



# June 12, 2025

### Special Section: Changing Political Landscape

- The Trump administration is <u>rushing</u> to <u>rehire</u> thousands of federal workers it previously dismissed after service disruptions and court rulings forced agencies like the FDA and IRS to reverse staff cuts.
  - Efforts also include bringing back experienced staff who took voluntary buyouts and early retirements to address major experience gaps.
- Jim O'Neill was <u>sworn in</u> as Deputy Secretary of HHS on June 9, 2025. He previously held HHS leadership roles during the G.W. Bush presidency. He will help oversee agency operations and lead innovation efforts focused on AI, emerging technologies, and system modernization.
- HHS <u>announced</u> Paula M. Stannard as Director of the Office for Civil Rights, who most recently served as
   Chief Legal Counsel of the Montana Department of Public Health and Human Services. She will be
   charged with enforcing HIPAA as well as civil rights protections.
- Congressional updates:
  - NIH Director Jay Bhattacharya <u>faced</u> questions about the Trump administration's proposed \$18B budget cut to the agency during a Senate hearing on June 10. Democratic lawmakers raised concerns about canceled clinical trials and the politicization of science.
  - A House Subcommittee <u>advanced</u> the Trump administration's proposed 2026 budget for the FDA, cutting funding by \$300M compared to last year. The full House Appropriations Committee met on Wednesday, June 11, to <u>hold its markup</u> of the bill.
  - The U.S. House Oversight and Government Reform Committee <u>held</u> a hearing on Tuesday, June 10, about privacy and national security concerns related to **23andMe**'s bankruptcy sale.
    - 23andMe's interim CEO <u>also faced</u> privacy-related questions from the Senate Judiciary Committee, with members asking if any of the genetic data tested by **Labcorp** was breached, in a hearing on Wednesday, June 11.
  - The House Energy and Commerce Subcommittee on Health <u>held</u> a hearing on Wednesday, June 11, to examine health care supply chain challenges and consider regulatory modernization efforts that would ensure sustainable access to safe medicines.



#### **GENERAL NEWS**

• The NIH <u>issued</u> a request for information (RFI) asking for industry input on a new, institute-wide AI strategy and one-year action plan. Specifically, <u>the RFI</u> asks how to move from current data-driven analytics to fully autonomous, self-documenting biomedical AI tools. Comments are due by July 15, 2025.

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- On Thursday, June 5, the House Oversight Committee <u>held</u> a hearing to examine the federal government's approach to Al. During the hearing, members discussed the 10-year moratorium on states enforcing Al laws in the House-passed reconciliation bill.
  - Adam Thierer, Senior Research Fellow at the R Street Institute, explained that the moratorium is tied to a section of the bill that allocates funding to modernize the Department of Commerce's technology systems and is designed to prevent a patchwork of conflicting state regulations from undermining national efforts. Rep. Clay Higgins (R-LA) clarified that the moratorium does not prevent states from considering or enacting Al-specific legislation. Rather, it asks states to refrain from enforcing new Al laws and recognize that Al is, by nature, interstate commerce.
- The FDA <u>said</u> it will use AI to "radically increase efficiency" across several initiatives, including accelerating new drug and medical device approvals and food ingredient reviews in a <u>JAMA</u> article.
- On June 11, The Joint Commission and the Coalition for Health AI (CHAI) <u>announced</u> a partnership to accelerate the development and adoption of health AI best practices and guidance.
- The first group of healthcare organizations in Duke's Health AI Partnership (HAIP) peer-learning program, created to help under-resourced healthcare organizations understand and manage long-term AI use, <u>implemented</u> ambient scribes and is sharing best practices on incorporating AI into daily clinical care routines.
  - o In July, HAIP's Mark Sendak will be speaking at a HIMSS in-person event in NYC on the <u>Future of</u> AI.
- A global survey of patients across 74 hospitals <u>found</u> limited trust for AI in providing information related to treatment responses. The majority of patients preferred explainable AI systems and physician-led decisions, even if keeping a human in the loop compromised the accuracy of that decision.
- In its annual <u>'State of U.S. Nursing & Technicians Report,'</u> *Incredible Health* found that 85% of nurses want more AI training, though some remain concerned about impacts on patient-provider relationships.
- **Microsoft** <u>plans to add</u> a "safety" category to its <u>Azure Foundry AI model leaderboard</u>, helping cloud customers evaluate the security of AI products according to quality, cost, and output speed.
- Meta is considering a \$14B investment in the data-labeling startup Scale AI, which would be one of its largest outside investments.

