ASTP Assistant Secretary for Technology Policy

Sequoia Project Annual Meeting 2024

HHS Assistant Secretary Micky Tripathi

December 10, 2024
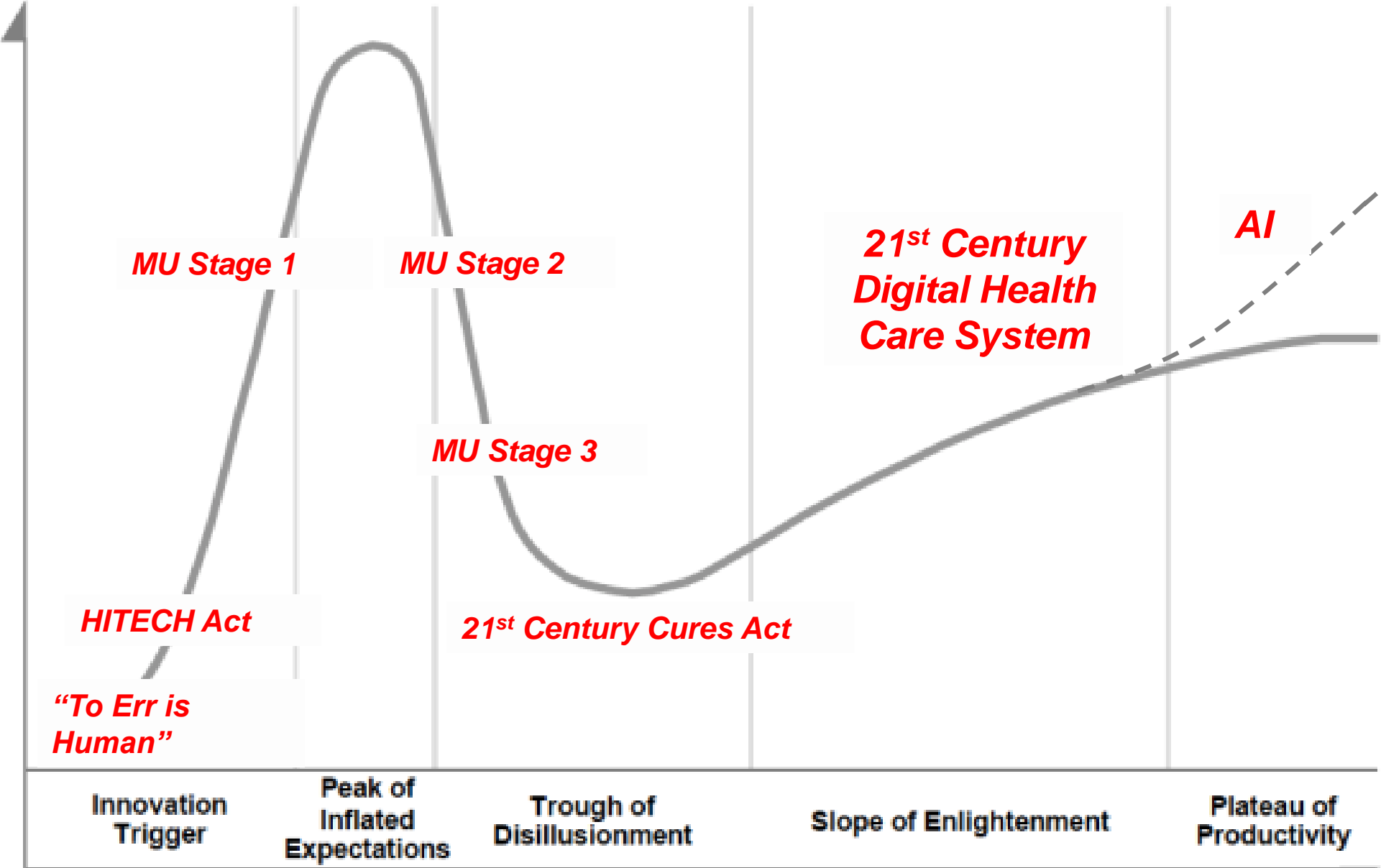
ONC > ASTP TEFCA FHIR® **Information Blocking** Health AI

