Arnold&Porter

Virtual and Digital Health Digest 2023 Year in Review: Regulatory Pocket Guide

U.S.

FDA Regulatory

1. Following enactment of legislation permitting the Food and Drug Administration (FDA) to approve predetermined change control plans (PCCP) for medical devices, FDA issued draft guidance on marketing submission recommendations for PCCPs for artificial intelligence (AI)/machine learning (ML)-enabled device software functions. The agency also issued guiding principles for PCCPs for AI/ML-enabled devices in collaboration with Health Canada and the UK's MHRA.

   To watch in 2024: Finalization of the PCCPs guidance for AI/ML-enabled device software functions, and issuance of new draft guidance on PCCPs for other types of devices (both are included in the Center for Devices and Radiological Health's (CDRH) 2024 guidance agenda).

2. Issuance of several Warning Letters to companies marketing violative software devices, including for exceeding the scope of non-device clinical decision and remote monitoring software functionalities and for failure to submit new 510(k)s for certain algorithm changes and labeling changes.

   To watch in 2024: Issuance of draft guidance on lifecycle management considerations and premarket submission recommendations for AI/ML-enabled device software functions (included in CDRH's 2024 guidance agenda) and potential for additional enforcement actions further clarifying FDA's expectations for modifications to AI/ML-based software devices.

3. Issuance of a discussion paper on use of AI/ML in the development of drugs and biological products.

   To watch in 2024: Continued solicitation of feedback and engagement from stakeholders to help provide a foundation for a future framework or guidance.

4. Release of a framework document for the use of digital health technologies (DHTs) in drug and biological product development.

   To watch in 2024: Identification by FDA's DHT Steering Committee of areas where additional guidance may be beneficial, and public meetings and demonstration projects to identify topic areas of public health importance.

5. Enactment of legislation requiring inclusion of cybersecurity information in premarket applications for cyber devices, and issuance of related FDA guidance on quality system and premarket submission considerations for cybersecurity in medical devices.

   To watch in 2024: Updates to FDA's premarket cybersecurity guidance on cyber devices (included in CDRH's 2024 guidance agenda).

6. Announcement that FDA is establishing a Digital Health Advisory Committee to provide advice on complex scientific and technical issues relating to digital health technologies, and a request for nominations for committee members.

   To watch in 2024: Announcement of committee members and further information about the committee.

7. Issuance of draft guidance on prescription drug-use related software, describing the application of FDA's drug labeling authorities to certain software outputs that are disseminated by or on behalf of a drug sponsor for prescription drug or drug-led combination products.

   To watch in 2024: Consideration of stakeholder comments to inform finalization of the guidance.

Healthcare Fraud and Abuse

1. OIG Toolkit: Analyzing Telehealth Claims to Assess Program Integrity Risks

   To watch in 2024: Increased scrutiny of certain claims that have potential to result in higher reimbursement rates (e.g., genetic testing, certain durable medical equipment (DME), etc.).

2. Telemedicine false claims act (FCA) actions (e.g., Cerebral Inc. *qui tam*, DOJ June 2023 US$2 Billion Nationwide Enforcement Action on Telehealth Schemes)

   To watch in 2024: Continued crackdown, including potential government intervention in *qui tams*, especially in light of recent changes to telehealth reimbursement under the 2024 physician fee schedule (PFS).

3. OIG Consumer Alert: Remote Patient Monitoring (RPM)

   To watch in 2024: OIG awareness and consumer education initiatives to arm patients in the fight against telehealth fraud.

Provider Reimbursement

1. CMS implemented the Consolidated Appropriations Act, 2023 by extending telehealth flexibilities through December 31, 2024.

   To watch in 2024: With many telehealth flexibilities from the public health emergency (PHE) set to expire in 2025, federal lawmakers are considering proposals to make the flexibilities permanent.

2. DEA temporarily extended all telehealth flexibilities regarding the prescription of controlled substances through December 31, 2024.