#### **ADMINISTRATIVE APPLICATIONS**

- Stanford Medicine is <u>piloting</u> ChatEHR, an AI software designed to summarize patient charts and pull specific data points from EMRs to answer clinical questions, mirroring the capabilities of ChatGPT and other integrated LLMs.
- **Vim** <u>partnered</u> with **ForeSee Medical** to integrate Al-based risk adjustment tools into EHR workflows, helping providers identify Hierarchical Condition Categories.
- Vouched, an Al-powered identity verification platform, <u>was approved</u> for integration with the EPIC
  Toolbox, enabling providers to automate patient identity checks and reduce time spent on manual intake
  processes.
- Mayo Clinic <u>partnered</u> with <u>hellocare.ai</u>, an Al-integrated virtual care platform, to leverage ambient documentation and digital tools in proactive care and hospital-at-home services. Mayo Clinic also became an investor in the company's recent funding round.

#### **CLINICAL APPLICATIONS**

- AstraZeneca's rare disease unit <u>partnered</u> with UK-based health tech startup Pangaea Data, which <u>scaled</u> its AI platform for hard-to-diagnose diseases in 2023 with Microsoft Azure. The new partnership will focus on developing and applying for regulatory approval of an AI clinical decision support system (AI-CDSS) for early detection of hypophosphatasia, a rare metabolic disorder.
- **CIVIE** <u>launched</u> RadPod, an Al-enabled platform that allows radiologists to interpret medical imaging remotely. The platform includes tools to support workflow efficiency, such as voice recognition, automated quality checks, and real-time payment.

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- Artera, the developer of multimodal artificial intelligence (MMAI)-based prognostic and predictive cancer tests, received its New York State lab permit.
- RadNet <u>acquired</u> See-Mode Technologies, developer of an FDA-approved ultrasound AI for thyroid nodule and breast lesion imaging, expanding subsidiary DeepHealth's portfolio of AI-powered screening tools.
- **Perimeter Medical Imaging** <u>launched</u> a database of previous surgical cases that provides real-time, high-resolution tissue imaging and margin measurements to support surgical decisions.
- A recent <u>study</u> examining the use of four leading LLMs (including Gemini, ChatGPT, and Claude) in
  psychiatric diagnosis and treatment planning found that models recommended lower-quality psychiatric
  treatments when patient race was implicitly or explicitly indicated, reinforcing concerns that LLMs can
  perpetuate racial disparities in clinical care.

#### **RESEARCH APPLICATIONS**

- **Komodo Health** <u>launched</u> its full-stack analytics platform for healthcare and life sciences companies called <u>MapLab Enterprise</u>.
- **IQVIA** <u>announced</u> custom-built Al agents at **NVIDIA**'s GTC 2025 Al Conference in Paris, designed to simplify life sciences operations such as target identification and clinical data review.
- **Medeloop.ai**, an AI research platform used by NYC's Department of Health, <u>partnered</u> with real-world data provider **HealthVerity**, <u>expanding</u> pharmaceutical, biotech, and public health researchers' access to de-identified patient records.
- The Lieber Institute for Brain Development <u>will migrate</u> its IT infrastructure to **AWS**, expand the use of generative and predictive AI in drug discovery and development for brain disorders.



#### **GENERAL NEWS**

- Omada Health—a virtual diabetes and weight management company—<u>raised</u> \$150M for its IPO at a valuation of \$1.1B. The company's valuation signals a potential resurgence in the digital health market, following the **Hinge Health** IPO last month (see <u>here</u>, <u>here</u>).
- **Nourish**, a virtual nutrition counseling company valued at over \$1B earlier this year, <u>added</u> Al-powered features—including meal logging, a scribe tool, and provider-facing nutrition summaries—designed to surface actionable insights for nutrition-related care.
- **Berry Fertility**, a fertility patient management platform, <u>launched</u> new tools for personalized treatment, medication management, comprehensive tracking, and educational resources.