ONC > ASTP

ONC is now the Assistant Secretary for Technology Policy

U.S. Department of Health and Human Services
Enhancing the health and well-being of all Americans

FOR IMMEDIATE RELEASE
July 25, 2024

Contact: HHS Press Office
202-690-6343
media@hhs.gov

HHS Reorganizes Technology, Cybersecurity, Data, and Artificial Intelligence Strategy and Policy Functions

The U.S. Department of Health and Human Services (HHS) today announced a reorganization that will streamline and bolster technology, cybersecurity, data, and artificial intelligence (AI) strategy and policy functions.

Opportunities in data and technology in healthcare and human services have grown significantly in recent years. Historically, responsibility for policy and operations has been distributed across the Office of the National Coordinator for Health Information Technology (ONC), the Assistant Secretary for Administration (ASA), and the Administration for Strategic Preparedness and Response (ASPR). This reorganization will clarify and consolidate these critical functions, as follows:

- ONC will be renamed the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP/ONC);
- Oversight over technology, data, and AI policy and strategy will move from ASA to ASTP/ONC, including the HHS-wide roles of Chief Technology Officer, Chief Data Officer, and Chief AI Officer; and
- The public-private effort between the health sector and the federal government on cybersecurity ("405(d) Program") will move from ASA to ASPR, joining the other health sector cybersecurity activities already located in ASPR's Office of Critical Infrastructure Protection, and advancing the Department's one-stop-shop approach to healthcare cybersecurity.
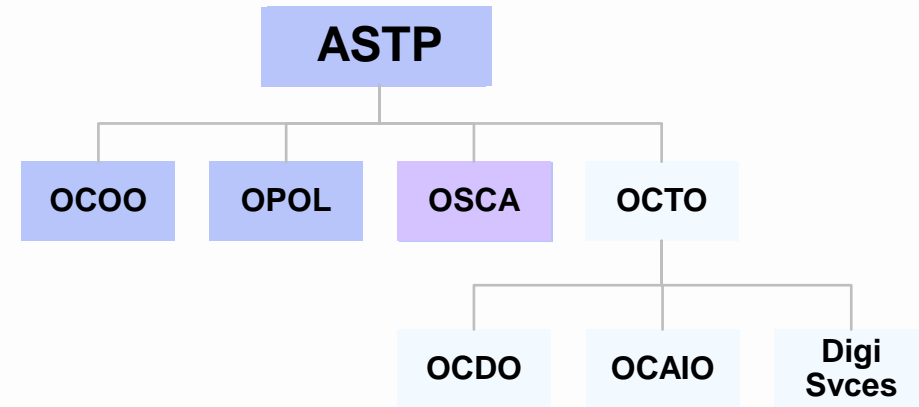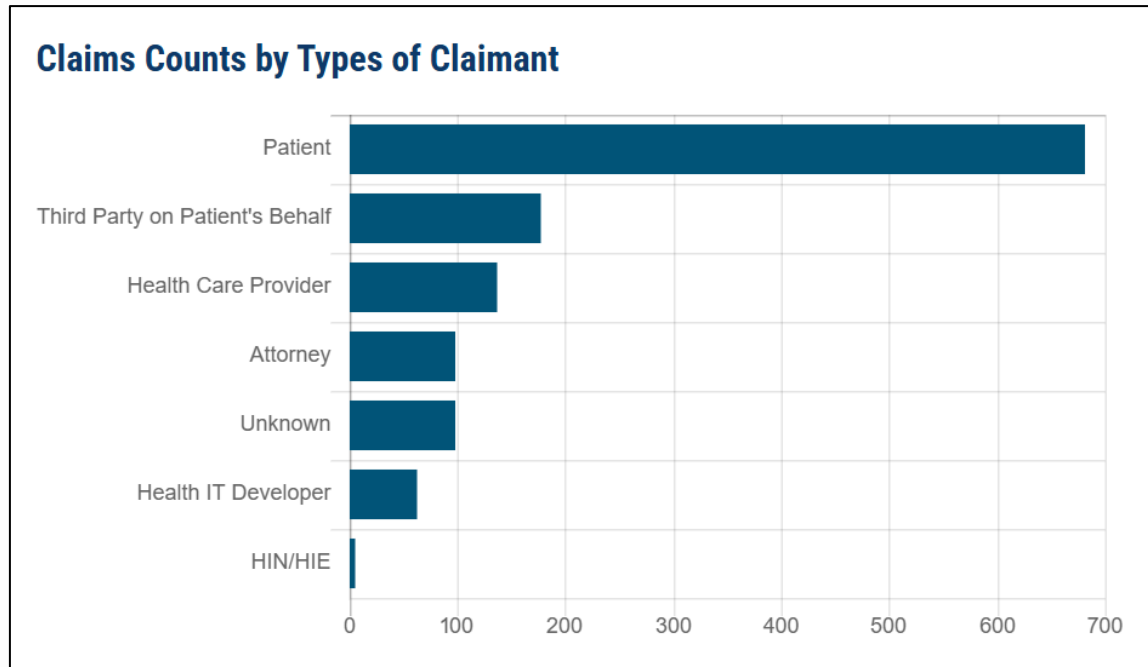
- Consolidates and focuses management resources within the Secretary's office

