Maverick Health Policy

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NEWSLETTER CONTENTS

Digital Health

DIGITAL HEALTH INVESTMENTS

- While healthcare venture investment jumped in 2020 and 2021 for life science companies, venture capital funds are now looking to digital startups that apply machine-learning to data sets that will create insights into new treatments and better patient care.
- Global digital health funding stabilized for the first time in 4 quarters, reaching $3.4 billion in Q1 2023, according to a CB insights report.
  - o While digital health "mega-rounds," funding rounds of $100 million or more, declined 85% year over year, there are still some recent eye-popping standouts:
    - ▪ Kindbody, a virtual, at-home fertility and genetic testing service, raised $100M to increase its valuation to $1.8B.
    - ▪ Devoted Health, the Medicare Advantage plan company owned by tech genius brothers Todd and Ed Park, raised $1.15B in its Series D round, increasing its valuation to $12.6B.
- **Strive Health**, a value-based kidney care company, raised $166M in series C funding.

- **Carrum Health**, a value-based care platform designed to help self-funded employers reduce spending on costly care conditions, raised $45M in series B funding.
- **Axuall**, a workforce intelligence company that connects healthcare organizations to data for analytics, raised $20M in series B funding.

ARTIFICIAL INTELLIGENCE NEWS
- The Biden Administration launched three new national AI strategies designed to regulate AI tools, including:
    - Updates to the National AI R&D Strategic Plan, which outlines key priorities for federal AI investments.
    - A White House Office of Science and Technology Policy (OSTP) Request for Information (RFI) seeking input on creating a comprehensive strategy to mitigate AI risks.
    - A report on the future of teaching and learning from the U.S. Department of Education's Office of Educational Technology.
- The FDA is reviewing a citizen petition from the Center for U.S. Policy that argues **Bamboo Health's** NarxCare product – a clinical decision support (CDS) tool that evaluates a patient's criminal history, electronic health records, and medical claims data to make more informed painkiller prescribing decisions – should be considered a medical device.
    - **Bamboo Health** argues that NarxCare is exempt from FDA regulation because it does not make clinical recommendations, but only assists providers in their decisions.
    - This news comes as the FDA is already reviewing a February 2023 citizen petition from the CDS Coalition requesting the agency rescind its 2022 CDS guidance that allegedly violates the 21st Century Cures Act – which sets limits on FDA's authority to regulate certain CDS software functions.
- **Microsoft** introduced Copilot – its new AI assistant for Windows 11. Copilot uses whatever website the user is currently visiting as context to complete tasks elsewhere — like drafting a memo to staff or sending an email.
- ChatGPT failed the American College of Gastroenterology Self-Assessment Test despite passing various other U.S. medical exams – scoring 62.4%, below the required 70% mark.
- Large technology companies – like **Google** and **Amazon** – are more successful at integrating AI into clinical settings than early-stage digital health and healthcare AI entrepreneurs because of barriers to integration, according to a recent study.
- Providers hope that AI and other data science capabilities can address healthcare's labor shortage, particularly a lack of nurses. Contract workers increased expenses by 20% over the last year (March 2022 – March 2023), according to a report by Kaufmann Hall. (See the Providers section below for an article in *Health Affairs* that claims it is hospital reimbursement models that are causing the nursing shortage.)
- **January AI**, a precision health technology company, released a generative AI-enabled application to help predict a patient's glucose response to 32 million different foods.
- **Wellen**, a bone-health-focused fitness startup with personalized strength training programs, launched an AI chatbot built on ChatGPT.

- **Skyflow**, a data privacy startup that traditionally serves to keep personally identifying information (PIL) in defined borders, underlined built a data storage service that supports generative AI services.
- **Inovaare**, a healthcare compliance software provider, launched Usher – its new generative AI-powered regulatory compliance assistant for payers and providers.
- **SameSky Health**, the developer of a software platform that assists in engaging health plan members, integrated natural language processing and ML into its platform to create better, culturally tailored experiences.

