

# CAPITOL STREET

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April 6, 2026

## FY27 Budget: Trump Healthcare Plan 2.0

340B Oversight & Demo Coming, FDA Accelerates First To Human Trials, MA Oversight

Relevant Companies

ALL HEALTHCARE

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**The President's FY 2027 budget request released April 3 focuses on MA fraud and abuse (RADV), speeding first in human trials (FDA) as well as a more modest NIH cut (which is unlikely to happen).** We note the proposed budget again includes a reorganization of HHS, along with a (smaller than last year) \$5 B cut to NIH funding. The President's budget is an opening salvo, frequently aspirational and almost never enacted as proposed. Overall, the budget calls for a 12% cut in discretionary non-defense spending (not including Social Security, Medicare, and Medicaid). Link to HHS Budget in Brief [here](#).

**340B reform is addressed: both with a 60% bump in funding for oversight and for a request for the program to be regulated by CMS (vs HRSA).** Addressing MA fraud and abuse (via RADV audits) is a major policy priority, despite the courts slowing down the aggressive audit schedule put forth by Dr. Oz in 2025. Funding would be provided for FDA on initiatives on AI, nonanimal testing, and domestic inspections as speeding first in human trials appears to be forthcoming and aligns with our take on 2026 policymaking ([here](#)).

### »» Key Points

#### HHS

**HHS proposes \$111.1 B in discretionary budget authority for FY 2027.** The funding request is larger than last year's request of \$94.7 B, but 16% below the \$125.8 B Congress provided for FY 2026.

**Similar to last year's budget request, HHS proposes combining multiple agencies into a new, unified entity called the *Administration for a Healthy America (AHA)* that would have \$14.7 B in funding on prevention efforts.** Agencies to be combined include the Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), Office of the Assistant Secretary for Health (OASH), and several programs from the CDC.

**The budget request continues the admin's priorities on AI, continued consolidation of agencies, and combatting fraud & abuse.** The agency particularly highlights how the budget will be used to expand the use

of AI and machine learning-driven analytics for fraud investigation, building on the various FWA (fraud waste & abuse) programs that began last year.

### **CMS: FRAUD, MA & 340B**

**The FY 2027 budget again focuses heavily on program integrity and weeding out fraud, waste and abuse (largely in MA, FFS Medicare, Medicaid and the Federally-Facilitated Exchange).** The FY26 budget (our take [here](#)) initiated various anti-fraud task groups and programs, and emphasized investing in infrastructure that promoted greater oversight of pre-payment controls. Goals in this budget align with the efforts that began last year.

- **Modernizing Original Medicare (Parts A & B):** CMS's FY 27 priorities center on long-overdue system modernization, dedicating \$750 M to replace old claims systems via ClaimsCore, while simultaneously insourcing rulemaking and analytics work from contractors to in-house staff to cut costs.
- **Tightened oversight of Medicaid:** At \$785.2 B in mandatory grants to states, Medicaid dominates the CMS budget with FY 2027 focused on fraud containment and system modernization. This includes \$25M to begin replacing Medicaid's fragmented state-by-state claims infrastructure, alongside tightened Section 1115 oversight and eligibility audits tied to the *Working Families Tax Cut*.
- **FWA in Federal Obamacare Exchange:** CMS requests \$2.1 B for Exchange operations, with the agency's FY 2027 priorities shifting notably from enrollment growth toward program integrity. \$41M of funds will go towards a new machine learning fraud detection tool targeting unauthorized plan changes by agents and brokers, with improper payment audits set to extend to State-Based Exchanges for the first time in benefit year 2027.

**CMS's budget goals also place a focus on strengthening MA oversight and payment accuracy.** The budget funds monthly payment validation, actuarial bid reviews, and retroactive enrollment processing through a \$33.6 M discretionary request for Provider and Plan Oversight. CMS will also review plan benefits for regulatory compliance, monitor network adequacy and appeals standards, and develop quality measures for MA organizations and special needs plans, tasks growing in complexity with the introduction of new benefit flexibilities.

**MA rates are due this afternoon with the MA and Part D final rule released last week (our take [here](#)).** The rule finalized greater outcomes-focused Star Ratings measures, supplemental benefit and marketing reforms, while punting risk adjustment and C-SNP (chronic special needs plans) reform to future rulemaking.

**RADV (risk-adjustment data validation audits) remain a priority, though the agency's ambitious timeline is slowed due to court challenges (our take [here](#)).** A federal district court threw out CMS's 2023 RADV rules on procedural grounds in September 2025, and HHS's subsequent appeal to the Fifth Circuit means audits are unlikely to resume for another 6-12 months while CMS likely rewrites the underlying rules. In FY 2027, discretionary funding will continue to support the expanded RADV audit efforts that will include auditing all eligible MA contracts and conducting increased levels of medical review per audit. In FY 2027, CMS expects to conduct:

- Approximately 250 financial audits (also known as one-third financial audits), including work to resolve audit issues noted in the audit reports;
- 30 Program audits of MA organizations and PDP sponsors;
- 45 audits of PACE plans; and

- Audits of 8-11 Medicare managed care cost reports to ensure payment accuracy.

