Healthcare Regulatory Roundup #94

One Big, Beautiful Webinar
Washington Updates

May 21, 2025

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Housekeeping

- Slides, handouts, and forms available in **Resources Panel**
- Enter questions in **Q&A Panel**
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- Enlarge, rearrange, or close panels as you prefer

Introductions

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Today's Agenda

1. One Big, Beautiful Bill Act (OBBBA)
2. HHS Reorganization/President's FY 2026 Discretionary Funding Request
3. De-Regulation Initiatives
4. Proposed Rule – Medicaid Directed Payment Reforms
5. CMS Innovation Center 2025 Strategy to Make America Healthy Again
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10. Request for Information – Health Technology Infrastructure

1. One Big, Beautiful Bill Act (OBBBA)

OBBBA at 30,000 Feet

- **Tax cuts and credits = $3.819T**
  - Extend and expand TCJA individual provisions ($3.8T)
  - Revive TCJA business provisions ($278B)
  - Adopt new tax cuts/credits ($663B)
    - No tax on tips, overtime, vehicle loan interest; higher senior standard deduction (all expire in 2028)
    - Health savings account expansions
    - New “MAGA” accounts
    - Other individual and business tax cuts and credits
  - Repeal/restrict eligibility for tax credits, impose new taxes ($980B offset)
- **New spending = $321.1B**
  - Judiciary ($110B)
  - Armed Services ($144B)
  - Homeland Security ($67.1B)
- **Offsets (spending reductions) = $1.57T**
  - Medicaid ($625B)
    - ~7.6M will lose Medicaid coverage
  - SNAP ($290B)
    - Committee also approved $60B in new aid to farmers
  - Student loans and grant programs ($349.1B)
- **Increases debt by $3.3T by 2034**

Data compiled by Committee for Responsible Federal Budget From Congressional Budget Office and Joint Committee on Taxation publications, available at https://www.crfb.org/blogs/adding-house-reconciliation-bill

