



PRE-HLTH NEWSLETTER: WHAT HAPPENED LAST?

September & October 2024



Artificial Intelligence

GENERAL NEWS

- **The Digital Medicine Society (DiMe)** is partnering with **Google** and the **Mayo Clinic** to create a consensus-driven AI implementation playbook for the healthcare industry.
- After his indecision made national news, California Governor Gavin Newsom vetoed Senate Bill 1047, which would have been a first-in-the-nation sweeping set of requirements designed to establish safeguards for technology that incorporates AI. The Governor's "veto note" to the legislature is worth a read, and he has plans for how to create a new bill. More here.
- A review of 692 FDA-approved AI/ML-enabled medical devices found that they underreport demographic and socioeconomic characteristics—which exacerbates health biases—and that regulatory oversight is necessary to evaluate the safety and efficacy of these programs.
 - The FDA has authorized 950 AI or ML-enabled devices as of August 7, 2024.
- U.S. Senator Edward J. Markey (D-Mass), member of the Senate Committee on Commerce, introduced the *Artificial Intelligence (AI) Civil Rights Act*, to place guardrails on companies' use of algorithms for consequential decisions. 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."
- **Pieces Technologies** reached a settlement with the Texas attorney general regarding allegations that it falsely portrayed the accuracy of its AI-generated clinical tools.
- CMS issued a Request for Information to health care companies who use artificial intelligence models to improve health care outcomes and efficiencies, including diagnostics analysis, business administration automation, utilization management, clinical decision support, patient engagement, fraud detection, and other purposes.
 - CMS intends to establish a quarterly CMS AI Demo Day featuring health AI tech submitted under this RFI.
- 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.
- 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.

RESEARCH APPLICATIONS (Drug Discovery, etc.)

- Four of the nation's leading cancer centers formed the **Cancer AI Alliance (CAIA)** with over \$40M in funding and AI technology from **Amazon Web Services, Microsoft, Deloitte, NVIDIA, and Slalom**. The



CAIA will provide computational resources, help maintain compliance with regulatory requirements and allow the centers to derive insights about types of cancers and targets for treatments.



Digital Health

GENERAL NEWS

- Spending on digital health solutions is going to increase in the coming year, according to the Peterson Health Technology Institute (PHTI)'s [2024 State of Digital Health Purchasing survey](#). The new survey includes information about purchasers' selection process, contracting approach, and future adoption plans of health systems, employers, and health plans.

FEDERAL NEWS

- Vice President Kamala Harris [released](#) a [plan](#) to cover long-term at-home care for all Medicare beneficiaries if she is elected president.
 - The Brookings Institution [claims](#) the cost might amount to ~\$40B per year.
- CMS could not [conclude](#) whether its Acute Hospital Care at Home initiative lowered Medicare spending due to the patient selection criteria, which was primarily made up of higher-income, less complex white patients. Report [here](#).
- The FDA [published final guidance](#) on decentralized clinical trials (DCTs) addressing concerns from clinical experts.
- The FDA [authorized](#) the first over-the-counter hearing aid software, Hearing Aid Feature (HAF), for use with **Apple AirPods Pro**.
- The BIOSECURE Act – a bill that would prevent U.S. companies from working with China-based biotech companies out of national security fears attributable to sharing personal health and genetic information – [passed](#) the U.S. House of Representatives, and now needs to be passed by the Senate.
 - Drugmakers that have contracts with the five “companies of concern” [have until 2032](#) to allow those deals to expire, if the bill becomes law.
 - **WuXi** companies are looking to [sell](#) parts of their operation after failing to secure contracts after being named in the BIOSECURE Act.
- On September 18, 2024, the U.S. House Energy & Commerce Committee **unanimously passed** the the Telehealth Modernization Act of 2024 out of committee. The bill, which will now go to the full House for consideration, extends **pandemic-era telehealth flexibilities** for two years which will expire at the end of the year if it is not included as part of a must-pass spending package.

