SAFEGUARDING HEALTH INFORMATION: BUILDING ASSURANCE THROUGH HIPAA SECURITY 2024

WASHINGTON, DC

OCTOBER 23-24 2024
HOSTED BY NIST & HHS

2024 OCR NIST
Safeguarding Health Information: Building Assurance through HIPAA Security

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office for Civil Rights

HIPAA Priorities

- Prioritizing investigations that follow HIPAA complaint and breach trends:
  - Hacking
  - Ransomware
  - *Right of Access Enforcement Initiative*
  - *Risk Analysis Enforcement Initiative*
- Engaging with Health Care Industry on Cybersecurity
  - Increased presence regionally across the country
  - Videos/Guidance/Newsletters
  - Webinars/Technical Assistance
- Review and Update HIPAA Security Rule

Large Breaches Received and # of Individuals Affected 2018 - 2023

- 2018: 369 — 15,236,139
- 2019: 511 — 44,917,698
- 2020: 663 — 34,800,838
- 2021: 715 — 59,364,053
- 2022: 720 — 55,962,895
- 2023: 745 — 162,807,187

Legend: Large Breaches Received | # of Individuals Affected

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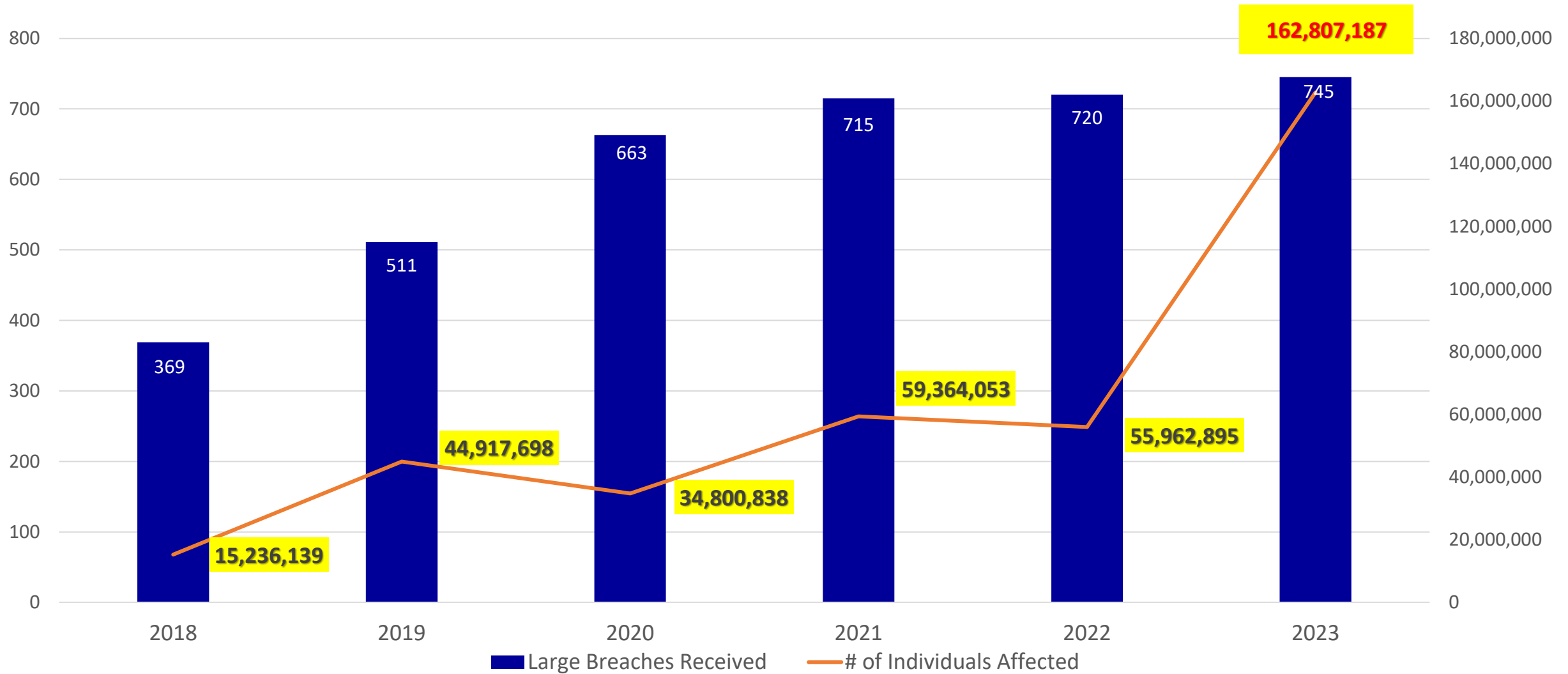
Recent Announced OCR HIPAA Enforcement Actions

