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ADVANCE DIRECTIVE

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ANNALS OF HEALTH LAW
Advance Directive

THE *STUDENT* HEALTH POLICY AND LAW REVIEW OF
LOYOLA UNIVERSITY CHICAGO SCHOOL OF LAW

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Beazley Institute for Health Law and Policy

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ANNALS OF HEALTH LAW
Advance Directive

Editors' Note

The *Annals of Health Law and Life Sciences* is proud to present the first edition of our thirty-first volume of our online, student-written publication, *Advance Directive*. This *Fall 2021 Advance Directive* Issue focuses on technology and innovations in health care and healthcare systems.

The Issue dives into a broad spectrum of topics within the current conversation taking place in the United States surrounding new technologies and healthcare innovations. The COVID-19 pandemic brought new technologies and innovations to the forefront of healthcare discussion by the COVID-19 pandemic, while also exemplifying a need for improved healthcare solutions.

The range of topics covered in this Issue include: modern technology's impact on treatment and systems of care; new data technology and data privacy in healthcare; the use of innovative technology to increase access to healthcare and improve health equity and justice; and regulation and compliance of health technologies and pharmaceutical and medical device development in the United States. The range of topics covered in this Issue illustrates the many challenges and systematic barriers to care that new technologies seek to address.

The members of Annals deserve recognition for their hard work, dedication, and well-thought articles. We would like to thank Meera Patel, our Annals Editor-in-Chief, for her leadership and support. We would also like to thank and acknowledge our Annals Executive Board Members: Edwin Caro, Josh Wiedner, and Abby Higgins. Lastly, we must thank the Beazley Institute for Health Law and Policy and our faculty advisors, Professors Nadia Sawicki and Kristin Finn for their guidance and support.

We hope you enjoy this Issue of *Advance Directive*.

Sincerely,

Sarah Ryan
Advance Directive Executive Editor
Annals of Health Law
Loyola University Chicago School of Law

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Dangerous Speech: The Impact of Misinformation on Technological Advancements in Healthcare

Anna Armel

INTRODUCTION

The emergence of the novel coronavirus (COVID-19) placed science under a public microscope. Health misinformation surrounding COVID-19 has created confusion, reduced trust in public health measures, and hindered efforts to get Americans vaccinated.[1] While health misinformation has always been an issue, today it spreads at an unprecedented speed and scale.[2] The ability to reach hundreds of thousands with just the click of a mouse makes controlling the transmission of false information extremely challenging.[3] The COVID-19 pandemic has triggered widespread disinformation that has undermined both understanding and acceptance of science, thereby undermining vaccine acceptance and application.[4] Despite widespread recognition that COVID-19 is a critical issue globally, many still remain unwilling to be vaccinated.[5] This is a prime example of how skepticism and misinformation can, and will, undermine the success of public health interventions and the implementation of healthcare technology.[6]

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[1] VIVEK H. MURTHY, CONFRONTING HEALTH MISINFORMATION: THE U.S. SURGEON GENERAL'S ADVISORY ON BUILDING A HEALTHY INFORMATION ENVIRONMENT 16 (2021).
[2] *Id.* at 5.
[3] Katherine E. Bliss et al., *Vaccine Confidence & National Security in the COVID-19 Crisis*, CTR. FOR STRATEGIC & INT'L STUDIES [CSIS] (2021), https://www.csis.org/features/vaccine-confidence-national-security-covid-19-crisis.
[4] OECD, ENHANCING PUBLIC TRUST IN COVID-19 VACCINATION: THE ROLE OF GOVERNMENTS 3 (MAY 10, 2021).
[5] *Id.*
[6] Peter Suwondo, et al., *Ten Urgent Reforms to Protect the CDC and FDA from Harmful Political Interference*, HEALTH AFFS. (Nov. 24, 2020), https://www.healthaffairs.org/do/10.1377/hblog20201120.456386/full/.

Simply put, a scientific endeavor that is not trusted by the public cannot adequately contribute to society.[7]

This article will first discuss what occurred during the COVID-19 pandemic regarding the complications surrounding the vaccine in connection with the spread of misinformation, followed by how misinformation can adversely affect the success of future health technologies and attempts at public health interventions. The article will specifically discuss how public officials, through their attacks on the integrity of public health agencies, have undermined vaccine and health care technology, as well as the public's perception of these agencies. Finally, this article will propose that Congress enact statutory protections for the integrity of federal science and to create a better platform for implementing health technologies now and in the future.

THE FUTURE OF HEALTHCARE TECHNOLOGY AND INNOVATION

In late 2020, two of the vaccine contenders in clinical trial demonstrated safety and effectiveness in preventing infection of the virus that causes COVID-19.[8] However, this remarkable achievement was complicated by the public receiving information, guidance, and recommendations that vastly differed based on their news consumption and preferred political leaders.[9] A September 2020 survey found that Americans were evenly divided as to whether they would get the vaccine to prevent COVID-19 if one were available then, despite widespread recognition of the current public health crisis.[10] The pandemic thus exhibited that the science of vaccine development will not be successful if enough people do not trust that the

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[7] Sudip Parikh, *Why We Must Rebuild Trust in Science*, PEW TREND MAG., Feb. 9, 2021, https://www.pewtrusts.org/en/trend/archive/winter-2021/why-we-must-rebuild-trust-in-science.
[8] *Id.*
[9] *Id.*
[10] *Id.*

vaccines will help prevent COVID-19.[11] Given the nature of pathogens coupled with a history of major pandemics and epidemics that have already afflicted humanity, it is evident that pandemics are inevitable, possibly imminent, and likely to be devastating to the health of the U.S. people.[12] As harmful as COVID-19 has been, a novel influenza virus could be even worse, potentially killing millions more and destabilizing governments and economies alike.[13] The skepticism displayed by the American public throughout the COVID-19 pandemic, if continued, will undermine the success of future public health technologies, not only for vaccine-preventable diseases, but for any technology that is cast in the public spotlight.[14] A growing body of research reveals associations between trust in government and health-related behaviors and outcomes.[15] For instance, in a study of HIV-positive adults, individuals with higher trust in government reported greater use of health care services and of antiretroviral medications.[16] Similarly, other studies have demonstrated the importance of how governmental trust intersects with vaccination intentions and uptake.[17] Misinformation can create the impression that no consensus exists on a topic or that official sources of information are not credible, which can generate feelings of

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[11] *Id.*
[12] SYLVIA MATTHEWS BURWELL, ET AL., COUNCIL ON FOREIGN RELS., IMPROVING PANDEMIC PREPAREDNESS: LESSONS FROM COVID-19 68 (2020) (noting pathogens frequently emerge); Jocelyne Piret & Guy Boivin, *Pandemics Throughout History*, NAT'L CTR. FOR BIOTECHNOLOGY INFO (Jan. 10, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7874133/.
[13] *Id.*
[14] Suwondo et al., *supra* note 6.
[15] Sarah D. Kowitt, et al., *Awareness and Trust of the FDA and CDC: Results from a National Sample of US Adults and Adolescents*, NAT'L CTR. FOR BIOTECHNOLOGY INFO. (May 16, 2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5433718/.
[16] *Id.*
[17] *Id.*

apathy, confusion and mistrust.[18] Subsequently, individuals may refrain from seeking health information and avoid health care, ultimately doing the same with health technology.[19] The success of some of the key public health technologies of our time, including vaccines, medical devices, and pharmaceutical access and uptake, relies heavily on trust in the sources of messages surrounding these technologies.[20] This pandemic has demonstrated that when misinformation leads to mistrust, it hinders the success of healthcare technology and innovation – a trend that may not prove to be unique to COVID-19.[21]

LESSONS FROM THE PANDEMIC

The COVID-19 pandemic exposed inherent weaknesses in the U.S.'s pandemic response plan and revealed future risks associated with the current laws surrounding pandemic readiness.[22] However, the detrimental effects of COVID-19 could also be seen as a transformative moment for the improvement of scientific integrity.[23] Designing successful improvement measures starts with an understanding of what drives misinformation.[24] As drivers of misinformation during the pandemic, elected U.S. officials, including the President at the time, often fell short as communicators, failing to offer the American public clear, reliable and science-based information about the risk of infection.[25] U.S. officials also failed to adequately defend public health officials against harassment and personal attacks, and to release

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[18] Wen-Ying S. Chou, et al., *Where we go From Here: Health Misinformation on Social Media*, 110 AM. J. PUBLIC HEALTH 273, 273 (2020).
[19] *Id.* at 274.
[20] Kowitt, *supra* note 15.
[21] *Id.*
[22] *See generally* BURWELL ET AL., *supra* note 12 (explaining that the United States was caught unprepared by the COVID-19 pandemic).
[23] *Id.* at 68.
[24] Chou et al., *supra* note 18.
[25] BURWELL ET AL., *supra* note 12 at 5-6.

timely guidance to help combat the spread of disease.[26] For decades, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) have served as two of the country's most respected sources of health information and guidance.[27] During the ongoing pandemic, however, the work of both the CDC and FDA was politicized and undermined in an unprecedented manner.[28] The public's trust in these agencies was reduced to historic lows as politicians' communications about the agencies jeopardized the perceived integrity of their decision making.[29] By attempting to use the CDC and FDA as political tools and refusing to follow their basic health guidelines, U.S. officials fueled the public's decreasing trust in these agencies and undermined their institutional integrity.[30]

Further, top officials' politicization of COVID-19 fashioned growing partisan divides over reliable sources of health information.[31] During the COVID-19 pandemic, the American public watched as White House officials censored the CDC and prohibited CDC scientists from speaking to the public.[32] Those same officials undercut agency efforts to mandate mask wearing.[33] Further, the President and his top officials invoked public distrust of the FDA's emergency authorization process and stripped regulatory

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[26] *Id.*
[27] Suwondo et al, *supra* note 6.
[28] *Id;* MURTHY, *supra* note 1 at 5.
[29] Suwondo, *supra* note 6.
[30] Jeff Tollefson, *How Trump Damaged Science – And Why it Could Take Decades to Recover*, NATURE (Oct. 5, 2020), https://www.nature.com/articles/d41586-020-02800-9.
[31] *See generally* Liz Hamel et al., *KFF Health Tracking Poll – September 2020: Top Issues in 2020 Election, The Role of Misinformation, and Views on a Potential Coronavirus Vaccine*, KAISER FAM. FOUND. (Sep. 10, 2020), https://www.kff.org/coronavirus-covid-19/report/kff-health-tracking-poll-september-2020/ (displaying polls showing strong partisan divide on different issues in the 2020 presidential election).
[32] Suwondo et al., *supra* note 6.
[33] *Id.*

authorities from the FDA.[34] The adminstration even suppressed the agency's efforts to improve the safety standards for COVID-19 vaccine development by blocking strict new federal guidelines for the emergency release of the vaccine that would have almost certainly guaranteed that no vaccine could be authorized before the 2020 presidential election.[35] The Trump administration's undermining of scientific integrity and prioritization of politics could be seen across many agencies.[36] There are clear correlations between officials' actions surrounding federal agencies on the front lines of the pandemic response, such as those aforementioned, and the public's perceived integrity of them.[37] People with different political leanings generally have faith in different authority figures.[38] This proved to be detrimental during the COVID-19 public health emergency, as deep partisan divides affected perceptions of the danger of COVID-19, self-reported behaviors like mask wearing and social distancing, and ultimately views on vaccinations.[39] Political partisanship is a stronger predictor of whether someone has received the COVID-19 vaccine than demographic factors such as age, race and level of education, displaying the reach the politicization of COVID-19 has had on vaccination uptake.[40] The effects of such government action manifested as vaccine hesitancy, with strong partisan differences

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[34] *Id.*
[35] *Id.*; Sharon LaFraniere & Noah Weiland, *White House Blocks New Coronavirus Vaccine Guidelines*, THE N.Y. TIMES, https://www.nytimes.com/2020/10/05/us/politics/coronavirus-vaccine-guidelines.html (Oct. 23, 2020).
[36] *See generally* Tollefson, *supra* note 30 (discussing how President Trump's actions exacerbated the pandemic and undermined science and scientific institutions).
[37] *See* Suwondo et al., *supra* note 6 (discussing how the actions of the Trump administration jeopardized the perceived integrity of the CDC and FDA).
[38] Bliss et al., *supra* note 3.
[39] Ashley Kirzinger et al., *KFF Covid-19 Vaccine Monitor: The Increasing Importance of Partisanship in Predicting COVID-19 Vaccination Status*, KAISER FAM. FOUND. (Nov. 16, 2021), https://www.kff.org/coronavirus-covid-19/poll-finding/importance-of-partisanship-predicting-vaccination-status/.
[40] *Id.*

evident in vaccine intentions formed.[41] For example, one study found that a large majority of unvaccinated adults are more likely to identify as Republicans or be Republican leaning, and this disproportionate gap only continues to grow.[42] COVID-19 is a key example of how politics can obstruct public health and hinder the use of new health technologies.[43]

