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Digital Health

DIGITAL HEALTH INVESTMENTS

- **TPG**, a private equity firm focused on leveraged buyouts and growth capital, <u>acquired</u> **Nextech**, an offerer of EHR, practice management, and patient engagement software, from Thomas H. Lee Partners for \$1.4 billion.
- **The Riverside Company**, a private investment firm with several healthcare companies in its portfolio, <u>raised</u> \$350M for its new fund.
- **K Health**, a digital primary care startup, <u>raised</u> \$59M in a funding round, jointly announced with a *Forbes* article detailing how the AI chatbot assisted over 3 million people to date.
- VitalConnect, a remote patient monitoring company, <u>raised</u> \$30M in Series F financing.
- **SiPhox Health**, a lab-grade home health testing company, <u>raised</u> \$27M in funding, including \$10 million in seed funding and \$17 million in Series A funding.
- **Herself Health,** a value-based primary care provider for women over 65, <u>received</u> \$26M in Series A funding to expand both digital and in-person offerings.
- **Affect Therapeutics**, a digital addiction recovery platform, <u>raised</u> \$16M in Series A funding to enable national expansion, program expansion, and development of the Affect app.

- **Eureka Health**, a startup that self-describes as "Yelp for healthcare treatments," <u>raised</u> \$7M in seed funding to advance its treatment experience dashboard.
- **Fold Health**, a digital platform providing value-based primary care, <u>secured</u> \$6M to expand operations.
- **Gradia Health**, an integrated concierge care platform, <u>received</u> \$4.2M in seed funding.

ARTIFICIAL INTELLIGENCE NEWS

- One of the first attempts by the federal government to regulate AI in healthcare (beyond the FDA's medical device jurisdiction) is part of ONC's <u>HTI-1 proposed rule</u> that it released in April. *STAT* is reporting that multiple stakeholders (e.g., **Epic**, **Google**, several payers and providers) objected in formal comments to the ONC's proposed transparency requirement that developers of electronic health records provide details about the training of predictive AI models.
- **Health Care Services Corporation** (HCSC) <u>announced</u> the success of its Al-enabled prior authorization system. The tool, first developed in 2021, accelerated the claims approval process from 14 days to 6 minutes.
 - There is a mix of reactions to the use of automation in payers' coverage determinations. Congressional committees (see here, here) have been questioning whether the use of AI in payer's coverage decisions is appropriate, despite a bipartisan congressional effort to encourage CMS to finalize regulations to make prior authorization processes automated.
- <u>Avia</u>, a Chicago-based organization that evaluates digital health solutions for health systems, <u>launched</u> the <u>Generative Al Strategic Collaborative</u> – a group of over 20 health systems, industry members, technology experts, and government stakeholders that will develop a strategy for generative Al adoption in healthcare.
- All can reduce costs for providers by automating administrative tasks, such as complex billing systems, according to an **AMA** report.
- After the Medical Futurist Institute <u>published</u> its recommendations to regulate generative Al in health care with Dr. Eric Topol in *Nature's* digital medicine journal, it posted its <u>own blog</u> entitled *Why and How to Regulate ChatGPT-like Large Language Models in Healthcare?*
- The responses to healthcare-related questions and clinical notetaking from both ChatGPT and human providers are virtually indistinguishable, according to research conducted by NYU and Stanford University.
- In a provocative statement, Dr. John Halamka, the Mayo Clinic Platform leader, <u>stated</u> that failing to use assistive Al in colorectal cancer screening could be considered malpractice soon.

ARTIFICIAL INTELLIGENCE INVESTMENTS

- **Causaly**, an AI biomedical research platform serving 12 of the top 20 pharmaceutical companies, <u>raised</u> \$60 million in Series B funding to further product innovation.
- Al computing company **Nvidia** <u>invested</u> \$50 million into biotech company **Recursion**, initiating a partnership to drive Al-powered drug discovery.
- **CarePredict**, an Al-powered digital health platform for seniors, <u>raised</u> \$29 million in Series A-3 funding to expand its operations to best enable preventative care.



- Gen.Health AI, a medical prediction startup, <u>secured</u> \$13 million in seed funding to better minimize administrative burdens for payers, including streamlining prior authorization and care management.
- Upon receiving a \$10 million donation, **Northwell Health** plans to <u>establish</u> the Scott and Debby Rechler Center for Health Outcomes, dedicated to advancing big data and Al technology and addressing health disparities.