**The budget provides \$3.7 B in discretionary investments for CMS in FY 2027.** The budget request provides \$6.8 B in Program Level funding for CMS, which is \$1.4 B below FY 2026 enacted. This total includes \$3.7 B in discretionary budget authority, \$3.1 B in user fees, and \$93 M in current law mandatory funds.

**The budget continues and enhances 340B Program funding (\$21 M) and calls for 340B to be moved from the somewhat toothless HRSA to CMS as the regulatory body.** Funding would provide oversight and auditing of covered entities and drug manufacturers, support operational improvements, and increase operational efficiencies. In accordance with the HHS Reorganization plan, the budget would shift the program into CMS for streamlined processes and the ability to utilize in-house drug-pricing resources and expertise.

- **We note that the administration also proposed integrating 340B at CMS in last year's budget.** We do not envision major 340B legislative changes to pass this year, but the 340B program growth remains a revenue headwind for manufacturers and a key PhRMA lobbying priority.
- **A new 340B rebate model pilot is under development at CMS.** CMS is working through comments on the potential benefits and costs of a 340B rebate model, including potential cash flow impact to hospitals. RFI [here](#). We may see the administration try to launch another 340B rebate model to address 340B program abuse and address the risk of “double dipping” or duplicate discounts. Previously, the Trump admin proposed a 340B alternative rebate model on the 2026 first ten Medicare negotiation drugs, but was forced to shelve it after litigation and a preliminary injunction.

## **NIH**

**The budget includes a smaller (but still significant) -11% cut to medical research at NIH, coupled with a reorganization of institutes and centers.** The Administration's FY 2027 budget proposal would reduce NIH funding by \$5 B to \$41.2 B, which represents a smaller reduction than the 40% cut proposed in last year's budget. The budget also provides \$945 M for ARPA-H, \$555 M below FY 2026.

**We expect NIH funding will ultimately not be cut, as we saw Congress provide flat-to-slightly up funding for FY26.** Recall that in FY 2026, lawmakers pushed back on NIH funding cuts proposed by Trump and instead increased NIH funding by +1% to \$49 B. See our prior take [here](#).

**The proposed NIH reorganization would reduce its institutes and centers from 27 to 22, though major institutes like the National Cancer Institute are unaffected.** Recall, last year's budget proposed a more expansive consolidation of NIH programs into five (5) new focus areas. See our prior take [here](#).

## **FDA: SPEEDING FIH TRIALS, NON-ANIMAL TESTING & AI**

**Proposed FDA funding includes \$3.3 B in discretionary budget authority and \$3.9 B in user fees (a slight increase in funding).** FDA initiatives focus on food reform, strengthening foreign and domestic inspection capacities, and updating tobacco regulations. Current user fees are authorized through September 2027 and we note that negotiations are already underway with manufacturers on the next reauthorization.

**NEW: FDA proposes a new, accelerated first to human trial pathway as we previewed as likely in our "FDA: Where Are We?" Mar 31 analysis [here](#).** The FDA is taking seriously the feedback from the CEO roadshow on the delay to first in human trials compared to China and Australia. The proposed clinical trial

pathway reflects the quicker path to Phase 1 trials that other countries have. This would be an optional, risk-based Expedited IND pathway for certain Phase 1 clinical trials where there is existing preclinical data.

**Funding for AI initiatives & non-animal testing are still priorities.** We note that funding is incremental compared to the proposed budget on food initiatives.

- **On AI, the budget proposes \$2 M to upgrade the FDA’s two centralized process systems with AI and machine learning capabilities.** Funding is likely intended to improve the FDA’s AI tool Elsa and further refine the FDA’s machine learning tools for use in review and admin work.
- **The budget includes \$5 M to help the FDA develop and use new methods that can replace or reduce animal testing.** Funding may be intended for both research and new guidance to validate New Approach Methodologies (NAMs) -- such as AI, organ-on-a-chip, and cell-based assays.

**The budget funds domestic pharmaceutical manufacturing to accelerate review (PreCheck Program).** The FY 2027 budget request provides \$9 M to establish the FDA PreCheck Program. As a reminder, FDA PreCheck facilitates the development of new U.S. drug manufacturing facilities by streamlining the review and inspection process. See our past analysis [here](#).

## CDC

**The CDC budget reflects the administration’s shift away from vaccine policies and toward chronic disease.** We have noted the administration's pivot away from anti-vax messaging, despite RFK Jr’s MAHA movement, as a mid-term election strategy (our take [here](#)). The budget includes \$13.3 B in total program level funding for CDC, which is \$475 M below FY 2026.

**The budget calls for a new National Center for Chemicals and Toxins within CDC to establish a more “proactive and coordinated” approach.** The Center consolidates the following programs across HHS: the Agency for Toxic Substances and Disease Registry, CDC’s National Institute for Occupational Safety and Health and National Center for Environmental Health, the FDA’s National Center for Toxicological Research, and the NIH’s National Institute for Environmental Health Sciences. While reaction from stakeholders has been muted thus far, there will likely be concern that consolidation will bring staff cuts and/or reduced research funding.

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