Healthcare Regulatory Roundup #107

Happy New Year!

New Proposed Rules, New Payment Models, New Guidance

January 21, 2026

Housekeeping

- Slides, handouts, and forms available in **Resources Panel**
- Enter questions in **Q&A Panel**
  - If question not addressed during webinar, will follow-up via e-mail
- Enlarge, rearrange, or close panels as you prefer
- For technical difficulties, try refreshing browser

Introductions

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Today's Agenda

1. Another Government Shutdown Averted?
2. Proposed Transparency in Coverage Regulations
3. 2027 Medicare Advantage Proposed Rule
4. New Alternative Payment Models: ACCESS, LEAD ACO, GUARD/GLOBE, BALANCE
5. Proposed Interoperability Rule
6. Proposed Hospital Medicare Condition of Participation on Sex Change Procedures
7. Initial Guidance on Medicaid Work Requirement Implementation
8. Outpatient Prospective Drug Acquisition Cost Survey
9. Rural Health Transformation Program Award Announcement
10. The Great Healthcare Plan
11. CMS 2024 Health Expenditures Report

1. Another Government Shutdown Averted?

Consolidated Appropriations Act, 2026

- FY2026 HHS discretionary budget = $116.8 billion, slight increase over FY2025
  - President's budget requested $83.3 billion
  - Restricts HHS restructuring, prevents Secretary from unilaterally cutting, defunding, or altering major programs
- Health Care Extenders – Highlights
  - Delays Medicaid DSH cuts until FY 2028
  - Renews expanded Medicare telehealth coverage through December 31, 2027
  - Renews hospital-at-home coverage through September 30, 2030
  - Extends Low Volume Hospital and Medicare Dependent Hospital programs, MPFS work geographic index floor, add-on payment for ambulance services through FY2026
  - Reinstates MPFS 3.1% bonus for practitioners in advanced alternative payment models through 2028
  - Requires hospitals to secure separate provider numbers for off-campus outpatient departments (prelude to site neutral payments)
  - Requires Medicare Advantage plan to maintain accurate provider lists
  - Imposes new restrictions on pharmacy benefit managers
  - Allocates $4.6 billion to community health centers for FY 2026 + $1.16 billion for first 3 months of FY 2027
  - New funding for No Surprises Act enforcement
- Does **not** address ACA subsidies (more later on this topic)

2. Proposed Transparency in Coverage Regulations

Transparency in Coverage Proposed Rule

- Notice of Proposed Rulemaking (NPRM) issued December 19; **comments due February 21**
- Goal is to improve data usability while enhancing accuracy and standardization
- Key provisions:
  - Exclude in-network data for those services a provider is unlikely to perform
  - Revises reporting timeframes from monthly to quarterly
  - Files organized by provider network rather than plan or policy
  - Adds change logs and utilization files
  - Revises how insurers report information on out-of-network pricing
  - Insurers would be required to make the same level of detail available online, in print or by phone

