Significant New Medicare, Medicaid, and Other Health Policy and Payment Provisions Adopted in Bipartisan Budget Act

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Contents

The Bipartisan Budget Act of 2018 (the Act), signed into law by President Trump on February 9, 2018, includes extensive and far-reaching Medicare, Medicaid, and other health policy and payment provisions. Many of these provisions will impact federal health policy for years to come.

Some of the provisions will be welcome to health care providers and manufacturers, such as: repeal of the Independent Payment Advisory Board (IPAB); elimination of the Medicare outpatient therapy caps; codification of certain recent changes to the Stark Act; and extension of various Medicare provisions that are regularly renewed (so-called extenders).

On the other hand, the Act includes health-related offsets that the Congressional Budget Office (CBO) estimates will save more than $38 billion over 10 years. Significant Medicare and Medicaid offsets include: reduced Medicare payment updates for various types of providers; increased Medicaid rebate obligations with respect to line extension drugs; cuts in Medicaid disproportionate share hospital (DSH) allotments; changes to manufacturer discount obligations in the Medicare Part D "donut hole"; and extension of the hospital post-acute transfer policy to early discharges to hospice care. Moreover, the Act once again significantly hikes penalties for violations of various anti-fraud statutes.

This Client Briefing focuses on the major Medicare, Medicaid, and public health provisions of the Act. We would be pleased to provide you with additional information about any of these provisions.

Medicare Extenders

Extension of Work GPCI floor (Section 50201)

The Social Security Act (SSA) established three categories of Geographic Practice Cost Indices (GPCI) (physician work, practice expense, and malpractice) to provide for adjustments to physician payment based on geographic differences in the labor and other costs of providing physician services. For the physician work GPCI, Congress previously established a floor GPCI of 1.00 for any locality with a work GPCI that is less than 1.00; the floor applied to services furnished before January 1, 2018. The Act extends the 1.00 GPCI floor for an additional two years, through December 31, 2019.

Repeal of Medicare Payment Cap for Therapy Services (Section 50202)

The Act permanently repeals the annual caps on Medicare payments for physical therapy (PT), speech-language pathology, and occupational therapy (OT) services as of January 1, 2018. It does, however, continue to require that a modifier be attached to claims over the current exception threshold (e.g., $2,010 for PT and speech-language pathology combined, and $2,010 for OT in 2018) in order to indicate the PT, speech-language pathology, or OT services are medically necessary.

The Act also lowers the threshold amount that can trigger a medical review process to assess the medical necessity of therapy services. The previous annual therapy expenditure amount of $3,700 has been reduced to $3,000 until 2028, at which point the amount will increase according to a specified formula.

Quality Measure Endorsement, Input, and Selection Funding (Section 50206)

The Act extends funding for quality measure endorsement, input, and selection by providing an additional $7.5 million for each of financial years (FYs) 2018 and 2019. Section 50206 of the Act also requires:

- The Secretary of Health and Human Services (HHS) to prepare annual reports to Congress identifying quality measurement program and initiative needs, strategic planning, financial accounting of past expenditures, as well as future funding requirements to execute the quality measurement program strategy.
- The Government Accounting Office (GAO) to conduct a study relating to the quality measurement efforts to determine whether HHS has set, prioritized, and met quality measurement objectives and developed a comprehensive long-term plan for future quality measurement objectives. The GAO study must also include an examination of associated financial expenditures.

Extension of Home Health Rural Add-On (Section 50208)

The Act extends a temporary Medicare add-on for payment of home health services furnished in a rural area.

First, the Act extends the 3 percent add-on for an additional year, through calendar year 2018. Second, the Act provides additional temporary add-on payments depending on the rural area's home health utilization rates:

- For rural counties (or equivalent areas) in the highest quartile of home health utilization (and that presumably do not face barriers to access), the add-on is reduced to 1.5 percent in 2019 and 0.5 percent in 2020.

- Outside of those counties, for rural areas with a population density of six individuals or fewer per square mile, the add-on is 4 percent for 2019, 3 percent for 2020, 2 percent for 2021, and 1 percent for 2022.
- In all other areas, the add-on is 3 percent for 2019, 2 percent for 2020, and 1 percent for 2021.

Beginning in 2019, home health claims must contain the code for the county in which the home health service was furnished. The HHS Office of the Inspector General (OIG) must conduct an analysis of home health utilization and provide recommendations to Congress.

