HEALTHCARE REGULATORY ROUND-UP - Episode #50

Debt Limit Deal and Other Legislative Developments

June 14, 2023

Introductions

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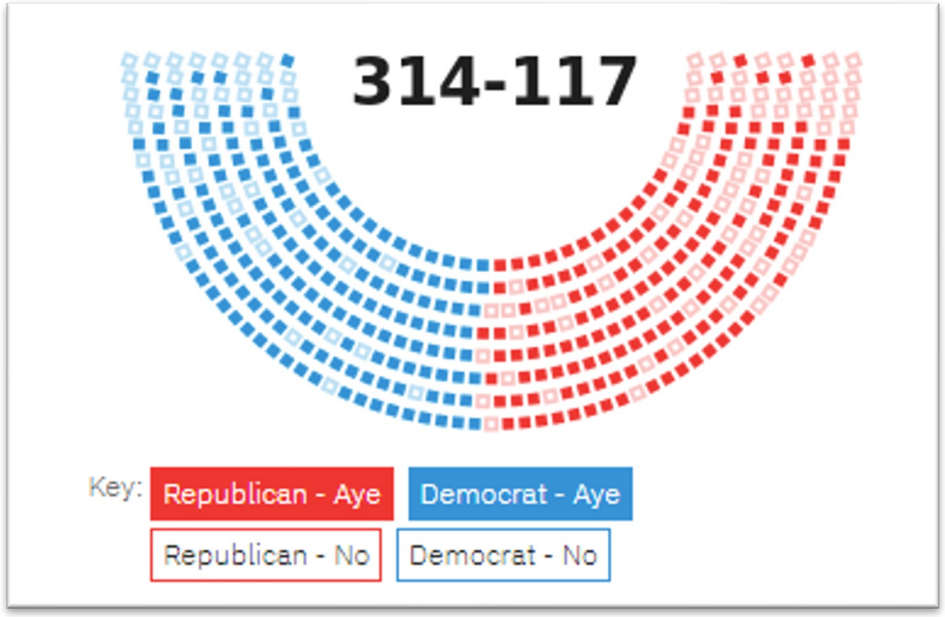
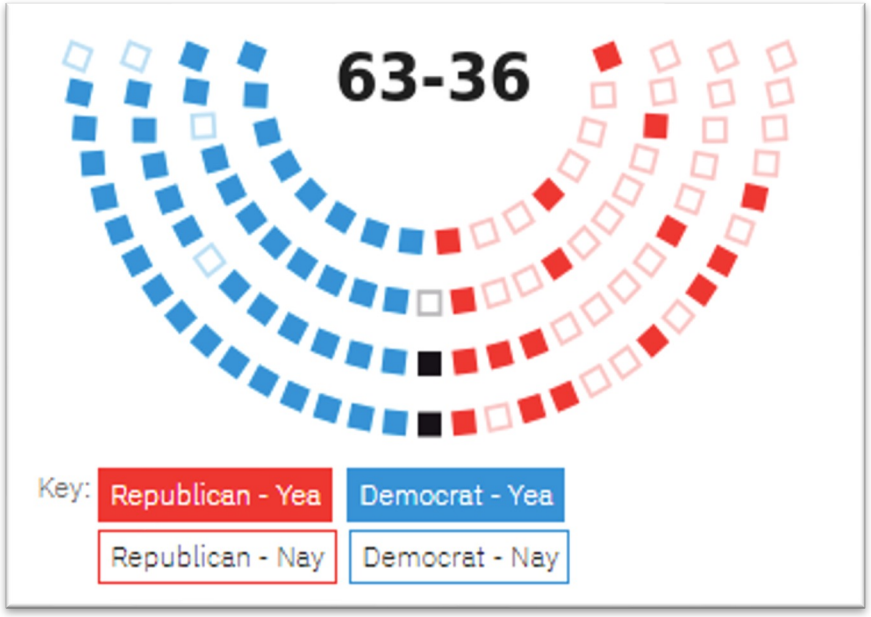
Fiscal Responsibility Act of 2023

Meet in the Middle





https://www.govtrack.us/congress/votes/118-2023/s146

No one is very happy.
Which means it's a good compromise.