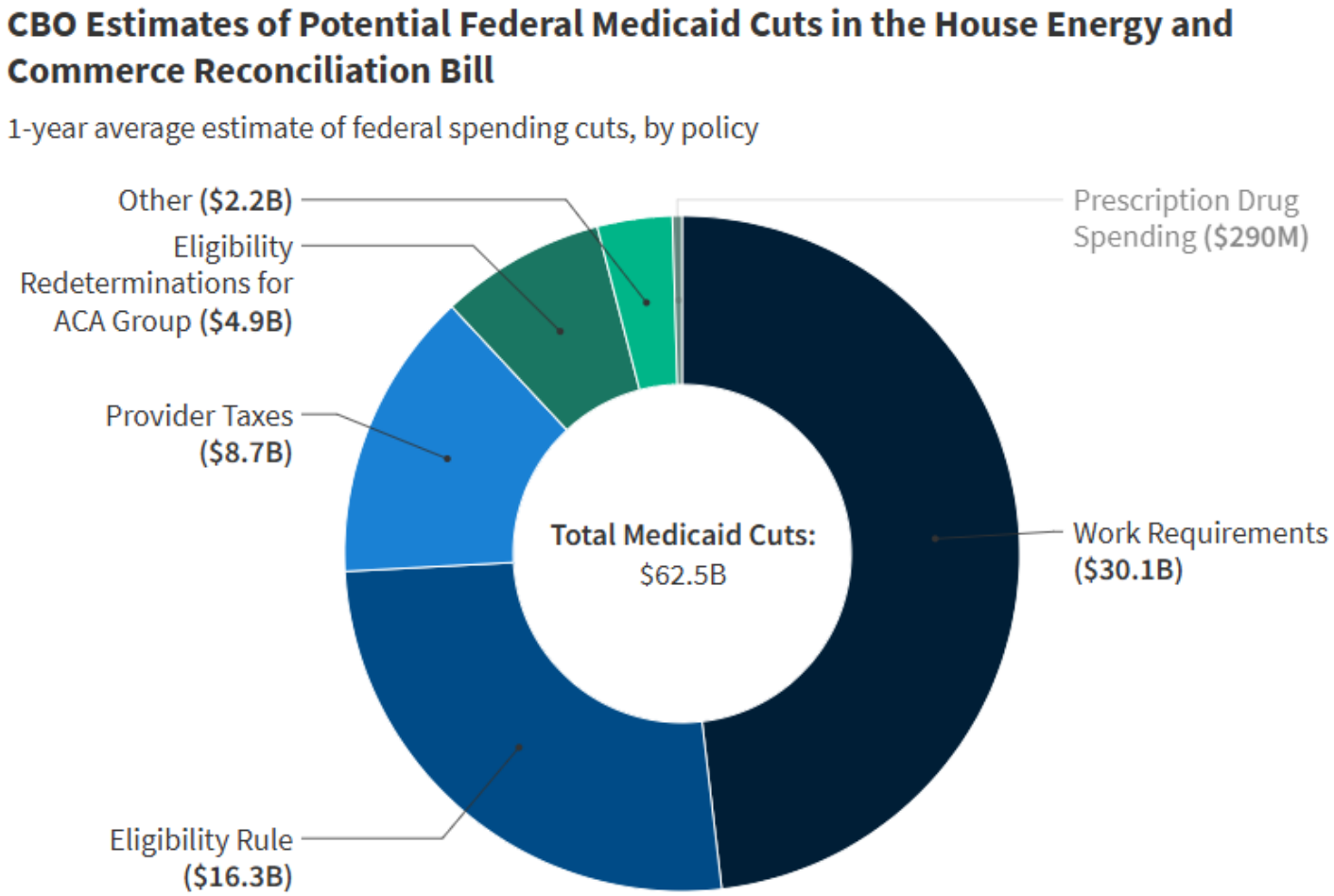
Reconciliation Timeline

- **April 10** – Reconciliation resolution approved by House and Senate
- **May 11** – House Energy & Commerce Committee (E&C) releases text of healthcare provisions of reconciliation bill
- **May 14** – Following 26-hour mark-up, E&C advances healthcare provisions
- **May 15** – House Budget Committee releases text of Concurrent Resolution on the Budget for Fiscal Year 2025, H. Con. Res. 14, One Big, Beautiful Bill Act
- **May 16** – First House Budget Committee vote to favorably advance OBBBA fails (*5 Republicans vote no*)
- **May 16-18** – Behind-closed-door negotiations
- **May 18** – Second House Budget Committee vote to favorably advance OBBBA passes (*4 abstain, 1 changes vote*)
- **May 19-20** – More behind-closed-door negotiations
- ➢ **May 21** – House Rules Committee meeting (started at 1:00 am)
- **May 22?** – Full House vote
- **Post-Memorial Day Holiday** – Process begins in Senate

OBBBA – Key Medicaid Provisions

- **Work requirements:** Effective 01/01/2029, states must condition Medicaid eligibility for non-disabled individuals ages 19-64 on working or participating in qualifying activities for ≥ 80 hours/month, with specific exceptions
  - States must verify applicant meets requirement for ≥ 1 month prior to application and complete re-verifications every 6 months
- **Eligibility and Enrollment Final Rule:** Delays implementation until 2035
- **Redeterminations for expansion population:** Effective 10/1/2027, states must conduct eligibility redeterminations at least every 6 months for expansion population
- **Provider taxes:** States prohibited from establishing any new provider taxes or increasing rates of existing taxes.
  - States required to restructure existing taxes to meet specified requirements
- **State-directed payments:** States prohibited from adopting new SDPs for hospitals and nursing facilities that exceed published Medicare rates (no future SDPs based on average commercial rates)