The CDC and FDA have been at the forefront of the pandemic, and the public's perception of these agencies' credibility has led to mistrust in the COVID-19 vaccine that continues to jeopardize the best path to ending the pandemic.[44] Throughout the pandemic, the FDA has been responsible for the authorization of vaccines and diagnostic tests for the disease.[45] The CDC, on the other hand, is mandated with protecting the health of Americans, fighting disease globally, conducting research, and acting as a first responder to crisis.[46] Ensuring both the actual and perceived scientific integrity in these agencies is of crucial importance in ending the global pandemic and restoring trust in science and healthcare technology.[47] The success of future technologies will largely be influenced by the extent to which people trust in their effectiveness, the competence and reliability of the institutions that deliver them, and the principles that guide government decisions and actions surrounding the technologies.[48] Therefore, it is crucial to enact measures that

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[41] Grace Sparks et al., *KFF COVID-19 Vaccine Monitor: Profile of the Unvaccinated*, Kaiser Fam. Found. (Jun. 11, 2021), https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-profile-of-the-unvaccinated/.
[42] *Id.;* Kirzinger et al., *supra* note 39.
[43] *Id.*
[44] Suwondo et al., *supra* note 6.
[45] Claire Felter, *What is the FDA's Role in Public Health?* COUNCIL ON FOREIGN RELS., https://www.cfr.org/backgrounder/what-fdas-role-public-health (Sep. 10, 2021, 2:40 PM).
[46] Claire Felter, *What Does the CDC Do?* COUNCIL ON FOREIGN RELS., https://www.cfr.org/backgrounder/what-does-cdc-do (May 18, 2021, 7:00 AM).
[47] Suwondo et al., *supra* note 6.
[48] *Enhancing Public Trust in COVID-19 Vaccination: The Role of Governments*, *supra* note 4.

safeguard these principles and protect against threats to scientific integrity that materialized during the COVID-19 pandemic. These measures should proscribe political interference that undermines the credibility of federal institutions like the CDC and FDA as unlawful and establish credible enforcement mechanisms to deter and penalize such behavior.[49] The harm to these agencies will linger well beyond the COVID-19 pandemic unless interventions are enacted to restore public trust in science.[50]

INTERVENTION: DANGEROUS SPEECH AND THE PROTECTION OF SCIENCE

For over two decades, the United States has declared pandemics to be a national security threat but has not acted or organized itself accordingly.[51] During the COVID-19 pandemic, amid other problems, too many federal, state, and local officials failed to communicate a clear, science-based, consistent message to the U.S. population, and the White House continuously downplayed the seriousness of the pandemic.[52] This resulted in wasting precarious weeks that could have been used to implement public health interventions.[53] Displayed through the outbreak of COVID-19, it is clear certain speech can undermine the general welfare and threaten national security.[54] Further, in recent years, the norms and expectations that once ensured that our government was guided primarily by public interest have significantly weakened as current rules allow moneyed interests to provide substantial support to public officials before, during, and after their public

[49] Suwondo et al., *supra* note 6.
[50] Parikh, *supra* note 7.
[51] BURWELL ET AL., *supra* note 12 at 5, 51.
[52] *Id.* at 51, 52.
[53] *Id.* at 52.
[54] *See generally* BURWELL ET AL., *supra* note 12 (noting that the United States has declared the pandemic to be a national security threat).

service.[55] This creates monetary incentives for public officials to put their personal or political interests ahead of the public interest.[56] In order to alleviate the effects of this, legislators should establish clear red lines and consequences for political interference at the CDC and the FDA by passing new statutory protections for the integrity of federal science.[57] Accurate, non-political, government-supported research and analysis should be statutorily protected.[58] To achieve this, Congress should rapidly institute safeguards with language adopted from the Brennan Center Report on the topic of scientific integrity and previously introduced legislation such as the 2019 Scientific Integrity Act.[59] Broadly speaking, Congress should pass legislation to define and prohibit politically motivated manipulation and suppression of government research and data in the executive branch.[60] This legislation should also prohibit discrimination and retaliation against government researchers on the basis of their scientific conclusions.[61] In support of this, mechanisms to deter and punish inappropriate politicization of scientific conclusions should be employed.[62] Specific provisions could, for example: (1) make it unlawful for government officials to tamper with the conduct of federally funded scientific research or data for personal financial or partisan political gain; (2) make it unlawful for government officials to direct the dissemination of scientific information that the directing official knows is false or misleading; and (3) make it unlawful for

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[55] Preet Bharara et al., *Proposals for Reform*, 2 NAT'L TASK FORCE ON RULE OF L. & DEMOCRACY, 2019, at 1, 28.
[56] *Id.* at 28.
[57] Suwondo et al., *supra* note 6.
[58] Bharara et al., *supra* note 55 at 1.
[59] Suwondo et al., *supra* note 6.
[60] *Id*. at 9.
[61] *Id.*
[62] Bharara et al., *supra* note 55 at 2.

government officials to retaliate or discriminate against government researchers for the development or dissemination of scientific research or analysis that the researchers reasonably believe to be accurate and valid.[63] Communication by the government needs to be balanced and contextualized to clearly convey to the American public what is and is not known, and to avoid reinforcing cognitive biases.[64] Additionally, political authorities should be prepared to adjust their public health guidance as scientific evidence emerges.[65]

Such provisions all aim for the same effect: restoring the public's trust in science and the scientific process, thereby maintaining the public's confidence in the healthcare technology that results from it.[66] A statute like the one aforementioned collectively aims to demand that U.S. officials deliver clear, science-driven communication, especially on public health matters.[67] Additionally, by rebuilding scientific integrity, such a statute could better enable agencies like the CDC and FDA to be front and center in public health education efforts, further garnering trust in new healthcare technology.[68] These suggestions serve to uphold the value of effective political leadership in solidifying the global importance of public health.[69] To ensure that such legislation would not penalize legitimate supervisory interventions in scientific research, differences of opinion, and mere negligent errors in scientific judgment, the statute should demonstrate clear

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[63] *Id.* at 10; *See generally* Scientific Integrity Act, 117 H.R. 849 (2021) (A reintroduction of the 2019 Scientific Integrity Act establishing certain scientific integrity policies for federal agencies that fund, conduct, or oversee scientific research, and for other purposes.).
[64] *Enhancing Public Trust in COVID-19 Vaccination: The Role of Governments*, *supra* note 4 at 6.
[65] BURWELL ET AL., *supra* note 12 at 95.
[66] *See generally* Scientific Integrity Act, 116 H.R. 1209 (2019) (establishing certain scientific integrity policies for federal agencies that fund, conduct, or oversee scientific research, and for other purposes).
[67] BURWELL ET AL., *supra* note 12 at 94.
[68] *Id.* at 74.
[69] *Id.* at 3.

standards for intent.[70] For example, provisions should state that findings of prohibited political interference display a significant departure from accepted practices of the relevant research community; that the misconduct be committed intentionally, knowingly, or recklessly; and that the allegation be proven beyond a preponderance of evidence.[71] Creating legislation to protect scientific integrity is the only way to hold political officials accountable for the harm they have caused during the COVID-19 pandemic and will continue to cause in the future absent action being taken.[72] These protections would ensure that science, not political ideology or industry interests, informs our nation's policies, protects public health, and enhances public safety.[73]

These suggested provisions are not without merit, nor are they novel, as other countries have already implemented policies to protect federal scientific agencies and the scientific process from the influence of politics, ideology, and financial conflicts of interest.[74] For example, Canada's chief science advisor published a government-wide policy on scientific integrity, with directives against falsifying data, destroying records, and ignoring conflicts of interest, and a process to deal with infractions.[75] Additionally, some countries, like Spain, have begun monitoring disinformation campaigns in a systemic way and have implemented laws in response.[76] France, for example, passed a law against the manipulation of information in 2018.[77] In the United States, other scientific committees such as the National

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[70] Bharara et al., *supra* note 55 at 10.
[71] *Id.*
[72] Jacob Carter, *The Scientific Integrity Act's Reintroduction*, THE EQUATION (Feb. 4, 2021), https://blog.ucsusa.org/jacob-carter/the-scientific-integrity-acts-reintroduction/.
[73] *Id.*
[74] Bharara et al., *supra* note 55 at 7.
[75] *Id.*
[76] *Enhancing Public Trust*, *supra* note 4 at 16.
[77] *Id.*

Aeronautics and Space Administration (NASA), already have mechanisms in place that establish scientific integrity standards and create policies guaranteeing those standards.[78] For instance, during the George W. Bush administration, NASA's public affairs office engendered uncertainty around government findings when it censored government research for political reasons by changing report titles to obscure findings, eliminating politically controversial terms such as "global warming," and altering scientists' quotations.[79] Fortunately, NASA had laws and agency mechanisms in place to respond to this attack.[80] The NASA public affairs office had violated the National Aeronautics and Space Act's requirement that NASA offer "the widest possible practicable and appropriate dissemination" of information about its work.[81] Because of these measures, the NASA administrator was able to renew the agency's commitment to scientific openness and reform its public relations policy.[82]

Additionally, attempts by Congress have already been made to pass legislation protecting the integrity of science.[83] In response to threats to scientific integrity during the Bush administration, the Restore Scientific Integrity to Federal Research and Policymaking Act was introduced in 2005.[84] This legislation would have made political interference a prohibited personnel practice.[85] This is just one example of past attempts by Congress to spearhead reforms aimed at the growing politicization, and ultimately

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[78] Bharara et al., *supra* note 55 at 7.
[79] *Id.*
[80] *Id.*
[81] *Id.;* National Aeronautics and Space Act of 1958 (NASA), Pub. L. 85–568, §203(a)(3), July 29, 1958, 72 Stat. 426.
[82] Bharara et al., *supra* note 55 at 7.
[83] Scientific Integrity Act *supra* note 66; *see* Restore Scientific Integrity to Federal Research and Policymaking Act, 109 H.R. 839 (2005).
[84] Bharara et al., *supra* note 55 at 10.
[85] *Id.*; *see* Restore Scientific Integrity to Federal Research and Policymaking Act, 109 H.R. 839 (2005).

mistrust of government science that have threatened scientific integrity.[86] In 2019, when the Brennan Report was released by the National Task Force on Rule of Law and Democracy and the Scientific Integrity Act was introduced, the emergence of the novel coronavirus had not yet occurred. The Brennan Report focused largely on ongoing issues of scientific integrity such as those surrounding climate change.[87] As COVID-19 took the lives of millions, science and healthcare technology were thrust into the spotlight, putting scientific integrity at risk in an era where information, whether accurate or not, can reach millions at an unprecedented speed.[88] The COVID-19 pandemic has thus been a wakeup call, displaying that harm to the integrity of science through inaccurate or contradictory information conveyed by the government can be detrimental not only to public health, but to the application of healthcare technology now and in the future.

CONCLUSION

Though the pandemic is ongoing, it is not too early to begin extracting lessons so the United States is in a better position for the future.[89] COVID-19 illustrated that falsehoods can now spread faster and farther than accurate information, and that misinformation can pose a deadly threat to trust in science and scientific institutions.[90] In an effort to maintain social-political approval, officials prioritized politics thereby undermining science and creating distrust in key public health agencies such as the CDC and FDA.[91]

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[86] Bharara et al., *supra* note 55 at 5.
[87] *See generally id.*
[88] MURTHY, *supra* note 1 at 5.
[89] BURWELL ET AL., *supra* note 12 at 2.
[90] Wen-Ying, *supra* note 18.
[91] *See generally* Tollefson, *supra* note 30 (explaining how Trump's administration undermined scientific integrity to support political decisions).

