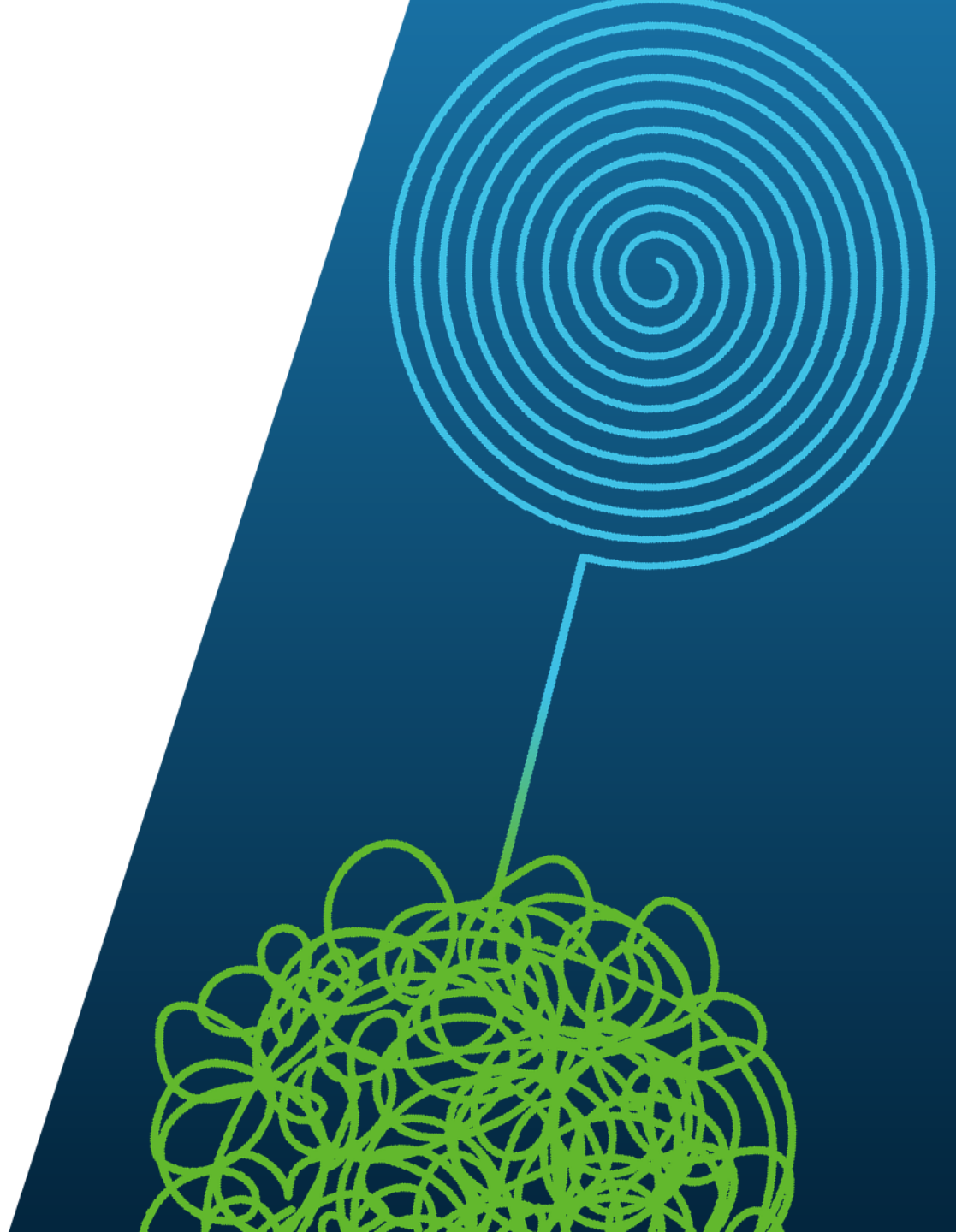
Healthcare Regulatory Roundup #102

Washington Updates: FY 2026 First Day, Fresh Questions

Happy New Federal Fiscal Year!

