



CHIME Policy & Politics Monthly Webinar

Return from Recess - What to Watch for in September
August 17, 2023



Speakers



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Congressional Update

Congressional Calendar – What to Know

- The Senate returns on Tuesday, Sept. 5 and the House of Representatives returns on Tuesday, Sept. 12.
- There are 17 session days scheduled in the Senate and 12 in the House
 - What does this mean?
- The biggest priority in September is passing a government funding bill. Congress must pass a bill before Sept. 30 to avoid a government shutdown
 - The start of Fiscal Year 2024 starts on Oct. 1

Senate Calendar

SEPTEMBER						
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30

House Calendar

SEPTEMBER						
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30

What We're Watching – Congressional Government Funding Update

- **Positive development:** Congressional leaders have publicly agreed on a strategy to avert a government shutdown at the end of next month.
- Speaker Kevin McCarthy (R-CA) told the GOP Conference that he is eying a continuing resolution (CR) that would keep the government funded into early December.
- The timing would allow for appropriators to finalize all 12 spending bills to avoid both a holiday season legislative pile-up, as well as a one percent across-the-board spending cut that would go into effect if the measures are not passed by the end of the year.
- Senate Majority Leader Chuck Schumer (D-NY) expressed support for the framework that Speaker McCarthy outlined, telling reporters that a short-term funding bill “makes a good deal of sense.”

What We're Watching – Congressional AI

- Earlier this year, Senate Majority Leader Chuck Schumer (D-NY) announced plans to develop a comprehensive, bipartisan policy proposal for regulating AI.
 - He convened a small bipartisan working group to craft the proposal
 - Members include Schumer, Young, Heinrich, and Rounds
 - "AI Insight" briefings will start in Sept.
- Separately, the New Dems Coalition [announced](#) their first ever AI Working Group.
 - The group is led by Working Group Chair Derek Kilmer and Vice Chairs Don Beyer (VA-08), Jeff Jackson (NC-14), Sara Jacobs (CA-51), Susie Lee (NV-02), and Haley Stevens (MI-11).
 - Details are scarce; find the full list of members [here](#)
- Additionally, individual members are weighing in as well. Examples:
 - On Aug. 16, Sen. Warner sent letters to companies that have not participated in the administration's efforts to move toward the safe development of AI technology.
 - [Fact sheet](#) on voluntary commitments from 7 AI companies
 - Reps. Lieu, (D-CA), Eshoo (D-CA), and Buck (R-CO) have introduced legislation that would create a commission to review, recommend, and establish AI regulations
- Moving vehicles for AI legislation?

What We're Watching – Congressional PAHPA

- When Congress comes back from August recess, they will have to contend with the reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA).
 - PAHPA is set to expire on Sept. 30th
- Both the House and Senate have introduced respective pieces of legislation ([H.R. 4421](#); [S. 2333](#)) aimed at reauthorizing the programs contained within the original law.
- PAHPA is responsible for the creation of: (1) the Assistant Secretary for Preparedness and Response (ASPR) position at the Department of Health and Human Services (HHS); (2) the Biomedical Advanced Research and Development Authority (BARDA); and (3) the ability to develop medical countermeasures, among several other items.
- CHIME is asking lawmakers to add cyber-attacks to the list of threats eligible for tapping into ASPR's Hospital Preparedness Program (HPP), the only source of federal funding for healthcare delivery system readiness.
 - [Learn more](#)



Federal Update

What We're Watching – Regulations

Check out CHIME's Regulatory Cheat Sheet [here](#)

Regulations Recently Commented On

- FTC – Health Breach Notification Rule proposal [here](#)
 - CHIME comment letter [here](#)

Regulations Coming Soon

- ONC proposed rule – Establishment of Disincentives for Health Care Providers who Have Committed Information Blocking
- FDA Final Guidance Document – Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions - Draft Guidance for Industry and Food and Drug Administration Staff (Draft Guidance [here](#))
 - CHIME & AEHIS comment letter [here](#)
- ONC final rule – Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1)