Other Medicare Extenders

The Act also extends, and in some cases modifies, a number of special Medicare payment programs. For instance, the Act:

- Extends Medicare add-on payments for ground ambulance transports through 2022. The Act also requires the Secretary to develop an ambulance cost data collection system; effective January 1, 2022, an ambulance supplier may be subject to a 10 percent payment reduction for failure to submit required data (Section 50203).
- Extends the inpatient hospital payment adjustment for certain low-volume hospitals through September 30, 2022, and modifies the payment adjustment standard for FYs 2019–2022 (Section 50204).
- Extends the Medicare-dependent hospital program for five years, through September 30, 2022 (Section 50205).
- Extends through September 30, 2019 various outreach, counseling, education, and information assistance programs for Medicare beneficiaries, including the State Health Insurance Programs, Area Agencies on Aging, Aging and Disability Resource Centers, and the National Center for Benefits and Outreach Enrollment. The Act also directs the Agency for Community Living to post on its website funding and other information relating to state health insurance assistance program grants (Section 50207).

Part B Improvement Act and other Part B Enhancements

Modernizing the Application of the Stark Rule under Medicare (Section 50404)

The Act codifies prior Centers for Medicare and Medicaid (CMS) regulatory changes to refine Stark Law technical requirements for certain provider arrangements. In particular, the Act broadens the writing and signature requirements for compensation arrangements, and extends the length of time parties may continue operating under holdover periods for applicable leasing and personal services arrangements. CMS previously adopted these guidelines, which are further described below, in connection with its 2016 Medicare Physician Fee Schedule revisions.

- The writing requirement pertaining to certain Stark compensation arrangement exceptions may be satisfied by "such means as determined by the Secretary," which, rather than requiring a single written instrument, may specifically include "a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties involved."
- The signature requirement underlying several Stark compensation arrangement exceptions may be met within a 90-calendar day window from the date of the parties' related noncompliance, regardless of the reason for the missing signature.
- A prior 6-month limit on "holdover" periods for leasing and personal service arrangements under Stark is replaced by an indefinite time period, so long as such arrangements continue on the same terms and otherwise continue to satisfy the applicable exceptions.

Medicare Part B Improvement Act Provisions (Sections 50401–50403)

The Act incorporates several provisions from H.R. 3178, the Medicare Part B Improvement Act, which previously had been approved by the House of Representatives but not the Senate:

- Section 50401 of the Act establishes a temporary transitional Medicare payment methodology for home infusion therapy services beginning January 1, 2019, and continuing until the 21st Century Cures Act's home infusion therapy benefit goes into effect on January 1, 2021. The Act directs the Secretary to assign home infusion drugs to one of three payment categories, each of which will be assigned a single payment amount that includes reimbursement for the infusion drug administration. Note that the CBO estimates that this provision will reduce federal spending by $910 million.
- Section 50402 of the Act provides that documentation created by an orthotist or prosthetist is considered part of the individual's medical record to support determinations of the medical necessity of orthotics and prosthetics.
- Section 50403 of the Act is intended to expedite accreditation of dialysis facilities by allowing private organizations approved by the Secretary to accredit new facilities.

Medicare Classification of Speech Generating Devices as Routinely Purchased Durable Medical Equipment (DME) (Section 50411)

The Steve Gleason Act of 2015 temporarily classified speech-generating devices as "routinely purchased durable medical equipment," payable on a lump-sum basis, rather than capped rental equipment. This designation was scheduled to sunset on October 1, 2018. The Act makes permanent the classification of speech-generating devices as routinely purchased DME.

Increased Civil and Criminal Penalties and Sentences for Fraud and Abuse (Section 50412)

The Act doubles – and in some cases more than doubles – civil and criminal penalties for fraud and abuse violations. The maximum civil monetary penalty increases include the following: current penalties of up to $10,000 increase to $20,000; current penalties of up to $15,000 increase to $30,000; and current penalties of up to $50,000 increase to $100,000. Penalties for provision or receipt of inducements increase from up to $2,000 to $5,000. Additionally, criminal fines for violations of the Anti-Kickback Statute and other prohibitions increase from $10,000 to $20,000 and from $25,000 to $100,000. Prison sentences increase from not more than five years to not more than 10 years.