- Establishes HHS focus on technology innovation as a key mission priority and enabler

- Formalizes department-level and cross-agency work that ONC has already been doing

- Builds on well-established ONC coordination, technical, policy, and regulatory chassis
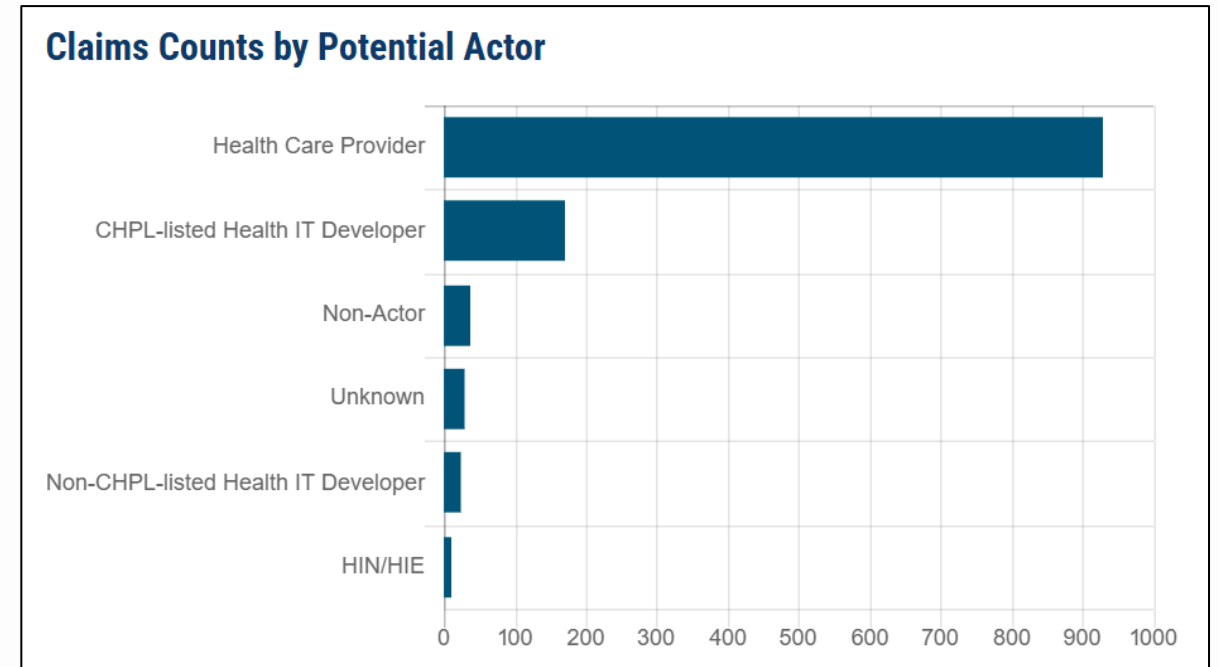
Information Blocking