#### **TELEHEALTH**

• **CRH Medical Corporation**, a gastrointestinal-focused subsidiary of **WELL Health Technologies**, <u>partnered</u> with virtual specialty care platform **WovenX** to deliver integrated practice solutions that improve patient access and operational capacity.

#### REMOTE PATIENT MONITORING

- Tandem Diabetes Care <u>announced</u> an agreement to integrate its insulin delivery systems into **Abbott**'s upcoming dual glucose-ketone sensor, enabling early detection of diabetic ketoacidosis.
- Sleep Cycle <u>initiated</u> a clinical study in Australia to validate its AI-powered smartphone feature for screening obstructive sleep apnea without wearables or sensors. The company has also completed presubmission dialogue with the FDA.

#### **MOVING CARE HOME**



- **Lucet**, a behavioral health company, <u>acquired</u> **Emcara Health**—a value-based provider delivering athome care—to expand integrated offerings for physical and behavioral health management.
- **Ultrahuman**—a health monitoring company—<u>launched</u> Ultrahuman Home, a new indoor home health device that allows users to fine-tune environmental factors such as air quality and light to support sleep, cognition, and overall well-being.



### 🖳 Interoperability and Health IT

#### **FEDERAL NEWS**

 The VA is <u>currently using</u> Al in 100+ use cases, including risk scoring for risk of suicide and a ChatGPT for VA employees and clinicians, according to Charles Washington, the VA's CAIO and CTO, in a *Healthcare IT* News article.

#### **INDUSTRY NEWS**

- Alexandra Mugge, formerly CMS Chief Health Informatics Officer, <u>left</u> the agency after more than fifteen years to join **Oracle**, according to a <u>report</u> from *InsideHealthPolicy*.
- **TeleTracking Technologies**, an integrated healthcare operations platform, <u>is partnering</u> its Operations IQ product with **Palantir**'s AI-powered Foundry and AIP systems. The collaboration intends to optimize staffing, forecast demand, and improve patient flow for health systems.
- Altera Digital Health is joining Health Gorilla's QHIN through TEFCA, giving Altera's EHR access to long-term records directly within workflows and optimizing clinical decision-making processes.
- MD Anderson Cancer Center is <u>developing</u> an Al-powered tool with **Healthex**, a data rights management platform, to streamline the data consent process and help patients understand how their data advances research.
- **PointClickCare** <u>filed</u> a renewed motion to dismiss **Real Time Medical System's (RTMS)** lawsuit accusing the EHR company of information blocking, claiming RTMS' suit is based on faulty claims and a misinterpretation of the law.
- Pangea Data will partner with Alexion to <u>develop</u> an Artificial Intelligence Clinical Data Support System (AI-CDSS), improving the detection of hypophosphatasia—a rare genetic disease impairing bone and teeth mineralization—based on EHR records.
- Data from more than 5,000 U.S. hospitals revealed that, on average, hospitals <u>spend</u> about 2.29% of their total operating budget on IT operating expenses, or about \$9.51M.

#### **DATA PRIVACY AND SECURITY**

- The Trump administration <u>issued</u> an <u>Executive Order</u> (EO) to strengthen cybersecurity measures, replacing the Biden administration's EO on the same topic. Key differences include eliminating mandatory software security compliance attestations and focusing on AI vulnerabilities and containment.
- Ohio-based Kettering Health <u>restored</u> access to its online patient portal MyChart three weeks after the <u>ransomware attack</u> on May 20. According to a recent <u>report</u>, the health system believes that ransomware group Interlock is responsible for the attack.
- The FBI and CISA issued an advisory warning of the <u>Play ransomware group's</u> actions and tactics, which have affected more than 900 people to date.
- Emails <u>remain</u> the most vulnerable and underfunded healthcare cybersecurity weakness despite
  confidence expressed by health IT leaders to prevent email-based breaches, according to a new **Paubox**<u>report</u>. Overdependence on manual safeguards in outdated systems leads to frequent protocol bypass,
  reflecting a need for more automated email encryption solutions.



