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Highlights of the Administration's FY 2019 Budget

February 26, 2018 (revised)

This summary provides highlights of healthcare-related proposals included in the President's budget for fiscal year (FY) 2019, which was released by the Trump Administration on February 12, 2018. All budget estimates shown are those provided by the Office of Management and Budget (OMB) or drawn from the Department of Health and Human Services (HHS) *Budget in Brief.* As in the past, the Congressional Budget Office (CBO) is expected to prepare an analysis of the President's budget proposals, and CBO scoring may differ.

Table of Contents

Budget Overview

President Trump's budget for FY 2019 proposes policies that it estimates would reduce federal deficits by a total of $4.4 trillion over the next 10 years (FYs 2019-2028). Federal spending would be reduced by $3.6 trillion; the Administration incorporates into its estimates an additional $813 billion associated with anticipated economic growth ("post-policy boost") from its fiscal, economic, and regulatory policies. The $3.6 trillion reduction in federal spending is comprised of cuts to mandatory spending of $1.8 trillion, cuts to discretionary programs of $1.5 trillion, and about $319 billion in reduced interest payments on the debt.

It is notable that the budget baseline and policy proposals do not reflect the enactment on February 9, 2018 of the Bipartisan Budget Act of 2018 (P.L.115-123), which amended discretionary spending caps for 2018 and 2019 and included numerous provisions affecting Medicare and Medicaid and other programs. In particular, the budget proposes to extend the Children's Health Insurance Program (CHIP) through 2019, but under the new law CHIP has been extended through 2028. In a few other cases, proposals offered in the budget are similar or related to provisions enacted under that law (e.g., repeal of the Independent Payment Advisory Board). Relevant overlaps are noted in this summary. As discussed below, the Administration has issued a brief addendum to the budget documents that addresses additional discretionary spending priorities in light of the higher spending caps provided under the new law.

Proposed reductions in Medicare spending total $532 billion over 10 years (2019-2028); about $333 billion of these reductions (involving elimination of Medicare payments for graduate medical education and uncompensated care payments to disproportionate share hospitals) would be partially offset by new spending for these purposes outside the Medicare program, totaling

$216 billion. Some $38 billion of the proposed savings would come from administrative actions and the balance ($494 billion) would require legislation. Further details on the proposed Medicare savings are provided below. The budget also proposes reforms intended to address the pending backlog of Medicare appeals and prioritizes reducing provider burden.

A total of $1.389 trillion in Medicaid savings is incorporated into the budget's proposal for repeal and replacement of the Affordable Care Act (ACA). Other Medicaid proposals in the budget are estimated to reduce Medicaid spending by almost $50 billion – although HHS indicates that interactions with repeal and replacement of the ACA would reduce of some of those savings. The repeal and replace proposal has a government-wide net 10-year savings of about $680 billion; this is the result of the $1.4 trillion in Medicaid savings plus about $475 billion in other program savings offset by $1.2 trillion in funding for a new Market Based Health Care Grant Program for states. The $1.4 trillion in Medicaid savings reflects both repeal of the ACA Medicaid expansion and establishing per capita limits on program spending.

The budget includes $95.4 billion in FY 2019 discretionary funding for HHS, $13.5 billion above the FY 2018 level. A budget addendum issued after enactment of the Bipartisan Budget Act supplements the spending levels proposed in the FY 2019 budget and provides an additional $15.8 billion for HHS.[1] Some $10 billion in HHS discretionary funding is proposed for FY 2019 for opioids and serious mental illness. Proposed agency funding levels vary; the Agency for Healthcare Research and Quality would be eliminated and it activities folded into the NIH, with a reduction in funding of about 10 percent.

The budget also includes initiatives to address the opioid epidemic and to reform medical liability. Further, the budget proposes that the federal government, along with state and local governments receiving federal financing for health-related activities, would be prohibited from penalizing or discriminating against health care providers who refuse to be involved in or provide coverage for abortion services.

Medicare Proposals

As noted above, the budget proposes a 10-year reduction in Medicare spending of $532 billion; estimated budget effects for some provisions were not available at the time the budget was released. The proposals are listed in the table below, with brief descriptions following the table.

A few of the budget's Medicare proposals were included in the recently enacted Bipartisan Budget Act of 2018. These include repeal of the Independent Payment Advisory Board, changes to payment to hospitals for patients discharged from short inpatient stays to hospice care, modifications to the prospective payment for home health services, and application of Merit Based Incentive Payment System adjustment to physician fee schedule payments only.

[1]The Bipartisan Budget Act of 2018 significantly raised the defense and non-defense discretionary spending caps in FY 2018 and FY 2019 after the FY 2019 budget had been finalized. OMB published a budget addendum to lay out additional funding for a limited set of priorities. See Office of Management and Budget. Addendum for the FY 2019 Budget. February 12, 2018. Downloaded from https://www.whitehouse.gov/wp-content/uploads/2018/02/Addendum-to-the-FY-2019-Budget.pdf

MEDICARE PROPOSALS IN THE PRESIDENT'S BUDGET FOR FY 2019		
	Savings (-) /cost (+) in $ millions	
	FY19	FY19-28
Drug Pricing and Payment Improvements		
Require Part D plans to apply a portion of rebates at the point of sale	1,785	42,160
Establish out of pocket maximum in the Part D catastrophic phase	377	7,359
Exclude manufacturer discounts from out of pocket costs in coverage gap	-1,490	-47,020
Increase Part D plan formulary flexibility	-280	-5,517
Eliminate Part D cost sharing on generics for low-income beneficiaries	-30	-210
Permanent pilot on retroactive Part D coverage for low-income beneficiaries	--	-300
Improve manufacturer reporting of average sales prices	--	--
Inflation limit for reimbursement of Part B drugs	TBD[a]	TBD[a]
Shift certain drugs covered under Part B into Part D	TBD[a]	TBD[a]
Modify the 340B discount program[a]	TBD[a]	TBD[a]
Reduce payments based on wholesale acquisition cost	TBD[a]	TBD[a]
Effect on Medicare of changes to first generic exclusivity	-118	-1,786
Opioid-Related Medicare Proposals		
Require Part D plans to participate in prescription drug abuse prevention	-10	-100
Provide comprehensive coverage of substance abuse treatment in Medicare	TBD[a]	TBD[a]
Reform of Delivery and Payment Systems		
Reform graduate medical education payments (Note: New non-Medicare mandatory funding to be made available totaling $168b over 10 years)	-13,310	-195,040
Restructure payments to hospitals for uncompensated care (Note: New non-Medicare mandatory funding to be made available totaling $69b over 10 years)	--	-138,410
Post-acute site of care payment neutrality	-780	-80,190
Reduce Medicare payments for bad debt	-400	-37,030
Pay all off-campus hospital outpatient departments at the physician office rate	-1,240	-33,980
Reform and expand competitive bidding for durable medical equipment	--	-6,480
Hospital transfer payments for patients quickly discharged to hospice[b]	-70[b]	-1,260[b]
Zero out the Medicare Improvement Fund[b]	--	-193[b]
Permit beneficiaries to make tax deductible contributions to health or medical savings accounts (Note: revenue reduction = $11.3b through 2028.)	--	180
Modify beneficiary assignment for Accountable Care Organizations (ACOs)	--	-140
Allow ACOs to cover cost of primary care visits	--	-60
Expand ability of MA organizations to pay for services delivered via telehealth[b]	--	--
Reform physician self-referral laws to align with alternative payment models	TBD[a]	TBD[a]
Require prior authorization for physicians with excessive service ordering	TBD[a]	TBD[a]
Modify Electronic Health Record requirements[b]	--	--
Eliminate face-to-face provider visit for durable medical equipment	--	--
Simplify Merit-based Incentive Payment System requirements	--	--
Eliminate barriers to participation in Advanced Alternative Payment Models	TBD[a]	TBD[a]
Improvements to Medicare appeals system (Note: proposes mandatory annual appropriations of $127 million; amounts shown net of Part B premiums.)	111	1,111
Program integrity	-42	-907
Effect on Medicare of Medicare-Medicaid enrollee proposals	-38	-693
Effect on Medicare of medical liability proposal	-88	-30,703
Repeal the Independent Payment Advisory Board (IPAB)[b]	--	29,482[b]