Steady stream of information blocking complaints

- *1143 complaints passed to OIG as of 11/30/2024*
- *About 1 every business day*

Claims Counts by Types of Claimant

(bar chart, values approximate)
- Patient: ~680
- Third Party on Patient's Behalf: ~180
- Health Care Provider: ~140
- Attorney: ~100
- Unknown: ~100
- Health IT Developer: ~60
- HIN/HIE: ~5

x-axis: 0 to 700

Claims Counts by Potential Actor

(bar chart, values approximate)
- Health Care Provider: ~920
- CHPL-listed Health IT Developer: ~170
- Non-Actor: ~35
- Unknown: ~30
- Non-CHPL-listed Health IT Developer: ~25
- HIN/HIE: ~10

x-axis: 0 to 1000

83% of complaints by or on behalf of patients

81% of complaints against providers

ASTP — Assistant Secretary for Technology Policy

Information Blocking Regulatory Framework Now in Place

Pie chart with three equal segments:
- **Cures Act Final Rule** — Apr 2021
- **OIG Enforcement Rule** — Sep 2023
- **Appropriate Disincentives Rule** — Jun 2024

Interoperability

Getting Real about Information Blocking and APIs

Micky Tripathi | OCTOBER 8, 2024

Provider

- Doesn't publish service base URLs
- Doesn't provide same day access to EHI where available
- Doesn't allow patients to transmit EHI to 3rd party
- Restricts API to patient access and not B2B
- Imposes false regulatory hurdles such as BAA for patient-authorized app

Certified health IT developer

- API documentation not available or unsusable
- 3rd party apps closed out by onerous fees, contracts, IP requirements
- Provider endpoints not accessible to 3rd party apps
- Failure to respond to API access requests

FHIR®

2021

CURES ACT FINAL RULE
Standards-based Application Programming
Interface (API) Certification Criterion

2022

Achieving a Major Milestone: Health IT
Developers Certify to Cures Update

Robert Anthony | FEBRUARY 10, 2023

2024

Global Edition   Government & Policy

HTI-2 proposed rule includes
new certification criteria for
payer and public health IT

2024

Adding new standard for dynamic registration
• Dynamic client registration using HL7 FHIR® Unified Data Access Profiles (UDAP™) Security IG v1.0.0

Adding new standards-based API workflow capabilities
• API-based workflow triggers using HL7® CDS Hooks Release 2.0
• Verifiable health records using SMART Health Cards Framework v1.4.0 and HL7® SMART Health Cards: Vaccination and Testing IG v1.0.0
• API-based event notifications using HL7® FHIR® Subscriptions R5 Backport IG v1.1.0

1. **Interoperability → Interactivity**

2. **HTI-2 NPRM: Broaden and Deepen FHIR Adoption**

3. **FHIR API integration with network shared services (e.g., patient and endpoint look-up)**

4. **Speak up for patients:**
   - SMART Health Links
   - Scheduling
   - Imaging

