Digital Health Law Update—An Overview of Notable Happenings Affecting Digital Health, Mobile Health, and Telemedicine
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Industry Insights

What Does the DOJ's Recent Consent Decree with Miami University Mean for Digital Health Service Providers?

by Robert A. Naeve

The Americans with Disabilities Act of 1990 is one of several important federal laws defining whether and to what extent telehealth professionals might be required to modify their business practices to ensure that they are accessible to individuals with disabilities. The Act generally prohibits public entities and private businesses from discriminating on the basis of disability, and from excluding disabled individuals from using and enjoying the goods, services, facilities, programs, and activities they provide.

On October 17, 2016, the United States Department of Justice announced that it had entered into a comprehensive consent decree resolving claims that Miami University in Oxford, Ohio violated Title II of the ADA by maintaining inaccessible websites and by using other inaccessible classroom technologies. This announcement follows on the heels of DOJ's findings and conclusions that the University of California at Berkeley violated Title II of the ADA by failing to make online audio and video content accessible to individuals who are deaf or hard of hearing. In this article, we briefly summarize the basic terms of the Miami University Consent Decree and outline what it may mean to digital health providers.

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UPCOMING EVENTS

November 10, 2016: Todd Kelly will be moderating a Health Tech/Cybersecurity Joint Forum hosted by TechTitans in Dallas, Texas.

February 19–23, 2017: Alexis Gilroy will be speaking at the Annual HIMSS Conference & Exhibition on Telehealth Laws and Policy in Orlando, Florida. Alexis is presenting on

Federal Features

CMS Issues Final MACRA Rule—Implications for Digital Health Providers
On October 14, 2016, the Centers for Medicare and Medicaid Services ("CMS") released a pre-publication version of the final rule with comment period ("Final Rule") implementing the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"). MACRA repealed the Medicare Sustainable Growth Rate and instituted the Quality Payment Program in its place, a new model based on rewarding quality care and outcomes at a provider level, while promoting Medicare's long-term goals to transition away from fee-for-service payment.

The new rule is likely to have implications for telehealth providers, as new value-based programs encourage activities that improve the quality of care and reward providers for reducing costs. Moreover, telehealth is an important tool that providers can use to help fulfill the goals of MACRA, such as improved information sharing, greater patient engagement, and broader provider partnerships. A series of more detailed alerts on MACRA, the Quality Payment Program, and the impact for telehealth providers is coming soon.

HHS Releases E-Health and Telemedicine Report to Congress
On August 12, 2016, the U.S. Department of Health and Human Services ("HHS") released its Report to Congress: E-health and Telemedicine ("Report") in response to a Congressional request for HHS to provide an update on its telehealth efforts. The Report offers background on telehealth modalities, discusses current telehealth policy challenges, and highlights federal telehealth activity. As background, the Report cites the importance of telehealth services (defined broadly to include live video interactions, store-and-forward technologies, remote patient monitoring, and mobile health apps) as a means to increase access to care, improve health outcomes, and reduce health care costs.

The Report then highlights a number of challenges to widespread use of telehealth, including reimbursement/payment issues, state licensure barriers, and gaps in access to affordable high-speed broadband connections in rural hospitals and clinics. According to the Report, four out of five states require out-of-state clinicians providing telehealth services to be licensed in the state where the patient resides, highlighting the importance of licensure flexibility for physicians utilizing telehealth modalities.

"Opportunity in Telehealth — Strategies for Understanding & Managing Multi-Jurisdictional Laws to Achieve Scale."

May 22–23, 2017: Alexis Gilroy will be speaking at the Medical Informatics World Conference in Boston, Massachusetts. Alexis is presenting as part of Cambridge Healthtech Institute Business of Telemedicine Symposium: Impact & Opportunity — Evolution of Laws and Policy in the Business of Telehealth.

DIGITAL HEALTH LAW UPDATE ARCHIVES

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In addition, the Report notes that the payment environment for telehealth services continues to evolve. Medicare fee-for-service spending on telehealth services amounted to less than 0.01 percent of total spending by Medicare on health care services in 2015, while reimbursement for telehealth by Medicaid and private insurers varies greatly (48 state Medicaid programs currently provide some level of telehealth coverage, and 22 percent of large employers in 2014 covered telemedicine consultations, with more than 68 percent set to do so by 2017).