MEDICARE PROPOSALS IN THE PRESIDENT'S BUDGET FOR FY 2019		
	Savings (-) /cost (+) in $ millions	
	FY19	FY19-28
Interactions	190	5,996
Subtotal Medicare Legislative Proposals	-15,434	-493,731
Medicare Administrative Proposals		
Home health payment reform[b]	--	-16,670[b]
Switch from fee-for-service to patient encounter date for MA risk adjustment	-110	-11,110
Revise methodology for payment to MA Employer Group Waiver Plans	-530	-10,690
Improve valuation of physician services to set rates	--	--
Subtotal Medicare Administrative Proposals	-640	-38,470
TOTAL, MEDICARE LEGISLATIVE AND ADMINISTRATIVE	-16,074	-532,201
[a] The *HHS Budget in* Brief states that the budget impact was unavailable at the time of publication.		
[b] Similar or related provision enacted in the Bipartisan Budget Act of 2018.		

Medicare: Legislative Proposals

Note: Unless otherwise stated, the proposals would be effective beginning in 2019.

Require Part D plans to apply a portion of rebates at the point of sale. Part D sponsors would have to apply at least one-third of total manufacturer rebates and price concessions at the point of sale. This could reduce enrollees' costs although premiums could increase. **(**CMS included a Request for Information on the general approach of requiring all or a portion of rebates to be reflected in the point-of-sale price in its November 2017 MA/Part D proposed rule.)

Establish a beneficiary out-of-pocket maximum in the Part D catastrophic phase. Over four years, Part D plan liability for the cost of prescription drugs in the catastrophic phase of the benefit would increase from 15% to 80%, Medicare's reinsurance liability would decrease from 80% to 20%, and beneficiary coinsurance would decrease from 5% to 0%.

Exclude manufacturer discounts from the calculation of beneficiary out-of-pocket costs in the Part D coverage gap. The coverage gap discount program would newly exclude manufacturer discounts from the calculation of the enrollee's true out-of-pocket costs ("TrOOP"), thus slowing the progression of the enrollee through the coverage gap phase of the benefit.

Increase Part D plan formulary flexibility. The existing plan formulary standard requiring 2 drugs per category or class would be changed to 1 drug per category or class and the use of plan utilization management tools would be expanded in unspecified ways for specialty drugs and drugs in protected classes to enable plans to better manage the Part D benefit.

Eliminate Part D cost-sharing on generic drugs for low-income beneficiaries. Cost-sharing for generics, including biosimilars and preferred multiple source drugs, would be reduced to $0 for Part D low-income subsidy beneficiaries so as to encourage the use of lower-cost alternatives.

Permanently authorize a pilot on retroactive Part D coverage for low-income beneficiaries. A current demonstration would be permanently authorized to allow CMS to contract with a single Part D plan to provide part D coverage to low-income beneficiaries while their eligibility is being determined.

Improve manufacturers' reporting of Average Sales Prices (ASPs). Under current policy, Part B drug manufacturers are required to report ASP only for those drugs where the manufacturer has a Medicaid rebate agreement. Part B drug manufacturers would be required to report ASP for all drugs; the Secretary would be authorized to apply civil monetary penalties of up to $10,000 per day for not timely reporting.

Establish an inflation limit for reimbursement of Part B drugs. Medicare Part B drug payment would be limited to the lower of ASP+6 percent or the 1st quarter CY 2017 ASP+6 percent adjusted by the Consumer Price Index for All Urban Consumers (CPI-U).

Shift certain drugs covered under Part B into Part D. The Secretary would be authorized to "consolidate" certain drugs currently covered under Part B into Part D, based on the likelihood of achieving cost savings.

Modify the 340B Discount Program. Rather than redistribute savings from Medicare's policy of paying for drugs acquired under the 340B drug discount program at ASP-22.5 percent to all hospitals through an adjustment to all non-drug outpatient hospital services, this policy would redistribute savings based on each hospital's share of aggregate uncompensated care costs. All hospitals (not just 340B hospitals) would be eligible for a share of the redistributed savings. If a hospital did not spend at least 1 percent of total costs on uncompensated patients, its share of 340B program savings would be returned to the Trust Fund.[2]

Reduce payments based on wholesale acquisition cost. Medicare Part B payment would be reduced to wholesale acquisition cost (WAC)+3% when ASP is not available rather than WAC+6%.

Effect on Medicare of changes to first generic exclusivity Medicare savings are attributed to the budget's proposal to increase the availability of generic drugs by allowing the FDA to tentatively approve a subsequent generic drug application that is blocked by the first generic applicant's 180-day exclusivity.

Require Part D plan participation in program to prevent prescription drug abuse. The Secretary would be authorized to establish a mandatory prescriber and/or pharmacy lock-in program in Part D that would apply to all Part D plans beginning in 2020. (The plans can currently do this at their option.)

[2] The *Economic Report of the President* (p. 317) provides additional explanation of this proposal. https://www.whitehouse.gov/wp-content/uploads/2018/02/ERP_2018_Final-FINAL.pdf

Provide comprehensive coverage of substance abuse treatment in Medicare. CMS would conduct a demonstration to test the effectiveness of covering comprehensive substance abuse under Medicare which could be expanded nation-wide if successful in key metrics. Medicare would provide bundled reimbursement on a per patient basis to providers for methadone treatment or similar medication-assisted therapy and recognize treatment programs and facilities as independent provider types.

Reform graduate medical education (GME) Payments. All federal payments for GME from Medicare, Medicaid and the Children's hospitals GME program would be eliminated and replaced with a single grant program jointly administered by CMS and HRSA. Aggregate payments from the new grant program would equal base year (2016) payments adjusted annually by the increase in the CPI-U minus one percentage point. Payments would be distributed by the number of residents at a hospital up to its current caps and Medicare and Medicaid inpatient utilization. The Secretary could adjust payments based how training meets health workforce goals. All funding would be from the Treasury general revenue (no longer from Medicare Trust Funds).