Note that the current statutory penalties have been periodically updated through regulation in compliance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

Repeal of Requirement for More Stringent Meaningful Use Standards (Section 50413)

The Health Information Technology for Economic and Clinical Health Act required that CMS continue to make meaningful use standards (using certified Electronic Health Records) more stringent over time; providers who do not achieve meaningful use may be subject to penalties and lack of incentive pay. As a result of these increasingly stringent meaningful use standards, many healthcare providers have had difficulties meeting such standards and have requested significant hardship waivers from CMS. This, in turn, has increased the administrative burden on CMS to process a growing volume of hardship requests.

The Act removes the mandate that meaningful use standards become more stringent over time, a measure expected to reduce the volume of future significant hardship requests submitted to CMS.

Competitive Bidding for Diabetic Testing Strips (Section 50414)

Congress and CMS have previously established safeguards intended to protect beneficiary access to a wide range of diabetic testing supplies under the Medicare durable medical equipment, prosthetics, orthotics and supplies competitive bidding program. For instance, the SSA requires bidders to demonstrate that their bids cover at least 50 percent, by volume, of *all* types of mail order diabetic testing strips. CMS also adopted regulations to prohibit a contract supplier from attempting to influence or incentivize an individual to switch the brand of glucose monitor or diabetic testing strip product selected.

In light of Congressional concerns about CMS enforcement, the Act includes specific and detailed provisions to strengthen these protections. First, the Act establishes more stringent standards with regard to the "50 percent" rule. Effective for bids to furnish diabetic testing supplies on or after January 1, 2019:

- In determining a supplier's ability to cover 50 percent of product volume, CMS must utilize multiple sources of data from mail order and non-mail order Medicare markets, including market-based data measuring sales of diabetic testing strip products that are not exclusively sold by a single retailer from such markets.
- The Secretary may not count unlisted types of diabetic testing strip products in calculating volume.
- The bidding supplier must attest that it has the ability to obtain an inventory of the requisite types and quantities of diabetic testing strips. Further, that ability must be demonstrated through letters of intent with manufacturers, wholesalers, or other suppliers, or other evidence as the Secretary may specify (or the supplier must demonstrate that it has made a good faith attempt to obtain such evidence).
- The Secretary must establish a process to monitor whether contract suppliers continue to cover the product types included in the entity's bid. Failure to maintain inventory or ready access to the type of products in the entity's bid is grounds for termination of the supplier's contract (with certain exceptions).

Second, the Act codifies and strengthens the anti-switching rule. Specifically, the Act requires contract suppliers to furnish to each individual a brand of diabetic testing strips that is compatible with the beneficiary's home blood glucose monitor. The contract supplier "may not attempt to influence or incentivize" a beneficiary to switch brands, including by "persuading, pressuring, or advising the individual to switch," or providing information about alternative brands if the individual has not request such information.

Third, the Secretary must develop standardized information for beneficiaries about their rights with regard to diabetic testing supplies. Once this information is developed, a contract supplier may not communicate directly with a beneficiary until it has verbally provided the individual with the standardized information.

Finally, the Act establishes new rules regarding diabetic testing strip refills. For products furnished on or after January 1, 2019, contract suppliers must contact and receive a request from the individual for diabetic testing strip products not more than 14 days prior to dispensing a refill.

Other Medicare Payment Policies

Home Health Payment Reform (Section 51001)

CMS currently uses a 60-day episode as the unit of payment for home health services under the home health prospective payment system (PPS). The Act replaces the 60-day unit with a 30-day unit of payment beginning 2020. To ensure budget neutrality of the payment changes, the Secretary is authorized to "make assumptions about behavior changes that could occur" as a result of the reduction to a 30-day unit of payment, as well as account for certain case mix adjustment factors. The Act also eliminates the use of therapy thresholds in case mix adjustment factors, beginning 2020. Home health providers, patient representatives, and other stakeholders will have the opportunity to participate in a technical expert panel mandated under the Act and charged with identifying and prioritizing recommendations with respect to the home health PPS. For further public input, the Secretary is also required to pursue notice and comment rulemaking on the revised payment system.

Information to Satisfy Documentation of Medicare Eligibility for Home Health Services (Section 51002)

Pursuant to the Affordable Care Act (ACA), a certifying physician must document that the physician (or certain specified designees) has had a face-to-face encounter with a patient prior to making a certification of eligibility for home health services.

