



## Artificial Intelligence

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### GENERAL NEWS

- This week, California Governor Newsom will decide whether to sign or veto a broad-based AI bill that is considered the most significant AI safety legislation to date and a catalyst for the upcoming national debate about how to regulate AI.
  - Serious lobbying on both sides of the issue is bringing great pressure to bear: the bill is opposed by most of the AI industry and former House Speaker Nancy Pelosi, but powerful unions – including Hollywood’s SAG-AFTRA – is pushing Newsom to sign it.
- Senator Edward J. Markey (D-Mass), member of the Senate Committee on Commerce, Science and Transportation, introduced the *Artificial Intelligence (AI) Civil Rights Act*, to place guardrails on companies’ use of algorithms for “consequential decisions” in an effort to gain consumer trust in these models. The definition of consequential decisions includes but is not limited to “having a material effect on access to, eligibility for, or the cost of ... health care.”
  - Speaking of trust, *the New York Times* published an article about how doctors are sending messages to patients using AI and most patients have “no idea” that AI is being used.
- **Duke-Margolis** and Duke Health AI are hosting an event on October 28 to discuss how to keep patients safe while encouraging innovation.
- **The Coalition for Health AI (CHAI)** is hosting an event on Capitol Hill on November 21, 2024, to “explore the frontiers of AI in healthcare and foster dialogue on the future of legislative collaboration.” RSVP using this form by November 11, 2024.
- **Pieces Technologies** reached a settlement with the Texas attorney general regarding allegations that it falsely portrayed the accuracy of its AI-generated clinical tools.
  - Although the company denied misconduct claims, it agreed to provide clearer information about the performance and risks of its tools moving forward. The settlement did not include any monetary penalties.
- **Google** is raising eyebrows for its \$2.7B deal to buy Character.AI, a chatbot. It was developed by former Google employee Noam Shazeer -- who is credited with starting that AI boom -- and will now return to working for Google.
- The Federal Trade Commission is taking action against multiple companies that have relied on AI to deceive consumers -- part of its new law enforcement sweep called Operation AI Comply. The FTC announced five cases, none of which involve healthcare.
- The U.S. Department of State announced The Partnership for Global Inclusivity on AI, a collaboration with **Amazon, Anthropic, Google, IBM, Meta, Microsoft, Nvidia, and OpenAI** to use AI for sustainable development in developing countries. Over \$100 million was committed to increasing AI access, capacity, and local data resources.



- Secretary Blinken also announced U.S. funding to promote AI education, human rights, and responsible governance. This includes a \$1.2 million project to create a Safe, Secure, and Trustworthy AI Policy Framework for member states of the Organization of American States, an initiative relevant to health AI policy.
- The **Consumer Technology Association (CTA)** signed a memorandum of understanding with the **Association for the Advancement of Medical Instrumentation (AAMI)** and will collaborate to produce standards for AI and machine learning in healthcare products.
- Health systems are partnering with software vendors for AI solutions and prioritizing foundational IT improvements while dealing with the challenges of hiring skilled cybersecurity professionals, according to an article in *Becker's*.
- Four health system leaders were recognized in **Constellation Health's** "Artificial Intelligence 150," a list of the top executives leading global AI transformation efforts.
- Only 53% of patients trust the use of AI in healthcare, but increased implementation should be explored, according to a study by **Upvio**.