- Tyrion Lannister (Game of Thrones)

The Price to Avoid Catastrophe

- Suspends federal debt limit through 01/01/25; increases limit on 01/02/24 to accommodate obligations issued during suspension period
- In exchange for -
  - New discretionary spending limits for FY24 and FY25 enforced with sequestration
  - Statutory authority through 2024 for administrative pay-as-you-go rules
  - Rescission of certain unobligated COVID-19 relief and IRS funds
  - Ending suspension of federal student loan payments
  - Expanded work requirements for SNAP and TANF
  - Expedited permitting process for certain energy projects
- Plus funding for VA's Cost of War Toxic Exposure Fund and Department of Commerce Nonrecurring Expenses Fund

Discretionary Spending Limits

- FRA imposes discretionary spending limits for FY2024 and FY2025 that reduce budget authority by $246 billion relative to baseline projections

	Non-Defense	Defense
FY 2023	$767B	$858B
FY 2024	$704B	$886B
FY 2025	$711B	$895B

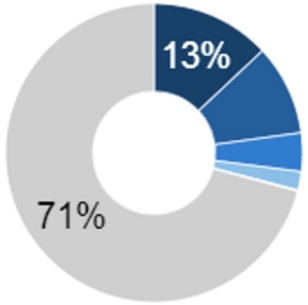
  - Certain discretionary programs (e.g., disaster relief, certain programs under 21st Century Cures Act, Harbor Maintenance Trust Fund) exempt from limits
  - To incentivize regular full-year appropriations legislation, caps lowered if continuing resolution in effect on 01/01/24 or 01/01/25 for any budget account
  - Sequestration (across-the-board reductions of nonexempt spending) triggered if discretionary appropriations exceed these limits
  - Projected to reduce noninterest outlays by $1.3 trillion over 10 years if Congress funds programs at inflation-adjusted FY2025 levels for remainder of 10-year budget window

Federal Healthcare Spending

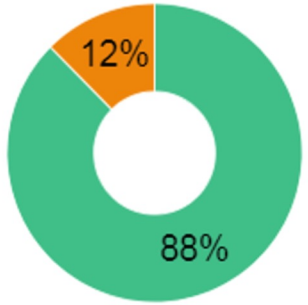
Federal Spending on Domestic and Global Health Programs and Services Accounted for 29% of Net Federal Outlays in FY 2023

Mandatory spending accounted for 88% of outlays on health programs and services

- Medicare ($829.9B)
- Medicaid and CHIP ($625.4B)
- Other Health (non-Medicare) ($265.9B)
- Veterans' hospital & medical care ($127.0B)
- Global health ($8.4B)
- Other federal outlays ($4.5T)
- Mandatory ($1.63T)
- Discretionary ($231.2B)