   To watch in 2024: According to the Biden administration's fall 2023 Unified Agenda, DEA will propose new regulations concerning the prescription of controlled substances through telemedicine in December 2023.

Corporate Transaction

1. Q3 2023 Digital Health Funding: Smaller But Mighty | Rock Health

   To watch in 2024: With historically high interest rates in 2023 and their effect on capital, startups will likely continue to work with more strategics such as Amazon and Apple, who are already some of the biggest investors in digital health and can easily fund off their balance sheets.

2. Tackling Healthcare's Biggest Burdens With Generative AI

   To watch in 2024: There was no shortage of headlines about AI's ability to transform digital health in 2023, and in 2024, we will begin to see whether the influx of funds into digital health AI startups will pay off in the long run. In 2024, hospitals will also likely continue to partner with companies that leverage AI capabilities to ensure they are not late to the game in integrating generative AI into their technology for staff use.

3. InnovationRx: Digital Health IPO Drought (forbes.com)

   To watch in 2024: There were zero digital health IPOs in 2023, and with companies such as Waystar Holding Corp. preparing to go public in early 2024, it seems likely that the digital health IPO drought will finally come to an end soon.

Policy

1. White House Unveils National Cybersecurity Strategy as Congress Contemplates Legislative Response. President Biden previously summarized his commitment on this issue during his State of the Union address to Congress in February.

   To watch in 2024: In 2024, Congress and federal agencies are expected to continue to collaborate on ways to protect against cybersecurity threats facing the U.S. health system.

2. White House Secures Private Industry Commitments to Self-Regulate AI Innovation. Seven of the AI industry leaders — Amazon, Anthropic, Google, Inflection, Meta, Microsoft, and OpenAI — committed to strengthen the promise of "safety, security, and trust" in the development of AI technology.

   To watch in 2024: The White House is expected to continue to work with the private sector to increase public trust related to AI-enabled technologies.

3. House Members Push for Digital Therapeutic Coverage During Congressional Hearing. Led by Reps. Kevin Hern (R-OK), Mike Thompson (D-CA), Bill Johnson (R-OH), and Doris Matsui (D-CA), members considered the Access to Prescription Digital Therapeutics Act of 2023 (H.R. 1458), which would require Medicare and Medicaid reimbursement coverage of FDA-approved prescription digital therapeutics.

   To watch in 2024: According to Congress.gov, the House and Senate held over 100 committee meetings in 2023 related to AI. In 2024, Congress will continue to consider proposals related to digital therapeutics and AI-enabled systems in the midst of industry's rapid technological advancements.

4. White House Releases Executive Order for Agency Regulation of AI.

   To watch in 2024: Senate Majority Leader Chuck Schumer (D-NY) and Sens. Martin Heinrich (D-NM), Todd Young (R-IN), and Mike Rounds (R-SD) have held hundreds of staff-level meetings in 2023 with academic, association, and industry groups on AI-related issues. Congress may develop a federal AI framework by the end of 2024.

Privacy

1. The Federal Trade Commission (FTC) took aggressive actions to discipline the use of personal health information by companies providing healthcare or access to healthcare through digital technologies. FTC Enforcement Action to Bar GoodRx from Sharing Consumers' Sensitive Health Info for Advertising | Federal Trade Commission; FTC to Ban BetterHelp from Revealing Consumers' Data, Including Sensitive Mental Health Information, to Facebook and Others for Targeted Advertising | Federal Trade Commission; Ovulation Tracking App Premom Will be Barred from Sharing Health Data for Advertising Under Proposed FTC Order | Federal Trade Commission

   To watch in 2024: Continuing focus by the FTC on companies' sharing of consumers' personal health information, particularly through the use of online tracking technologies.

2. The FTC proposed to amend its Health Breach Notification Rule to, among other things, make it clear that sharing personal health information without consumer consent may be a "breach" of security that required notification to the FTC and affected consumers. FTC Proposes Amendments to Strengthen and Modernize the Health Breach Notification Rule | Federal Trade Commission

   To watch in 2024: Issuance of a final rule implementing the proposed changes and clarifying the applicable scope of the Health Breach Notification Rule (HBNR), including to mobile applications.