October 1, 2025



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. Government Shutdown
2. Rural Health Transformation Program Application Process
3. Congressional Hearings on Non-Profit Status for Hospitals
4. HB-1 Visa Fees
5. Pharmaceutical Tariffs

1. Government Shutdown


closed

So, What Does That Mean?

- Medicare funding is mandatory, and thus not impacted by shutdown
  - CMS: "MACs will continue to perform all functions related to Medicare Fee-for-Service claims processing and payment."
  - Approximately 50% of CMS workforce now furloughed
- HHS reports sufficient funds to continue Medicaid payments to states through Q1 2026
- Expired health care provisions:
  - **Medicare Dependent Hospital and Low Volume Hospital programs**
    - CMS will hold claims for 10 business days; retroactively reinstated following 2018 shutdown
  - **Reauthorization and additional funding for Community Health Center Fund**
    - FQHCs can continue to draw down Section 330 grant funding
    - Retroactively reinstated following 2018 shutdown
  - **Work GPCI floor + ambulance add-on payments**
    - CMS will hold claims for 10 business days; retroactively reinstated following 2018 shutdown
  - **ACA Medicaid DSH cuts**
    - Action to be determined at state level regarding distribution of quarterly payments
    - Delay in cuts was extended as part of legislation that ended 2018 shutdown
  - **Hospital at home**
    - Per CMS, "all inpatients must be discharged or returned to the hospital on September 30 … in the absence of Congressional action to extend the initiative"

