

CHIME Cheat Sheet – July 11, 2024 Annual Regulatory Outlook

Overview

Each year, on a semiannual basis, the White House’s Office of Information and Regulatory Affairs (OIRA) publishes what is called the “Unified Agenda of Regulatory and Deregulatory Actions Publication” in the [Federal Register](#). The “Fall Unified Agenda” is generally released in January, while the “Spring Unified Agenda” is generally released in late June.

The Unified Agendas provide important public notice and transparency about proposed regulatory and deregulatory actions within the Executive Branch. Additionally, they report on the actions administrative agencies (e.g., the Department of Health and Human Services [HHS], the Centers for Medicare and Medicaid Services [CMS], and the Office of the National Coordinator for Health IT [ONC]) plan to issue in the near and long-term. In short, the Unified Agenda is a blueprint of what actions the Administration has planned.

The complete Unified Agenda and Regulatory Plan can be found [here](#); the HHS Statement of Regulatory Priorities for the remainder of fiscal year (FY) 2024 and through 2025 can be found [here](#), the HHS preamble can be found [here](#), and additional background information can be found [here](#).

Summary

This year’s “Spring 2024 Unified Agenda” – or “Regulatory Plan” – was published on July 5, 2024. Agencies will consider the regulatory actions outlined in this agenda in the coming months and the administration will continue to engage with Congress, the public, and stakeholders to include additional regulations.

Across the many federal agencies under the Department of Health and Human Services’ (HHS) umbrella, there are additional regulatory actions that CHIME’s Public Policy team are monitoring closely, given their potential impact on our members. The regulatory actions forecasted in the HHS Agenda reflect the priorities of Secretary Xavier Becerra and the administration.

While the Agenda list is fairly comprehensive, there remains the possibility that agencies will release regulations or “Requests for Information” (RFIs) that are not published in the Unified Agenda. Additionally, agencies such as the Food and Drug Administration (FDA) release other forms of policy action such as “Guidance Documents” that are not listed in the Agenda. We keep our ear to the ground and keep our members apprised of any federal policy making that will impact them and their organizations.

Additionally, the Congressional Review Act (CRA)¹ is a mechanism Congress can use to overturn actions taken by federal agencies. The CRA is most frequently used during a change in administration and when there is a shift in majority control – although it has only been successful to overturn a relatively small number of rules, given that this year is a presidential election year it is worth mentioning. Most recently, the CRA was used in the 115th Congress to repeal 16 rules promulgated by the Obama administration and was utilized again in the 117th Congress to similarly repeal three rules promulgated by the Trump administration.²

¹ 5 U.S.C. §§ 801-808

² *Congressional Review Act | Overview and tracking*. (2024, July 5). <https://www.ncsl.org/state-federal/congressional-review-act-overview-and-tracking>

Also of note, the recent Supreme Court decision to overturn the Chevron deference precedent — a 40-year-old legal doctrine that required courts to defer to federal agencies' reasonable interpretations of ambiguous statutes — could fundamentally impact the federal rulemaking process. Federal agencies operating in the healthcare space have revised and added numerous regulatory priorities for 2024 through this Unified Agenda. However, courts now have greater discretion to reject these agencies' expertise or interpretations, calling into question how federal agencies will issue rulemaking in light of the decision.

Timing of Release of Rules

Additionally, while the Unified Agenda includes the month and year regulatory actions are planned to be released, these dates are often subject to delays and/or changes. These dates are considered targeted publication dates, and many are aspirational. CHIME's Public Policy Team monitors the White House's Office of Management and Budget (OMB) and OIRA for when these rules are ["under review"](#) — the final phase before they are released and thus has a better sense of when rules are forthcoming. As a previous Agenda noted:

Agencies prepared entries for this publication to give the public notice of their plans to review, propose, and issue regulations. They have tried to predict their activities over the next 12 months as accurately as possible, but dates and schedules are subject to change. Agencies may withdraw some of the regulations now under development, and they may issue or propose other regulations not included in their agendas. Agency actions in the rulemaking process may occur before or after the dates they have listed. The Unified Agenda does not create a legal obligation on agencies to adhere to schedules in this publication or to confine their regulatory activities to those regulations that appear within it.³

Finally, "Long-Term Actions" are rulemakings reported during the publication cycle that are outside of the required 12-month reporting period for which the Agenda was intended. Long-Term RINs "do not represent the ongoing, forward-looking nature intended for reporting developing rulemakings in the Agenda."⁴ Therefore, to differentiate Long-Term Actions from active rulemakings, they are reported separately, and listed as such in the chart below.