#### ADMINISTRATIVE APPLICATIONS

- **Kyruus Health** announced Guide, an AI-based conversational search tool, and Provider Data Solutions, a curated source of provider data and appointment scheduling information.
- **United Healthcare** launched the Find Care and Costs tool, using AI to offer users personalized recommendations for in-network providers, cost estimates, and quality metrics.
- **RadiantGraph** launched integration services with Google Cloud Platform, AWS, Databricks, and Snowflake, enabling health plans to synthesize complex healthcare data from several sources and deliver personalized communication to improve patient outcomes.
- **Wellsheet** integrated **Wolters Kluwer Health's** evidence-based UpToDate content into its Smart EHR UI application, providing streamlined access to important clinical tools to improve patient care.
- **Nabla** integrated 31 new languages into its AI-based note-taking tool.
- **The International Myeloma Foundation** launched Myelo, a multilingual chatbot that simplifies advanced medical terms, answers questions, and provides detailed information to patients throughout their multiple myeloma diagnosis and treatment.
- **Suki's** AI Assistant was implemented in over a dozen **MEDTECH Expanse** health systems, integrating its voice AI assistant with EHR.
- Nallan Sriraman, CTO of **Mass General Brigham**, discussed the hospital system's introduction of ambient documentation, balancing patient privacy with policy compliance, and the patient-centered focus of AI in healthcare with *Becker's*.
  - Sriraman also discussed challenges of integrating AI into healthcare, particularly in privacy, data accuracy, and the importance of interdisciplinary collaboration across the organization.
- Varun Ganapathi, cofounder and CTO of **Akasa**, stated that generative AI can improve revenue cycle management by helping coders work faster and more accurately.

#### CLINICAL APPLICATIONS

- **Neuralink** received FDA Breakthrough Device Designation for Blindsight, a brain implant designed to restore vision by sending signals to the visual cortex, helping patients process them as low-resolution images.
- **Family Heart Foundation** announced the FIND Lp(a) model that identifies patients with high Lp(a) levels and improves Lp(a) screening efforts in cardiovascular disease patients. The model demonstrated 60% precision when tested using the Family Heart Database of lab data and medical claims.
- **Duke Health** partnered with **SAS** to develop AI-based digital-twinning tools that illustrate the impact of operating system changes pre-implementation. This partnership provides Duke Health access to SASViya data, AI platform, and health applications, helping improve efficiency and quality of care.
- **Gusi** announced a Sage AI tool that answers multilingual open-ended ultrasound questions.



- **Fabric** acquired **TeamHealth Virtual Care**, improving its conversational AI technology to expand patient navigation and access to virtual and in-person care across the country.
- **Mendel AI** announced the availability of Hypercube in the Snowflake Data Cloud, a tool that integrates advanced LLMs with a clinical hypergraph to synthesize fragmented healthcare data into clinical insights.
- Despite AI's ability to provide therapy, it cannot replace therapists due to a limited understanding of the pathways leading to particular AI responses, AI's inability to imitate human connection, and current limited information on psychotherapy, according to an article in *Forbes*.
- AI-assisted pathology is predicted to improve the diagnosis and treatment of fibrotic liver disease by providing more precise, quantitative assessments and improving clinical trial consistency.

#### RESEARCH APPLICATIONS (Drug Discovery, etc.)

- **Morehouse School of Medicine** partnered with **Manifold** to advance cancer research by merging social and genomic data, striving to understand disparities in underrepresented populations.
  - This collaboration will allow the Institute of Translational Genomic Medicine to modernize its data analysis, starting with an investigation into how cancer affects breast cancer patients of African ancestry.
- Neurosymbolic AI can improve diagnostic accuracy and explainability, interpret neural signals, and apply logical rules for patient-specific treatments, according to three members of the **Forbes Technology Council**.
- Experts led by the Society for Imaging Informatics and Medicine Machine Learning Tools and Research Subcommittee are using NVIDIA-powered federated learning to advance AI models for tumor segmentation. This initiative is designed to improve data-sharing and increase AI-assisted annotation accuracy, while ensuring patient data privacy and security.
- **Ginkgo** launched a new model API, providing machine learning scientists access to advanced biological AI models, starting with a large-scale protein model trained on proprietary Ginkgo data.
- **Dandelion Health** announced an AI marketplace to validate AI models and use them in clinical trials, by integrating third-party algorithms with Dandelion's data.
  - Their study demonstrating the effectiveness of GLP-1 on reducing heart disease risk demonstrates their goal to advance drug testing by validating AI algorithms.
- **Insilico Medicine's** AI-developed drug ISM001-055 demonstrated dose-dependent lung function improvements in a Phase 2a study for idiopathic pulmonary fibrosis.
- **Generate:Biomedicines** partnered with **Novartis** to develop new protein therapeutics using *de novo* generation and AI-based optimization.
- **Komodo Health** partnered with **Cornerstone AI** to improve their MapEnhance platform with AI-powered data cleaning technology, after a successful pilot that improved the clinical trial data quality and drug development findings.