Restructure payments to hospitals for uncompensated care. Beginning with FY 2020, Medicare payments to disproportionate share hospitals for uncompensated care under the inpatient hospital prospective payment would be eliminated and replaced with a grant program funded out of general revenue. Total grant funds available would be 2018 funding levels increased annually by the CPI-U. Funds would be distributed based on the share of charity care and non-Medicare bad debt reported on cost report worksheet S-10.

Post-acute site of care payment neutrality. Effective with FY 2024, would implement a unified post-acute care prospective payment system for skilled nursing facilities, inpatient rehabilitation facilities, long-term care hospitals, and home health agencies.

Reduce Medicare payments for bad debt. Reduces Medicare reimbursement of bad debt from 65 percent to 25 percent over three years, exempting rural hospitals with less than 50 beds, critical access hospitals, rural health clinics and federally qualified health centers.

Pay all off-campus hospital outpatient departments at the "physician office rate." Medicare pays 40 percent of the outpatient prospective payment system rate (but CMS calls it a "physician fee schedule" payment) for services at off-campus hospital outpatient departments that opened after November 2, 2015. This proposal would expand the policy to all off-campus hospital outpatient departments beginning 1/1/2019.

Reform and expand competitive bidding for durable medical equipment. Competitive bidding would be expanded to all areas of the country, including rural areas. Winning bidders would be paid at their bid amounts instead of the median bid price.

Hospital transfer payments for patients quickly discharged to hospice. Beneficiaries discharged to hospice after a short inpatient stay would be treated as transfer patients for purposes of hospital payment. This provision was enacted in the Bipartisan Budget Act of 2018.

Zero out the Medicare Improvement Fund. The budget would eliminate funds from the Medicare Improvement Fund. However, this has been enacted under the Bipartisan Budget Act of 2018.

Permit beneficiaries to make tax deductible contributions to health savings accounts or medical savings accounts. Medicare beneficiaries could make tax-deductible contributions to HSAs or MSAs, subject to IRS contribution limits. (This is currently prohibited.) Beneficiaries electing this option would forgo the ability to purchase Medigap plans.

Modify beneficiary assignment for Accountable Care Organizations. Beneficiary assignment to an ACO could be based on a broader set of primary care providers, including nurse practitioners, clinical nurse specialists, physician assistants, as well as physicians.

Allow ACOs to cover cost of primary care visits. ACOs could elect to pay beneficiaries for a primary care visit. Those with no supplemental coverage would have cost sharing covered by the ACO and those with supplemental coverage would receive a payment equal to the cost sharing amount.

Expand the ability of MA organizations to pay for services delivered via telehealth. Eliminates the requirement that MA organizations provide certain covered Part B services exclusively through face-to-face encounters. A provision of the Bipartisan Budget Act of 2018 will allow MA plans to offer additional telehealth services as basic benefits to chronically ill enrollees beginning in plan year 2020 as long as those same services are also available through face-to-face encounters.

Reform physician self-referral laws to align with alternative payment models. Beginning in 2020, would create new exceptions to the physician self-referral law for arrangements resulting from participation in Advanced Alternative Payment Models. Also, would modify the process for self-reporting of inadvertent violations, and would exclude physician-owned distributors from the indirect compensation exception if more than 40 percent of the business is generated by physician owners.

Require prior authorization for physicians with excessive service ordering. Effective in 2020, would create a prior authorization program for high utilization practitioners (2 standard deviations above the national per capita rate for the service area) of radiation therapy, therapy services, advanced imaging and anatomic pathology services.

Modify Electronic Health Record requirements. The budget proposes to modify the meaningful use programs for hospitals and physicians by removing “ineffective” federal penalties, reduce reporting burden and eliminating low-value metrics. (The Bipartisan Budget Act of 2018 eliminated the statutory requirement that mandates the use of more stringent measures over time.)

Eliminate face-to-face provider visit for durable medical equipment. Requirement for face-to-face encounter as a condition for Medicare payment of DME would be eliminated.

Simplify Merit-based Incentive Payment System (MIPS) requirements. Effective 2021, MIPS would be simplified by removing the improvement and advancing care information categories. Performance would be assessed by CMS without requiring any reporting from clinicians, and CMS would use broader claims and beneficiary survey calculated measures that assess clinician performance on quality and cost during the performance period at the group-level only. The MIPS adjustment would apply only to fee schedule payments rather than all Part B payments; this change has already been enacted under the Bipartisan Budget Act of 2018.

Eliminate barriers to participation in Advanced Alternative Payment Models. Instead of receiving the five percent bonus on all fee schedule payments only after reaching the Advanced APM pre-set payment or patient threshold, the bonus for a physician would be limited to five percent of payments made under the Advanced APMs in which they participate.

Improvements to Medicare appeals system. Additional funds ($127 million a year) would be provided to address the backlog of pending Medicare appeals. The standard of review would be changed from de-novo to an appellate-level standard. A post-adjudication user fee would apply to level 3 and level 4 unfavorable Medicare appeals, other than beneficiary appeals. The minimum amount in controversy required for adjudication of an appeal by an Administrative Law Judge would be increased to $1,600 in 2018 and updated annually. Medicare magistrates would be used for appealed claims below the controversy threshold. Decisions could be issued without a hearing if there is no material fact in dispute. The right to appeal a redetermination of a claim that was denied due to lack of documentation would be limited, except for beneficiary appeals. Appeals would be remanded to the redetermination level with the introduction of new evidence. All appellants would have to include an attestation that the appeal is made under a good-faith belief that they are entitled to Medicare reimbursement.

Program integrity. Savings to Medicare from a series of CMS program integrity initiatives, discussed below, are shown.

Effect on Medicare of Medicare-Medicaid enrollee proposals. Medicare savings are shown from proposals affecting Medicare-Medicaid dual eligible beneficiaries. The proposals are discussed in the Medicaid section below.

Effect on Medicare of Medical Liability Proposal. The Administration estimates savings to Medicare from its proposal to reform medical liability, which is discussed below.

Repeal the Independent Payment Advisory Board. The budget proposes to repeal the IPAB, but repeal was just enacted as part of the Bipartisan Budget Act of 2018.

Medicare: Administrative Proposals

***Home health payment reform*.** Effective with 2020, the budget proposes to use the home health grouping model to measure clinical differences in patients for payment under the home health prospective payment system. The Bipartisan Budget Act of 2018 included a provision requiring the Secretary to obtain stakeholder input on the home health grouping model and other case mix models and to pursue rulemaking on a new case mix system before the end of 2019. That law also established a 30-day episode of care under the payment system effective January 1, 2020.

Switch from fee-for-service to patient encounter date for MA risk adjustment. The use of MA encounter data for calculating plan risk scores for the risk adjustment payments would be phased in from 75% fee-for-service diagnoses ("RAPS data") and 25% MA encounter data in 2019 to 100% MA encounter data in payment year 2022. (In the CY 2019 Advance Notice and Draft Call Letter, CMS also has proposed using 75% RAPS-25% MA encounter data for the calculation of risk scores in 2019.)

Revise methodology for determining payment to MA Employer Group Waiver Plans (EGWPs). The bid-to-benchmark ratios would be calculated using individual market plan bids only, rather than a 50/50 blend of individual market plan bids and EGWP bids from the previous year. (In the CY 2019 Advance Notice and Draft Call Letter, CMS proposes to complete the transition to using bid-to-benchmark ratios in 2019, but is considering alternative policies.)