Despite challenges, HHS continues to invest in telehealth, particularly through Medicare, Medicaid, and the Indian Health Service. In addition, other HHS Operating Divisions, such as the Health Resources and Service Administration ("HRSA"), the Agency for Healthcare Research and Quality, and the Office of the National Coordinator for Health Information Technology ("ONC") support telehealth activities, the development of mobile technologies, and other research programs. Importantly, the Report concludes by noting that HHS's legislative proposal for 2017 would expand the ability of Medicare Advantage organizations to deliver certain medical services via telehealth by eliminating otherwise applicable Part B requirements that certain covered services be provided exclusively through in-person encounters.

GAO Issues Report on Electronic Health Information
In August 2016, the U.S. Government Accountability Office ("GAO") released a report to the Senate Committee on Health, Education, Labor, and Pensions entitled "Electronic Health Information, HHS Needs to Strengthen Security and Privacy Guidance and Oversight" ("Report"). The Report found that while electronic health information can offer substantial benefits to providers and patients, the systems for storing and transmitting such information are vulnerable to cyber-based threats. The number of data breaches involving health care records has increased dramatically in recent years, from zero breaches in 2009 to 56 breaches in 2015 (involving more than 113 million records). According to the GAO, although HHS has published HIPAA compliance guidance for covered entities, such as health plans and health care providers, that guidance does not address all elements called for by other federal cybersecurity guidance. According to the Report, in order to improve effectiveness of HHS guidance and oversight of privacy and security for health information, HHS should update its guidance for protecting electronic health information to address key security elements, improve the technical assistance it provides to covered entities, follow up on corrective actions, and establish metrics for gauging the effectiveness of its audit program.

ONC Releases EHR Contract Guide and Expanded Health IT Playbook
On September 26, 2016, ONC released two health IT practical tools: an electronic health record ("EHR") contract guide titled *EHR Contracts Untangled: Selecting Wisely, Negotiating Terms, and Understanding the Fine Print* ("EHR Contract Guide"), and an expanded *Health IT Playbook*. The new EHR Contract Guide is intended to help providers and health administrations planning to acquire an EHR system negotiate contract terms with vendors. Specifically, the EHR Contract Guide explains important concepts in EHR contracts, such as key rights and vendor obligations, safety and security risks, and ensuring data integrity, and it includes example contract language. The *Health IT Playbook* is a web-based tool intended to help providers implement and use health information in a way that best serves their practices. For example, the *Health IT Playbook* identifies leading practices in EHR implementation, offers solutions to providers on key issues and challenges to optimize health IT, provides guidance on health IT laws such as HIPAA, and serves as a central resource for health care providers and health IT professionals on the most up-to-date technologies and processes to support patient care.

Bipartisan Bill to Improve Medicare ACO Program Includes Telehealth Provisions
On September 21, 2016, Representatives Diane Black (R-TN) and Peter Welch (D-VT) introduced a bipartisan bill in the House of Representatives aimed at improving Medicare accountable care organizations ("ACO"). The ACO Improvement Act, which would amend title XVIII of the Social Security Act, is intended to improve health outcomes through greater beneficiary engagement, including by improving care coordination through

telehealth. Among other things, the Act provides that the Secretary of HHS shall grant a waiver to ACOs to have the restrictions on the use of telehealth contained in Section 1834 of the Social Security Act ("special payment rules for particular items and services"), such as limitations on originating site and the use of store-and-forward technologies, not apply. In addition, the law clarifies that ACOs are not prevented from paying for remote patient monitoring and home-based video conferencing services in connection with the provision of home health services in a manner that is not more expensive than a home health visit.

Federal Government Awards Millions in Telemedicine Grants
On September 19, 2016, Secretary Tom Vilsack announced that the U.S. Department of Agriculture will invest more than $4 million in Distance Learning and Telemedicine program grants to support 18 projects in 16 states, including seven telemedicine projects. The telemedicine awards total nearly $2 million and will, among other things, fund projects at hospitals and health centers to connect health care providers in a "central hub" to remote end-user sites in different regions and states. The grants will also provide funding for telemedicine equipment, a free 24-hour nurse help line, and a comprehensive telehealth care management program.

