Wynne Health Group

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THE PRESIDENT'S FY 2019 BUDGET REQUEST: AN EXAMINATION OF KEY HEALTHCARE PROVISIONS

I. INTRODUCTION

The White House released a $4.4 trillion Fiscal Year (FY) 2019 Budget Request[1], titled "An American Budget." Accompanying the President's Budget Request is an addendum[2] accounting for the recently-enacted two-year agreement to raise the budget caps, along with a volume[3] delineating major savings and reforms. The budget blueprint is expected to add more than $7 trillion to the deficit over the next decade.[4]

With respect to the Department of Health and Human Services (HHS), the Budget includes $68.4 billion for HHS – a roughly 21 percent ($17.9 billion) decrease over the 2017 enacted level. This includes a repeat proposal to dismantle the Affordable Care Act (ACA) – via enactment of legislation modeled on the Graham-Cassidy-Heller-Johnson (GCHJ) bill[5], followed by "additional reforms," including overhauling Medicaid by block-granting Medicaid funding, akin to the GCHJ bill, and pursuing other reforms already underway such as work requirements.

The corresponding HHS FY 2019 Budget in Brief (BIB)[6] provides more detail on the administration's key legislative and administrative proposals. Of note, the Budget Request proposes to reorganize HHS by streamlining the National Institutes of Health (NIH's) administrative functions, improving the management of the Strategic National Stockpile, and implement other efficiencies.

Highlighted below is a comprehensive – though not exhaustive – summary of the key HHS proposals, by agency, encompassed in the White House Budget Request. Unless otherwise noted, the corresponding budget impact (cost/savings) is over a 10-year period.

II. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The Budget Request proposes $632b/10y in mandatory savings derived from CMS programs. Key provisions are delineated below.

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[1] https://www.whitehouse.gov/wp-content/uploads/2018/02/budget-fy2019.pdf (see also fact sheet: https://www.whitehouse.gov/briefings-statements/building-stronger-america-president-donald-j-trumps-american-infrastructure-initiative/)
[2] https://www.whitehouse.gov/wp-content/uploads/2018/02/Addendum-to-the-FY-2019-Budget.pdf
[3] https://www.whitehouse.gov/wp-content/uploads/2018/02/msar-fy2019.pdf
[4] https://www.nytimes.com/2018/02/12/us/politics/white-house-budget-congress.html
[5] https://mypolicyhub.com/content_entry/graham-and-cassidy-announce-no-vote-will-be-held-on-repeal-this-week-mcconnell-indicates-taxes-are-the-next-twin-priority/
[6] https://www.hhs.gov/sites/default/files/fy-2019-budget-in-brief.pdf

A. BROADER HEALTHCARE REFORMS

- **ACA Repeal and Replace through Graham-Cassidy-Type Approach –** The Budget Request supports "a two-part approach to repealing and replacing Obamacare, starting with enactment of legislation modeled closely after the Graham-Cassidy-Heller-Johnson bill as soon as possible, followed by enactment of additional reforms to help set Government healthcare spending on a sustainable fiscal path that leads to higher value spending."

  Elaborating on such an approach, the Budget Request discusses a block-grant approach, called the Market-Based Health Care Grant Program, that "reflects the Administration's view that Government subsidies are better targeted to States and consumers rather than funneled through insurance companies." This would enable states to "use the block grant for a variety of approaches in order to help their citizens, including those with high cost medical needs, afford quality healthcare services," the blueprint elaborates.

- **Insurance Market Reforms –** The Budget Request includes proposals related to relief of insurance market rules that will provide for more options in the individual market, including those that would: (1) reduce the grace period for individuals on Exchange plans to pay premiums (from 90 Days to 30 Days) (-$1.3b to Treasury; no HHS budget impact); (2) permit Federally-Facilitated Exchange (FFE) states to conduct Qualified Health Plan (QHP) certification (no budget impact); and (3) provides mandatory appropriations for Cost-Sharing Reduction (CSR) payments (FYs 2018-2019) (no budget impact) and to fully fund the risk corridors program – including exempting the latter program from sequestration (+$812m in FY18). The Budget Request also prohibits governmental discrimination against health care providers that refuse to cover abortion (no budget impact).

