

MYMAVERICK RECAP May 11, 2023

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Digital Health

DIGITAL HEALTH INVESTMENTS

- Modern Healthcare identified 7 digital health "unicorns" that are struggling:
 - o <u>Cerebral</u>, a digital mental health startup
 - o TruePill, a digital pharmacy company
 - o Olive AI, a technology company that helps automate the revenue cycle
 - o <u>Pear Therapeutics</u>, a prescription digital therapeutics solution for opioid use disorder
 - o <u>Elemy</u>, virtual applied behavioral analysis services for children with autism
 - o <u>Talkspace,</u> a virtual therapy app
 - o Akili Interactive, a video game treatment for children with ADHD
- **Andreesen Horowitz** ("a16z"), venture capital giant-turned-crypto firm, released a <u>playbook</u> on key go-to-market strategies for digital health companies.
 - o a16z retained lobbying firm **Mehlman Consulting** to monitor crypto issues on the Hill.

- Global venture funding reached \$21B in April, down from \$47.8B in April 2022, a 56% decline. According to the Crunchbase <u>report</u>, healthcare and AI lead in funds raised.
- **Cowen Healthcare Investments** <u>raised</u> \$555.6M for its CHI IV fund, which focuses on life sciences primarily but includes opportunities for digital health funding.
- **Hygieia**, a digital diabetes management tool, <u>raised</u> \$22M in series B funding.
- **Embr Labs**, the developer of a wearable device that treats menopause, <u>raised</u> \$35M.
- In an all-equity deal, **Oura**, the developer of a health-tracking wearable device, <u>acquired</u> **Proxy**, a developer of digital identity technology.

ARTIFICIAL INTELLIGENCE NEWS

- The Office of Management and Budget (OMB) <u>announced</u> it will release draft policy guidance for public comment on the use of AI systems by the U.S. government to ensure security, safety, and equity.
- The National Science Foundation <u>received</u> \$140M in funding to launch seven new National Al Research Institutes to further responsible Al research and development.
- Less than a year after IBM sold the Watson Health business, the corporation is <u>introducing</u> a new AI platform called <u>watsonx</u>.
- **UC San Diego Health** received a \$22M donation to <u>establish</u> a digital information and artificial intelligence center that will consolidate the health system's digital information gathered through various programs and pilots.
- **Columbia University** <u>received</u> \$20M from the National Science Foundation to establish and lead the AI Institute for ARtificial and Natural Intelligence (ARNI) that will draw connections between artificial intelligence and neuroscience.
- **Ubie**, an Al-powered symptom checker with 7 million monthly users across Japan and the U.S., <u>partnered</u> with **Google's** Health Connect (Beta) in Japan.
- **Cedars-Sinai** <u>established</u> its Center for Artificial Intelligence Research and Education which will focus on applying AI and ML to personalized medicine.
- Artificial intelligence can <u>improve</u> patient outcomes, but regulation of large language models is critical to the future, according to FDA Commissioner Dr. Robert Califf.
- Pathologists using Al-based models can <u>avoid</u> 40% of misdiagnosis of organ transplant rejections and improve patient risk stratification, according to a study in *Nature Medicine*.
- Al-based population screening can <u>identify</u> pancreatic cancer three years before clinical diagnosis, according to a study from Harvard Medical School researchers.
- Vinod Khosla, an entrepreneur and venture capitalist, <u>predicted</u> the FDA would approve an app qualified to practice primary care medicine within 5 to 6 years.

ARTIFICIAL INTELLIGENCE INVESTMENTS

- **Inbox Health**, a provider of an Al-enabled tool for billing and payment automation, <u>raised</u> \$22.5 million in series B funding.
- **MultiPlan**, a developer of healthcare payment and revenue tools, <u>acquired</u> **Benefits Science**, an Al-powered data and advanced analytics company.



Interoperability & Health IT

FEDERAL NEWS

- Digital health tool development is <u>outpacing</u> the FDA's ability to regulate them, according to FDA Commissioner Dr. Robert Califf.
- FDA's number two digital health regulator, <u>Brendan O'Leary</u>, the Deputy Director of the Digital Health Center for Excellence, left the agency.