***Improve valuation of physician services to set rates*.** $5 million in discretionary program management funds to be provided to develop independent assessments of service costs to improve accuracy of relative value units in the physician fee schedule.

Medicare Baseline Assumptions

The budget displays assumptions related to current law activities that are incorporated into Medicare baseline spending estimates. Some of those assumptions are displayed below, along with program enrollment assumptions.

Assumptions in the Medicare Baseline
(Outlays in millions of dollars)

	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	10 yrs
DME Competitive Bidding (net of premium)	-2,420	-2,400	-2,580	-2,810	-3,050	-3,290	-3,320	-3,360	-3,390	-3,420	-32,530
MACRA Advance APM 5% Bonus	481	971	1,317	1,592	1,903	2,245					8,509
Medicare Part A Enrollment	60,708	62,460	64,245	66,047	67,823	69,551	71,292	73,019	74,676	76,274	
MA enrollment	21,819	22,680	23,557	24,458	25,350	26,209	27,051	27,882	28,680	29,441	
MA enrollment as % of Part A	36%	36%	37%	37%	37%	38%	38%	38%	38%	39%	

Source: Excerpts from Table 23-4, Impact of Regulations, Expiring Authorizations, and Other Important Assumptions in the Baseline, *Analytical Perspectives for Fiscal Year 2019*, https://www.whitehouse.gov/omb/analytical-perspectives/

Medicaid and CHIP Proposals

The Administration's legislative proposals for Medicaid would shrink the program by a total that exceeds $1.4 trillion over 10 years. The savings would come predominantly from reforms modeled on legislation introduced in 2017 by Senators Graham, Cassidy, Heller, and Johnson that would repeal the ACA Medicaid expansion and establish per capita caps (or at state option for certain beneficiaries, block grants) for Medicaid spending. Those provisions described below are estimated to save a total of $1.39 trillion over the period.

In addition to the Medicaid changes incorporated in the Administration's proposal to repeal and replace the ACA, the budget includes a set of Medicaid proposals that together would reduce Medicaid spending by almost $50 billion if they were enacted independently of the ACA reforms. HHS notes, however, that the budgetary effect of the two sets of provisions cannot be added because there are interactions between the two sets of policies that have not been estimated.

MEDICAID PROPOSALS IN THE PRESIDENT'S BUDGET FOR FY 2019		
	Savings (-) /cost (+) in $ millions	
	FY19	**FY19-28**
Repeal and replace the ACA	-2,885	-1,389,235
Strengthen Medicaid operations and increase state flexibility		
Increase limits on Medicaid copayments for non-emergency use of emergency department	-60	-1,290
Allow states to apply asset test to MAGI populations	-50	-2,050
Pathway for permanent Medicaid managed care waivers	--	--
Increase duration of 1915(b) managed care waivers	--	--
Refocusing Medicaid Eligibility on the Most Needy		
Reduce maximum allowable home equity for Medicaid eligibility	--	--
Require documentation of satisfactory immigration status for eligibility	-170	-2,190
Count lottery winnings and other lump-sum payments for eligibility*	-3	-50
Other Medicaid Proposals		
Test allowing states to negotiate prices with drug manufacturers and set formulary for coverage	--	-85
Prohibit Medicaid payment to public providers in excess of cost	**	**
Continue Medicaid DSH allotment reductions	--	-19,470
Clarify definitions under drug rebate program	-26	-319
Require coverage of medication assisted treatment (MAT)	35	-865
Medicare-Medicaid Enrollee Proposals		
Coordinated Review of Dual Eligible Special Needs Plan Marketing Materials	--	--
Improve Appeals Notifications for Dually Eligible Individuals in Integrated Health Plans	--	--
Clarify the Part D Special Enrollment Period for Dually Eligible Beneficiaries	--	--
Medicaid impact of Multi-Agency Proposals (Other than ACA Repeal)		
Reform GME payments	-1,600	-21,200
Medical Liability Reform	-57	-57
Effect on Medicaid of changes to first generic exclusivity	**	**

MEDICAID PROPOSALS IN THE PRESIDENT'S BUDGET FOR FY 2019		
	Savings (-) /cost (+) in $ millions	
	FY19	FY19-28
Cut Fraud, Waste, Abuse and Improper payments	--	-8
Extend Special Immigrant Visa Program	7	128
Extend CHIP program through 2019*	-3,400	-7,000
Interactions	**--**	**4,856**
Subtotal Medicaid Legislative Proposals	**-8,209**	**-1,438,835**
Medicaid Administrative Proposals		
Require minimum standards in drug utilization review programs	-20	-245
Make Medicaid Non-emergency transportation optional	--	--
Improve data collection on Medicaid supplemental payments	--	--
Subtotal Medicaid Administrative Proposals	**-20**	**-245**
TOTAL, MEDICAID LEGISLATIVE AND ADMINISTRATIVE	**-8,229**	**-1,439,080**
*Under the Bipartisan Budget Act of 2018 CHIP has been extended through 2028.		
****** The *HHS Budget in Brief* states that the budget impact was unavailable at the time of publication.		

Medicaid Effects of ACA Repeal

Medicaid expenditures would be greatly affected by the budget's proposal to repeal and replace the ACA using the Graham-Cassidy-Heller-Johnson legislation as a model. Under that proposal, the ability of states to choose to cover childless adults with income below 138% of the federal poverty level would eliminated. In addition, federal funds for state Medicaid programs would be subject to a spending cap. Each state's spending cap would be based on per capita amounts multiplied by the number of people enrolled in the program for the relevant year. The per capita amounts would be calculated based on spending in a base year and would be permitted to grow for each year.

For FYs 2020-2024 the per capita amounts would increase by:

- The medical component of the Consumer Price Index (medical-CPI) for non-disabled children and non-elderly, non-disabled adults; and
- The medical-CPI plus 1 percentage point for the elderly and those who are blind or disabled excluding children.

For FY 2025 and thereafter, the growth of the per person caps would be limited to:

- The CPI-U for non-disabled children, and non-elderly, non-disabled adults; and
- The medical-CPI for the elderly and those who are blind or disabled excluding children.

In addition to the Medicaid changes incorporated in the Administration's proposal to repeal and replace the ACA, the budget includes a set of Medicaid proposals that together would reduce Medicaid spending by almost $50 billion if they were enacted independently of the ACA reforms. HHS notes, however, that the budgetary effect of the two sets of provisions cannot be added because there are interactions between the two sets of policies that have not been estimated.

Medicaid: Other Legislative Proposals

Increase limits on Medicaid copayments for non-emergency use of emergency department. Under current law, states are permitted to charge co-pays of up to $8 for emergency department use. In addition, a state can request a waiver of that copayment restriction to allow it to charge higher copayments for non-emergency use of the emergency department. Under the proposal, states would no longer need to apply and receive a waiver to charge higher copayment amounts for non-emergency use of the emergency department. Savings are estimated to be $1.29 billion over the 10-year period.