Medicaid Cuts

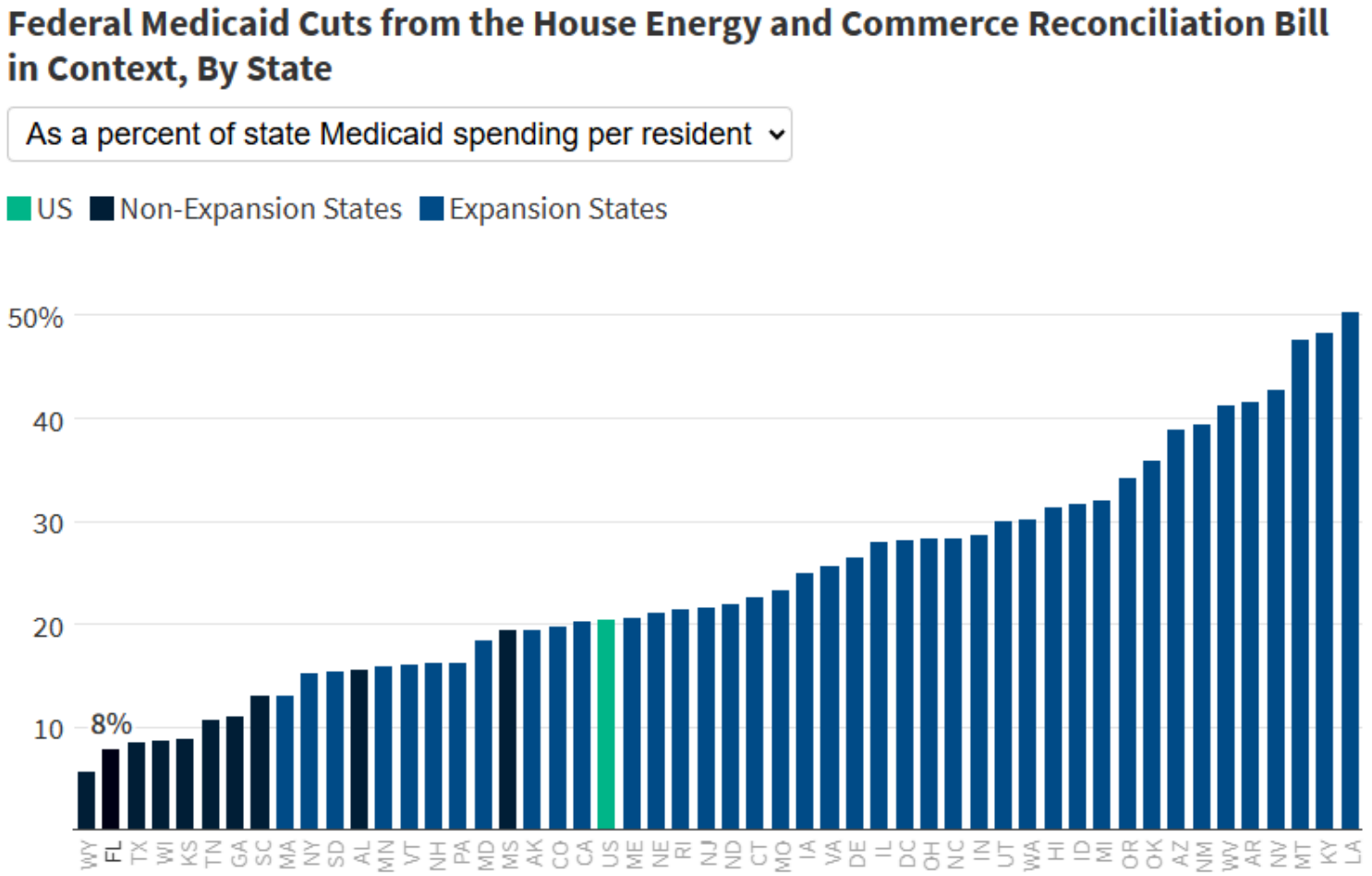


https://www.kff.org/medicaid/issue-brief/state-level-context-for-federal-medicaid-cuts-of-625-billion-and-enrollment-declines-of-10-3-million/ (based on CBO estimates)

OBBBA – Other Medicaid Provisions

- **Retroactive coverage:** Effective 10/1/2026, states must provide Medicaid coverage for qualified medical expenses incurred for up to 30 days (vs. current 90 days) prior to date of application
- **Cost sharing:** Effective 10/1/2028, states must impose up to $35 cost-sharing on expansion adults with incomes 100-138% FPL; maintains exemptions for specific services and population and 5% of family income cap on out-of-pocket expenses
- **Enrollee contact information:** States must verify data to prevent multiple-state enrollments, payments to deceased individuals
- **Provider screening requirements:** Effective 10/1/2028, states must conduct monthly exclusion checks and quarterly Death Master File checks
- **Erroneous Medicaid payments:** Beginning in FY 2030, states subject to FMAP reductions for payment errors (payments to ineligible individuals + overpayments to eligible individuals)
- **Changes to immigrant coverage rules**
- **Rules for calculating Section 1115 waiver budget neutrality**
- **Prohibition on payment of Medicaid funds to Planned Parenthood**
- **Prohibition on use of federal matching funds for gender transition procedures**