Medicare Coverage for Telehealth

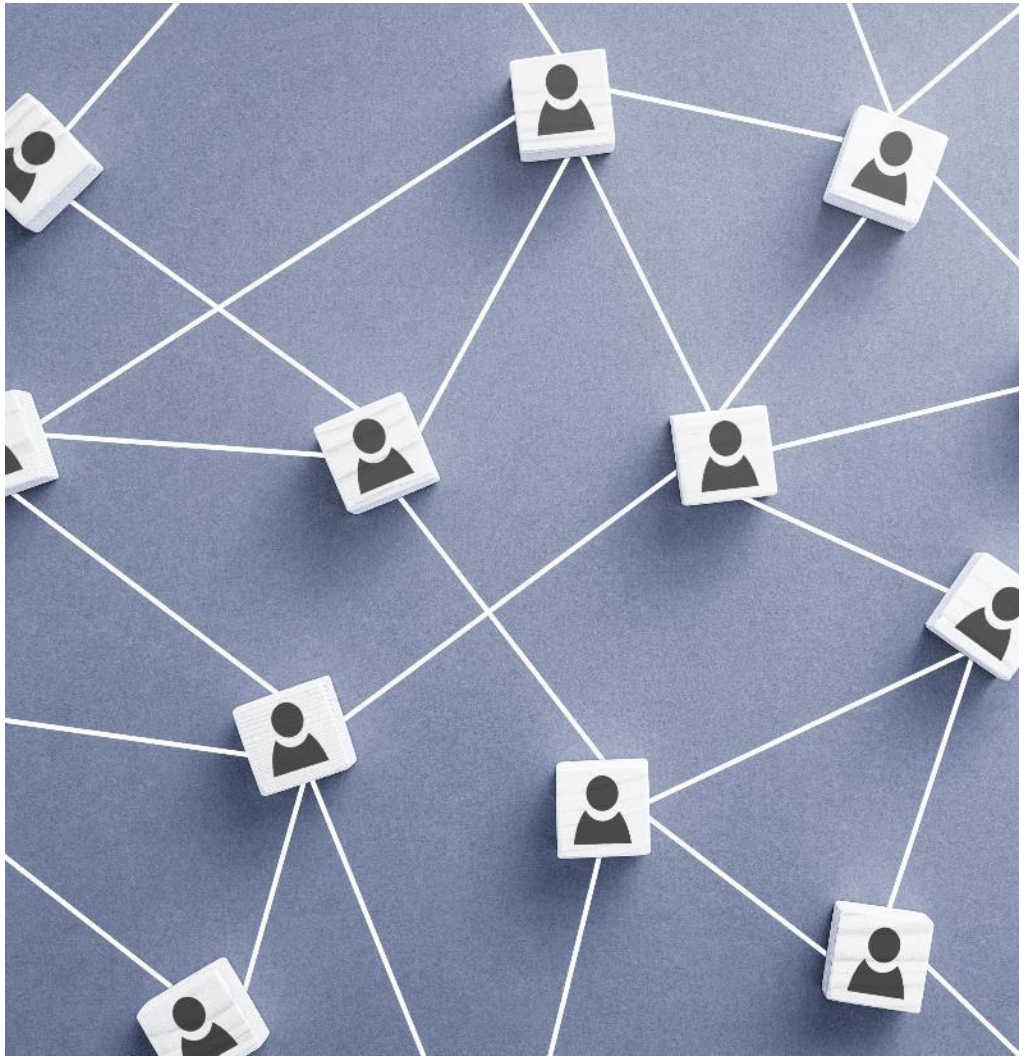
- As of today:
  - Medicare covers tele-behavioral health services furnished to beneficiary at home
    - May be billed by physicians, practitioners, and RHCs/FQHCs
    - (1) Must have face-to-face visit within 6 months of initiating telehealth services (delayed until 1/1/2026 for RHCs and FQHCs), and (2) must have face-to-face visit once every 12 months following initiation of tele-behavioral health services (with certain exceptions)
  - Medical telehealth services covered only if beneficiary physically present at a facility in rural area at time of service
  - PTs, OTs, and speech language pathologists cannot bill Medicare for telehealth services
  - Through 12/31/2025, RHCs/FQHCs may bill Medicare for medical telehealth services under HCPCS G2025 (~$97)
  - Medical telehealth services CMS previously identified as covered when using audio-only platform no longer covered
  - On a permanent basis, any telehealth service will be covered when furnished audio-only if (1) beneficiary is at home when service provided, (2) practitioner is capable of audio-video connection, and (3) beneficiary cannot or does not want to connect by video
- CMS: "[P]ractitioners who choose to perform telehealth services that are not payable by Medicare on or after October 1, 2025, may want to evaluate providing beneficiaries with an Advanced Beneficiary Notice of Noncoverage. Practitioners should monitor Congressional action and may choose to hold claims associated with telehealth services that are not payable by Medicare…."

Any Light at the End of the Tunnel?

- Need 60 votes in Senate to pass legislation ending shutdown
- Democratic leadership demands
  - Bill on which Senate voted on Sept. 19 included making ACA enhanced premium tax credits permanent, reversing OBBBA Medicaid cuts, and limits on Administration's ability to rescind or reallocate funds approved by Congress
  - Appears now focused on making ACA enhanced premium tax credits permanent
- Sequestration?

