Maverick Health Policy

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NEWSLETTER CONTENTS

Digital Health

DIGITAL HEALTH INVESTMENTS

- The collapse of Silicon Valley Bank (SVB), the 16th largest bank in the U.S., is causing uncertainty in the digital health startup landscape. SVB played an outsized role in more than 75% of the healthcare VC-based IPOs over the past three years. The latest reports on the fallout are from _healthleaders, Modern Healthcare, Axios, Fierce Healthcare, Wall Street Journal_, and Rock Health.
- **Assured Allies** finished a Series B round with $42.5M to bolster the expansion of the insurtech's machine learning and predictive analytics platform for long-term care.
- **Maribel Health**, a startup launched by General Catalyst that provides a tech platform and advisory services to health systems to operate hospital-at-home programs, raised $25M in series A funding.
- **Aiberry** raised $8M for its AI-powered mental health screening solution.
- **Iron Health** collects $4.5M for its virtual women's health platform.
- Virtual OB-GYN tech developer **Iron Health** raised $4.5M in seed funding to bolster patient care with a digital accessible medical team.

- Fifth Third Bank underline acquired Big Data Healthcare, which sells "FUSE" -- an online portal that automates remit reconciliation.
- A report from **PitchBook** showed digital health investments hit $7B in 2022, down from $15.6B in 2021, with venture funding continuing to trend down for telehealth.

ARTIFICIAL INTELLIGENCE NEWS

- A lengthy *STAT* investigative report about the use of AI in Medicare Advantage (MA) coverage decisions alleges that government oversight is needed.
  - The reporters claim that while AI used in medical devices are regulated by the FDA, insurers that use AI to make coverage decisions have no oversight.
  - Specifically, the article accuses UnitedHealth Group's **NaviHealth** program of using an algorithm that discharged nursing home residents too soon.
  - The report tracks the history of NaviHealth from Tom Scully's initial investment, to being sold to Cardinal Health, to a private equity firm, and ultimately to UnitedHealth Group -- saying that as the entity changed hands, providers claim that there was a noticeable increase in coverage denials.
- At its Google Health event, **Google** announced that it is continuing to build out its health-related AI initiatives, including ultrasounds, cancer treatment and tuberculosis screenings.
  - **Google** released Open Health Stack, an open resource to help developers build FHIR-based digital health apps quickly.
  - **Google** also announced that it is updating its large language model, Med-PaLM 2, which can perform at an "expert" level on medical exams.
- **OpenAI** released **GPT-4**, its latest multimodal model, touting its "human-level" performance on academic and professional exams and highlighting the model's recent updates.
- A study published in the *Journal of Clinical Oncology: Oncology Practice* found that the Jvion Care Optimization and Recommendation Enhancement (CORE) AI tool may reduce emergency department visits for cancer patients by 18%, leading to a cost-savings of $2.8M annually.
- A systemic review published in *JAMA Network Open* found that the risk of bias and clinical applicability issues will prevent neuroimaging-based AI and ML models from directly creating psychiatric diagnoses.
- On an AMA video and podcast, Dr. John Halamka, President of Mayo Clinic Platform, discussed the pros and cons of the integration of AI -- specifically, ChatGPT -- in medicine.

Interoperability & Health IT

FEDERAL NEWS

- President Biden released his presidential budget, including allocations for improving cybersecurity and public health resilience, and increasing funding for health data and experience improvements.
  - The proposed budget is widely considered "dead on arrival" by Republicans, but it does signal a growing focus on national health IT.

- A new House bill, referred to the Energy and Commerce Committee, would require HHS to submit a report on the interoperability of medical devices to Congress.
- ONC published a blog highlighting actions, updates, and shoutouts from Health Datapalooza.
- ONC published a blog identifying the top takeaways from the TEFCA Recognition event that occurred in February, including representatives from each Qualified Health Information Network agreeing to go-live by the end of 2023

INDUSTRY NEWS
- Google is launching Open Health Stack, a suite of open-source tools to help developers create digital health apps and adopt HL7 FHIR standards.
- **Avaneer Health**, a consortium including **CVS, Anthem**, and **Cleveland Clinic**, among others, launched a first-of-a-kind, decentralized, peer-to-peer digital network built on blockchain enabling secure, real-time data-sharing in healthcare.
- **DirectTrust** was selected as part of **AWS** Health Equity Initiative to bolster the non-profit alliance's interoperability directory.
- An MIT study found that health information exchanges (HIEs) only work well when they have state policy support.
- The HL7 Fast Healthcare Interoperability Resources (FHIR) Accelerator CodeX announced a new steering committee to advance FHIR as the data standard to obtain high-quality data for patient care and research.