CMS Cyclical Rulemaking & Additional Regulatory Actions

Annual payment regulations – including the Inpatient Prospective Payment System (IPPS) and Physician Fee Schedule (PFS) – are proposed and finalized at around the same general time each year. The IPPS rule is proposed in April and finalized in August, and the PFS rule is proposed between June and July, and finalized in November.

Below is a chart of additional regulatory actions CHIME will be paying close attention to from agencies under HHS, including policies from the Centers for Medicare and Medicaid Services (CMS), the Office of the Inspector General (OIG), the Office for Civil Rights (OCR), and the Office of the National Coordinator for Health IT (ONC). Additionally, there are regulatory actions from the Department of Homeland Security (DHS), the Department of Justice (DOJ), the Federal Trade Commission (FTC), and the Federal Communications Commission (FCC) that we will be monitoring.

Contact Us

The chart below includes proposed and final rules included in the administration's Spring 2024 Unified Agenda that will likely be of significant impact and interest to our members.

³ *Introduction to the Unified Agenda of Federal Regulatory and Deregulatory Actions-Spring 2023*. (2023, June 14). [www.reginfo.gov. https://www.reginfo.gov/public/jsp/eAgenda/StaticContent/202304/RiscPreamble.pdf](https://www.reginfo.gov/public/jsp/eAgenda/StaticContent/202304/RiscPreamble.pdf).

⁴ Pursuant to Executive Order 12866, section 4(b) and 4(c)

It is important to note that outside of the information included in the brief “Abstract” under each action (i.e., Regulation Identifier Number or RIN), we cannot know the details of the policies that will be included in the proposed or final actions. You can find the “Abstract” for each in the chart below under the “Links” column.

If you want to get involved in shaping public policy with us, you can contact us anytime to let us know if you are interested in any of these regulations, and/or lend us your expertise as we comment on some of these important proposals. Please reach out to policy@chimecentral.org if you are interested or have any questions.

CHIME Public Policy Cheat Sheet – Regulations to Watch				
Title	Agency	Expected Date	Stage	RIN Link
Healthcare System Resiliency and Modernization	HHS-CMS	July 2024	Proposed Rule	View Rule (reginfo.gov)
Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers II	HHS-CMS	July 2024	Proposed Rule <i>(to be merged w/Healthcare System Resiliency & Modernization)</i>	View Rule (reginfo.gov)
Administrative Simplification: Modifications to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Electronic Transaction Standards Version 8020	HHS-CMS	Dec. 2024	Proposed Rule	View Rule (reginfo.gov)
Interoperability Standards and Prior Authorization for Drugs	HHS-CMS	Nov. 2024	Proposed Rule	View Rule (reginfo.gov)
Administrative Simplification: Adoption of Standards for Health Care Attachment Transactions and Electronic Signatures	HHS-CMS	Nov. 2024	Final Action	View Rule (reginfo.gov)
Administrative Simplification: Modifications of Operating Rules for Eligibility for a Health Plan, Health Care Claim Status and Health Care EFT and ERA Transactions	HHS-CMS	March 2025	Interim Final Rule	View Rule (reginfo.gov)
Proposed Modifications to the HIPAA Security Rule to Strengthen the Cybersecurity of Electronic Protected Health Information	HHS-OCR	Dec. 2024	Proposed Rule	View Rule (reginfo.gov)
Privacy Act Regulations	HHS-OS	Sept. 2024	Proposed Rule	View Rule (reginfo.gov)
Health and Human Services Acquisition Regulation: Standards for Health Information Technology	HHS-OS	July 2024	Proposed Rule	View Rule (reginfo.gov)
Special Registrations for Telemedicine and Limited State Telemedicine Registrations	DOJ-DEA	Sept. 2024	Supplemental Proposed Rule	View Rule (reginfo.gov)

Cyber Incident Reporting for Critical Infrastructure Act (CIRCA) Reporting Requirements	DHS-CISA	Oct. 2025	Final Rule	View Rule (reginfo.gov)
Children's Online Privacy Protection Rule	FTC	July 2024	Staff Review of Public Comments	View Rule (reginfo.gov)
Long-Term Actions				
HIPAA Privacy: Changes to Support, and Remove Barriers to, Coordinated Care and Individual Engagement	HHS-OCR	Nov. 2025	Final Action	View Rule (reginfo.gov)
Rulemaking Implementing Provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act, as Amended	HHS-OCR	May 2026	Proposed Rule	View Rule (reginfo.gov)
Broadband Data Collection	FCC	TBD	TBD	View Rule (reginfo.gov)