**Maverick Health Policy**

**MYMAVERICK WEEKLY NEWSLETTER**
# September 5, 2024

# Artificial Intelligence

**GENERAL NEWS**

- FDA's Center for Drug Evaluation and Research (CDER) launched an AI Council to steer the agency's internal AI use and policy pertaining to regulatory decisions.
- HHS announced funding for **ARPA-H**'s PRECISE-AI initiative to develop tools that fix performance issues in AI-based medical devices, increasing their precision and reliability in clinical settings.
- Race-based algorithms are still widely used in medicine despite some tools negatively impacting black patients, according to a *STAT News* investigation.
- Experts discussed issues in AI risk management, debated its effects on health disparities, and advocated for stronger government oversight at the Responsible AI For Health Symposium.
- AI remains the most exciting new technology in healthcare for the fourth consecutive year, with 85% of executives believing it has significant potential to improve administration, operations, and clinical care, according to a survey by the **Center for Connected Medicine** at UPMC.
- **Samsung** acquired **Sonio** to improve global maternal care growth and ultrasound technology by combining Sonio's AI-based solutions with Samsung's engineering experience.

**ADMINISTRATIVE APPLICATIONS**

- **CareMessage** launched a new automated mobile messaging tool to improve the management of uncontrolled diabetes in Federally Qualified Health Centers.
- **Elation Health** announced Note Assist, a tool designed to improve documentation for primary care physicians by automatically structuring patient visit details in real-time.
- **Medscape** introduced Medscape Scribe, a free AI medical scribe for US physicians that transcribes patient visits and generates summaries using SOAP, H&P, or POMR templates.

**CLINICAL APPLICATIONS**

- **Bot Image**'s FDA-cleared ProstatID AI software improves early cancer detection and is now reimbursable by Medicare and United Healthcare.
- AI-driven clinical decision support in EDs does not improve cardiovascular outcomes, but it does lead to better evidence-based care and fewer unnecessary invasive procedures, according to research presented at ESC Congress 2024.
- ChatGPT-4 Vision, the first AI capable of interpreting both text and images, performed well on text-based radiology exam questions. However, it correctly answered only 47.8% of image-based questions, according to a study published in Radiology.
- Researchers from **Weill Cornell Medicine** and **HSS** developed an ML tool that effectively identifies rheumatoid arthritis subtypes from pathology slides.

- - This technology was designed to automate the subtyping process, which can increase accuracy in RA care and clinical trials, according to a study published in *Nature Communications*.
- AI-guided screening improved the diagnosis of left ventricular systolic dysfunction in pregnant and postpartum women, according to a study published in *Nature*.
- ML models trained on hand surgery data predicted persistent opioid use with varying accuracy, demonstrating their potential to identify at-risk patients and support early interventions to prevent addiction.
- **TQIntelligence**'s AI-enabled voice algorithm for measurement-based care in community behavioral health challenged the belief that these systems are too complex for low-income pediatric populations, according to this study published in *Telehealth and Medicine Today.*
- **Ava** announced an AI rewards platform to help home care providers lower turnover and increase caregiver engagement through automation and simplified recognition systems.

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

- **Recursion**'s phase 2 trial of REC-994 met safety and tolerability goals but only showed partial efficacy, leading to a 10% drop in its share price. However, the company hopes future trials and its partnership with **Exscientia** will lead to better results.
- A discredited study, published in 2020, used a form of AI to discover microbial DNA indicative of particular cancers, demonstrating the pitfalls of using AI when it is used to assist with scientific data analysis. *The Wall Street Journal* reported on the study that was retracted in late June showing that a blood test could diagnose cancer by detecting certain microbes. Before the study was discredited, the new and clinically significant finding attracted investors and ~600 research papers relied on it.

# Digital Health

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**TELEHEALTH**

- **Reimagine Care**, a cancer-care platform, expanded its relationship with **Memorial Hermann Health System** and will offer oncology patients virtual, digital, and in-home care beyond the flagship hospital.
- **The Vitamin Shoppe** expanded its telehealth service, Whole Health Rx, to include prescription Testosterone Replacement Therapy (TRT) in partnership with **Marius Pharmaceuticals**.
- **Truepill** partnered with **ScriptDrop** to integrate same-day prescription delivery into its digital pharmacy platform, allowing users to receive medications within two hours.
- Female physicians, older physicians, psychiatrists, and neurologists deliver a greater proportion of visits via telehealth than other Medicare fee-for-service physicians, according to a new study and accompanying podcast with *Health Affairs*.

**REMOTE PATIENT MONITORING**

- **Huawei** announced the HUAWEI TruSense System, an advanced health and fitness technology that integrates vital signs. This system will be incorporated into the product launch starting this September.
- **Embecta** developed a new patch pump for insulin delivery, incorporating feedback from Type 2 diabetes patients. The company has submitted an open-loop version to the FDA and is working on a closed-loop system.
- UK-based health tech startup **Doccla**, the largest remote patient monitoring provider for the NHS, raised a £35M Series B round to expand its virtual ward technology across France, backed by investors including **Lakestar**, **Elaia**, and **General Catalyst**.

