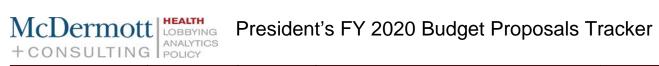
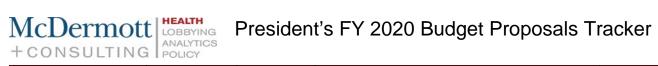


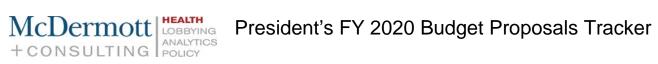
Proposal	Payment System/ Program	Effective Date	Description	Budget Impact	Commentary
			2020 Proposals		
Reprioritize Primary and Preventive Care in Medicare	PFS	FY 2021	Creates a risk-adjusted monthly Medicare Priority Care payment for providers who are eligible to bill for evaluation and management (E/M) services and who provide ongoing primary care to Medicare beneficiaries.	No budget impact	The Administration has shown a strong interest in restructuring E/M payment. Expect further development of E/M policy in the Physician Fee Schedule rules this year.
Expand Basis for Beneficiary Assignment for Accountable Care Organizations	ACOs	CY 2020	Allows the Secretary to base beneficiary assignment on a broader set of primary care providers. This option broadens the scope of accountable care organizations to better reflect the types of professionals that deliver primary care services to fee-for-service beneficiaries.	\$80 million in savings over 10 years	The Administration completed a significant overhaul of the Medicare Shared Savings Program earlier this year. An area to watch will be what happens to participation in the program as a result of those changes - both in terms of new entries and drop outs.
Create a Consolidated Hospital Quality Payment Program	IPPS		Establishes a new consolidated hospital quality payment program that combines and streamlines these four existing programs. Would require hospitals, as a Medicare Condition of Participation, to accurately report hospital acquired infections data to the CDC's National Health Safety Network.	No budget impact	In their March 2019 Report to Congress, the Medicare Payment Advisory Commission (MedPAC) made a similar recommendation to replace the current four hospital quality programs with an alternative program referred to as the Hospital Value Incentive Program. MedPAC feels that the current hospital quality programs are redundant and burdensome and that they should be redesigned to better encourage hospitals to improve their performance. Implementation of this proposal would require legislative and administrative action.
Reform Physician Self-Referral Law to Better Support and Align with Alternative Payment Models and to Address Overutilization	QPP (AAPMs)	FY 2021	A new exception to the physician self-referral law for arrangements that arise due to participation in Advanced Alternative Payment Models and identify the types of arrangements and the minimum risk levels and level of participation in the model required for such exceptions will be established. A new process will be established for physicians to self-report inadvertent, technical non-compliance violations of the law and excluding physician-owned distributors from the indirect compensation exception, if more than 40 percent of the physician-owned distributor's business is generated by physician-owners.	Budget impact not available	Watch for a proposed rule on the Stark law resulting from the Deputy Secretary's Regulatory Sprint to Coordinated Care.



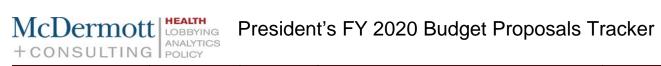
Proposal	Payment System/ Program	Effective Date	Description	Budget Impact	Commentary
Implement Value- Based Purchasing Program for Outpatient Hospitals and Ambulatory Surgical Centers	OPPS/ASC	CY 2021	Implementation of a value-based purchasing program for hospital outpatient departments and ambulatory surgical centers, offering them incentives to improve quality and health outcomes; under this budget neutral program, two percent of payments would be linked to performance on quality and outcome measures.	No budget impact	Currently, hospital outpatient departments and ambulatory surgical centers participate in a Medicare pay-for-reporting, quality data program. Facilities must meet program requirements to receive the full annual update. Medicare has a value-based purchasing program for acute inpatient hospitals which is funded by reducing participating hospitals' base operating MS-DRG payments by two percent. Implementation of this proposal would require legislative and administrative action.
Redesign Outpatient Hospital and Ambulatory Surgical Center Payment Systems to Make Risk-Adjusted Payments	OPPS/ASC		Risk-adjust payments to hospital outpatient and ASC facilities based on the severity of patients' diagnoses (versus setting of care). These adjustments would be made in a budget neutral manner.	No budget impact	Risk adjustment continues to be an area of focus for payment across the board. This proposal could create a longer term opportunity for organizations to put forward solutions.
Reform and Expand Durable Medical Equipment Competitive Bidding	DME		Changes the way Medicare pays for DME under the competitive bidding program, from a single payment amount based on the maximum winning bid to the winning suppliers' own bid amounts. As a result, low bidders will be paid their low bid amount. The proposal also expands competitive bidding to additional geographic areas, including rural areas.	\$7.1 billion in Medicare savings and \$410 million in Medicaid savings over 10 years	CMS's prior policy of setting the payment amount for competitively bid DME at the median of all acceptable bid amounts, was criticized as incentivizing low-ball bidding. In 2018 CMS finalized a policy that would use the maximum winning bid as the payment amount for competitively bid DME. This proposal would scale back that new policy, effectively binding bidders to their bid amount.
Support Coverage for Innovative Alternatives to Durable Medical Equipment for Treatment and Management of Diabetes	DME		This proposal allows Medicare coverage for disposable devices that can serve as alternatives to durable devices that treat and manage diabetes.	No budget impact	This would require legislative and regulatory changes, since blood glucose meters are defined as "durable medical equipment" in both. This proposal would allow coverage of devices that last less than three years for patients with diabetes.



