Welcome to the first installment of Arnold & Porter's Virtual and Digital Health Digest. This inaugural edition covers September and October highlights across the virtual and digital health space. This newsletter focuses on key virtual and digital health and telehealth-related developments in the United States, United Kingdom, and European Union in the healthcare, regulatory, privacy, and corporate transactions space.

US News

FOOD AND DRUG ADMINISTRATION

FDA Issues Final Clinical Decision Support Software Guidance: On September 28, 2022, the Food and Drug Administration (FDA) issued a long-awaited final version of a guidance governing the regulation of clinical decision support (CDS) software as medical devices (Final CDS Guidance). As amended in 2016 by the 21st Century Cures Act (Cures Act), the statutory definition of a "device" excludes certain lower-risk software functions, including certain CDS software functions. FDA previously issued draft guidance explaining the agency's interpretation of the Cures Act criteria for exempt non-device CDS functions in 2017 and issued a revised draft guidance in 2019 (Draft CDS Guidance). The Final CDS Guidance issued differs in important ways from the Draft CDS Guidance, and suggests FDA intends to take a more expansive view of CDS software functions subject to agency oversight. Significantly, the Final CDS Guidance eliminates the enforcement discretion policy for certain low-risk patient and caregiver device CDS functions described in the Draft CDS Guidance. Although FDA interprets the Cures Act non-device CDS exemption as being limited to qualifying CDS functions intended for healthcare providers (HCPs), the Draft CDS Guidance articulated that the agency did not intend to enforce compliance with device requirements for certain device CDS functions for patients and caregivers for non-serious diseases or conditions under certain circumstances. The Final CDS Guidance does not include this enforcement discretion policy nor the enforcement discretion policy for low-risk device CDS functions for HCPs that fail to qualify as a non-device under the Cures Act criteria. In the Final CDS Guidance,

FDA indicates that such CDS functions are considered medical device functions, but notes that certain such functions could fall within the scope of enforcement discretion policies described in other existing FDA digital health guidance.

In addition, the Final CDS Guidance includes important clarifications about each of the four Cures Act criteria that a CDS function must meet to be exempt from the device definition. For example, under the Final CDS Guidance, to meet Cures Act criterion 3, a non-device CDS software function's outputs or recommendations should not be directive or specific to a particular treatment or diagnosis. The Final CDS Guidance also provides more clarity around the information that should be included in a CDS software or its labeling to meet the Cures Act criterion 4 end-user transparency element, which often is the most difficult of the four mandatory exemption criteria for medical software developers to meet—particularly those using proprietary datasets, algorithms or artificial intelligence-driven analysis tools. The Final CDS Guidance also provides clearer examples of the types of CDS software functions that are and are not subject to regulation as medical devices.

Additional information about the Final CDS Guidance can be found in Arnold & Porters' October 17 Advisory.

FDA Holds Webinar on Final CDS Guidance: On October 18, 2022, FDA officials hosted a public webinar to discuss and answer questions about the Final CDS Guidance. Of note in the webinar, FDA emphasized that the Final CDS Guidance more clearly than ever before makes clear that even some of the most complex machine learning technologies can meet the Cures Act criteria for a non-device CDS, and that the Final CDS Guidance provides a roadmap for developers who choose to go that route. With respect to the enforcement discretion policies question, FDA officials confirmed that the Final CDS Guidance does not contain the enforcement discretion policies described in the Draft CDS Guidance and stated that the focus of the Final CDS Guidance is on statutory criteria for non-device CDS. However, FDA explained that enforcement discretion policies in other FDA guidance could apply to certain device CDS functions. For example, the agency suggested that certain CDS software tools could fall within the enforcement discretion policy for software functions that "help patients (i.e., users) self-manage their disease or conditions without providing specific treatment or treatment suggestions" described in FDA's Policy for Device Software Functions and Mobile Medical Applications.

Despite the Final CDS Guidance not including the two enforcement discretion policies described in the Draft CDS Guidance, FDA suggested that there are no products that previously were not devices that would now be considered devices due to the Final CDS Guidance. Rather, the agency expressed its view that the Final CDS Guidance is consistent with how FDA has been implementing the Cures Act since 2016. FDA recommended that developers with questions about the regulatory status of their CDS tools under the Final CDS Guidance contact the agency or consult FDA's Digital Health Policy Navigator resource

(see below). Materials from the webinar, including links to the transcript and video, can be found under the "Specialty Technical Topics" tab of the CDRH Learn website.