It should be a fundamental obligation of U.S. officials to communicate with the American people in a clear, transparent, and science-based manner.[92] Congress should respond to potential threats to the integrity of government research and data, and ultimately their applications in healthcare technologies, by passing legislation that promotes a culture of openness and scientific inquiry, free from politically motivated suppression and manipulation.[93] The COVID-19 pandemic will likely not be the last time that health care technology is essential to society's triumph over existential threats.[94] Health emergencies are inevitable, but the systemic policy failures that we saw accompany the spread of COVID-19 are not.[95] The recommendations put forth are designed to ensure that in the wake of future public health emergencies, or in the release of highly publicized healthcare technology, the United States is better prepared to avoid at least some of what has occurred during COVID-19.[96] Science and its application through healthcare technology and innovation have been hurt. It will take time to regain the public's trust, but Congress must act now to prevent public health and technology advancements from being used as political tools as they have been during the COVID-19 pandemic, when instead, they should have been used to save lives.[97]

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[92] BURWELL ET AL., *supra* note 12 at 10.
[93] Bharara et al., *supra* note 55 at 7.
[94] Parikh, *supra* note 7.
[95] BURWELL ET AL., *supra* note 12 at 101.
[96] *Id.* at 12.
[97] *Id.* at 56.

Ensuring the Continued Efficacy of Telepsychiatry: Amending the Ryan Haight Act

Caitlin Bradford

COVID-19 LANDSCAPE

In response to the COVID-19 pandemic, the United States has seen an increase in the use of telehealth services.[1] "Telehealth" is an umbrella term that generally refers to three different types of physician-patient interaction via technology: synchronous audio-visual visits; "store and forward" communication that allows patients to share videos, photographs, and other health data with physicians; and remote patient monitoring, which implements technology that collects data and electronically transmits it to healthcare providers.[2] The use of technology to reduce in-person contact between patients and medical providers has allowed health systems to "facilitate patient triage, … conserve personal protective equipment, and reduce disease transmission."[3] Overall, the increase in virtual health care leads to improved access by decreasing the barriers of transportation and physical distance between patients and their healthcare providers.[4]

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[1] *See, e.g.*, Lisa M. Koonin et al., *Trends in the Use of Telehealth During the Emergence of the COVID-19 Pandemic—United States, January—March 2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 1595, 1598 (Oct. 30, 2020) ("Health care delivery has shifted during the COVID-19 pandemic, with telehealth encounters sharply increasing in late March 2020."); *see also* Devin M. Mann et al., *COVID-19 Transforms Healthcare Through Telemedicine: Evidence From the Field*, 27 J. AM. MED. INFORMATICS ASS'N 1132, 1133 (2020) ("In the nonurgent care setting, the forced transition to video visits has demonstrated its feasibility, satisfaction, and value in promoting social distancing."). Telehealth usage has fallen from the heights observed in 2020, but "adoption levels are still far higher than they ever were before the pandemic." Rhea Patel, *Telehealth use is waning, but not all is lost—here's how telehealth vendors can hold onto their new customers*, INSIDER INTELLIGENCE EMARKETER (Jun. 29, 2021), https://www.emarketer.com/content/telehealth-use-waning-not-all-lost-here-s-how-telehealth-vendors-hold-onto-their-new-customers.

[2] Jeremy Sherer & Amy Joseph, *Physician Law Evolving Trends and Hot Topics: Telehealth*, 32 NO. 3 HEALTH LAW. 20, 21 (2020).

[3] Hanna B. Demeke et al., *Trends in Use of Telehealth Among Health Centers During the COVID-19 Pandemic—United States, June 26—November 6, 2020*, 70 MORBIDITY & MORTALITY WKLY. REP. 240, 242 (Feb. 19, 2021).

[4] William Barbosa et al., *Improving Access to Care: Telemedicine Across Medical Domains*, 42 ANN. REV. PUB. HEALTH 463, 467 (2021) ("[I]ssues related to transportation and geographic distance will serve as less of a barrier to entry into the health care system and ideally lead to improved access.").

In particular, there has been a sharp increase in, and need for, the delivery of mental health care via telehealth during the pandemic.[5] In January 2021, an American Psychiatric Association (APA) survey of its members found that eighty-one percent of respondents reported seeing between seventy-five percent and one-hundred percent of their patients via telehealth.[6] This is a sharp increase from pre-COVID-19 surveys, in which a majority of respondents reported treating zero percent of their patients via telehealth.[7] Correspondingly, stressors of the pandemic have also increased the need for mental health care.[8] In fact, eighty-four percent of respondents to the APA's recent survey confirmed that they began seeing new patients during the pandemic.[9] The APA also reports that the ability to see healthcare providers in the comfort of patients' own homes contributes to overall patient satisfaction and increases the likelihood of continued treatment.[10] Overall, the recent use of telehealth in mental health care contexts has improved the quality of mental health care—"improved access, better outcomes overall, decreased cost[, and preservation of] limited community resources (e.g., too few psychiatric beds)."[11]

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[5] Jacob C. Warren & K. Bryant Smalley, *Using Telehealth to Meet Mental Health Needs During the COVID-19 Crisis*, THE COMMONWEALTH FUND (June 18, 2020), https://www.commonwealthfund.org/blog/2020/using-telehealth-meet-mental-health-needs-during-covid-19-crisis; Jacob T. Kannarkat et al., *Mobilization of Telepsychiatry in Response to COVID-19—Moving Toward 21st Century Care*, 47 ADMIN. & POL'Y MENTAL HEALTH & MENTAL HEALTH SVCS. RSCH. 489, 490 (2020).

[6] *Psychiatrists Use of Telepsychiatry During COVID-19 Public Health Emergency: Survey Results*, AM. PSYCHIATRIC ASS'N, 1 (July 2021), https://www.psychiatry.org/File%20Library/Psychiatrists/Practice/Telepsychiatry/APA-Telehealth-Survey-2020.pdf.

[7] *Id.*

[8] *See* Warren & Smalley, *supra* note 5 (discussing the increase in need for mental health services during the pandemic); Kannarkat, *supra* note 5, at 490 ("With widespread shelter-in-place orders and impending economic recession, many of our patients are put at risk of negative mental effects from a worsening life situation.").

[9] *Psychiatrists Use of Telepsychiatry During COVID-19 Public Health Emergency: Survey Results*, *supra* note 6, at 2.

[10] *Id.*

[11] *Id.*

In an era that prioritizes the reduction of person-to-person contact to mitigate the spread of disease, telehealth not only serves as a safety measure within physician-patient interaction but also offers the potential for improved care.[12] The benefits of telepsychiatry, including the writing of prescription medications during telehealth services, should be allowed to continue even after the end of the COVID-19 public health emergency. Writing prescriptions for patients is one of the core aspects of psychiatric treatment.[13] However, the prescription of certain medications—controlled substances[14]—has, since 2008, been restricted by a requirement that psychiatrists evaluate their patients in person.[15]

In 2008, Congress passed an amendment to the Controlled Substances Act (CSA)—the Ryan Haight Online Pharmacy Consumer Protection Act (Ryan Haight Act).[16] The act's namesake, Ryan Haight, was a seventeen-year-old who purchased Vicodin[17] and other drugs from an online pharmacy

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[12] *See* Demeke, *supra* note 3, at 242 ("Telehealth visits can facilitate patient triage, which can reduce the effect of patient surge on facilities…conserve personal protective equipment, and reduce disease transmission."); *see Psychiatrists Use of Telepsychiatry During COVID-19 Public Health Emergency: Survey Results*, supra note 6, at 2 (reporting improvements telepsychiatry has made to mental health care).

[13] *What is Psychiatry?*, AM. PSYCHIATRIC ASS'N, https://www.psychiatry.org/patients-families/what-is-psychiatry-menu (last visited Oct. 23, 2021).

[14] The controlled substances most commonly prescribed by psychiatrists are benzodiazepines (e.g. clonazepam and alprazolam, Schedule IV controlled substances, to treat anxiety) and stimulants (e.g. methylphenidate and amphetamine, Schedule II controlled substances, to treat attention deficit hyperactivity disorder (ADHD)). *Most Common Psychiatric Controlled Substances*, THERANEST (Nov. 23, 2020), https://theranest.com/blog/most-common-psychiatric-controlled-substances/.

[15] 21 U.S.C. § 829(e)(2)(A)(i) (2012) ("a practitioner who has conducted at least 1 in-person medical evaluation of the patient").

[16] Ryan Haight Online Pharmacy Consumer Protection Act, Pub. L. No. 110-425, 122 Stat. 4820 (codified in scattered sections of the Controlled Substances Act, 21 U.S.C. § 801 et seq.).

[17] Vicodin is a pain medication containing hydrocodone, an opioid painkiller, that is a Schedule II controlled substance. Michelle Andrews, *DEA: Vicodin, Some Other Pain Meds Will Be Harder to Get*, KAISER HEALTH NEWS (Sep. 26, 2014), https://khn.org/news/dea-painkiller-reclassification-harder-prescription/. It is not a medication typically prescribed by psychiatrists. *See Most Common Psychiatric Controlled Substances*, *supra* note 14.

and subsequently passed away from an overdose.[18] Congress acted in response to the danger of online pharmacies filing prescriptions for controlled substances without ensuring that the prescribing doctor had in fact communicated with the patient seeking to fill the prescription.[19] The act imposes many restrictions on the virtual prescription of controlled substances, including the requirement that a physician conduct an in-person medical evaluation of their patient for the prescription to be considered "valid."[20]

The Drug Enforcement Agency (DEA) is the federal agency responsible for enforcing the Ryan Haight Act.[21] The declaration of a Public Health Emergency (PHE) by the Secretary of Health and Human Services (HHS), in response to COVID-19, prompted the DEA to allow the prescription of controlled substances without an in-person consultation.[22] Through the temporary removal of this restriction on telehealth services, physicians are only required to use "a real-time, two-way, audio-visual communications device" to evaluate a patient before prescribing a controlled substance.[23] In other words, physicians can use a synchronous virtual visit instead of an in-person visit to lawfully prescribe controlled substances under the DEA's

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[18] Bethany Lipman, *Prescribing Medicine for Online Pharmacies: An Assessment of the Law and a Proposal to Combat Illegal Drug Outlets*, 50 AM. CRIM. L. REV. 545, 545-46 (2013).
[19] *Id.*
[20] 21 U.S.C. § 829(e)(2)(A)(i) (2012).
[21] Kierin Bernard, *Telemedicine and the Ryan Haight Act: An Analysis of the Ryan Haight Act's Statutory Purpose, Its Inadvertently Negative Impact on the Telemedicine Industry, and the Future of Telemedicine*, 10 WAKE FOREST J. L. & POL'Y 59, 59 (2020).
[22] Roger Cohen & Madison Marcus, *Prescribing Controlled Substances Via Telemedicine Remains Reliant On Public Health Emergency Exception*, JDSUPRA (Jan. 29, 2021), https://www.jdsupra.com/legalnews/prescribing-controlled-substances-via-1402604/; *How to Prescribe Controlled Substances to Patients During the COVID-19 Public Health Emergency*, DEA DIVERSION CONTROL DIV. (effective Mar. 31, 2020), https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-023)(DEA075)Decision_Tree_(Final)_33120_2007.pdf.
[23] *How to Prescribe Controlled Substances to Patients During the COVID-19 Public Health Emergency*, *supra* note 22.

policy in response to the pandemic. It is noteworthy that, despite the potentially lethal consequences of controlled substance misuse—consequences the COVID-19 pandemic does not lessen—the DEA chose to adopt policies that relax the in-person consultation requirement to allow patients to receive valid prescriptions.[24] Yet, this leniency is only in effect for the duration of the PHE.[25] It is clear from the agency's publication of the "Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008" that, once there is no longer a PHE, the DEA intends to enforce the in-person requirement for prescriptions of controlled substances.[26] This publication delineates the DEA's final rule for the Ryan Haight Act, effective October 30, 2020.[27] The DEA explains that the Ryan Haight Act "makes it unambiguous that it is a per se violation of the CSA for a practitioner to issue a prescription for a controlled substance by means of the internet [sic] without having conducted at least one in-person medical evaluation."[28] Therefore, the PHE is the sole reason why physicians are currently able to prescribe controlled substances without an in-person consultation.[29]

The relaxation of the in-person requirement because of the PHE is "essential" for mental health physicians and patients to continue to benefit from the current expansion of telehealth.[30] Although the DEA engages in selective enforcement of certain drug laws and may generally use discretion

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[24] The DEA, on its COVID-19 Information Page, promises to "work to assure that patients will have access to necessary drug products containing controlled substances." *COVID-19 Information Page*, DEA DIVERSION CONTROL DIV., https://deadiversion.usdoj.gov/coronavirus.html (last visited Oct. 24, 2021).
[25] *Id.*
[26] Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, 85 Fed. Reg. 61594, (Sept. 30, 2020) (to be codified at 21 C.F.R. pt. 1300, 1301, 1304, 1306).
[27] *Id.* at 61594.
[28] *Id.* at 61595.
[29] *How to Prescribe Controlled Substances to Patients During the COVID-19 Public Health Emergency*, *supra* note 22.
[30] *Psychiatrists Use of Telepsychiatry During COVID-19 Public Health Emergency: Survey Results*, *supra* note 6, at 1.

in deploying its resources,[31] the DEA has shown its willingness to enforce the in-person requirement as soon as the PHE ends. Telepsychiatry providers and patients should not rely on future selective enforcement to provide and receive effective care. The PHE will eventually end, and the benefits of expanded telehealth services, especially telepsychiatry, made apparent by the PHE, will end with it—unless Congress acts. Consequently, Congress should amend the Ryan Haight Act to specifically allow mental health professionals to prescribe controlled substances to patients without an in-person consultation requirement to ensure the continued efficacy of telepsychiatry.[32]

HISTORY OF ATTEMPTS TO AMEND THE RYAN HAIGHT ACT

There have been three attempts by Congress to amend the Ryan Haight Act.[33] First, the Improving Access to Remote Behavioral Health Treatment Act was introduced in the House of Representatives in July of 2019.[34] This bill aimed to ensure that "qualified community mental health centers" could

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[31] Rachel E. Barkow, *Overseeing Agency Enforcement*, 84 GEO. WASH. L. REV. 1129, 1158 (2016).