The Act provides that, for certifications and recertifications made on or after January 1, 2019, the Secretary may use documentation in the home health agency's (HHA's) medical record, in addition to the documentation in the certifying physician's medical record, when determining a patient's eligibility for home health services.

Technical Amendments to MACRA MIPS Provisions (Section 51003)

As mandated by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), CMS implemented the Merit-based Incentive Payment System (MIPS) under which MIPS-eligible clinicians (physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists) receive a positive, negative, or neutral payment adjustment based on certain performance measures. The Act implements several technical amendments to MIPS as described below:

- Under MACRA, MIPS applied a payment adjustment to the cost category for "items *and* services," which included separately billable physician-administered drugs covered under Medicare Part B. As modified by the Act, a payment adjustment will be applied to the cost category for "*covered professional services*" only as opposed to "items and services." This change is likely to have a significant impact on physician cost scores, as it removes the costs associated with separately billable drugs covered under Medicare Part B from the calculation of physician cost scores.
- Under MACRA, separately billable Part B drugs also factored into the low-volume threshold determinations for clinician participation in MIPS. The Act excludes Part B drug costs from low-volume threshold determinations for clinician participation.
- The Act provides that not less than 10 percent nor more than 30 percent of the cost score shall be based on performance for the cost category for years two through five (2018–2021), and it removes the improvement portion of the cost performance score through 2021.
- The Act requires the Secretary to post on CMS's website information relating to current and future measures.

The Act also establishes new requirements for the Physician-Focused Payment Model Technical Advisory Committee (PTAC), an ad hoc committee established by the CMS Council for Technology and Innovation that is responsible for reviewing physician-focused payment models submitted by interested stakeholders. The Act authorizes the PTAC to provide initial feedback to relevant stakeholders regarding whether the submitted model meets the criteria along with an explanation of the basis for the determination. The PTAC shall continue providing comments and recommendations to the Secretary regarding such models.

Expanded Access to Medicare Intensive Cardiac Rehabilitation Programs (Section 51004)

Under prior law, Medicare provided coverage for physician-supervised intensive cardiac rehabilitation programs for beneficiaries who have stable angina pectoris or have had:

- An acute myocardial infarction within the preceding 12 months
- Coronary bypass surgery
- Heart valve repair or replacement
- Percutaneous transluminal coronary angioplasty or coronary stenting, or
- A heart or heart-lung transplant

The Act expands Medicare coverage for physician-supervised intensive cardiac rehabilitation programs to include beneficiaries who have stable, chronic heart failure (defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association class II

to IV symptoms despite being on optimal heart failure therapy for at least six weeks), and any additional condition(s) identified by the Secretary.

Extension of Blended Site Neutral Payment Rate for Certain Long-Term Care Hospital (LTCH) Discharges; Temporary Adjustment to Site Neutral Payment Rates (Section 51005)

Patients who stay three days or more in an intensive care or coronary care unit or patients who require mechanical ventilation services for at least 96 hours are reimbursed under the long-term care hospital (LTCH) PPS. Other LTCH discharges that do not meet these specific patient criteria are paid at a reduced "site neutral" payment rate intended to approximate the rates paid to a general acute care hospital. When the site neutral payment rate was initially adopted in the Balanced Budget Act of 2013, Congress included a two-year transition period applicable to hospital cost reporting periods beginning on or after October 1, 2015 through September 30, 2017. During the initial two-year transition period, a blended rate was paid for Medicare patients not meeting the specific LTCH patient criteria, equaling 50 percent of the site neutral payment rate amount and 50 percent of the standard LTCH PPS rate amount.

The Act extends the transition period by an additional two years to include cost reporting periods beginning before September 30, 2019. For discharges in cost reporting periods beginning on or after October 1, 2019, only the site neutral payment rate will apply for Medicare patients not meeting the patient criteria. To offset the cost of extending the transition period, the Act reduces the site neutral payment rate by 4.6 percent for hospital cost reporting periods beginning on or after October 1, 2017 through September 30, 2026.

Role of Physician Assistants for Hospice Patients (Section 51006)

Current law imposes certain certification and other requirements on an individual's "attending physician" for purposes of that individual qualifying for the Medicare hospice benefit. Effective January 1, 2019, the Act permits "attending physician" to include physician assistants (in addition to nurse practitioners) for purposes of establishing and reviewing an individual's plan of care and other purposes. However, the Act maintains the requirement that only a physician – not a physician assistant or a nurse practitioner – can participate in decisions to certify and recertify an individual as having a terminal diagnosis, in order to qualify the individual for hospice care.