INDUSTRY NEWS

- The American Medical Informatics Association <u>released</u> a <u>Toolkit</u> addressing reducing documentation burden.
- UC San Diego Health <u>piloted</u> a SMART health QR code initiative to digitally standardize health insurance cards, streamline patient check-ins, and reduce billing errors.
- **Tegria**, a healthcare technology services firm, <u>acquired</u> **Sisu Healthcare IT Solutions**, a MEDITECH certified hosting and services firm.
- The Trusted Exchange Framework and Common Agreement (TEFCA) will <u>ease</u> platform-to-platform interoperability, according to Michael Palantoni, VP of platform and data services at athenahealth.
- Less than 1 in 5 healthcare organizations <u>use</u> data to identify clinical best practices, according to a survey from MDClone.

PUBLIC HEALTH DATA

- According to the <u>American College of Medical Informatics</u> (ACMI), sustainable funding and a trained workforce are <u>necessary</u> for public health interoperability. This seems obvious, but it is a decent review of the issues.
- Most healthcare organizations are not prepared to collect data needed for advancements.
 Only 16% of health leaders surveyed <u>noted</u> they use data wisely to improve performance levels.
 - Only 36% of the surveyed health organizations said they <u>have</u> allocated funding for quality improvement.

DATA PRIVACY AND SECURITY

- U.S. House Energy and Commerce Committee members <u>asked</u> data brokers how they purchase, collect, use, license, and sell Americans' data, including health data.
- People are generally <u>willing</u> to share their health data, but there needs to be more choice and transparency and a shift in how the health system treats patients, according to Anne Wojcicki, co-founder and CEO of 23andMe.
- Meta <u>sought</u> dismissal of a class action lawsuit alleging the company gains access to
 protected health information, claiming its pixel-tracking tools do not violate healthcare
 privacy laws.
- **NextGen Healthcare**, a provider of EHR software, <u>reported</u> a data breach compromising the personal information of 1 million patients.



Payers & Providers

HEALTHCARE TRANSPARENCY

- The U.S. Senate HELP committee <u>delayed</u> the markup of bills designed to address high drug costs until May 11, the day after a hearing that will feature testimony from pharmaceutical leaders.
 - Unlike the federal government, Florida Gov. Ron DeSantis <u>signed</u> a prescription drug reform bill that will force drugmakers to report large price increases, as well as ban typical PBM tactics like mail-order rebates and patient steering.
- After months of legislative debate on PBM business practices, **Cigna** <u>pledged</u> more transparency about its PBM **Evernorth** subsidiary.

PAYERS AND PROVIDERS

- Along with the <u>health plan trade associations</u>, all of the hospital trade associations are
 publicly supportive of maintaining the Affordable Care Act's requirement that insurers must
 offer no-cost preventative services. The AHA, two other hospital associations, and the
 Association of American Medical Colleges filed a <u>joint amicus brief</u> in *Braidwood v. Becerra* to
 urge the U.S. Court of Appeals to reverse the lower court's ruling and continue the
 Affordable Care Act's no-cost preventive services.
 - University of Michigan Professor Mark Fendrick <u>explained</u> how the Braidwood ruling could impact cost-sharing.
 - Most employers <u>intend</u> to continue providing full preventive coverage, according to a National Alliance of Healthcare Purchaser Coalitions survey.
- **Accountable for Health** (A4H) <u>launched</u> on May 10, 2023, naming Mara McDermott as its CEO. The lobbying coalition is focused on value-based care delivery.
- <u>Draft guidance</u> from the U.S. Preventive Services Task Force <u>recommended</u> women begin regular mammograms starting at age 40, a decade earlier than their prior recommendation.
- Birth control may be a non-prescription OTC drug soon: An FDA advisory committee unanimously endorsed selling one specific pill, the progestin-only Opill, in pharmacies without a prescription.

