

Government Affairs: What's in Store for '24

Moderator:

Chantal Worzala



Panelists:

Lindsay Austin

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Congressional & Legislative Affairs

Lindsay Austin – Troutman Pepper Strategies

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2023
SAN DIEGO *California*

Speaker Mike Johnson (R-LA04)

- Elected Oct. 25 after multiple failed nominations and floor votes by the GOP
 - McCarthy ousted Oct. 3
 - 7 years in Congress, lawyer by trade
- Speaker's health policy priorities
 - Passing FY24 Labor-HHS spending bill (with cuts)
 - Health costs and transparency package (H.R. 5378)
 - SUPPORT Act (opioid provisions HRSA & SAMHSA expired Sept. 30)
 - PAHPA reauthorization (expired, extensions)
- Speaker's healthcare experience
 - Former chair of RSC, led push in 2019 to replace ACA with RSC's health plan
 - Former senior counsel for Alliance Defending Freedom; organization behind 2022 Supreme Court case to overturn Roe v. Wade



End of Year Outlook

FY 2024 Appropriations – Continuing Resolution

- “Laddered” CR passed House yesterday:
 - 336 – 95 (**127 R – 209 D**)
 - Senate expected to pass, WH supports
 - Extends Ag-FDA, Energy & Water, Milcon-VA, and T-HUD funding through **Jan. 19, 2024**
 - Extends other eight bills to **Feb. 2, 2024**

- Health Programs Extended to Jan 19, 2024 (like Oct CR):
 - Community Health Centers
 - Delays DSH cuts
 - Some Medicare payment cuts (diagnostic lab tests)
 - National Health Security (a few PAHPA programs)

13 Legislative Days Left – What remains?

- FY24 ALL 12 bills: House passed 7, Senate passed 3
- Labor-HHS on House floor now (140 amendments)
- \$14 billion difference between House/Senate FY24 Labor-HHS versions
- National Security Aid for Israel, Ukraine, Taiwan, Border
- WH \$56B domestic spending request
- *Expiring bills*: NDAA, FAA reauthorization, PAHPA reauthorization

	House FY24	Senate FY24	FY23 Enacted
HHS Total	\$103.3B	\$117B	\$117.3B
ONC	\$56.2M	\$71.2M	\$66.2M
CDC	\$7.66B	\$9.19B	\$9.26B
NIH	\$43B	\$49.2B	\$49.18B

Federal Shutdown Impacts

General Info

- Shutdown severity depends on how long the shutdown lasts
 - Funding gaps lasting only a few days don't give federal departments time to implement shutdown measures
 - Funding gaps lasting several days or weeks will result in shutdowns, agencies furloughing employees, and paused federal services
- Agencies develop their own shutdown plans, following guidance from the OMB and determine which activities continue
- Mandatory spending and services, such as Social Security and Medicare payments, can continue during funding gaps or shutdowns
- Only agencies and programs that depend on discretionary funding are impacted
- Excepted employees continue to work while others (non-excepted) will be furloughed

HHS and Public Health Impacts

- HHS – 58% of staff will be retained
- ONC – employees being furloughed could impact efficiencies and program operations
- OIG – will continue Medicare/Medicaid oversight and enforcement activities
- CMS – Medicare is mandatory, Medicaid and CHIP will continue as both programs are appropriated by Congress in advance (49% of CMS employees will be retained)
- NIH – may postpone clinical trials for diseases like cancer or Alzheimer's, according to the White House
- Covid-19 response and research, including vaccine and therapeutic development, would carry on at HHS

HIT & Healthcare in 2024 – Congress

- **FY 2025 (& FY2024) Appropriations**
 - House cuts will continue to HHS and subagencies
 - Senate likely to keep spending in line with debt limit deal
 - April 1, 2024 – 1% cut if no FY24 bills
- **Health Tech and AI**
 - HELP Committee + Energy & Commerce focus
 - Schumer AI continued “Insight Forums” on topics
- **Health Costs & Transparency**
 - Negotiations to continue on costs/transparency legislation
 - Lower Costs, More Transparency Act (H.R. 5378)
 - Bipartisan Primary Care and Health Workforce Act (S. 2840)
- **Mental Health**
 - Bipartisan interest in providing additional coverage, support and resources for mental health
- **Telehealth**
 - Some telehealth extensions and flexibilities expired at the end of the PHE, but Congress set others to Dec. 31, 2024
 - CONNECT for Health Act (H.R.4189/S.2016) – bipartisan bill extending and making permanent dozens of telehealth flexibilities
- **Fentanyl & Opioids**
 - House has passed bipartisan legislation
 - Interest in classifying fentanyl as a Schedule I
- **Senate Finance Package**
 - Committee recently passed the Better Mental Health Care, Lower-Cost Drugs, and Extenders Act, likely will spill over to 2024
 - Mitigates Medicare payment cuts, extends certain expiring Medicare and Medicaid provisions, and aims to increase access to mental health care

HIT & Healthcare in 2024 – Administration

- **Expanding Healthcare Access**
 - Make permanent expanded ACA premium tax credits that were extended through Inflation Reduction Act (IRA)
 - Expand Medicaid to states that have not adopted Medicaid expansion
 - Expanding coverage of mental health benefits
 - Improving rural healthcare access, including access to broadband/internet
- **AI Executive Order Actions (*more on that later*)**
- **Cancer Moonshot**
 - Long time priority for Biden
 - Includes activities across CDC, IHS, HRSA, and FDA
- **Reducing Drug and Healthcare Costs**
 - Implementing Medicare drug negotiation provisions of IRA; various provisions rolling out until to 2029
 - Implementing No Surprises Act
 - In late Oct, administration released proposed rule on the NSA’s federal independent dispute resolution process
- **Cybersecurity**
 - Admin may consider tying cybersecurity requirements to payments for federal health programs
 - Admin views cybersecurity as a patient safety issue
 - Earlier this year, HHS released the “Healthcare Sector Cybersecurity Framework Implementation Guide”
 - On Oct. 26, HHS and the Cybersecurity and Infrastructure Security Agency (CISA) released a cybersecurity toolkit tailored for the healthcare sector

