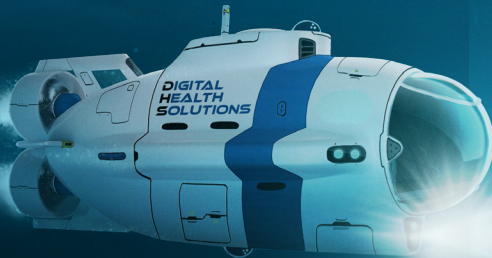


DIGITAL BYTES

EDITION 1 • MARCH 2023

INCREASE FORWARD VISIBILITY



IN THIS ISSUE

- Demonstrating [\[improved outcomes\]](#) for digital health solutions
- Paving the way for regulatory innovation of digital products with [\[a new FDA leader\]](#)
- Enhancing digital health conversations with [\[the PIE Act of 2022\]](#)
- Providing standardized care pathways for Medicaid enrollees with a [\[potential bill\]](#)
- Expanding digital health access with [\[California\]](#) and [\[Florida\]](#) state Medicaid programs

THE DIGITAL HEALTH SOLUTIONS LANDSCAPE IS RAPIDLY EVOLVING, with payers, manufacturers, and patients recognizing the value digital products bring as a new modality of disease management. This newsletter will enable you to gain forward visibility and shine light onto the latest developments in the digital health space.

*Please reach out to your Sanofi Account Director if you'd like to continue the conversation [\[or visit **digitalhealthcaresanofi.com.**\]](#)*

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REAL-WORLD EVIDENCE AND RESEARCH

Digital therapeutic sparks improved management of diabetes across demographic lines

Published on: 1/16/2023

DESCRIPTION:

A recent report analyzed a group of 1000 individuals with type 2 diabetes who used a digital platform in a real-world setting over a period of 12 months. Diabetes is estimated to be more prevalent among ethnic minority groups in comparison with white individuals, underscoring the importance of this analysis.

PAYER IMPLICATIONS:

- Continued real-world evidence will be a main driver for the uptake of digital health solutions, answering many questions about its value and efficacy across demographics

[\[Click here to read the full article.\]](#)

LEGISLATION AND REGULATION

Former Oracle exec Troy Tazbaz tapped as FDA Director of digital health

Published on: 1/31/2023

DESCRIPTION:

The new Food and Drug Administration (FDA) director of digital health's extensive background in cloud data is a promising step on the path to continued innovative regulatory approaches. This is particularly important given digital therapeutics (DTx)-specific data security and solution-related lifecycle considerations.

PAYER IMPLICATIONS:

- Tazbaz will be at the forefront of the FDA's Digital Health Center of Excellence, which emphasizes innovative regulatory frameworks for digital health solutions
- With the new director, there may be more of a regulatory push to enhance digital growth

[\[Click here to read the full article.\]](#)

LEGISLATION AND REGULATION CONT.

Codified language with the Pre-Approval Information Exchange (PIE) Act

Published on: 12/29/2022

DESCRIPTION:

When the FDA finalized guidance related to PIE in 2018, there was no clear pathway for digital health solutions manufacturers to communicate prior to approval. Additionally, guidance stated that communications addressing healthcare economic information (HCEI) did not apply to both drug and device manufacturers. The PIE Act of 2022 changes that. With passage of the bill, the language has been updated to include drugs and devices, which would include digital health solutions.

PAYER IMPLICATIONS:

- Now, payers will be able to assess digital health solutions ahead of FDA approval or clearance, without sacrificing the quality of your reviews
- Payers can now efficiently plan for and update formularies for the plan year in which digital solutions will be approved
- There is the potential for expedited contracting efforts for digital health solutions, particularly value-based contracts, which requires thoughtful risk tolerance conversations
- The codified language will enable open lines of communication for payers to obtain necessary formulary, benefit, and reimbursement decisions

[\[Click here to read the full article.\]](#)

Senators introduce bill to support coverage of digital therapeutics

Published on: 12/15/2022

DESCRIPTION:

Introduced in the Senate in December 2022, the Medicaid and the Children's Health Insurance Program (CHIP) Access to Prescription Digital Therapeutics Act (S.5238) would support coverage of digital health solutions. If passed, the bill would define the term "prescription digital therapeutic" (PDT) as it relates to Medicaid coverage, create standardized coverage for digital treatments authorized by the FDA in Medicaid and CHIP programs, and give the Department of Health and Human Services (HHS) the ability to provide technical assistance to states considering coverage.

PAYER IMPLICATIONS:

- This bill may be altered considering the introduction of the Access to Prescription Digital Therapeutics Act of 2023 in both the House and Senate
- If passed, the legislation would create a standardized pathway for public health plans to cover PDTs, ultimately leading to improved access
- Increased access to PDTs may reduce medical costs compared with standard-of-care treatments and improve access to care, especially in medical desert areas

[\[Click here to read the full article.\]](#)

REIMBURSEMENT AND COVERAGE

**California and Florida State Medicaid
Programs partner with Pear Therapeutics
to expand DTx access**

Published on: 1/12/2023 • 1/18/2023

DESCRIPTION:

California's Medicaid program recently announced a partnership with Pear Therapeutics to support the state's Recovery Incentives program for individuals with stimulant use disorder. Eligible Medi-Cal beneficiaries will follow a 24-week outpatient program that includes the use of Pear's digital health solution to track patients and enable on-demand collaboration with providers.

Similarly, the Florida Medicaid program included Pear Therapeutic's reSET® and reSET-O® solutions on their January 2023 preferred drug list (PDL) for the treatment of substance abuse disorder and opioid use disorders.

PAYER IMPLICATIONS:

- Both Medicaid partnerships with Pear Therapeutics may serve as templates for other states to improve access to cost-effective, evidence-based technologies
- Though federal legislation would accelerate the coverage of digital health solutions, movement can be slow. Direct contracting with manufacturers expedites access, reduces barriers to care, and can make a difference in health outcomes

[[Click here to read the full article on California.](#)]

[[Click here to read the full article on Florida.](#)]

UPCOMING EVENTS

AXS23 Summit

April 30-May 4, 2023 • Las Vegas, NV
www.asebiasummit.com

Reuters Digital Health 2023

May 16-17, 2023 • San Diego, CA
<https://events.reutersevents.com>

Digital Health Transformation Summit

May 22-24, 2023 • Chicago, IL
<https://www.medigy.com>

2023 Digital Therapeutics Alliance Inaugural Summit

June 7-9, 2023 • Washington, DC
<https://whova.com>

AHIP

June 13-15 • Portland, OR
<https://www.ahip.org>

Sanofi strives to be the leading digital healthcare platform for patients, providers, payers, and researchers by providing digital solutions that can transform the discovery, development, and delivery of therapies through novel data insights and accelerated approaches.

**Please reach out to your Sanofi Account Director
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