## Digital Health

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#### FEDERAL NEWS

- Senators and healthcare organizations are urging the DEA to extend telehealth prescribing flexibilities for another two years, but it's unclear whether the DEA will pass any extensions due to the fear of misuse of controlled substances prescribed through telehealth.
  - Further, a two-year extension of pandemic-era flexibilities for telehealth unanimously passed out of the House Energy & Commerce Committee and is very similar to the bill passed out of the House Ways & Means Committee – meaning the House likely has a unified position when it enters into negotiations with the Senate.



## TELEHEALTH

- **Pomelo Care** is acquiring Doula Network to offer a hybrid model of maternity care that features unlimited virtual care visits for pregnancy, postpartum, and infant care, along with a connection to community doulas that can offer in-person care.
- **Fabric Health** – a care enablement system company – is acquiring TeamHealth to expand their virtual care offerings – including urgent care, primary care, and behavioral health services – to payers, employers, and health systems across the 50 states.
- A digital health readiness screening tool, which tests for technical readiness and quality-of-care concerns, can help identify patient barriers to adoption of digital health – a study published in JAMA Network Open suggests.

## REMOTE PATIENT MONITORING

- HHS OIG urged CMS to implement additional protections around remote patient monitoring (RPM) to ensure RPM is being used appropriately and to protect against RPM fraud, after an OIG review found that RPM may not be currently used as intended.
  - The Alliance for Connected Care, a lobbying group, requested that the HHS OIG retract its report.



## Interoperability and Health IT

### FEDERAL NEWS

- ASTP released the 2024 Draft Federal FHIR Action Plan for the use and implementation of Health Level Seven (HL7) FHIR standard in federal agencies across six areas: core, network, payment and health equity, care delivery and engagement, public health and emergency response, and research.
  - Public comments will be accepted until November 25.
- ASTP released a data brief about the interoperability of laboratory data with health information exchange organizations (HIOs) and the challenges HIOs faced when gathering data – based on a national survey of HIOs conducted in 2023.
- HHS awarded \$2M in funding through the Leading Edge Acceleration Projects in Health IT, an initiative that provides funding to entities that are addressing various challenges related to interoperable Health IT. The two awardees are:
  - The Trustees of Columbia University in the City of New York for their study of nursing data used to create more comprehensive AI tools.
  - Oregon Health & Science University (OHSU) for their project that seeks to implement MyCarePlanner/eCarePlanner apps in behavioral health settings to improve the exchange of health information.

### INDUSTRY NEWS

- **Particle Health** – a company that uses AI to create a comprehensive display of patient medical data – filed a federal antitrust lawsuit against **Epic**, alleging they blocked Particle from leveraging patient medical records. The lawsuit claims that Epic uses its monopoly on EHRs to block competitors from entering the market.
  - Epic, however, says that Particle’s claims are “baseless,” and that Particle violated HIPAA privacy regulations.
- **Real Time Medical Systems** filed a lawsuit against **PointClickCare**, arguing the company’s overly restrictive data sharing and policy against bot-enabled screen scraping amounts to information blocking.
  - The AHA and Electronic Health Record Association filed an amicus brief in support of PointClickCare.



- The AMA wrote a [letter](#) to the Biden Administration support ASTP/ONC's information blocking exception updates in its proposed HTI-2 rule.
- **Labcorp** [joined](#) **CommonWell Health Alliance's** QHIN to participate in TECCA.
- **Bain and Company's** annual healthcare IT survey showed that approximately 75% of U.S. providers and payers [increased](#) their IT investments over the last year.