TELEHEALTH

- While telehealth is convenient for many, barriers persist and patient experience varies widely depending on telehealth offering type, visit-type complexity, socioeconomic status, and other patient demographics – a J.D. Power [study](#) suggests.
- Over 300 organizations [urged](#) the White House and Congress to extend telehealth prescribing rules for controlled substances by two years, as the DEA lacks time to finalize new regulations. The extension faces challenges over concerns about prescribing Schedule 2 drugs, like Adderall, via telehealth. More [here](#).

REMOTE PATIENT MONITORING

- HHS OIG [urged](#) CMS to implement additional protections to prevent fraud related to remote patient monitoring (RPM).
 - The Alliance for Connected Care, a lobbying group, [requested](#) that the HHS OIG retract its report.



Interoperability and Health IT

FEDERAL NEWS

- HHS' ASTP/ONC released the 2024-2030 Federal Health IT Strategic Plan, which is designed to promote access to TEFCA-compliant electronic health information, improve health equity in health IT and AI, and increase the exchange of public health data.
- Micky Tripathi, HHS' Assistant Secretary for Technology Policy and Acting Chief AI Officer, published a blog claiming that behavior, not technology, is the biggest impediment for information sharing.
- HHS awarded \$2M in funding through the Leading Edge Acceleration Projects in Health IT, an initiative that provides funding to entities addressing various challenges related to interoperable Health IT.
- CMS is partnering with the state of Oklahoma on a pilot project intended to serve as a model for a National Directory of Healthcare, where qualified health plans and providers would be listed in a centralized directory. More here.

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 prevent competitors from entering the market.
 - **Carequality** has since released the partially redacted dispute resolution for **Epic** and **Particle Health's** case.
- **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.

DATA PRIVACY AND SECURITY

- HHS decided not to appeal its loss in the case brought by the American Hospital Association (AHA) about the use of website tracking technologies. The decision finalizes the AHA's victory, allowing hospitals to use these technologies, as the court ruled that HHS exceeded its authority under HIPAA.
- Only about 350 of 1,800 small and rural U.S. hospitals have accessed the cybersecurity help offered through a new program with **Microsoft** and **Google**.
- The state of Texas is challenging an HHS rule that limits the disclosure of reproductive health information to law enforcement under HIPAA. The lawsuit argues that the rule, which is designed to protect patient privacy, oversteps HHS's authority and hinders state enforcement of local laws.
- Two Senators introduced the Health Infrastructure Security and Accountability Act – a bill that would require HHS to establish cybersecurity standards, provide \$1.3B in funding for hospitals to improve their cybersecurity, and remove the caps on HIPAA cybersecurity fines.
- **23andMe** agreed to pay \$30M and provide three years of security monitoring to settle a lawsuit accusing the company of failing to protect the personal information of 6.9M customers.



Investments

GENERAL NEWS

- **Flare Capital Partners** analyzed healthcare venture capital deals from 2014 to 2023, finding that of the \$60B invested in AI-related companies, 70% of those investments happened in the last five years. Most investments related to clinical care and health plan-specific investments focused on care coordination.



- With health IT investments **increasing** 75% over last year, **Bain & Company** and **KLAS** just **published a survey** of 150 U.S. providers and payers explaining which IT solutions each sector is investing in.
- VC-backed companies that receive funding from a lead investor with high domain expertise are 1.2x more likely to successfully exit via IPO or acquisition, according to a **report** from **Pitchbook**.



Payers and Providers

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.

HEALTHCARE TRANSPARENCY

- CMS currently does not have enough information about the completeness and accuracy of hospital price transparency data and should assess machine-readable files on these metrics, according to a GAO [report](#).
- The Ground Ambulance and Patient Billing Advisory Committee, a special committee chartered by Congress under the No Surprises Act, sent [its report](#) to Congress with recommendations on how to reduce surprise billing from ground ambulances.