Interoperability & Health IT

INDUSTRY NEWS

- HL7 and the AMA are collaborating to integrate the former's FHIR data standard with the AMA's Current Procedure Terminology (CPT) code set to promote interoperable exchange.
- **Omada Health**, a virtual-first healthcare provider focused on chronic conditions, launched a behavioral- and lifestyle-change-focused program to support patients who use GLP-1 drugs like Wegovy for weight loss.
- Elon Musk's neurotechnology company, **NeuraLink**, received FDA approval to begin human clinical trials and evaluate the company's brain-implanted microchip with a computer interface to enhance sensory function.
    - o Following the NeuraLink news, *STAT News* released a special report about another neurotech startup, **Stimwave**, that uses nerve-stimulating devices to treat chronic pain. The report revealed that the company used a "fake component" to increase the cost of the device.
    - o In related news, a paralyzed man can walk again after a Switzerland company, **NeuroRestore**, repaired the severed connection between his brain and his spinal cord, according to a paper published in *Nature*.
- Despite improved efforts to diversify wearable device studies, older populations – those that would likely benefit most from remote patient monitoring – are still underrepresented, according to a study published in *The Lancet*.

PUBLIC HEALTH DATA

- A new partnership between HL7 and the AMA combines Fast Healthcare Interoperability Resources (FHIR) with the AMA's Current Procedure Terminology (CPT) code set to advance interoperability in clinical care, research, and public health.
- Dozens of U.S. senators reintroduced the *My Body, My Data* Act, which aims to protect reproductive health data by preventing sensitive information from being stored and disclosed, despite not being a HIPAA-covered entity. More here.

DATA PRIVACY AND SECURITY

- Montana passed the Montana Consumer Data Privacy Act (MTCDPA), making it the ninth state to pass a comprehensive privacy law, but the only one to include a ban on **TikTok**.

- o   The MTCPDA grants consumers the right to revoke their consent to data processing, allows consumers to opt out of personal data sales, permits a consumer to request the deletion of all personal data, and prohibits businesses from nonconsensually selling the personal data of a consumer between the ages of 13-16.
- A Cybersecurity and Infrastructure Agency (CISA) and FBI task force published an updated guide to assist hospitals and other healthcare facilities in preventing ransomware attacks and data extortion tactics.

Payers & Providers

HEALTHCARE TRANSPARENCY
- Two price transparency articles were published in *Health Affairs* last week:
  - One suggests how health plans can make their price transparency data more useful;
  - The other compared transparency data of four national insurers – **Aetna**, **Humana**, **UnitedHealthcare**, and **Cigna** – but found issues with data accuracy that limited meaningful comparisons.
- More than 125,000 Medicare Part D beneficiaries will benefit from reduced out-of-pocket costs for expensive prescription drugs following the 2025 implementation of the Inflation Reduction Act's out-of-pocket cap of $2000 per year.
- The FDA issued a proposed rule to amend its prescription drug labeling regulations to require the inclusion a one-page, easy-to-read Patient Medication Information (PMI) document. The PMI would be given to patients with their prescription drug products accompanying outpatient services to help them understand how to use their medications and encourage adherence to treatment plans.
- The Pharmaceutical Care Management Association (PCMA) – the PBM trade association – launched a seven-figure ad campaign to position PBMs as a safety net against corruption by pharmaceutical companies. PCMA criticized congressional efforts to investigate PBM business practices, artificially-high drug costs, and other barriers to price transparency.
- As PBMs face mounting scrutiny, **Optum Rx** launched a series of initiatives to support independent and rural pharmacies to bridge community resource gaps.

PAYERS
- CMS issued a statement confirming, despite pressure by Congress and advocates, that Medicare will only cover Alzheimer's drugs that have traditional FDA approval "when a physician participates in the collection of evidence about how these drugs work in the real world, also known as a registry."
- In 2023, healthcare costs for a hypothetical family of four reached $31,065, according to the 2023 Milliman Medical Index (MMI), which measures costs for individuals and families with employer-sponsored preferred provider plans (PPO).
- According to a Mercer survey, the average per-employee cost of health insurance rose by 3.2% in 2022, only about half the rate of general inflation at 6.5%.