3. 2026 Medicare Advantage Proposed Rule

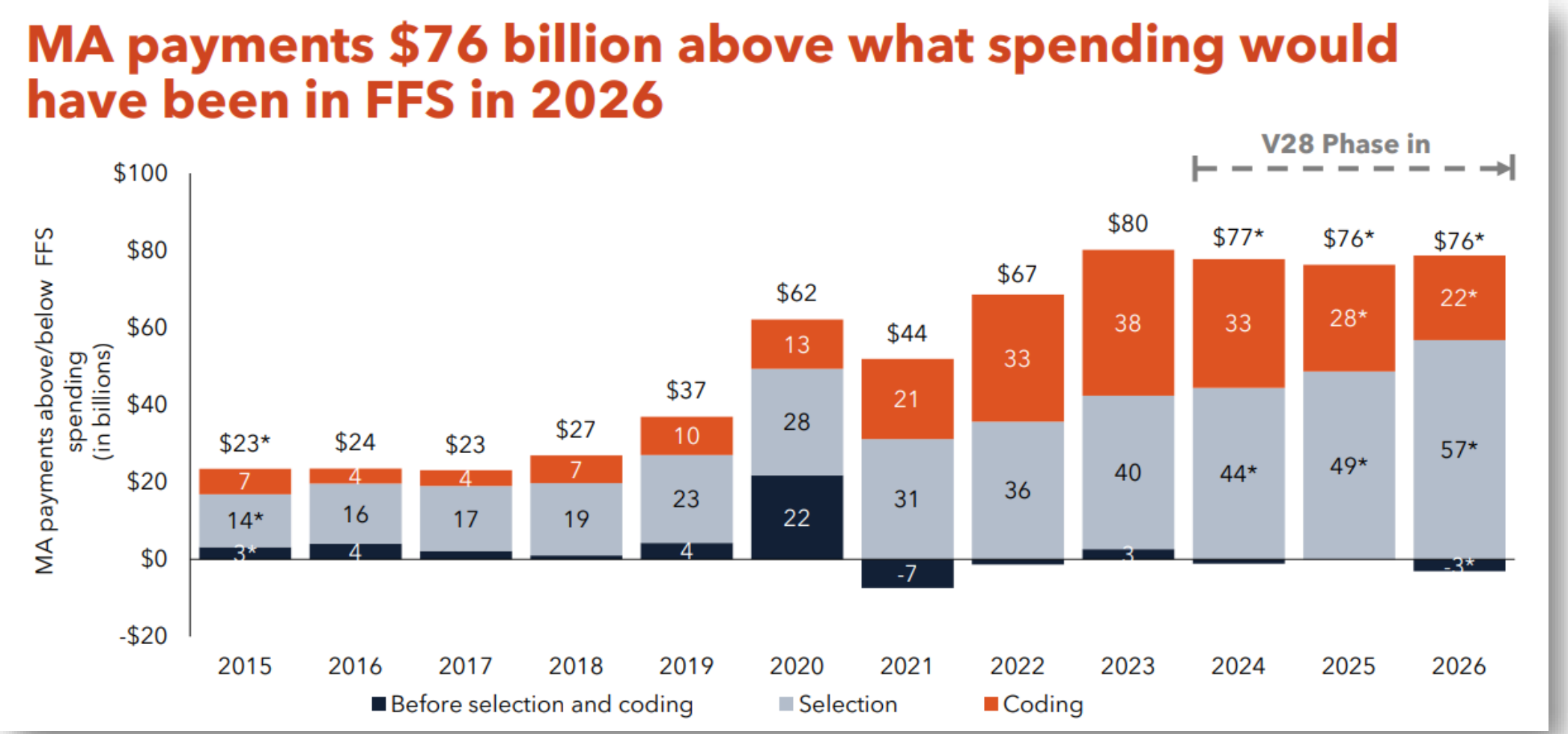
2027 Technical Changes Proposed Rule

- Proposed rule issued November 25; comments due January 26
- Proposes to reform Stars Quality Measures
  - Removes 12 process-heavy or administrative measures, shifting focus to outcomes
  - Includes removing appeals timeliness, call center support (TTY/foreign language), health plan complaints, Plan Finder accuracy, Maximus concurrence rate, eye exams for diabetes, and statin therapy, plus patient experience measures like “Members Choosing to Leave the Plan”

Medicare Advantage Complaints Tracking Module

- New online complaint tool to capture basic information about the complainant, beneficiary, provider, and Medicare Advantage plan, a complaint summary, and optional fields for date(s) of service and claim number
- Provider complaints will be placed into a queue in the CTM, where CMS will review and triage prior to assigning a contract number
- Available at https://www.cms.gov/medicare/health-drug-plans/provider-complaints-form

MedPAC Medicare Advantage Status Report



https://www.medpac.gov/wp-content/uploads/2026/01/Tab-N-MA_Status-Jan-2026.pdf

4. New Alternative Payment Models: ACCESS, LEAD ACO, GUARD/GLOBE, BALANCE

WISeR, GENEROUS, GUARD, GLOBE, BALANCE, MAHA ELEVATE, ACCESS, LEAD, TEAM, and ASM

- Enhancing traditional Medicare program integrity: WIsER model
- Reducing drug costs: GENEROUS, GUARD, GLOBE, and BALANCE models
- Testing lifestyle and functional medicine interventions: MAHA ELEVATE
- Providing outcome-based payments for chronic disease management: ACCESS model
- Replacing ACO REACH with model designed to accommodate rural providers: LEAD model
- Engaging specialists though mandatory alternative payment models: TEAM and ASM models