**HOME-BASED CARE**

- **Compassus** and **OhioHealth** finalized their partnership to create "OhioHealth at Home in partnership with Compassus," offering home health and hospice services.

# Interoperability and Health IT

**FEDERAL NEWS**

- HHS decided <u>not to appeal</u> its loss in the <u>case</u> against the American Hospital Association (AHA) regarding the enforcement of a HIPAA on online tracking technologies. This decision finalizes the AHA's victory, allowing hospitals to use these technologies, as the court ruled that HHS had exceeded its authority under HIPAA.
- The FDA <u>finalized</u> its <u>guidance</u> for the Voluntary Malfunction Summary Reporting (VMSR) program, allowing medical device manufacturers to submit quarterly summaries of certain device malfunctions instead of monthly individual reports.
- *Forbes* <u>interviewed</u> ASTP/ONC Leader / Acting Chief Health AI Officer <u>Micky Tripathi</u> about TEFCA, the HTI-2 proposed rule, the Epic-Particle controversy about data exchange, information blocking, and so much more.

**INDUSTRY NEWS**

- **CommonWell Health Alliance** <u>announced</u> three members joined its new TEFCA platform – **athenahealth**, **ModuleMD**, and **Solace Health** – and updates to the platform.
- **Geisinger** <u>changed</u> its ED note templates and reduced the average length of provider notes by 40%.

**DATA PRIVACY AND SECURITY**

- Only about 350 of 1,800 small and rural U.S. hospitals have <u>accessed</u> the cybersecurity help offered through a new program with **Microsoft** and **Google**.
- U.S. House of Representatives Homeland Security Committee Chairman Mark E. Green <u>announced</u> that Adam Meyers of **CrowdStrike** will testify on September 24, 2024, regarding a global IT outage caused by a faulty software update. The IT outage had previously impacted the regular functions of many hospitals.
- The FBI, CISA, MS-ISAC, and HHS <u>released</u> a joint advisory announcement on RansomHub ransomware, providing mitigation recommendations to help network defenders protect against such ransomware attacks.

# Investments

**GENERAL NEWS**

- *Business Insider* <u>listed</u> the top 22 most promising healthcare AI startups according to VC firms.
- **Sozo Ventures**, a venture firm focused on investing in IT, including health IT, is <u>raising</u> $500M for its newest fund.
- **New Enterprise Associates**, a venture capital firm that invests in multiple sectors, including digital health and life sciences, <u>raised</u> over $468M for a secondary fund.
- **PruVen Capital**, a multi-stage venture firm that invests in multiple sectors, including healthcare, <u>raised</u> $378M for its second fund.
- **Pebblebed**, a venture capital firm that invests in technical founders solving difficult problems, including AI and biotech, is <u>raising</u> a $125M fund.
- **Amplify.LA**, a venture firm that invests in early-stage tech companies, including health tech, <u>raised</u> $60M for its newest fund.
- **Oncology Ventures**, a new venture firm focused on improving care with data through early detection and optimal treatment plans, <u>raised</u> $30M for its inaugural fund.

- **Arāya Ventures**, a UK-based fund that invests in pre-seed and seed stage founders in health tech and other sectors, <u>raised</u> $10.9M for its Super Angel Fund.
- **Harmonix Management**, a venture firm that invests in healthcare, life sciences, and data-driven technologies, is <u>announcing</u> the close of its third fund at the end of October.

**AI INVESTMENTS**

- **Samsung Medison**, Samsung Electronics' medical device unit, <u>acquired</u> **Sonio**, a startup that develops AI-powered software for ultrasound workflows, for $92.7M.
- **Noetik**, an AI-native biotech company using machine learning to develop cancer therapeutics, <u>raised</u> $40M in Series A funding.
- **Piramidal**, an AI-powered neurotech startup that is designed to give users an instant diagnosis of neurological conditions, <u>raised</u> $6M in Seed funding.
- **PsychoGenics**, an AI-enabled phenotypic drug discovery company, <u>received</u> a $3M SBIR Grant from the National Institute of Mental Health.

**DIGITAL HEALTH INVESTMENTS**

- **Doccla**, a virtual and remote patient-monitoring care solution, <u>raised</u> £35M in Series B funding.
- **Segmed**, a startup that offers real-world imaging data for AI/ML development, <u>raised</u> $10.4M in Series A funding.
- **Flex**, developer of infrastructure for accepting HSA and FSA payments, <u>raised</u> $3.2M in seed funding.

# Payers and Providers

**HEALTHCARE TRANSPARENCY**

- **Health Care Service Corporation (HCSC),** a company that owns a regional set of Blue Cross Blue Shield plans – the fifth largest insurer in the U.S., <u>launched</u> a new health plan that will allow members to choose from providers based on their quality ratings, see their out-of-pocket costs up front, and pay a monthly bill for services instead of paying for services at the time of delivery.