TEFCA

TEFCA Go-Live

Designated QHINs as of October 2024

commonwell® HEALTH ALLIANCE

eHealth Exchange™

Epic

HEALTH® GORILLA

Kno2®

KONZA HIE

MedAllies

+

eClinicalWorks

Netsmart

surescripts®

First federal health agency joins TEFCA via eHealth Exchange

Indian Health Service moves forward on interoperability by selecting the health information network as its designated QHIN under the national agreement.
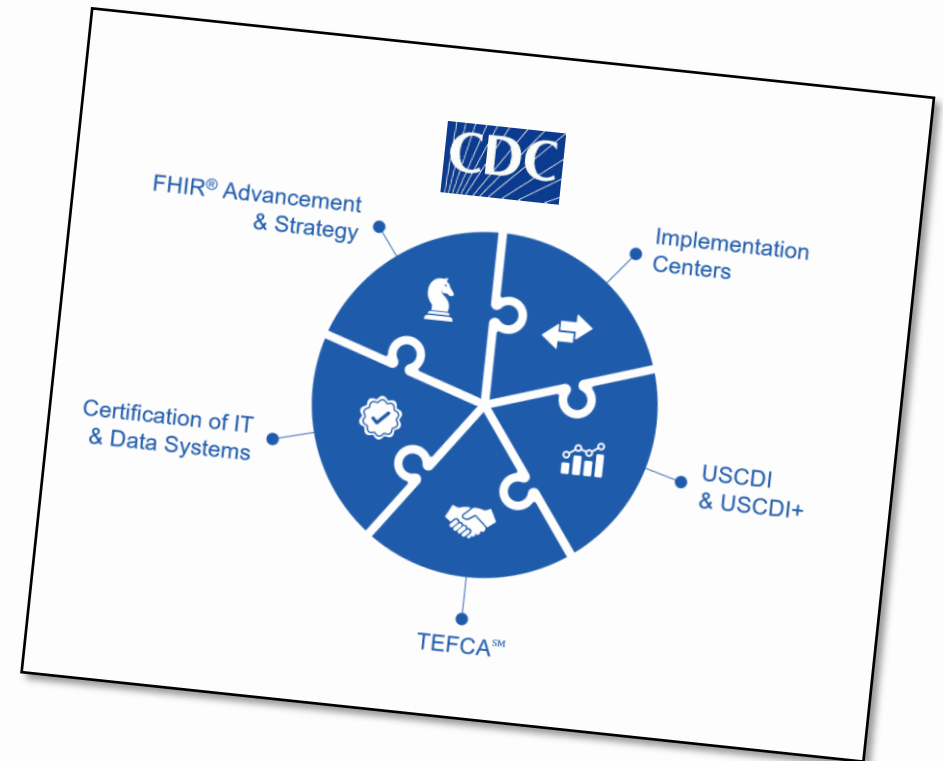
By **Andrea Fox** | December 09, 2024 | 03:45 PM

VHA Touts TEFCA to Streamline Patient Records

Vulnerable Americans Win When EHRs Work With Social Security

DC JOURNAL
AN INSIDESOURCES PUBLICATION

Posted to Politics November 25, 2024 by David Camp, Ladd Wiley

With a use case for Social Security disability claims, every American healthcare organization on TEFCA could send medical records to the SSA electronically, regardless of their EHR. This would provide a better experience for the millions of Americans who submit disability claims, save the SSA money they spend on paper records, and reduce uncompensated care provided by hospitals nationwide.

CDC

FHIR® Advancement & Strategy

Implementation Centers

Certification of IT & Data Systems

USCDI & USCDI+

TEFCA℠

TEFCA Framework Addressing Growing Market Needs for Trust and Scale

April 2024

U.S. Department of Health and Human Services
Enhancing the health and well-being of all Americans

FOR IMMEDIATE RELEASE
April 22, 2024

Contact: HHS Press Office
202-690-6343
media@hhs.gov

ONC Releases Common Agreement Version 2.0, Paving the Way for TEFCA Exchange via FHIR

The U.S. Department of Health and Human Services (HHS), through the Office of the National Coordinator for Health Information Technology (ONC) and its Recognized Coordinating Entity® (RCE™), The Sequoia Project, Inc., announced today that Common Agreement Version 2.0 (CA v2.0) has been released. The Common Agreement establishes the technical infrastructure model and governing approach for different health information networks and their users to securely share clinical information with each other – all under commonly agreed-to rules-of-the-road. The seven designated Qualified Health Information Networks™ (QHINs™) under the Trusted Exchange Framework and Common Agreement℠ (TEFCA℠) can now adopt and begin implementing the new version. Also published today is the Participant and Subparticipant Terms of Participation, which sets forth the requirements that each Participant and Subparticipant must agree to and comply with to participate in TEFCA.