FEDERAL REGISTER

The Daily Journal of the United States Government



Changes to ePrescribing via Telehealth

The Drug Enforcement Administration (DEA) may loosen policies related to electronic prescribing via telehealth

- In preparation for end of COVID-19 Public Health Emergency (PHE), in Feb., the DEA issued a [proposal](#) on ePrescribing controlled substances
 - Would have limited telemedicine prescribing of controlled substances (schedules 2-5) for new patients (i.e., new during COVID-19 PHE) – including buprenorphine, to a 30-day initial supply
 - In-person visit then required
- Proposal received significant pushback from stakeholders
- Thus, DEA delayed/extended proposal until Nov. 11; will hold listening sessions Sept. 12-13
 - "DEA is open to considering – for some controlled substances – implementation of a separate Special Registration for telemedicine prescribing for patients without requiring the patient to ever have had an in-person medical evaluation at all."

Final IPPS Rule

- On Aug. 1, the Centers for Medicare & Medicaid Services (CMS) published the final Inpatient Prospective Payment System (IPPS) rule for fiscal year (FY) 2024 [here](#); CMS fact sheet [here](#)
- CHIME comment letter [here](#) focused on specific new mandates under consideration and the revision of existing requirements for eligible hospitals and critical access hospitals (CAHs) participating in the Medicare Promoting Interoperability (PI) Program
 - Strongly opposed CMS' proposal to modify the Safety Assurance Factors for EHR Resilience (SAFER) Guides measure
- **However, CMS decided to finalize this part of the regulation as proposed**
- **Beginning in the calendar year (CY) 2024 EHR reporting period, eligible hospitals & CAHs must attest “yes” to having conducted an annual self-assessment of all nine SAFER Guides – or face a downward payment adjustment**

Proposed PFS Rule

CMS published the proposed Physician Fee Schedule rule for calendar year (CY) 2024 ([here](#)); fact sheet [here](#)

- It's only 2,033 pages – not a typo
- Comments are due Sept. 11
- Final Rule is released in November
- Most policies effective Jan. 1, 2024 – unless otherwise indicated
- Continuing with administration's focus on health equity & Social Determinants of Health (SDOH)
- Appropriate Use Criteria (AUC) for advanced diagnostic imaging program being paused
- Promoting Interoperability (PI) Performance Category
 - Shifting Shared Savings Program to align with MIPS PI performance category measures & requirements
 - Aligning with ONC's "HTI-1" proposed rule
 - Performance period increasing from 90 to 180 days

Administration & Cyber

- Biden administration published the [National Cybersecurity Strategy Implementation Plan](#) (NCSIP)
 - Follows the [White House's National Cybersecurity Strategy](#) released in March
 - Plan is largely sector agnostic (with exception of clean energy mentions)
 - The Office of the National Cyber Director (ONCD) will coordinate activities under plan – and is working on a Request for Information (RFI) regarding cybersecurity regulatory harmonization
 - This is the first iteration of the plan, which is a living document that will be updated annually
- CISA released their [Cybersecurity Strategic Plan](#) for FYs 2024 - 2026, calling cybersecurity a “whole of nation mission” – has 3 goals:
 - 1) Address Immediate Threats
 - 2) Harden the Terrain
 - 3) Drive Security at Scale

Administration & AI

The Biden administration is continuing their ongoing action and efforts related to AI

- Secured voluntary commitments from seven AI companies to manage risks
- Currently developing a new executive order (E.O.)
- Plans to issue a Request for Information (RFI) in the near future
- Has expressed that they will support bipartisan legislation

WH also announced a new two-year competition seeking to leverage AI to bolster cybersecurity and protect critically-important software, press release [here](#)

- Led by DARPA & private sector partners, "AI Cyber Challenge" (AIxCC) will offer monetary prizes to teams who identify and fix software vulnerabilities using AI



Questions?

**Reach out to our team at
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