#### **GENERAL INVESTMENTS**

- Rapid AI startup growth with high valuations <u>reveals</u> greater investment risk due to immature operational infrastructure, making investors' confidence in founders' adaptability crucial, according to CapitalG Partner Jill Chase.
- **Paytient** <u>received</u> \$40M from **Trinity Capital** to expand its financing services nationwide for employers and insurers looking toward affordable out-of-pocket cost smoothing solutions.

#### **AI INVESTMENTS**

- **Canid**, the developer of an Al-powered pediatric vaccine management platform, <u>secured</u> \$10M in Series A funding.
- GuideHealth, an Al-driven value-based care provider, <u>secured</u> a \$10M investment from Emory Healthcare.

#### **DIGITAL HEALTH INVESTMENTS**

- **MyLaurel**, a telehealth-enabled medical group focusing on home-based acute and transitional care, raised \$12M to scale its Acute Care at Home program with Oschner Health and expand to new markets.
- Clara Home Care, a startup focused on improving senior caregiver hiring, <u>received</u> \$3.1M in seed funding from several investors including **Y Combinator**. The company employs AI to match families with caregivers and simplify administrative tasks such as scheduling and payroll.
- **Salvo Health**, a digital company focused on gastrointestinal health, <u>received</u> \$4M in extended seed funding to expand its workforce and care coordination technology.



## Payers and Providers

#### **GENERAL**

 Cigna and CVS Health <u>reached</u> a settlement for undisclosed amount about the former Express Scripts president, Amy Bricker, leaving the Cigna PBM in violation of her noncompete agreement to become CVS' EVP and chief product officer.

#### **TRANSPARENCY**

• The 5th Circuit Court of Appeals agreed to <u>rehear</u> a case from the Texas Medical Association, that challenged how qualifying payment amounts (QPA) are determined under the No Surprises Act. This means courts will vacate the previous decision reinforcing HHS' calculation for the QPA used in dispute resolutions for surprise out-of-network bills. It will also give providers another chance to argue that current QPA calculation favors insurers.

#### **DRUG PRICING**

- On the heels of <u>last month's executive order</u> directive to align drug prices with other countries' in a
  "most-favored nation" plan, and a subsequent HHS <u>announcement</u>, U.S. Senate health committee Chair
  Bill Cassidy (R-La.) is <u>reportedly</u> circulating a proposed bill that would link U.S. drug prices to those in
  other countries.
- The FTC, Justice Department, HHS and the Department of Commerce are hosting <u>listening sessions</u> to discuss ways to make prescription drugs more affordable for Americans by promoting competition:

- June 30 at 2 pm ET Anticompetitive Conduct by Pharmaceutical Companies Impeding Generic or Biosimilar Competition
- July 24 at 2 pm ET Formulary and Benefit Practices and Regulatory Abuse Impacting Drug Competition
- o August 4 at 2 pm ET Turning Insights into Action to Reduce Drug Prices
- PCMA, a trade association representing PBMs, and **Navitus Health Solutions**, joined **Caremark** and **Express Scripts** in suing Arkansas over its new law banning PBMs from owning pharmacies.
  - They argue the law would force dozens of pharmacies to close, restrict home delivery, and violate federal law.
- **GoodRx** <u>launched</u> Community Link, an option that allows independent pharmacies to directly contract with them, bypassing PBMs and providing access to cost-plus pricing.
- **Serve You Rx**, an alternative PBM, is <u>adding</u> two Stelara biosimilars—Otulfi and Yesintek—to its specialty formulary through a partnership with **Waltz Health**. This offers members significant savings and simpler access, with support from copay assistance and Waltz's Al-powered pharmacy platform.