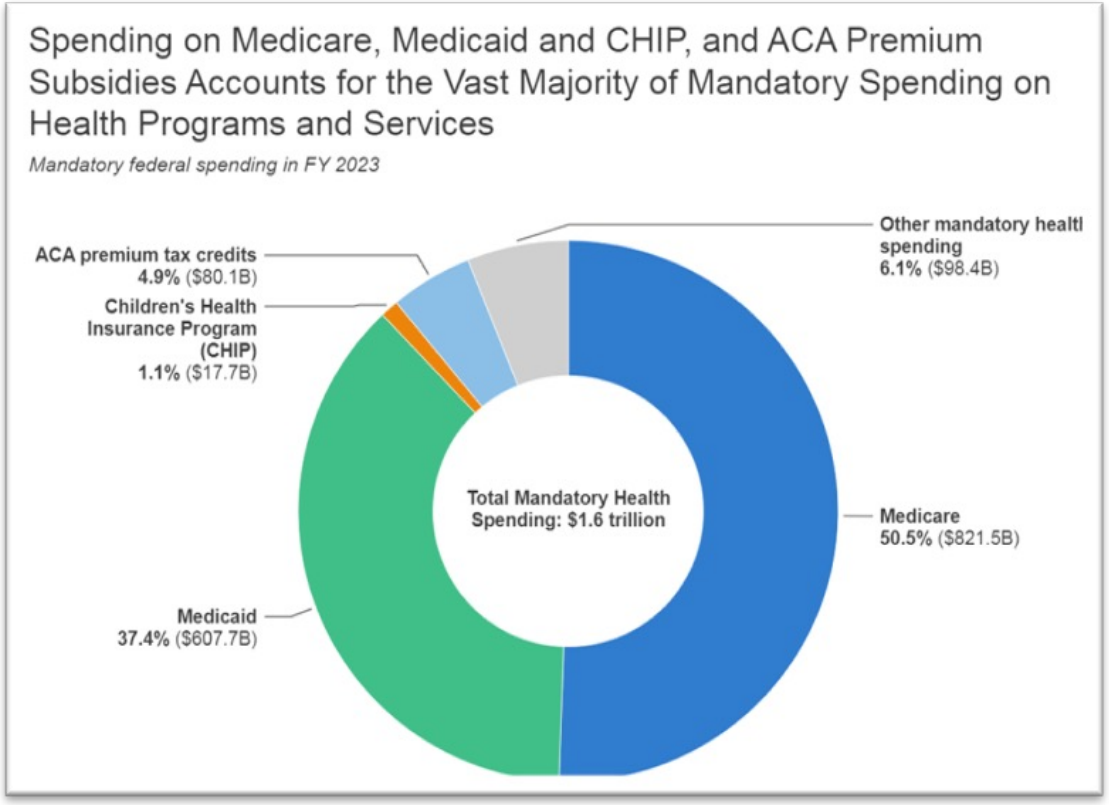
Total Outlays in FY 2023: $6.4T

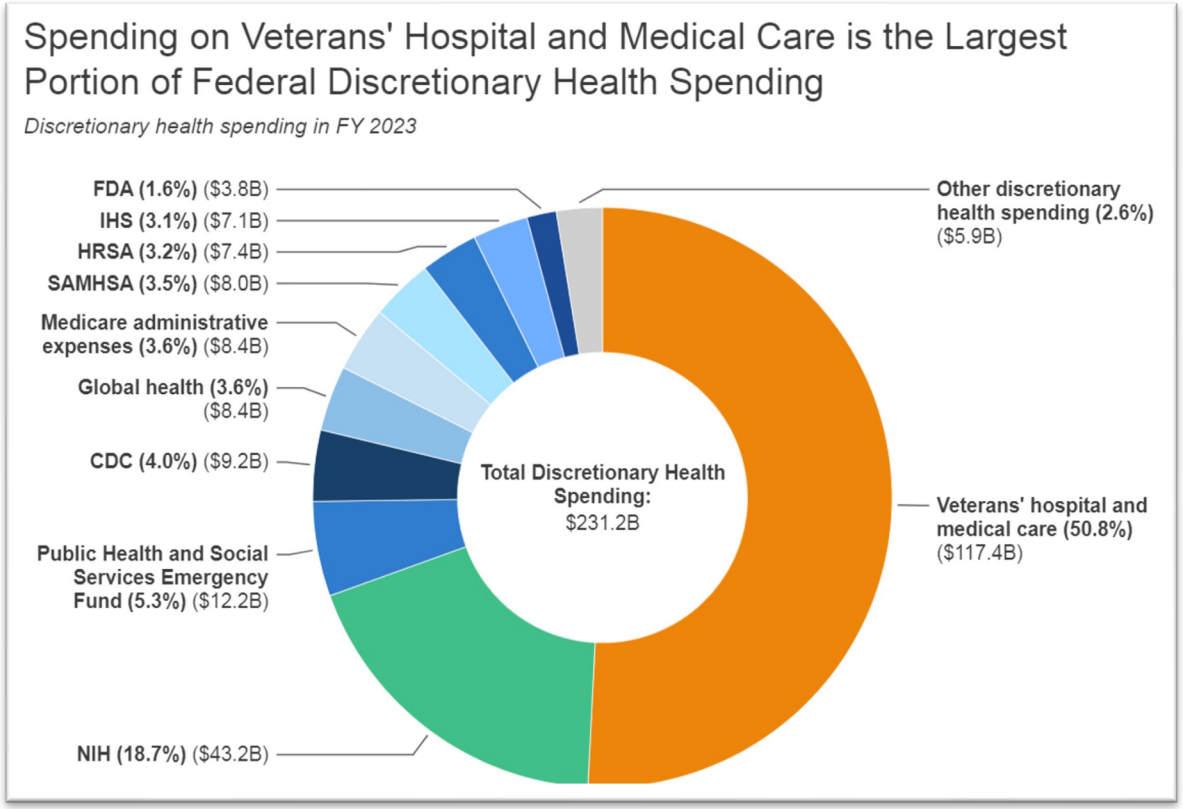


Outlays on Health Programs and Services in FY 2023: $1.9T

https://www.kff.org/medicare/issue-brief/faqs-on-health-spending-the-federal-budget-and-budget-enforcement-tools/