#### DATA PRIVACY AND SECURITY

- **UnitedHealth Group** was forced to "start over" and build a new, safer environment after the Change Healthcare ransomware attack. The insurer is still working to repair the damage caused by the attack, their Chief Information Security Officer [stated](#) at the Mandiant Worldwide Information Security Exchange (mWISE) Cybersecurity Conference.
- **Ascension** – a U.S. healthcare system – is [facing](#) a \$1.1B net loss for the 2024 fiscal year after a cyberattack in May impacted operations across the system.



## Investments

#### GENERAL NEWS

- **ARCH Venture Partners**, a firm that invests in biotechnology, [raised](#) \$3 billion for a new fund that is in part focused on AI-supported tools.
- **Headline**, a VC firm with a history of investing in digital health companies, [raised](#) \$865M for its fourth growth fund.
- **YK Bioventures**, an early-stage biotech VC firm, is [planning](#) to raise \$100M for its latest fund.
- **Z21 Ventures**, a VC firm focused on early-stage tech investments in AI and healthcare, [announced](#) it raised \$20M so far of a \$40M target for its second fund.
- **Aeroflow Health**, a healthcare company using technology to support medical product and service delivery, [launched](#) a venture arm, Aeroflow Ventures.

#### AI INVESTMENTS

- **Qure.ai**, an AI-powered company for early disease detection, [raised](#) \$65M in Series D funding.
- **Hippocratic AI**, a company using LLMs for healthcare workforce augmentation, [raised](#) \$17M from **Nvidia**.
- **Ferrum Health**, a software platform that allows physicians to validate AI performance on their datasets and deploy AI into their workflows, [raised](#) \$16M in Series A funding.
- **Letta**, a startup developing AI tools that store historical data in long-term memory, [raised](#) \$10M in Seed funding.
- **Cercle**, an AI-powered women's healthcare data startup, [raised](#) \$6M in Seed funding.
- **Arya Health**, a startup leveraging AI to streamline healthcare scheduling, payroll, onboarding, and compliance, [raised](#) \$4M in Seed funding.
- **DeepLook Medical**, an AI-powered diagnostic company for breast cancer, [raised](#) an undisclosed amount in Series A funding.

#### DIGITAL HEALTH INVESTMENTS

- **Zing Health**, an MA insurer designed to empower members with personalized care through technology and value-based care delivery, [raised](#) \$140M in funding.
- **Centivo**, a health plan designed to reduce inefficiency and waste in employer-sponsored health plans that offers a tech-enabled member engagement platform, [raised](#) \$75M in equity and debt financing.
- **Coral Care**, an in-home provider of pediatric speech, occupational, and physical therapy services, [raised](#) \$5.2M in Seed funding.
- **Canopie**, a digital preventive maternal health company, [raised](#) \$3.7M in Seed funding.



## Payers and Providers

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### GENERAL

- The U.S. health system is the worst, according to a [2024 Commonwealth Fund report](#) of health systems in 10 countries. The think tank said the U.S. is a “clear outlier” with “dramatically lower” scores in the categories of access to care, administrative efficiency, equity, and health outcomes.
- U.S. Senate Finance Committee Chair Ron Wyden [announced](#) that Stacy Sanders will serve as the Committee’s “Health Chief” beginning mid-October. Sanders has served as a Counselor to the HHS Secretary since 2022 and was named the department’s first Chief Competition Officer in January 2023.
- The U.S. House Ways and Means committee [delayed](#) a markup of health bills that was expected to include Medicare physician payments alterations along with surprise billing and rural health legislation, to when Congress returns after the 2024 election, according to [Axios](#).

### HEALTHCARE TRANSPARENCY

- A new healthcare [savings calculator](#) and contract template for purchasers when negotiating with plans or third-party administrators was [published](#) by 32BJ Labor Industry Cooperation Fund, an organization that advocates for lower healthcare costs for employers and unions and has called for more price transparency.