#### **PAYERS**

- U.S. Senators are considering <u>adding</u> a provision to the House-passed budget bill that <u>limits</u> the payments Medicare Advantage (MA) plans can receive related to diagnosis codes recorded during at-home risk assessments and chart reviews. This move, which would address "upcoding," or the practice of inflating diagnosis codes to make beneficiaries seem sicker than they are to receive higher payments, is being considered to reduce federal budget spending.
  - o Both UnitedHealth Group and Humana are supporting the provisions, whereas AHIP opposed it.
- **Democratic governors** Gavin Newsom of California, JB Pritzker of Illinois, and Tim Walz of Minnesota are planning to roll back state-funded health care for undocumented immigrants.
- A federal judge <u>denied</u> **MultiPlan** (now **Claritev**) and its insurer codefendants' motion to dismiss antitrust and consumer protection claims alleging the companies colluded to suppress provider reimbursement rates.
- Nebraska <u>passed</u> a new <u>prior authorization reform law</u> requiring insurers to make prior auth requirements public, use a standard prior auth form no longer than two pages, and make decisions during specific timeframes. It also prohibits prior auth denials based solely on Al-driven algorithms and mandates physician reviews. The law takes effect January 1, 2026.
- Coventry Health and Life Insurance Company, an Aetna subsidiary, received an estimated \$6.9M in MA overpayments in 2018 and 2019, according to an HHS Office of Inspector General audit. The agency urged the payer to repay the funds and improve compliance, but Coventry disputed some of the findings and all recommendations.
- UnitedHealth Group <u>filed</u> a defamation lawsuit against *The Guardian*, alleging its article used doctored documents and misleading anecdotes to falsely claim the company paid nursing homes to reduce hospital transfers. UHG's stocks fell after the article was published on May 21.
- A group of state ACA exchange directors sent a <u>letter</u> to Senate leaders, <u>urging</u> them to extend ACA premium tax credits scheduled to expire at the end of 2025 and to address concerns that the reconciliation bill, if passed, would lead to higher costs and increased uninsured rates.
- Insufficient data on MA supplemental benefits hinders efforts to evaluate their value to enrollees and taxpayers, according to a *Health Affairs Forefront* blog post by KFF staff. Recent CMS reporting requirements could fill these gaps, but usage and spending data remain unavailable.

#### **PROVIDERS**

• The AMA <u>swore in</u> Bobby Mukkamala, MD as its 180<sup>th</sup> President during its Annual Meeting of the House of Delegates. During his inauguration speech, Dr. Mukkamala <u>spoke</u> about his recent brain tumor diagnosis, concerns over biomedical research funding cuts, and support for federal insurance programs.

- o The AMA <u>elected</u> Willie Underwood III, MD, MSc, MPH, a New York-based urologist, as its President-Elect. More here.
- o As we <u>reported</u> a few weeks ago, the AMA also has a new CEO, John Whyte, MD.
- Also at its Annual Meeting, the AMA adopted <u>public health policies</u> related to alcohol and ultraprocessed foods, <u>guardrails around the collection of physicians' personal data</u> to improve workplace wellbeing, and <u>guidance for physicians</u> considering entering into a relationship with a corporate entity.
- HHS Secretary Kennedy <u>removed</u> all 17 sitting members of the Advisory Committee on Immunization
  Practices (ACIP), an independent committee <u>established by Congress</u> to advise the CDC on vaccine safety,
  efficacy, and clinical use. He replaced them with <u>8 new members</u>, several of whom have a history of
  expressing anti-vaccine sentiment or voicing concerns about COVID-19 or mRNA vaccines. Secretary
  Kennedy <u>described</u> the move as a "clean sweep" necessary to restore public trust in science in a *Wall*Street Journal op-ed. The next ACIP meeting is June 25-27.
  - The AMA <u>passed</u> an emergency resolution that asks Secretary Kennedy to reinstate the dismissed committee members and calls on the U.S. Senate to investigate his decision.
  - More than half of the 258 randomized and placebo-controlled vaccine clinical trials in Stanford's <u>crowdsourced vaccine research platform</u> included inert placebos, contradicting Kennedy's statements at a May 14 Senate HELP hearing. Stanford launched the project in April to clarify how vaccines are tested.
- The U.S. Government Accountability Office (GAO) <u>said</u> HHS needs a coordinated, national strategy for diagnostic testing to monitor and respond to infectious disease threats. GAO <u>outlined</u> four key recommendations to improve diagnostic testing and establish a national testing forum in its <u>220-page</u> report.
- Over 300 NIH employees <u>outlined concerns</u> about Trump administration policies impacting biomedical research and Director Jay Bhattacharya's stated commitment to scientific dissent. In a letter titled the "<u>Bethesda Declaration</u>," a nod to Bhattacharya's 2020 "<u>Great Barrington Declaration</u>" that criticized vaccine mandates, employees described actions that undermine the NIH's mission to protect the health of Americans
  - Several Nobel laureates and recognized scientists co-signed a letter of support.
- The Administration for a Healthy America requested \$20.6B for FY 2026 in its <u>budget outline</u> to Congress, that included the elimination of several CDC programs, including ones for obesity, heart disease, diabetes, and cancer prevention, <u>along with</u> the agency's National Center for Chronic Disease Prevention and Health Promotion.
- Former FDA and HHS officials <u>raised concerns</u> about the procedural aspects of the FDA's review for **Novavax**'s COVID-19 vaccine, including public statements about how vaccines are approved and delayed regulatory action, which they claim depart from traditional agency practices.
  - In a <u>JAMA</u> viewpoint article, the authors warned that the impact of political appointees in regulatory decision-making could undermine broader vaccine policy and deter long-term investment by introducing unpredictable approval standards.
- President Trump's executive order to <u>restore gold standard science</u>, which directs agencies to publicize
  the scientific data informing public policy decisions, could roll back evidence-based health protections,
  according to a STAT op-ed by SciLight founder Jacob Carter and Union of Concerned Scientists CEO
  Gretchen Goldman.
- A federal judge <u>ruled</u> that HHS and the Equal Employment Opportunity Commission cannot require providers, plans, or employers to deliver or cover gender-affirming care if it violates religious beliefs. The Trump administration is unlikely to appeal the decision about the Biden-era rule.
- Chip Kahn will <u>retire</u> as CEO of the Federation of American Hospitals at the end of 2025 after 24 years leading the organization.