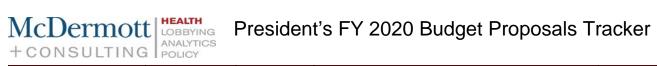
Proposal	Payment System/ Program	Effective Date	Description	Budget Impact	Commentary
Give Medicare Beneficiaries with High Deductible Plans the Option to Make Tax Deductible Contributions to Health Savings Accounts or Medical Savings Accounts	Beneficiary		This proposal allows beneficiaries enrolled in Medicare MSA Plans to contribute to their MSAs, subject to the annual HSA contribution limits determined by the Internal Revenue Service.	\$240 million in Medicare costs over 10 years	Related legislation was approved with bipartisan support by the House in 2018.
Modify Payments to Hospitals for Uncompensated Care	IPPS	FY 2021	This proposal establishes a new process to distribute uncompensated care payments to hospitals based on share of charity care and non-Medicare bad debt, as reported on Medicare cost reports. The total amount of available uncompensated care payments will be equal to FY 2019 funding levels, grown annually by the Consumer Price Index for all Urban Consumers (CPI-U). Uncompensated care payments will be funded from the general fund of the Treasury rather than the Medicare Trust Fund. Empirically justified Disproportionate Share Hospital payments will not be changed.	\$182.5 billion in Medicare savings over 10 years; this proposal would increase spending from general revenues by \$84.5 billion over 10 years, for a net savings to the federal government of \$98.0 billion over 10 years	Members of Congress and CMS have been been interested DSH reforms since passage of the ACA, and this could be a signal of CMS intentions in FY 2020.
Pay On-Campus Hospital Outpatient Departments at the Physician Office Rate for Certain Services	OPPS	CY 2020	This proposal makes site neutral payments between on-campus hospital outpatient departments and physician offices for certain services such as clinic visits, eliminating the disparity between what Medicare pays in these settings for the same services.	\$131.4 billion in savings over 10 years	CMS is eager to eliminate payment system- driven payment disparities, and has been taking steps to achieve that in recent years. CMS has some congressional support, and may try to further push the envelope in 2020.
Address Excessive Payment for Post- Acute Care Providers by Establishing a Unified Payment System Based on Patients' Clinical Needs Rather than Site of Care	PAC	FY 2020	Under this proposal, skilled nursing facilities, home health agencies, and inpatient rehabilitation facilities will receive a lower annual Medicare payment update from FY 2020 to FY 2024 and, beginning in FY 2025, a unified post-acute care payment system would span all four post-acute care settings, with payments based on episodes of care and patient characteristics rather than the site of service.	\$101.2 billion in savings over 10 years	In their June 2018 Report to Congress MedPAC comcluded that it is feasible to design a PAC PPS that spans the four settings and uniformly bases payments on patient characteristics. Implementation of this proposal would require legislative and administrative action.