Advancing Chronic Care with Effective, Scalable Solutions (ACCESS)

- RFA released December 19; apply by April 1 for July 1 start date
- Tests Outcome-Aligned Payments (OAPs), recurring payments made to Part B-enrolled entity for managing patients' qualifying conditions, with full payment tied to achieving measurable health outcomes + avoiding duplication of services
  - ACCESS participants must enroll traditional Medicare beneficiaries
  - Clinicians who co-manage ACCESS beneficiaries with ACCESS participant may bill new ACCESS Model Co-Management service for documented review of ACCESS updates and care coordination activities
  - Participant payment reduced if beneficiaries receive substitute services from other providers for same condition
  - Waivers of co-payments and deductibles
- Four tracks:
  1. Hypertension, dyslipidemia, obesity or overweight with marker of central obesity, and prediabetes
  2. Diabetes, chronic kidney disease, and atherosclerotic cardiovascular disease (including heart disease)
  3. Musculoskeletal conditions: chronic musculoskeletal pain
  4. Behavioral health conditions: depression and anxiety

Long-Term Enhanced ACO Design (LEAD ACO)

- Replaces ACO REACH in 2027 and continues through 2036
- Key enhancements:
  - Improved benchmarking to overcome obstacles to broader participation in ACO models
  - Capitated population-based payments to support team-based care
  - Episode-based risk arrangements (EBRAs) between ACOs and Preferred Providers
  - Optional beneficiary engagement incentives and benefit enhancements

Traditional Medicare Mandatory APMs: TEAM and ASM

- TEAM: Mandatory 5-year episodic payment model launched 01/01/2026 making selected PPS hospitals financially accountable for total cost of defined episode of care
  - Episode of care = anchor event (specified inpatient stay/outpatient procedure) + 30 days post-discharge/post-procedure
  - Total cost = all non-exempt Part A & B payments (prorated if service staddles episode)
  - Accountable = owe money if total cost > target price, receive additional payment if total cost < target price
  - Focus on reducing post-acute care costs (e.g., swing bed vs. SNF)
- ASM: Mandatory 5-year MIPS-like model launching 01/01/2027 for cardiologists (heart failure) and orthopedists, neurosurgeons, and pain specialists (lower back pain)
  - Specialists ranked by score across 4 MIPS categories (limited measures for quality, improvement activities, promoting interoperability, and cost) with corresponding payment adjustments
    - Initially -9 to +9, increasing to -12 to +12

5. Proposed Interoperability Rule

New Rules Related to Health IT

- Proposed rule and withdrawal notice released December 29
- Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability; Withdrawal
  - Eliminates outstanding proposals from 2025 health IT rule on interoperability (HTI-2)due to concerns with clarity and cost
    - Proposals related to encryption and decryption of EHI; implementation of APIs to ease data exchange between payers, providers and patients; public health data exchange
  - Withdrawal effective with publication

New Rules Related to Health IT (*cont.*)

- Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions To Unleash Prosperity (HTI-5)
  - Comments due February 27
  - Proposing to remove over 50% of existing certification criteria; revise others to increase deregulation
  - Would provide for transition to Fast Healthcare Interoperability Resources (FHIR) APIs:
    - Patient access
    - Electronic prior authorization
    - Public health reporting
  - Strengthens rules against withholding EHI
  - Modifies definitions of access, use, and exchange to clarify inclusion of automated means of access

6. Proposed Hospital Medicare Condition of Participation on Sex Change Procedures

Proposed Rule Published December 19

- Key provisions
  - Prohibits hospitals participating in Medicare and Medicaid from offering, facilitating, or performing “sex-rejecting procedures” to individuals under age 18
  - SRPs include pharmaceutical or surgical interventions intended to align child's physical body with asserted identity that differs from their biological sex
  - Narrow exceptions for treating medically verifiable sexual development disorders, or for treating injuries/complications caused by previous procedures
  - Non-compliance could lead to termination of hospital’s provider agreement with CMS
- **Comments due February 17**
- Separate proposed rule to exclude gender dysphoria from definition of "disability" under Rehabilitation Act to ensure restrictions do not violate federal disability discrimination laws

