

## Updates from Inside the Beltway: Analyzing Health Policy Activity and Trends in an Election Year



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## **2024 Election Year:** More Regulation, Less Legislation

### **Executive Branch**

- Regulations become more common in an election year – particularly if the legislative process is stalled
  - Used to advance policy agenda
- So far, the Executive Branch is flexing this ability: •
  - FTC Health Breach Notification Rule finalized
  - HIPAA Privacy Rule to Support Reproductive Health Care Privacy
  - Section 1557 Final Rule
  - And more...

### **Legislative Branch**

- Legislators prioritize bills that they believe will resonate with voters – slows down the legislative process
  - Not a hard and fast rule if there is a sense of urgency or bipartisan agreement large legislation can be passed
- A lot has been introduced:
  - Telehealth Modernization Act
  - Health Care Cybersecurity Improvement Act •
  - American Privacy Rights Act
  - And more...



#### Artificial Intelligence

## **Updates on President Biden's AI EO**



### **Major Announcement**

All federal agencies with • 180-day deadlines from the AI EO completed all required tasks

### **HHS Actions**

- Released a Plan for **Promoting Responsible** Use of Artificial Intelligence in in Public **Benefit Administration**.
- Section 1557 final rule clarifies requirements apply to the use of AI

### **Commerce Actions**

comment draft



• Released for public documents on managing generative AI risks and securely developing generative AI systems



## Al Oversight Takes a Multi-Pronged Approach

Industry Organizations Look to Self-Regulate

- Mar. 4: Coalition for Health AI (CHAI) launched
- Mar. 11: Microsoft launched TRAIN
- Mar. 13: Consumer Technology Association (CTA) convened stakeholders to create a common understanding of healthcare AI
- Apr. 8: The National Academy of Medicine released a Draft Code of Conduct for AI in healthcare

### **Federal Agencies Flex Their Oversight Muscle**

- Jan. 29: DOJ begins investigating AI in healthcare
- Feb. 6: CMS warned MA plans about using an algorithm for coverage determinations
- Mar. 28: White House OMB issued the first government-wide policy to mitigate the risks of AI
- Apr. 24: Lina Khan, chair of the FTC, expressed concern that algorithms could lead to healthcare price fixing

### **States Act Because of Federal Inaction**

- Apr. 18: AK, CO, CT, GA, TX, VA collaborate on Al legislation
- Apr. 24: The Connecticut Senate passed a bill to regulate AI decision-making
- May 1: Utah's AI Act



**Utilization Management** 

## **Increased scrutiny of U.M. practices** leads to unfavorable market for some

- Study: restrictions on Medicare Part D drugs (i.e., prior authorization, formulary restrictions, etc.) increased between 2011 - 2020
- Point32Health announced updates to its prior authorization requirements for home health care services – no UM for first 30 days post-discharge

- CY 2025 MA and Part D final rule
- CMS Administrator says more prior authorization rules could come
- UnitedHealth Group's naviHealth division laid off 114 people





Interoperability

## **Agencies are Doubling Down on FHIR and APIs**

Jan. 17: CMS finalized Advancing Interoperability and **Improving Prior** Authorization Processes rule

Feb. 5: SAMHSA and **ONC** launched the **Behavioral HIT** Initiative -- will invest \$20M of SAMHSA funds within three years to support behavioral health integration

Mar. 27: ONC

publishes its Federal Health IT Strategy for 2024-2030

#### **Apr. 22: ONC**

releases the Common Agreement Version 2.0 for TEFCA, requiring QHINs to use FHIR



#### **Digital Health**

### **Congress, the Executive Branch, and Collaboratives** are Trying to Find Value in Digital Health

### **Congressional Action**

- Feb. 1: Congressional Digital Health Caucus
- Mar. 12: Telehealth Modernization Act of 2024
- **Apr. 10:** House E&C holds hearing on telehealth permanency

### **Executive Branch**

- Feb. 2: Final rule on flexibilities for opioid treatment prescriptions via virtual care
- Mar. 11: President Biden's proposed 2025 HHS budget included virtual care expansion
- Apr. 11: MedPAC gives telehealth status update

### **Commercial Partners**

- Feb. 21: PHTI launched Digital Health Collaborative
- Mar. 21: PHTI issued first report on digital type 2 diabetes tools
- Apr. 23: Joint Commission announces telehealth accreditation





Cybersecurity

## **Change Healthcare Cyberattack Causes Increased Focus on Cybersecurity**

Feb. 21: Change Healthcare reports cyberattack

Mar. 15: Change Healthcare announces electronic payments platform was restored

Mar. 19: Change announces it will release medical claims preparation software to resume services

Apr. 3: Change Healthcare submits request to consolidate 24 class-action lawsuits it faces due to the cyberattack

Apr. 11: A second ransomware gang claims to have data from the Change Healthcare cyberattack and demands additional ransom to not leak data – representing double extortion