PUBLIC HEALTH DATA
- As part of President Biden's budget proposal, the Biden Administration signaled its wish to continue to fund efforts to improve SDOH data collection and analysis to improve maternal health outcomes.

DATA PRIVACY AND SECURITY
- The HHS requested $78M in OCR funding for FY 2024, a $38M increase from last year, to manage a higher number of HIPAA complaints.
- The Senate Committee on Homeland Security and Governmental Affairs will hold a hearing to explore healthcare cybersecurity strategies.
  - Stirling Martin, **Epic**'s senior VP and chief privacy and security officer, is on the witness list for the hearing.
- In partnership with the Healthcare and Public Health Sector Coordinating Council (HSCC), HHS released its HPH Sector Cybersecurity Framework Implementation Guide, suggesting how leaders can prevent cybersecurity breaches amid an increase in system attacks.
- The Health Sector Coordinating Council, an industry-led advisory council with 400 health care organizations, including pharma, labs, med tech, payers, digital health organizations, released its cybersecurity guidance for medical device manufacturers and healthcare delivery organizations.
- **Cerebral** notified patients of a data breach impacting more than three million patients, resulting from their use of pixel tracking technologies.

- Medical device company **ZOLL Medical Corporation** notified more than a million individuals of a data breach that exposed patient names and Social Security numbers.

Payers & Providers

DRUG PRICING
- On March 15, 2023, CMS issued a 91-page initial guidance detailing the requirements—including requests for public comment by April 14, 2023— on key elements of the new Medicare Part D Drug Price Negotiation Program for 2026, the first year the negotiated prices will apply. Fact sheet here, press release here.
- CMS also announced 27 prescription drugs for which Part B beneficiary coinsurances may be lower from April 1-June 30, 2023. Fact sheet here.
  - On February 9, 2023, CMS released initial guidance to manufacturers regarding the payment by manufacturers of inflation rebates for Part B rebatable drugs beginning January 1, 2023.
    - The AHA commented on it, asking for two changes: Mitigate the risk of incentivizing drug companies to artificially extend the duration of shortages of drugs to receive reductions in the IRA's inflation rebate, and refrain from requiring the use of "JG" and "TB" modifiers for drugs purchased under the 340B program in implementing the IRA's inflation rebate.
- The Alliance to Save America's 340B Program, a coalition of big pharma and community health centers, announced plans to advocate for increased transparency and accountability within the 340B program. They released 10 policy proposals.
- A group of Republican senators sent a letter to HHS Secretary Xavier Becerra and CMS Administrator Chiquita Brooks-LaSure warning that the new Accelerating Clinical Evidence drug pricing model will lower reimbursement rates and undermine access to high-quality medications and delay treatment for Medicare beneficiaries.
- **Novo Nordisk** announced it will follow **Eli Lilly** in capping the cost of several of its insulin products beginning January 2024.

HEALTHCARE TRANSPARENCY
- As part of President Biden's proposed 2024 budget, the Biden Administration will continue to fund enforcement of the No Surprises Act transparency provisions.
- CEO of **CapitalRx**, A.J. Loiacono, responded to growing PBM criticism by stating PBM drug pricing processes should be revised but not eliminated, citing their critical administrative role in care.
- The Illinois Department of Insurance fined **BCBS of Illinois** $605K after an investigation found the payer did not adhere to transparency rules.
- Senate Republicans wrote a letter to CMMI criticizing its Accelerating Clinical Evidence Model, claiming it undermines the FDA's regulatory process and drug benefits payments.
- The AHA responded to criticism of hospitals' non-compliance with transparency policies, affirming that health systems and care facilities are making progress to comply with regulations.

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- - AHA's Senior VP for public policy analysis and development also <u>addressed</u> misinformation about the issue.

PAYERS AND PROVIDERS (M&A)
- Recovery Centers of America <u>acquired</u> Adolescent & Young Adult Advocates, an addiction and mental health provider, to expand outpatient services and reduce substance use in young adults.
- **Chartis**, a healthcare advisory firm, <u>announced</u> that it <u>acquired</u> revenue cycle consultant **Chi-Matic** to integrate technology processes and increase staff efficiency for the revenue cycle.
- Robotics company **Clarapath** <u>acquired</u> **Crosscope**, a digital pathology company, to establish a tissue sectioning and transfer system and to help labs provide high-quality, efficient care.
- A **PitchBook** <u>report</u> <u>advocated</u> for greater consolidation in the digital behavioral health industry, stating it is necessary to expand service access and tailor care to communities.