In addition, in August 2016, HRSA announced $16 million in funding to improve access to health care in rural communities, including funds to expand the use of telehealth technology for veterans and other patients. The awards, to be administered by the Federal Office of Rural Health Policy, will support 60 rural communities in 32 states. Specifically, HRSA is awarding more than $6 million to 21 community health organizations to build sustainable telehealth programs and networks in medically underserved areas. In addition, HRSA is granting three awards totaling $900,000 to use telehealth and health information technology to bring mental health and other health services to veterans living in rural areas.

State Summaries

Alaska Regulations Propose Advanced Business Registration for Telemedicine Business
In what appears to be a unique new regulatory requirement among states for telemedicine business, on September 20, 2016, the Department of Commerce, Community, and Economic Development issued a notice of its intent to adopt new regulations regarding special business registry requirements for health care providers delivering telehealth services in the state. Once finalized, the new regulations will establish initial registration, application, and renewal requirements, fees, and other miscellaneous provisions. Importantly, the new regulations require a telemedicine business to register with the Department at least 60 days before delivering telemedicine services in the state. The regulations implement provisions of Alaska SB 74, signed into law on July 11, 2016, and discussed in our previous *Update*. The bill enables out-of-state telemedicine providers licensed in Alaska to treat Alaska residents without first establishing an in-person relationship, subject to practice standards the legislation directs the Alaska State Medical Board to establish consistent with national norms. Comments on the proposed regulations closed on October 24, 2016.

Arkansas Medical Board Adopts Telemedicine Rules
Effective September 4, 2016, the Arkansas Medical Board adopted an amendment to its Regulation 2.8 to allow for a proper physician-patient relationship to be established by a "face to face examination using real time audio and visual telemedicine technology that provides information at least equal to such information as would have been obtained by an in-person examination." On October 6, 2016, the Board also approved new Regulation 38, which creates standards for telemedicine practice in the state. As discussed in our previous *Update*, specific requirements of Regulation 38 incorporate elements that telemedicine services: (i) be held to the same standard of care as in-person services; (ii) incorporate arrangements for follow-up care if indicated; (iii) limit prescribing of controlled substances unless certain additional requirements are met; (iv) enable the availability to

the patient of patient's medical record documenting the encounter upon request; (v) identify the physician and certain facts about the physician in advance of the telemedicine encounter; and (vi) establish protocols for referrals for emergency services. The approval of Regulation 38 was delayed due to disagreement over its original provision on store-and-forward technology, which clarified that the use of store-and-forward technology, such as X-rays, MRIs, and digital images, was not restricted, but that a patient completing a medical history online and forwarding it to a physician would not qualify as store-and-forward technology. The adopted rule deletes the statement that store-and-forward technology is not restricted. Regulation 38 will be considered by a legislative subcommittee on December 16, 2016, and, if approved, will become effective 10 days after it is sent to the Arkansas Secretary of State office. We also note that while not specifically referenced in the newly adopted regulations, telemedicine services in Arkansas are subject to other requirements set forth in the authorizing legislation Arkansas Code § 17-80-118, including limitations on the patient location (originating site), except in very limited circumstances necessitating that a patient be located at a physician's office or licensed health care facility.

Kentucky Adopts Telehealth Standards for Nurses
Effective July 20, 2016, the Kentucky Board of Nursing adopted telehealth standards for licensed practical nurses, registered nurses, and advanced practice registered nurses providing nursing services to persons physically located in Kentucky. The new rule requires nurses delivering telemedicine services to, upon initial contact with the patient, make attempts to verify the identity of the patient and exchange provider contact information, such as a telephone number or mailing address. In addition, nurses using telehealth to deliver nursing services must ensure that telehealth is appropriate for the patient, document the services provided via telehealth, use secure communications with each patient, and inform the patient and document acknowledgement of the risk and limitations of the use of telehealth to provide nursing services. Further, the new regulations call out prohibitions on misleading or deceptive advertising and fee splitting as it pertains to nurses utilizing telehealth to deliver services.