### DRUG PRICING

- The FTC [filed](#) an administrative complaint against the three largest PBMs in the U.S. – **CVS Caremark, Optum RX, and Express Scripts** – and each companies group purchasing organizations, for using anticompetitive practices to inflate prescription drug prices.
  - An administrative judge will assess the FTC’s complaints that these PBMs allegedly [employ](#) drug rebate systems and limited formularies that steer patients to purchase higher-cost insulin medication manufactured by pharmaceutical companies paying the PBMs.
- The U.S. Senate HELP Committee [held](#) a hearing to investigate the costs of Ozempic and Wegovy, prescription diabetes and weightless drugs, with **Novo Nordisk’s** President and CEO providing testimony.
  - **Novo Nordisk’s** executive attributed drug costs to PBMs and insurance companies who take part in price negotiations underlying pharmaceutical supply chain operations. Chairman Sanders [cited](#) commitments from the three largest PBMs – **Cigna’s Express Scripts, CVS Health’s Caremark, and UnitedHealth Group’s Optum**, to continue coverage for the medications if they are offered at lower prices and [pushed](#) the CEO to agree to lower prices.
- *The Wall Street Journal* [reported](#) on a “price war” between **Novo Nordisk** and **Eli Lilly** for brand-name GLP-1 receptor drugs to increase coverage. More [here](#).
  - Wegovy was [included](#) on a [list](#) of drugs that could soon be the target of price negotiations, in an analysis published by the *Journal of Managed Care & Specialty Pharmacy*.
- A new *JAMA* article [predicts](#) the estimated savings under the CMS’ 2023 Medicare High-Value Drug List Model.

### PAYERS

- CMS [announced](#) a newly designed Medicare enrollment software, PECOS 2.0, that streamlines the application process by creating national profiles for all individuals and organizations, pre-populates information, sends renewal reminders, and allows for enrollment in multiple states through one application. More [here](#).
- **Cigna** will [reduce](#) MA plans in eight states, with the majority of 5,400 members impacted by the rollback residing in Florida.
- **Zing Health**, a value-based MA plan, [raised](#) \$140M to expand its special needs plans for dually-eligible beneficiaries.





- Ambetter, a subsidiary of **Centene**, is the subject of a *ProPublica* investigation that connects a patient's death to the company's mishandling of months of requests for access to a behavioral health provider and unsuccessful guidance from a care manager.
- Two private sector web-brokers, **TrueCoverage** and **Benefitalign**, sued HHS after being suspended from the ACA marketplace, which is the subject of a *Health Affairs* forefront article.

#### PROVIDERS

- The U.S. Senate HELP Committee voted 20-0—with Senator Rand Paul abstaining—to charge Dr. Ralph de la Torre, CEO of **Steward Health Care**, with civil and criminal contempt for defying the committee's subpoena to testify about the bankrupt hospital chain's alleged abuse of finances.
- The U.S. Senate Finance Committee (SFC) held a hearing on September 24 to examine potential violations to the Emergency Medical Treatment and Active Labor Act (EMTALA) by hospitals in states with abortion bans.
  - Prior to the hearing, Chairman Wyden sent letters to eight hospitals to request records.
- Hospitals facing readmission penalties for reducing Medicare FFS payments will continue to decrease in FY 2025 according to preliminary data from CMS that reported 100 facilities dropped from the federal readmissions program since FY 2021. Final CMS data will be released on October 1.
- Several provider organizations reported layoffs this week:
  - **Lifespan**, a five-hospital system in Rhode Island, will lay off under a quarter of its executive leaders as part of a restructuring to save \$6M during a rebranding to **Brown University Health**. The organization also purchased two hospitals earlier in the month from the now bankrupt **Steward Health Care**.
  - **CarePoint Health** filed notices with state labor regulators in New Jersey detailing potential plans to cut 2,600 employees at three hospitals in December, following financial struggles.
  - **OptumCare**, a division of **UnitedHealth Group**, also reported plans to lay off over a hundred workers in the coming months, following previous warnings that employees would be laid off in California and Ohio.