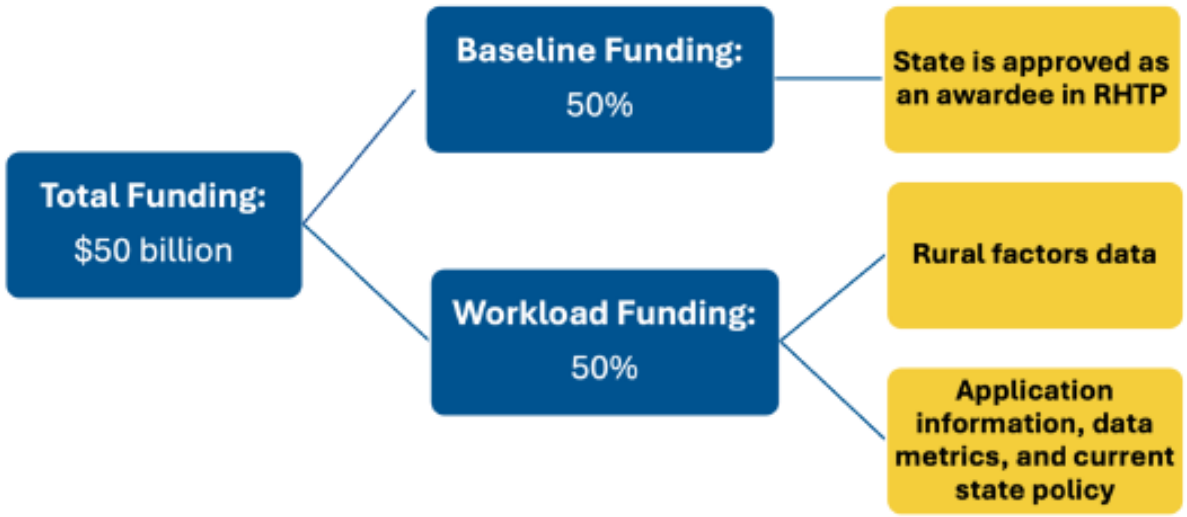
Never Let a Good Crisis Go to Waste

- Last week, White House budget office circulated memo to federal agencies directing them to prepare reduction-in force plans for mass firings during shutdown
- Goal is to permanently reduce size of federal workforce, not just managing through shutdown



2. Rural Health Transformation Program Application Process

$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
- States instructed to submit budget based on $200M/year award

Factor Scoring

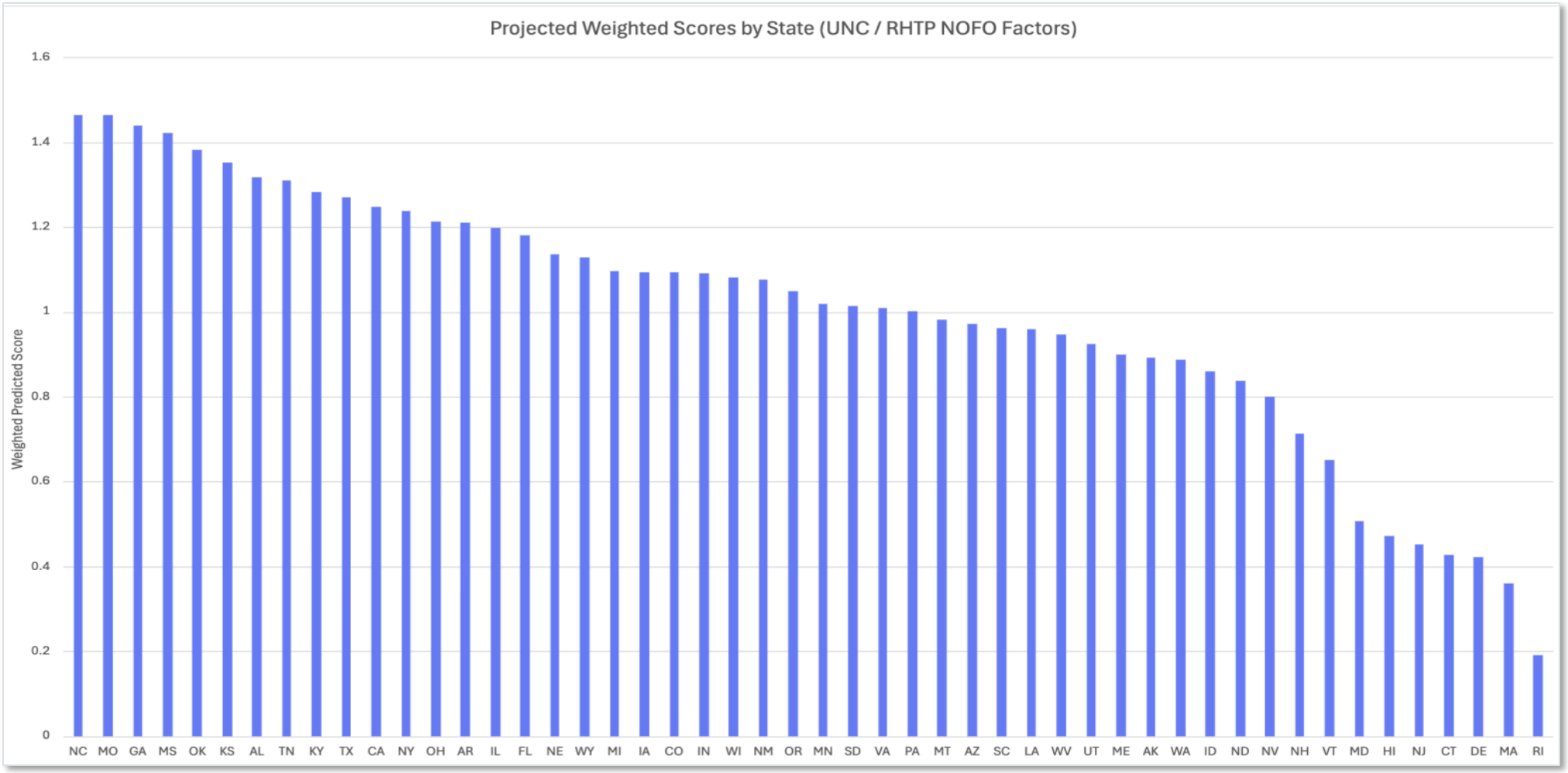
- Workload funding based on state's score across 23 factors relative to other states
  - Rural facility and population score factors
  - State policy factors
  - Initiative-based factors
- Each factor assigned 100 total points
- State's total point score for each budget period = weighted sum of score for each factor
  - Rural facility and population score factor points assessed once during Q4 2025
  - Other factors assessed annually based on state's progress on state policy and initiative-based factors