PAYERS

- A dispute about who must be on a fishing boat may have a direct impact on HHS regulations.
 The U.S. Supreme Court agreed to hear <u>Loper Bright Enterprises v. Raimondo</u> (a dispute by the
 fishing industry against the Commerce Department for forcing them to allow a compliance
 officer to be on their boats), which could lead to a decision to <u>overturn four decades of
 deference</u> to federal agencies.
 - Oral arguments will not be heard until the fall, with a decision unlikely until late spring 2023.
 - Chevron was an air pollution case that allowed President Reagan's Environmental Protection Agency (EPA) to change the definition of "source of air pollutants" so that companies could keep polluting the air. Federal



- agencies have relied on the deference afforded them by the *Chevron* doctrine ever since, which says that a federal agency can implement regulations as it sees fit, even if a law does not explicitly say what the agency is supposed to do to make the statute's mandates operational.
- Justice Ketanji Brown Jackson recused herself from the case; she heard oral arguments in this case when she was a judge on the D.C. Circuit.
- Fun Fact: Sitting U.S. Supreme Court Justice Neil Gorsuch's mother was the EPA Administrator that made the *Chevron*-related definition change.
- U.S. Senate Finance Chair Ron Wyden <u>released</u> a <u>secret shopper survey</u> revealing inaccurate Medicare Advantage provider directories. The findings were released shortly before the U.S. Senate Finance Committee held a <u>hearing</u> on barriers to mental health care.
- A <u>survey from the Medical Group Management Association</u> found that 84% of group practices saw an increase in prior authorization requirements from MA plans.
- AHIP <u>released</u> an <u>infographic</u> showing that low-value services with little to no clinical benefit cost a lot of money.
- The first quarter of 2023 proved to be <u>profitable for payers</u>, with **UnitedHealth Group** once again ranking first. The national insurer reported \$5.6B in profits, more than double that of **CVS Health**, which reported \$2.4B following a series of declining quarters.
- Advantage plan. It cannot maintain the loan keeping it in business without a buyer willing to pay about \$300M.
 - o **Oscar Health** is also leaving California markets.
- More data is crucial to determine the <u>quality of care</u> Medicare Advantage beneficiaries with serious illnesses receive, according to a group of researchers in the *New England Journal of Medicine*.
- CMS distributed a <u>National Quality Strategy (NQS) handout</u> during its 2023 Quality Conference on May 1-3, 2023, outlining quality goals about health equity, outcomes, safety, and interoperability.

PROVIDERS

- In February, CMS announced its <u>Universal Foundation</u> to align quality measures across its programs. An influential primary care expert explains in *Health Affairs* why this initiative <u>negatively affects</u> primary care practices.
- The AHA is worried about the U.S. House Energy & Commerce's May 17th hearing on site neutral payment reform (and other items like 340B) that it pushed out <u>an action alert</u> with typos in it. (In *STAT*'s DC Diagnosis newsletter).
- Hospital finances continue to <u>stabilize</u> following nearly a year of negative margins, however, rising labor costs and thin operating margins leave providers <u>vulnerable</u>.
- **Community Health Systems** <u>reported</u> a \$51M loss in Q1 2023. The for-profit hospital cited heightened expenses and lower patient acuity as driving forces.
- In contrast, **Kaiser Permanente** <u>reported</u> \$1.2B in Q1 profits driven by higher care volumes. The posted profit follows a difficult financial year for the health system, having lost \$4.5B for all of 2022.
- Multispecialty provider staffing company **Envision** is likely to <u>file for bankruptcy</u> after the No Surprises Act prohibited the out-of-network balance bills that produced most of the company's profits.



- To combat rising labor expenses, health systems are considering laying off non-clinical employees at all levels.
- The U.S. added 253,000 jobs in April 2023, and 40,000 of them were healthcare jobs -- mostly in the ambulatory services sector, <u>according to the Bureau of Labor Statistics</u>.
- HHS Secretary Xavier Becerra commended America's nurses in a <u>statement</u>, highlighting the Biden Administration's investment in nursing training programs, grants, and loans.