Sep-23	LA Care Health Plan	$1,300,000
Oct-23	Doctors' Management Services	$100,000
Nov-23	St. Joseph's Medical Center	$80,000
Dec-23	Lafourche Medical Group	$480,000
Jan-24	Optum Medical Care of New Jersey	$160,000
Feb-24	Montefiore Medical Center	$4,750,000
Feb-24	Green Ridge Behavioral Health, LLC	$40,000
Mar-24	Phoenix Healthcare	$35,000
Apr-24	Essex Residential Care, LLC	$100,000
July-24	Heritage Valley Health System	$950,000
Aug-24	American Medical Response	$115,200
Sep-24	Cascade Eye and Skin Centers, P.C.	$250,000
Oct-24	Providence Medical Institute	$240,000
Oct-24	Gums Dental Care	$70,000

Recent and Upcoming HIPAA Cybersecurity Activities

- Cybersecurity Newsletters
- Cybersecurity Month Blog
- Ransomware Video
- Proposed Modifications to the HIPAA Security Rule

- Sign up for the OCR Listserv: http://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html
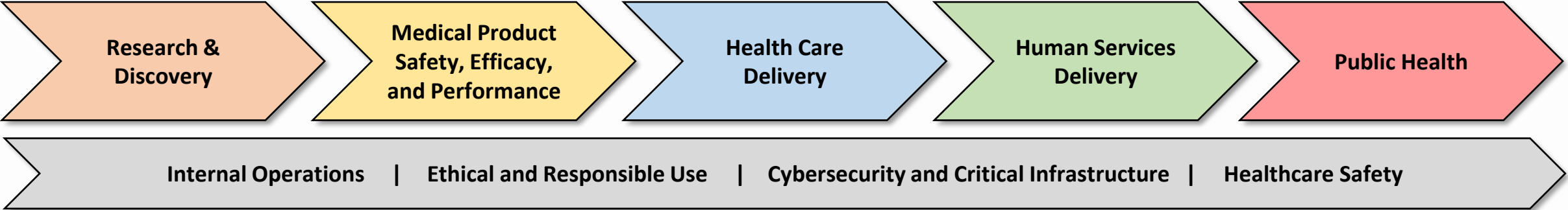
AI in Healthcare

Micky Tripathi PhD MPP

Assistant Secretary for Technology Policy

October 24, 2024

HHS AI Strategic Plan: Planned Release January 2025

Strategic Domains

Research & Discovery	Medical Product Safety, Efficacy, and Performance	Health Care Delivery	Human Services Delivery	Public Health

Internal Operations | Ethical and Responsible Use | Cybersecurity and Critical Infrastructure | Healthcare Safety