Mandatory vs. Discretionary Spending





Health spending = 30% of total discretionary spending

https://www.kff.org/medicare/issue-brief/faqs-on-health-spending-the-federal-budget-and-budget-enforcement-tools/

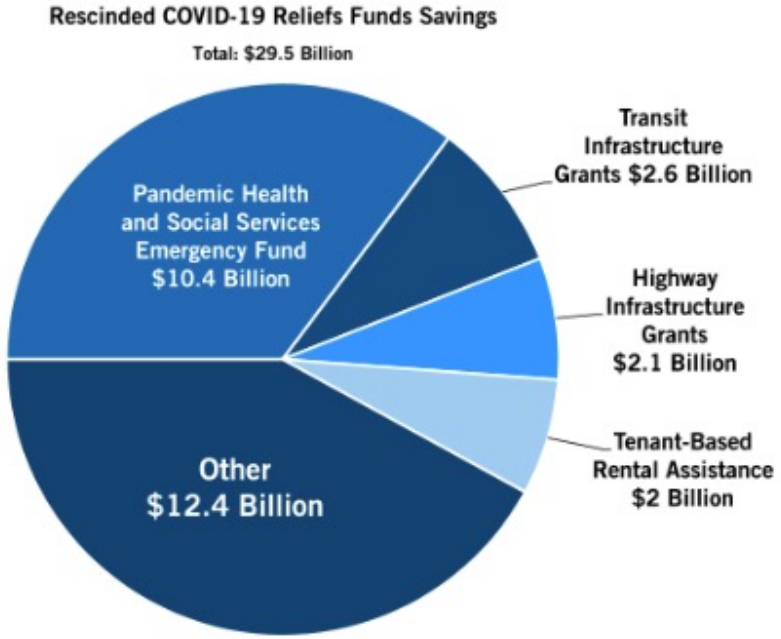
Administrative PAYGO

- OMB implemented administrative PAYGO in 2005; 2019 Executive Order intended to institutionalize and reinvigorate administrative PAYGO
- FRA creates statutory authority for administrative PAYGO
  - Before finalizing any discretionary administrative action, agency must –
    - Submit to OMB estimate of budgetary effects of such action, and
    - If such action would increase direct spending, propose other administrative action(s) that would reduce direct spending to cover cost of such action
  - OMB to publish guidance by 08/01/23; requirement sunsets on 12/31/24
  - Impact on CMS rulemaking (e.g., No Surprises Act)?