- **Graduate Medical Education (GME) Reform –** Effective FY 2019, the Budget Request aims to consolidate federal GME spending from Medicare, Medicaid and the Children's Hospitals Graduate Medical Education program (CHGME) into a single grant program for teaching hospitals that would be jointly-administered by CMS and HRSA. HHS is authorized to "modify the amounts distributed based on the proportion of residents training in priority specialties or programs (e.g., primary care, geriatrics) and based on other criteria identified by the Secretary, including addressing health care professional shortages and educational priorities" (-$48.1b).

- **Opioid Epidemic –** The Budget Request proposes $10 billion to combat the opioid epidemic. The proposed funding would be used to prevent opioid abuse and provide access to overdose reversal drugs, treatment, and recovery support services for addicted individuals.

  Specifically, it proposes a national media campaign, efforts to encourage safer prescribing practices to reduce unnecessary prescriptions, and to help states strengthen their Prescription Drug Monitoring Programs. The Budget includes recommendations specific to Medicaid as well as Medicare. For Medicaid, it proposes expanding coverage of Medication Assisted Treatment (MAT) options, requires states to track and act on high prescribers and utilizers, and previews CMS guidance that is anticipated to be released soon. Aspects of these provisions are addressed below.

  For Medicare, the Budget Request proposes to test and expand a nationwide bundled payment for community-based MAT, including Medicare reimbursement for methadone treatment for the first time. With respect to Medicare Part D, the Budget Request aims to prevent prescription drug abuse

and to require plans to participate in a program intended to realize this. Lastly, the Budget Request proposes to authorize the Secretary to work with the Drug Enforcement Administration (DEA) to "revoke a provider's certificate when that provider is barred from billing Medicaid based on a pattern of abusive prescribing."

- **Various Medical Liability Reforms** (-$30.8b to HHS programs; -$52.1b to government-wide net deficit reduction); and

- **Program Integrity –** Broader program integrity-related proposals are delineated on pp. 73-76 of the BIB. The latter includes proposals focused on opioids as well as tracking high prescribers and utilizers of prescription drugs in Medicaid.

B. MEDICARE

The Budget Request delineates $494b/10y in Medicare savings, including:

- **Part D Proposals –** A number of policies aimed at modernizing the Part D benefit and enhancing program management, namely: (1) requiring plans to share at the point of sale a portion of rebates that plans receive from drug manufacturers (+$42.2b); (2) establishing a beneficiary out-of-pocket (OOP) maximum in the Medicare Part D catastrophic phase (+$7.4b); (3) excluding manufacturer discounts from the calculation of beneficiary OOP costs in the Medicare Part D coverage gap (-$47b); (4) increasing Medicare Part D plan formulary flexibility (-$5.5b); and (6) eliminating cost-sharing on generic drugs for beneficiaries who receive the low-income subsidy (-$210m).

- **Other Drug Pricing and Payment Reforms –** Policies that would: (1) permanently authorize a pilot on retroactive Medicare Part D coverage for low-income beneficiaries (-$300m); (2) improve manufacturers' reporting of average sales prices (ASPs) to set accurate payment rates (no budget impact); (3) address abusive drug pricing by manufacturers by establishing an inflation limit for reimbursement of Part B drugs (budget impact not available); (4) authorize the HHS Secretary to leverage Medicare Part D plans' negotiating power for certain drugs covered under Part B (budget impact not available); and (5) reduce Wholesale Acquisition Cost (WAC) based payments (budget impact not available). The Budget Request also delineates **340B program** and **opioid focused reforms**, detailed more fully below.

- **340B Program –** The Budget Request notes that it would modify "hospitals' payment for drugs acquired through the 340B drug discount program by rewarding hospitals that provide charity care and reducing payments to hospitals that provide little to no charity care." Further details of this policy are enumerated at pp. 62-63 of the BIB. Specifically, the Budget Request proposes that effective for CY 2019, the savings from hospitals that provide uncompensated care (UC) equaling at least one percent of their patient costs are redistributed based on their share of aggregate UC (budget impact not available).