Allow states to apply asset test to MAGI populations. This proposal would reverse the ACA provisions that instituted a simple income test based on modified adjusted gross income (MAGI) without regard for assets for non-elderly, non-disabled eligibility groups. Under the proposal states would be provided with an option to re-institute an asset test in determining eligibility for those groups. It is estimated to save $2.1 billion over 10 years.

Increase duration of 1915(b) managed care waivers. The Secretary would be provided with the flexibility to determine the timeframe for renewal of managed care waivers authorized under section 1915(b) of the SSA. Under existing law, managed care waivers for dual-eligible individuals must be renewed every 5-years and those for other enrollees are renewed every 2 years. The budget assumes this proposal would have no budgetary impact.

Pathway for permanent Medicaid managed care waivers. States would be provided with the option to continue indefinitely managed care programs that are currently authorized under waivers and demonstration programs without the need to seek re-approval. The option would apply as long as the state makes no substantive changes to the program and that the waiver or demonstration has already been renewed at least one time. The budget assumes this proposal would have no budgetary effect.

Reduce maximum allowable home equity for Medicaid eligibility. Under existing law, states must apply an assets test to determine the eligibility of individuals in need of nursing home care or other long-term care services. States must count the value of equity in an individual's home and if it exceeds $500,000, or at state option $750,000, the person is not eligible for the program. The proposal would eliminate the option for a state to begin counting the equity of an applicant's home once it exceeds $750,000 in determining Medicaid eligibility for those in need of nursing home or other long-term care services. Under the proposal, all states would be required count equity interest above $500,000, which is the statutory minimum. The budget assumes this proposal would have no budgetary effect.

Require documentation of satisfactory immigration status for eligibility. Under current law, eligible individuals who declare to be U.S. citizens or nationals must be provided with a reasonable opportunity to present satisfactory documentation of citizenship or nationality and must be enrolled in coverage pending the reasonable opportunity to document that claim. The budget would prohibit Medicaid payments for services before such evidence is provided. Under the proposal, Medicaid spending is estimated to be reduced by $2.2 billion over 10 years.

Count lottery winnings and other lump-sum payments for eligibility. States would be required to count lottery winnings, inheritances, and other lump sum income received by an applicant when determining their eligibility for Medicaid. The lump sum income would be counted over a period of months rather than in the month it is received. The budget incorporates $50 million in savings over 10 years for this proposal. The same or a similar proposal was enacted in the Bipartisan Budget Act of 2018.

Demonstration to allow states to negotiate drug prices and change formularies. Under the proposed demonstration, up to 5 states would be allowed to be exempt from the Medicaid drug rebate program. They would have greater flexibility to negotiate their own prices and rebates and to establish formularies. States would be required to incorporate an appeals process to make non-covered drugs available based on medical need. The demonstration is estimated to save $85 million over 10 years.

Prohibit Medicaid payment to public providers in excess of cost. The Administration proposes to prohibit Medicaid reimbursement to providers that are "operated by a unit of government" to amounts that do not exceed the cost of providing services to Medicaid beneficiaries. It does not include an estimate of the savings attributable to this proposal.

Continue Medicaid DSH allotment reductions. Under existing law Medicaid disproportionate share (DSH) payments to hospitals are subject to a series of specified reductions for 2020 through 2025. The President's budget would extend those reductions through FY 2028. The proposal is estimated to save $19.47 billion over 10 years.

Clarify definitions under drug rebate program. HHS indicates that it would codify existing regulations clarifying the definitions of brand, over-the-counter, and drugs approved under a biologic license application. The codification of those regulations is estimated to save $319 million by ensuring proper Medicaid drug rebates.

Require coverage of medication assisted treatment (MAT). States would be required to provide coverage for all FDA-approved Medication Assisted Treatment for opioid use disorder. The MAT benefit would include associated counseling. It is estimated to reduce federal Medicaid costs as more individuals recover from opioid abuse by $865 million over 10 years.

Medicaid impact of Multi-Agency Proposals (Other than ACA Repeal)

Medicaid spending is expected to be affected by other proposals including those impacting graduate medical education (savings of $21.2 billion to Medicaid for the FY 2019 – 2028 period), medical liability reform (savings of $57 million to Medicaid for the period); changing generic exclusivity periods (not estimated), reducing Medicaid waste, fraud and abuse (savings of $8 million for the period), and extending the special immigrant visa program (increased cost of $128 million for the period).

The proposal to extend CHIP funding is also estimated to reduce Medicaid spending. The budget incorporates savings to Medicaid of $7.0 billion over the FY 2019 to 2028 period from

extending the CHIP program for FY 2019. The recently passed Bipartisan Budget Act of 2019, however, has already funded the CHIP program through 2028.

Medicaid: Administrative Proposals

Allow for joint review of dual eligible special needs plan marketing materials. Marketing materials prepared for Dual Eligible Special Needs Plans (SNPs) are required to undergo review both at the state level and at the federal level. The budget proposes to allow for joint review of the documents to lower administrative burden on participating plans. The proposal is not estimated to have a budgetary impact.

Improve appeals notification for dual-eligible individuals in integrated health plans. The proposal would streamline communications provided to dual-eligible enrollees of health plans related to appeals. HHS describes the proposal as reducing conflicting instructions because of different Medicare and Medicaid requirements. The proposal is not estimated to have a budgetary impact.

Clarify the Part D special enrollment period (SEP) for dual-eligible enrollees. Under existing law, a person who is dually eligible for Medicare and Medicare qualify for the dual-eligible SEP which enables them to change Medicare plans as often as once per month. The proposal would narrow the availability of the existing SEP for dual-eligible enrollees. Beginning for plan year 2019, the SEP would be available for individuals who are auto-assigned into a Part D plan to switch to an integrated Medicare/Medicaid plan or to change plans following auto-assignment. The proposal is not estimated to have a budgetary impact.

CHIP Proposals

The budget includes several other CHIP proposals in addition to extending the program for an additional year. It would:

- Eliminate the 23-percentage point increase in the federal match that was provided to states under the ACA;
- Cap eligibility for CHIP so that federal CHIP matching funds are not available for children in families with income that exceeds 250% of the federal poverty level;
- Eliminate the maintenance of effort requirement ensuring that through 2019, states keep Medicaid and CHIP eligibility levels at least as high as those in place when the ACA was enacted; and
- Allow states to move children ages 6 to 18 with incomes between 100% and 133% FPL from Medicaid to CHIP.

Repeal and Replace the Affordable Care Act

The budget proposes to repeal and replace the ACA with legislation "modeled closely" after the proposal offered by Senators Graham, Cassidy, Heller and Johnson.[3] The proposal would include repeal of the Medicaid expansion and enactment of a new Market-Based Health Care Grant Program under which states would develop health insurance options for their citizens. As noted above, this proposal would also implement federal limits on per capita Medicaid expenditures.

The net budget effects of the proposal total about $680 billion in federal savings over 10 years. Medicaid reductions of $1.389 trillion would be offset by $1.542 trillion in spending for the replacement program; another $460 billion in savings would come from other HHS programs and $373 billion from non-HHS program savings. The Medicaid savings would come from both eliminating the ACA expansion and instituting federal limits on per capita Medicaid spending.