- The Congressional Budget Office (CBO) reported that only 8.3% of Americans under 65 were uninsured in 2023. The historic low rate of uninsured Americans is tied to COVID-19 policies that ended recently – like the Medicaid continuous enrollment policy.
- Influential health care reporter and Editor-in-Chief of *Kaiser Health News*, Elisabeth Rosenthal, wrote a piece urging Congress and CMS to increase its monitoring and enforcement of health insurance coverage denials.
- Minnesota Gov. Tim Walz signed legislation requiring health plans in the state to cover the no-cost preventative care provisions enforced by the ACA. The state action follows the federal district court ruling blocking the enforcement of those provisions.
    - More than 10 million Americans rely on the preventative services once protected under the ACA and they could incur higher healthcare costs because of the court's ruling, according to a report from Peterson-KFF.
- **CVS Health** is anticipating a $1B loss due to Aetna's drop in its Medicare Advantage star ratings.
    - **CVS Health** reported only 21% of its members in 2023 were enrolled in MA plans with a star rating of 4 or higher -- the benchmark to receive a full quality bonus -- a reduction of 66% from 2022.
- In a case that preceded the No Surprises Act, a federal appeals court allowed a lawsuit to proceed against **Cigna** by eight Florida hospitals that are alleging the insurer underpaid their out-of-network charges.
- **After getting serious pushback from provider groups, UnitedHealthcare is** not going to require prior authorizations for colonoscopies and other endoscopic procedures.
- **UPMC's** rival in Pittsburgh, **Highmark Health**, released its first quarter earnings report -- showing that it grew 4.6% in the first quarter of 2023 to $6.7 billion, mostly because of a 2.5% increase in health insurance enrollment and higher patient volume at its Allegheny Health Network arm.
- Member satisfaction with commercial health plans is dwindling, according to a study by J.D. Power. Those born between 1974 and 2004 are especially critical of their health plan's communication and customer service.

PROVIDERS
- Physician pay is rising but not meeting inflation rates according to the **Medical Group Management Association's** annual report. This is affecting compensation growth and highlighting the disparities between physician-owned and hospital-owned practices,
    - Median total compensation for primary care doctors rose 4.41% last year, compared to 2.13% in 2021, but was lower than inflation rates of 7% and 6.5%, respectively.
- The May 2023 *KLAS Research* report shared **Epic's** electronic health record system gained 83 hospitals and **Oracle Cerner** gained 22 hospitals, whereas **Meditech** lost 6 hospitals.
- Less than a month after **CVS Health** acquired **Oak Street Health**, the primary care provider announced plans to expand into four more states: Arkansas, Iowa, Kansas and Virginia.
- **Kaiser Permanente** committed $10M to the safety-net hospital **Denver Health** as the facility faces continued financial stress.
- Over 200 rural hospitals face immediate risk of closure due to inflation, staff shortages, and other financial stressors, according to a **C**P**enter for Healthcare Quality Payment Reform** report.

- Two nurses co-authored an article in *Health Affairs* explaining why hospitals' reimbursement model is the reason for the nation's nursing shortage.
- Tech enablement and intentional delegation can reduce the workforce gap by approximately 300,000 nurses, according to a **McKinsey** report.
- Adopting home care technologies like at-home infusion, virtual clinical exam rooms, digital therapeutics, and home care management platforms can lower costs and the prevalence of chronic diseases caused by the growing elderly population, according to an AHA market scan.

PAYERS AND PROVIDERS (M&A)
- **BJC HealthCare** of St. Louis and **Saint Luke's Health System** of Kansas City are in merger talks that would create a 28-hospital, $10 billion, integrated, non-profit academic health system.
- The Atlanta-based nonprofit **Centurion Foundation** submitted its application seeking approval for the acquisition of **CharterCare Health Partners** under **Centurion**'s subsidiary health system **CharterCare of Rhode Island.**

VALUE-BASED CARE
- Home Health Value-Based Purchasing (HHVBP) models, which provide payment adjustments for higher quality care facilities, improved care quality and decreased spending on hospitalization and skilled nursing facilities, as found in a recent CMS report**.**
- **Sunshine Health** and **Johns Hopkins All Children's Hospital** reached a two-year value-based agreement to improve care access and patient outcomes for Florida Medicaid beneficiaries, mirroring national efforts to expand care accessibility.

HEALTH EQUITY & SDOH
- **Aetna** allocated $250K to 10 Michigan community-based organizations to address social determinants of health, including workforce development, housing stability, food security, and care quality.