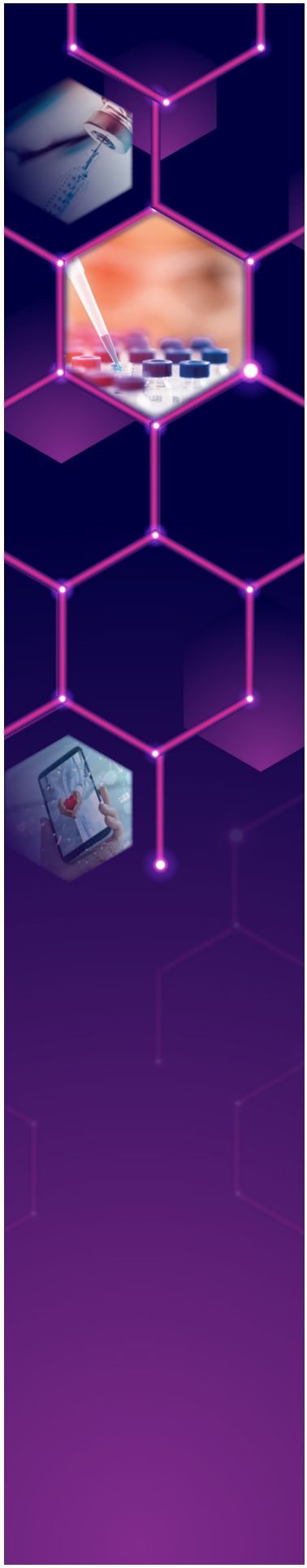
FDA Updates Other Digital Health Guidance Documents: On the same day that FDA released the Final CDS Guidance, the agency also made updates to several other previously finalized digital health guidance, including FDA's Policy for Device Software Functions and Mobile Medical Applications (Software Functions and MMA Guidance), which specifies the types of software functions, including mobile medical application software functions, that FDA intends to actively regulate as devices. FDA revised the Software Functions and MMA Policy to ensure consistency with the Final CDS Guidance and last year's final rule, titled "Medical Devices; Medical Device Classification Regulations to Conform to Medical Software Provisions in the 21st Century Cures Act" (Device Classification Final Rule). That rule updated FDA device classification regulations to be in accordance with the Cures Act (e.g., removing statutorily exempt software functions from the classification regulations). Notably, in step with the Final CDS Guidance, the Software Functions and MMA Policy now specifies that software functions performing patient-specific analyses and providing patient-specific recommendations to users that are not HCPs are devices and revised examples of CDS software functions that are not devices to explicitly include certain non-device CDS criteria (e.g., enabling the HCP to independently review the basis for the information).

FDA also issued a revised Medical Device Data Systems, Medical Image Storage Devices and Medical Image Communications Devices Guidance (MMA Guidance). The guidance ensures consistency with the Device Classification Final Rule, as well as makes minor changes addressing submitted comments. FDA's policy for, and definitions of, non-device medical device data systems (MDDS) and device MDDS remains largely the same. Please refer to our October 17 advisory for additional information about the revised Software Functions and MMA Policy, the revised MDDS Guidance, and for a list of other digital health guidance updated by FDA.

FDA Makes Available Digital Health Policy Navigator and Other Digital Health Resources: In conjunction with release of the Final CDS Guidance and revisions to other digital health guidance, FDA also posted to its website various resources intended to assist developers understand whether their proposed digital health software products could be subject to regulation as medical devices. These resources include a new "Digital Health Policy Navigator" (Policy Navigator) which provides an interactive overview of the FDA digital health policies that might apply to a proposed software function. The Policy Navigator includes seven steps, with the answers to each question guiding users through the most relevant FDA medical device regulatory considerations. The webpage for the Policy Navigator cautions that the results of the Policy Navigator are not a formal device determination for a product. During the Q&A portion of the above-referenced October 18 Final CDS Guidance webinar, FDA referred individuals with questions about the regulatory status of certain CDS tools to this Policy Navigator. Another example of a new FDA digital health resource is a decision tree intended to help CDS developers analyze whether a proposed CDS software function is a medical device function available on the agency's website.

FDA Updates List of Devices That Incorporate Artificial Intelligence/Machine Learning: On October 5, 2022, FDA updated its "Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices" webpage to include 178 additional AI/ML-based devices. First made available in September 2021, this webpage identifies FDA-cleared, approved or authorized medical devices that incorporate AI or ML marketed in the US. FDA assembled the list by searching FDA's publicly-facing information and other publicly available resources, and notes that the list is not intended to be an exhaustive or comprehensive resource of AL/ML-enabled devices. When FDA first released the list of AI/ML-enabled devices, the agency explained that it intended to update the list on a periodic basis. The October 5 update appears to potentially be the first update

since FDA's initial issuance of the list in 2021. While the 178 newly added devices span therapeutic areas, the majority appear to be radiology devices. Of the 178 devices, 91 were cleared, approved or authorized in 2022.



Visibly Receives FDA Clearance for First Online Visual Acuity Test: Although occurring in August, a notable recent FDA marketing authorization in the digital health space is the 510(k) clearance for Visibly's online visual acuity test. On August 12, 2022, Visibly received 510(k) clearance for the "Visibly Digital Acuity Product" (VDAP), as a web-based, self-guided software application intended for use by adults (ages 22 to 40) who have the capability to perform a self-test at home to aid in the evaluation of visual acuity with or without correction. The software allows users to view and respond to displayed optotypes and uses the responses to categorize a patient's visual acuity into one of two categories. It is intended to provide supportive recommendations to be used by an eye care provider in conjunction with other patient information. Visibly, which formerly operated as Opternative Inc., previously marketed a mobile app-based online eye examination test without FDA marketing authorization. In October 2017, FDA issued Opternative a public Warning Letter in which the agency asserted marketing of the test without clearance or approval violated the Federal Food, Drug, and Cosmetic Act (FDCA).