Interoperability & Health IT

FEDERAL NEWS

- The FTC and DOJ released new, draft <u>merger guidelines</u> that apply to deals across the economy, but <u>highlight</u> obstacles to competition among <u>digital platforms</u>. More on this below, under the Payers & Providers section.
- ONC's electronic health record (EHR) <u>proposed rule</u> is receiving <u>negative comments</u> from powerful stakeholders, including <u>Epic</u>, **Google**, and **Amazon**.
- The 4th annual CMS HL7 FHIR virtual Connectathon <u>began</u> on July 18, 2023, bringing together developers, analysts, and CMS employees together to test FHIR APIs and refine FHIR Implementation Guides.
- A group of bicameral democratic Members of Congress are <u>urging</u> HHS Secretary Xaiver Becerra to update HIPAA privacy rules to protect sensitive reproductive health records from access by law enforcement agencies.

INDUSTRY NEWS

- The 7th Circuit Appellate Court <u>affirmed</u> the judgment granting \$140 million in compensatory damages to **Epic Systems** in the trade-secrets lawsuit between **Epic** and India-based **Tata Consultancy Services**, which alleged that Tata employees stole proprietary information and data from Epic.
- The **Peterson Center on Healthcare**, a non-profit organization designed to improve the quality and affordability of healthcare, <u>launched</u> the **Peterson Health Technology Institute**, a \$50 million initiative devoted to assessing digital health tools for their benefit to patients.
- **NextGen Healthcare** <u>agreed</u> to pay the Department of Justice (DOJ) \$31 million to settle a whistleblower lawsuit alleging the EHR company fraudulently misrepresented the capabilities of certain versions of its software in violation of the False Claims Act (FCA).
- **Universal Health Services** (UHS) <u>partnered</u> with **Oracle Cerner** to implement the Oracle Cerner EHR system in over 200 behavioral health facilities nationwide.
- **Civitas Networks for Health** <u>added</u> 11 new members since January 2023. These organizations will collaborate to promote interoperability and secure health data exchange.
- **CommonWell Health Alliance** <u>announced</u> it shares health data for 62% of Americans after surpassing a network population of 200 million individuals.
- The AHA <u>published</u> four principles for easing digital healthcare access, reflecting the findings from a recent <u>Experian Health survey</u> of more than 1,200 providers and consumers.



PUBLIC HEALTH DATA

- Health Information Exchange (HIE) Healthix partnered with health IT vendor Unite Us to establish SDOH interoperability between healthcare systems and social care networks across New York City and Long Island.
- The American College of Physicians provided policy recommendations for modernizing the U.S. public health infrastructure in a <u>position paper</u> published in the *Annals of Internal Medicine*.

DATA PRIVACY AND SECURITY

- The FTC <u>issued</u> a <u>final order</u> requiring **BetterHelp** to pay \$7.8 million to resolve the allegations that the company shared users' personal health information. The order will prohibit the company from disclosing health data or sharing personal information.
- The Federal Communications Commission <u>released</u> a proposal for a voluntary cybersecurity labeling program that would use the National Institute of Standards and Technology's criteria to label connected health devices.
- Over 4-in-5 Americans believe their health data that is stored in third-party applications is protected under HIPAA, according to a <u>report</u> from **ClearData**.
- <u>Data breaches</u> are rising as healthcare organizations invest in and advance health IT systems.
 - A data breach at **Pension Benefit Information** (PBI) potentially <u>exposed</u> the health information of more than 1.2 million individuals. This ranks among the top ten biggest breaches reported to HHS in 2023.
 - The law firm **Orrick**, **Herrington & Sutcliffe** <u>suffered</u> a data breach exposing vision benefits plan information for 40,0000 individuals for the second time.
 - Imagine360 reported two subsequent third-party data breaches impacting over 112,000 individuals.
 - **Henry Ford Health** was the victim of a <u>phishing scheme</u> that potentially <u>exposed</u> 168,000 patients' protected health information.
 - A <u>data breach</u> at **Phoenician Medical Center** in Arizona potentially impacted 162,500 patients.
- **HCA Healthcare** faces four class action <u>lawsuits</u> following the data breach that exposed potentially 11 million patients' personal information.
- QuickBlox's software development framework that is used in telemedicine and finance left millions of personal records unprotected and easily accessible, <u>according</u> to a joint study conducted by Check Point Research (CPR) and Team 82.

Payers & Providers

HEALTHCARE TRANSPARENCY

• On July 13, 2023, CMS released a proposed rule to update payment rates for Medicare services provided in hospital outpatient and ambulatory surgical center (ASC) settings for 2024. In the proposed rule, CMS included reforms to the Hospital Price Transparency rule



that added formatting requirements to hospitals' published machine-readable files and mechanisms to streamline enforcement.

- Notably, the proposed rule also included a Request for Information asking how to align hospital price transparency measures with the payers' Transparency in Coverage rule and the No Surprises Act.
- At a Consumer Financial Protection Bureau hearing, panelists <u>urged</u> the agency to abolish deferred interest credit cards. The hearing was about the agency's joint <u>request for</u> <u>information</u> on the impact of medical credit cards on medical debt.