COVID Relief Claw Back

PETER G. PETERSON FOUNDATION

Rescinding COVID-19 relief funds would reduce outlays by nearly $30 billion



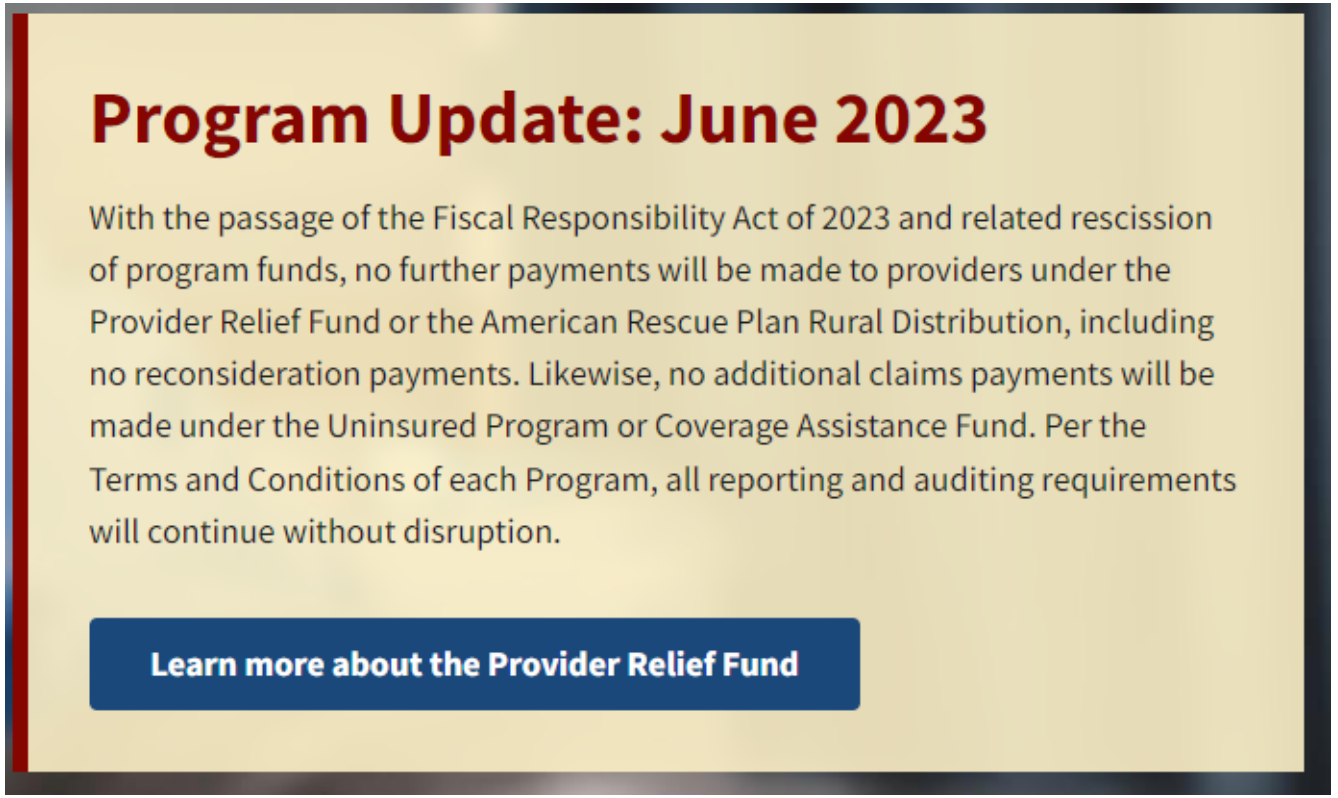
SOURCES: Committee for a Responsible Federal Budget, *Rescinding COVID Relief Funds Saves $30 Billion*, May 2023; *CBO's Estimate of the Budgetary Effects of H.R. 2811, the Limit, Save, Grow Act of 2023*, April 2023.

https://www.pgpf.org/blog/2023/06/how-much-covid-funding-remains-unspent

PHSSEF – Reserved Funds

- All remaining unobligated funds appropriated to Pandemic Health and Social Services Fund rescinded except -
  - CARES Act: $2.127 billion + certain transfers
  - American Rescue Plan: $7.3 billion
- FRA does not specify how reserved funds are to be used
  - Press reports indicate funds intended for next generation vaccines, test procurement capacity, long COVID research, other priorities
- Fate of funds re-paid by and recovered from recipients?

HRSA Provider Relief Fund



Uninsured Program (UIP)

- HRSA allocated portion of Pandemic Health and Social Services Fund to reimburse providers for COVID-19 vaccination, testing, and treatment furnished to uninsured
  - "[D]designed to prevent the further spread of the pandemic by providing access to uninsured patients for testing and treatment"
- For a deeper dive, we're joined by Brian Stimson and Dawn Helak, attorneys with McDermott Will & Emery

UIP

- The UIP T&Cs state that “[t]he Secretary will reimburse” claims for COVID-19 testing, vaccination, and treatment
- HRSA stopped accepting claims in March/April 2022, stating it lacked sufficient funds
- HRSA, however, had sufficient funds and continued to pay claims.
- And sufficient funds remain available
  - Billions in reserved unobligated funds
  - Additional funds (and counting) being recouped
- Many providers have continued to provide free services under agreements HHS