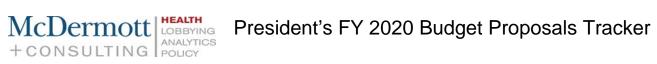
Proposal	Payment System/ Program	Effective Date	Description	Budget Impact	Commentary
Pay Site Neutral Rates to All Hospital- Owned Physician Offices Located Off- Campus	OPPS	CY 2020	This proposal requires all off-campus hospital outpatient departments to be paid under the Physician Fee Schedule effective CY 2020.	\$28.7 billion in savings over 10 years	CMS substantially extended outpatient site- neutral payment policies in 2019. Additional services (codes) could be added in 2020.
Authorize Long-Term Care Hospital Site Neutral Exceptions Criteria	LTC	FY 2020	Medicare pays a higher prospective payment rate to Long Term Care Hospitals (LTCHs) when admissions follow an acute care hospital stay with three or more days in an intensive care unit (ICU), or the LTCH provides at least 96-hours of mechanical ventilation services. This proposal raises the ICU stay threshold from three days to eight days to more accurately identify the chronically ill patients who typically receive the specialized care LTCHs provide.	Savings of \$10.0 billion over 10 years	Consistent with CMS's interest in eliminating site-specific payment disparities, as well as the agency's skepticism of LTCH services, CMS may try to advance this proposal in the forthcoming IPPS-LTCH PPS payment update for FY 2020.
Reduce Medicare Coverage of Bad Debts	Institutional providers	FY 2020	This proposal reduces Medicare reimbursement of bad debt from 65 percent to 25 percent over three years. Rural hospitals with fewer than 50 beds, Critical Access Hospitals, Rural Health Clinics and Federally Qualified Health Centers are exempt from the reduction.	\$38.5 billion in savings over 10 years	This proposal is a perennial in presidential budgets and legislation offset lists but does not seem to advance. If Congress gets desperate for savings, this could appear in Medicare legislation.
Increase End-Stage Renal Disease (ESRD) Networks Funding to Match Consumer Price Index	ESRD Networks		Currently, ESRD Networks are funded by withholding 50 cents from each treatment payment under the ESRD Prospective Payment System, unchanged since 1989. This proposal updates the amount from 50 cents to \$1.50 and inflates that amount annually by the CPI-U to ensure funding is adequate for the networks to continue to carry out their work.	No budget impact	The Administration recently announced its intent to pursue an ESRD demonstration project. Watch for ESRD payment changes on the regulatory side.
Eliminate Arbitrary Thresholds and Other Burdens to Encourage Participation in Advanced Alternative Payment Models	QPP	CY 2020	The five percent bonus for clinicians in Advanced Alternative Payment Models (APMs) would be paid based on physician fee schedule revenues received through Models in which they participate rather than all Medicare physician fee schedule payments.	\$280 million in savings over 10 years	Legislative re-opening of MACRA is possible, especially in light of the zero percent legislated update to the fee schedule. But expect a food fight especially to the extent that a proposal like this would reduce the APM bonus pool.



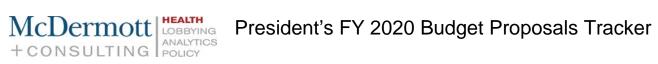
Proposal	Payment System/ Program	Effective Date	Description	Budget Impact	Commentary
Eliminate the Unnecessary Requirement of a Face-to-Face Provider Visit for Durable Medical Equipment	DME		This proposal allows CMS flexibility in the enforcement of the face-to-face requirement - a requirement established in 2013 to provide heightened assurance of the medical necessity of DME.	No budget impact.	This proposal would scale back CMS's requirement for a face-to-face visit, an effort that was originally established by law but subsequently delayed, as an effort to control fraud and abuse. Eliminating the face-to-face requirement would require regulatory changes in addition to legislative changes.
Improve Safety and Quality of Care by Publicly Reporting Medicare Survey and Certification Reports Conducted by Accreditation Organizations	Institutional providers		This proposal would provide CMS with the authority to publish surveys for all accredited facilities, including hospitals, hospices, ambulatory surgical centers, outpatient physical therapy and speech-language pathology services, and rural health clinics.	No budget impact.	This proposal fits in to the Administration's transparency efforts, but the appetite for a policy like this on the Hill may be small.
Remove the Redundant Requirement that Physicians Certify that All Critical Access Hospital Patients are Expected to be Discharged within 96 Hours of Admission	CAH		Under current law, physicians must certify that all patients at critical access hospitals are reasonably expected to be discharged or transferred within 96 hours of admission. This proposal removes the 96-hour physician certification requirement.	No budget impact.	This issue has been circling around the Administration and Congress for several years. Legislation to remove the 96-hour rule has been introduced in the past and is expected to be reintroduced this Congress. However, if history is an indication, this proposal faces an uphill battle.
Remove Timeframe for Initial Surveys for End-Stage Renal Disease Facilities under the Bipartisan Budget Act of 2018	ESRD		The Bipartisan Budget Act of 2018 established a time frame by which compliance surveys should be initiated for new dialysis facilities seeking their initial certification. The proposal clarifies that the time frame is only applicable to surveys conducted by state survey agencies on behalf of CMS.	No budget impact.	This change likely requires legislative action.
Simplify and Eliminate Reporting Burdens for Clinicians Participating in the Merit-based Incentive Payment System	QPP	CY 2022	This proposal alters the MIPS program by adopting a uniform set of broader claims calculated measures and simplifying beneficiary surveys to assess performance at the group practice level instead of the individual clinician level during the performance period to reduce burden and provide meaningful and comparable results to clinicians and patients.	No budget impact.	Legislative re-opening of MACRA is possible, especially in light of the zero percent legislated update to the fee schedule. But expect a food fight among providers who want more rigid requirements and those who want exemptions.