### May 1: UHG CEO Andrew Witty testifies before two separate House Committees—Energy & Commerce and Finance

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Cybersecurity

## **Cybersecurity Takes Front Seat After 2023 Sees 116M Records Exposed**

January 2024 CISA issued 1,200 pre-ransomware notifications to over 150 U.S. healthcare organizations



January 24, 2024 HHS published voluntary cybersecurity goals



February 27, 2024 HSCC WG published the "Health Industry Cybersecurity Strategic Plan" – call to action



March 22, 2024

Senator Mark Warner introduced Health Care Cybersecurity Improvement Act of 2024



#### March 27, 2024

CISA released a proposed rule requiring covered entities to report cyber incidents, ransom payments





Data Privacy

## The Executive Branch and Congress Try to Ensure Data Privacy for Americans

#### Feb. 21:

U.S. Senator Bill Cassidy report on privacy protections

#### Feb. 28:

EO to protect Americans' sensitive personal health data from countries of concern

#### **Apr. 7**:

U.S. Senate and House Commerce Committees release discussion draft of "American Privacy **Rights Act**"

#### **Apr. 22**:

HHS issued the HIPA A Privacy Rule to Support Reproductive Health Care Privacy

#### Apr. 26:

FTC updated the Health Breach Notification Rule, to strengthen privacy protections of personal health information on digital health apps



#### M&A Scrutiny

## **PE and M&A Takes Center Stage in** Healthcare

### **Focus: Competition**

- Jan. 8: Stacey Sanders first-ever HHS **Chief Competition Officer**
- Mar. 5: WH Competition Council "strike force" on unfair pricing
- **Apr. 3**: Senate HELP Committee holds hearing about "corporate greed" in healthcare

### **Focus: Private Equity**

- Mar. 5: FTC hosts PE in healthcare workshop
- Mar. 5: HHS, FTC, and DOJ issue joint RFI on PF in healthcare
- **Apr. 1:** Sen. Peters initiates inquiry about PE involvement in emergency staffing firms

#### **Other Actions**

- Jan. 25: FTC sues to block Novant Health from acquiring two Community Health Systems hospitals in North Carolina
- Feb. 27: DOJ launches investigation into UnitedHealthcare
- Mar. 8: U.S. Senate confirms two Republican nominees to the FTC



M&A Scrutiny

## **Increased Scrutiny Impacts Deals in Payer and Provider** A&M



- Jan. 17: General Catalyst signed a non-binding letter of intent to acquire Summa Health for new innovation-focused health system
- Feb. 14: SCAN Group and CareOregon call off merger one year after its announcement after regulatory scrutiny
- Feb. 14: BCBS of Louisiana and Elevance once again pause merger following regulatory scrutiny
- Mar. 11: Elevance Health acquired Paragon Health, an infusion and drug therapy company, for an estimated \$1B
- Mar. 27: Optum announces it will buy Massachusetts-based Steward Health Care's physician group
- Apr. 2: Kaiser Permanente officially acquires Geisinger, creating the new, non-profit entity of "Risant Health"



## Medicare Advantage Updates

#### **Payers Face Scrutiny Over MA**

- Jan. 25: CMS issues RFI on MA data
- Mar. 5: Chartis Group MA Marketplace report -- new enrollment (mostly) goes to 3 national payers
- Mar. 15: MedPAC March Report says \$83B in overpayments to plans
- Apr. 1: '25 MA Rate Announcement, slight decrease in plan payments
- Apr. 4: '25 MA rule, reforming broker compensation and including new UM health equity requirements
- Apr. 15: CMS Administrator says more prior auth rules could come

#### MA Plans React to CMS Policy Changes

- Jan: SCAN Health Plan and Elevance sue CMS over 2024 Star Rating calculations
- Jan. 31: Cigna announces it will sell its MA business to HCSC
- Apr. 24: Humana predicts cut to benefits in 2025 after MA rate announcement
- Apr. 30: CVS acquires MA broker, Hella Health •
- May 1: CVS stocks drop after admitting Aetna's unexpectedly higher claims and changing MA reimbursement



2024 and Beyond

## What's Next? A Lot of Unknowns...



M&A

FTC, DOJ, and HHS Chief Competition officer – Stacy Sanders – will continue to act against mergers it deems bad for patients – Congress increases focus (Health Over Wealth Act)



#### Digital Health U.S. Congress will have to allow for telehealth permanency before the end of 2024 – in an election year



#### Interoperability

Will **TEFCA** reach significant adoption? **HTI-2** still at OMB – will it include corollary requirements for providers (ePA)?



#### AI

More principles before policy...

Industry organizations will continue to educate Congress and federal agencies – states may take action first (e.g., Utah)



#### Cyber

Reactions to Change Healthcare breach

 increasing scrutiny and incentives before requiring cyber practices for healthcare



# **Questions?**

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# Download our full Market Report

**MARKET REPORT** 

The State of Utilization Management, Care Management, and Population Health Management in 2024





# Thank you

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