[32] Of the 25 most commonly prescribed psychiatric medications in 2018, five—Adderall (amphetamine), Concerta (methylphenidate), Vyvanse (lisdexamfetamine), Xanax (alprazolam), and Ativan (lorazepam)—are controlled substances under the CSA. John M. Grohol, *Top 25 Psychiatric Medications for 2018*, PSYCHCENTRAL (Dec. 15, 2019), https://psychcentral.com/blog/top-25-psychiatric-medications-for-2018?c=866065314688#Most-Prescribed-Psychiatric-Drugs-for-2018; *see Controlled Substances by CSA Schedule*, DEA DIVERSION CONTROL DIV. (Aug. 27, 2021), https://www.deadiversion.usdoj.gov/schedules/orangebook/e_cs_sched.pdf. None of those drugs are opioids like the Vicodin that killed Ryan Haight.

[33] Improving Access to Remote Behavioral Health Treatment Act of 2019, H.R. 4131, 116th Cong. (2019); Special Registration for Telemedicine Clarification Act of 2018, H.R. 5483, 115th Cong. (2018) (codified at 21 U.S.C. § 831(h)(2)), enacted as part of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act, Pub. L. No. 115-271, § 3232, 132 Stat. 3894, 3950 (2018); Telehealth Response for E-prescribing Addiction Therapy Services Act, S. 340, 117th Cong. (2021-2022).

[34] H.R. 4131.

"administer controlled substances through the practice of telemedicine."[35] Therefore, the bill proposed to expand the existing provision of the Ryan Haight Act that allows for prescription of controlled substances via telemedicine if "the patient is being treated by, and [is] physically located in, a hospital or clinic" that is registered with the DEA.[36] Correspondingly, the bill would have allowed mental health centers to "obtain the necessary DEA registration as a clinic" so their patients could be prescribed controlled substances via telehealth.[37]

Second, the Special Registration for Telemedicine Clarification Act of 2018 was enacted as part of the Substance-Use Disorder Prevention that Promotes Opioid Recovery and Treatment ("SUPPORT") for Patients and Communities Act in 2018.[38] The act set a deadline of "not later than 1 year after" its enactment to activate "a special registration to engage in the practice of telemedicine."[39] The special registration clause, present since the Ryan Haight Act's passage in 2008, "was designed to allow telemedicine prescribing…without an in-person exam."[40] The SUPPORT Act simply requires the DEA to 1) enact regulations delineating the circumstances where a special registration can be issued and 2) establish the procedure for obtaining a special registration.[41] Yet, the DEA missed this deadline and has

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[35] *Id.* at §2.
[36] 21 U.S.C. § 802 (54)(A)(i) (2018).
[37] Bernard, *supra* note 21, at 72.
[38] Bernard, *supra* note 21, at 74; Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, *supra* note 26.
[39] 21 U.S.C. § 831(h)(2) (2018); Jacqueline N. Acosta & Nathaniel M. Lacktman, *President Signs New Law Allowing Telemedicine Prescribing of Controlled Substances: DEA Special Registration to Go Live*, FOLEY & LARDNER LLP: HEALTH CARE TODAY (Oct. 25, 2018), https://www.foley.com/en/insights/publications/2018/10/president-signs-new-law-allowing-telemedicine-pres.
[40] Acosta & Lacktman, *supra* note 39; 21 U.S.C. § 802(54)(E) (2021).
[41] 21 U.S.C. § 831(h)(2).

not complied with the act; therefore, there is no current special registration option for physicians.[42]

The third, and currently ongoing, attempt to amend the Ryan Haight Act was introduced in the Senate on February 22, 2021.[43] The Telehealth Response for E-prescribing Addiction Therapy Services (TREATS) Act, if passed, would allow Schedule III or IV drugs to be prescribed without the in-person requirement, provided that physicians conduct evaluations through two-way audio-visual technology.[44]

Overall, the proposed exception for patients in certain mental health care clinics to be validly prescribed controlled substances via telemedicine is so narrow that the in-person requirement remains a substantial barrier; ultimately, this change would still require the patient to be physically present at a mental health clinic. Telemedicine's benefits should not be limited only to those who have access to in-person mental health treatment. Also, the DEA's failure to enable the special registration process demonstrates its de-prioritization of the benefits of telepsychiatry. Unfortunately, the DEA's regulatory idleness will directly affect the efficacy of patient care once the PHE ends. In addition, even if the DEA were to enable the special

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[42] Malka Berro, *DEA Misses Deadline for Teleprescribing Special Registration*, NAT'L COUNCIL FOR MENTAL WELLBEING (Oct. 31, 2019), https://www.thenationalcouncil.org/capitol-connector/2019/10/dea-misses-deadline-for-teleprescribing-special-registration/.

[43] Telehealth Response for E-prescribing Addiction Therapy Services (TREATS) Act, S.340, 117th Cong. (2021), https://www.congress.gov/bill/117th-congress/senate-bill/340/actions. There is also an identical bill that was introduced in the House of Representatives on March 8, 2021. Telehealth Response for E-prescribing Addiction Therapy Services (TREATS) Act, H.R. 1647, 117th Cong. (2021), https://www.congress.gov/bill/117th-congress/house-bill/1647/actions.

[44] S.340; Marshall E. Jackson & Emma Chapman, *Treats Act Aims to Expand Use of Telehealth to Treat Substance Use Disorder*, MCDERMOTT WILL & EMORY LLP: INSIGHTS (Aug. 13, 2020), https://www.mwe.com/insights/treats-act-aims-to-expand-use-of-telehealth-to-treat-substance-use-disorder/ ("While Senators Portman and Whitehouse introduced a bill largely to expand the use of telehealth to treat substance use disorder, it would have broader ramifications because the bill (as proposed) would apply to all Schedule III and IV controlled substances, regardless of the reason for which the substances are prescribed.").

registration process through (overdue) regulation, it could still write regulations "so narrow that it would be nearly impossible to receive the special registration."[45] Therefore, more extensive Congressional action is necessary.

The TREATS Act is bolder than the other two attempts, as it directly addresses the Ryan Haight Act's in-person requirement. However, the bill fails to provide flexibility for all mental health care providers, since it limits the removal of the in-person requirement to the prescription of Schedule III and IV drugs. Mental health patients also require Schedule II drugs; for example, amphetamine, methylphenidate, and lisdexamfetamine—stimulants commonly used to treat ADHD—are Schedule II drugs.[46] Therefore, the amendment does not improve access for all patients struggling with mental health issues, since it maintains the in-person requirement for individuals who need Schedule II drugs.

Significantly, the attempts to amend the Ryan Haight Act center on the policy goal of improving mental health care.[47] To further that aim, Congress may be open to amending the Act to specifically improve mental health care, though concerns about risks surrounding other specialties—the risks that led to the passage of the Ryan Haight Act in the first place—may remain.[48]

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[45] Dillon Vaughn, *Amending the Ryan Haight Act: Elevating Telemedicine Law to New Heights*, 7 TEX. A&M L. REV. 475, 484 (2020).

[46] *Mental Health Medications*, NAT'L INST. MENTAL HEALTH, https://www.nimh.nih.gov/health/topics/mental-health-medications (last visited Oct. 17, 2021); *Controlled Substances—Alphabetical Order*, DEA 1, 12 (Aug. 27, 2021), https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf.

[47] This policy goal is indicated in the proposed legislation's designations: "The Improving Access to Remote Behavioral Health Treatment Act" and "Substance-Use Disorder Prevention that Promotes Opioid Recovery and Treatment ("SUPPORT") for Patients and Communities Act."

[48] As noted above, five of the most commonly prescribed psychiatric medications are controlled substances. *Supra*, note 32. Of the most commonly prescribed psychiatric medication, none are opioid painkillers of the sort that caused the death of Ryan Haight and kill about 50,000 Americans each year. *Opioid Overdose Crisis*, NIH NAT'L INST. ON DRUG ABUSE (Mar. 11, 2021), https://www.drugabuse.gov/drug-topics/opioids/opioid-overdose-crisis.

Nevertheless, past efforts by Congress have failed to make comprehensive changes to the Ryan Haight Act that reflect the post-COVID-19 mental health care landscape and consider the needs of all mental health patients. Therefore, Congress must amend the in-person requirement to allow mental health professionals to prescribe controlled substances, of all Schedules, to their patients by conducting a two-way audio-visual exam.

DISCUSSION OF PROPOSED ACTION–ALLOWING PSYCHIATRIST TO PRESCRIBE CONTROLLED SUBSTANCES BY CONDUCTING AN AUDIO VISUAL EXAM

The hesitancy to void the in-person requirement for the prescription of controlled substances is grounded in policy concerns over drug misuse.[49] The in-person requirement can be viewed as a protection "preventing individuals with drug habits from 'virtual-doctor shopping' for dangerous drugs and controlled substances."[50] Yet, to properly confront the concern surrounding "virtual-doctor shopping" requires us to ask the question: is an in-person medical evaluation fundamentally different than a two-way audio-visual visit in the psychiatric care context?

The literature suggests that the answer to that question is no. The APA reports that many mental health patients find comfort in virtual visits and that

[49] The Senate Judiciary Committee reports, in response to the proposed Ryan Haight bill, that there is a need for legislation because of an "alarming rise in abuse of prescription controlled substances." S. REP. NO. 110-521, at 2 (2008). *See generally* Charles Preuss et al., *Prescription of Controlled Substances: Benefits and Risks*, STAT PEARLS (Aug. 31, 2021), https://www.statpearls.com/ArticleLibrary/viewarticle/40661 ("In the 1990s…opioid analgesic prescribing was expanded …[and] led to increased overuse, diversion of drugs, opioid use disorder, and overdose.").

[50] Madeline Rosuck, *Telemedicine is the New Narcotics Candy Store: Teladoc Opens the Floodgates for the Unrestricted Sale of Dangerous Drugs*, 21 SMU SCI. & TECH. L. REV. 89, 93 (2018) (demonstrating concern for the prescription of controlled substances without an in-person evaluation).

they "can create enhanced feelings of safety, security, and privacy."[51] Therefore, the cornerstone of the mental health treatment model, talk therapy, can be more effective through a screen.[52] That telepsychiatry is effective for talk therapy is not surprising, considering that the pandemic has increased everyday use of technology in other spaces that were traditionally in-person—for example, work, school, and religious worship.[53] Further, psychiatric care models often include the prescription of medications along with psychotherapy.[54] The classes of medications psychiatrists typically prescribe include antidepressants, antipsychotic medications, sedatives, anxiolytics, hypnotics, mood stabilizers, and stimulants.[55] As alluded to in the previous section, psychiatrists prescribe a range of Schedule II, III, and IV drugs to address the specific needs of their patients.[56] Like many other practitioners, psychiatrists complete thorough evaluations—which can be done with a synchronous online visit—before prescribing medications.[57]

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[51] *What is Telepsychiatry?*, *Benefits*, AM. PSYCHIATRIC ASS'N, https://www.psychiatry.org/patients-families/what-is-telepsychiatry (last visited Sept. 15, 2021).

[52] *Id.* ("Some people may be more relaxed and willing to open up from the comfort of their home or a convenient local facility.").