State-Level Impacts – % of Medicaid Spending per Resident



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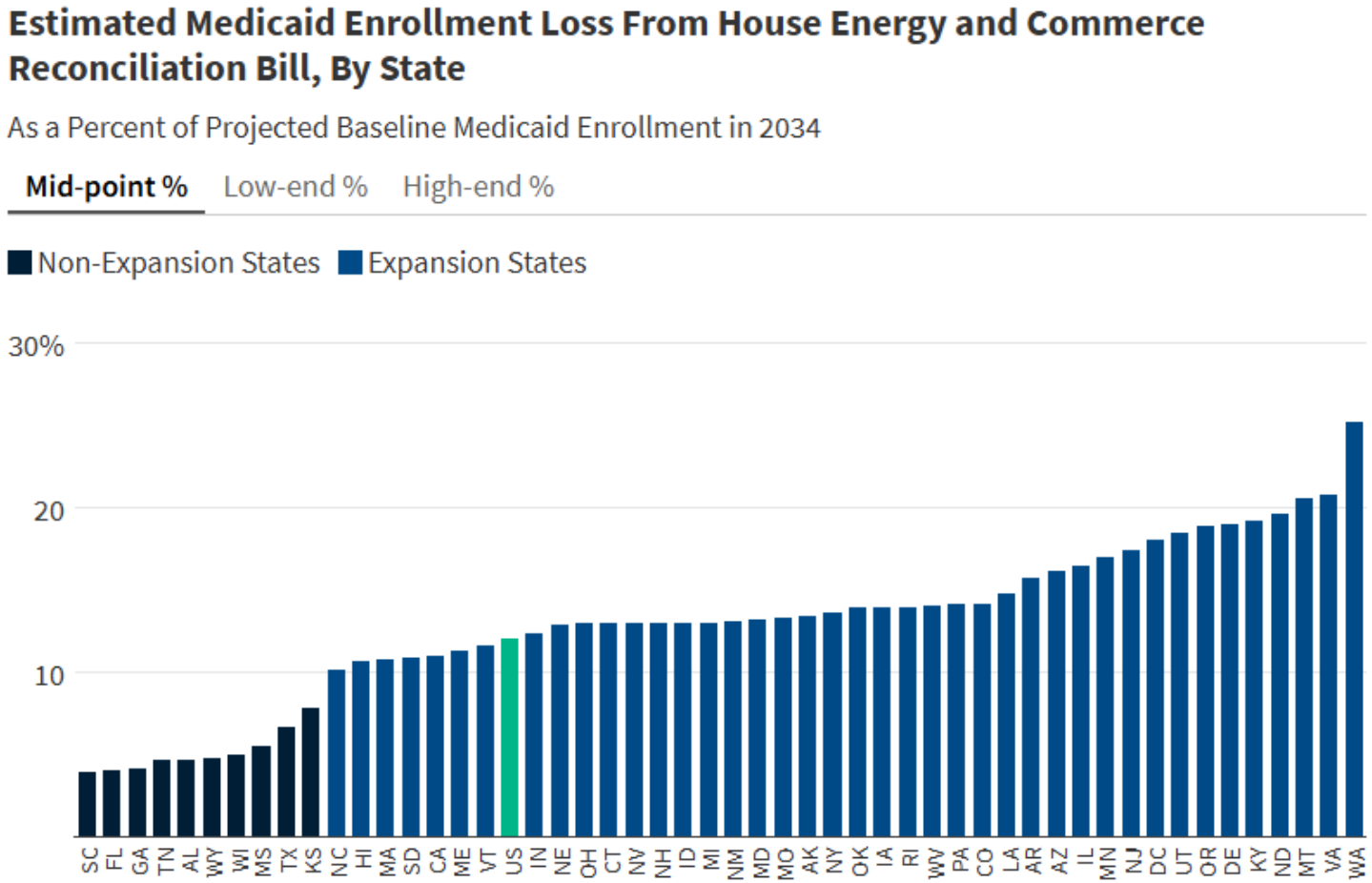
State-Level Impacts – Enrollment



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Impact on Rural Hospitals?