New York Office of Mental Health Finalizes Telepsychiatry Rule
Effective August 31, 2016, the New York Office of Mental Health ("OMH") adopted a proposed rule establishing basic standards and parameters for the use of telepsychiatry in certain OMH-licensed programs. As discussed in a previous *Update*, the rule defines "telepsychiatry" to mean the use of "two-way real-time interactive audio and video" to provide and support remote clinical psychiatric care. Importantly, the proposed rule expands the ability to provide telepsychiatry services to qualified mental health professionals, including physicians, licensed practical nurses, nurse practitioners, licensed psychologists, and physician assistants. In addition, the rule specifies the conditions for reimbursement for telepsychiatry services by Medicaid. The rule replaces the existing regulations, which allow for the use of telepsychiatry by OMH-licensed clinics only.

Ohio Medical Board Continues to Consider Telemedicine Rule
As discussed in our previous *Updates* (here and here), the State Medical Board of Ohio proposed a new rule in April 2016 outlining the standards for a physician's prescribing of drugs to patients based only upon a remote encounter. The proposed rules were filed with the Common Sense Initiative Office on July 5, 2016, and interested parties were invited to submit comments. The Medical Board considered the comments at its September 14, 2016 meeting and approved minor amendments to the proposed language originally filed to reflect comments received. Comments on the latest drafts of Rule 4731-11-01 and Rule 4731-11-09 were due to the Common Sense Initiative Office and the Medical Board on September 26, 2016.

The new rule would replace the current Rule 4731-11-09, which requires a physician to have personally and physically examined a patient before prescribing any drug to the patient, except in specific situations.

Texas Adopts Call Coverage Rule Clarifying Utilization of On-Call Telemedicine

Services
Effective October 9, 2016, Texas physicians relying on call coverage arrangements to provide services (including through telemedicine) must comply with a new Medical Board rule that includes entering into a call coverage agreement. The new rule sets out specific components of the call coverage arrangement given whether the coverage relationship is reciprocal, including, in the case of non-reciprocal arrangements, that the agreement must: (i) be in writing, (ii) identify all physicians that may provide the call coverage, (iii) require the covering physician to have access to necessary patient medical records, and (iv) require the covering physician to provide certain reports to the requesting physician.

Reimbursement Review

New Jersey Considers First Telemedicine Bill
After several years of discussion, New Jersey is now considering its first telemedicine legislation. Introduced in January 2016, S 291 allows a health care practitioner to "remotely provide health care services to a patient in the State, and a bona fide relationship between health care practitioner and patient [to] be established, through the use of telemedicine." The bill defines "telemedicine" as "the delivery of a health care service using electronic communications," including two-way video conferencing and store-and-forward technology, but not including audio-only telephone conversation, email, or text. The bill also requires payment parity for services provided by telemedicine, both by New Jersey's Medicaid program and by private payors. On September 26, 2016, the bill was approved by a Senate panel and referred to the Budget and Appropriations Committee.

Pennsylvania Senate Introduces Telemedicine Standards, Payment Parity
On August 5, 2016, the Pennsylvania Senate introduced telemedicine legislation (SB 1342) to establish standards concerning the use of telemedicine. The bill defines "telemedicine" as "the delivery of health care services provided through telecommunications technology to a patient by a healthcare practitioner who is at a different location." Telemedicine would include remote patient monitoring but excludes "the use of audio-only telephone conversation, facsimile, e-mail, instant messaging, phone text, answers to an online questionnaire or any combination thereof." If passed, the bill would also require insurers to adopt payment parity for services provided through telemedicine. The bill has been referred to the Senate Banking and Insurance Committee for review.

Study Finds Reimbursement May Affect Use of Telehealth in Family Practices
The Robert Graham Center for Policy Studies in Family Medicine and Primary Care recently published the findings from a 2014 survey conducted by the American Academy of Family Physicians ("AAFP") on the use of telehealth by family physicians. According to the study, only 15 percent of the family care physicians surveyed in 2014 had used telehealth in the prior year. The study also reports that use of telehealth is more likely among physicians working in federally qualified health centers or health maintenance organizations than those working in accountable care organizations or patient-centered medical homes. According to the leader of the study, telehealth use lags because "payment is not aligned with services yet." While telehealth reimbursement has improved since 2014, particularly in certain states, CMS's 2017 Medicare physician fee schedule still provides limited reimbursement for telehealth services. The AAFP study is part of a growing body of research on telehealth and reimbursement by organizations that include the American Telehealth Association, the Health Information and Management Systems Society, and the Center for Connected Health Policy.