[53] *See, e.g.*, Michael Liedtke, *The Zoom boom is ebbing; what's videoconferencing app's post-pandemic future?*, CHI. TRIBUNE (Mar. 2, 2021, 8:04 AM), https://www.chicagotribune.com/business/ct-biz-zoom-videoconferencing-covid-19-20210302-wvcc376ni5c2rhsc3grzztjsva-story.html ("... Zoom's name became synonymous with the way millions of people have been forced to gather in online video panels while being corralled at home.").

[54] *What is Psychiatry?*, *supra* note 13.

[55] *Id.*

[56] Amphetamine is a Schedule II drug marketed under the brand name Adderall and usually prescribed to address ADHD. *Mental Health Medications*, *supra* note 46; *Controlled Substances—Alphabetical Order*, *supra* note 46, at 6. Buprenorphine is a Schedule III drug used to treat opioid abuse. Brian Mund & Kate Stith, *Law and the Opioid Crisis: Buprenorphine MAT as an Imperfect Fix*, 46 J. L. MEDICINE & ETHICS 279, 279 (2018); *Controlled Substances—Alphabetical Order*, *supra* note 46, at 6. Alprazolam, marketed under the brand name Xanax, is a Schedule IV drug that is commonly prescribed to patients with anxiety. *Mental Health Medications*, *supra* note 46; *Controlled substances—Alphabetical Order*, *supra* note 46, at 5.

[57] *What is Psychiatry?*, *supra* note 13; M. O'Brien & F. McNicholas, *The Use of Telepsychiatry During COVID-19 and Beyond*, 37 IRISH J. PSYCH. MED. 250, 251 (2020) ("Research has indicated has indicated that telepsychiatry is comparable to face-to-face services in terms of reliability of clinical assessments and treatment outcome."); according to

Even before this pandemic, there was substantial evidence supporting the conclusion that there is "no difference between reliability and diagnostic accuracy of telepsychiatric assessments, compared to face-to-face assessments."[58] This conclusion suggests that physicians who prescribe controlled substances after tele-visits are just as confident in their diagnostic determination as when they see a patient face-to-face. The unvaried degree of diagnostic accuracy between an in-person and telepsychiatry evaluation indicates that an in-person consultation requirement is unnecessary to mitigate risks of patients' untethered access to controlled substances.

Other telehealth models, such as "store and forward" practices, offer an asynchronous opportunity for diagnosis and treatment that may not alleviate "virtual-doctor shopping" concerns.[59] First, the lack of a real-time conversation with a physician is similar to the circumstances that prompted Congress to pass the Ryan Haight Act in the first place; that similarity may deter Congress from approving prescription of controlled substances without a real-time conversation.[60] Further, unlike other medical conditions, mental health issues are often intangible and must be confirmed by a real-time conversation.[61] For example, unlike a dermatology patient, a patient

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the DEA's current policy, physicians may complete the evaluations necessary to lawfully prescribe controlled substances through a synchronous virtual visit. *How to Prescribe Controlled Substances to Patients During the COVID-19 Public Health Emergency*, *supra* note 22.

[58] Subho Chakrabarti, *Usefulness of Telepsychiatry: A Critical Evaluation of Videoconferencing-Based Approaches*, 5 WORLD J. PSYCHIATRY 286, 290 (2015).

[59] The nature of the "store and forward" telehealth model requires an "image" to be "sufficient to competently treat a patient." Sherer & Joseph, *supra* note 2, at 21. Patients who participate in "virtual doctor shopping" benefit from the lack of an in-person requirement, which is inherent in the store and forward model; the practice may "essentially allow […] for the unrestricted distribution of drugs" because there is no requirement for "a doctor to conduct a physical examination to determine whether the drugs are medically necessary." Rosuck, *supra* note 50, at 93, 95.

[60] *See supra* note 49.

[61] *See* Chakrabarti, *supra* note 58, at 290 ("… videoconferencing-based assessments appear to be comparable to face-to-face evaluations.").

suffering from depression cannot take a picture of their symptoms. By contrast, psychiatrists are able to assess their patients through videoconferencing just as effectively as they can in person.[62]

In addition, it is important to note that changing the in-person visit requirement to a virtual two-way audio-visual exam will not completely eliminate barriers to mental healthcare access.[63] However, this amendment increases access to care, as it will offer an additional avenue to full psychiatric treatment—talk therapy and medication.[64] Therefore, the value of telepsychiatry in a post-pandemic world is that it offers patients with mental health concerns an additional, effective care option centered around convenience and efficiency.[65] For some mental health patients, virtual visits may be preferable to in-person visits due to the nature of their illness.[66] Yet, even if telepsychiatry simply makes patients' lives easier by providing virtual access to full psychiatric care, the accuracy of telepsychiatry[67] supports eliminating the need for an in-person exam to prescribe controlled substances. Nearly two years into the COVID-19 pandemic, the nature of daily life and its intersection with the online world have drastically changed,

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[62] Amy Gajaria et al., *Telepsychiatry: Effectiveness and Feasibility*, 3 SMART HOMECARE TECH. & TELEHEALTH 59, 61 (2015).

[63] Access to a computer with video capability and reliable Internet access is not feasible for many low-income patients. *See* O'Brien & McNicholas, *supra* note 57, at 252 (discussing "the digital divide—the uneven distribution of access to required technology" across geographical and socioeconomic populations).

[64] Because technology is not accessible to every patient, the need for in-person care can never be completely eliminated. *See* Chakrabarti, *supra* note 58, at 298 ("Accordingly, at present telepsychiatric services can only serve as an adjunct to the more traditional modes of service-delivery, but can never replace them.").

[65] O'Brien & McNicholas, *supra* note 57, at 251-252.

[66] *See id.* at 251 (noting that patients with severe anxiety disorders may prefer virtual visits to in-person interaction).

[67] *See* Donald M. Hilty et al., *The Effectiveness of Telemental Health: A 2013 Review*, 19 TELEMEDICINE & E-HEALTH 444, 451 (determining that telemental health services are "unquestionably effective" for diagnosis and assessment across many populations and are comparable to in-person care).

and the federal regulation of telehealth should reflect that change, regardless of the nation's PHE status.

Of course, if Congress were to carve out a telepsychiatry exception to the Ryan Haight Act, it would have to justify its treatment of mental health as different—less risky—than other types of telecare. While some may call for the complete, unqualified removal of the in-person medical exam requirement,[68] that may be a tougher sell for certain practice areas, depending on their adaptability to telemedicine. For instance, if a provider must engage with a patient via physical contact to determine their diagnosis, like physicians treating chronic pain, their practice is not as adaptable to telemedicine as psychiatry, which involves diagnosis solely through conversation.[69] Also, based on the policy concerns of previous attempts to alter the Act, Congress may be more willing to amend the Act for the direct purpose of improving mental health care.[70] Further, psychological burdens of lockdowns, social distancing, and family loss have placed mental health front and center in a way that it arguably has not been before.[71] In our

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[68] *See* Joshua D. McCann, *Do No Good: How Controlled Substance Regulations Prohibit the Use of Telemedicine to Provide Medication-Assisted Therapy for Opioid Use Disorder*, 56 TULSA L. REV. 313, 336 (2021) ("Congress should remove the in-person medical examination requirement from the CSA…").

[69] *See* David J. Tauben et al., *Optimizing Telehealth Pain Care After COVID*-19, 161 PAIN 2437, 2437 (2020) ("Pain medicine clinicians can interview, observe, and counsel patients with chronic pain through audiovisual technologies. However, performing the physical examination…is a crucial portion of accurate and thorough diagnostic evaluation of patients with chronic pain, needing to touch, press, palpate, and move patients.").

[70] Congress is currently amenable to legislation that focuses on mental health care treatment. *See, e.g.,* Mental Health Services for Students Act of 2021, H. R. 721, 117th Cong. (2021), https://www.congress.gov/bill/117th-congress/house-bill/721 (providing support for school-based mental health services); *see also* Resilience, Investment, Support, And Expansion ("RISE") From Trauma Act, S. 2086, 117th Cong. (2021), https://www.congress.gov/bill/117th-congress/senate-bill/2086/actions ("To improve the identification and support of children and families who experience trauma.").

[71] The COVID-19 Mental Health Research Act was introduced in the Senate on March 9, 2021. The bill requires the National Institute of Mental Health "to conduct or support research on the mental health consequences of COVID-19." COVID-19 Mental Health Research Act, S. 631, 117th Cong. (2021), https://www.congress.gov/bill/117th-congress/senate-bill/631/text (establishing funds to be used to research the impact of

increasingly divisive political landscape, measures to address this collective trauma may generate bipartisan support among legislators and their constituents.[72]

CONCLUSION

Congress should learn from the use of telepsychiatry throughout this pandemic and view its success as an opportunity to fundamentally improve mental health care.[73] Upon that reflection, Congress should look to amend the Ryan Haight Act to allow mental health providers to prescribe controlled substances by means of a two-way audio-visual visit. This action will allow patients to continue to be treated in their own homes and gain greater access to mental health care. Thus, this amendment is a necessary step to ensure the continued efficacy of telepsychiatry and evolution of mental health care.

COVID-19 on the mental health of a wide variety of subjects). The introduction of this bill suggests that the pandemic has directly affected mental health in ways that must be quantified and demonstrates that Congress has a heightened focused on mental health due to the pandemic.

[72] In fact, there is already bipartisan support for the TREATS Act, which is focused on accessibility to mental health care via telehealth but offers a narrower view of what this paper is proposing. The Senate bill is sponsored by a Republican and cosponsored by a Democrat. S. 340. The identical House bill is sponsored by a Republican and cosponsored by three Democrats and four Republicans. H.R. 1647.

[73] *See* O'Brien & McNicholas, *supra* note 57, at 254 ("It is crucial that this current era of increased use of telemedicine be seen as fertile ground for research, providing guidance for future direction.").

Impact Of Legislation Efforts On Telehealth Access And Disparities In Rural Illinois

Allyson Bremer

INTRODUCTION

The COVID-19 pandemic has demonstrated an expansion in use of telehealth resources while simultaneously highlighting disparities in access.[1] Scholars have documented inequities in access to digital health and online resources as the "digital divide," disparately affecting communities based on socioeconomic status.[2] For those in rural areas, the digital divide and access to care is influenced by various factors including access to reliable internet and broadband.[3] One potential lasting outcome from the pandemic is the codification of modern telehealth legislation that improves reimbursement rates and eliminates administrative barriers to providers and facilities administering telehealth.[4] The longer term effects from this legislation are yet to be seen, but will likely close the gap in coverage and access to rural populations, and potentially create new health delivery models for continuity of care.[5]

First, this paper will address current disparities in access to telehealth, including barriers to access and how the digital divide leads to inequalities in care. Additionally, this paper will discuss how rural populations are

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[1] Lauren A. Eberly et al., *Patient Characteristics Associated with Telemedicine Access for Primary and Specialty Ambulatory Care During the Covid-19 Pandemic*, JAMA NETWORK OPEN (2020), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2774488.
[2] Sarah Ryan, *Bridging The Digital Divide: How Covid-19's Telemedicine Expansion May Exacerbate Health Disparities For Low-Income, Urban, Black Patients*, 30 ANNALS HEALTH L. ADVANCE DIRECTIVE 295, 295 (2020).
[3] *Barriers to Telehealth Adoption*, TELEHEALTH EQUITY COAL. (Feb. 2, 2021), https://www.telehealthequitycoalition.org/barriers-to-telehealth-adoption.html.
[4] *See* Matthew Shatzkes, *The "State" of Telehealth: Illinois Moves to Expand Telehealth Coverage*, NAT'L L. REV., Volume XI, Number 159 (June 8, 2021), https://www.natlawreview.com/article/state-telehealth-illinois-moves-to-expand-telehealth-coverage (exploring Illinois' legislative efforts regarding newly passed HB 3308 and the Connect Illinois investment project).
[5] *Id.*

especially vulnerable to telehealth inequalities due to lack of access to in-person hospitals or clinics and unreliable broadband. Next, this paper will present legislative measures Illinois has taken to expand access to both telehealth and expanding broadband capabilities of the state. Finally, this paper will argue that these legislative efforts will have a significant impact on access to telehealth and create new options for delivery models in rural Illinois communities.