#### PAYERS & PROVIDERS (M&A)

- **Cardinal Health** entered into an agreement to acquire over 50 community oncology centers for \$1.1B in a deal that joins a trend of healthcare organizations strengthening specialty care offerings with oncology practices, according to *Reuters*.
- **Advocate Health**, one of the national's largest nonprofit health systems, will cancel over 11,500 real estate judgement liens for properties of patients with unpaid medical bills and forgive associated debt in a plan that builds on affordability policies.
- A subsidiary of **Community Health Systems** agreed to acquire 10 urgent care facilities in Arizona from **Carbon Health** in a deal expected to close by the end of the year.
- The **Alice L. Walton Foundation**, **Heartland Whole Health Institute**, **Mercy**, and the **Cleveland Clinic** announced a 30-year, \$700M facility in Northwest Arkansas, including the construction of a new cardiac care center and an outpatient center for specialty care.

#### VALUE-BASED CARE

- CMS issued a final rule to address suspect billing by ACOs. The rule is entitled "Medicare Program: Mitigating the Impact of Significant, Anomalous, and Highly Suspect Billing Activity on Medicare Shared Savings Program Financial Calculations in Calendar Year 2023."
- Two articles make suggestions about how the CMS Innovation Center (CMMI) may change its operations or be evaluated differently.

#### MEDICAID

- In an informational bulletin, CMS told states that they must be fully-compliant with Medicaid eligibility redetermination requirements by December 31, 2026.



- **Anthem, CareSource**, a subsidiary of **Centene, MDwise**, and several hospital systems were implicated in an Indiana lawsuit alleging Medicaid misuse and violations of the False Claims Act.
- Medicaid enrollment levels are higher than pre-pandemic levels despite Medicaid eligibility redeterminations, according to a *KFF Health News* analysis. Five states reported disenrollment rates over 50% and 25M total Americans were disenrolled while 56M American's renewed their coverage according to the report. Some states, including New York, North Carolina, and Washington, D.C. are still completing the redetermination process.

#### HEALTH EQUITY & SDOH

- HHS announced several grant programs including:
  - \$240 for mental health services in 400 community health and primary care, furthering a commitment to address the mental health crisis in the Unity Agenda.
  - \$75M for substance use disorder treatment and recovery services in rural areas.
  - \$9M for women's health coverage in 14 states through the Affordable Care Act
  - \$3.6M for dementia care in tribal and urban Indian health systems, awarded over three years as part of the agency's National Plan to Address Alzheimer's Disease
- *News on access to care:*
  - HHS' Advanced Research Projects Agency for Health (ARPA-H) announced the Emerging Health Innovators Initiative, which will invest in early career and community-based innovators to reduce healthcare gaps. Awards will be available in two tracks: technology-driven innovation and community-center innovation.
  - A study by George Washington University researchers examining race and ethnicity in physicians found family physicians who identified as Black, Latino, Hispanic, or of Spanish origin care for a disproportionate amount of Medicaid beneficiaries, underscoring barriers in access to care and a need for greater diversity in the workforce. More here.
  - In 2022, nearly one-third of counties in the U.S. lacked a provider or program for opioid use disorder that treated a single Medicare or Medicaid beneficiary, according to a recent report by HHS Office of Inspector General.
- *News on women's health:*
  - The Department of Defense is investing \$500M toward researching women's health, as well as adopting a new policy to ensure women's health is considered during every step of the military's research process. This builds on an executive order in March for federal agencies to integrate research on a range of women's health conditions in portfolios.
  - *The Hill* reported on systemic failures to treat chronic pain in female patients and clinician who minimize symptoms reported by women, delay treatment, or misdiagnose patients with endometriosis, rheumatoid arthritis, fibromyalgia, and migraines.