

CHIME Cheat Sheet – January 18, 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 July. 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., HHS, CMS, 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](#); additional background information can be found [here](#).

Summary

This year’s “Fall 2022 Unified Agenda” – or “Regulatory Plan” – was [published](#) on Jan. 4, 2023. Agencies will also be continuing to implement landmark new legislation passed in 2022, including the implementation of the Inflation Reduction Act, ([Pub. L. 117–169](#)); and the CHIPS and Science Act, ([Pub. L. 117–167](#)); as well as ongoing efforts to implement the Infrastructure Investment and Jobs Act (Bipartisan Infrastructure Law, [Pub. 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 Fall 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 Regulatory Plan and Unified Agenda do 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 separately in [the chart below](#).

CMS Cyclical Rulemaking

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, 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).

ONC Information Blocking and Certification Proposed Rule

One of the major proposed rules we are anticipating any day now is from ONC; the Unified Agenda indicated a Dec. 2022 release, and this proposal has been [under review](#) at OMB since Sept. 1, 2022. Below is the “Abstract” as described in the Fall 2022 Unified Agenda under its RIN:

- **Title:** ONC Health IT Certification Program Updates, Health Information Network Attestation Process for the Trusted Exchange Framework and Common Agreement, and Enhancements to Support Information Sharing
Abstract: The rulemaking implements certain provisions of the 21st Century Cures Act, including: the Electronic Health Record Reporting Program condition and maintenance of certification requirements under the ONC Health IT Certification Program; a process for health information networks that voluntarily adopt the Trusted Exchange Framework and Common Agreement (TEFCA) to attest to such adoption of the framework and agreement; and enhancements to support information sharing under the information blocking regulations. The rulemaking would also include proposals for new standards and certification criteria under the Certification Program related to the United States Core Data for Interoperability, real-time benefit tools, electronic prior authorization, and potentially other revisions to the Certification Program.

As detailed further below, there are additional regulatory actions expected from ONC.

Contact Us

The chart below includes this proposed rule, as well as the other proposed and final rules included in the Administration’s Fall 2022 Unified Agenda that will likely be of significant impact and interest to our members. If you are interested in shaping public policy with us, you can [join](#) CHIME’s “Regulatory Advisory Team” and lend us your expertise as we comment on some of these important proposals. You can also just email us anytime and let us know you’re interested! Please reach out to policy@chimecentral.org if you have any questions or would like to discuss anything public policy.

¹ *Introduction to the Unified Agenda of Federal Regulatory and Deregulatory Actions-Fall 2022.* (2022, December 20). www.reginfo.com. Retrieved January 16, 2023, from <https://www.reginfo.gov/public/jsp/eAgenda/StaticContent/202210/RiscPreamble.pdf>

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

CHIME Public Policy Cheat Sheet – Regulations to Watch in 2023

Title	Agency	Expected Date	Stage	Link
ONC Health IT Certification Program Updates, Health Information Network Attestation Process for the Trusted Exchange Framework and Common Agreement, and Enhancements to Support Information Sharing	HHS-ONC	Any day now (Dec. 2022)	Proposed Rule	https://www.reginfo.gov/public/do/eAgendaViewRule?publd=202210&RIN=0955-AA03
Amendments to Civil Monetary Penalty Law Regarding Grants, Contracts, and Information Blocking	HHS-OIG	March 2023	Final Rule	https://www.reginfo.gov/public/do/eAgendaViewRule?publd=202210&RIN=0936-AA09
HIPAA Privacy: Changes to Support, and Remove Barriers to, Coordinated Care and Individual Engagement	HHS-OCR	March 2023	Final Rule	https://www.reginfo.gov/public/do/eAgendaViewRule?publd=202210&RIN=0945-AA00
Establishment of Disincentives for Health Care Providers who Have Committed Information Blocking	HHS-ONC	Sept. 2023	Proposed Rule	https://www.reginfo.gov/public/do/eAgendaViewRule?publd=202210&RIN=0955-AA05
Patient Engagement, Information Sharing, and Public Health Interoperability	HHS-ONC	Nov. 2023	Proposed Rule	https://www.reginfo.gov/public/do/eAgendaViewRule?publd=202210&RIN=0955-AA06
Long-Term Actions				
Rulemaking Implementing Provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act, as Amended	HHS-OCR	March 2024	Proposed Rule	https://www.reginfo.gov/public/do/eAgendaViewRule?publd=202210&RIN=0945-AA04
Request for Information Regarding Electronic Prior Authorization in the ONC Health IT Certification Program	HHS-ONC	TBD	Undetermined	https://www.reginfo.gov/public/do/eAgendaViewRule?publd=202210&RIN=0955-AA04
Medical Devices; Quality System Regulation Amendments	HHS-FDA	Dec. 2023	Final Rule	https://www.reginfo.gov/public/do/eAgendaViewRule?publd=202210&RIN=0910-AH99