Receipt of 510(k) clearance for the VDAP indicates Visibly worked with the agency to bring its test into compliance with the FDCA and obtain the necessary marketing authorization. In a press release announcing the clearance, Visibly describes its test as the "first FDA-cleared online visual acuity test on the US market."

FDA Reports Learnings From Completion of Software Precertification Pilot: Earlier this year, it was reported that FDA had ended its software precertification pilot program (Pre-Cert Pilot). Confirming those reports, in September 2022, FDA issued a report with learnings and findings from the now completed pilot, titled "The Software Precertification (Pre-Cert) Pilot Program: Tailored Total Product Lifecycle Approaches and Key Findings" (Pre-Cert Pilot Report). FDA first established the Pre-Cert Pilot in 2017 to explore an innovative total product lifecycle (TPLC) approach to regulatory oversight of software as a medical device developed by organizations that demonstrate a robust culture of quality and organizational excellence and that commit to monitoring the real-world performance of their products once on the market. The Pre-Cert Pilot focused on exploring the viability of the TPLC approach under current FDA authorities and whether such an approach could be used to efficiently and successfully assess medical device software safety and effectiveness.

As further detailed in the Pre-Cert Pilot Report, FDA's decision to end the pilot was partly due to a lack of statutory authority to implement the program in the manner FDA wanted. FDA also experienced challenges stemming from the limited number of participants (and thus devices) in the Pre-Cert Pilot and being unable to establish pilot program-specific special controls through the de novo classification process. FDA also could not require Pre-Cert Pilot

participants to provide information that was not otherwise already required under the existing statute. Despite these challenges, FDA reports that the Pre-Cert Pilot provided key insights and informed what new statutory authorities could support a future regulatory paradigm that builds on the Pre-Cert Pilot concepts. FDA reports that the Pre-Cert Pilot reinforced that a systems-based approach that leverages structured objective data can support a learning regulatory system that benefits from data-driven insights to provide efficient and consistent regulatory decisions. In the report, FDA emphasizes that "[a] flexible, risk-based approach to regulation could allow FDA to tailor regulatory requirements more efficiently for devices based on the latest science, the benefits and risks posed by devices, their real-world performance, and their contribution to promoting health equity." FDA believes new legislative authority establishing such an approach could be supplemental to, and not replace, the established medical device regulatory pathways. In the interim, the agency intends to continue to develop policies and tools within current authorities to improve the efficiency and effectiveness of regulatory oversight, including through collaborative engagement with the public, such as the Medical Device Innovation Consortium. Please see the full Pre-Cert Pilot Report for additional information about program findings.

FDA Announces Total Product Life Cycle Advisory Program (TAP) Pilot: On October 11, 2022, FDA's Center for Devices and Radiological Health (CDRH) announced the launch of the Total Product Life Cycle Advisory Program Pilot (TAP Pilot), a new voluntary program that aims to encourage development of, and increase patient access to, safe, effective, high-quality medical devices by improving communication between the FDA and medical device sponsors. While the TAP Pilot is not specific to digital health devices, it could conceivably encompass certain innovative digital health devices that qualify for Breakthrough Device status. During the TAP Pilot, FDA will provide strategic engagement for innovative devices, including by (i) providing for more timely premarket interactions, (ii) facilitating improved strategic decision-making during device development, including earlier identification, assessment and mitigation of device development risk, (iii) facilitating regular, solutions-focused engagement between FDA review teams, participants and other stakeholders beginning early in device development, and (iv) collaborating to better align expectations regarding evidence generation, improve submission quality, and improve the efficiency of the premarket review process. FDA hopes that by providing earlier and more frequent interactions between FDA and medical device developers, the quality of submissions will improve and any issues that might delay FDA authorization will be discovered more quickly.

The TAP Pilot is one of the commitments agreed to between FDA and industry as part of the MDUFA V reauthorization. To implement the TAP Pilot, FDA intends to take a phased-enrollment approach throughout the duration of MDUFA V (FY 2023-2027). The first phase is the TAP Pilot Soft Launch, which will be conducted during FY 2023 and begin on January 1, 2023. During the TAP Soft Launch, FDA intends to enroll up to 15 devices in the Office of Health Technology 2: Office of Cardiovascular Devices using certain enrollment criteria, including Breakthrough Device designation status. In subsequent years, FDA intends to expand the TAP Pilot to enroll more devices and include devices reviewed in other OHTs following the schedule outlined in the MDUFA V commitment letter. Sponsors of eligible devices can request consideration for enrollment in the TAP Pilot by submitting an amendment to the Q-submission under which their device was granted Breakthrough designation. As announced in an October 11 *Federal Register* notice, FDA is requesting comments on the TAP Pilot. The comment deadline is January 10, 2023.