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- The operators of a Florida-based substance use disorder treatment clinic, Evoke Wellness, have <u>agreed</u> to pay \$1.9 million, settling FTC's allegations that they used deceptive Google search ads and telemarketing to impersonate other treatment providers.
- Hospital operating revenue <u>rose</u> in early 2025 compared to same period in 2024 with improved patient volume and efficiency, according to a **Kaufman Hall** report.
- Hospital charity care policies <u>vary</u> widely, with eligibility thresholds ranging from 100% to 600% of the
  federal poverty level, according to a new Lown Institute <u>report</u>. The Institute urged for federal standards
  to reduce discrepancies between hospitals' practices, which can cause unpredictability for patients.

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

• UnitedHealth Group is considering a \$1B sale of its Latin American business, including its subsidiary, Banmédica. The potential exit follows a \$7.1B loss from its Brazil exit and reflects a broader strategy to refocus on U.S. operations amid ongoing financial challenges.

#### **VALUE-BASED CARE**

A <u>study</u> in the journal *Health Affairs Scholar* found that value-based care models may improve access to
primary care for Medicare patients. Physicians in a full-risk, supported value-based care model accepted
more new traditional Medicare patients and kept their panels open longer compared with those in feefor-service models.

#### **MEDICAID**

- As Congress considers Medicaid work requirements, insurers are pushing to lift a ban from 1991 that
  restricts texting and outreach to enrollees. Advocates argue this ban will complicate efforts to verify
  eligibility, complete renewals, and help people stay covered.
- The American Public Health Association, along with 65 other public health scholars, is <u>urging</u> HHS to reject Georgia's request to extend Medicaid work requirements in <u>public comments</u>, arguing the policy raises costs and limits coverage without boosting employment.

#### REPRODUCTIVE HEALTH

 Attorneys general from four Democratic states <u>requested</u> the FDA to lift restrictions on the abortion pill mifepristone. The <u>petition</u> challenges a planned safety review ordered by HHS Secretary Kennedy, arguing existing data over the past 25 years confirms the drug's safety.

#### **HEALTH EQUITY & SDOH**

Nurses <u>cite</u> high workloads, staffing shortages, and financial misalignment as major barriers to delivering
equitable care to disadvantaged patients, according to a new *JAMA Network Open* <u>study</u>. Nurses also
pointed to bias, language barriers, and gaps in cultural competency training, but noted technology tools
and community partnerships can be important supports in addressing these gaps.