Supervision Requirements for Outpatient Therapeutic Services in Critical Access and Small Rural Hospitals (Section 51007)

The 21st Century Cures Act (Section 16004, Continuing Access to Hospitals Act of 2016) instructed CMS not to enforce physician direct supervision requirements for outpatient therapeutic services in critical access hospitals and small rural hospitals through 2016. The Act extends this instruction for another year, or through 2017.

Supervision of Cardiac, Intensive Cardiac, and Pulmonary Rehabilitation Programs (Section 51008)

Under the current law, items and services furnished under a Medicare cardiac rehabilitation, intensive cardiac rehabilitation, or pulmonary rehabilitation program must be supervised by a physician. The Act provides that these programs also may be supervised by a physician assistant, nurse practitioner, or clinical nurse specialist, effective January 1, 2024.

Transitional Payment Rules for Certain Radiation Therapy Services under the Physician Fee Schedule (Section 51009)

In 2015, certain radiation therapy codes were identified as being potentially misvalued under the Medicare physician fee schedule, and the relevant specialty society indicated that radiation therapy treatments could not accurately be reported with the existing code set. As a result, CMS created several new Healthcare Common Procedure Coding System (HCPCS) G codes (G6001-G6015) to replace predecessor (CPT) codes.

In December 2015, the Patient Access and Medicare Protection Act was enacted, requiring CMS to apply the same code definitions, work relative value units (RVUs), and direct inputs for the practice expense RVUs in 2017 and 2018 as applied in 2016 for HCPCS codes G6001–G6015. The Act extends the definitions, RVUs, and inputs for these services through 2019.

Protecting Seniors' Access to Medicare Act

Repeal of the Independent Payment Advisory Board (Section 52001)

The Act achieves a longstanding priority of the healthcare provider community: repeal of the IPAB. By way of background, the ACA established the IPAB as a failsafe mechanism for cutting Medicare spending if Congress failed to act. Specifically, the ACA directed the IPAB to submit Medicare spending plans to Congress if projected spending growth exceeded specified targets, and the IPAB proposals were to go into effect automatically unless Congress enacted alternative legislation achieving required savings. IPAB members were never appointed, and the spending trigger

was never met, but the CBO has projected that the IPAB would be triggered in coming years.

Under the Act, statutory provisions establishing the IPAB are repealed immediately. CBO estimates that this provision will have the impact of increasing federal spending beginning in FY 2022, with a total estimated increase of $17.5 billion over the period of FYs 2022–2027.

Offsets

Medicaid Disproportionate Share Hospital Allotments (Section 53101)

The Act increases reductions in DSH allocations across the next several years. Rather than incremental increases in reductions from $4 billion to $8 billion, the Act eliminates the DSH reductions for FY 2018 and FY 2019; maintains the $4 billion reduction for FY 2020; and holds reductions flat at $8 billion each year from 2021 to 2025. The CBO estimates that this provision would reduce federal spending by $185 million over the period of FYs 2018–2027.

Third-Party Liability in Medicaid and Children's Health Insurance Program (CHIP) (Section 53102)

Among other changes, the Act repeals a provision in the Bipartisan Budget Act of 2013 that allowed states to recover costs from Medicaid beneficiary liability settlements, and also extends the third-party liability provisions to apply to CHIP. Additionally, the Act eliminates the requirement that states pay providers for prenatal care before seeking reimbursement by third parties. The CBO estimates that the 10-year savings from this provision will exceed $4 billion.

Treatment of Lottery Winnings and Other Lump-sum Income for Medicaid Income Eligibility Purposes (Section 53103)

The Act adds a new provision detailing when and under what circumstances lottery winnings constitute income, along with the factors to consider when determining whether the individual lottery winner is still eligible for medical assistance. The CBO estimates that this provision will save $475 million over 10 years.

Rebate Obligation with Respect to Line Extension Drugs (Section 53104)

Historically, the Medicaid rebate statute required brand drug manufacturers to pay a "basic" rebate and an "additional" rebate, which was designed to discourage price increases faster than the rate of inflation. As part of the ACA, Congress mandated an alternative calculation for Medicaid rebates for "line extensions" of single source or innovator multiple source oral solid dosage form drugs, under which the rebate due would be the greater of (i) the rebate calculated under the traditional formula, or (ii) only the highest "additional" rebate with respect to any strength of the original drug.