Global Happenings

Telemedicine Services Reimbursable in Guizhou Province of China
On September 12, 2016, the Guizhou Human Resources and Social Security Bureau

announced that certain qualified telemedicine services are now reimbursable under the Chinese social insurance program. The pilot program, which started August 1, 2016, will last for one year. Guizhou Province is the first province in China to adopt such a policy at the provincial level. Under the program, the following nine items are reimbursable: (i) single disciplinary consultations, (ii) multidisciplinary consultations, (iii) traditional Chinese medicine treatment consultations, (iv) synchronous pathological consultations, (v) asynchronous pathological consultations, (vi) electrocardiogram consultations, (vii) medical image consultations, (viii) inspection and diagnoses, and (ix) pathological diagnoses. To qualify for reimbursement, these telemedicine services must be carried out through a provincial telemedicine platform and must be performed on behalf of patients who are hospitalized. If an insured patient or his/her family members unilaterally ask for telemedicine services under other circumstances, the service would not be reimbursable.

China has published various rules and policies promoting telemedicine services, and many businesses are interested in developing this market. However, one of the main hurdles is that telemedicine services are not covered by the Chinese social insurance program. Although this new policy adopted by Guizhou Province is just a provincial policy, is still in a pilot phase, and applies to only a few limited circumstances, it is widely viewed as a positive step for the entire Chinese health care industry. Other provinces are expected to issue similar policies, paving the way for a more open and accessible telemedicine market for both the Chinese patients and the businesses involved.

EU and US eHealth IT Roadmap
The European Commission's Directorate General for Communications Networks, Content and Technology ("DG Connect") and HHS, after consulting with stakeholders, updated the roadmap for their Memorandum of Understanding ("MOU") on eHealth/health information technologies.

DG Connect and HHS first published a "roadmap" for their actions under the MOU in the spring of 2013. The roadmap focused on two priority areas: (i) standards development to foster transnational interoperability of electronic health information and communication technology, and (ii) workforce skills to develop and expand the Health IT workforce in Europe and the United States. In late 2015, DG Connect and HHS agreed to add a third priority area, "Transatlantic eHealth/Health IT Innovation Ecosystems," to encourage innovation in the eHealth/Health IT industry. Specifically, the program seeks to identify key EU and U.S. stakeholders and enlist their support for greater collaboration between companies and ecosystems located in each jurisdiction. Program activities are outlined in the annex to the roadmap and will begin in fall 2016.

UK's MHRA Issues Guidance on Health Apps
On August 25, 2016, MHRA issued updated guidance to help identify the health apps that are medical devices and make sure they comply with regulations and are acceptably safe. The guidance is presented as a step-by-step interactive PDF. Aimed at both users and developers, users can use this guidance to check if their health app is a medical device and to determine what to look for to make sure the app is safe and works. In addition, the guidance serves as an aid to developers in navigating the regulatory system so they are aware of procedures they need to have in place to get a CE mark and applicable reporting responsibilities.

EU Actions on eHealth
On September 7, 2016, the European Commission's Directorate Generals on Health and Food Safety and Communications, Networks, Content and Technology jointly published a leaflet that describes European actions in the field of eHealth. Specifically, the leaflet describes the EU's Digital Single Market Strategy and the eHealth Action Plan 2012–2020, discussing tools the EU intends to employ to meet its goals. Such tools include: (i) the eHealth Network of Member State representatives, established by the Cross-Border Healthcare Directive; (ii) the European Reference Network; (iii) dialogue with stakeholders; (iv) financing instruments, such as the third EU Health Program, Horizon 2020, and Connecting Europe Facility; and (v) an EU-wide eHealth Digital Service

Infrastructure, which will allow health data (such as ePrescriptions and patient summaries) to be exchanged across national borders. EU goals include creating a digital infrastructure and fostering interoperability, reliability, and increased digitalization of and innovation in health care systems.

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The Americans with Disabilities Act of 1990, 42 U.S.C. §§ 12101 *et seq.* ("ADA" or "Act"), is one of several important federal laws defining whether and to what extent telehealth professionals might be required to modify their business practices to ensure that they are accessible to individuals with disabilities. The Act generally prohibits public entities and private businesses from discriminating on the basis of disability, and from excluding disabled individuals from using and enjoying the goods, services, facilities, programs, and activities they provide. 42 U.S.C. § 12133; 28 C.F.R. § 35.172.