- **Delivery and Payment System Reforms –** Beginning on p. 64 of the BIB, the Budget Request delineates numerous policies that would:

- Give Medicare Beneficiaries with high deductible plans the option to make tax deductible contributions to Health Savings Accounts (HSAs) or Medical Savings Accounts (MSAs) (+$180m);
- Modify Medicare hospital uncompensated care payments – removing uncompensated care payments from the Inpatient Prospective Payment System (IPPS) and establishing a new process to distribute such payments to hospitals based on the share of charity care and non-Medicare bad debt (per the S-10) (-$138.4b in Medicare savings; -69.5b net savings to the federal government);
- Establish a **unified post-acute care (PAC) payment system** based on patients' clinical needs rather than site of care (-$80.2b);
- Reduce Medicare coverage of bad debts (-$37b);
- Re: the "site-neutral" policy, effective for CY 19, eliminate the current exemption for certain grandfathered off-campus hospital outpatient departments (OPDs) that were billing or under construction as of Nov. 2, 2015 (as well as EDs and cancer hospitals), such that all hospital-owned, off-campus physician offices would be paid at the physician office rate (-$34.b)
- Implement reforms and expand the durable medical equipment (DME) competitive bidding program (CBP), including via an expansion of CBP to all areas of the country, including rural areas (-$6.5b);
- Establish a hospital transfer policy such that payments are reduced when a patient is quickly discharged to a hospice (note: similar provision included in latest CR) (-$1.3b);
- Address various Accountable Care Organization (ACO) reforms (totaling roughly -$200m);
- Address telehealth provisions that would expand the ability of Medicare Advantage (MA) organizations to pay for services delivered via telehealth (note: related provision included in latest CR) (no budget impact);
- Effectuate changes to Medicare physician self-referral law to align with Alternative Payment Models (APMs) (budget impact not available); and
- Require prior authorization when physicians order certain services excessively to their peers (budget impact not available).

- **Other Provider-focused Reforms –** Beginning on p. 66 of the BIB, the Budget Request delineates numerous proposals that would:

  - Repeal the Independent Payment Advisory Board (note: provision included in latest CR) (+$29.5b);
  - Eliminate certain reporting burdens and requirements associated with electronic health records (EHRs) and 'meaningful use' (no budget impact);
  - Eliminate the requirement of a face-to-face provider visit for DME (no budget impact);
  - Refine the Merit-based Incentive Payment System (MIPS) to simplify and eliminate reporting burdens, allowing the HHS Secretary the authority to set the MIPS performance threshold during the 2019-2020 transition years (no budget impact); and
  - Encourage participation in APMs (budget impact not available).

- **Medicare Appeals –** The BIB provides an overview of various proposals to reform the Medicare appeals process on pp. 67-68.

- **Other Administrative Proposals –** In addition to the above legislative proposals, the BIB highlights various administrative efforts that include proposals to:

    - Implement a new patient case-mix classification methodology for home health (-$16.7b);
    - Eliminate excessive MA payments by using claims data from patient encounters (-$11.1b) as well as make reforms to MA employer group waiver plans (-$10.7b); and
    - Initiate efforts to improve the accuracy of payments to physicians and other health care professionals (no budget impact).
    - Other administrative proposals include: (1) addressing excessive billing for Medicare DME equipment that requires refills or serial claims (budget impact not available); (2) addressing overutilization and billing of Medicare DME by expanding prior authorization; and (3) establishing a unique identifier for Medicaid personal care service attendants (no budget impact available).

C. MEDICAID

The Budget Request proposes several significant reforms to the Medicaid program that would provide states with additional flexibility as well as target Medicaid to "the populations Medicaid was intended to serve – the elderly, people with disabilities, children, and pregnant women." Total savings amount to roughly $1.4 trillion over the decade, the bulk of which is derived from Medicaid reforms pursuant to the administration's presumed enactment of ACA repeal/replace legislation.

- **Medicaid Block Grants, Work Requirements Modeled on Graham-Cassidy –** The Budget Request includes a focus on Medicaid changes similar to those included in the Graham-Cassidy-Heller-Johnson amendment that failed to advance in Congress last year. Such an approach, which would require legislation, would be based on block grants to states that would grow at CPI-U, the Administration says, and states would be able to share in savings with the federal government. The Administration notes that provider taxes and other "state gimmicks" that raise federal costs would be reduced under the approach. The Administration adds that "Medicaid financing reform would empower States to design individual, State-based solutions that prioritize Medicaid dollars for the most vulnerable and support innovations such as community engagement initiatives for able-bodied adults."