Key Policy Levers

- Regulations, policies, and guidance
- Grants and funding programs and procurement
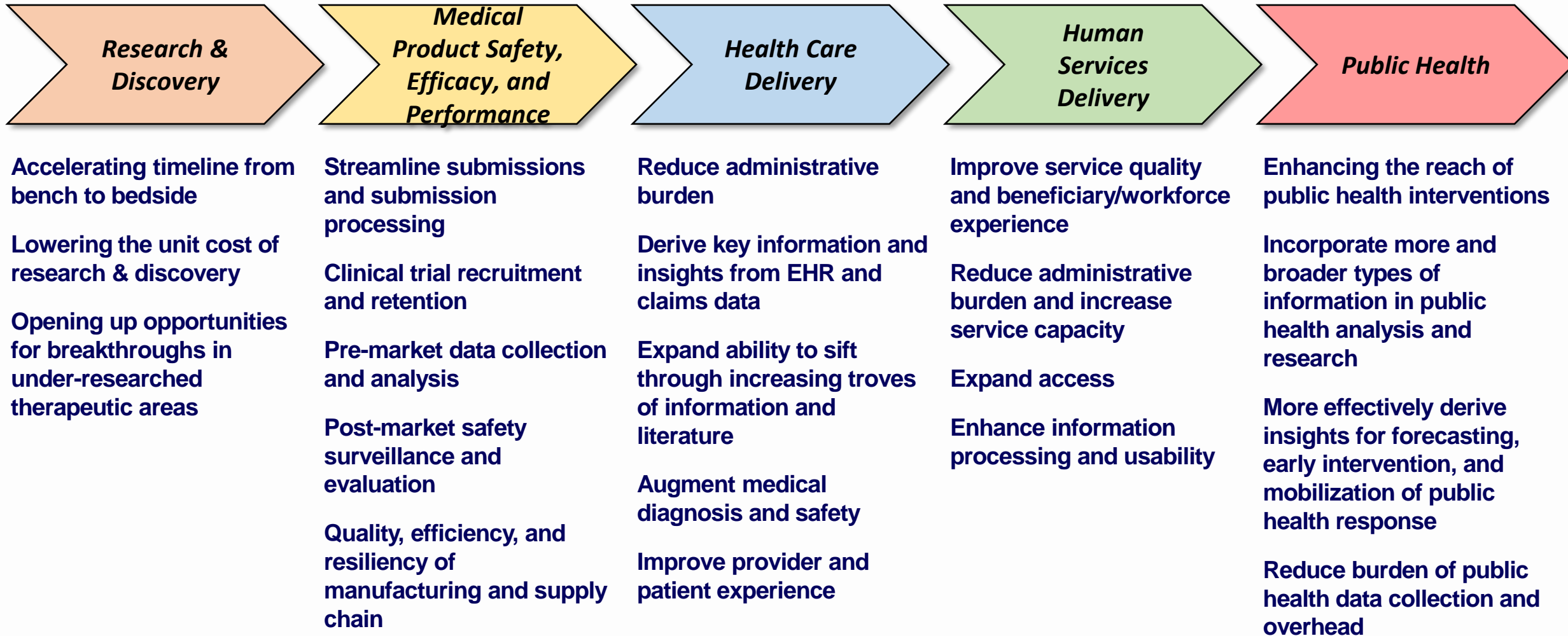- Public education and outreach
- Internal infrastructure and operations

Main Policy Objectives

1. Encourage health AI innovation and adoption
2. Promote trustworthy AI development and use
3. Democratize AI technologies and resources
4. Cultivate AI-empowered workforces and organization cultures

Opportunity potential across the health care value chain

Research & Discovery	Medical Product Safety, Efficacy, and Performance	Health Care Delivery	Human Services Delivery	Public Health
Accelerating timeline from bench to bedside **Lowering the unit cost of research & discovery** **Opening up opportunities for breakthroughs in under-researched therapeutic areas**	**Streamline submissions and submission processing** **Clinical trial recruitment and retention** **Pre-market data collection and analysis** **Post-market safety surveillance and evaluation** **Quality, efficiency, and resiliency of manufacturing and supply chain**	**Reduce administrative burden** **Derive key information and insights from EHR and claims data** **Expand ability to sift through increasing troves of information and literature** **Augment medical diagnosis and safety** **Improve provider and patient experience**	**Improve service quality and beneficiary/workforce experience** **Reduce administrative burden and increase service capacity** **Expand access** **Enhance information processing and usability**	**Enhancing the reach of public health interventions** **Incorporate more and broader types of information in public health analysis and research** **More effectively derive insights for forecasting, early intervention, and mobilization of public health response** **Reduce burden of public health data collection and overhead**

Risk potential is also high across the health care value chain

FAVES Principles

Fair	Does not exhibit prejudice or favoritism toward an individual or group based on their inherent or acquired characteristics
Appropriate	Outputs are well matched to produce results appropriate for specific contexts and populations to which they are applied
Valid	Outputs have been shown to estimate targeted values accurately and as expected in both internal and external data
Effective	Outputs have demonstrated benefits in real-world conditions
Safe	Use is free from any known unacceptable risks, for which the probable benefits of AI use outweigh any probable risks

Health AI Regulation and Collaboration

Core Infrastructure	Health Care Products	Health Care Uses

Core Infrastructure

JULY 21, 2023

FACT SHEET: Biden-Harris Administration Secures Voluntary Commitments from Leading Artificial Intelligence Companies to Manage the Risks Posed by AI

BRIEFING ROOM ▸ STATEMENTS AND RELEASES

U.S. National Science Foundation (NSF)