PAYERS
- MedPAC <u>released</u> its March 2023 report to Congress, including a chapter on Medicare Advantage. The Commission <u>reiterated</u> its past suggestion that risk adjustment methodology should not include health risk assessments that are driving the coding differences among MA plans, and that quality of care in MA plans is impossible to measure. More <u>here</u>.
- The White House <u>released</u> President Biden's <u>proposed budget</u>, which contains several <u>healthcare proposals</u>, including a plan to keep the Medicare trust fund solvent and a requirement for MA plans to implement an 85% medical loss ratio requirement on supplemental benefits. More <u>here</u>, <u>here</u>.
- An article in *Fierce Healthcare* <u>considered</u> how President Biden's new budget will impact MA plans, highlighting coverage requirements for mental health services and restrictions on supplemental benefits.
- The FDA sent a <u>warning letter</u> to **ElectRx** – a company that connects foreign pharmacies to employer-sponsored health insurance plans to provide beneficiaries with prescription drugs – alleging that ElectRx provided its customers with non-FDA approved prescription drugs which put its members at significant health risk.
- *Fierce Healthcare* <u>outlined</u> challenges MA plans may face after CMS's new advanced notice plan and RADV rule, emphasizing that smaller organizations will be hit hardest.
- Retirees are <u>concerned</u> about employers' growing trend toward using MA plans to provide benefits, <u>citing</u> high supplemental costs and benefits that may not be sustainable.
- A KFF <u>brief</u> <u>found</u> that most Medicaid beneficiaries who intend to re-enroll, have not been asked to renew their contact information for their plan to prepare for redeterminations.
- A *Stat News* investigation <u>found</u> MA plans sometimes use AI to deny patient claims – basing their decision to stop covering patients' care on an unregulated algorithm - a practice that hurts beneficiaries by delaying treatment and increasing the cost of care.
- According to the National Health Care Anti-Fraud Association, Medicaid and Medicare <u>fraud reaches</u> over $100B annually, often due to fraudulent billing.
- An article in *<u>NEJM</u>* <u>warned</u> about straining Medicare if it covers weight loss medications and the higher premiums that would result in the long run.

- A patient group that claimed **United Behavioral Health** wrongly denied mental health service claims is seeking a federal appeal after a 2020 court decision in their favor – supported by the AMA and APA – was overturned last year.

PROVIDERS
- CMS released guidance for assessing hospitals' compliance with Medicare quality standards that included the evaluation of hospitals' Quality Assessment & Performance Improvement (QAPI) programs as well as the hospital leadership and governance involvement in these programs.
- The Health Resources and Services Administration (HRSA) announced the availability of $25M to expand primary health care – including mental health care – in schools. Currently, HRSA-funded health centers serve over 3,400 schools across the U.S.
- A new analysis from the Urban Institute found that around 15% of nonelderly American adults have past-due medical debt, much of which is owed to hospitals.
- Around 30% of patients who received medical care between 2016 and 2022 did not see a primary care physician, according to a FAIR Health analysis, underlining gaps in care and health equity issues.
- A Kaiser Family Foundation brief reported that while nonprofit hospitals are required to provide charity care in return for their tax-exempt status, they received more funds through tax exemptions than they contributed to charity care in 2020.
- According to a U.S. Bureau of Labor Statistics report, the largest growth in hospital jobs since September 2022 occurred in February. According to experts, it will still take around 20 months to return to pre-pandemic employment levels.
- A *Fierce Healthcare* article revealed the challenges hospital executives expect to encounter in 2023, noting that the financial difficulties hospitals faced in 2022 will continue to impact hospitals this coming year.
- **Providence Health System** reported a $1.7B operating loss and a $6.1B net loss in 2022.
- **Ascension** reported a $410M operating loss but is implementing an economic improvement plan.