Section 53104 of the Act amends prong (ii) of the alternative calculation to provide that the alternative rebate is the sum of the basic rebate for the line extension drug and the highest additional rebate with respect to any strength of the original drug. The effect of this provision will be to increase the rebate due with respect to line extension drugs by a minimum of 23.1 percent of the line extension drug's average manufacturer price.

The CBO estimates that this provision will save almost $5.7 billion over the period of FYs 2018–2027.

Payment for Outpatient PT and OT Services Furnished by a Therapy Assistant (Section 53107)

The Act reduces the rate paid by Medicare for services furnished in whole or in part by PT and OT assistants to 85 percent of current rates. The Secretary is directed to create a modifier code to identify services provided by PT and OT assistants on each request for payment or bill submitted. The modifiers will become effective January 1, 2020, and the 85 percent payment rate will apply to payments on or after January 1, 2022. The CBO estimates that the 10-year savings from this provision will exceed $1.2 billion.

Reduction for Non-Emergency ESRD Ambulance Transports (Section 53108)

The Act increases the reduction to the ambulance service fee schedule for non-emergency transportation of end stage renal disease (ESRD) patients for dialysis services to 23 percent, beginning September 30, 2018. Currently, a 10 percent reduction applies unless such services are provided in an emergency.

Hospital Transfer Policy for Early Discharges to Hospice Care (Section 53109)

Medicare has longstanding transfer payment policies that adjust Medicare payments to acute inpatient hospitals for certain "early" discharges to other hospitals or to post-acute care facilities (e.g., skilled nursing facilities (SNFs), inpatient rehabilitation facilities, HHAs, LTCHs, and certain PPS-exempt hospitals). CMS considers early transfers to be those in which the length of stay is less than the geometric mean length of stay for the Medicare Severity Diagnosis Related Group (MS-DRG) to which the case is assigned. Under this policy, transferring facilities generally are paid a per diem rate instead of the usual MS-DRG when the patient's discharge is assigned to a qualifying MS-DRG (based on a high volume of discharges to post-acute care facilities and a disproportionate use of post-acute care services).

The Act adds to the list of post-acute entities to which the transfer policy applies. Specifically, the Act extends the current transfer payment restrictions to discharges to hospice care for discharges occurring on or after October 1,

2018. The Act directs the Secretary to implement the policy in the FY 2019 inpatient PPS proposed rulemaking. The CBO estimates that this provision will save almost $4.9 billion over 10 years.

Reduced Medicare Payment Updates for Physicians, HHAs, and SNFs (Sections 53106, 53110, 53111)

The Medicare physician payment rate is determined by multiplying the conversion factor by geographically adjusted RVUs for physician work, practice expense, and malpractice. Section 53106 of the Act reduces the conversion factor by 0.25 percent for 2019 (10-year savings of almost $1.86 billion).

Section 53110 of the Act sets the update for the Medicare home health PPS at 1.5 percent in 2020, rather than the productivity-adjusted home health market basket percentage increase (10-year savings of $3.5 billion).

In addition, section 53111 of the Act sets the FY 2019 update to the Medicare SNF PPS at 2.4 percent; the update otherwise would have been set at the percentage change in the SNF market basket index, reduced by a productivity adjustment (10-year savings of $1.9 billion).

Star Ratings after Consolidation of Medicare Advantage (MA) Plans (Section 53112)

This provision is designed to prevent individual Medicare Advantage (MA) organizations that hold more than one Medicare contract from artificially inflating quality ratings to receive larger quality bonuses following consolidation of the organization's MA plans. Under this provision, quality increases and rebate amounts will be adjusted based on a weighted average of the contracts involved in consolidations under certain circumstances. The CBO estimates that this change will save $520 million over 10 years.