Rural Facility and Population Score Factors

- 7 data-driven factors – 50% total score
  1. Absolute size of rural population in a state – 10%
  2. Proportion of rural health facilities in a state – 10%
  3. Uncompensated care in a state – 10%
  4. % of state population located in rural areas – 6%
  5. Metrics that define a state as being frontier – 6%
  6. Area of a state in total square miles = 5%
  7. % of hospitals in a state that receive Medicaid DSH payments – 3%
- CMS will calculate states' scores
  - States to submit data on number of hospitals receiving Medicaid DSH payments

NOFO, Table 3

UNC Analysis



https://www.ruralhealth.us/programs/center-for-rural-health-innovation-and-system-redesign/rural-health-transformation-program/rhtp-resources/unc-analysis

8 State Policy Factors

1. Health and lifestyle (not counted in 2026) (25 points; other 75 points assigned to initiative-based factor) (0.9375%)
   - State requires schools to re-establish Presidential Fitness Test per Executive Order 14327
2. SNAP waivers (3.75%)
   - State has USDA-approved waiver prohibiting purchase of non-nutritious items with SNAP
3. Nutrition Continuing Medical Education (not counted in 2026) (1.75%)
   - State requires nutrition to be included in mandatory CME
4. Certificate of Need (1.75%)
   - State has 0 score on Cicero report (no CONs across facility categories)

8 State Policy Factors (cont.)

5. Licensure compacts (1.75%)
   - Average of physician, nurse, EMS, psychology, and physician assistant score
6. Scope of practice (1.75%)
   - Average of physician assistant, nurse practitioner, pharmacist, and dental hygienist score
7. Short-term limited-duration insurance (1.75%)
   - State does not restrict such insurance beyond latest federal guidance
8. Remote care services (50 points; other 50 points assigned to initiative-based) (1.875%)
   - Average of score based on Medicaid reimbursement for live video, store and forward, RPM, exceptions to in-state licensing, telehealth license/registration process