- **More on "State Flexibility" –** The Budget delineates proposals to provide more flexibility to states, including those that would:

    - Increase the limit on Medicaid co-pays for non-emergency use of the ED ($-1.3b);
    - Allow states to apply asset tests to modified adjusted gross income (MAGI) standard populations (-$2.1b);
    - Provide a pathway for permanent established Medicaid managed care waivers (no budget impact); and
    - Increase flexibility in the duration of section 1915(b) managed care waivers (no budget impact).

- **Drug Payment Policies –** Among the various Medicaid drug payment proposals is the call for a "new demonstration authority for up to five states" to "determine their own drug formularies, coupled with an appeals process to protect beneficiary access to noncovered drugs based on medical need, and negotiate drug prices directly with manufacturers." Another proposal requires Medicaid coverage of all FDA-approved medication-assisted treatments (MAT) for opioid use disorder (-$865m). Finally, a handful of Medicaid administrative proposals are also listed, including one requiring minimum standards in Medicaid State Drug Utilization Review Programs (-$245m).

- **Medicaid Disproportionate Share Hospital (DSH) Payments –** The Budget Request proposes to continue Medicaid DSH allotment reductions at $8b/yr from FY 26-28 (-$19.5b).

- **Program Integrity –** With the intention of improving fiscal integrity and transparency in Medicaid payment policy, the Budget proposes to limit reimbursement to government providers to no more than the cost of providing services to Medicaid beneficiaries. As outlined in the proposal, the White House indicates that current law allows states to make Medicaid payments "far in excess of actual service costs." By adding additional limits to Medicaid reimbursement rates, the Budget proposes to address this "misuse of funds." Additionally, the Budget proposes legislative and administrative actions to give CMS additional tools to combat fraud and abuse as well as to promote high-quality and efficient healthcare. Forthcoming CMS guidance is mentioned but additional details are not included at this time.

- **Other Proposals –** Various legislative proposals pertaining to **dual-eligibles** are enumerated on p. 84, as well as additional Medicaid administrative proposals, including making Medicaid non-emergency medical transportation optional (no budget impact); and improving data collection on Medicaid supplemental payments (no budget impact).

Finally, a legislative proposal to **extend the Children's Health Insurance Program (CHIP)** through 2019 with reforms is delineated on p. 89 of the BIB, though does not appear to account for the latest additional extension under the most recent CR. Other provisions pertaining to state grants and demonstrations are listed on pp. 91-92 of the BIB.

III. FOOD AND DRUG ADMINISTRATION (FDA)

The Budget Requests roughly $5.8 billion in total funding for FDA programs – roughly $663 million more than the FY 2018 CR. Significant investments in opioid funding are detailed in this section. Key proposals include:

- Investment to counter the **opioid epidemic** and address Serious Mental Illness (SMI) (+$10b);
- Medical **product safety** investments ($3.6b, $572m more than FY 2018);
- New Oncology Center of Excellence (+$20m);
- FDA infrastructure and facilities ($435m, +$35m more than FY 2018);
- Medical countermeasures program ($24.5m);
- Expanded **user fees** (+$142m); and
- User fees to support the FDA tobacco program ($712m).

With respect to **generic approval reform**, the Budget Request proposes to allow FDA to approve a subsequent generic filer when a first-to-file applicant has "parked" their application by failing to fix a defect in their application. This would trigger a 180-day exclusivity period for a first-to-file generic applicant and could allow generic products to reach the market sooner (-$1.8b).

IV. NATIONAL INSTITUTES OF HEALTH (NIH)

The Budget Requests $35.5 billion in total funding for the NIH – an estimated $1.4 billion more than in FY 2018. Key proposals include:

- **Tackling Complex Challenges by Leveraging Partnerships –** NIH is engaged in multiple public-private partnerships addressing the opioid crisis, cancer biomarkers, and more. The Budget Request proposes to continue to invest in public-private partnerships to address public health priorities.

- **Accelerating Medicines Partnerships –** The Budget Request proposes to continue to partnership between NIH, the FDA, and ten biopharmaceutical companies, and non-profits to increase the number of new diagnostics and therapies for patients. The data and analysis from the partnership is available publicly for the broad biomedical community to use.

- **Future Partnerships: Combatting the Opioid Epidemic through Public-Private Partnership** (+$500m) – Funding is intended to leverage public-private partnership to accelerate the development of safe, non-addictive, and effective strategies to prevent and treat pain, opioid misuse, and overdose as well as to optimize implementation. Of the initial $10 billion allocation, $400 million is intended to address the opioid crisis and support persons with SMI.