On October 17, 2016, the United States Department of Justice ("DOJ") announced that it had entered into a comprehensive consent decree resolving claims that Miami University in Oxford, Ohio ("Miami University" or "University") violated Title II of the ADA by maintaining inaccessible websites and by using other inaccessible classroom technologies. This announcement follows on the heels of DOJ's findings and conclusions that the University of California at Berkeley violated Title II of the ADA by failing to make online audio and video content accessible to individuals who are deaf or hard of hearing. In the paragraphs that follow, we briefly summarize the basic terms of the Miami University Consent Decree and outline what it may mean to digital health providers.

Miami University Consent Decree

In January 2014, Ms. Aleeha Dudley, who is blind, filed a civil action against Miami University, alleging among other things that the University excluded her from participation in and the benefit of its services, programs, and activities; discriminated against her on the basis of disability; and failed to take appropriate steps to ensure equally effective communication with her, all in violation of Title II of the ADA and other federal laws. *Dudley v. Miami University*, Case No. 1:14-cv-38 (S.D. Ohio Jan. 10, 2014). In May 2015, DOJ's Civil Rights Division joined with Ms. Dudley in prosecuting this action by filing a complaint in intervention against Miami University on behalf of the United States of America. DOJ generally alleged in its complaint in intervention that the University used technologies that are inaccessible to qualified individuals with disabilities and failed to ensure that qualified individuals with disabilities could access the University's curricular and co-curricular materials on an equal basis with individuals who do not have disabilities.

On October 17, 2016, the DOJ announced that the United States and the University had resolved all claims asserted in *Dudley* pursuant to the terms of a proposed Consent Decree, which has since been filed for approval by the United States District Court for the Southern District of Ohio. While the district court has not yet formally approved it, the Consent Decree's terms should be of interest to any entity that conducts business online or through the use of electronic information technology.

The Consent Decree obligates the University to improve accessibility of online and other content it provides. For example:

- All new and "redeveloped" "web pages, web applications, and web content, created by Miami University, on websites and subdomains used for Miami's academic divisions, academic departments, and administrative offices" six months after the approval of the Consent Decree must comply with the Worldwide Web Consortium's Web Content Accessibility Guidelines, version 2.0, compliance level AA ("WCAG 2.0, AA"). Consent Decree, ¶ 21(a). Preexisting web pages, web applications, and web content must be brought into WCAG 2.0 AA compliance within 18 months. *Id.* ¶ 21(b). During this 18 month period, the University must, upon request, provide equally effective alternate access of legacy and archive content. *Id.* ¶ 21(c).
- Web content that may exist apart from "web pages, web applications, and web content, created by Miami, on websites and subdomains used for Miami's academic divisions, academic departments, and administrative offices" must be remediated upon request. *Id.* ¶ 23.
- To the extent the University uses third party content, websites, or applications for admissions or financial aid, or for completion of other specified "important transactions," it must either "(1) cause such third-party content, websites, or applications to conform with WCAG 2.0 AA and this Decree; or (2) provide equally effective alternate access to qualified individuals with disabilities" until the content can be remediated. *Id.* ¶¶ 21(d) & (e).
- "Videos embedded within the home page of each academic division and Vice-Presidential office, and all videos relating to the completion of critical or important transactions must also comply with WCAG 2.0 AA." *Id.* ¶ 22(a). Other forms of specified video content must be remediated upon request. *Id.* ¶ 32.
- Documents posted by the University's various "offices, divisions, and departments must comply with WCAG 2.0 AA," although the University may seek exemptions to this requirement if "(1) the documents are of interest to a specific and limited audience (e.g., researchers in a particular academic discipline); (2) the set of documents requiring remediation to conform with WCAG 2.0 AA is voluminous (i.e., the total page count of the electronic documents that reside on a single web page exceeds 100 pages), or is—from a technical perspective—exceptionally difficult to remediate; and (3) the documents are presented in such a way that individuals with disabilities are able to identify documents of particular interest and request remediation of those documents." *Id.* ¶ 22(b).
- Learning management software applications used to plan, create, administer, document, track, report, deliver, and maintain electronic educational courses and course content and to assess student performance generally must be brought into WCAG 2.0 AA compliance by the end of the 2016–17 academic year. *Id.* ¶ 25.
- Curricular materials (e.g., textbooks, workbooks, articles, compilations, presentations, collaborative assignments, videos, and images or graphical materials) must be converted into alternate formats upon request by students who have registered with the University's Student Disability Services department. *Id*. ¶ 28. The Consent Decree further obligates the University to meet with disabled students who register with its Student Disability Services office "before the beginning of each semester to determine whether the student will require curricular materials in alternate formats, what assistive technologies the student uses or needs, and what formats will work with the student's assistive technologies." *Id*. ¶ 28(b).