CDRH Issues List of Planned 2023 Guidance: On October 19, FDA's CDRH released its list of proposed guidance for publication FY2023. Relevant to digital health, finalization of the "Content of Premarket Submissions for Device Software Functions" guidance is listed as an "A-list" priority. Although a "B-list" priority, the list also includes issuance of a draft guidance on "Marketing Submission Recommendations for A Change

Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions." As further detailed in a 2019 discussion paper and 2021 work plan, inclusion of pre-determined change control plans in premarket submissions for AI/ML-enabled devices is one aspect of FDA's proposed approach to regulation of such devices. Additional information about FDA's evolving approach to AI/ML technology regulation can be found in a *Chambers* publication authored by Arnold & Porter attorneys, available here.

In addition to identifying guidance CDRH intends to issue in 2023, the guidance agenda also lists numerous previously-issued final guidance for which CDRH is interested in receiving external feedback regarding whether these guidance should be revised or withdrawn. Included on the list is a 2013 final guidance on 510(k)s for pulse oximeters. FDA had previously issued safety communications regarding pulse oximeter accuracy and limitations, and recently (November 1, 2022) convened a public advisory committee meeting to share information and perspectives about ongoing concerns about pulse oximeters. Devices, including digital health devices, with pulse oximeter-type functionality have been an area of increased focus for FDA, as reflected in FDA's issuance of a Warning Letter to Owlet Baby Care, Inc. (in October 2021) in relation to the company's marketing of the Owlet Smart Socks without FDA marketing authorization. In the Warning Letter, FDA asserted, in part, that products that measure blood oxygen saturation and pulse rate are devices when they are intended to identify desaturation and bradycardia and provide an alarm to notify users that measurements are outside preset values.

The deadline for submission of comments on the pulse oximeter and other guidance identified for possible revision or withdrawal is December 16, 2022.

HEALTHCARE FRAUD AND ABUSE

OIG Special Fraud Alert on Telefraud and Recent Enforcement Action:
The Office of Inspector General (OIG) is cracking down on arrangements involving companies purporting to provide telehealth, telemedicine or telemarketing services, but are generating problematic referrals and potentially leading to medically unnecessary items and services. On July 20, 2022, the OIG released a Special Fraud Alert (SFA) on the potential fraud and abuse risks telehealth companies can face when entering into arrangements with physicians and practitioners. See Arnold & Porter's overview of the SFA here.

The SFA contains a list of seven suspect characteristics related to practitioner arrangements with telemedicine companies which, taken together or separately, could suggest a heightened risk of fraud and abuse:

- The Practitioner orders or prescribes items or services to purported patients that were identified or recruited by the Telemedicine Company.

- The Practitioner does not have sufficient contact with or information from the purported patient to meaningfully assess the medical necessity of the items or services ordered or prescribed.
- The Telemedicine Company compensates the Practitioner based on the volume of items or services ordered or prescribed.
- The Telemedicine Company only furnishes items and services to federal healthcare program beneficiaries and does not accept insurance from any other payor.
- The Telemedicine Company claims to only furnish items and services to individuals who are not federal healthcare program beneficiaries but may in fact bill federal healthcare programs.
- The Telemedicine Company only furnishes one product or a single class of products, potentially restricting a Practitioner's treating options to a predetermined course of treatment.
- The Telemedicine Company does not expect Practitioners (or another Practitioner) to follow up with purported patients nor does it provide Practitioners with the information required to follow up with purported patients.

Some of these alleged fraud schemes involve using kickbacks to aggressively recruit and reward practitioners in order to further these fraud schemes, raising considerable concerns. For example, in *United States v. Gustavo Geraldes*, Geraldes pled guilty in the Southern District of Florida to conspiracy to offer and pay healthcare kickbacks as part of a COVID-19 healthcare fraud scheme. Geraldes exploited temporary amendments to telehealth restrictions implemented during the COVID-19 pandemic, colluding with other co-conspirators to pay kickbacks to a particular intermediary. Following OIG and DOJ investigation, Geraldes faces a maximum penalty of five years in prison. In another case, a doctor paid $720,000 and agreed to be excluded from federal healthcare programs for 15 years for violating the False Claims Act (FCA) by knowingly conspiring to submit and cause the submission of false claims to Medicare. The government alleged that Dr. Mangesh Kanvinde established improper financial arrangements with temporary physician staffing agencies and telehealth companies to furnish durable medical equipment (DME) and genetic testing items. He would then receive illegal kickbacks in exchange for ordering the medically unnecessary DME and genetic tests and services. Dr. Kanvinde agreed to pay $720,000 and accepted a 15-year exclusion from federal healthcare programs for violating the FCA.

We expect that telefraud will continue to be a high priority enforcement area for DOJ and OIG.