July-August 2024

Multiple Policy Releases:
- Treatment Required Response
- Delegates
- Health Care Operations
- Public Health
- Governance, Security, Cooperation
- SSRAA (dynamic client registration)
- Required response to patient-initiated FHIR/OAuth queries

November 2024

What Makes TEFCA Different: New Standard Operating Procedure Strengthens Trust

Micky Tripathi and Mariann Yeager, CEO, The Sequoia Project (the TEFCA Recognized Coordinating Entity) | DECEMBER 10, 2024

Health Data, Technology, and Interoperability: Trusted Exchange Framework and Common Agreement (HTI-2) Final Rule

ASTP's HTI-2 final rule finalizes certain Trusted Exchange Framework and Common Agreement™ (TEFCA™)-related proposals from the HTI-2 proposed rule to advance interoperability and support the access, exchange, and use of electronic health information. The HTI-2 final rule amends the information blocking regulations by including definitions related to the TEFCA Manner Exception. It also implements provisions to support the reliability, privacy, security, and trust within TEFCA.

- The HTI-2 Final Rule finalizes a new part of the Code of Federal Regulations (CFR) for provisions related to TEFCA in 45 CFR Part 172. These final provisions further implement the Public Health Service Act section 3001(c)(9) as added by the Cures Act and provide greater transparency of TEFCA processes.

- The HTI-2 Final Rule makes no changes to the TEFCA Manner Exception (§ 171.403) and adopts the TEFCA-related definitions as proposed.

TEFCA Implementation Updates and Roadmap

Transactions (thru Aug 2024)
- Patient searches: 486,415,622*
- Document queries: 4,906,280
- Document retrieve: 2,592,841

TEFCA live participants (thru Q2 2024)**
- Total directory entries: 10,385
- Hospitals: 439
- Physician offices: 5,255
- Mental health centers: 58
- LTPAC: 150
- Public health agencies: 37
- Individual clinicians: 116,505
- Payers: 0

*Patient searches go to all QHINs

**Number of available facility endpoints as defined by Participants

Treatment
- "Optional" exchange

Health Care Operations
- Launching 10x10 Payer-Provider TEFCA sprints for exchange of clinical and claims data – multiple efforts being launched

Individual access
- Patient notification of record exchange
- Individual access enhancement to support technology-only apps
- Adoption of secure, portable, verifiable patient identity and governance for TEFCA-wide trust

Federal partners: SSA, VHA, FDA, CMS (CMMI), NIH

Health AI Regulation and Collaboration

Core Infrastructure

Health Care Products

Health Care Uses

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

FDA

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

January 2021

ONC

HTI-1 Rule: Algorithm Transparency

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
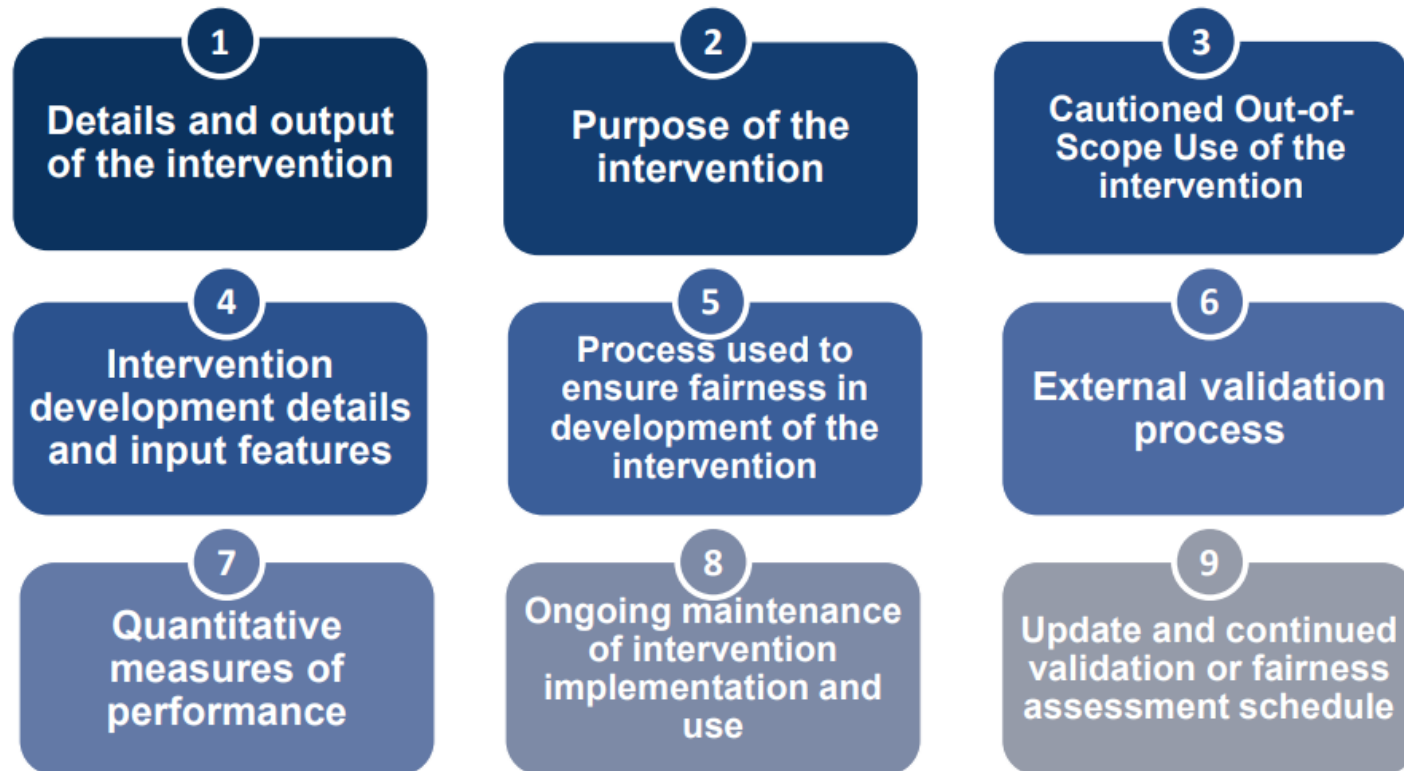
DECEMBER 14, 2023