The PRF

- Agencies may change their policies, within limits
- Agencies must announce policy changes, state good grounds for the changes, and account for reliance interests
  - Good grounds are neither arbitrary nor capricious
- HRSA announced a major policy change: ending payments of PRF and ARP dollars notwithstanding the availability of funds
  - HRSA did not state why it ended payments, or how it accounted for the reliance interests of applicants in Phases 3 and 4 and ARP Rural
- McDermott recently settled PRF litigation with DOJ worth $43 million

Next Steps

- The current situation is unfair to providers
- Providers have compelling arguments for PRF and UIP relief
- McDermott is hosting a registration-only webinar at 3pm EST on Tuesday, June 20, 2023, to share opportunities for potential PRF and UIP relief
- We have posted the registration link in the chat. Please email Olivia Moll (omoll@mwe.com) or Madeline Holihan (mholihan@mwe.com) to receive the link by email or for any registration issues
- Please email us at bstimson@mwe.com and dhelak@mwe.com to connect directly about the PRF or UIP opportunity

Other Legislative Developments

HR 3561 - Promoting Access to Treatments and Increasing Extremely Needed Transparency (PATIENT) Act

- Advanced out of House Energy and Commerce Committee on May 24 (49-0)
- Includes –
  1. Hospital price transparency
  2. Health insurer transparency
  3. Provider-based status approval
  4. Site neutral payments
  5. Delay of Medicaid DSH cuts
  6. Mandatory reporting of ownership information
  7. *Medicare Advantage plan reporting requirements*
  8. *Clinical lab price transparency*
  9. *Pharmacy benefits managers oversight*
  10. *Extension of certain graduate medical education programs*

https://docs.house.gov/meetings/IF/IF00/20230524/116022/BILLS-118-NA-M001159-Amdt-6.pdf

1. Hospital Price Transparency

- As of 01/01/25, must provide list of 300 shoppable services (price estimator tool no longer substitute for such list)
- CMS to publish standard, uniform method and format for reporting (with all rates expressed as dollar amount) hospitals must use by 01/01/25
  - Plain language description with appropriate code (HCPCS, DRG, NCD, etc.)
  - Gross charge (inpatient and outpatient) (chargemaster rate absent discounts)
  - Any payer-specific negotiated charges with name of third-party payer and plan (inpatient and outpatient)
  - De-identified maximum and minimum negotiated charges
  - Discounted cash price (enter gross charge if no cash discount available)

Hospital Price Transparency, Con't

- CMS/OIG to establish process to regularly monitor accuracy of price information
- Increased penalties for non-compliance effective 01/01/24; thereafter, CMS has authority to increase penalties through rulemaking
  - $300/day for hospitals with 30 beds or less
  - $10/day per bed for hospitals with 30+ beds ($5,500/day limit lifted 01/01/24); minimum penalty of at least $5 million for hospital that fails to comply for year or more
- CMS to maintain publicly available list of hospital found to be non-compliant (warning letter, corrective action plan, penalties) + hospitals currently under review
- CMS to submit annual report to Congress on complaints and enforcement activities
- GAO to provide report within 1 year on needed improvements and increased CMPs
- CMS to establish requirements to ensure accessibility of pricing information to individuals with limited English proficiency (e.g., interpretation services)

2. Health Insurer Transparency

- HR 3561 would impose additional transparency requirements on health plans beyond current Transparency in Coverage rules
- Beginning 01/01/25 and every 3 months thereafter, health plans would make available in manner specified by regulation the following information for each covered item or service
  - In-network rate for each participating provider (identified by NPI)
  - Amount billed by and allowed amount for each non-participating provider (with certain exceptions)
- Health plans would publish instructions written in plain language on how to use publicly reported data

Health Insurer Transparency - Reports

- By 01/01/25, Comptroller General would submit report to Congress regarding health plan compliance, enforcement activities, and opportunities for improvement
- By 01/01/28, Comptroller General would submit report to Congress assessing differences in negotiated rates in private market
  - Rural and urban areas
  - Individual, small group, and large group markets
  - Consolidated and unconsolidated health care provider areas
  - Non-profit and for-profit hospitals
  - Non-profit and for-profit insurers
  - Insurers serving local or regional areas and insurers serving multi-state or national areas