FY23 U.S. Rural Hospital Operating Margins

Source: Medicare Cost Reports

	Number of Hospitals			% of Total		
	Operating Margin			Operating Margin		
	Negative	Positive	Total	Negative	Positive	Total
PPS	491	193	684	72%	28%	100%
CAH	775	271	1,046	74%	26%	100%
	1,266	464	1,730	73%	27%	100%

PYA analysis of 2023 hospital cost report data

OBBBA – Other Medicaid Provisions (Good News)

- Delays Medicaid DSH reductions ($8B/year for 4 years) through 9/30/2028
- Prohibits HHS from enforcing nursing home minimum staffing rules
- Requires states to establish streamlined enrollment processes for out-of-state pediatric providers by 2029
- New prescription drug pricing rules for pharmacy benefit managers (PBMs)
  - Requires pharmacies to complete NADAC survey on drug acquisition costs
  - Requires publication of NADAC survey data
  - Requires PBM reforms

Medicare Physician Fee Schedule (MPFS) Changes

- **Current law (MACRA)**
  - Payment rate for specific service = conversion factor x assigned RVU
    - Conversion factor = how MPFS "pie" is divided based on projected total RVUs
  - For 2025, base adjustment to conversion factor was 0, but reduced by 2.9% to satisfy budget neutrality requirements (expanded coverage + changes in assigned RVUs = higher total RVUs)
  - On annual basis beginning in 2026, conversion factor will increase by 0.75% for advanced APM participants, 0.25% for everyone else
    - Still subject to budget neutrality adjustments

- **OBBBA**
  - For 2026, increase in conversion factor equal to 75% of Secretary's estimate of the percentage increase in Medicare Economic Index (MEI) for the year
    - Estimated 2.25% increase over 2025 current conversion factor
  - Thereafter, annual increase in conversion factor equal to 10% of Secretary's estimate of the percentage increase in MEI for the year
    - E.g., assume estimated 3.5% increase in MEI in 2027 = 0.35% increase in conversion factor
  - Still subject to budget neutrality adjustments

Rural Emergency Hospital (REH) Program

- Permit CAH or PPS hospital with <50 beds that closed between 2014 and 2020 to “re-open” as REH
  - “New” REH within specified distances of CAH/PPS hospital subject to reduced facility payment and reimbursement
  - Implementing regulations to address ownership, licensure, location, etc.
- No 340B eligibility, no swing bed reimbursement

Other Healthcare Related Provisions

- ACA Marketplace (included in tax offsets)
  - Does NOT extend expanded premium tax credits expiring in 2025
  - Institutes eligibility and income verification for enrollees
  - Rolls back income-based special enrollment periods
  - Limits definition of “lawfully present” to qualify for premium tax credits
- Artificial Intelligence (AI)
  - Appropriates $25 million for HHS to contract with AI vendors and data scientists to identify and recoup improper Medicare payments.
  - Requires HHS to report to Congress on progress in reducing improper payments using AI
- Tax advantaged accounts
  - Codifies regulations from President Trump’s first term that allow Individual Coverage Health Reimbursement Arrangements to be used for purchasing qualified health insurance on the individual market; greater flexibility for employers/employees using these arrangements
  - Expands Health Saving Account eligibility, allowing more individuals to contribute and broadening list of services covered

Next Up – The Senate

- Only requires 50 votes (vs. 60 usually required to end debate), ***but….***
  - Medicaid cuts
  - SALT deduction
  - Clean energy tax credits
  - Medicare provider payment cuts (e.g., site neutral payments)
- Byrd Bath
  - Compliance with Senate budget reconciliation rules, including requirement each provision have non-incidental budgetary impact