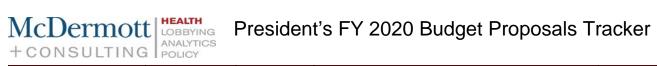
Proposal	Payment System/ Program	Effective Date	Description	Budget Impact	Commentary
Encourage Meaningful Measures for the End-Stage Renal Disease Quality Incentive Program	ESRD		Current law is prescriptive about which measures to include in the ESRD Quality Incentive Program. This proposal provides the Secretary with broad authority to add and remove measures to the ESRD Quality Incentive Program through rulemaking.	No budget impact.	ESRD services could be next up for services to receive a Meaningful Measures overhaul.
Change the Medicare Appeal Council's Standard of Review	Provider		This proposal changes the Council's standard of review from a de-novo to an appellate-level standard of review.	No budget impact	Hospitals and other health-care providers stuck in the years-long Medicare appeals backlog at the HHS have long agitated for reforms. These reforms, if made, would go a long way to relieving the backlog and improving the process. Unfortunately, many of these proposals also were in the President's FY 2019 budget, and these still have not been implemented.
Establish a Post- Adjudication User Fee for Level 3 and Level 4 Unfavorable Medicare Appeals	Provider		Currently, there are no administrative fees charged for filing a Medicare appeal. This proposal establishes a post-adjudication user fee for all unfavorable Medicare appeals.	No budget impact	Hospitals and other health-care providers stuck in the years-long Medicare appeals backlog at the HHS have long agitated for reforms. These reforms, if made, would go a long way to relieving the backlog and improving the process. Unfortunately, many of these proposals also were in the President's FY 2019 budget, and these still have not been implemented.
Expedite Procedures for Claims with No Material Fact in Dispute	Provider		This proposal allows the Office of Medicare Hearings and Appeals to issue decisions on the record without holding a hearing if there is no material fact in dispute.	No budget impact	Hospitals and other health-care providers stuck in the years-long Medicare appeals backlog at the HHS have long agitated for reforms. These reforms, if made, would go a long way to relieving the backlog and improving the process. Unfortunately, many of these proposals also were in the President's FY 2019 budget, and these still have not been implemented.



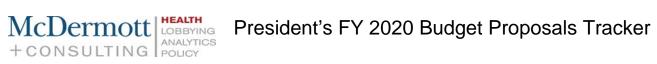
Proposal	Payment System/ Program	Effective Date	Description	Budget Impact	Commentary
Increase Minimum Amount in Controversy for Administrative Law Judge Adjudication of Claims to Equal Amount Required for Judicial Review	Provider		The Social Security Act requires a hearing by an Administrative Law Judge for a Medicare appeal even in situations where the amount-incontroversy is below the cost of adjudicating the claim. This proposal increases the minimum amount in controversy required for adjudication of an appeal by an Administrative Law Judge to the Federal District Court amount in controversy requirement, which is \$1,630 in calendar year 2019 and updated annually.	No budget impact	Hospitals and other health-care providers stuck in the years-long Medicare appeals backlog at the HHS have long agitated for reforms. These reforms, if made, would go a long way to relieving the backlog and improving the process. Unfortunately, many of these proposals also were in the President's FY 2019 budget, and these still have not been implemented.
Establish Magistrate Adjudication for Claims with Amount in Controversy Below New Administrative Law Judge Amount in Controversy Threshold	Provider		The Social Security Act requires a hearing by an Administrative Law Judge for a Medicare appeal even in situations where the amount-incontroversy is below the cost of adjudicating the claim. This proposal allows the Office of Medicare Hearings and Appeals to use Medicare magistrates for appealed claims below the Federal District Court amount in controversy threshold, which is \$1,630 in CY 2019 and updated annually.	No budget impact	
Limit Appeals When No Documentation is Submitted	Provider		Currently, appellants may pursue Medicare appeals when they have not submitted any documentation. This proposal limits the right for non-beneficiary appellants to appeal a redetermination of a claim that was denied because no documentation was submitted to support the items or services billed. This proposal does not apply to beneficiary appeals.	No budget impact	
Remand Appeals to the Redetermination Level with the Introduction of New Evidence	Provider		This proposal permits the remand of an appeal to the first level of appeal when new documentary evidence is submitted into the administrative record at the second level of appeal or above. This proposal incentivizes appellants to include all evidence early in the appeals process and ensures the same record is reviewed and considered at subsequent levels of appeal.	No budget impact	