Modernizing Medicine Agrees to Pay $45 Million to Resolve Allegations of Accepting and Paying Illegal Kickbacks and Causing False Claims: On November 1, 2022, DOJ announced that Modernizing Medicine, Inc. (ModMed) agreed to pay $45 million to resolve allegations that it violated the FCA. ModMed's alleged FCA violation stemmed, in part, from business arrangements that allegedly violated the Anti-Kickback Statute and caused the submission of false claims to federal healthcare programs including the Medicare and Medicaid Electronic Health Record Incentive Programs. The government alleged that:

1. ModMed solicited and received kickbacks from Miraca Life Sciences, Inc. (Miraca) in exchange for ModMed recommending and arranging their users to use Miraca pathology lab services;
2. ModMed planned with Miraca to improperly donate ModMed's electronic health records (EHR) to healthcare providers in an effort to increase lab orders to Miraca and add customers to ModMed's user base simultaneously;

3. ModMed paid kickbacks to its current healthcare provider customers and other influential sources in the healthcare industry to recommend ModMed's EHR and refer potential customers to ModMed.

As a result of ModMed's actions, the government alleged that ModMed generated these sales for itself and Miraca, causing healthcare providers to submit false claims to the federal government for pathology services, and for incentive payments from the Department of Health and Human Services (HHS) for the adoption and "meaningful use" of ModMed's EHR technology.

California AG Launches Probe of Bias in Health Care Algorithms: California Attorney General Rob Bonta has asked leaders of hospitals and other healthcare facilities how they plan to address certain biases embedded in commercial decision-making tools and algorithms. This includes algorithms for clinical decision-making, population management, operational optimization, payment management, and prior authorization and approvals. According to Bonta, this request is the first step in a California Department of Justice investigation into whether such algorithms have discriminatory impacts based on race and ethnicity.

Medication Abortion, Telemedicine and *Dobbs*—Complying With State Telemedicine Laws: Following the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, healthcare providers are contemplating methods to provide abortion services to patients, including telemedicine. Laws that prohibit the use of telemedicine to provide abortion services or require an abortion inducing drug to be administered in the physical presence of a physician who prescribed the medication can act as *de facto* limitations on utilizing telemedicine in this manner. For example, Wisconsin restricts the use of telemedicine modalities by requiring an initial dose of mifepristone or other drugs that cause abortion to be administered to the patient in the same room and in the physical presence of the physician who prescribed the medication. In addition, Kansas prohibits the use of telemedicine modalities to provide abortion services completely. Providers should stay up-to-date on legal requirements in the telehealth space, especially given the shifting landscape of COVID-19 telehealth waivers as many states end public health emergency (PHE) exceptions.

Benefits and Challenges of Machine Learning Technologies For Medical Diagnostics: On September 29, 2022, the US Government Accountability Office (GAO) published an overview of its findings regarding machine learning (ML) technologies that can help identify hidden or complex patterns in diagnostic data to detect diseases earlier and improve treatments. ML technologies have not been widely adopted but can assist with the diagnostic process by detecting diseases earlier, consistently analyzing medical data and increasing access to care, particularly for underserved populations. While these technologies can improve their own accuracy by learning new data, developing and adopting these technologies has its challenges, which GAO hopes to address. GAO identified three policy options that could help address the challenges or enhance the benefits of ML diagnostic technologies:

1. Creating incentives, guidance or policies, to encourage or require the evaluation of ML diagnostic technologies across a range of deployment conditions and demographics representative of the intended use.
2. Developing or expanding access to high-quality medical data to develop and test ML medical diagnostic technologies.
3. Promoting collaboration among developers, providers and regulators in the development and adoption of ML diagnostic technologies.

PROVIDER REIMBURSEMENT

CY 2023 Medicare Physician Fee Schedule Final Rule: Telehealth Services: On November 1, 2022, the Centers for Medicare & Medicaid Services (CMS) released its Final Rule updating the Medicare Physician Fee Schedule for Calendar Year (CY) 2023. This rule is scheduled to be published in the Federal Register on November 18, 2022, and will take effect on January 1, 2023. In the Final Rule, CMS finalized a number of policies related to Medicare telehealth services. Most notably, CMS is making several services that are temporarily available as telehealth services for the PHE available through at least CY 2023 to allow additional time to collect data that may support their inclusion as permanent additions to the Medicare Telehealth Services List.

CMS is also finalizing its proposal to allow physicians and practitioners to continue to bill with the place of service (POS) indicator that would have been reported had the telehealth service been furnished in-person through the end of CY 2023 or the end of the year in which the PHE ends. These claims require the modifier "95" to identify them as services furnished as telehealth services. Final Rule at p. 169.