2024 Election

- Top health-related campaign topics
 - Abortion
 - Public health trust & Covid-19 response
 - Medicaid expansion & ACA
 - Healthcare spending & transparency
 - Medicare & SSA stability
- Trump polling well over 50% among GOP candidates
- Recent national polls have Biden-Trump tied or Trump ahead by several points

- House – **221 GOP** vs **213 Dem**
- Senate – **51 Dem** vs **49 GOP** (34 seats up- WV, OH, PA, MT key states)

Democrats



Biden Williamson Uyur Phillips

Republicans



Trump Haley Ramaswamy Hutchinson Binkley Scott



DeSantis Christie Burgum

Independent and third-party



Kennedy West Stein

Dropped out



Suarez Hurd Johnson Elder Pence

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Regulatory Update

Zoe Barber – The Sequoia Project

Office of the National Coordinator for Health IT (ONC)

Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule

OMB Review

Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) NPRM

Expected 2024

TEFCA CAv2

Expected 2024

Centers for Medicare & Medicaid Services (CMS)

Interoperability and Prior Authorization Final Rule

OMB Review

CY 2024 Physician Fee Schedule

Final rule published

CMS and ONC

21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking

Comments due January 2, 2024

Office of the Inspector General (OIG)

Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General's Civil Money Penalty Rules

Final rule published

Office for Civil Rights (OCR)

Proposed Modifications to the HIPAA Privacy Rule to Support Reproductive Health Care Privacy

NPRM published

Rulemaking Implementing Provisions of the Health Information Technology for Economic and Clinical Health (HITECH) Act, as Amended

NPRM Expected 2024

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Information Sharing Policy and Work Group Update

Chantal Worzala

ISWG Co-Chairs:



Dr. Matt Eisenberg
Associate Chief
Medical Information
Officer,
Stanford Medicine
Health Center



Josh Mast
Director and Product
Regulatory Strategist,
Oracle Corporation



Ammon Filmore
Associate Chief Legal
Officer: Information &
Technology,
Advent Health

Information Sharing Workgroup 2023 Milestones

- Regulatory Analysis
 - OCR proposed rule on HIPAA privacy rule and reproductive health data
 - HTI-1 refinements to Information Blocking Rules and discussion of data segmentation for privacy
 - Proposed rule on disincentives for providers
- Sharing of implementation experiences across Actor groups
 - Export of “All EHI”
 - Clinician/staff education
 - Working with the exceptions

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Our Information Sharing Workgroup members, Lauren Riplinger, Melissa Soliz and Chantal Worzala, penned this article on the Office of the National Coordinator for Health Information Technology (ONC)'s proposals to enhance federal information sharing requirements. Read more and share:



Perpetual Progression: ONC Proposals To Enhance the Information Sharing Rules
The Sequoia Project on LinkedIn • 5 min read
By Lauren Riplinger, Melissa Soliz and Chantal Worzala The Sequoia Project's Information ...

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Read the latest from our Information Sharing Workgroup members, Deven McGraw and Chantal Worzala, on the importance of privacy in new Proposed Rules:

#interoperability #privacy



Information Sharing Still Requires Attention to Privacy: Two Proposed Rules from HHS Highlight Need for Data Privacy Tools
The Sequoia Project on LinkedIn • 5 min read
By Deven McGraw and Chantal Worzala Since the passage of HIPAA, federal policy ...

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Privacy, OCR, & AI

Lindsey Elkind – The Sequoia Project

Policy Spotlight – Artificial Intelligence

Administration

- **10/30 EO & 11/2 OMB Directive**
 - Directs HHS to create AI task force and strategic plan on responsible use of AI, including generative AI, real-world performance monitoring, equity and reducing burden
 - HHS can consult with other agencies on how nondiscrimination laws intersect with AI
 - Potential precursor to new federal cybersecurity regulations focused on critical infrastructure, such as healthcare
 - OMB directive says HHS has until Aug. 1, 2024, to implement minimum guardrails for AI that impacts rights or safety, or it can no longer use the tech
- **National AI Research Resource (NAIRR)**
 - NAIRR Task Force released final report in Jan.
 - Report requests \$2.6B from Congress over 6 years to stand up a national research infrastructure to broaden access to the resources essential to AI R&D
- **RFI**
 - In June, OSTP released an RFI on National Priorities for AI

Congress

- **Senate AI Workgroup**
 - Sens. Schumer (D-NY), Young (R-IN), Heinrich (D-NM), and Rounds (R-SD) are leads
 - Held AI summits on Capitol Hill in Sept. and Oct.
 - Schumer rolled out AI policy framework in June as a launchpad for comprehensive bipartisan legislation
 - Major legislation is possible in 2024
- **Hearings**
 - Senate and House committees held dozens of hearings and classified briefings over the year to examine the challenges of AI and how it should be regulated
- **RFI**
 - Senate HELP RM Bill Cassidy (R-LA) released a WP on potential benefits of AI, including healthcare, in Sept.
 - Also released an RFI for stakeholder feedback