Sunsetting Exclusion of Biosimilars From Medicare Part D Coverage Gap Discount Program (Section 53113)

This section of the Act ends the exclusion of biosimilars from the Medicare Part D Coverage Gap Discount Program, beginning in 2020. Under the Medicare Part D Coverage Gap Discount Program, prescription drug manufacturers are required to provide mandatory discounts ("Coverage Gap Discounts") on prescriptions for "applicable drugs" dispensed to non-low income subsidy beneficiaries during the Part D "coverage gap" (when such beneficiaries are responsible for a greater portion of their prescription drug costs). Those discounts are effectively passed through to the beneficiaries as a reduction in the price they are required to pay for these prescriptions at the point of sale. Like generic drugs, biosimilars are currently excluded from the definition of the "applicable drugs" to which the Coverage Gap Discount Program applies; consequently, manufacturers have not been required to pay Coverage Gap Discounts on prescriptions for biosimilars. With this change, manufacturers will be required to pay Coverage Gap Discounts on prescriptions for biosimilars dispensed in 2020 and thereafter. Notably, under the ACA provisions to close the coverage gap by 2020, Part D plans were already required to provide beneficiaries essentially the same cost-sharing level in 2020 as will now apply to biosimilars after this change. As a result, this change likely will not affect amounts payable by beneficiaries, but will shift costs from Part D plans (and, due to the resulting reduction in federal subsidies, from the federal government) to manufacturers. Accordingly, this provision is included in a portion of the Act entitled "Offsets" -- i.e., it results in a reduction in federal spending to help fund other provisions of the Act.

Medicare Premiums for Higher Income Individuals (Section 53114)

Medicare Part B and Part D premiums are higher for beneficiaries with income exceeding certain thresholds since their federal subsidies are reduced. Beginning in 2019, the Act reduces by 5 percent the Part B and Part D premium subsidies for individuals with modified adjusted gross incomes of at least $500,000 ($750,000 for couples filing jointly). These income levels would apply through 2027, after which they would be indexed to inflation.

Closing the Donut Hole for Seniors (Section 53116)

Section 53116 of the Act makes a significant change to the mandatory Coverage Gap Discounts that manufacturers are required to pay on prescriptions for "applicable drugs" under the Medicare Part D Coverage Gap Discount Program, increasing them from 50 percent to 70 percent of the "negotiated price" of the given drug, beginning in 2019. This change will not reduce the amounts that beneficiaries must pay on these drugs, but will instead reduce the portion of the cost payable by the Part D plan from approximately 25 percent to 5 percent (for 2020 and subsequent years). This will in turn reduce federal subsidies that otherwise would have been payable. CBO has scored this provision (together with Section 53113) as resulting in federal savings of $3.12 billion over FYs 2018-2022 and $10.05 billion over FYs 2018-2027. Consistent with existing law, the 70 percent Coverage Gap Discounts will count towards beneficiaries' out-of-pocket costs, resulting in beneficiaries moving more quickly through the coverage gap and into the Part D catastrophic coverage phase.

Section 53116 of the Act will also accelerate the closing of the Medicare Part D coverage gap for certain drugs by one year, so that it will close for such drugs in 2019 rather than in 2020 under prior law. Specifically, for "applicable drugs" on which Coverage Gap Discounts are payable (in general, name-brand drugs and authorized generics that are on a Part D plan's formulary or covered through an exception or

appeal), prior law provided for beneficiary cost sharing of 30 percent in 2019 and 25 percent in 2020. The Act provides for the 25 percent level to apply in 2019 and all subsequent years. For drugs other than applicable drugs (principally generics), the coverage gap will still close in 2020, as had been provided under prior law.

Reductions to Medicaid Improvement Fund, Medicare Improvement Fund, and Prevention and Public Health Fund (Sections 53105, 53115, 53119)

Section 53105 of the Act eliminates recently enacted funding for the Medicaid Improvement Fund. As part of a continuing appropriations bill signed into law January 22, 2018, Congress previously provided $980 million to allow for oversight of contracts, contractors, and evaluation of demonstration projects; however, this funding is now reduced to $0. In addition, Section 53115 of the Act eliminates all of the $220 million in current funding for the Medicare Improvement Fund. Section 53119 Act reduces funding for the Prevention and Public Health Fund to $900 million in FY 2019, $950 million in FYs 2020 and 2021, $1 billion in FYs 2022 and 2023, $1.3 billion in FYs 2024 and 2025, and $1.8 billion in FYs 2026 and 2027. Funding in FY 2028 and each year thereafter will be $2 billion. This will result in savings of $998 million over the 10-year period of FYs 2018–2027.