TELEHEALTH ADOPTION AND BARRIERS FOR RURAL COMMUNITIES

Telehealth, or telemedicine, is the delivery of health care to patients through remote means such as virtual visits, chat-based interactions, remote patient monitoring, and other technology-based modalities.6 Telemedicine can increase access to healthcare services, save time and expended resources when traveling to a physical office, lower healthcare costs, and improve care continuity for patients.7 Further, patients report very high satisfaction with telehealth visits.[8]

The COVID-19 pandemic highlighted the use of telehealth resources and brought telehealth into mainstream use.[9] Patient adoption of telehealth during the pandemic increased dramatically, in part due to limited availability of in-person clinics during shelter in place orders and fear of catching the virus while at a provider location.[10] While appointments at

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[6] ATA, *Telehealth: Defining 21st Century Care* (2020), https://marketing.americantelemed.org/hubfs/Files/Resources/ATA_Telehealth_Taxonomy_9-11-20.pdf.
[7] E. Ray Dorsey, *State of Telehealth*, 375(2) NEW ENG. J. MED. 154, 154–55 (2016).
[8] Jennifer M. Polinski, *Patients' Satisfaction with and Preference for Telehealth Visits*, 31(3) J. GEN. INTERNAL MED. 269, 271–72 (Mar. 2016).
[9] Bonnie Kaplan, *Revisiting Health Information Technology Ethical, Legal, And Social Issues and Evaluation: Telehealth/Telemedicine and Covid-19*, 143 INT. J. MED INFORM. (Nov. 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7831568/ (Summarizing ethical, legal, and social issues related to information technology in healthcare through the lens of telehealth and telemedicine).
[10] Eberly, *supra* note 1.

many institutions during the height of the pandemic were held almost exclusively through virtual modalities, not all populations had the same access to care.[11]

Patients who are low income, non-English speaking, or older are less likely to have access to or utilize telehealth resources.[12] There is substantial documentation of this "digital divide" in relation to access to health care and impact on health disparities.[13] Technological barriers contributing to the digital divide include access to digital devices (smartphone, laptop with video capability), internet access with adequate streaming speed, and an economically feasible data or Wi-Fi plan.[14] Social and other factors also contribute to the digital divide, such as age, access to a private location in which to conduct an appointment, and language barriers.[15] Major gaps in access remain surrounding affordability, availability, accessibility, accommodation, and acceptability of telehealth resources.[16]

One significant barrier to telehealth use is access to reliable highspeed broadband.[17] Patients without cellular or internet access are significantly

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[11] *Id.*
[12] *Id.*
[13] Ryan, *supra* note 2.
[14] *Barriers to Telehealth Adoption*, *supra* note 3.
[15] *Is Telehealth Transforming Care for Everyone?* TELEHEALTH EQUITY COAL. (Feb. 2, 2021), https://www.telehealthequitycoalition.org/is-telehealth-transforming-care-for-everyone.html.
[16] *See* Chad Ellimoottil et al., *Telehealth Research Incubator's Research Snapshots*, UNIV. OF MICH. INST. FOR HEALTHCARE POL. & INNOVATION (July 2021), https://ihpi.umich.edu/sites/default/files/2021-08/Telehealth_Research_Snapshots_Databook_2021.pdf (researching relationships between demographics, telehealth, and health care access).
[17] Kelly A. Hirko, *Telehealth In Response To The Covid-19 Pandemic: Implications For Rural Health Disparities*, 27(11) J. OF THE AM. MED. INFORMATICS ASS'N, 1816, 1817 (2020).

disadvantaged in utilizing telehealth expansion.[18] Populations from a lower socioeconomic class, older people, communities of color, and those in rural areas are more likely to live without access to reliable internet and broadband.[19] For rural populations in particular, the lack of access to broadband is critical for utilizing telehealth resources.[20]

Even prior to COVID-19, rural populations have struggled to obtain care due to closure of rural hospitals.[21] Nationwide, 138 rural hospitals have closed since 2010.[22] The surge in emergency and intensive care unit (ICU) care coupled with closed or limited-service units during the COVID-19 pandemic only exacerbated these closures, with more than three dozen hospitals going bankrupt or closing during the first year of the pandemic alone.[23] While nearly 20% of the U.S. population live in rural areas, rural health systems are struggling to survive financially for a multitude of reasons.[24] Challenges to rural hospitals include low patient volumes, higher patient morbidity, geographic isolation, and workforce shortages.[25] Rural communities face unique challenges such as declining populations, limited economic opportunities, and an older average population with compounding

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[18] Emily C Webber et al., *Health Care Disparities and Access to Video Visits Before and After the COVID-19 Pandemic: Findings from a Patient Survey in Primary Care*, J. TELEMEDICINE & E-HEALTH, (Aug. 27, 2021), https://pubmed.ncbi.nlm.nih.gov/34449270/.
[19] *Id.*; *See also* Robert Longley, Understanding America's Digital Divide, THOUGHTCO, (July 26, 2021), https://www.thoughtco.com/the-digital-divide-introduction-4151809.
[20] AM. HOSP. ASS'N, RURAL REPORT: CHALLENGES FACING RURAL COMMUNITIES AND THE ROADMAP TO ENSURE LOCAL ACCESS TO HIGH-QUALITY, AFFORDABLE CARE, (2019), https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/.
[21] Sean McCarthy, *Impact of Rural Hospital Closures on Health-Care Access*, 258 J. OF SURGICAL RSCH., 170, 170 (October 2020).
[22] CECIL G. SHEPS CTR. FOR HEALTH SERVS. RSCH., RURAL HOSPITAL CLOSURES, UNIV. OF N. C., https://www.shepscenter.unc.edu/programs-projects/rural-health/rural-hospital-closures/ (last visited Sept. 15, 2021).
[23] *See* AMERICAN HOSPITAL ASSOCIATION (AHA), FACT SHEET: COVID-19 PANDEMIC RESULTS IN BANKRUPTCIES OR CLOSURES FOR SOME HOSPITALS (2020), https://www.aha.org/fact-sheets/2020-11-09-fact-sheet-covid-19-pandemic-results-bankruptcies-or-closures-some-hospitals (describing the impact of Covid-19 on US hospitals through 2020).
[24] AM. HOSP. ASS'N, *supra,* note 20.
[25] *Id.*

health issues and comorbidities.[26] Although rural hospitals face a multitude of barriers, they are often a primary safety net for communities struggling to find essential health services, including primary care, emergency aid, and reproductive services.[27] Expanding telehealth is one alternative for rural communities to maintain access to care.[28]

ILLINOIS LEGISLATION THAT COULD EXPAND ACCESS TO TELEHEALTH

In Illinois, there are two recent legislative efforts designed to increase access to telehealth and expand telehealth capabilities. First, H.B. 3308, signed in July 2021, increases coverage for telehealth services by extending payment parity and restricting administrative burdens to patients and providers.[29] Second, Connect Illinois, a "strategic component of the comprehensive 2019 Rebuild Illinois infrastructure program and the state's five-year economic plan," is a broadband investment program that aims to increase broadband services across the state.[30]

Governor Pritzker signed Illinois H.B. 3308 into law on July 22, 2021.[31] The bill addresses continuation of access to medical and behavioral telehealth services mobilized during the COVID-19 pandemic and extends payment parity requirements for mental health and substance use disorder services, while authorizing all other telehealth services to be covered equally to in-

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[26] *Id.*
[27] *Id.*
[28] *Id.* (providing data on the increase in rural hospital closures, limiting access to care).
[29] H.B. 3308, 102nd Gen. Assemb. (Ill. 2021).
[30] *Connect Illinois,* IL. DEPT. OF COM. & ECON. OPPORTUNITY, https://www2.illinois.gov/dceo/ConnectIllinois/Pages/ConnectIL.aspx. (last visited Nov. 17, 2021). *See also Illinois Office of Broadband*, IL. DEPT. OF COM. & ECON. OPPORTUNITY, https://www2.illinois.gov/dceo/ConnectIllinois/Pages/ILOfficeofBroadband.aspx (last visited Nov. 17, 2021).
[31] Press Release, Governor JB Pritzker, Gov. Pritzker Signs Landmark Legislation Expanding Telehealth Access (July 22, 2021), https://www.illinois.gov/news/press-release.23606.html.

patient care though 2027.[32] H.B. 3308 is touted as one of the country's most progressive telehealth bills, eliminating outdated reimbursement and delivery provisions that previously have limited telehealth expansion.[33] Specifically, the bill establishes payment parity for services, expands covered services, and eliminates procedural and administrative barriers prior to accessing telehealth.[34] The legislation also prevents insurance plans from requiring a patient to prove hardship or an access barrier, or requiring a patient to attend an in-person visit before providing telehealth services.[35]

Additionally, Connect Illinois allocates $400 million to the development and expansion of the state's broadband network, including the creation of a Broadband Advisory Council and Broadband Office.[36] The Council was formed to explore broadband use, identify barriers to adoption, promote education, and advocate for the state.[37] The Council will also have several working groups with special focus on access, economic development, education, infrastructure, technology, and telehealth.[38] Governor Pritzker started the statewide initiative in August 2019 to "promote digital literacy, adoption, and inclusion while leveraging investment in new broadband infrastructure to spur advances in such areas as economic development, education, precision agriculture, and telehealth".[39] The Illinois broadband grant program announced the first round of funding in June 2020, and

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[32] *Id.*
[33] Eric Wicklund, *New Illinois Law Gives Patients the Right to Choose - or Reject - Telehealth*, MHEALTHINTELLIGENCE (July 23, 2021), https://mhealthintelligence.com/news/new-illinois-law-gives-patients-the-right-to-choose-or-reject-telehealth.
[34] H.B. 3308, *supra* note 29.
[35] *Id.*
[36] *Connect Illinois*, *supra* note 30.
[37] *Id.*
[38] Office of Broadband, *Connect Illinois Broadband Strategic Plan*, IL. DEPT. OF COM. & ECON. OPPORTUNITY (Feb. 2020), https://www2.illinois.gov/dceo/ConnectIllinois/Documents/Broadband%20Strategic%20Plan%202.5.20.pdf.
[39] *Id.*

additional rounds of funding are forthcoming.[40] This investment aims to improve access to high-speed broadband in every corner of the state, improving the capabilities for all internet based activities, including health care.[41]

IMPACT OF LEGISLATION ON TELEHEALTH DISPARITIES IN RURAL ILLINOIS

A. H.B. 3308

H.B. 3308 has significant potential to increase access to care via telehealth services in rural areas across Illinois.[42] With rural hospital closures occurring across the U.S., expanding channels of health care is critical to maintain access to care.[43] Telehealth bridges an essential continuity of care for those residing in rural areas who cannot easily access local clinics or hospitals, especially given the hardship of travel or time necessary to access in-person care.[44] Further, the quality of care provided via telehealth increases when patients can choose their doctor and have greater access to specialty care.[45]

Of the amendments included in H.B. 3308, several will improve access to rural Illinois populations.[46] First, equal reimbursement for telehealth services, including those for specialists and behavioral health, will increase

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[40] *Id.*
[41] *Id.*
[42] *See* Shatzkes, *supra* note 4. (exploring Illinois' legislative efforts regarding newly passed HB 3308 and the Connect Illinois investment project).
[43] Dorsey, *supra* note 7.
[44] *Id.*
[45] COVID-19 HEALTHCARE COALITION, *Telehealth Impact: Patient Survey Analysis*, https://c19hcc.org/static/catalog-resources/telehealth-patient-survey-analysis-c19hcc.pdf (last visited Nov. 17, 2021).
[46] H.B. 3308, *supra* note 29.

access to those services for rural populations.[47] Second, reducing technological and geographical barriers by allowing phone and audio-only visits will benefit those still lacking broadband access, while use of asynchronous monitoring reduces the need for frequent in-person visits.[48] Lastly, removing the administrative barriers of requiring an initial in-person visit or demonstrating need prior to a telehealth visit will eliminate potentially lengthy travel and unnecessary processes.[49]

The first major change H.B. 3308 introduces is payment parity for health care services by reimbursing care under the same rate whether via telehealth or in-person.[50] The amended law requires that insurers "reimburse an in-network health care professional or facility for telehealth services provided through an interactive telecommunications system on the same basis, in the same manner, and at the same reimbursement rate that would apply to the services if the services had been delivered via an in-person encounter."[51] Focusing on payment parity for services is essential to widespread adoption and implementation of telehealth.[52]

Creating payment parity is critical to increase the number of providers utilizing telehealth, especially for specialty care.[53] Specialists are most often concentrated in well-equipped hospitals in larger cities, whereas rural infrastructure tends to be limited, with a greater focus on primary care and