3. Washington State, Connecticut, and Nevada enacted privacy legislation specifically applicable to consumer health information. Protecting Washingtonians' Personal Health Data and Privacy | Washington State; CGA — Connecticut General Assembly; Nevada Senate passes a health data privacy bill (iapp.org)

   To watch in 2024: Enactment of similar laws by additional states.

4. The Senate Committee on Health, Education, Labor and Pensions solicited comments in aid of its drafting legislation to protect patient privacy while encouraging the development of digital and other technologies to improve healthcare delivery and enhance scientific research. Ranking Member Cassidy Seeks Information … | Senate Committee on Health, Education, Labor and Pensions

   To watch in 2024: Proposed legislation to impose restrictions on the collection, use, and disclosure of personal health information by entities not regulated under the HIPAA privacy and security rules.

Arnold & Porter

EU and UK

Regulatory

1. EU's AI Act: A provisional agreement on the new EU legislation was reached between the EU Parliament and Council on 9 December 2023

   To watch in 2024: Adoption of the final legal text, assessment of the impact for industry and practical implementation

2. UK government's AI White paper, focusing on a "pro innovation approach" rather than legislation

   To watch in 2024: Ongoing discussion about whether UK should adopt legislation on AI, in line with U.S. and EU.

3. UK medical devices regulatory reform, including extended transitional period for recognition of EU CE marks; introduction of Integrated Data Analytics Platform (IDAP)

   To watch in 2024: Draft legislation to be published and IDAP to be implemented.

4. Guidance from EU Medical Device Coordination Group and UK Medicines and Healthcare products Regulatory Agency on software medical devices

   To watch in 2024: Additional guidance from authorities as they seek to increase adoption of digital technologies and provide clarity to industry.

5. European Medicines Agency reflection paper on use of AI in the product lifecycle

   To watch in 2024: Finalized version of guidance to be published.

6. Extension of transition periods for medical device reporting (MDR) finalized in Regulation (EU) 2023/607

   To watch in 2024: Further implementation of MDR and In Vitro Diagnostic Regulation (IVDR). Key dates of May 26, 2024 to have QMS in place and application with Notified Body and September 26, 2024 to have contract with Notified Body.

Data Privacy

1. European Health Data Space (EHDS) proposal being heavily debated in EU Parliament and the Council

   To watch in 2024: Finding compromise, adoption of legislation, and assessing the impact for industry.

2. EU-U.S. Data Privacy Framework finalized and adoption of UK-U.S. Data Bridge

   To watch in 2024: Ongoing litigation in EU General Court and comments from UK ICO about adequacy of framework.

3. Progress of the UK Data Protection and Digital Information (No.2) Bill (DPDI) to reform UK privacy laws

   To watch in 2024: Finalization and adoption of the DPDI into UK law and possible consequences, including revocation by the EC of the UK Adequacy Decision if the UK departs from EU data protection standards.

4. Increased focus on cybersecurity

   To watch in 2024: EU cybersecurity act for products with digital elements being finalized.

5. Guidance from data protection authorities across the EU on use of AI

   To watch in 2024: Guidance specific to use in healthcare.

Arnold&Porter

Reimbursement

1. French fast track "PECAN" reimbursement pathway finalized

   To watch in 2024: Additional reimbursement pathways being introduced across the EU, such as in Italy and amendment to system in Belgium, with hope of harmonization of data requirements and procedures.

2. UK National Institute for Health and Care Excellence (NICE) Early Value Assessment

   To watch in 2024: Increased use of scheme and NICE evidence standards, plus hope for greater coordination with National Health Service (NHS) Digital Technology Assessment Criteria (DTAC).

Product Liability

1. EU Product Liability Directive and AI Liability Directive: Ongoing discussions and publication of position from EU Parliament and Council

   To watch in 2024: Finalizing legal text and adoption of legislation.