Public Health Programs (Sections 50901–50902)

The Act extends by two years (through FY 2019) funding for Community Health Centers, with funding levels of $3.8 billion for FY 2018 and $4 billion for FY 2019. It also includes a number of provisions intended to improve services at such centers, including new supplemental grant funds to implement evidence-based models for increasing access to high-quality primary care services.

The Act also provides $310 million in funding for the National Health Services Corps in each of FYs 2018 and 2019. Likewise, the Act provides $126.5 million for each of FYs 2018 and 2019 for teaching health centers that operate graduate medical education programs, with revisions to the payment parameters.

Furthermore, the Act extends funding for the Special Diabetes Program for Type 1 Diabetes and the Special Diabetes Program for Indians, with each program receiving $150 million in each of FYs 2018 and 2019.

Creating High-Quality Results and Outcomes Necessary to Improve Chronic (Chronic) Care

Overview/Framework

The Act incorporates provisions of section 870, the CHRONIC Care Act of 2017, which was unanimously approved by the Senate in September 2017. The CHRONIC Care Act is a multi-faceted initiative intended to improve care for chronically ill individuals in fee-for-service Medicare, MA plans, and accountable care organizations (ACOs).

In brief, the Act expands the use of telehealth by MA plans and ACOs, and for ESRD beneficiaries undergoing home dialysis. In addition, the Act seeks to promote care coordination, including through a new ACO Beneficiary Incentive Program that permits certain incentive payments to beneficiaries to encourage the use of medically necessary primary care services. Furthermore, the Act expands the ACA Independence at Home Program and permanently authorizes ACA Special Needs Plans (if certain conditions are met).

Providing Prescription Drug Plans with Parts A and B Claims Data (Section 50354)

Section 50354 of the Act requires the HHS Secretary to establish a process under which HHS would provide sponsors of Part D standalone prescription drug plans (PDPs) with standardized extracts of their enrollees' Part A and B claims data on a periodic basis, if requested by a PDP sponsor, beginning in 2020. The data is to be used by PDP sponsors to optimize therapeutic outcomes through improved medication use, to improve care coordination so as to prevent adverse health outcomes (such as preventable emergency department visits and hospital readmissions), and for any other purpose determined appropriate by the Secretary. However, the sponsor cannot use the data to inform Part D coverage determinations, conduct retroactive reviews of medically accepted indication determinations, facilitate enrollment changes to a different Part D plan offered by the same parent organization, inform marketing of benefits, or engage in activities otherwise prohibited by the Secretary in order to protect individuals' identity or the security of personal health information.

CHIP Provisions (Sections 50101–50103)

The Continuing Appropriations Act, which was signed into law on January 22, 2018, funded CHIP through FY 2023. The Act further extends the CHIP program through FY 2027, with revisions to the funding formula beginning in FY 2024. The Act also extends through FY 2027: the Child Enrollment Contingency Fund; the Qualifying States Option; the Express Lane Eligibility option; the pediatric quality measures program (with mandatory, rather than voluntary, state reporting on a core measure set); and funding for grants to improve outreach and enrollment.

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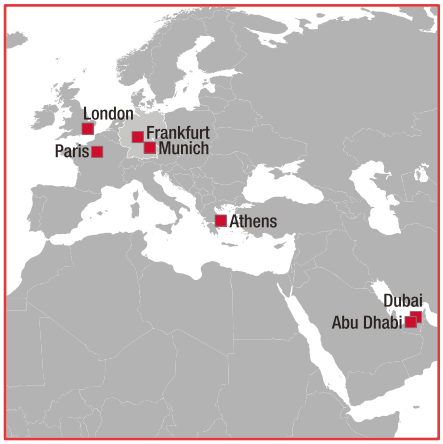

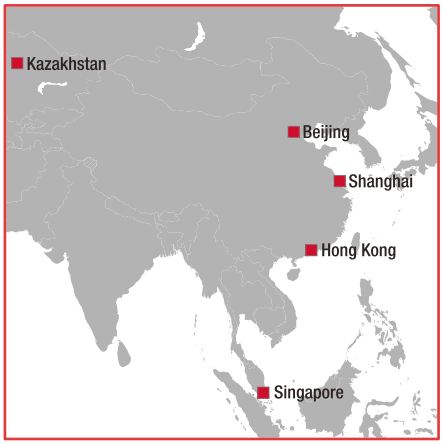

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