State Policy Factors

- CMS to access 3rd party resources to determine current state policy
  - State must include attestation regarding current policy in application
- State may receive partial credit by committing to specific policy changes
  - State must follow through on meeting policy commitments by 12.31.2027 (12.31.2028 for Presidential Fitness Test and nutrition requirement for physician CME)
  - Failure to meet policy commitment = claw-back of funds awarded based on commitment

10 Initiative-Based Factors

1. Population health clinical infrastructure (3.75%)
   - Enhancement of and/or creation of community-based initiatives
   - Strengthen rural health ecosystem through tech innovation, focus on primary care and behavioral health, expanded scope of practice
   - Coordination among providers, CBOs, and other stakeholders to improve access to care and social services
2. Health and lifestyle (2.8125%) (25 points assigned to state policy factor)
   - Evidence-based novel prevention-focused models on lifestyle changes, nutrition, exercise
   - Engagement of multiple stakeholders and community resources
3. Rural provider strategic partnerships (3.75%)
   - Exchange of best practices and care coordination partially facilitated through remote care services
   - Expand access to specialty services
   - Centralize/streamline back-office functions
   - Improve financial viability of rural providers, keep care local where appropriate
   - Converting (right-sizing) hospitals

10 Initiative-Based Factors (cont.)

4. EMS (3.75%)
   - State policy/infrastructure supporting coordination between EMS and other provider types (e.g., community paramedicine)
   - Infrastructure to support alternative site of care treatment ("in place" as part of emergency call)
   - Other investments to improve speed and access and reduce cost to deliver services
5. Talent recruitment (3.75%)
   - Career education infrastructure in rural communities (career pathways)
   - New residency training programs, fellowships tied to 5 years of service
   - Relocation grants tied to 5 years of service
   - IHS recruitment, as appropriate
   - Pathways for non-physician healthcare providers
6. Medicaid provider payment incentives (3.75%)
   - Payment mechanism incentivizing providers/ACOs to reduce costs, improve quality, shift to lower cost of care settings
   - Value-based programs with pathway to two-sided risk models supported by evidence suggesting will change patient/provider behavior

10 Initiative-Based Factors (cont.)

7. Dual eligible enrollment in integrated plans (3.75%)
   - Investments to promote enrollment, e.g., data integration, technical assistance to improve duals support and resources, enrollment support
8. Remote care services (50 points assigned to state policy factor) (1.875%)
   - Enhancement of state's remote care services infrastructure
9. Data infrastructure (3.75%)
   - Investments in EHR, clinical support, and operational software infrastructure upgrades that enable participation in data exchange and interoperability (aligned with CMS' Health Technology Ecosystem criteria and ASTP/ONC criteria, as applicable
10. Consumer-facing technology (3.75%)
    - Support development and appropriate usage/deployment of tools for prevention/management of chronic disease
    - Align with CMS' Health Technology Ecosystem criteria for patient-face apps, as applicable

Required Details For Each Initiative

1. Name (not to exceed 10 words)
2. General description
3. At least four quantifiable metrics to evaluate initiative's impact
   - Including data collection methodology for purposes of reporting on each metric
4. Timeline of proposed activities from FY26 to FY31
5. Estimate of annual funding for FY26 to FY 31
6. Sustainability plan
   - Specific strategies to ensure lasting change vs. temporary infusions of funding)

Scoring Criteria for Initiative-Based Factors

- Reviewers assign full score potential for each factor (maximum 100 points) based on 5 equally-weighted criteria:
  1. Strategy
  2. Workplan and Monitoring
  3. Outcomes
  4. Projected Impact
  5. Sustainability
- Initial score = 50% of full potential score
- Scores increase as state meets application milestones identified in application

Funding Restrictions

- No new construction
  - Renovations or alterations clearly linked to program goals permitted (e.g., hospital “right-sizing”), but capital expenditures and infrastructure capped at 20% of total funding in given budget period
- Cannot replace payment for clinical services that could be reimbursed by insurance (or change payment amounts of existing fee schedules)
  - Only pay for services not already reimbursable and needed to fill gap in care coverage and/or transform current delivery model; capped at 15% of total funding in given budget period
- No more than 5% of total funding in given budget period to replace EMR system if previous HITECH certified system in place
- Cannot back-fill programs that have lost funding

