approximately \$2 billion per year under current law. The Act significantly reduces annual funding of the PPHF account over the next nine years according to the following schedule:

- \$900 million in 2019
- \$950 million in 2020 and 2021
- \$1 billion in 2022 and 2023
- \$1.475 billion from 2024 through 2027

Funding rises back to \$2 billion in 2028 and every year thereafter.

Reauthorization of the Special Diabetes Program

The BBA 97 created two Special Diabetes Programs: the Special Diabetes Program for Indians at the Indian Health Service (IHS) and the Special Statutory Funding Program for Type 1 Diabetes Research at the National Institutes of Health (NIH). Funding for these programs expired in September 2017. The new law reauthorizes these programs with funding of \$150 million per year in 2018 and 2019.

Reauthorization of the Maternal, Infant, and Early Childhood Home Visiting Program

The Maternal, Infant, and Early Childhood Home Visiting Program (Home Visiting Program) is an evidence-based program that supports maternal and child health and was established in the ACA. Current funding for the Home Visiting Program expired in 2017. The new law reauthorizes funding through 2022 and directs the Secretary to properly target resources through needs assessments, to continue to monitor progress and outcomes, and to implement a corrective action plan for participants

that fail to meet expectations. It also initiates a pay-for-outcomes funding option for entities electing that formula, allowing up to 25 percent of grant funds to be used for performance-based contracts. These funds are available for up to 10 years, and require additional evidence through pilot, feasibility and outcomes studies. The program is expected to work in concert with other federal agencies and state governments towards interoperable data standards and data exchange to facilitate information sharing, reporting and evaluation.

PRESCRIPTION DRUG COVERAGE

Modifications to Closure of the Part D Coverage Donut Hole

Under Part D coverage, a beneficiary enters a coverage gap—referred to as the “donut hole”—once the beneficiary’s out-of-pocket spending hits \$3,750, but before he or she receives full coverage after spending \$4,950 (the applicable amount for 2017). The new law accelerates the current timeline for closing the coverage gap by lowering beneficiaries’ responsibility (coinsurance) for covered Part D drugs to 25 percent in 2019 rather than 2020. In addition, this section increases the percentage discount that the manufacturer must apply, increasing from 50 percent as currently required to 70 percent starting in 2019, with another 5 percent covered by the Part D plan. As with current law, the manufacturer discount would still go toward the out-of-pocket costs for the beneficiary.

Sunset of Biosimilar Drug Exclusion from the Medicare Part D Coverage Gap Discount Program

Under Part D, beneficiaries who fall into the “donut hole” where Medicare reimbursement is not available instead become eligible for drug discounts to help defray their exposure to the additional expenses. The Medicare Coverage Gap Discount Program facilitates a 50 percent discount for brand and original biologic drugs. These discounts count towards beneficiaries’ total out-of-pocket spending. Biosimilar drugs, however, were excluded from the discount program, which may incentivize the use of more expensive therapies. The new law ends the exclusion of biosimilars from the discount program to encourage use of less-expensive therapies when available and appropriate.

Revision of Medicaid Rebate Requirements for Line Extension Drugs

The amount of the Medicaid rebates that drug manufacturers are required to pay under the Medicaid program varies depending on the type of drug (*e.g.*, single source, innovator multiple source, *etc.*). The new law modifies the formula for calculating the rebate obligation for line extension (*i.e.*, new formulations) drugs by clarifying that the rebate is the greater of the basic rebate plus the growth in AMP OR rebate calculated using the existing methodology. These changes become effective at the beginning of 2019.

OTHER POLICIES OF INTEREST

Means-Based Medicare Part B and D Premiums

Higher-income Medicare beneficiaries will be required to contribute more to the Part B and Part D premiums starting in 2019. Currently, individuals earning \$500,000 or more and households earning \$750,000 or more contribute 80 percent to their Part B and D premiums. The new law increases these contribution rates to 85 percent. The income thresholds will increase starting in 2028 per the consumer price index.

Reauthorization of State Health Insurance Assistance Program (SHIP)

SHIP (formerly the Information, Counseling and Assistance Grants Program) is a state-based program funded by grants from CMS to offer counseling and assistance to Medicare beneficiaries and their

families. The program has been extended numerous times, most recently under MACRA, but the extension expired on September 30, 2017. The new law authorizes \$13 million in funding per year for 2018 and 2019 for SHIP, \$7.5 million per year for 2018 and 2019 for aging and disability resource centers, \$5 million per year for 2018 and 2019 for area agencies on aging, and \$12 million per year for 2018 and 2019 for the National Center for Benefits and Enrollment Outreach. The law also establishes new reporting requirements for the Agency for Community Living.

Extension of Funding for Quality-Measure Endorsement, Input and Selection; Reporting Requirements

The federal rulemaking process for the development and selection of quality measures for the various Medicare quality programs includes a consensus-based endorsement process that is implemented through the use of a consensus-based entity. This legislation extends funding for a contract for a consensus-based entity at the amount of \$7,500,000 for each of FY 2018 and FY 2019. This funding, which expired in October 2017, has been extended several times, most recently in MACRA.