2. HHS Reorganization/President's FY 2026 Discretionary Funding Request

President's FY 2026 Discretionary Spending Proposal

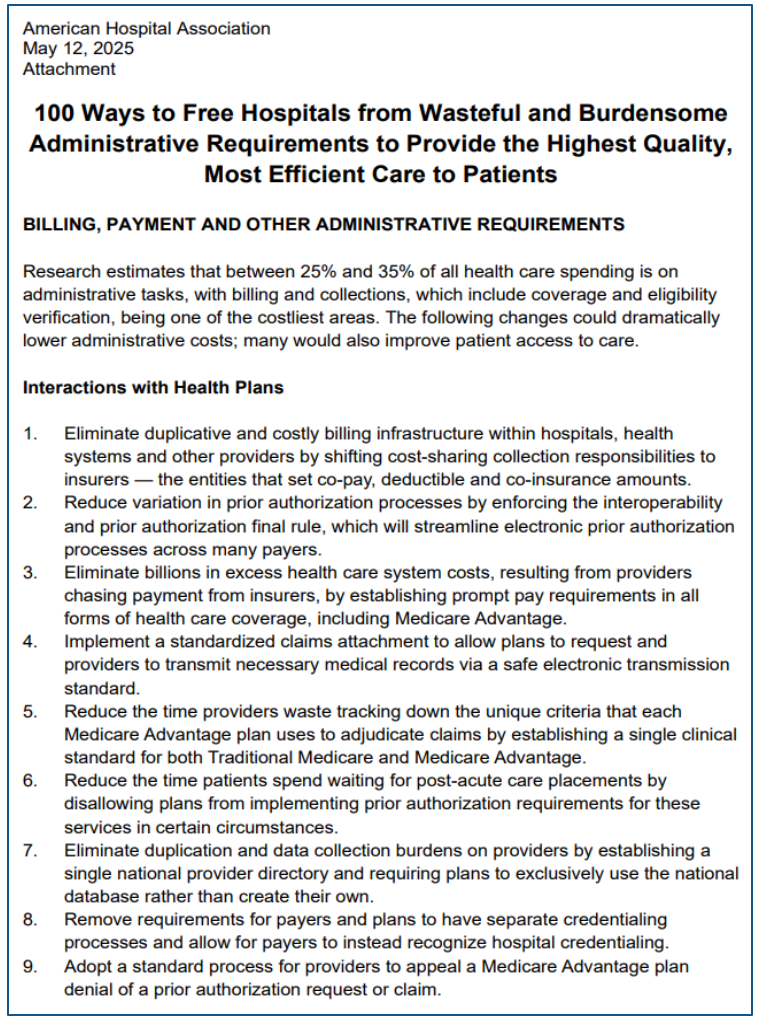
- "Skinny budget" released May 2; full proposal released later in summer
  - FY 2026 non-defense discretionary funding request of $163 billion, 22.6% less than FY 2025 funding
  - FY 2026 HHS discretionary budget of $93.8 billion, 26.2% less than FY 2025 funding
    - Unclear how budget treats DOGE cuts (i.e., are reductions in addition to previously announced DOGE cuts?)
    - Impact of court decisions reversing DOGE cuts (e.g., state COVID-19 grants canceled in late March)
- HHS specifics
  - Only includes funding for some current agencies; does not address funding for new agencies created in HHS reorganization (Administration for a Healthy America; Offices of the Assistant Secretaries for Innovation, Enforcement, Strategy, Product Safety)
    - Includes $500M for Make America Healthy Again initiative
  - Silent on funding for several current agencies (e.g., FDA, OIG, OCR, Indian Health Service)

Proposed Funding Reductions for Current Agencies

- Health Resources and Services Administration
  - 18% cut ($9.5B to $7.8B)
  - Cuts to maternal/child health programs ($274M million) and workforce programs ($1B)
- Centers for Disease Control and Prevention
  - 43% cut ($8.4B to $4.8B)
  - Refocus agency's mission on core activities on emerging and infectious disease surveillance and maintaining public health infrastructure
- National Institute of Health
  - 40% cut ($45.4B to $27.5B)
  - Consolidate programs into 5 focus areas: National Institutes on Body Systems Research, Neuroscience and Brain Research, General Medical Sciences, Disability Related Research, and Behavioral Health
- Substance Abuse and Mental Health Services Administration
  - 14% cut ($7.4B to $6.3B)
- Centers for Medicare & Medicaid Services
  - 16% cut ($4.1B to $3.5B)
- Administration for Strategic Preparedness and Response
  - Eliminate funding for Hospital Preparedness Program ($240 million)
- Agency for Healthcare Research and Quality
  - 34% cut ($374B to $245B)

3. De-Regulation Initiatives

Still Time to Comment!