PAYERS AND PROVIDERS (M&A)

- Last week we reported Kaiser Permanente's <u>definitive agreement</u> to acquire Geisinger Health. If approved by antitrust enforcers, some analysts believe this massive deal may build <u>industry confidence</u> in value-based care.
- **Humana** <u>announced</u> a 3-year partnership with **Longevity Health Plan** to tailor and expand <u>special needs health plan</u> offerings for Medicare beneficiaries in skilled nursing and senior living facilities.
- **Option Care Health** <u>acquired</u> home health firm **Amedisys** to bolster its post-acute care services and value-based care model.
- **Care First BCBS** <u>partnered</u> with **Noom** to provide prediabetes and obesity behavioral and preventative services to CareFirst members.

VALUE-BASED CARE

- MedPAC Chairman Michael Chernew and other co-authors of a new *Health Affairs* analysis
 <u>found</u> that high-spending ACOs <u>exited</u> the Medicare Shared Savings Program (MSSP) after
 CMS updated its benchmarks to reflect regional spending in June 2016.
- NAACOS held its <u>spring conference</u> this week, where it <u>recognized</u> three ACOs with Quality Excellence Awards and shared successful initiatives from its membership.

HEALTH EQUITY & SDOH

- **L.A. Care Health Plan** and **Health Net** <u>pledged</u> \$114M in initiatives to address homelessness and housing insecurity in Los Angeles County.
- **UnitedHealthcare of North Carolina** granted \$275,000 to assist local organizations provide SDOH services to children in foster care.
- Tulane University <u>research</u> suggested <u>Black health disparities</u> in heart failures cost Medicare more than \$60M through preventable hospital admissions.

MEDICAID

- Republican-backed Medicaid work requirements in the U.S. House debt ceiling bill <u>threaten</u> <u>coverage</u> for 1.7 individuals, according to a <u>KFF analysis</u>. While the bill is not expected to pass the Senate, it is anticipated that similar restrictions will be debated to secure a deal. More <u>here</u>, <u>here</u>.
- The Arkansas Department of Human Services <u>reported</u> almost 73,000 Medicaid coverage terminations in April after the continuous enrollment mandates were lifted, setting a benchmark for redeterminations nationwide.



Virtual Health

FEDERAL NEWS

- The DEA issued a <u>rule</u> to <u>extend</u> telehealth prescription flexibilities without an in-person provider visit until November 11, 2023, bowing to pressure to at least temporarily extend public health emergency flexibilities that helped address opioid disorder and mental health conditions. More <u>here</u>.
- A new HHS OIG <u>audit report</u> shows that a vast majority of Medicare payments for telepsychiatry were billed incorrectly: \$591M were billed as telehealth services and \$439M we billed as in-person services, which are not compliant. More <u>here</u>.

NEW LAUNCHES AND PARTNERSHIPS

- **Hendrick Health** partnered with **Gozio Health** to create an app that helps patients find and access health providers, view patient portals, and access directions to health facilities.
- **Samsung** will <u>release</u> its digital health research tool called Samsung Health Stack in June. The tool will simplify the digital collection of health data to lessen barriers between researchers and technology experts. More <u>here</u>.

OTHER TELEHEALTH NEWS

- After **Anthem Blue Cross** refused to reimburse **Carbon Health**'s filed claims, the insurance company decided to process Carbon Health's out-of-network claims.
- In-home urinalysis and wound care company **Healthy.io** <u>laid</u> off 70 employees, despite receiving a \$50M investment to further its digital kidney test.
- Amwell, a telehealth company, reported a first-quarter loss of \$389.5M.
 - Nearly \$330M of **Amwell**'s total loss was <u>attributed</u> to an impairment charge from a decline in their stock share price.
- Telehealth company **Him & Hers** <u>reported</u> a first-quarter gain of \$190.8M, indicating the company will have a total 2023 revenue between \$810M and \$830M. More <u>here</u>.