This section also requires an annual report by the Secretary to Congress no later than March 1 of each year on a comprehensive quality measurement development plan that identifies the needs of different quality initiatives and provides a strategy for using the consensus-based entity under contract.

Additionally, this section also establishes revisions to the annual report from the consensus-based entity to Congress and the Secretary. It requires an expansion of financial information provided in the report and updates to various internal policies and other procedures. These changes apply to reports submitted beginning in 2019.

Finally, this section also requires the Government Accountability Office to conduct a study on healthcare quality measurement efforts. The report will examine if quality measurement objectives have been met and review efforts undertaken by the Secretary, funding and allocation of funding for these efforts, and the extent to which the Secretary has developed a comprehensive and long-term plan to achieve quality measurement objectives.

Extension of the Independence at Home Demonstration

The Independence at Home (IAH) demonstration was established in the ACA and offers a home-based primary care benefit to select Medicare beneficiaries with multiple chronic conditions. Currently in its fifth year of operation, the demonstration produced Medicare savings in its first two years with evaluation of later years still pending. The new law extends the demonstration for an additional two years and provides CMS with more time and flexibility to evaluate performance under the initiative.

Modernization of Stark Laws

The legislation codifies a number of changes that CMS adopted in the CY2016 Medicare Physician Fee Schedule Final Rule relating to the writing and signature requirements in various exceptions and holdover arrangements for leases and personal services arrangements. Notably, the legislation codifies CMS's stated policy that a party can satisfy the writing requirement through a collection of documents evidencing the course of conduct between the parties involved. Currently, CMS's policy is not memorialized in the text of the regulations; it is only reflected in the regulatory preamble. The new statutory language thus offers greater assurances to parties seeking to rely on a collection of documents to meet the writing requirement.

Permanent Repeal of the DME Rental Cap for Speech-Generating Devices

The new law permanently eliminates the payment cap under the Medicare program with respect to speech-generating devices. Previously, under rules issued by CMS, speech-generating devices were categorized and covered under a capped rental payment. However, if the beneficiary entered a nursing

home, hospital or hospice, the payment ended. Congress responded in 2015 by removing speech-generating devices from the capped rental categorization for three years, and this section removes the 2018 sunset, making this payment category change permanent.

Increased Civil and Criminal Penalties

The new law substantially increases various civil and criminal penalties for violations of healthcare fraud and abuse laws. The maximum penalties under the Civil Monetary Penalties Law will generally increase as follows: existing penalties of up to \$10,000 increase to \$20,000, existing penalties of up to \$15,000 increase to \$30,000 and existing penalties of up to \$50,000 increase to \$100,000. Penalties for beneficiary inducements increase from up to \$2,000 to \$5,000. Similarly, criminal fines for violations of the Anti-Kickback Statute and other prohibitions in 42 U.S.C. 1320a-7b increase from \$25,000 to \$100,000 and corresponding prison sentences also increase from not more than five years to not more than ten years.

Improvements to the Competitive Bidding Program for Diabetic Testing Supplies

Congress established the Competitive Bidding Program (CBP) for Durable Medical Equipment and Supplies to achieve savings and address fraud concerns. However, Congress recognized that incentives inherent in any CBP could adversely affect beneficiary access to products. As such, it included a number of protections to ensure that beneficiaries continued to have access to a range of suppliers and items in the program. The Act enhances certain existing protections and establishes new additional protections applicable to the National Mail Order program for Diabetic Testing Supplies (DTS). Specifically, the new law:

- Requires bidding suppliers to attest to (subject to a good faith effort exception) an ability to obtain an inventory of strips by volume consistent with the inventory mix provided in that supplier's bid.
- Requires CMS to establish and maintain a surveillance program to ensure that suppliers comply with the 50 Percent Rule, and authorizes CMS to terminate a supplier who fails to comply with the 50 Percent Rule.
- Requires CMS to use multiple sources of data, and data that measures consumption and utilization of DTS by individuals other than just those Medicare beneficiaries who purchase DTS through Medicare-participating mail order suppliers, for purposes of measuring compliance with the 50 Percent Rule.
- Bars CMS from giving bidding suppliers additional percentage credit toward satisfying the 50 Percent Rule by selecting "Other—Not Listed."
- Codifies the Anti-Switching Rule.
- Requires suppliers to contact and receive a refill order from the beneficiary not more than 14 days prior to dispensing a refill.
- Requires suppliers to verbally provide beneficiaries with an explanation of the beneficiary's rights, including the beneficiary's right to receive DTS compatible with the beneficiary's blood glucose testing system, the right not to be influenced or incentivized to switch blood glucose testing systems, the right to obtain strips from another mail order supplier or retail pharmacy, and the right to reject unwanted DTS.

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