PAYERS

- CMS <u>proposed</u> <u>removing the national coverage determination</u> that imposes a single-test limit for PET scans for patients with Alzheimer's disease, <u>allowing</u> Medicare contractors to make regional-based decisions.
- The push by **Novo Nordisk** and **Eli Lilly** to provide <u>oral anti-obesity drugs</u> and the resulting high demand for them is giving rise to medical concerns and alerts <u>by the AMA</u> and <u>others</u>. See <u>here</u>, <u>here</u>, <u>here</u>.
- A new *Health Affairs* blog post <u>explores</u> a recently-suggested policy proposal to improve the risk adjustment issues related to favorable selection in the Medicare Advantage program that allegedly result in overpayments to health plans.
- A new <u>study</u> shows that extreme heat is causing higher utilization of medical services -- <u>costing</u> the healthcare system more than \$1 billion per year.
- CMS Administrator Chiquita Brooks-LaSure sent a <u>letter</u> to payers reminding them of their responsibilities for covering COVID-19 vaccines after the end of the PHE.
 - The CDC also <u>announced</u> a new "Bridge Access Program," to launch in Fall 2023, which will provide free COVID-19 vaccines and treatments to uninsured and underinsured adults.
- CMS issued a <u>proposed National Coverage Determination</u> for Pre-Exposure Prophylaxis (PrEP) in individuals at risk of HIV infection without patient cost-sharing.
- An HHS OIG <u>investigation claimed</u> that **Excellus BCBS** received \$5.4M in Medicare Advantage overpayments in 2017 and 2018, due to unvalidated diagnosis codes. The agency recommended Excellus only repay HHS \$3.1M due to limits from February's RADV rule, which limited the recoupment of audits before 2018.
 - Excellus disagreed with OIG's recommendations or its audit methodology, use of extrapolation, standards for data accuracy, and medical record review process.
- **UnitedHealth Group** reported nearly \$5.5B in Q2 profits following steady growth in its health plan and **Optum** businesses, despite rising costs.
- **Elevance Health** <u>posted</u> double-digit profit growth in Q2, with its earnings rising by 13.2% year-over-year to \$1.9 billion. More here.
- In 2021, unnecessary utilization <u>accounted</u> for approximately 2 million healthcare services and \$134M in spending in Colorado, according to <u>an analysis</u> from The Center for Improving Value in Health Care.



PROVIDERS

- CMS <u>proposed</u> reimbursement rate changes in the CY 2024 Medicare Physician Fee Schedule (PFS), lowering overall payments to physicians by 1.25%.
 - Industry groups including the AMA and American Medical Group Association (AMGA) are <u>urging</u> Congress to block the cuts to the fee schedule.
 - Other reforms in the CY 2024 PFS included a new add-on code for complexity, policies to promote behavioral health and SDOH, a raised threshold for the Merit-Based Incentives Program (MIPs), and an end the appropriate use criteria (AUC) program. See a summary of the PFS here.
- CMS also <u>released</u> the CY 2024 Hospital Outpatient Prospective Payment Systems (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems Proposed Rule. The proposal suggests increasing pay for hospital outpatient facilities that meet quality reporting requirements by 2.8% and strengthening price transparency efforts. More <u>here</u>.
- The proportion of physicians employed by private practices <u>declined</u> by 13% over the last decade due to challenges in payer relationships, rising costs, and labor shortages, according to an AMA <u>survey</u>.
- <u>HCA Healthcare</u> and the <u>Johns Hopkins Health System</u> are facing lawsuits alleging the companies failed to employ adequate safety measures to protect patient data during massive data breaches.
- Unionized healthcare coalitions are <u>picketing</u> 50 **Kaiser Permanente** facilities on the west coast about allegedly low staffing levels in hospitals and clinics.

PAYERS AND PROVIDERS (M&A)

- The FTC and DOJ <u>released</u> a draft update to merger guidelines, with a focus on technology companies and whether a merger would harm workers. Comments are due September 18, 2023. The White House released <u>an issue brief</u> about the proposed changes. More <u>here</u>, <u>here</u>, <u>here</u>.
 - This announcement follows the FTC's <u>withdrawal</u> of two healthcare market antitrust policy statements, published in 1996 and 2011, <u>aligning</u> with DOJ's <u>similar action</u> from February. Citing that the two unbinding guidance documents were "outdated," the agencies proposed to use general market principles of antitrust enforcement and competition for healthcare.
 - The proposed merger guidelines also follows the DOJ and FTC's <u>proposal</u> in late June 2023 to change the pre-merger notification requirements to force merging companies to provide additional information about their proposed deals. This week, the AHA, PhRMA and other industry groups <u>asked</u> for more time to respond to the pre-merger notification changes.
- Healthcare M&A transactions in Q2 2023 <u>reached</u> comparable levels to before the COVID-19 pandemic, according to a **Kaufman Hall** report.