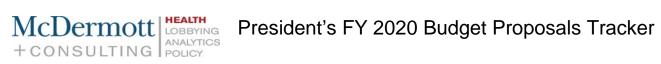
Proposal	Payment System/ Program	Effective Date	Description	Budget Impact	Commentary
Require a Good- Faith Attestation on All Appeals	Provider		This proposal requires all appellants to include in their initial appeal filing an attestation that they are submitting their appeal under a good-faith belief that they are entitled to receive Medicare reimbursement. This proposal also authorizes the Secretary to sanction or impose civil monetary penalties on appellants who submit attestations that are found to be unreasonable or made in bad faith.	No budget impact	
			2020 Medicare Administrative Propos	als	
Encourage Adoption of High-Value Innovative Technologies through Bundled Payment Demonstrations	Innovation Center		Under this proposal, the Center for Medicare and Medicaid Innovation would use existing authorities to identify bundled payment arrangements for certain high value devices.	No budget impact	The Innovation Center has been rumored to be considering upwards of a dozen models. However, the pace of model design and release has been modest.
Improve Clarity and Transparency around Medicare Coverage Process	Coverage		This proposal requires CMS to issue additional guidance around the Medicare coverage process, including sub-regulatory guidance on the evidence standards that CMS utilizes in assessing coverage and the process to appeal coverage determinations, in an effort to improve clarity around Medicare coverage.	No budget impact	This is part of an ongoing congressional and Medicare effort to enhance the transparency of the CMS coverage process. CMS updated the Program Integrity Manual sections describing the local coverage determination (LCD) process last fall (to address transparency-related requirements from 21st Century Cures), but Congress may impose certain incremental requirements.
Strengthen the Parallel Review Process to Streamline Medicare Coverage	FDA/CMS		The Parallel Review program is a collaborative effort between the Food and Drug Administration (FDA) and CMS that is intended to reduce the time between FDA approval of a drug or device and Medicare coverage of that item. This proposal strengthens the existing parallel review process to improve device manufacturer participation and increase transparency.	No budget impact	The Parallel Review process has shown the potential to reduce the time lag between FDA approval of a medical device and Medicare coverage for such device (or the service in which the device has used). However, only two companies have successfully taken products through the program to date.



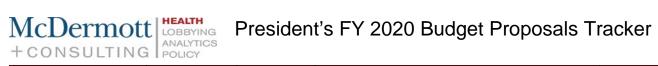
Proposal	Payment System/ Program	Effective Date	Description	Budget Impact	Commentary
Improve Medicare Beneficiary Access to Breakthrough Devices	FDA		There is currently no expedited pathway for Medicare beneficiaries to access innovative devices that have received FDA breakthrough designation. This proposal provides Medicare coverage of devices approved through the Breakthrough Device Program.	No budget impact	The breakthrough device designation has historically entitled manufacturers to expedited FDA review, but has not been directly relevant from a Medicare coverage perspective. If enacted, this proposal would expand Medicare coverage for certain medical devices in trials beyond the scope of current coverage (which is limited to certain non-experimental/investigational devices).
Add Additional Items to Durable Medical Equipment Competitive Bidding Program	DME	2021	This proposal adds ventilators and orthotics to the next round of the competitive bidding program with implementation of prices beginning in 2021.	\$6.1 billion in Medicare savings over 10 years	This proposal would add two new product categories to the competitive bidding program, possibly signaling a renewed commitment to seeking pricing for DME more in line with market rates.
Eliminate Excessive Payment in Medicare Advantage by Using Claims Data from Patient Encounters	Medicare Advantage	2020	This proposal phases-in the use of encounter data for Medicare Advantage payment risk adjustments.	No budget impact	The movement to encounter data is one the plans and the past two Administrations have been fighting for years.
Publicly Report Drugs with Significant Wastage Using Part B Claims Data	Part B drugs		This proposal requires CMS to make public which Part B drugs have the highest reported drug wastage using data gathered from claims.	No budget impact	CMS has allowed separate payment for wasted drugs, that is the amount of unused drug in a single use container. CMS has not publicly made available metrics on how much Medicare spend is devoted to wasted drugs.
			2020 Prescription Drug (Medicare) Prop	osals	
Reduce Average Sales Price Based Payments When the Primary Patent Expires to Increase Competition and Reduce Gaming	Part B drugs	CY 2020	This proposal reduces payment for innovator drugs from average sales price (ASP) plus six percent to ASP minus 33 percent when a manufacturer files a pay-for-delay agreement or takes another anti-competitive action after the primary patent or market exclusivity period expires, whichever date is earliest. Once a competitor is commercially available, CMS will pay for both innovator and competitor drugs at ASP plus six percent.	Budget impact not available	Critics of the +6% add on claims it has no basis in actual drug overhead costs. This change would require a legislative change and would likely require a regulatory change in order to determine the workflow and processes required to make the adjustments accurately.