- No more than 10% of state’s allotment may be used for administrative purposes
- Cannot use funds to pay clinician salaries or wage supports for facilities that subject clinicians to non-competes
- Subject to federal salary rate limitation (currently $225,750)
- Funding for “start-up” initiatives cannot exceed lesser of 10% of total funding in given budget period or $20M per budget period + subject to specified restrictions/requirements
- Cannot use funds as expenditure that is attributable to intergovernmental transfer, certified public expenditure, or otherwise finance non-Federal share of expenditures required by law
- Other standard limits on grant expenditures

Noncompliance

- Significant state reporting requirements + CMS auditing to evaluate progress in meeting milestones and identify potential non-compliance
- Types of non-compliance
  - Using funds in manner inconsistent with application or program limitations
  - Using funds on unapproved activities
  - Failure to finalize proposed state policy actions
  - Not investing funds in manner that broadly affects state's rural areas and residents in positive manner
  - Failure to submit required reporting
  - Failure to follow through on initiative work plans
  - Violating award terms & conditions
  - Improperly managing funds
- Remedies
  - Must correct noncompliance within 90 days of notification
  - Failure to remedy = recover past payments and withhold further payments

3. Congressional Hearings on Non-Profit Status for Hospitals

Congressional Attention = Congressional Action?

- Recent hearings
  - July 2025: House Judiciary Subcommittee on Oversight, *How Leftist Nonprofit Networks Exploit Federal Tax Dollars To Advance a Radical Agenda*
  - September 2025: House Ways and Means Oversight Subcommittee, *Virtue Signaling vs. Vital Services: Where Tax-Exempt Hospitals Are Spending Your Tax Dollars*
- Key take-aways
  - Legislators and witnesses drew distinction between large not-for-profit health systems and rural hospitals
  - Apparent bi-partisan support for greater transparency and more detailed reporting requirements
- New area of interest: rural reclassification
  - In 2017, 3 hospitals had reclassified; by 2022 up to 425
  - Allows hospital to benefit from higher wage index while enjoying other benefits intended for rural hospitals (e.g., lower DSH percentage to qualify for 340b drug pricing program, expanded GME spots)

4. H1-B Visa Fees

$100K Employer Fee for H1-B Visas

- New program announced by Trump Administration on September 19
- Out-sized impact on health care employers – especially those in rural and underserved areas – that rely on H-1B visas to sponsor doctors and medical students.
  - Numerous stakeholders have expressed significant concerns regarding rural hospitals' ability to meet their communities' needs.
  - Concerted push to convince Administration to exempt employers of doctors and medical students

5. Pharmaceutical Tariffs

Current Status?

- In July, Trump Administration announced deal with European Union capping tariffs on pharmaceuticals at 15% (excluding generic drugs).
- On July 31, President Trump sent letter to 17 manufacturers giving them until September 30 to comply with May 12 Executive Order regarding most favored nation pricing.
- On September 25, President posted on his Truth Social account:
  - "Starting October 1st, 2025, we will be imposing a 100% Tariff on any branded or patented Pharmaceutical Product, unless a Company IS BUILDING their Pharmaceutical Manufacturing Plant in America. 'IS BUILDING' will be defined as, 'breaking ground' and/or 'under construction.' There will, therefore, be no Tariff on these Pharmaceutical Products if construction has started."
- On September 30, Pfizer and Trump Administration announced Pfizer has agreed to most favored nation pricing for Medicaid in exchange for tariff relief.
  - Pfizer also will participate in newly-announced TrumpRx.gov website that will take consumers to pharmaceutical companies' direct-to-consumer websites to fulfill order.

Our Next Healthcare Regulatory Roundup Webinars

November 12, 2025; 11 am – 12 pm ET

Healthcare Regulatory Roundup #103: OPPS Final Rule

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