National AI Research Resource

NIST

US AI Safety Institute

Health Care Products

FDA

Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan

January 2021

ONC

HTI-1 Rule: Algorithm Transparency

Health Care Uses

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office for Civil Rights

ACA Section 1557: Non-Discrimination in Health Programs and Activities

CMS.gov

February 06, 2024 06:34 PM

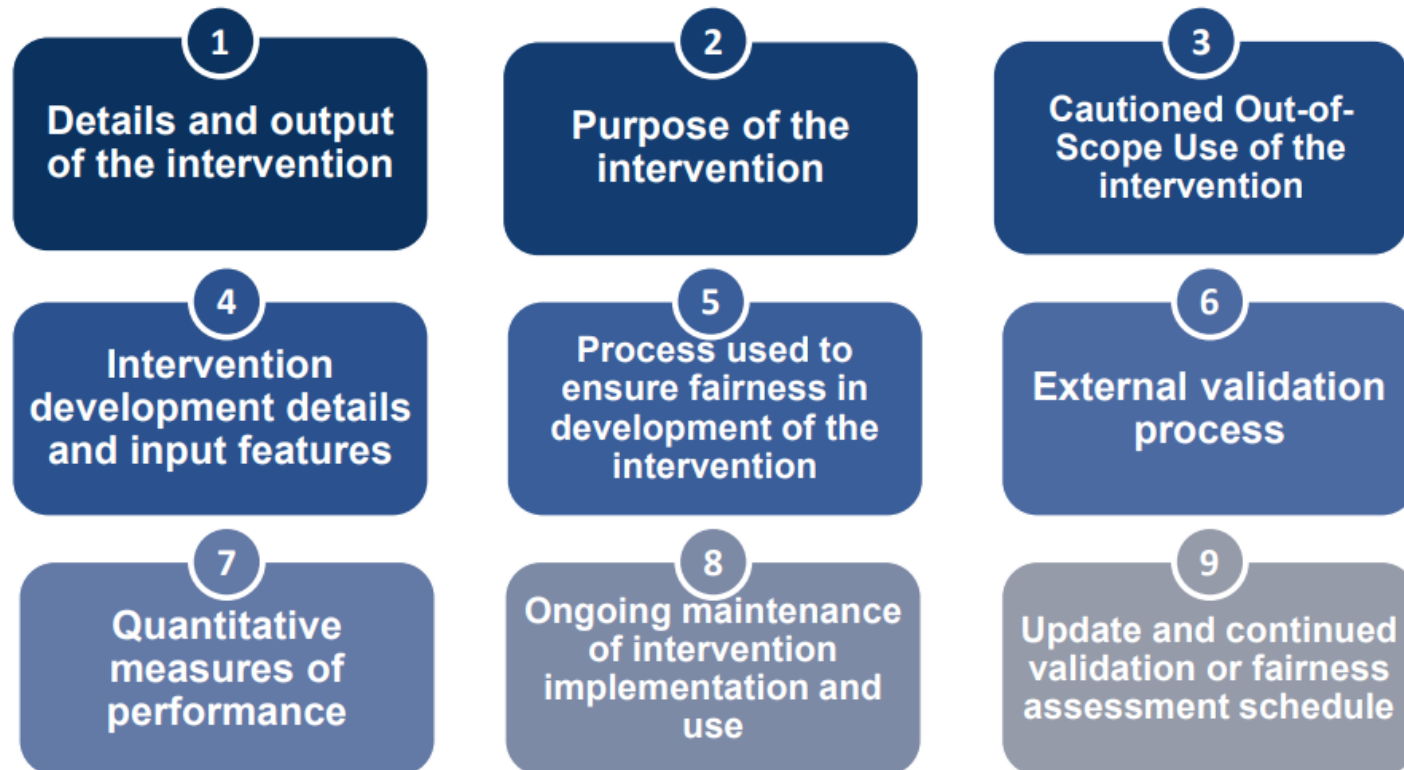**CMS outlines limits on Medicare Advantage AI usage**

ALISON BENNETT

DECEMBER 14, 2023

Delivering on the Promise of AI to Improve Health Outcomes

BRIEFING ROOM ▸ BLOG

28 providers and payers have joined today's commitments: Allina Health, Bassett Healthcare Network, Boston Children's Hospital, Curai Health, CVS Health, Devoted Health, Duke Health, Emory Healthcare, Endeavor Health, Fairview Health Systems, Geisinger, Hackensack Meridian, HealthFirst (Florida), Houston Methodist, John Muir Health, Keck Medicine, Main Line Health, Mass General Brigham, Medical University of South Carolina Health, Oscar, OSF HealthCare, Premera Blue Cross, Rush University System for Health, Sanford Health, Tufts Medicine, UC San Diego Health, UC Davis Health, and WellSpan Health.

