FY 23 Biden budget with healthcare policies is here. A reminder that the President's budget is an opening salvo, frequently aspirational and almost never enacted as proposed. However, specific policies tend to make it across the finish line in various other bills, regulations.

- **There is no explicit discussion of drug price reforms, but the budget does allow for a BBB fund.** A deficit neutral reserve fund means that Congress will determine the components here, without prescriptive language from the administration.

- **Cancer Moonshot gets $20 M**. There would be a one-time funding for the FDA to strengthen current Moonshot programs, which aims to cut cancer deaths by 50% (in 25 years) CDC will also see a $72 M increase to enhance a range of cancer programs. CDC funding will be aimed towards cancer prevention-related programs, including National Breast and Cervical Cancer Early Detection Program, Colorectal Cancer Control Program, National Program of Cancer Registries, and the National Comprehensive Cancer Control Program.

- **Science commitments and funding galore (ARPA-H, NIH) $4 B increases to ARPA-H funding.** $5 B is provided for ARPA-H, $4.0 B than FY 2022 enacted. The budget provides $49.0 B in discretionary funding for the NIH, which is $4.3 B more than FY 2022 enacted.

- **340 B drug pricing program would be improved but not drastically modified, despite complaints by pharmaceutical companies and hospitals alike.** The 340B drug pricing program is a component of the health care safety net, requiring drug manufacturers to provide discounts on outpatient prescription drugs to certain health care providers that serve vulnerable and underserved patient populations. The budget provides $17 M to improve operations and oversight of the 340B Program, an increase of $6 M over FY 2022 enacted. The budget also improves program integrity by providing additional regulatory authority to support program implementation and oversight.

- **Vaccines would all be shifted to Medicare Part B.** The budget also includes a proposal to consolidate vaccine coverage under Medicare Part B. [$3.6 B in costs over 10 years]

- **Mental health funding would be funded significantly: $20.8 B for FY23.** $7.5 B Mental Health System Transformation Fund would invest in workforce development and service expansion including the development of nontraditional health delivery sites**.** The budget also provides $413 M to Community Mental Health Centers in FY 2023, with an expected $4.1 B over ten years.
  - Opioid addiction is also funded with $11.4 B being dedicated to programs addressing opioids and overdose-related activities across HHS.
  - States and territories would participate in the existing Certified Community Behavioral Health Clinics (CCBHCs) demonstration program and would convert existing and any new demonstration programs to a more sustainable Medicaid state plan option. [$24 B in costs over 10 years].
  - Medicaid parity proposal would prevent states from prohibiting same day billing and allow providers to be reimbursed for Medicaid mental health and physical health visits that occur on the same day. [$2.4 B in costs over 10 years.
  - $2.5 B performance bonus fund allows HHS to award payments to states over five years, contingent upon improvements on the behavioral health core set and access measures.

- **Regulation of private insurers improves access to behavioral health & addresses access issues.**
  - Plans and issuers, including group health plans, to provide mental health and substance use disorder benefits. The Secretaries of HHS, Labor and Treasury would be authorized to regulate behavioral health network adequacy, and to issue regulations on a standard for parity in

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reimbursement rates based on the results of comparative analyses submitted by plans and issuers. [$720 M in costs over 10 years]
  - Plans must cover three (3) behavioral health visits and three (3) primary care visits each year without charging a copayment, coinsurance, or deductible-related fee. [$310 M in cost over the next 10 years].
  - Self-insured non-federal governmental plans may not opt out of PHSA provisions including behavioral health parity rules, covering hospital care after childbirth and breast reconstruction after a mastectomy, and providing a coverage safety net if an employee's child takes a leave of absence from college for a serious illness. [No budget impact]

- **Pandemic preparedness gets $81 B over five years.** This funding will be spread across ASPR, CDC, NIH, and FDA. CDC alone is expected to receive $28 B.
  - $2.1 B would be for the Vaccines for Adults program, a new mandatory program modeled after the existing Vaccines for Children. This program is expected to provide uninsured adults with access to vaccines recommended by the Advisory Committee on Immunization Practices. Note that HRSA's COVID-19 vaccinations for uninsured adults is expected to end in April.
  - $600 M in flexible funding to support core local and state public health capacity investments.
  - $50 M for the Center for Forecasting and Outbreak Analytics (CFA) at CDC. The American Rescue Plan Act of 2021 (ARP) provided the initial funding to establish CFA which provides disease modeling and outbreak analytics.
  - $124 M in investments for leadership, communication, and public health innovation, an increase of $10 M above FY 2022. Note this is the first request for increased funding for this activity in over a decade.

- **FDA is expected to get a $2.1 B increase in program funding**. The Biden admin. also envisions a $48 M increase in User Fees compared to FY 2022.
  - Pandemic Preparedness funding $1.6 B. FDA will be expected to expand and modernize regulatory capacity, information technology, and laboratory infrastructure to respond effectively to any future pandemic or high consequence biological threat.
  - Emergency Use Authorization drugs and devices during a PHE would have $0 cost-sharing**,** for Medicare, Medicaid, CHIP enrollees, and for the uninsured. [Not scoreable].
  - FDA enterprise technology and data modernization efforts would get $83 M in funding**.** Over half, $45 M, will be dedicated to investments to strengthen the common data infrastructure established through the Technology Modernization Action Plan and Data Modernization Action Plan.
  - Medical product safety investments would get $4.2 B**,** an increase of $253 M above FY 2022 enacted. This includes $2.0 B in budget authority and $2.2 B in user fees to support premarket animal drug review capacity, bolster medical device cybersecurity, and support Cancer Moonshot activities.
  - FDA-wide new Alternative Methods Program $5 M in new funding. The program intends to advance the development, qualification, and implementation of FDA's new alternative methods for product safety and efficacy testing. Funding aims to spur the adoption of new alternative methods for regulatory use that can replace, reduce and refine animal testing, and improve predictivity of nonclinical testing.
  - User fee programs proposed for reauthorization: PDUFA, the Generic Drug User Fee Act, the Biosimilars User Fee Act, and the Medical Device User Fee Act**.** In addition, the following user fee programs will be submitted to Congress for reauthorization covering FY24—28: The Animal Drug User Fee Act and the Animal Generic Drug User Fee Act.

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