7. Initial Guidance on Medicaid Work Requirement Implementation

December 8 Informational Bulletin

- Individual applying for or enrolled in either Medicaid expansion programs or expansion-like coverage provided through waiver must engage in qualifying activities or be exempt/excluded in month(s) prior to enrollment or renewal
  - Qualifying activities = work, community service, participation in work program, enrollment in educational program, or maintenance of minimum monthly income ($580/month)
  - States must independently verify compliance/exemption or exclusion
  - Look-back period for medically frail individuals?
- States may request extension of 01/01/2027 effective date, but will be granted only if state making meaningful efforts towards implementation and experience severe and/or unexpected issues that hinder progress
- Interim final rule by 06/01/2026; additional guidance anticipated

Hospitals' Medicaid DSH Percentage

- Medicaid Ratio = percentage of total patient days attributable to patients eligible for Medicaid but not entitled to Medicare Part A coverage (Medicaid, non-Medicare days divided by total patient days)

Impacts of lower Medicaid Ratio

- Reduces hospital's add-on payment on each Medicare inpatient claim
- Potential loss of 340B
  - Standard qualification threshold = 11.75% DSH percentage
  - Sole Community Hospitals and Rural Referral Centers – 8% DSH percentage (no discount on orphan drugs)

Potential solutions

- Run patients' Medicaid eligibility checks after fiscal year-end (more likely to have qualified)
- Check Medicaid eligibility for out-of-state patients
- Ensure quality demographic data for Medicaid eligibility lookups
- Consider programs with higher Medicaid percentages (OB, psychiatry)

8. Outpatient Prospective Drug Acquisition Cost Survey

Medicare OPPS Drug Acquisition Cost Survey (ODACS)

- April 15 Executive Order “Lowering Drug Prices by Once Again Putting Americans First”
- CMS to survey acquisition costs for each separately payable drug acquired by all hospitals paid under OPPS
  - Provider registration between December 9 and December 31
    - Point of contact (POC) and submitter (can be the same person)
  - Submission window opening January 1 – March 31, 2026 (11:59 pm EST)
  - Data period covered: July 1, 2024 – June 30, 2025
  - List of hospitals identified as paid under OPPS during the required reporting period found at: https://www.cms.gov/files/document/odacs-provider-ccn-table.pdf
- CMS wants to use the data for CY 2027 OPPS NPRM

Medicare OPPS Drug Acquisition Cost Survey

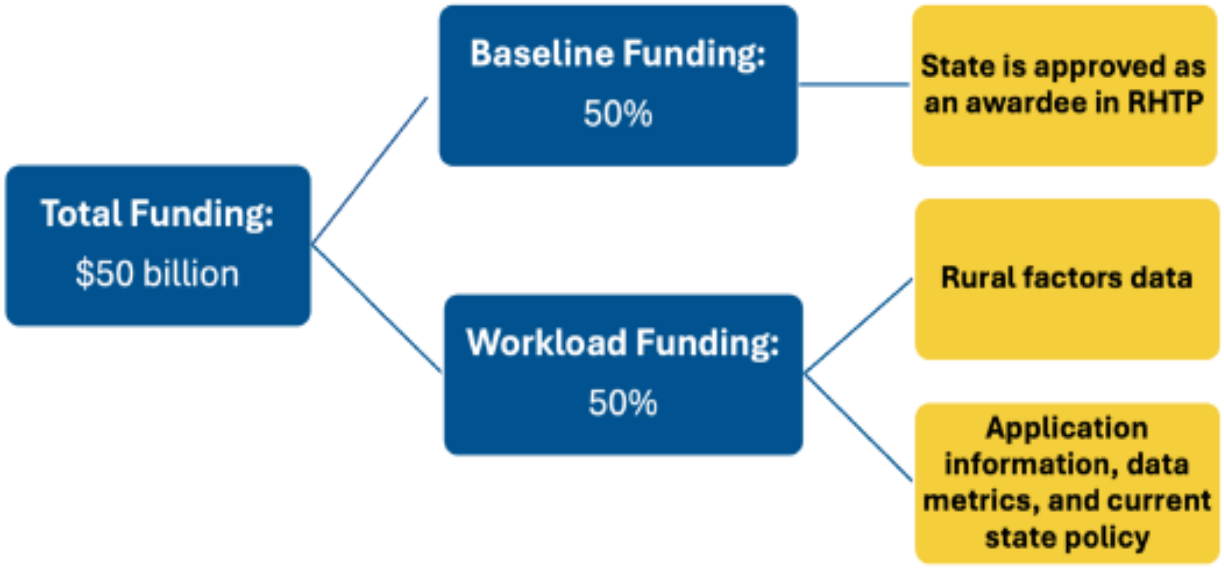
- Providers should report net acquisition costs for required NDCs purchased (leave blank for drugs not acquired during applicable period)
  - Should be inclusive of all discounts and rebates at NDC level
  - Also need to report rebates (in price concessions tab) through group purchasing organizations or other buying group (likely not at the NDC level)
  - For each NDC, in an 11-digit format, hospitals should provide:
    - Total units purchased – non-340B
    - Total units purchased – 340B
    - Total net acquisition cost – non-340B
    - Total net acquisition cost – 340B