Starting Jan 1, 2025: EHR Vendors Required to Provide "Nutrition Label" for AI-based Technologies Offered in their Products

1. Details and output of the intervention
2. Purpose of the intervention
3. Cautioned Out-of-Scope Use of the intervention
4. Intervention development details and input features
5. Process used to ensure fairness in development of the intervention
6. External validation process
7. Quantitative measures of performance
8. Ongoing maintenance of intervention implementation and use
9. Update and continued validation or fairness assessment schedule

- *Establishes transparency to Providers to empower local AI governance*
- *Complements FDA device regulations*
- *Motivates market to FAVES principles*
  - *Fair*
  - *Accurate*
  - *Valid*
  - *Effective*
  - *Safe*

Data is the fuel for AI innovation

We have a digital foundation

- 97% of hospitals and 78% of physician use certified EHRs

Interoperability is common and growing

- FHIR APIs required in certified EHRs by ASTP regs and for regulated payers by CMS regs
- Trusted Exchange Framework and Common Agreement (TEFCA) enabling network interoperability nationwide
- ASTP information-blocking regulations – agnostic to where the data lives

Patient access is unprecedented

- HIPAA right-of-access
- ASTP information-blocking regulations – "electronic health information"

ASTP Assistant Secretary for Technology Policy

Some key areas of consideration

Privacy

- Re-identification risk

- Data "greediness"

- AI development and HIPAA regulations related to research

- Innovative growth outside the boundaries of HIPAA

Device/EHR regulatory scope

- Consistency in risk frameworks

- Innovative growth in "gray areas" of regulatory boundaries

- Quality and safety assurance definitions, metrics, processes, infrastructure, responsibilities

- Life-cycle management

The AI-Empowered Patient

ASTP
Assistant Secretary
for Technology Policy

Reach out via phone or web

📱 202-690-7151

💬 Feedback Form: https://www.healthit.gov/form/healthit-feedback-form

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in Assistant Secretary for Technology Policy

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HHS Artificial Intelligence Panel

Panelists

- **Erin Szulman** (Moderator), HHS Counselor to the Deputy Secretary

- **Troy Tazbaz**, FDA Director of Digital Health Center of Excellence

- **Jeff Wu**, CMS Deputy Director for Policy for the Center for Consumer Information and Insurance Oversight

- **Kathryn Marchesini,** ASTP Chief Privacy Officer

- **Susan Gregurick,** NIH Associate Director for Data Science

- **Martin Stanley**, NIST AI Innovation Laboratory AI and Cybersecurity Researcher

- **Nick Heesters**, HHS Office for Civil Rights (OCR) Senior Advisor for Cybersecurity

Related Resources

Department of Health and Human Services (HHS)
- https://www.hhs.gov/programs/topic-sites/ai/strategy/index.html

Food and Drug Administration (FDA)
- https://www.fda.gov/science-research/science-and-research-special-topics/artificial-intelligence-and-medical-products

Centers for Medicare & Medicaid Services (CMS)
- https://ai.cms.gov/

Assistant Secretary for Technology Policy (ASTP)
- https://www.healthit.gov/test-method/decision-support-interventions

National Institutes of Health (NIH)
- https://datascience.nih.gov/artificial-intelligence

National Institute of Standards and Technology (NIST)
- https://airc.nist.gov/home

Small and Rural Cybersecurity Considerations Panel

Panelists

○ **Charlee Hess**, Director, Healthcare and Public Health Cybersecurity, HHS ASPR

○ **Nitin Natarajan**, Deputy Director, Cybersecurity and Infrastructure Security Agency (CISA)

○ **Kendra Siler**, PhD; CEO CommHIT

○ **Daniel Eliot** (Moderator), Lead for Small Business Engagement, National Institute of Standards and Technology (NIST)

Related Resources

HHS

○ HPH Cybersecurity Gateway: https://hhscyber.hhs.gov

○ HHS 405(d) – Aligning Health Care Industry Security Approaches: https://405d.hhs.gov

CISA

○ Healthcare and Public Health Cybersecurity: https://www.cisa.gov/healthcare

CommHIT

○ https://commhit.org/

NIST

○ Small Business Cybersecurity Corner: https://www.nist.gov/itl/smallbusinesscyber