MEDICAID
- A CMS official urged states to avoid terminating eligible Medicaid beneficiaries during the determination process due to administrative barriers – such as not responding or "red tape" – which are accounting for a substantial portion of Medicaid disenrollments.
- President Biden and House Speaker Kevin McCarthy's recent debt ceiling agreement excluded the House Republican proposal to require Medicaid beneficiaries to work for at least 80 hours per month, which would reduce overall Medicaid coverage by 600,000.
- Medicaid redeterminations may disproportionately impact individuals qualifying for pregnancy after 60 days postpartum because certain state legislatures fail to follow the majority in expanding Medicaid and extending postpartum coverage to a year.
- Throughout the U.S., 33 state Medicaid programs failed to provide accessible core behavioral health crisis services due to challenges with funding, workforce, location, and training.

However, 28 programs plan to enact the American Rescue Plan Act to allocate Medicaid funds to mobile crisis intervention services.
- Home-health providers criticized two provisions CMS proposed in late April to reform home- and community-based services (HCBS). The providers cited implementation barriers and unfavorable reductions in compensation, which may disincentivize providers from utilizing Medicaid services and change the way providers employ direct care workers.

Virtual Health

FEDERAL NEWS
- The *Protecting Rural Telehealth Access Act* was introduced in the U.S. House with bipartisan support to make Medicare coverage of virtual care permanent and expand telehealth access in rural communities.

NEW LAUNCHES AND PARTNERSHIPS
- Researchers at Washington University in St. Louis unveiled a new deep-learning model, WearNet, that uses Fitbit data to detect mental health risk factors for conditions such as anxiety and depression.
- To address the reduction of STI testing due to COVID, **Grindr**, the LGBTQ+ dating app, partnered with **Emory University** to provide free at-home HIV tests to residents ages 17 and older.
- **Samsung** partnered with **HeartBeam**, a cardiac monitoring company, to improve the standard of cardiac diagnostic capabilities and the use of 3D-vector electrocardiograms at home. More here.
- Researchers from Georgia Tech developed a wearable device that utilizes AI and machine learning to detect and predict sleep apnea.
- **Hello Heart**, a smartphone application, launched a new feature that provides menopausal women with tools and insights on how to manage their heart health.
- UC San Diego engineers developed a finger clip that uses the camera and flash features on a smartphone to monitor blood pressure.
- **UMPC Chautauqua** received a grant from **Univera Healthcare** to expand its telehealth services and prioritize underserved patients including those without internet access and transportation.
- **UVA Health** is improving telehealth for aging adults in geriatric care through its Center for Excellence for Telehealth and Aging.

OTHER TELEHEALTH NEWS
- A 2023 report by *KLAS Research* listed the top 10 remote patient monitoring companies, with **CareSignal** scoring the highest at 93.2 out of 100.
- Employees are demanding obesity treatment coverage from employers. Weight loss drugs like Ozempic and Wegovy are not covered by health plans, so virtual care companies – like **Noom** and **Omada Health** – are capitalizing on the surging demand for obesity treatment

by combining prescriptions for Ozempic and Wegovy with online programs that target lifestyle and behavior change. More on the weight loss drug surge here.

- Between 2013 and 2019, the coverage of telehealth by Medicaid was associated with an increase in telehealth use and access. The same association was not found with private insurance coverage of telehealth services during the same time. Study here.
- Phyllis Yale, partner at Bain & Company and board member of **Aledade** and **Blue Cross Blue Shield of Massachusetts**, commented on virtual care being an increased risk of medication nonadherence.
- Chris Raphaely, the co-chair of the healthcare practice group at Cozen O'Connor, predicted that the end of the PHE will bring a natural reduction in telemedicine utilization, but with a focus on individual patient access to technology, telemedicine challenges can be effectively addressed.
- Low-income Hispanic and Asian patients are more likely to use telehealth services compared to white and Black patients, according to a study from the *Journal of Medical Internet Research.*
- Young insured adults had the highest participation rates in overall and telehealth-enabled addiction treatment during the COVID-19 pandemic with no evidence of addiction treatment disparities, according to a study published in *JAMA Network Open.*