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[47] Shatzkes, *supra* note 4.
[48] *See* Joel Barthelemy, *Solving Access to Specialty Care for Rural Communities*, GLOBALMED (May 5, 2021), https://www.globalmed.com/solving-access-to-specialty-care-for-rural-communities/ (discussing methods of telehealth and access to specialty care).
[49] *IHA Detailed Summary of Telehealth Legislation– HB 3308*, ILLINOIS HEALTH AND HOSPITAL ASSN. (IHA), https://www.team-iha.org/files/non-gated/advocacy/member-memo-hb3308-summary.aspx.
[50] Shatzkes, *supra* note 4.
[51] H.B. 3308, *supra* note 29.
[52] Dorsey, *supra* note 7.
[53] *Telehealth Models for Increasing Access to Specialty Care*, RURAL HEALTH INFO. HUB (RHI), https://www.ruralhealthinfo.org/toolkits/telehealth/2/care-delivery/specialty-care (last visited Sept. 15, 2021).

disease management.[54] Rural areas often lack access to providers, leading to a forty percent higher preventable hospitalization rate and a twenty-three percent higher mortality rate for rural populations, which could be lowered by a specialist visit.[55] Telemedicine can also be used in immediate situations, such as onset of a stroke or heart attack, when the nearest hospital could be too far.[56] By increasing payment parity, the number of specialists participating in telehealth will grow, allowing those in rural areas to access care without having to travel where the specialist practices.[57]

Importantly, the bill also specifically extends payment parity to behavioral health providers.[58] There are fewer mental health clinicians in rural compared to urban areas.[59] In addition, suicide and avoidable drug overdose rates are also higher in rural areas.[60] These provisions will increase access to behavioral health providers and substance abuse services, especially for those in rural areas where provider shortages lead to greater disparity in access to mental health care.[61] Increasing access to mental health care through telehealth will help facilitate individuals struggling with mental health to see a clinician without the geographic limitations.[62]

Further, rural populations may not have equal access to digital devices capable of video communications.[63] This is partly due to limited adoption of

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[54] RURAL ACTION PLAN, US DEP'T OF HEALTH & HUM. SERVS. (HHS), (Sept. 2020), https://www.hhs.gov/sites/default/files/hhs-rural-action-plan.pdf.
[55] *Id.*
[56] Barthelemy, *supra* note 48.
[57] *Telehealth Models for Increasing Access to Specialty Care*, *supra* note 53.
[58] H.B. 3308, *supra* note 29.
[59] RURAL ACTION PLAN, *supra,* note 54.
[60] *Id.*
[61] Dawn Morales, *A Call To Action To Address Rural Mental Health Disparities*, 4 J. OF CLINICAL & TRANSLATIONAL SCI. 463, 465 (2020).
[62] *Id.*
[63] *Barriers to Telehealth Adoption*, *supra* note 3.

technology, as many rural, older populations are less technology literate, but also due to broadband access.[64] The amended bill addresses technological and geographical barriers by permitting audio only services, prohibiting geographic or facility restrictions for delivery of telehealth, and including asynchronous monitoring.[65] By expanding the definition to include audio, or voice only visits, the bill expands service to those with cellular or landline communication, increasing access to telehealth services.[66]

H.B. 3308 strives to eliminate geographic restrictions for both patients and providers.[67] For patients, the bill prohibits insurers from imposing geographic or facility restrictions for telehealth services, e-visits, or virtual check-ins.[68] For providers, the bill allows professionals to determine appropriate location and technology for telehealth services if the location complies with applicable privacy, security, and confidentiality regulations.[69]

Additionally, the bill expands the telehealth definition to include remote patient monitoring services.[70] Rural residents are more likely to die from chronic illness including heart disease, cancer, unintentional injury, chronic lower respiratory disease, and stroke than urban residents.[71] Remote monitoring can be critical for continuity of care between hospital stays and it

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[64] *Id.*
[65] H.B. 3308, *supra* note 29.
[66] *See* Ellimoottil et al., *supra* note 16 (summary of data showing audio only telehealth use by rurality and broadband).
[67] H.B. 3308, *supra* note 29.
[68] *Id.*
[69] *Id.*
[70] *Id.* Remote patient monitoring refers to continuous monitoring of patients outside hospital conditions by the means of technology. Remote monitoring of patients is common with patients diagnosed with chronic illnesses, patients with mobility issues, or other disability, post-surgery patients, neonates and elderly patients, where patients have conditions that are better to be monitored continuously. *See* Lakmini Malasinghe, *Remote Patient Monitoring: A Comprehensive Study*, 10 J. AMBIENT INTEL. & HUM. COMPUTING 57, 57 (2019).
[71] RURAL ACTION PLAN, *supra,* note 54.

allows physicians to monitor progress and management of disease without requiring frequent in-person visits.[72]

Lastly, the amended telehealth bill removes administrative barriers to telehealth, including prohibiting requirements that impose treatment limitations, prior authorization, documentation, or record keeping requirements that are more stringent than in-person appointments.[73] The bill also eliminates any requirements of patients to use a separate panel of health experts to receive telehealth service.[74] Finally, the bill prohibits proof of a hardship or access barrier for coverage and reimbursement of telehealth services.[75] The elimination of these administrative barriers align telehealth with in-person care, and allows patients to access telehealth more efficiently.

B. Connect Illinois Broadband Investment

Even with meaningful telehealth legislation, telehealth reform cannot truly make an impact without equitable access to broadband.[76] To fill the gap in access to reliable, high-speed internet, Connect Illinois aims to bring access to the entire state by investing $400 million in grant matching programs.[77] Beyond connectivity and access, the project aims to address economic development, education infrastructure and technology, and telehealth.[78] Similar projects such as the FCC Connected Care Pilot Program initiated in 2020 strive to increase broadband connectivity, network equipment, and information services necessary to provide connected care services to patients

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[72] *Telehealth Models for Increasing Access to Specialty Care*, *supra* note 53.
[73] H.B. 3308, *supra* note 29.
[74] *Id.*
[75] *Id.*
[76] Hirko, *supra* note 17 at 1816.
[77] *Connect Illinois*, *supra* note 30.
[78] *Id.*

in rural areas.[79] The Connect Illinois working group for telehealth has identified the need for related equipment for telehealth services and facilities, and the bandwidth necessary for real-time interaction between a patient and heath care professional.[80]

There are still several regions of rural Illinois lacking basic internet capabilities.[81] However, the Connect Illinois Broadband Strategic Plan outlines aggressive infrastructure and connectivity measures, with the goal of connecting all of Illinois to basic broadband access by 2024.[82] The program focuses on addressing infrastructure disparities tied to population sparsity and geography in rural regions, where private investment entities historically have not invested.[83] Infrastructure grants will be allocated to areas of greatest broadband need, characterized by unserved areas that do not meet basic internet speed.[84] Access to broadband is critical to implementation of telehealth reforms, without access to internet or cellular services, patients cannot participate in true telehealth equity.[85]

TELEHEALTH AS AN ALTERNATIVE FOR RURAL ILLINOIS HOSPITALS

With advances in technology and recent legislative efforts, telehealth has the potential to close gaps in access to care in rural Illinois. From the onset of the COVID-19 pandemic, legislators have been swift to implement sweeping regulations, increasing access to telehealth resources.[86] Many of

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[79] *Connected Care Pilot Program*, FED. COMMC'N COMM'N (FCC), https://www.fcc.gov/wireline-competition/telecommunications-access-policy-division/connected-care-pilot-program (last visited Oct. 20, 2021).
[80] Office of Broadband, *supra* note 38.
[81] *Id.*
[82] *Id.*
[83] *Id.*
[84] *Id.*
[85] Hirko, *supra* note 17.
[86] *Telehealth Use in Rural Healthcare*, RURAL HEALTH INFO. HUB (RHI), https://www.ruralhealthinfo.org/topics/telehealth#covid-19 (last visited Nov. 17, 2021).

the temporary initiatives to expand telehealth have now been transitioned into permanent laws, including in Illinois through H.B. 3308.[87] Further, CMS has announced continuation of reimbursement for telehealth services through 2023.[88] Telehealth is being increasingly utilized in novel ways and to more individuals, and this is reflected in reform of telehealth policies.

Because of this expansion, telehealth is well suited to bridge gaps in care for essential services in rural areas. Rural areas face clinician shortages for specialist care, mental health, and chronic care management.[89] In addition, rural hospitals continue to close, unable to stay profitable with ongoing challenges including decreasing patient populations, inconsistent funding, aging infrastructure, and workforce shortages.[90] Telehealth has the potential to transform the model of care in rural areas, including rural Illinois.[91] This can be done by prioritizing funding and resources for critical services, like emergency and trauma care, while utilizing telehealth for other essential services, such as primary and specialist care.[92]

Rural resources are finite and must be utilized efficiently to ensure that communities are not left without access to care. With advances in telehealth technology, and recent legislative efforts expanding access and reimbursement, rural health systems could prioritize certain critical in-person services and utilize telehealth to bridge gaps in care. Rather than having a rural hospital close, resources could be allocated to keep critical services open and divert other care to telehealth providers.

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[87] H.B. 3308, *supra* note 29.
[88] *Calendar Year (CY) 2022 Medicare Physician Fee Schedule Final Rule*, CMS (Nov. 2, 2021), https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2022-medicare-physician-fee-schedule-final-rule.
[89] AM. HOSP. ASS'N, RURAL REPORT, *supra* note 20; Morales, *supra* note 61.
[90] AM. HOSP. ASS'N, RURAL REPORT, *supra* note 20.
[91] *Id.*
[92] *Id.*

There are several benefits to this type of model. Telehealth can reduce cost to providers and patients and potentially lower cost to federal health programs.[93] Patients save time and resources traveling to and from appointments, waiting at the clinic or hospital, and actual provider interaction time, which can be compounded if a patient must take time away from work to travel for an in-person visit.[94] Physicians can also benefit from efficiency in patient visits, the potential to reduce practice expenses, and increase in patient volume.[95] Further, rural hospitals could prioritize staffing of physicians and support staff to meet critical needs. By prioritizing essential services, rural hospitals can function more efficiently and effectively to care for a smaller subset of patients, and delegate or supplement other care to telehealth providers, such as mental health, primary care, and specialists.

Lastly, infrastructure could be modified to reduce overall bed volume and overhead costs associated with maintaining a large hospital facility. Rural hospitals have already been reducing bed numbers, focusing on quality and not quantity of care to reflect community need, and establishing alternative care models.[96] This is further demonstrated by a new Medicare provider type, the Rural Emergency Hospital (REH), established as part of the Consolidated Appropriations Act effective January 1, 2023.[97] The model is designed to continue access to emergency and outpatient care in rural areas by converting critical access hospitals and other small rural hospitals meeting eligibility criteria.[98] Rural hospitals must adapt to current challenges and opportunities faced by their communities. One potential solution to

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[93] *Telehealth Use in Rural Healthcare, supra* note 86; Dorsey, *supra* note 7.
[94] *Telehealth Use in Rural Healthcare, supra* note 86.
[95] *See* Ellimoottil et al., *supra* note 16 (discussing potential for reduced physician costs depending on use).
[96] AM. HOSP. ASS'N, RURAL REPORT, *supra* note 20.
[97] *Rural Hospitals*, RURAL HEALTH INFO. HUB (RHI), https://www.ruralhealthinfo.org/topics/hospitals (last visited Nov. 17, 2021).
[98] *Id.*

maintaining access to healthcare is a mixed care model integrating essential in-person services with telehealth.

CONCLUSION

In the early months of the COVID-19 pandemic, policymakers acted swiftly to expand access to telehealth. H.B. 3308 codified these temporary provisions into law, and today is one of the country's leading modern telehealth reform bills, reducing barriers to care and increasing reimbursement to providers and facilities on par with in-person services. In addition to updated telehealth regulations, the Connect Illinois project aims to increase access across the state and provide rural areas with reliable internet access. These two legislative actions will increase access to telehealth in rural areas, thereby improving access, continuity, quality, and cost of care. Because of the increase in access to telehealth resources, there is potential to transform rural health to a mixed care system, with essential in-person services supplemented by telehealth providers for everyday care. This model has potential to reduce costs, keep rural health centers open, and redistribute staff and funding. As advances in telehealth technology and regulation continue, these models will likely become more common to maintain continuity of care in rural communities.

Digital Health Companies and Data Protection: Ensuring Compliance With Continually Evolving, Piecemeal State Regulations Surrounding Data Use and Data Subject Rights

Danielle Feingold

INTRODUCTION

A variety of Big Tech organizations and related start-ups have moved into the healthcare space in the roughly five years since the introduction of the European Commission's General Data Protection Regulation EU 2016/679 (GDPR).[1] Disruptor companies are also contributing to growth within the medical device and digital health sectors.[2] The increased production of digital health devices and related software has facilitated research by various types of organizations such as technology companies, start-up biotechnology and medical device manufacturers, and software firms.