VALUE-BASED CARE

• In the CY 2024 Physician Fee Schedule proposed rule, CMS <u>addressed</u> concerns raised by ACOs and other stakeholders participating in the <u>Medicare Shared Savings Program</u>.



- Changes included revising benchmark and assignment methodology, as well as expanding advanced investment payments for certain ACOs.
- The CMS Innovation Center (CMMI) issued a <u>Request for Information</u> (RFI) to gather information from the public regarding the future design of an episode-based payment model to increase value and decrease the volume of services used.
- Value-based care models should include drug utilization and spending considerations, according to a Commonwealth Fund <u>report</u>.

HEALTH EQUITY & SDOH

- CMS <u>highlighted</u> the advancements to health equity within its CY 2024 Physician Fee Schedule proposed rule.
- CMMI is <u>struggling</u> with the lack of reliable data to back its initiative to embed health equity into CMS payment models, according to a recent <u>white paper</u>.
- WHO seeks <u>proposals</u> utilizing the Health Equity Assessment Toolkit. The purpose of this
 APW is to further develop HEAT and HEAT Plus, specifically by integrating new visualizations
 showing SDOH data.
- Ahead of the one-year anniversary of the 988 Suicide and Crisis Lifeline's launch, HHS <u>announced</u> new Spanish text and chat services.
- A <u>study that is not yet peer-reviewed indicates</u> that using GPT-4 may potential to perpetuate racial and sexual biases in clinical diagnoses.

MEDICAID

- An OIG <u>audit</u> found Medicaid managed care organizations deny 1 in 8 prior authorization requests, raising concerns over states' oversight of Medicaid denial processes.
- As of July 17, 2023, 2.7 million people <u>lost Medicaid coverage</u> during the redetermination process, with at least 75% of disenrollment accredited to procedural reasons, according to <u>KFF's Medicaid enrollment and unwinding tracker</u>.
 - o CMS posted training slides for community workers to help people enroll in Medicaid.
- **Elevance Health** <u>announced</u> it lost 135,000 Medicaid members as the redetermination process moves forward.
- The Commonwealth Fund <u>released</u> five strategies for states to protect eligible children from losing Medicaid & CHIP coverage during the redetermination process.

Virtual Health

FEDERAL NEWS

- In its <u>proposed Physician Fee Schedule</u>, CMS recommended <u>increasing</u> Medicare home-based virtual care provider payments, considering that most physicians maintain physical offices while furbishing virtual services.
- The U.S. House Energy & Commerce Health Subcommittee <u>advanced</u> a bill designed to permanently allow employers to offer telehealth as a tax-free benefit separate from their sponsored health plans.
- Two Florida men <u>pleaded</u> guilty to a \$67 million Medicare telehealth fraud scheme.



NEW LAUNCHES AND PARTNERSHIPS

- **Piedmont Health Services** <u>partnered</u> with **UNC Family Medicine** and the Chatham County Public Health Department to launch a maternal health quality improvement project, which included a virtual care service.
- The Peterson Center on Healthcare <u>launched</u> the Peterson Health Technology Institute (PHTI) with \$50 million to analyze and determine the efficacy of digital health solutions.
- South Carolina-based **Prisma Health** <u>expanded</u> its partnership with virtual care company **HealthSnap** to integrate remote patient monitoring into its Epic EHR system.
- Big Health, an app-based mental health treatment provider, <u>revealed</u> its acquisition of Limbix, the maker of a prescription app for adolescent depression, for an undisclosed amount.

OTHER TELEHEALTH NEWS

- The AMA <u>released</u> an article highlighting the need for comprehensive telehealth reform, including proposing four telehealth licensure reform approaches.
- **Teladoc** <u>expanded</u> its collaboration with **Microsoft** by integrating **Nuance's** Dragon Ambient eXperience Express generative Al tool, which will use speech recognition to automatically produce clinical visit notes for providers.
- The Patient-Centered Outcomes Research Institute (PCORI) <u>approved</u> \$23 million in funding for three studies comparing telehealth strategies to improve chronic care management in primary care settings.
- **Anise Health**, a culturally responsive telemental health provider, <u>raised</u> \$1.2 million in pre-seed funding.
- Telehealth services are increasingly <u>relied upon</u> for menopause treatment, particularly for hormone therapy to manage symptoms.
- Virtual care <u>does not</u> significantly lower costs or reduce the number of future visits to emergency rooms or specialists for circulatory, respiratory, or infectious diseases, according to a University of Texas study.
- Mobile health apps that promote physical activity may <u>lack</u> the necessary data to properly gauge their generalized effectiveness, limiting their practicality.
- Patients increasingly <u>struggle</u> to obtain treatment for mental health conditions. Limited understanding, a lack of efficacy, and the absence of digital tools all contribute to patient challenges, according to a <u>report</u> from **Amwell**.