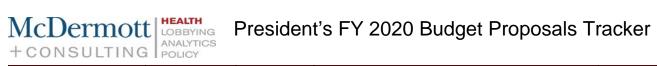
Proposal	Payment System/ Program	Effective Date	Description	Budget Impact	Commentary
Authorize the HHS Secretary to Leverage Medicare Part D Plans' Negotiating Power for Certain Drugs Covered Under Part B	Part B drugs	2020	Under Part B, providers have limited ability to negotiate for cheaper Part B drug prices. Beginning in CY 2020, this proposal provides the Secretary with authority to consolidate certain drugs currently covered under Part B into Part D when savings can be gained from price competition. The Secretary would not use this authority when it limits a beneficiaries' access to the drug or increases beneficiary cost-sharing. Beneficiary cost-sharing for any drugs shifted from Part B to Part D may be counted toward the Medicare Advantage out-of-pocket limit for plans that have a combined Part D benefit.	Budget impact not available	So called "B-to-D" has been a proposal floated by many, including CMS, as far back as 2005. Many administrative issues with moving drugs from Part B to D have been identified and would need to be addressed before this legislative proposal could be implemented.
Give the Secretary Authority to Contract with Pharmaceutical Manufacturers Entering into New Coverage Gap Discount Program Agreements on a Quarterly Basis	Part D drugs		This proposal allows the Secretary to initiate new contracts with pharmaceutical manufacturers on a quarterly, rather than an annual, basis.	Budget impact not available	The current Part D program utilizes annual contracts between plan sponsors and drug makers. Quarterly contracting could increase the government's negotiating power, and allow for more rapid price adjustments.
Improve Manufacturers' Reporting of Average Sales Prices to Set Accurate Payment Rates	Part B drugs		This proposal requires all Part B drug manufacturers to report ASP data and gives the Secretary the authority to penalize manufacturers who do not report required data.	No budget impact	The legislative change could address critics' concerns that the current ASP system allows manufacturers without Medicaid rebate agreements to avoid the reporting requirements of the ASP system.
Reduce Wholesale Acquisition Cost (WAC)-Based Payments	Part B drugs	2020	This proposal reduces the payment rate for single-source drugs, biologics and biosimilars from 106 percent to 103 percent of WAC to reduce excessive payments. The Budget would reduce payments on drugs for which ASP data isn't available, from WAC + 6% to WAC + 3%.	Budget impact not available	This proposal signals the Administration's commitment to reducing drug prices. Many, including MedPAC, have suggesting this change for many years. This proposal could be implemented administratively, since the +6% add on under WAC is not legislative.
Address Abusive Drug Pricing by Manufacturers by Establishing an Inflation Limit for Reimbursement of Part B Drugs	Part B drugs	2020	This proposal caps the growth of the ASP payment of Part B drugs at the Consumer Price Index for all Urban Consumers (CPI-U).	Budget impact not available	Capping price growth based on an inflationary benchmark has been considered by many over the years. Current law does not allow for any caps on price growth, so legislation and regulatory changes would be required.



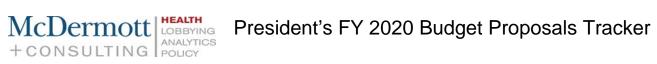
Proposal	Payment System/ Program	Effective Date	Description	Budget Impact	Commentary
Eliminate Pass- Through Payments for Drugs, Biologicals, and Biosimilars	OPPS	2020	This proposal removes transitional pass-through payment for drugs, biologicals, and biosimilars from the OPPS. Eliminating pass-through payment for drugs, biologicals, and biosimilars will lower cost by making them eligible for the reduced 340B payment level, or immediate bundling under the OPPS, if applicable.	\$4.3 billion in Medicare savings over 10 years	Emphasizing the Trump Administration's goal of increasing access to generics and improving competition, this proposal would reduce the barriers to market entry for biosimilars and other new drugs.
Permanently Authorize a Successful Pilot on Retroactive Medicare Part D Coverage for Low-Income Beneficiaries	Part D		Under current law, newly eligible low-income subsidy beneficiaries are randomly assigned to a qualifying Part D plan, which in turn is paid based on the standard Part D prospective payment regardless of a beneficiary's actual utilization of Part D services. This proposal permanently authorizes a current demonstration that allows CMS to contract with a single plan to provide Part D coverage to low-income beneficiaries while their eligibility is processed.	\$300 million in savings over 10 years	These proposals are consistent with the Administration's goals of reducing beneficiary out-of-pocket spending on drugs and of reducing Medicare spending on prescription drugs.
Exclude Manufacturer Discounts from the Calculation of Beneficiary Out-of- Pocket Costs in the Medicare Part D Coverage Gap	Part D		Under the current benefit structure, Part D plans are incentivized to encourage beneficiaries to use costly brand drugs in order to accelerate their progression through the coverage gap into the catastrophic phase, where Medicare covers 80 percent of costs. The manufacturer discounts mean that patients using generic drugs are required to spend more out of their own pockets before reaching this threshold, compared with patients using brand drugs. This proposal restructures the coverage gap discount program to exclude manufacturer discounts from the calculation of true out-of-pocket costs in order to correct this misaligned incentive that encourages plans to promote costly brand drugs.	\$74.7 billion in savings over 10 years	These proposals are consistent with the Administration's goals of reducing beneficiary out-of-pocket spending on drugs and of reducing Medicare spending on prescription drugs.
Eliminate Cost- Sharing on Generic Drugs and Biosimilars for Low- Income Beneficiaries	Part D		Low-income subsidy (LIS) beneficiaries are three times more likely than non-LIS beneficiaries to have drug spending high enough to enter the catastrophic phase of the benefit. This proposal encourages the use of higher value products among LIS beneficiaries by reducing cost sharing to \$0 for generics, biosimilars, and preferred multiple source drugs.	\$930 million in savings over 10 years	These proposals are consistent with the Administration's goals of reducing beneficiary out-of-pocket spending on drugs and of reducing Medicare spending on prescription drugs.