In alignment with the Consolidated Appropriations Act of 2022, CMS is extending the duration of time that services are temporarily included on the telehealth services list during the PHE for at least 151 days following the end of the PHE. Certain policies, including allowing telehealth services to be furnished in any geographic area and from any originating site setting (such as the patient's home), allowing certain services to be furnished through audio-only systems, and allowing other types of providers (physical therapists, occupational therapists, speech-language pathologists, and audiologists), will remain in place for 151 days after the PHE ends. These services include: psychotherapy, ophthalmological examination and evaluation, certain developmental tests, and assessment of aphasia. At this point in time, CMS is declining to make these temporarily available services permanent additions to the Medicare Telehealth Services List. Instead, CMS is adding these services to the Medicare Telehealth Services List on a Category 3 basis through the end of CY 2023. The final rule also updates the Telehealth Originating Site Facility Fee for 2023. Final Rule at p. 169.

The final rule also notes that the Consolidated Appropriations Act of 2022 delays the effective date for the requirement for in-person visits for mental health services furnished via telehealth until 152 days after the end of the PHE. See generally 42 CFR § 405.2463 (what constitutes a "visit").

Congress Seeks to Make Expansion of Mental Health Telehealth Services Permanent: On September 27, 2022, Senator Dan Sullivan (R-AK) introduced S. 4965, a bill to amend title XCIII of the Social Security Act. This bill seeks to permanently remove in-person requirements under Medicare for mental health services furnished through telehealth and telecommunications technology.

The Remote Patient Monitoring Debate: Thirty-four state Medicaid programs provide reimbursement for remote patient monitoring. The Center for Connected Health Policy, which has been studying remote patient monitoring since 2013, reports that many of these policies come with heavy restrictions on use. These restrictions include "only offering reimbursement to home health agencies, restricting the clinical conditions for which symptoms can be monitored, and limiting the type of monitoring device and information that can be collected [from an individual]." In October, POLITICO's Ruth Reader reported that states "are hesitant to invest partly because there is disagreement over how cost-efficient and clinically effective remote patient monitoring programs are when broadened to wider populations." She pointed to the lack of standard for the use of monitoring devices and the mixed success of remote monitoring for patients with chronic disease. The question remains whether states are willing to take the immediate risk of experimentation for greater cost savings in the future.

And, in some areas, the wait and see approach seems to pay-off. For example, one 2019 US Department of Veteran Affairs (VA) study found that Veterans enrolled in remote patient monitoring programs saw a 53 percent reduction of "bed days" of care and a 33 percent decrease in VA hospital admissions. Another study at Oschner Health System found that over 70 percent of patients got their high blood pressure in check after 90 days of remote patient monitoring services.

HRSA Releases Draft Telehealth Policy Guidance: On September 15, 2022, the Health Resources & Services Administration (HRSA) issued a draft Policy Information Notice (PIN) establishing telehealth policy guidance for health centers receiving federal award funds through the Health Center Program project, as authorized under Section 330 of the Public Health Service Act. The PIN lists several considerations that health centers using telehealth to deliver in-scope services to health center patients must address. These considerations include: (1) developing methods for ensuring patients receiving services via telehealth will have reasonable access to the health center's full scope of HRSA-approved services; (2) proper delineation in health center policy of roles and responsibilities for health center staff; (3) the creation of provisions for the health center to directly bill for the services provided via telehealth; (4) ensuring standards of care and compliance with all applicable federal, state and local requirements regarding provider licensure and scope of practice; and (5) compliance with all federal, state and local requirements applicable to the delivery of health services via telehealth.

The PIN also lists criteria that health centers must meet when delivering in-scope telehealth services. An individual receiving services via telehealth must receive proper documentation and undergo an appropriate intake process, receive an in-scope required or additional health service and be physically located within the health center's service area. In addition, the criteria establishes that the provider delivering the in-scope service on behalf of the health center be physically located at a health center service site or another

location and the health center must establish patient records for services delivered via telehealth.

Finally, the PIN addresses health center eligibility for other federal programs. The PIN notes that "[s]ervices and activities conducted by a health center that are not part of the health center's HRSA-approved Health Center Program scope of project (e.g., other lines of business) are ineligible for these associated federal benefits." HRSA is inviting public comment on the PIN until November 14, 2022.

PRIVACY

HHS Releases HIPAA Guidance on Privacy and Security For Audio-Only Telehealth: In a follow-up to guidance on data privacy and security in telehealth issued in March 2020, the HHS Office for Civil Rights (OCR) has released guidance on protecting patient privacy when using remote communication technologies to provide audio-only telehealth. OCR promulgated and enforces the data privacy and security rules implementing the Health Insurance Portability and Accountability Act of 1996 (the HIPAA Rules), which require HIPAA "covered entities" to apply reasonable safeguards to safeguard protected health information (PHI) against impermissible use or disclosure.