DRUG PRICING

- CMS [announced](#) which prescription drugs will be included in its new [CMMI model](#) that would cap Medicare beneficiaries’ copays for certain generic drugs at \$2 beginning in January 2027. The drug list includes prescriptions for high cholesterol, blood pressure, and chronic conditions. Comments are due December 9, 2024.
- On Oct. 2, 2024, CMS [issued guidance](#) about the second round of the Medicare drug price negotiation program. New prices will take effect in 2027.
- A recent CBO estimate [found](#) that expanding obesity treatments to include GLP-1 receptor drugs for Medicare beneficiaries would increase federal spending by \$35B from 2026 to 2034.
- **Express Scripts** [filed](#) a lawsuit against the FTC that claimed the agency’s July interim [report](#) – connecting the six largest PBMs to inflated drug prices and independent pharmacy closures – was “unfair, biased, erroneous, and defamatory.”
- Shortly after, in an unrelated action, 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.

PAYERS

- CMS issued the [Notice of Benefit and Payment Parameters for 2026 Proposed Rule](#), the annual rule that proposes and updates standards for the ACA Marketplace, which currently enrolls 50M Americans. New provisions in the rule [included](#) increased oversight of brokers, updates to risk adjustment programs, and simplified enrollment processes. Comments are due November 12, 2024. More [here](#), [here](#).
- CMS [announced](#) projections for Medicare Advantage programs in 2025, estimating enrollment will reach 35.7M and average monthly premiums will drop to \$17 from \$18.23 in 2024.
 - The agency’s projections [counter](#) claims from MA plan insurer’s that rate cuts would force them to decrease benefit offerings, according to *Reuters*.



- California Governor Gavin Newsom signed a bill that will require health plans to include patient medical history in its coverage decision technology and require a physician to oversee AI-supported technology utilization management tools.
- The U.S. Departments of Labor, Health and Human Services, and the Treasury issued a final rule to strengthen mental health parity requirements, directing private health plans to offer mental health services and substance use disorder treatments in the same way they cover medical and surgical care. The rule includes protections against “nonquantitative treatment limitations” – or restrictions that insurers place on the scope and duration of benefits, including prior authorization, that can limit access to care. It will go into effect, for the most part, in January 2025.
- A new milestone of 50M Americans are enrolled in health insurance through the Affordable Care Act marketplace, according to new data from the U.S. Treasury. Pandemic-era ACA tax credits, which will expire in 2024 unless Congress extends them, are partially responsible for the increase in insured Americans. More here, here.

PROVIDERS

- The Biden administration announced several new patient safety initiatives, including the formation of the Action Alliance for Patient and Workforce Safety, a new National Healthcare Safety Dashboard for statistics on patients and providers, and resources for hospitals to reduce diagnostic-related errors.
- The AMA published the Current Procedural Terminology (CPT) 2025, its updated national code set for medical procedures and services. The largest proportion of new codes were for proprietary laboratory analyses (e.g., novel genetic testing) and other key updates included revisions to remote therapeutic monitoring (RTM) services and its AI Taxonomy.
- **Steward Health Care** CEO Ralph de la Torre resigned and is suing the U.S. Senate HELP Committee, alleging that it violated his 5th Amendment rights by trying to force him to testify in front of the committee. **Steward** hospitals are transitioning to new owners.

PAYERS & PROVIDERS (M&A)

- Health system deals announced in Q3 reached record-highs since the pandemic, according to a report by Kaufman Hall analyzing 26 transactions, 11 involving **Steward Health Care**.

VALUE-BASED CARE

- CMS published a report of its accomplishments from 2021-2024 related to its six strategic pillars: advancing equity, expanding access, engaging partners, driving innovation, protecting programs, and fostering excellence.

MEDICAID

- HHS released guidance ensuring children enrolled in Medicaid or the CHIP program have access to comprehensive services, supporting Medicaid’s Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) requirement that states improve preventative care for children with special needs or behavioral health conditions.
- In an informational bulletin, CMS told states that they must be fully-compliant with Medicaid eligibility redetermination requirements by December 31, 2026.

HEALTH EQUITY & SDOH

- The FDA released an updated roadmap for women’s health, listing predictive biomarker tools and data exchange as areas for improvement, among other policy priorities.
- **Deloitte** estimated health equity initiatives could result in 2.4T in GDP savings for the U.S. by 2040 and increase profits for corporate entities by \$763B in a recent analysis.
- 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.