Medicare OPPS Drug Acquisition Cost Survey

- Cannot force hospitals to complete the survey; may consider non-responses in future rate reductions
  - FAQ: *"CMS is considering the assumptions it would be reasonable to make in the event a hospital does not adhere to the statute, including how those assumptions might be reflected **in that hospital's** future payment rates."*
- Final Rule: May impute values for non-responsive hospitals as equal to the lowest reported acquisition costs among similar hospitals, prices under the Federal Supply Schedule, 340B ceiling prices, or average sales price benchmarks. They also address packaging drug costs into APC payments for non-responders, **essentially not paying those providers separately for the 340B-acquired drugs on which they did not report.**

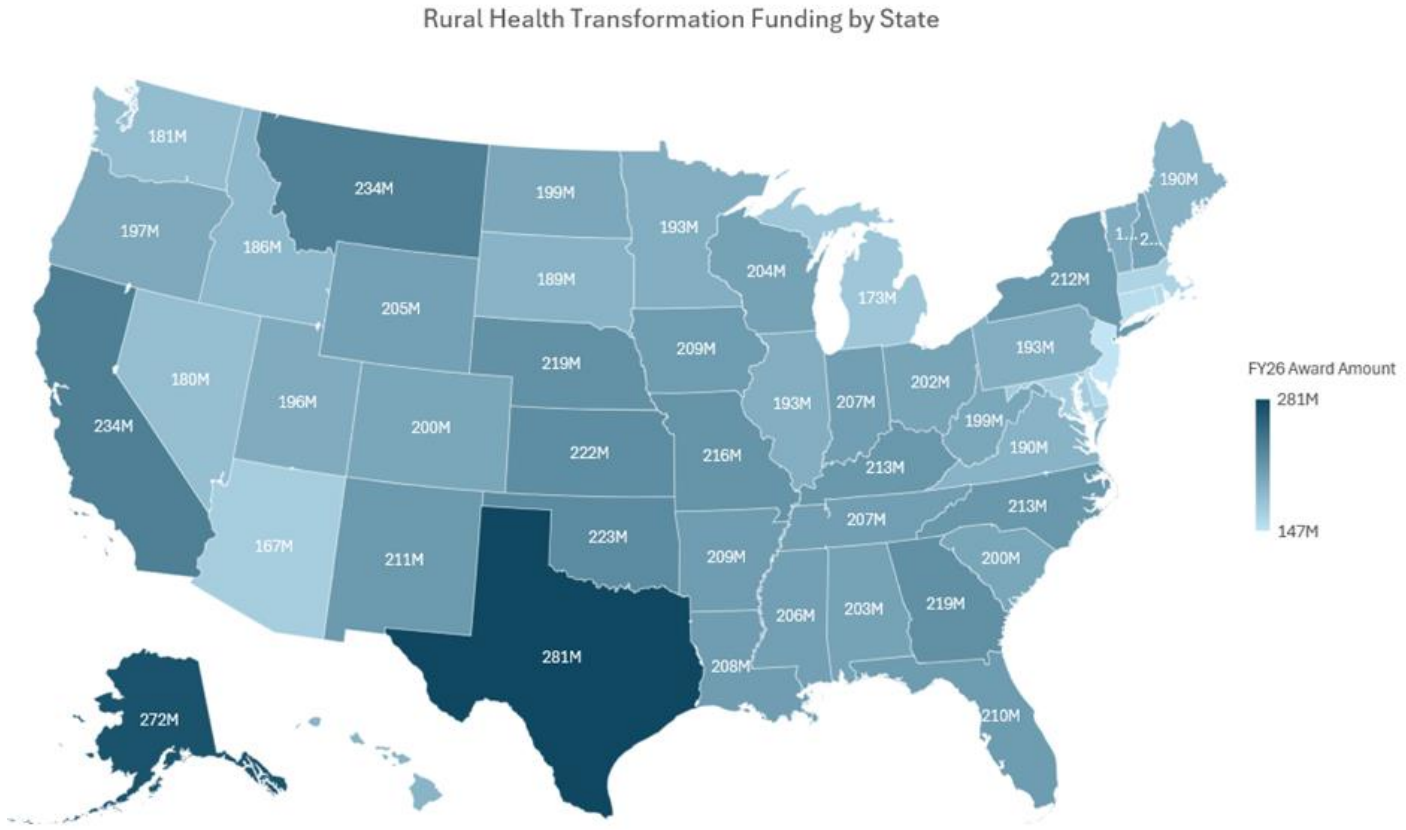
9. Rural Health Transformation Program Award Announcement

