

CHIME Cheat Sheet – July 10, 2023 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 preamble can be found [here](#); additional background information can be found [here](#).

Summary

This year’s “Spring 2023 Unified Agenda” – or “Regulatory Plan” – was [published](#) on June 14, 2023. Agencies will also be continuing to implement landmark new legislation passed in 2022, including the implementation of the Inflation Reduction Act, ([P.L. 117–169](#)); and the CHIPS and Science Act, ([P.L. 117–167](#)); as well as ongoing efforts to implement the Infrastructure Investment and Jobs Act (Bipartisan Infrastructure Law, [P.L. 117–58](#)).

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. 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. 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.

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.

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 the Spring Agenda notes:

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.¹

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.”² 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 (HHS-OIG), the FDA, the Office for Civil Rights (OCR), and the Office of the National Coordinator for Health Information Technology (ONC). Additionally, there are regulatory actions from the Department of Homeland Security (DHS), the Department of Commerce (DOC), 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 2023 Unified Agenda that will likely be of significant impact and interest to our members. 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 in 2023 & 2024				
Title	Agency	Expected Date	Stage	Link
Health and Human Services Acquisition Regulation: Standards for Health Information Technology	HHS-ONC	June 2023	Proposed Rule	View Rule (reginfo.gov)
Standards for Safeguarding Customer Information	FTC	Effective June 9, 2023	Final Rule	View Rule (reginfo.gov)
Establishment of Disincentives for Health Care Providers who Have Committed Information Blocking	HHS-ONC	Sept. 2023	Proposed Rule	View Rule (reginfo.gov)

¹ Introduction to the Unified Agenda of Federal Regulatory and Deregulatory Actions-Spring 2023. (2023, June 14). www.reginfo.com. <https://www.reginfo.gov/public/jsp/eAgenda/StaticContent/202304/RiscPreamble.pdf>.

² Pursuant to Executive Order 12866, section 4(b) and 4(c)

Nondiscrimination Provisions for Confidentiality of Substance Use Disorder Patient Records	HHS-OCR	Sept. 2023	Proposed Rule	View Rule (reginfo.gov)
Confidentiality of Substance Use Disorder Patient Records	HHS-OCR	Oct. 2023	Final Action	View Rule (reginfo.gov)
Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability	HHS-ONC	Nov. 2023	Proposed Rule	View Rule (reginfo.gov)
Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Exclusion Authorities	HHS-OIG	Nov. 2021	Proposed Rule	View Rule (reginfo.gov)
Taking Additional Steps to Address the National Emergency With Respect to Significant Malicious Cyber-Enabled Activities	DOC-ADMIN	Sept. 2023	Proposed Rule	View Rule (reginfo.gov)
Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers II	HHS-CMS	Dec. 2023	Proposed Rule	View Rule (reginfo.gov)
Medical Devices; Quality System Regulation Amendment	HHS-FDA	Dec. 2023	Final Rule	View Rule (reginfo.gov)
Medications for the Treatment of Opioid Use Disorder	HHS-SAMHSA	Jan. 2024	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	March 2024	Proposed Rule	View Rule (reginfo.gov)
Cybersecurity Incident Reporting for Critical Infrastructure Act Regulations	DHS-CISA	March 2024 Sept. 2025	Proposed Rule Final Rule	View Rule (reginfo.gov)

Privacy Act Regulations	HHS-OS	May 2024	Proposed Rule	View Rule (reginfo.gov)
Long-Term Actions				
HIPAA Privacy: Changes to Support, and Remove Barriers to, Coordinated Care and Individual Engagement	HHS-OCR	Dec. 2024	Final Rule	View Rule (reginfo.gov)
Request for Information Regarding Electronic Prior Authorization in the ONC Health IT Certification Program	HHS-ONC	TBD	Undetermined	View Rule (reginfo.gov)
Interoperability and Prior Authorization for MA Organizations, Medicaid and CHIP Managed Care and State Agencies, FFE QHP Issuers, MIPS Eligible Clinicians, Eligible Hospitals and CAHs	HHS-CMS	Dec. 2025	Final Action	View Rule (reginfo.gov)
Rural Health Care Support Mechanism	FCC	TBD	Undetermined	View Rule (reginfo.gov)