  NIH intends to pursue a two-pronged strategy: (1) develop new formulations and combinations of medications to treat opioid misuse, and prevent and reverse overdose; and (2) accelerate development of new non-addictive pain therapies. An additional $350 million of the total $10 billion investment is designated for NIH research pertaining to opioids, SMI, and pain. A further $5 million is included to support new evidence dissemination contracts on opioid abuse prevention and treatment in primary care, also as part of the broader $10 billion investment;

- **Supporting Basic Research to Drive New Understanding of Health and Disease in Living Systems;**

- **Investing in Translational and Clinical Research to Improve Health;**

- **Next Generation Researchers Initiative** (can draw from a $100 million fund allocated for this and other initiatives);

- **Innovation through Competition** ($50m);

- **Building Upon the Big Data Knowledge Initiative (BD2K)** ($30m);

- **New Caps on Researcher Salaries** – The cap on the grant funds that can be utilized for investigator salaries will be reduced from $187k to $152k and cannot exceed 90 percent of the salary;

- **Energy Employees Occupational Illness Compensation Program Act** ($55m); and

- **Disability, Independent Living, and Rehabilitation Research** ($95m)

V. OTHER AGENCY PROPOSALS

For the **Substance Abuse and Mental Health Services Administration (SAMHSA),** the Budget Request provides $3.5 billion, marking a reduction of $688 million compared with the FY 2018 CR level. The Administration notes that is providing $1.2 billion to SAMHSA for a range of opioid-related initiatives. When those resources are considered, the agency's overall budget rises to $4.8 billion or $522 million above the FY 2018 CR level.

Of SAMHSA's $1.2 billion for **opioid**s, the Budget provides:

- $1 billion for expanded State Targeted Response Grants;
- $123 million for existing activities;
- An ongoing $56 million for MAT, $20 million for Comprehensive Addiction and Recovery Act (CARA)-authorized programs, and $10 million for opioid prevention strategies for states; and
- $9 million for safe and effective operation of opioid treatment programs.

SAMHSA also would receive $1.9 billion for Substance Abuse Prevention and Treatment Block Grants, and $889 million for SMI efforts, including $15 million for the Cures-authorized Assertive Community Treatment for Individuals with Serious Mental Illness program. The Children's Mental Health Services program continues at $119 million. The Budget "does not include funding for the Primary and Behavioral Healthcare Integration program" (-$52 million).

The **Health Resources and Services Administration (HRSA)** would receive $9.6 billion under the Budget Request. This is $953 million beneath the FY 2018 CR level. HRSA would receive $550 million for addressing opioid abuse. The Teaching Health Center GME program would receive $60 million in discretionary funding. The Budget provides $400 million in FY 2019 for home visiting. The Budget provides $26 million for the **340B Drug Discount Program**, including $10 million in discretionary budget authority and $16 million from "a new user fee on drug purchases by covered entities."

The **Centers for Disease Control and Prevention (CDC)** and Agency for Toxic Substances and Disease Registry would see a FY 2019 funding level of $10.9 billion, marking a $1 billion cut. The Budget Request includes $180 million for flu-related activities, $9 million over the FY 2018 CR level, and $4.7 billion in mandatory funds for the Vaccines for Children program. Additionally, the CDC would receive $126 million for the **opioid epidemic**, a $1 million increase over the FY 2018 CR level, as well as an initial allocation of $175 million of the HHS-wide opioid funding for overdose prevention, **Prescription Drug Monitoring Programs**, and other activities.

Finally, other key proposals potentially impacting healthcare stakeholders – including rural broadband funding (e.g., for **telehealth**) – are delineated within other Department portions of the budget. On the latter, for example, the US Department of Agriculture (USDA) includes $30 million in broadband grants; $23 million in loans to create a private-public partnership to expand high speed e-connectivity to rural

Americans; and $24 million for distance learning and telemedicine loans (see p. 41 of the Department's budget).[7]

CONCLUSION

We hope this is a helpful overview of the Trump Administration's FY 2019 Budget Request. We are happy to provide further details on any of the above policies and answer any questions you may have.

[7] https://www.obpa.usda.gov/budsum/fy19budsum.pdf