Government Affairs: What’s in Store for ‘24

Moderator:
Chantal Worzala

Panelists:
Lindsay Austin
Zoe Barber
Lindsey Elkind
Congressional & Legislative Affairs

Lindsay Austin – Troutman Pepper Strategies
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

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<tr>
<th></th>
<th>House FY24</th>
<th>Senate FY24</th>
<th>FY23 Enacted</th>
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<tbody>
<tr>
<td>HHS Total</td>
<td>$103.3B</td>
<td>$117B</td>
<td>$117.3B</td>
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<tr>
<td>ONC</td>
<td>$56.2M</td>
<td>$71.2M</td>
<td>$66.2M</td>
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<td>CDC</td>
<td>$7.66B</td>
<td>$9.19B</td>
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<td>NIH</td>
<td>$43B</td>
<td>$49.2B</td>
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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
• Exected 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 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)
Regulatory Update

Zoe Barber – The Sequoia Project
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<tr>
<th>Office of the National Coordinator for Health IT (ONC)</th>
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<tr>
<td>Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm</td>
<td>OMB Review</td>
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<td>Transparency, and Information Sharing (HTI-1) Final Rule</td>
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<td>Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing,</td>
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<td>and Public Health Interoperability (HTI-2) NPRM</td>
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<td>Interoperability and Prior Authorization Final Rule</td>
<td>OMB Review</td>
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<td>CY 2024 Physician Fee Schedule</td>
<td>Final rule published</td>
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<td>21st Century Cures Act: Establishment of Disincentives for Health Care Providers That</td>
<td>Comments due January 2, 2024</td>
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<td>Have Committed Information Blocking</td>
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<td>Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of</td>
<td>Final rule published</td>
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<td>Inspector General’s Civil Money Penalty Rules</td>
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<td>Proposed Modifications to the HIPAA Privacy Rule to Support Reproductive Health Care</td>
<td>NPRM published</td>
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<td>Privacy</td>
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<tr>
<td>Rulemaking Implementing Provisions of the Health Information Technology for Economic and</td>
<td>NPRM Expected 2024</td>
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<tr>
<td>Clinical Health (HITECH) Act, as Amended</td>
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Information Sharing Workgroup 2023 Milestones

- Regulatory Analysis
  - OCR proposed rule on HIPPA 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
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)**
  - 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
  - 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