**DRUG PRICING**

- In a <u>letter</u> to HRSA, the agency that enforces the 340B drug discount program, the AHA <u>asked</u> for **J&J** to face financial penalties for its plan to offer hospitals rebates for discount drugs, instead of offering upfront discounts as historically implemented.
- **Sandoz**, a European generic drug manufacturer previously associated with **Novartis**, <u>announced</u> plans to capitalize on the patent expiration of GLP-1 receptor drugs and release a generic version of Ozempic in Canada and the U.S. in 2026 and 2030, respectively.
- Even with the negotiated prices through the Inflation Reduction Act program, the U.S. will still <u>pay more</u> than double, and sometimes five times more, what other high-income countries pay for the same drugs, according to a recent analysis.
- Another study about the Inflation Reduction Act program <u>evaluates</u> the accuracy of CMS' claim that they would have saved $6B last year if the program had been in place then. The authors conclude that CMS overstated the savings because net prices and utilization of selected drugs will continue to change, and the new Medicare Part D benefit design includes mandatory discounts that CMS will absorb for the negotiated drugs – and CMS didn't take that cost into account.
- While rebates <u>limited</u> drug price increases for insurers, consumers' out-of-pocket costs grew by a faster rate from 2007-2020, according to a <u>study</u> published in *Health Affairs.*

**PAYERS**

- After a partial launch last year, **UnitedHealthcare (UHC)** <u>announced</u> the details of their prior authorization <u>Gold-Card Program</u> that will be offered to in-network providers across all of their business

lines. Physicians that have submitted at least 10 prior authorization requests for eligible procedures over each of the past two years — with a 92% or higher UHC approval rate — can submit an "advance notification" and skip the prior authorization process for certain services. The program starts on October 1, 2024.

- o **UHC** will conduct assessments of providers' qualification annually, and they may lose their status for a number of reasons like patient safety and quality, or failure to respond promptly to information requests.
- *STAT's* third article investigating **UnitedHealth Group** claims the insurer bought a medical group in Connecticut and transformed it to prioritize physicals and wellness visits to increase coding for higher MA payments, and reducing availabilities to see patients who were actually sick.
- The Employee Benefits Research Institute released a report that showcased increasing interest in self-insurance of health plans among small and medium-sized employers.
- *ProPublica* launched a new investigation against payers' and why mental health providers often do not contract with insurers.
- Consultants at Milliman, one the world's largest actuarial and consulting firms, stated at a recent PBM conference that recent changes to the Medicare Advantage Star rating system will make it harder for plans to achieve higher ratings and therefore will reduce payments to MA plans. Changes to the risk-adjusted adherence measures and Health Equity Index, which will focus on social risk factors, will have the largest impact on plans.
- **GoHealth**, a health insurance marketplace, is acquiring Medicare-focused **e-TeleQuote**. In 2023, GoHealth invested heavily in its data science platform, Encompass, saying that it drove 75% of its 2024 enrollment.

**PROVIDERS**

- **UnitedHealthcare** and **HCA Healthcare** finalized contract terms to keep HCA's 38 hospitals and affiliated locations in-network only hours ahead of their Sept. 1 deadline.
- Hospitals' operating margins increased from June to July with increasing demand for both -patient and outpatient services, according to data from analytics company Strata.
  - o Kaufman Hall's July report concluded that hospitals' monthly operating margin index was 3.8% and named "stability" as the theme for hospital operating margins in 2024.
- Integrated health plan and system **UPMC** reported a $313M operating loss for the first half of 2024, citing restructuring efforts, high volumes and utilization, and falling membership due to Medicaid redeterminations as contributors.
- Even with the total number of healthcare workers expected to reach 18.6M by 2028, according to a study by **Mercer**, there will still be a shortage of 100,000 providers and uneven staffing shortages that vary across state lines and by occupational roles will likely exacerbate practitioner burnout and pressure on health facilities.
- This week, *The Wall Street Journal* reported on a study that was retracted in late June showing that a blood test could diagnose cancer by detecting certain microbes. Before the study was discredited, the new and clinically significant finding attracted investors and ~600 research papers relied on it. The study, published in 2020, used a form of AI to discover microbial DNA indicative of particular cancers, demonstrates the pitfalls of using AI when it is used to assist with scientific data analysis.
  - o Dr. Laurie Glimcher is stepping down as Dana-Farber Cancer Institute president and CEO and will be replaced by Dr. Benjamin Levine Ebert, chair of the Department of Medical Oncology, effective October 1. The Institute is credited with the development of 51% of all cancer drugs approved by the FDA in the last five years, but Dr. Glimcher was also the co-author of several retracted studies exposed by the *WSJ*.

**PAYERS & PROVIDERS (M&A)**

- **Jefferson Health** and **Lehigh Valley** <u>closed</u> their $14B merger, forming one of the largest not-for-profit health systems in the U.S. with 32 hospitals.

**MEDICAID**

- More very young children are being enrolled in Medicaid than ever before. A new *Health Affairs Forefront* <u>article</u> summarizes the causes and consequences of coverage gaps, the benefits of stable coverage, and current state activity on continuous enrollment policies.

**HEALTH EQUITY & SDOH**

- Patients with less resources – such as less education, lower income, or no health insurance – were less likely to <u>challenge</u> their medical bills, despite such challenges often leading to some form of financial relief, according to a recent <u>study</u>.