In addition to the repeal/replace proposal, the budget would implement several changes related to the ACA Exchanges:

- The grace period for individuals to make premium payments for Exchange plans would be reduced from 90 days to 30 days.
- Federally-facilitated Exchange states would be permitted to certify Qualified Health Plans.
- Cost sharing subsidies would be funded through a mandatory appropriation for FY 2018 through December 31, 2019.
- The risk corridors program would be fully funded through a mandatory appropriation ($812 million), and the program would be exempted from sequestration.

For FY 2019, the Administration requests $135 million in budget authority for the Exchanges, $123 million of which would support activities involving eligibility, call center operations, and information technology. CMS anticipates collecting approximately $1.0 billion in user fee revenues to support Exchange activities. The $1.2 billion total would fund Exchange functions as "allow for the wind down of the federal Exchange, consistent with the repeal and replace proposal.

Combating Opioid Abuse

The 2019 budget once again identifies combating opioid abuse, misuse, and overdose as a national priority. Unlike last year's budget, however, the 2019 budget proposal incorporates significant expanded resources for activities to build on what HHS refers to as its 5-point strategy: improving access to prevention and treatment, increase the availability of overdose-reversing drugs, to increase and improve data collection and surveillance activities to better understand the impact of the crisis, to support research on pain and addiction, and to advance safe pain management.

Under the proposal, the Office of the Secretary would be provided with a total of $3 billion in additional funding for FY 2018 and $10 billion in additional discretionary funding for FY 2019.

[3] https://www.cassidy.senate.gov/imo/media/doc/LYN17752.pdf

Details are not provided for the 2018 funding. Of the $10 billion total for 2019, $2.96 billion would be allocated among agencies in the Department of HHS in amounts shown in the table below. HHS indicates that the remaining $7.04 billion would be available to the Secretary who would be provided with the discretion to transfer those funds among Department agencies to support additional work addressing the opioid crisis and serious mental illness. The proposal indicates that some of the non-allocated $7 billion would be used to establish a new grant program for certified Community Behavioral Health Clinics that provide services to individuals suffering from serious mental illness.

FY 2019 Funding for Opioid Crisis	
	($, billions)
Substance Abuse and Mental Health Services Administration (SAMSHA)	$1.200
HRSA	0.550
CDC	0.175
NIH	0.750
HIS	0.150
FDA	0.010
Office of the Secretary	0.125
Total Initial Allocation	$2.960
Non-Allocated funds for the Office of the Secretary	$7.040
Total Funding for Combating Opioid Abuse	$10.000

Activities that would be supported with FY 2019 allocated funds would include:

- Substance Abuse and Mental Health Services Administration (SAMSHA) would receive a total of $1.2 billion. That amount includes $1 billion for State Targeted Response (STR) grants to states and funds for reducing injecting drug use, providing naloxone to first responders, drug courts, and services for pregnant and post-partum women.
- The Health Resources and Services Administration (HRSA) would receive $550 million for activities that include addressing the abuse of opioids and other substances in high risk communities, health centers activities, and for making quality improvement payments.
- The Centers for Disease Control (CDC) would receive $175 million for its Prescription Drug Overdose Prevention program, and for expanding state surveillance capacity.
- The National Institutes for Health (NIH) would receive $750 million to support a public-private collaborative research initiative on opioid abuse and to advance research on opioid use, serious mental illness, and pain treatment.
- The Indian Health Service (IHS) would receive $150 million for grants for prevention, treatment, and recovery.
- The Food and Drug Administration (FDA) would be provided with $10 million to support health professionals in delivering medication-assisted treatment, and to accelerate the development abuse deterrent products.
- The Office of the Secretary would retain $125 million to support HHS-wide activities to launch a nationwide digital and mass media campaign, and to support an evaluation of Medication-Assisted Treatment and its impact on reducing overdose deaths.

The budget includes proposals within the Medicare and Medicaid programs addressing the opioid epidemic. In Medicare, coverage would be provided for comprehensive substance abuse treatment and Part D plans would be required to participate in prescription drug abuse prevention. Under Medicaid, Medication Assisted Therapy would become a mandatory benefit. Those provisions are described more in the Medicare and Medicaid sections of this document.

Medical Liability Reform

Consistent with its 2018 budget proposal, the Administration proposes a series of medical liability reforms estimated to save, over 10 years, a total of $52 billion to the federal government -- $31 billion of which would accrue to HHS programs, virtually all from Medicare. The Federal Employee Health Benefits Program would also experience lower costs as a result of the reforms in this proposal. A significant portion of the savings for the proposals is attributed to a reduction in unnecessary services that are provided because of the practice of defensive medicine. The following reforms are proposed:

- Cap awards for noneconomic damages at $250,000, indexed to inflation;
- Provide safe harbors for providers based on clinical standards;
- Authorize the Secretary to provide guidance to states to create expert panels and administrative health care tribunals;
- Allow evidence of a claimants' income from other sources such as workers compensation and auto insurance to be introduced at trial;
- Provide a three-year statute of limitations;
- Allow courts to modify attorney's fee arrangements;
- Establish a fair-share rule to replace the current rule of joint and several liability;
- Exclude provider expressions of regret or apology from evidence; and
- Require courts to honor a request by either party to pay damages in periodic payments for any award equaling or exceeding $50,000.

CMS Program Integrity

For FY 2019, the budget assumes $2.15 billion in total mandatory and discretionary investments in the Health Care Fraud and Abuse Control program within HHS and the Department of Justice. (Of the $2.15 billion, $1.38 billion is mandatory funding and $770 million is discretionary funding, which would be $45 million above the FY 2018 Continuing Resolution.) The President's budget proposes a series of Medicare and Medicaid program reforms estimated to save, over 10 years, a total of $915 million ($907 million from Medicare reforms and $8 million from Medicaid). The following reforms are proposed:

<u>Medicare Proposals</u>

- Suspend coverage and payment for questionable Part D prescriptions and incomplete clinical information, and requiring diagnosis and incident codes on certain prescriptions;
- Prevent abuse of Medicare coverage when another source has primary responsibility for prescription drug coverage by extending mandatory Medicare secondary payer requirements;

- Prevent fraud by enforcing reporting of enrollment changes through civil monetary penalties for providers and suppliers who fail to update enrollment records;
- Assess an administrative penalty on physicians and practitioners who order high-risk, high-cost items or supplies without proper documentation;
- Ensure providers that violate Medicare's safety requirements and have harmed patients cannot quickly re-enter the Medicare program;
- Require clearinghouses and billing agents acting on behalf of Medicare providers and suppliers to enroll in the program; and
- Expand prior authorization to additional Medicare fee-for-service items at high risk of fraud, waste, and abuse.

Medicaid Proposals

- Streamline the Medicaid provider terminations process;
- Expand Medicaid Fraud Control Unit review to non-institutional care settings such as in-home and community-based settings; and
- Implement prepayment controls to prevent inappropriate Personal Care Services payment

Medicare and Medicaid Proposals

- Allow revocation and denial of provider enrollment based on affiliation with a sanctioned entity;
- Alter the open payments reporting and publication cycle from June 30th to October 1st;
- Clarify authority for the Healthcare Fraud Prevention Partnership;
- Consolidate provider enrollment screening for Medicare, Medicaid, and CHIP; and
- Publish the National Provider Identifier for covered recipients in the Open Payments Programs website.