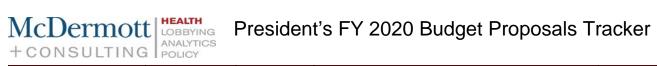
Proposal	Payment System/ Program	Effective Date	Description	Budget Impact	Commentary
Establish a Beneficiary Out-of- Pocket Maximum in the Medicare Part D Catastrophic Phase	Part D		The Part D benefit creates a perverse incentive structure for plans, wherein drug price increases shift more drug spending into the catastrophic phase, where Medicare pays 80 percent of costs. Beneficiaries who reach the catastrophic phase continue to be responsible for five percent of their drug costs. It increases Part D plan sponsors' risk in the catastrophic phase by increasing plan liability over4 years from 15 percent to 80 percent; decreases Medicare's reinsurance liability from 80to 20 percent; and, eliminates beneficiary coinsurance, creating a true out-of-pocket maximum in Part D for the first time in the program's history.	\$14.0 billion in costs over 10 years	These proposals are consistent with the Administration's goals of reducing beneficiary out-of-pocket spending on drugs and of reducing Medicare spending on prescription drugs.
			Medicaid Prescription Drug Proposa	ls	
Clarify Definitions under the Medicaid Drug Rebate Program to Prevent Inappropriately Low Manufacturer Rebates	Medicaid Drug Rebate Program		Ongoing misclassification of brand and generic drugs can result in lower rebates paid to the state and federal governments. This proposal clarifies the Medicaid definition of brand and over-the-counter drugs as well as drugs approved under a biologics license application by codifying existing regulations to ensure appropriate Medicaid drug rebates.	\$347 million in savings over 10 years	This proposal was included in last year's budget request.
Test Allowing State Medicaid Programs to Negotiate Prices Directly with Drug Manufacturers and Set Formulary for Coverage	Medicaid		This proposal includes a statutory demonstration authority allowing up to five states to test a closed formulary under which states negotiate prices directly with manufacturers, rather than participating in best price reporting or the Medicaid Drug Rebate Program. Participating states will include an appeals process so beneficiaries can access drugs outside the formulary based on medical necessity.	\$410 million in savings over 10 years	This proposal was included in last year's budget request. In 2018, Massachusetts submitted an 1115 waiver seeking the ability to create a closed formulary in the Medicaid program. However, CMS rejected that application as the state requested to continue to collect manufacturer rebates while also excluding certain drugs from coverage, which wouldn't be allowable under federal law.
Impose Greater Penalties for Manufacturer Reporting of False Information or False Product Data under the Medicaid Drug Rebate Program	Medicaid Drug Rebate Program		This proposal would increase the civil monetary penalty paid by drug manufacturers for providing false or late reporting of information to the Medicaid Drug Rebate Program.	N/A	This is conceptually similar to a 2018 MACPAC recommendation to give the Secretary of Health and Human Services the authority to level intermediate financial sanctions to compel drug manufacturers to submit accurate drug classification data and strengthen enforcement actions. It is also similar to language included in the IMPROVE Act and Right Rebate Act of 2018.



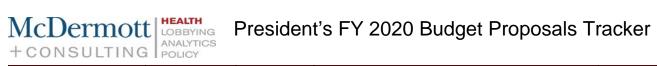
Proposal	Payment System/ Program	Effective Date	Description	Budget Impact	Commentary	
Exclude Brand Name and Authorized Generic Drug Prices from Medicaid's Federal Upper Limit	Medicaid		This proposal removes brand name and authorized generic drugs from the FUL calculation for drugs where there are generic options, reducing the maximum federal reimbursement.	\$980 million in savings over 10 years	This proposal was also included in <u>President Obama's budget request</u> , specifically the FY 2016 budget.	
Clarify Authorized Generic Drug Sales under the Medicaid Drug Rebate Program	Medicaid		Some drug manufacturers may be inappropriately reducing their rebates to the Medicaid program. They interpret current law and regulations as allowing the inclusion of heavily discounted authorized generic sales to secondary manufacturers in the primary manufacturer's average price. This proposal clarifies hat the primary manufacturer's average price must exclude these sales.	\$150 million in savings over 10 years	In 2018, MACPAC recommended eliminating authorized generic transactions from the calculation of rebates.	
Allow Rebates on Drugs that Exceed 100 Percent of the Average Manufacturer Price	Medicaid		This proposal removes the ACA's cap on Medicaid rebates, allowing rebates to offset the cost of drugs when list prices exceed the rate of inflation.	N/A	MACPAC is also examining a recommendation to remove the rebate cap, which could be included in their June 2019 Report to Congress.	
340B Proposals						
Establish and Collect User Fees from 340B Drug Pricing Program Participating Covered Entities	340B		This proposal allows HRSA to collect a user fee set at 0.1 percent of total 340B drug purchases from participating covered entities, which would support improvements to the 340B public database, program audits and oversight, and the program's automated compliance management tool.	N/A	Similar language was introduced in 2018 by Rep. Collins and Rep. Carter, H.R.6240 - Drug Discount Accountability Act.	