American Hospital Association
May 12, 2025
Attachment

100 Ways to Free Hospitals from Wasteful and Burdensome Administrative Requirements to Provide the Highest Quality, Most Efficient Care to Patients

BILLING, PAYMENT AND OTHER ADMINISTRATIVE REQUIREMENTS

Research estimates that between 25% and 35% of all health care spending is on administrative tasks, with billing and collections, which include coverage and eligibility verification, being one of the costliest areas. The following changes could dramatically lower administrative costs; many would also improve patient access to care.

Interactions with Health Plans

1. Eliminate duplicative and costly billing infrastructure within hospitals, health systems and other providers by shifting cost-sharing collection responsibilities to insurers — the entities that set co-pay, deductible and co-insurance amounts.
2. Reduce variation in prior authorization processes by enforcing the interoperability and prior authorization final rule, which will streamline electronic prior authorization processes across many payers.
3. Eliminate billions in excess health care system costs, resulting from providers chasing payment from insurers, by establishing prompt pay requirements in all forms of health care coverage, including Medicare Advantage.
4. Implement a standardized claims attachment to allow plans to request and providers to transmit necessary medical records via a safe electronic transmission standard.
5. Reduce the time providers waste tracking down the unique criteria that each Medicare Advantage plan uses to adjudicate claims by establishing a single clinical standard for both Traditional Medicare and Medicare Advantage.
6. Reduce the time patients spend waiting for post-acute care placements by disallowing plans from implementing prior authorization requirements for these services in certain circumstances.
7. Eliminate duplication and data collection burdens on providers by establishing a single national provider directory and requiring plans to exclusively use the national database rather than create their own.
8. Remove requirements for payers and plans to have separate credentialing processes and allow for payers to instead recognize hospital credentialing.
9. Adopt a standard process for providers to appeal a Medicare Advantage plan denial of a prior authorization request or claim.

- **Submit comments by June 11, 2025, at https://www.cms.gov/medicare-regulatory-relief-rfi**
- Topics
  - Streamline regulatory requirements
  - Opportunities to reduce administrative burden of reporting and documentation
  - Identification of duplicative requirements
  - Additional recommendations

https://www.aha.org/system/files/media/file/2025/05/aha-response-to-omb-deregulation-rfi-letter-5-12-2025.pdf

4. Proposed Rule
Medicaid Directed Payment Reforms

Provider Tax Loophole

- Medicaid provider tax basics
  - State imposes tax on providers and/or managed care organizations to generate state revenue to be used to draw down federal matching funds, but cannot shift disproportionate amount of tax burden to entities with high percentage of Medicaid business
    - Broad-based - tax must apply to all providers in a certain category, not just those who largely serve Medicaid patients.
    - Uniform across the group being taxed - tax rate must be the same for all providers within defined category
    - Generally redistributive - states cannot guarantee providers receive back in Medicaid payments what they paid in taxes
      - CMS uses statistical test defined by regulation to determine whether tax is redistributive, but test is sensitive to statistical outliers
      - According to CMS, 7 states have manipulated formula to increase federal match by excluding large Medicaid-heavy providers or using tiered rates
- Proposed rule intended to address loopholes in statistical test
  - Proposed rule published on May 15; **comments due July 14**

https://www.federalregister.gov/documents/2025/05/15/2025-08566/medicaid-program-preserving-medicaid-funding-for-vulnerable-populations-closing-a-health

Closing the Loophole

- Even if tax passes statistical test, still would fail redistributive requirement if:
  - Tax rate is higher for providers with more Medicaid business than those with less
  - State explicitly taxes Medicaid services at a higher rate than non-Medicaid or uses proxies (e.g., geography, income level, or service type) that functionally target Medicaid services
    - E.g., taxing payers' Medicaid business at higher rate than other business
  - State excludes providers with high Medicaid volume from the tax base in a way that skews the statistical test
- One-year transition period for non-compliant states with approvals 2+ years old; effective immediately for others
- According to CMS, changes would reduce federal Medicaid spending by $33.2 billion from 2026 through 2030
  - Also expect state spending to decline by $18.8 billion

5. CMS Innovation Center
2025 Strategy to Make America Healthy Again

Prevention, Patient Empowerment, Competition

- CMS Innovation Center created and funded by ACA to test alternative payment models (APMs) in federal healthcare programs
- On May 13, agency's new leader, Abe Sutton, rolled out new MAHA-based strategy to promote evidence-based prevention, patient empowerment, and greater competition while protecting federal taxpayers
  - Previously announced discontinuation/modification of several models to save $750 million
- Going forward, all models will involve downside financial risk borne by participating providers and be expanded to include Medicare Advantage plans
  - Resources to support rural and small provider participation
- Will be announcing several new models consistent with new strategy in coming weeks
  - Many openly speculating that CMS will introduce more mandatory APMs (like TEAM) based on new strategy

https://www.cms.gov/priorities/innovation/about/cms-innov)ation-center-strategy-make-america-healthy-again

6. CMS Fraud Detection Operation Center

A New Sheriff in Town?