The OCR guidance highlights specific risks that are present in the remote telehealth environment, and stresses that these risks must be "identified, assessed and addressed as part of a covered entity's risk analysis and risk management processes, as required by the HIPAA Security Rule." In an audio-only telehealth setting, one critical risk-mitigant is verifying the identity of the participating patient, which may require written communications, whether on paper or electronically. Other steps must be taken to mitigate the risks of, for example: (i) communication interception by an unauthorized third party; (ii) access by unauthorized persons to recordings or transcripts of recorded telehealth sessions; and (iii) unintended exposure due to patient misunderstandings about technology functions. As OCR's guidance emphasizes, communication technologies (e.g., networks, devices and apps) continue to evolve at a rapid pace, and without a robust inventory and asset management process, covered entities may fail to identify such technologies and the risks they pose, leaving themselves and their patients vulnerable.

The audio-only guidance also clarifies when a "business associate agreement" (BAA) is required with a telecommunication service provider (TSP) in the context of telehealth. As the guidance explains, when a covered entity uses a telephone to communicate with patients, the covered entity is not required to enter into a BAA with its TSP, so long as the TSP does not require more than transient access to the PHI it transmits in the call. That would be the case, for example, if the TSP is merely connecting the call and does not create, receive, or maintain any PHI from the telehealth session. However, if the covered entity uses a smartphone app to translate oral communications to another language to provide meaningful access to patients with limited English proficiency, the app developer would be a business associate because the app would be receiving and creating PHI, and therefore the covered entity would have to bind the app developer to a HIPAA BAA.

EU and UK News

REGULATORY

Joint Statements on EU AI Act: On September 30, 2022, a coalition of 12 European trade bodies (including MedTech Europe on medical devices) called for the alignment of the proposed EU AI Act with existing, sector-specific product safety legislation and the rules relating to medical devices. The AI Act is a draft regulation, introduced by the European Commission on April 21, 2021, that seeks to create a common regulatory framework for AI systems. The coalition argues that more could be done to align the AI Act with the New Legislative Framework, which includes the rules on medical devices. They point out that the proposal, in its current form, significantly risks overregulating these industries. If not addressed adequately, the duplicative requirements it creates could limit a wide range of products and technologies to access the EU market.
The recommendations include:

- amending the act such that only products for which safety criteria based on the relevant sectoral legislation dictate a third-party conformity assessment procedure are designated high-risk;
- amending the act such that economic operators are given the freedom to allocate responsibilities through contractual arrangements, subject to a 'best-placed actor' proviso; and
- developing and publishing binding, transparent criteria for the commissioning or applying of common specifications in a way that includes the industry.

UK MHRA Roadmap on Software as a Medical Device: In the UK, on October 17, 2022, the MHRA updated its 'Software and AI as a Medical Device Change Programme' and published a roadmap on the future regulation of software as a medical device (SaMD) and artificial intelligence as a medical device (AIaMD) in the UK. The roadmap sets out the 11 work packages of the Change Programme, as well as deliverables to meet the general objectives of protecting the public and making the UK an attractive place to launch SaMDs and AIaMDs. The work packages include what qualifies as SaMD, pre- and post-market requirements for SaMDs, cyber security, and ensuring AIaMDs are safe for their purpose. See our blog for more details on the work packages and deliverables, some of which are expected by the end of 2022.

IFPMA-EFPIA Joint Note For Guidance on Social Media and Digital Channels: Joint guidance from the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) was published on September 28, 2022 to assist member companies with their use of social media and a variety of digital channels. Among other matters, the guidance

advises companies to establish procedures to review and monitor their social media activities, keep published information up-to-date, provide training to employees on responsible conduct, and carefully consider any engagement with digital opinion leaders. The guidance is discussed in more detail on our blog.

Status of Telehealth in the European Region: A study published on October 27, 2022 has concluded that telemedicine technologies have been beneficial in the screening, diagnosis, management, treatment, and long-term follow-up of diseases in the WHO European Region. Although certain barriers (e.g., shortcomings in technology-related knowledge, resistance by healthcare professionals to using new tools and poor internet access) were identified, the provision of health services using technological devices provided enhanced clinical outcomes and offered logistical benefits. The study calls for policy-makers to consider the widespread implementation of telemedicine, specifically in poorer nations, and to address the identified barriers. Initiatives to develop and implement telemedicine through various policies have already been launched in Europe with the Regional Digital Health Action Plan for 2023-2030 approved in September 2022.