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*

Strategic Plan for the Use of Artificial Intelligence in Health and Human Services

DRAFT

November 2024
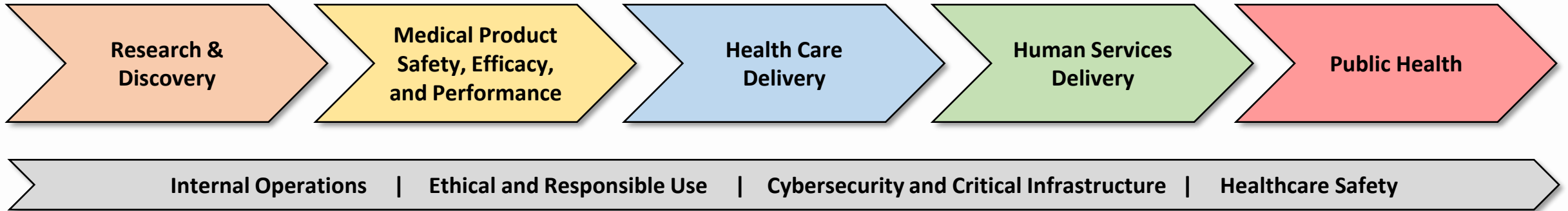
United States Department of Health and Human Services

HHS has significant AI equities across the value chain

NON-EXHAUSTIVE | ILLUSTRATIVE

Legend: ☐ Minimal equities   ☐ Moderate equities   ■ Highest equities between Operating Division and domain

Operating Divisions	Medical Research and Discovery	Medical Product Development, Safety, and Effectiveness	Healthcare Delivery	Human Services	Public Health
Administration for Children and Families (ACF)	Minimal	Minimal	Moderate	Highest	Moderate
Administration for Community Living (ACL)	Minimal	Minimal	Minimal	Highest	Moderate
Agency for Healthcare Research and Quality (AHRQ)	Moderate	Moderate	Highest	Minimal	Highest
Advanced Research Projects Agency for Health (ARPA-H)	Highest	Highest	Moderate	Minimal	Moderate
Administration for Strategic Preparedness and Response (ASPR)	Minimal	Minimal	Minimal	Minimal	Highest
Centers for Disease Control and Prevention (CDC)	Minimal	Moderate	Highest	Minimal	Highest
Centers for Medicare and Medicaid Services (CMS)	Minimal	Moderate	Highest	Moderate	Highest
Food and Drug Administration (FDA)	Moderate	Highest	Moderate	Minimal	Highest
Health Resources and Services Administration (HRSA)	Minimal	Minimal	Highest	Highest	Highest
Indian Health Service (IHS)	Minimal	Minimal	Highest	Moderate	Moderate
National Institutes of Health (NIH)	Highest	Highest	Moderate	Minimal	Highest
Substance Abuse and Mental Health Services Administration (SAMHSA)	Minimal	Minimal	Moderate	Highest	Highest