- The University must also promulgate an Accessible Technology Policy; modify its technology procurement policies; create an Accessible Educational Resources Portal; create an automated website and web application accessibility testing tool; designate a Web Accessibility Coordinator, an Accessible Technology Coordinator, and an Accessible Technology Specialist (who will audit the University's digital technologies); and create a University Accessibility Committee to be chaired by the University's Vice President for Information Technology. *Id*. ¶¶ 35-41.

Brief Comments

The Consent Decree is of importance to digital health service providers for a number of reasons.

First, while the use of electronic information and telecommunications technologies to support and deliver health care, health information, and health education at a distance is on the rise, relatively little attention has been given to the potential obligations of telehealth service providers to ensure that the services they provide are accessible to and usable by individuals with disabilities. For example, patients who are deaf or who have hearing impairments may not be able to participate in a teleconference with health professionals using telehealth applications that rely solely upon aural communication and that do not provide alternative forms of communication. Similarly, patients who are blind or who have vision disabilities may not be able to use kiosks, video relay services, smartphones, and other apps that communicate information through visual and no other means. The Consent Decree generally reminds all digital health service providers to evaluate whether and to what extent they can and should provide their services to individuals with disabilities in alternative formats and through alternative means.

Second, and on a more granular level, the Consent Decree should be of particular interest to digital health service providers whose operations are subject to the anti-discrimination provisions of Section 1557 of the Affordable Care Act, 42 U.S.C. § 18116. As briefly noted in a prior edition of the *Digital Health Law Update*, Section 1557 provides that an individual shall not, on the basis of race, color, national origin, sex, age or disability, "be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance…." *Id.* § 18116(a). The Department of Health and Human Services regulations interpreting Section 1557 obligate covered entities to comply with the very ADA Title II standards DOJ purports to enforce in the Consent Decree. *See, e.g.*, 45 C.F.R. § 92.202(a) (covered entities to effectively communicate with individuals with disabilities as mandated by DOJ's Title II rules); § 92.204(b)(requiring covered entities to "ensure that their health programs and activities provided through Web sites comply with the requirements of Title II of the ADA").

Finally, much attention has been paid over the past six-plus years as to whether and when DOJ might publish standards for website accessibility under Titles II and III of the ADA. DOJ first announced in a July 2010 Advanced Notice of Proposed Rulemaking that it planned to issue such regulations. DOJ, Advance Notice of Proposed Rulemaking, Accessibility of Web Information Services of State and Local Governments and Public Accommodations ("ANPRM"), 75 Fed. Reg. 43460, 43464 (July 26, 2010). However, DOJ has only haltingly pursued website accessibility rulemaking since then. Most recently, DOJ issued a Supplemental Advance Notice of Proposed Rulemaking ("SANPRM") in May 2016 indicating that it was accepting "additional public comment … to help the Department shape and further its rulemaking efforts" under Title II of the ADA. DOJ, SANPRM, 81 Fed. Reg. 28658 (May 9, 2016). It remains unclear when DOJ will complete this rulemaking effort, although it is worth noting that the comment period for the SANPRM closed October 6, 2016. DOJ, SANPRM; Extension of Comment Period, 81 Fed. Reg. 49908 (July 29, 2016). While the Consent Decree isn't binding on non-parties, and on addressees' claims asserted against a public university, it may very well be a harbinger of Title II (and Title III) regulations to come.

We note that this is only a summary of some of the Consent Decree's many and varied provisions and barely scratches the surface of the federal and state accessibility laws and regulations with which public entities and businesses must comply.

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