Discretionary Health Spending

Overall, the budget includes $95.4 billion in FY 2019 discretionary funding for HHS, $13.5 billion above the FY 2018 level. The budget addendum supplements the spending levels proposed in the FY 2019 budget and provides an additional $15.8 billion for HHS.[4] Proposed program level funding, which combines discretionary funding with mandatory funding and user fees, varies among HHS agencies ranging from a decrease of $1.0 billion for the CDC to an increase of $699 million for the NIH. In addition, the discretionary funding for HHS includes $10 billion for opioids and serious mental illness activities and $2.3 billion for the Public Health and Social Services Emergency Fund, an increase of $741 million.[5]

[4]The Bipartisan Budget Act of 2018 significantly raised the defense and non-defense discretionary spending caps in FY 2018 and FY 2019 after the FY 2019 budget had been finalized. OMB published a budget addendum to lay out additional funding for a limited set of priorities. See Office of Management and Budget. Addendum for the FY 2019 Budget. February 12, 2018. Downloaded from https://www.whitehouse.gov/wp-content/uploads/2018/02/Addendum-to-the-FY-2019-Budget.pdf

[5] The budget addendum provides an additional $75 million for increased public health preparedness.

Proposed HHS Health-Related Agency/Office Funding for FY 2019 (Program levels, in $ millions)		
HHS Agency/Office	**FY 2019**	**Change from 2018**
Agency for Healthcare Research and Quality (AHRQ)*	0	-422
Centers for Disease Control and Prevention (CDC)	10,921	-1,053
CMS Program Management**	5,729	-128
Food and Drug Administration (FDA)	5,799	+663
Health Resources and Services Administration (HRSA)	9,604	-953
Indian Health Service (IHS)	6,626	+263
National Institutes of Health (NIH)*	34,767	+699
Substance Abuse and Mental Health Services Administration (SAMHSA)	3,548	-688
Office of the National Coordinator for Health Information Technology	38	-22
Office of Medicare Hearings and Appeals (OMHA)	251	+144
Center for Medicare and Medicaid Innovation (CMMI) – obligations***	1,592	+314

*The 2019 budget includes $380 million in the NIH budget for the National Institute for Research on Safety and Quality that would incorporate proposed activities formerly carried out by the AHRQ.
**Some of the budget tables show the FY 2019 CMS program management levels decreasing by $12.5 billion from 2018. This figure reflects the budget's proposal to fully fund the Risk Corridors Program in FY 2018.
***CMMI reports obligations and outlays in lieu of program level funding.
Source: Department of Health and Human Services, *Fiscal Year 2019 Budget in Brief*

Centers for Disease Control and Prevention (CDC):

The proposed $10.9 billion FY 2019 budget for CDC is $1.0 billion below FY 2018 levels. Proposed funding for programs supported within the CDC's National Center for Immunization and Respiratory Diseases, such as the Vaccines for Children program, would decrease by $44 million to $701 million. Spending for domestic HIV/AIDS, viral hepatitis, sexually transmitted infections and tuberculosis prevention would increase by $8 million to $1.1 billion. The budget proposes $4.7 billion for vaccines for children (an increase of $326 million). Funding of $508 million would be a reduction of $60 million for Emerging and Zoonotic Infectious Disease activities. Funding of $333 million for the National Institute of Occupational Safety and Health and $55 million for the Energy Employee Occupational Illness Compensation Program would be eliminated and the funding and activities would shift from the CDC to NIH. Spending for chronic disease prevention and health promotion activities would decline $138 million to $939 million. Likewise, funding for Public Health Preparedness and Response is proposed for $800 million, a decline of almost $600 million from 2018. This is due to the proposed transfer of the Strategic National Stockpile from CDC to the Public Health and Social Services Emergency Fund. Other CDC activities with proposed decreases include birth defects and development disabilities (-$27 million), global health (-$23 million), public health preparedness and response (-$23 million), environmental health (-$21 million), and injury prevention and control (-$18 million).

The budget addendum provides an additional $309 million to CDC-wide Activities and Program Support account for infectious diseases and other priority public health activities.

CMS Program Management: CMS program management funding is proposed at $5.7 billion for FY 2019, a decrease of $128 million. Most of the decrease cited in the proposed FY 2019 budget is related to changes in program operations ($404 million). The budget includes $135.2 million to support Exchange operations, in addition to an anticipated $1.0 billion collected by CMS in user fee revenues to support the Federal Exchanges. New user fees are proposed for survey and certification revisits that occur as a result of deficiencies found during initial certification, recertification, or substantiated complaints survey. Surveys include mandated federal inspections of long-term care facilities, home health agencies, hospices, and other facilities. CMS expects to collect $14.1 million in user fees for this purpose (assumes a six-month lag for collecting fees). Funding of $18 million (a decrease of $2 million) is requested for research to maintain the Medicare Current Beneficiary Survey (MCBS) and other research databases to support Medicare rate-setting. With respect to 2019 legislative proposals, CMS is proposing to increase the user fees from Medicare Advantage Part D plans to support the National Medicare & You program ($30 million in additional collections in FY 2019).

The budget addendum, which supplements the proposed spending levels included in the FY 2019 budget, provides an additional $200 million to the program management account.

Food and Drug Administration (FDA)**:** The proposed $5.8 billion in FY 2019 funding for FDA includes a $663 million increase in agency spending above FY 2018 levels. Most of the increase is related to the proposed increase in budget authority of $473 million; user fees provide an increase of $190 million. The budget proposes an additional opioid allocation of $10 million as part of the $10 billion proposal to combat the opioid epidemic and address serious mental illness. Medical product safety investments would increase $572 million to $3.6 billion in FY 2019 ($1.8 billion in budget authority and $1.8 billion in user fees). Food safety activities would be increased by $10 million to $1.4 billion. Increases are planned for all current user fee programs including the human and generic drug, medical device, and biosimilars user fee programs. The largest increases are expected from the tobacco program ($81 million) and prescription drug ($49 million) user fees. The budget assumes resources from reauthorizing the animal drugs and animal generic user fee programs set to expire at the end of FY 2018 and proposes a new user fee to support over-the-counter monograph review activities. The budget also includes a legislative proposal to increase the availability of generic drugs by allowing the FDA to tentatively approve a subsequent generic drug application that is blocked by the first generic applicant's 180-day exclusivity. As noted above, this proposal is estimated reduce Medicare spending by $1.8 billion over 10 years.

The budget addendum provides an additional $500 million to the FDA's Food and Drug Administration's Salaries and Expenses account to strengthen medical product safety, development, and access.

Health Resources and Services Administration (HRSA)**:** The proposed $9.6 billion in the FY 2019 budget for HRSA is $953 million below FY 2018 levels. The largest budget reduction would be for health workforce activities, including nursing workforce development (a decrease of $145 million) and Children's Hospital Graduate Medical Education (a decrease of $298 million). The budget notes that as part of a larger Graduate Medical Education reform, funding for children's hospital GME in FY 2019 would be provided through mandatory resources in a

new consolidated GME program. Of note, the FY 2019 budget proposes to shift mandatory funding for the following programs to discretionary funding: Health Centers, National Health Service Corps, Teaching Health Center Graduate Medical Education, Home Visiting, and Family-to-Family Health Information Centers.