$50 Billion Over 5 Years (FY2026-FY2030)



- $10B available each year
- Baseline funding equally distributed among states with approved applications
- Workload funding based on “content and quality of your application and rural factors”
- Baseline and workload funds subject to same requirements
- All funds must be expended in support of initiatives detailed in State’s Rural Health Transformation Plan (including up to 10% for administration)
- All funds must be expended by end of fiscal year following receipt of funds

Year 1 Awards Announced December 29



- Awards ranged from $281.3M (Texas) to $147M (New Jersey)
- States must submit revised budgets to CMS by January 30
- CMS to approve release for specified expenditures (vs. lump-sum payments to states)
- Year 2 funding dependent on Year 1 performance
  - Year 1 performance report + Year 2 budget request due August 30

10. The Great Healthcare Plan

The Great Healthcare Plan

- Announced by President Trump on January 15
- Key components:
  - **Lower drug prices, including allowing more over-the-counter medicines**
  - **Lower insurance premiums**
    - Send dollars directly to eligible Americans rather than insurance companies
    - Fund cost-sharing reduction program for health plans
    - Cut PBM “kickbacks”
  - **Hold insurance companies accountable**
    - “Plain-English insurance” standard
    - Publish cost of overhead vs. claim payments
    - Display claim denial rates
  - **Increase price transparency**
    - “Post Prices on the Wall” – require any healthcare provider or insurer who accepts either Medicare or Medicaid to publicly and prominently post their pricing and fees to avoid surprise medical bills

11. CMS 2024 Health Expenditures Report

Galloping Growth…Where's It Taking Us?

- **U.S. healthcare spending in 2024 = $5.3 trillion**
  - Increased 7.2% in 2024 compared to 7.4% increase in 2023
  - Increased 279% since 2000
  - 18% of GDP; projected to reach 20.3% by 2033

- **Main drivers of higher spending are greater volumes and intensity of care, not prices**
  - Medical inflation rate (per unit prices) consistent with general inflation rate
  - Consistent with COVID-19 experience

Our Next Healthcare Regulatory Roundup Webinars

January 28, 2026, 11 am – 12 pm ET

Healthcare Regulatory Roundup #108

How to Mitigate Risk While Auditing for Revenue Integrity: Sample Design, Interpreting Results, & Navigating Compliance Next Steps

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