INTELLECTUAL PROPERTY

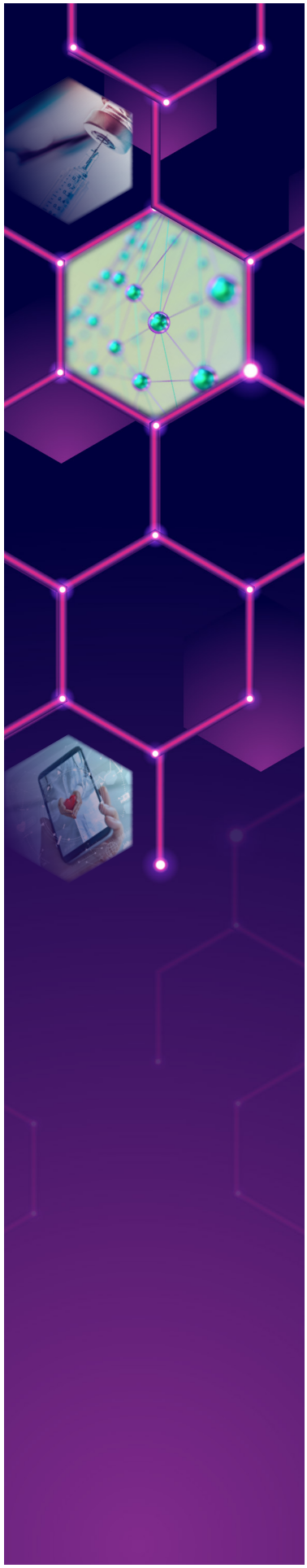
UK Supreme Court to Review Whether AI Can Be an Inventor: In the UK, on August 12, 2022, the UK Supreme Court granted leave to appeal to Dr. Stephen Thaler in the high-profile case over whether the AI-based machine known as DABUS developed by Dr. Thaler can be listed as the inventor of two patents and whether it has the capacity to assign ownership of such IP to Dr. Thaler. The UK Intellectual Property Office, the High Court and the Court of Appeal have all rejected this notion, although Lord Justice Birss (one of the three judges sitting in the Court of Appeal) gave a dissenting opinion. Dr. Thaler has sought to register patents elsewhere but has thus far been unsuccessful in the US, Australia, Germany, and before the European Patent Office. Although South Africa is the first country to grant a patent listing DABUS as the inventor and Dr. Thaler as the patent owner, its patent office does not formally examine patents and, consequently, it has not substantively considered the issues before other patent offices and courts. The Supreme Court is due to hear the appeal in March 2023 with judgment some months thereafter. The Court of Appeal judgment being appealed can be accessed here.

UK IPO Guidance on Patent Applications For AI Inventions: On September 22, 2022, the UK Intellectual Property Office issued enhanced guidelines for the examination of patent applications for AI inventions. The guidance confirms the position that, in the UK, patents are available for AI inventions in all fields of technology, so long as the inventions include a technical contribution such that they are not excluded from patent eligibility for being solely related to a mathematical method “as such” and/or a program for a computer “as such.” These exclusions are applied as a matter of “substance not form” by considering the task or process an AI invention performs when it runs. The guidance provides examples of technical contribution and is intended to help applications succeed by avoiding issues of excluded matter and providing more certainty for applicants. The guidance does not consider inventive step, inventorship or entitlement in the context of AI inventions.

REIMBURSEMENT

UK NICE Evidence Standards For Digital Technologies: The UK National Institute for Health and Care Excellence (NICE) updated its evidence standards framework (ESF) for digital health technologies (DHTs) on August 9, 2022. The framework describes standards for the evidence that should be available or developed for DHTs to demonstrate their value in the UK healthcare system to inform the decision of

whether the DHT should be used within the national healthcare system. The updated ESF for DHTs now includes the evidence requirements for AI and data-driven technologies with adaptive algorithms. For example, the ESF states that a company should describe actions taken in the design of the data-driven DHT to mitigate against algorithmic bias and should report on post-deployment changes in performance of the DHT.



PRIVACY

Current Status of the Draft European Health Data Space (EHDS) Regulation: On September 15, 2022, an "EU Legislation in Progress" briefing on the European Health Data Space (EHDS) regulation was published by the European Parliamentary Research Service. The EHDS proposal was put forward by the European Commission in May 2022 with the aims of improving individuals' access to and control of their health data and supporting the re-use of health data for healthcare delivery, better research and policy making. The briefing explains that the legislative procedure is still in its early stages and the next step in the European Parliament procedure is the publication of a draft report by the responsible committee. The Commission's proposal is also being negotiated by the Council of the European Union. More details on the Commission's EHDS proposal can be found on our blog.

UK ICO Guidance on AI and Data Protection: The UK's Information Commissioner's Office published guidance on October 14, 2022 on the relationship between AI and data protection. The guidance explains how data protection legal principles apply to AI systems that process personal data and emphasizes that data protection should be considered at the design stage of an AI project to ensure compliance. It also sets out recommendations that companies can use to limit data protection risks associated with AI projects, including security risks and compliance with the data minimization principle.

PRODUCT LIABILITY

Publication of the draft Product Liability Directive and draft AI Liability Directive: On 28 September 2022, the European Commission published two proposed directives, the draft Product Liability Directive (PLD) and the draft AI Liability Directive. The new PLD amends the definition of "product" such that AI systems would fall within its scope. The effect is that manufacturers of defective AI would be liable for damages under the PLD, which would be extended to include psychological harm and data loss. The regime would be supported by Member States' national, fault-based liability rules that would apply to claims beyond the scope of the PLD. The purpose of the AI Liability Directive is to harmonise those rules to ensure that persons claiming compensation for damage caused to them by an AI system would have a level of protection equivalent to that enjoyed by persons claiming compensation for damage caused without the involvement of an AI system.

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