3. Provider-Based Status Approval

- By 01/01/26, hospital must submit provider-based attestation for all off-campus outpatient departments demonstrating compliance with 42 C.F.R. § 413.65
- By 01/01/26, each hospital off-campus outpatient department must obtain and bill government payers under separate NPI
  - CMS to establish process for hospitals to obtain these NPIs

4. Site Neutral Payment Reductions – Drug Administration Services

- HR 3561 would reduce Medicare payments for drug administration services at all off-campus HOPDs to amount equivalent to what would have been paid "under the applicable payment system"
  - No exception for "grandfathered' off-campus HOPDs (i.e., those opening on/before 11/02/15; mid-build)
- 4-year phase-in period with full implementation by 01/01/28
  - AHA estimates these site neutral payments would cost hospitals $3 billion over 10 years
  - Any budget neutrality adjustments would not take into consideration savings generated through site neutral payments

MedPAC Site Neutral Payment Proposal

- HHS to annually identify services that can only be provided in hospital outpatient department – exempt from site neutral payment
- Create comprehensive APCs (C-APCs) for emergency, critical care, and trauma visits
- All other services -
  - If hospital outpatient had highest volume, services continue to be paid under OPPS
  - If ASCs had highest volume, hospital and ASC paid at ASC rate
  - If physician office and non-grandfather outpatient departments had highest volume, hospital and ASC paid weighted average of the difference between PFS facility and non-facility rates

5. Medicaid DSH

- Affordable Care Act reduced federal DSH allotments beginning in 2014, to account for anticipated decrease in uncompensated care
  - Congress has delayed cuts on 9 occasions
- Absent Congressional action, Medicaid DSH allotments will be reduced by $8 billion per year for 4 years beginning in FY24
  - Plus, American Rescue Plan's increases in DSH allotments sunset in FY24
- HR 3561 would delay cuts until FY26

6. Mandatory Reporting of Ownership Information

- Beginning 01/01/25, specified entities would report annually on business structure, mergers, acquisitions, changes in ownership, and other ownership-related matters as determined by CMS
  - "Specified entities" = hospital; physician-owned practices with more than 25 physicians; physician practice owned by hospital, health plan, private equity company, or venture capital firm; ASC; freestanding ED
- Penalty for failure to report
  - Hospitals with 30+ beds: no more than $5 million for each report not provided or report containing false information
  - All other entities: no more than $2 million for each report not provided or report containing false information

Mandatory Reporting of Ownership Information, Con't

- Additional required reporting for all hospitals –
  - Debt-to-earnings ratio
  - Average amount of debt incurred by the hospital and the entire specified entity
  - Real estate leases and purchases
- Additional required reporting for non-profit hospitals –
  - Capital gains investments (disaggregated by type of investment)
  - Taxes paid on those gains
- By 01/01/27, HHS to make specified data publicly available

HR 3290 - Transparency and Oversight of the 340B Drug Discount Program

- Advanced out of House Energy and Commerce Committee on May 24 (29-22)
- Requirements
  - Covered entities required to maintain records regarding use of 340B Program savings which may be audited by HHS
  - DSH covered entities (and potentially others) required to report annually regarding –
    - Number of individuals who received drugs purchased through 340B Program (by payer)
    - Percentage of the number of individuals treated who received drugs purchased through the 340B Program (by payer)
    - Costs incurred at each site, including costs of charity care
    - Costs incurred for treating patients entitled to Medicare Part A benefits or enrolled in Medicare Part B, enrolled in a Medicaid plan (or a waiver of such plan), or who were uninsured, minus the sum of Medicare reimbursements, Medicaid reimbursements and payments by uninsured patients
    - 340B Program saving

Rural Health

- Senate Finance Committee hearings on rural health care access (May 17 & 24)
- Pending legislation
  - Rural Hospital Closure Relief Act - re-open CAH necessary provider status
  - Rural Hospital Support Act – payment adjustments for rural PPS hospitals
  - Rural Health Innovation Act – grant funding for enhancing emergency services
  - Save America's Rural Hospital Act – reforms to numerous rural health programs

Our Next Healthcare Regulatory Round-Up:

June 28 – Proposed Rule(s)