The FY 2019 budget provides $5.1 billion (increase of $10 million) in discretionary funding for health centers. The Ryan White HIV/AIDS program would be funded at $2.3 billion ($43 million below FY 2018), including $900 million for the AIDS Drug Assistance Program ($6 million increase from FY 2018). Proposed cuts would reduce the budget for the rural health activities to $75 million (reduction of $80 million) through elimination of funding for the Hospital Flexibility Grants and State Offices of Rural Health. The budget would provide $26 million to the 340B Drug Pricing Program for FY 2018—$10 million of discretionary budget authority and $16 million from a new user free on drug purchases by entities covered by the 340B program (about 12,500).

Indian Health Service (IHS): The FY 2019 budget request for the IHS of $6.6 billion represents an increase of $263 million above FY 2018, of which $3.7 billion goes to Clinical Services. This primarily funds direct health care services the IHS provides through its network of 608 hospitals, clinics, and health stations across the nation. As part of the Clinical Service program, funding to support care referral for services unavailable at IHS facilities (purchased care) would increase by $32 million to $955 million. The budget also includes an additional $159 million—allocated across several funding lines with the IHS budget— to support staffing and operating costs for six new or replacement health facilities to be completed in 2018 and 2019.

The budget addendum provides an additional $200 million to the IHS— $100 million to IHS services, $75 million to facilities, and $25 million to contract support costs. Combined with the addendum, funding for IHS facilities is $581 million ($39 million above FY 2018), and contract support costs is $847 million ($47 million above FY 2018). Several other health activities would receive modest increases (behavioral health issues including substance abuse and suicide prevention, preventive health services, and diabetes programs).

National Institutes of Health (NIH)**:** The FY 2019 budget proposes NIH program level funding of $34.8 billion, an increase of $699 million from FY 2018. The budget proposes an additional opioid allocation of $750 million as part of the $10 billion proposal to combat the opioid epidemic and address serious mental illness. Increases are proposed for the National Institute of Neurological Disorders and Stroke ($67 million), National Institute on Drug Abuse ($54 million) and National Institute of Mental Health ($21 million). All other existing institutes would experience a reduction in budgetary resources with the National Institute of Allergy and Infectious Diseases; National Heart, Lung and Blood Institute; and National Institute of General Medical Services experiencing the largest decreases, $111 million, $73 million and $60 million, respectively. The FY 2019 budget would also consolidate the AHRQ within NIH as the National Institute for Research on Safety and Quality and provide the new agency with $380 million in funding to support activities previously in AHRQ and other "select research activities." The budget proposes the establishment of two additional NIH Institutes: the National Institute for Occupational Safety and Health and the National Institute on Disability, independent Living and Rehabilitation Research. The budget also includes a proposal to cap the percentage of

investigator salaries that can be paid with grant funds to 90 percent of the total salary and reduces the limit for salaries paid with grant funds from $187,000 to $152,000.

The budget addendum provides an additional $9.2 billion to the Office of the Director with transfer authority for the NIH Director to allocate these resources across NIH Institutes and Centers.

Substance Abuse and Mental Health Services Administration (SAMHSA): Proposed program level funding of $3.5 billion is sought for FY 2019 for SAMHSA, a decrease of $688 million. The budget would provide $2.1 billion – a decrease of $581 million from FY 2018 – for substance abuse treatment activities. The budget discontinues funding for Minority Fellowship Programs, and funding for Screening, Brief Intervention, and Referral to Treatment Program. The remainder of the decrease is the elimination of the Opioid Crisis Grants from this budget category. In a separate budget category, Opioids Allocation, the budget provided $1.2 billion to SAMHSA (from the $10 billion allocated to HHS) for purposes of fighting the opioid crisis.

The budget proposes a slight reduction in substance abuse prevention efforts by $1 million to $221 million in FY 2019. Within this amount, the budget includes $100 million for the Drug Free Communities. The budget proposes funding of $563 million for the Community Mental Health Services Block Grant, $4 million above FY 2018. Funding for states is intended to prioritize activities that insurance does not cover such as physician training and anti-fraud efforts. The budget proposes to maintain the Children's Mental Health Services Program at almost the same level ($1 million increase) as FY 2018 which would also include a set-aside of 10 percent of funds for a new demonstration that translates recent research from the National Institute of Mental Health. It also proposes to eliminate the $52 million in funding for the Primary and Behavioral Healthcare Integration program.

Office of the National Coordinator for Health Information Technology (ONC): The FY 2019 budget proposes ONC funding of $38 million, down $22 million from FY 2018. The ONC's budget focuses on the interoperability of health information and the usability of electronic health records. As directed by the 21st Century Cures Act, the FY 2019 budget will support a single Health IT Advisory Committee. In addition, ONC will focus on the implementation of the Trusted Exchange Framework and a Common Agreement (TEFCA), conditions of certification, its standard development work, and the standardization, implementation, and use of open application programming interfaces. In addition, the ONC will support the ongoing maintenance of standards conforming test tools, ONC Health IT Certification Program administration and oversight, and the ongoing support of the Certified Health IT Product List, among other priorities.

Center for Medicare & Medicaid Innovation (CMMI): The ACA appropriated $10 billion to support the creation and implementation of CMMI through FY 2019. FY 2019 obligations are estimated at $1.6 billion, an increase of $314 million. The budget does not provide detail on any proposed new CMMI initiatives for FY 2019. Estimated effects of current CMMI initiatives are presented, some of which are shown in the following table:

Approved and Implemented Demonstrations and Pilot Programs in Medicare Baseline (Outlays in millions of dollars)						
	2018	**2019**	**2020**	**2021**	**2022**	**2023**
Comprehensive ESRD Care						
Baseline	4,226	4,352	4,482	1,129		
Demonstration	4,150	4,233	4,333	1,090		
Oncology Care Model						
Baseline	6,071	6,107	5,851	1,496	---	
Demonstration	5,775	5,937	5,705	1,642	129	
Comprehensive Care for Joint Replacement						
Baseline	1,850	1,830	1,980	500		
Demonstration	1,820	1,800	1,910	420		
Medicare ACO Track 1+ Model						
Baseline	11,900	27,500	36,650	26,630	11,280	1,870
Demonstration	11,870	27,410	36,460	26,470	11,200	1,860
ACO Investment Model						
Baseline	5,620	5,870	1,480			
Demonstration	5,590	5,830	1,470			
MA Value Based Insurance Design						
Baseline	9,669	13,922	15,307	16,099	4,073	
Demonstration	9,639	13,861	15,209	15,952	4,033	
Home Health Value-Based Purchasing						
Baseline	1,821	1,821	1,821	607		
Demonstration	1,710	1,693	1,693	564		
Source: Excerpts from Table 23-4, Impact of Regulations, Expiring Authorizations, and Other Important Assumptions in the Baseline, *Analytical Perspectives for Fiscal Year 2019*, https://www.whitehouse.gov/omb/analytical-perspectives/						