ASTP Assistant Secretary for Technology Policy

HHS AI Strategic Plan

| 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*

This year, be thankful for AI in...

Flipped Healthcare: The AI-Empowered Patient

IF YOU'RE struggling to come up with something you're grateful for this Thanksgiving, here's a development all feastgoers can celebrate regardless of their political leanings: Artificial intelligence is revolutionizing medicine, making health care more accurate and less expensive for everyone.

AI is still in its infancy, yet it is already promising to transform how physicians do their jobs. Take, for example, cancer screenings. One [...] from 2022 [...]

EDITORIAL trai[...]

half the n[...]
A 2024 [...] that screenings [...] were more accurate [...] the technology. Another review [...] similar results for breast cancer screenings, while also showing that AI reduced the workload of radiologists by 68 percent.

The benefit here is twofold: The technology can help detect cancer at earlier stages, making it easier to treat. It is also better at determining which tumors are benign, limiting the number of unnecessary and expensive biopsies that patients must endure (as well as the anxiety that comes with the procedures). The purpose is not to eliminate humans in medicine; it is to give them better tools to help their patients. Then again, as AI models

improve, it's possible to imagine a future in which physicians are *required* to use them in screening and doctors devote more and more of the[...] doing things AI is less suit[...] interacting with patie[...] and thinking [...] circu[...]

[...] about [...]mon people who [...] every year are misdiagnosed [...] million people are unnecessarily [...] because of their misdiagnosis. Roughly [...]0,000 are permanently disabled or die.

Artificial intelligence has the potential to significantly reduce those tragedies. A recent study out of Boston comparing the performance of chatbot-assisted physicians in diagnosing patients with that of chatbots alone found that the bots performed considerably better. Given a patient's case history and symptoms, the chatbot alone scored an average of 90 percent in correctly diagnosing their condition. Physicians using the technology scored only 76 percent on average — just marginally better than the 74 percent average for humans with no AI help at all.

AI can also speed up care in emergency settings. One study found that hospitals that used AI to detect strokes from a patient's brain scans were

> As AI improves, doctors will be able to devote more of their time to interacting with patients, explaining the medicine, and thinking through unusual or unexpected circumstances.

already are. But it could free up physicians' time dedicated to mundane tasks and cut seemingly interminable wait times at medical practices.

Arguably, AI's greatest promise is the one that's hardest to see: its potential to turbocharge medical research. For instance, AlphaFold2, the artificial intelligence program developed by Google DeepMind, has started to crack the code on how proteins

take their specific shapes, a question that has confounded scientists for decades. This is important because the shape of proteins governs virtually every task carried out in the body, from delivering oxygen through the blood to controlling a person's appetite. In the past century, understanding these complex molecules took years of painstaking work. Machine learning is reducing that time frame to a tiny fraction. Such research power could uncover clues to therapies for an enormous variety of diseases.

The challenge with all these exciting developments, of course, is that AI technology can be expensive to adopt. It also requires a lot of energy, which will put pressure on the electrical grid and might accelerate climate change if powered by carbon-intensive sources. The federal government can help address these problems by, for example, offsetting new demand for electricity by expanding the grid with cleaner energy, including nuclear power.

The emergence of AI has provoked great alarm in recent years, and for good reason. The technology could disrupt the economy, upending industries in unpredictable ways. Its awesome power deserves caution, but not fear. Americans can take comfort in the fact that, when it comes to medicine, this bit of human ingenuity has been a force for good — and will probably continue to be.

ASTP — Assistant Secretary for Technology Policy