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Health Care Rulemakings to Watch in the Trump Administration's Unified Agenda

Key Takeaways:

- The Trump Administration recently released its semiannual Unified Agenda, providing an early look at the federal rulemakings agencies expect to pursue over the coming year and the Administration's broader regulatory priorities.
- While timelines may shift, the agenda gives organizations advance notice of regulatory actions that could affect reimbursement, privacy, health IT, drug regulation and fraud and abuse enforcement.
- Organizations should use the agenda to plan ahead, monitoring agency activity, incorporating expected rulemakings into strategic planning and identifying opportunities to comment on proposals that may affect their operations.

The Trump Administration released its semiannual Unified Agenda over the Fourth of July weekend, providing the clearest roadmap yet of the rulemaking priorities federal agencies expect to pursue over the next year. For health care organizations and other regulated businesses, the agenda serves as an important planning tool, offering advance notice of forthcoming rulemakings, opportunities to engage in the regulatory process and insight into the Administration's broader policy priorities before formal proposals are published.

Understanding the Unified Agenda and Its Rulemaking Timelines

A form of this requirement has been in place since 1978, and the fall edition of the Unified Agenda additionally includes the Regulatory Plan, which outlines significant future policy actions. Agencies have some discretion to speed up or delay work on a rulemaking and these schedules are good faith estimates of how long it will take executive branch offices to reach each milestone in the regulatory process.

Because notice and comment rulemaking procedure is clearly outlined in statute, it also is in the interest of each agency to carefully follow sufficient timelines associated with unveiling an Advance Notice of Proposed Rulemaking (ANPRM), a Notice of Proposed Rulemaking (NPRM), or a Final Rule to ensure that administrative actions are not legally challenged. Regulators also can expect Congressional oversight of the Unified Agenda and projected work during Capitol Hill hearings or anytime through official Congressional

Related People

- Sylvia Kornegay
- Mark W. Weller
- Steve Stranne
- Julius W. Hobson, Jr.
- Ronke Fabayo
- Michael M. Gaba

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Key Health Care Rulemakings to Watch

In addition to the annual Medicare payment rules with which we are all familiar, the Unified Agenda includes dozens of planned regulatory actions impacting public health, health care settings and providers. The sampling below highlights notable items by sector, with links to the corresponding Unified Agenda entries. Additional health care actions are outlined by the Department of Labor and Department of the Treasury.

Medicare and Medicaid

- **CMS proposed rule:** CY 2027 Physician Fee Schedule (CMS-1848)
  - *Next action (projected): July 2026*
- **CMS proposed rule:** FY 2027 Hospital Inpatient PPS (CMS-1849)
  - *Next action (projected): July 2026*
- **CMS proposed rule:** CY 2027 Hospital Outpatient PPS and ASC Payment System (CMS-1850)
  - *Next action (projected): July 2026*
- **CMS proposed rule:** CY 2028 Medicare Advantage and Part D (CMS-4214)
  - *Next action (projected): September 2026*
- **CMS proposed rule:** Medicare Drug Price Negotiation Program (CMS-4215)
  - *Next action (projected): July 2026*
- **CMS final rule:** Transparency in Coverage (CMS-9882)
  - *Next action (projected): July 2026*
- **CMS proposed rule:** Medicaid Managed Care State Directed Payments (CMS-2449)
  - *Next action (projected): July 2026*
- **CMS proposed rule:** Medicaid and CHIP Managed Care Integrity (CMS-2450)
  - *Next action (projected): July 2026*

Drugs and Biologics

- **FDA proposed rule:** Current Good Manufacturing Practice for Outsourcing Facilities
  - *Next action (projected): October 2026*
- **FDA proposed rule:** Biologics Regulation Modernization
  - *Next action (projected): October 2026*
- **FDA proposed rule:** Distribution of Compounded Drug Products
  - *Next action (projected): November 2026*
- **FDA proposed rule:** Pediatric Study Plan Requirements for New Drug and Biologics License Applications
  - *Next action (projected): November 2026*
- **FDA proposed rule:** Drug Supply Chain Transparency in Labeling
  - *Next action (projected): July 2026*

HIPAA, Health IT

- **CMS proposed rule:** Modifications to the HIPAA Electronic Transaction Standards (CMS-0061)
  - *Next action (projected): December 2026*
- **CMS proposed rule:** Interoperability Standards and Prior Authorization for Drugs (CMS-0062)
  - *Next action (projected): July 2026*
- **OCR proposed rule:** HIPAA Privacy Rule: Timely Access to Protected Health Information

    - *Next action (projected): November 2026*
- **OS final rule:** HHS Acquisition Regulation: Health IT Standards
    - *Next action (projected): February 2027*

Mental Health

- **CMS proposed rule:** Mental Health Parity and Addiction Equity Act Requirements (CMS-9878)
    - *Next action (projected): December 2026*

Waste, Fraud and Abuse

- **OIG prerule:** Anti-Kickback Statute and Beneficiary Inducements RFI
    - *Next action (projected): July 2026*
- **CMS proposed rule:** CRUSH Initiative (CMS-6098)
    - *Next action (projected): October 2026*
- **CMS proposed rule:** Cutting Administrative Requirements for Excellence in Patient Care (CMS-3484)
    - *Next action (projected): August 2026*
- **CMS proposed rule:** Exchange Pre-Enrollment Eligibility Verification (CMS-9873)
    - *Next action (projected): July 2026*
- **CMS proposed rule:** Section 1115 Demonstration Integrity (CMS-2412)
    - *Next action (projected): January 2027*
- **CMS final rule:** Accrediting Organization Oversight and Burden Reduction (CMS-3367)
    - *Next action (projected): February 2027*

How Organizations Can Prepare for Upcoming Federal Rulemakings

Organizations can take several practical steps now to prepare for the regulatory actions outlined in the Unified Agenda:

1. **Monitor agency activity.** Entities are advised to work with both their internal and external legal and compliance teams, including their Polsinelli contacts, to monitor agency statements, testimony and guidance on relevant topics as these deadlines near. These materials could preview an agency's approach to an upcoming regulation.
2. **Incorporate pending rulemakings into strategic planning.** Organizations additionally are encouraged to factor pending regulatory action into their future strategic planning, including advocacy, particularly in instances where an agency is preparing to unveil a final rule designed for immediate or near-term implementation (barring court action like a Temporary Restraining Order or temporary injunction).
3. **Evaluate opportunities to comment.** Lastly, organizations also should weigh whether to submit comments on proposed rules that may affect their operations. Even when an entity ultimately decides not to file comments, evaluating a proposed rule can provide valuable insight into legal, operational, financial and strategic implications.

Polsinelli's health care practice and bipartisan Public Policy Group work with clients to assess proposed regulations, develop advocacy strategies, engage with federal agencies and Congress where appropriate, and navigate the evolving regulatory landscape.

For questions on this regulatory schedule and next steps your organization or business should take, contact the Polsinelli Public Policy Group or your Polsinelli attorney.