VALUE-BASED CARE
- **PointClickCare** acquired **Patient Pattern**, a value-based care EHR, to expand its senior-focused, value-based care model as healthcare moves away from FFS models and towards VBC. This marks just one of a series of companies that have shifted focus toward senior-focused VBC.
- In a *Fortune* podcast, **CVS Health** CEO Karen Lynch emphasized that the Signify and Oak Street Health acquisitions will strongly position the company to advance value-based care.
- An *AJMC* article recapped the Value-Based Insurance Design Summit, where organizations outlined their agendas to improve coverage and drug costs.
- **CareFirst BlueCross BlueShield** is partnering with **Aledade** to help its in-network primary care practices to offer value-based care services by allowing their network physicians to access Aledade's technology platform.

HEALTH EQUITY & SDOH

- A *Health Affairs* study underlined challenges Medicaid MCOs will face when using social drivers of health (SDH) bonds, and proposed a Health Care Investment Act to encourage groups to invest in communities.
- **UnitedHealthcare** extended its partnership with the Morehouse School of Medicine to launch PM3, an app providing postpartum support to Black mothers to mitigate disparities.
- **NYC Health + Hospitals** announced plans to spend $14M to help homeless patients find housing in an effort to reduce costly emergency room spending.

MEDICAID

- HHS Secretary Becerra urged states to use consistent eligibility standards and 'every possible option' to ensure qualifying individuals retain Medicaid after redetermination. Becerra also highlighted the potential loss of Medicaid funds if states do not report enrollment statistics.
    - o A new survey from KFF, in collaboration with the Georgetown University Center for Children and Families, presents an overview of state activity to unwind the provision that has paused Medicaid disenrollments since February 2020, estimating that about 15M people may drop off Medicaid rolls in the coming year.
    - ○ A new coalition, Connecting to Coverage Coalition, led by AHIP, was launched with a website for stakeholders to access information about eligibility requirements and the Medicaid redetermination process.
- An article published in *Kaiser Health News* explained how Medicaid health plans have a strong financial incentive to retain Medicaid enrollees who are at risk of losing coverage in an ACA marketplace plan.
- President Biden released his annual budget proposal, part of which focused on closing the Medicaid coverage gap and directing more funding toward Medicaid home and community-based services.

Virtual Health

FEDERAL NEWS

- *Biopharma Dive* explained how the **Silicon Valley Bank** collapse impacted the biotech and digital health industry. According to *Axios*, 12% of the bank's $173B in deposits were from the life science and healthcare sectors, making it an essential resource for many digital health companies.
- The DEA's proposed telemedicine rules – which would require an in-person visit before patients can be prescribed highly regulated drugs – may help to address the Adderall shortage, which some experts claim was caused in part by the ease of virtual prescribing.
- An article in *mHealthIntelligence* provided an outlook on 2023 state-level telehealth policies, noting how policies about licensure, virtual prescribing, audio-only telehealth, and others will change at the state level over the coming year.

NEW LAUNCHES AND PARTNERSHIPS

- **Hopper Health** launched its virtual primary care service for neurodivergent adults, which helps patients with neurodivergent conditions like autism or ADHD better navigate their care.
- **Zaya Care** partnered with **Zocdoc** to launch its maternal healthcare marketplace to increase
- in-person or virtual maternal care access.
- **Flowly,** an app that uses virtual reality to help patients manage chronic pain and stress, released a program for providers that allows them to test out the app and track patient progress.
- MGH is planning to conduct a clinical trial with **Rocket VR Health (RVH)** to assess the use of virtual reality in mental and physical healthcare.
- *AxiosPro* published a list of recent telehealth fundraises for startups:
  - OpenLoop - $15M to help telehealth organizations accept insurance
  - Capable Health - $6M for its plug and play HIPAA-compliant software platform for messaging, scheduling, and lab orders
  - Opkit - $1M for its automated health insurance verification platform

OTHER TELEHEALTH NEWS

- **Cerebral**, a telemental startup, admitted that it shared the private health information, including mental health assessments, of more than 3.1 million patients in the United States with advertisers and social media giants like Facebook, Google and TikTok.
- **Opkit** created a user-friendly automated health insurance verification platform for virtual care providers to process patients' health insurance. The platform expedites insurance verification processes and provides greater price transparency.
- In an interview with *Healthcare IT News,* Wendy Deibert, a former nurse and senior vice president of clinical solutions at telehealth company **Caregility**, discussed the importance of virtual care, including its impact on the workforce shortage.
- According to data from **Trilliant Health**, telebehavioral health service use increased 45-fold during the COVID-19 pandemic, although investments in digital behavioral healthcare decreased.