Proposal	Payment System/ Program	Effective Date	Description	Budget Impact	Commentary	
Modify Payment for Drugs Hospitals Purchased through the 340B Discount Program and Require a Minimum Level of Charity Care for Hospitals to Receive a Payment Adjustment Related to Uncompensated Care	340B	2020	The law requires the savings from 340B be redistributed across Medicare payments to outpatient hospitals in a budget neutral manner. This proposal allows CMS to apply savings from these lower payments for drugs purchased under the 340B program in a non-budget neutral way. Hospitals providing at least one percent of patient care costs in uncompensated care will receive redistributed savings based on the percentage of all uncompensated care they provide compared with other outpatient hospitals. Hospitals not meeting that threshold will be ineligible for the redistribution, and the savings from their payment reduction will be returned to the Medicare Trust Funds.	No budget impact	This proposal expands on the OPPS regulation that reduced outpatient hospital payment for 340B drugs.	
Establish Requirements Regarding the Use of Savings and Expand Rulemaking Authority for the 340B Drug Pricing Program for Program Integrity	340B		This proposal also requires all 340B covered entities to report the savings achieved from the 340B program and their uses.	N/A	Legislation was introduced in the 115 th Congress that proposed similar requirements.	
Key Medicaid Legislative Proposals						
Empowering States and Consumers to Reform Health Care	Medicaid		Implements the 2017 Graham-Cassidy-Heller- Johnson legislation, including allowing states a choice between a per-capita cap or a block grant, and repealing Obamacare's Medicaid expansion.	\$1.4 trillion in Medicaid savings over 10 years	This proposals also have interactions with the Marketplace and was included in last year's budget proposal.	
Increase the Limit on Medicaid Copayments for Non-Emergency Use of the Emergency Department	Medicaid		Provide states the option to use state plan authority to increase copayments above the nominal statutory amounts for non-emergency use of the emergency department.	\$1.6 billion in savings over 10 years	Currently, sates can increase copayments above the nominal statutory amounts for non-emergency use of the emergency department.	



Proposal	Payment System/ Program	Effective Date	Description	Budget Impact	Commentary	
Strengthen Work Requirements to Promote Self Sufficiency	Medicaid		Requires that able-bodied, working-age individuals find employment, train for work, or volunteer (community service) in order to Medicaid benefits.	\$130.4 billion in savings over 10 years	States can submit an 1115 waiver to implement Medicaid work requirements. Eight states have received approval to implement Medicaid work requirements. These states are Arizona, Arkansas, Indiana, Kentucky, Michigan, New Hampshire, Ohio, and, Wisconsin. (Note that Maine also received approval to implement Medicaid work requirements but the new Governor withdrew the waiver.) The legality of Medicaid work requirements is currently being challenged in court.	
Continue Medicaid Disproportionate Share Hospital Allotment Reductions	Medicaid		Continues Medicaid DSH allotment reductions for FY 2026 through FY 2029.	\$25.9 billion in savings over 10 years	Currently, DSH allotment reductions are scheduled to go into effect between FY 2020 and FY 2025. (This proposal was also included in last year's budget request.)	
Allow States to Apply Asset Tests to Modified Adjusted Gross Income Standard Populations	Medicaid		Provides states the option to apply asset tests to populations determined financially eligible by the Modified Adjusted Gross Income (MAGI) standard. Provides states with the option to apply asset tests just to individuals eligible through the MAGI standard who are receiving long-term care.	\$2.1 billion in savings over 10 years	MAGI is the basis for determining Medicaid income eligibility for most children, pregnant women, parents, and adults. MAGI-based methodology does not allow for income disregards that vary by state or by eligibility group and does not allow for an asset or resource test.	
	Key Medicaid Administrative Proposals					
Make Medicaid Non- Emergency Medical Transportation Optional	Medicaid		Using regulatory authority to change the provision of Non-Emergency Medical Transportation from mandatory to optional to provide greater flexibility to states	No budget impact	This proposal was included in the FY 2019 President budget. A proposal to re-examine current regulations relating to NEMT coverage and providing states greater flexibility in covering the NEMT benefit is currently on the CMS unified agenda and is expected to be published by May 2019.	
Improve Transparency of Medicaid Supplemental Payments	Medicaid		The Budget commits to issuing a regulation requiring more complete and timely provider-level data on supplemental payments, including the financing of such payments.	No budget impact	This proposal was included in the FY 2019 President budget request.	



Proposal	Payment System/ Program	Effective Date	Description	Budget Impact	Commentary
Allow States the Flexibility to Conduct More Frequent Eligibility Redeterminations	Medicaid		Uses regulatory authority to allow states the option to conduct more frequent eligibility redeterminations for MAGI populations	\$45.6 billion in savings over 10 years	Aligns with other proposals from the Administration relating to MAGI populations.