- HHS announced on April 30 “DOGE and CMS are working on a number of program integrity rules, process improvements, and audit tools that have the potential to save over $40 billion per year.”
  - Achieving such savings would require significant increase in enforcement activity, as federal agencies reported ~$10 billion in such savings in 2024
- To that end, CMS announced on April 28 via social media launch of new Fraud Detection Operation Center
  - FDOC leverages current fraud prevention system that uses artificial intelligence and machine learning models to flag potentially fraudulent behavior by providers
  - Spend money to save money: HHS-OIG reports every $1 invested in ‘fraud fighting’ results in $10 returned to federal healthcare programs

https://www.hhs.gov/hhs-big-wins-maha/index.html

7. DOJ Memorandum on White Collar Crime

Going After “High Impact” White Collar Crime

- On May 12, DOJ Criminal Division published memo addressing prosecution of white collar crimes
  - Many hoped new Administration would put the breaks on such prosecution
- Will focus on 10 “high impact” areas, including healthcare fraud and abuse
- Announces changes to Criminal Division’s Corporate Enforcement and Voluntary Self-Disclosure Policy
  - Streamline self-disclosure incentives
  - Provide clear path to declination
- Makes revisions to Criminal Division’s monitorship policies
  - Strongly disfavored; will review all monitorships regularly to control costs, prevent scope creep

https://www.justice.gov/opa/media/1400141/dl?inline

8. Executive Order 14293, Regulatory Relief to Promote Domestic Production of Critical Medicines

Re-Shoring of Pharmaceutical Manufacturing

- May 5 Executive Order includes carrots and sticks to boost domestic manufacturing
  - Eliminate regulatory obstacles to expanded domestic production
  - Expand inspections of overseas manufacturing facilities funded by increased fees on those facilities
- Likely to lead to significant short-term increases in drug acquisition costs for healthcare providers
  - In addition to anticipated new tariffs on pharmaceuticals

https://www.federalregister.gov/documents/2025/05/15/2025-08876/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients

9. Executive Order 14297
Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients

First Step, Long Way to Go

- May 12 executive order aimed at lowering pharmaceutical prices using strategies carried over from first Trump Administration
- Two-step process
  - 30-day deadline for pharmaceutical companies to electively lower prescription drugs costs
  - If no progress, HHS will develop regulations tying price federal healthcare programs pays for pharmaceuticals to lower prices paid by other countries (most favored nation pricing)
- Drugmakers response
  - Lowering prices will result in deep cuts in research and development
  - Drugmakers subject to take-it-or-leave-it pricing from single-payer counties (i.e., everyone else)

https://www.federalregister.gov/documents/2025/05/15/2025-08876/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients

10. Request for Information
Health Technology Ecosystem

Digital Health Tools and Data Interoperability

- Published in Federal Register on May 16; r**esponses due June 16**
- Inform CMS/ASTP-ONC efforts to increase:
  - Beneficiary access to digital capabilities to make informed health decisions
  - Data availability for all stakeholders to improve health outcomes
- What works, what needs improvement, what impedes rapid progress?
- What gaps need to be filled (i.e., technology that can do X) and what incentives are needed to fill those gaps?
- What will drive adoptions of digital identity credentials?
- What data should CMS make available and how?

https://www.federalregister.gov/documents/2025/05/16/2025-08701/request-for-information-health-technology-ecosystem

Our Next Healthcare Regulatory Roundup Webinars

June 11, 2025; 11 am – 12 pm ET
HCRR #95 – 340B Update

June 25, 2025; 11 am – 12 pm ET
HCRR #96 – *Yet Another* Washington Update

Please leave a comment regarding topics for future HCRR webinars!

There's a lot going on in D.C. right now.
What do the policy changes mean for the healthcare industry?

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