Digital health encompasses any technology that engages users or consumers by collecting personal data for use in larger health-related purposes.[3] Such technologies are often not only subject to the same regulation as the manufacturers of medical devices or pharmaceutical products, but are also subject to other regulations relating to software functions.[4] Although the digital health market was proliferating prior to COVID-19, in response to the pandemic, the adoption of digital health technology has grown exponentially, creating new challenges for healthcare

[1] Commission Regulation 2016/679, 2016 O.J. (L 119) 1 (hereinafter GDPR); Luca Marelli et al., *Big Tech platforms in health research: Re-purposing big data governance in light of the General Data Protection Regulation's research exemption*, 8 BIG DATA & SOC'Y 1, 2, (2021), https://journals.sagepub.com/doi/pdf/10.1177/20539517211018783.
[2] Julianne Roseman, *Top 10 Digital Health Startups to Watch Out For in 2021*, PLUG AND PLAY (Jun. 15, 2021) https://www.plugandplaytechcenter.com/resources/top-10-digital-health-startups-watch-out/.
[3] *What is Digital Health?*, FDA, https://www.fda.gov/medical-devices/digital-health-center-excellence/what-digital-health (last visited September 15, 2021).
[4] U.S. FOOD & DRUG ADMIN., POLICY FOR DEVICE SOFTWARE FUNCTIONS AND MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF, 1, 10-11 (Sep. 27, 2019), https://www.fda.gov/media/80958/download.

systems.[5] Telemedicine can help reduce exposure to the virus and limit the pressure placed upon healthcare providers and health systems.[6] Additionally, cloud-based technologies can be used to streamline research and development processes at academic research hospitals and can support public adoption of personalized wearable medical devices.[7] In-person care has declined in the wake of the pandemic as more providers and researchers are utilizing telehealth applications such as videoconferencing, patient education applications, and remote patient monitoring.[8] Regardless of company size or power within the technology space, entrants into the digital health sector face a rapidly changing patchwork of regulations relating to data protection.[9]

This article addresses the compliance challenges that technology companies encounter as they work toward market approval of their respective digital health technologies, particularly relating to data privacy and protection regulations and sharing of clinical research data. The article first reviews the increased attention paid to data protection relating to digital health technologies and evaluates the merits of applicable laws and regulations pertaining to data protection. Then, this paper will recommend measures those digital health space entrants can use to maintain ethical data

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[5] Niels Peek et al., *Digital health and care in pandemic times: impact of COVID-19*, BMJ HEALTH & CARE INFORMATICS, 1, 2 (Jun. 02, 2020), https://informatics.bmj.com/content/bmjhci/27/1/e100166.full.pdf.

[6] *See* Ashwin Ramaswamy et al., *Patient Satisfaction With Telemedicine During the COVID-19 Pandemic: Retrospective Cohort Study*, 22 J. MED. INTERNET RSCH., (Sep. 09, 2020), https://www.jmir.org/2020/9/e20786/ (evaluating and discussing patient adoption of telemedicine visits during COVID-19).

[7] Peyar Radanliev et al., *COVID-19 what have we learned? The rise of social machines and connected devices in pandemic management following the concepts of predictive, preventive and personalized medicine*, EPMA J., 311, 324-327, (Jul. 30, 2020) https://doi.org/10.1007/s13167-020-00218-x.

[8] *See* Bokolo Anthony Jnr., *Integrating telemedicine to support digital health care for the management of COVID-19 pandemic*, INT'L J. HEALTHCARE MGMT., 280, 283 (Jan. 15, 2021), https://www.tandfonline.com/doi/full/10.1080/20479700.2020.1870354 (providing recommendations on how to use telemedicine to manage digital health care during COVID-19).

[9] Ryan Knox & Cara Tenenbaum, *Regulating digital health apps needs user-centered reform*, STAT (Aug. 03, 2021) https://www.statnews.com/2021/08/03/refor-regulatory-landscape-digital-health-applications/.

use policies and propose how states can best address data protection and governance through drafting their own legislation. As will be described, digital health companies should tailor their data governance programs to the most conservative and inclusive of current state laws which ultimately mirror, if not exceed, data protection laws of the European Union.

Because many organizations will work with international health data, or data coming from subjects located around the world, digital health companies would benefit from internal policies that comply with both domestic legislation (U.S. state laws) and international regulations. Crafting internal data governance policies to reflect the requirements of the strictest of current U.S. state laws will help organizations ensure that their processing of individual's data meets both domestic and international standards surrounding the changing field of health data protection.

INCREASING ATTENTION TO DATA PROTECTION AND PRIVACY

Access to health data is considered an essential component of continued and effective research within the scientific community, regardless of the condition to be addressed by such research.[10] The field of digital health and health technology has grown exponentially in the past decade, leading to advances in the delivery of precision medicine therapies for more individualized care at the patient level,[11] and an increased focus on the

[10] *See generally* Antonia Vlahou et al., *Data Sharing Under the General Data Protection Regulation*, 77 HYPERTENSION 1029, 1030-1031 (Apr. 2021), https://doi.org/10.1161/HYPERTENSIONAHA.120.16340 (noting data sharing is an ethical obligation of any researcher and helps advance scientific research).

[11] Luis Fernandez-Luque et al., *Digital Health for Supporting Precision Medicine in Pediatric Endocrine Disorders: Opportunities for Improved Patient Care*, 9 FRONTIERS IN PEDIATRICS 1, 2 (Jul. 29, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8358399/. The development and delivery of precision medicine, defined as "a pathway that employs

interoperability of health data across research platforms.[12] Researchers in the healthcare and medical device space have amassed large amounts of data from research participants which must be properly stored, protected, and subsequently re-examined by investigators and staff.[13]

It is projected that by 2023, approximately 65% of patients will utilize digital methods to access their care, as providers seek to integrate and improve access across multiple therapeutic areas and services.[14] Since the introduction of the GDPR in the European Union (EU), individual states in the U.S. have put forth data privacy laws and regulations to manage how health and identifying information is collected and processed, and what degree of control a data subject has over their information.[15] Though there has been continued conversation surrounding a national data protection policy, at this time the regulatory landscape remains piecemeal while there is no comprehensive national regulation, and data protection laws are determined at the state level.[16] Thus, digital health technologies must comply with a series of state laws and broader regulations such as the Health Information Technology for Economic and Clinical Health Act (HITECH),

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numerous technologies to guide individually tailored diagnostic methods and treatments", is supported by the increase in the use of digital health tools such as the internet, mobile phones, video technology, and computer applications. Additionally, digital health technologies allow for the "multi-level stratification of patients according to disease sub-types, risk profiles, demographic and socio-economic characteristics, enabling interventions to be delivered on an individual patient level."

[12] Kevin Yi-Lwern Yap, et al., *The Launch of the International Journal of Digital Health: Ensuring Digital Transformation in Healthcare Beyond Covid-19*, INT'L J. DIGITAL HEALTH, 1, 2 (Mar. 04, 2021), https://www.ijdigitalhealth.com/articles/10.29337/ijdh.27/.

[13] *Id.*

[14] Mike Miliard, *What to expect in 2021 and beyond? IDC offers 10 healthcare predictions*, HEALTHCARE IT NEWS (Dec. 28, 2020), https://www.healthcareitnews.com/news/what-expect-2021-and-beyond-idc-offers-10-healthcare-predictions.

[15] *Data Security Laws Private Sector*, NAT'L CONF. STATE LEGISLATURES (May 29, 2019), https://www.ncsl.org/research/telecommunications-and-information-technology/data-security-laws.aspx.

[16] Michele E. Gilman, *Five Privacy Principles (from the GDPR) the United States Should Adopt to Advance Economic Justice*, 52 ARIZ. ST. L. J. 368, 370-71 (2020).

the Health Insurance Portability and Accounting Act (HIPAA), and international data protection regulation and guidance documents.[17]

Digital health entities, on the other hand, are expected to comply with the federal laws noted previously—namely HIPAA, the HITECH Act,[18] as well as provisions prescribed by security standards that typically govern health data[19]—while maintaining a commitment to protecting individuals' privacy and to the security of the identifiable data. Data protection and confidentiality are both concerns within the medical community, particularly in regard to recent developments in health technologies.[20] The protection and use of health data as collected by digital health products requires prudent risk management.[21] The ambition of digital health is to generate and circulate patient data to health professionals at the point of care, ultimately providing the patient with their health information and the tools to manage this

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[17] *Id.* at 400.
[18] Brett Lockwood, *Digital Health and Privacy*, SGR LAW (2017), https://www.sgrlaw.com/ttl-articles/digital-health-privacy (noting uptake of technology in health care delivery systems due to the introduction of the HITECH Act, which provides incentives for the development and use of interoperable electronic health record systems).
[19] CORL Technologies, *Confronting Digital Health Privacy Risks via the New NIST Framework*, CORL TECHNOLOGIES (Feb. 10, 2020), https://corltech.com/confronting-digital-health-privacy-risks-via-the-new-nist-framework/ (describing how update to National Institute of Standards and Technology standards in January 2020 will apply to digital health technologies in addition to HIPAA, GDPR, and the CCPA); *see* Clemens Scott Kruse et al., *Security Techniques for the Electronic Health Records*, 41 J. MEDICAL SYSTEMS 1 (Jul. 21, 2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5522514/ (evaluating information security measures applicable to health data, including HIPAA, HITECH, ISO/IEC data system security standards, and risk management systems).
[20] Giulio Nittari et al., *Telemedicine Practice: Review of the Current Ethical and Legal Challenges*, 26 TELEMEDICINE AND E-HEALTH 1427, 1435 (Dec. 2020), https://www.liebertpub.com/doi/pdfplus/10.1089/tmj.2019.0158 (detailing increasing physician responsibility in the use of medical devices and transmission of patient data).
[21] *See generally* U.S. GOV'T ACCOUNTABILITY OFF., GAO-06-676, PRIVACY: DOMESTIC AND OFFSHORE OUTSOURCING OF PERSONAL INFORMATION IN MEDICARE, MEDICAID, AND TRICARE, 20 (Sept. 2006), https://www.gao.gov/assets/gao-06-676.pdf (recommending CMS require all agencies and *related contractors* [emphasis added] handling personal health information notify CMS of any breaches).

information.[22] In working with this identifying information, these digital health and healthcare organizations will need to ensure that patient privacy is maintained. Additionally, any liability resulting from a data breach must be placed appropriately amongst contributing parties, including but not limited to patients, physicians, and health systems.[23]

THE EUROPEAN UNION'S GENERAL DATA PROTECTION REGULATION

The EU's recent omnibus General Data Protection Regulation establishes a more homogenous privacy framework for the processing of any health data relating to EU citizens, or to those receiving care in the EU.[24] This comprehensive regulation is not, however, defining concepts of data protection for the first time for member states.[25] Many EU member states had individual data protection and privacy laws prior to the GDPR, despite the perceived novelty of data protection rights in the United States.[26] While the GDPR applies to companies within the EU, health care organizations within the U.S. that process data from patients from the EU are also subject to the regulation.

A defining element of the GDPR is the recognition that although consent can often be obtained before an individual's data is used or processed, this consent does not hold the same strength within clinical research, where data may be re-used for differing research purposes.[27] The GDPR sets forth various 'user rights,' allowing those whose personal health and identifying

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[22] Effy Vayena et al., *Digital health: meeting the ethical and policy challenges*, SWISS MED. WKLY. 1, 1 (Jan. 16, 2018), https://smw.ch/article/doi/smw.2018.14571.
[23] *See* GDPR, *supra* note 1, at Art. 4. Identifying Information, as defined within the GDPR, includes personal health information (PHI) as well as personally identifying information (PII) from other industries and sectors. Personal data as defined includes any information which are related to an identified or identifiable natural person.
[24] Vayena, *supra* note 22, at 1.
[25] Meg Leta Jones & Margot E. Kaminski, *An American's Guide to the GDPR*, 98 DENV. L. REV. 93, 105 (2020).
[26] *Id.*
[27] Vayena, *supra* note 22, at 5.

data is being processed by companies to protect and control their data.[28] The regulation provides that individuals have rights to 1) an explanation about the use of their data, 2) provide affirmative consent for the processing of their data, 3) withdraw this consent, 4) access their data in a readable and accessible format, 5) request correction of their data, 6) have personal data erased (a right to be forgotten), 7) transfer data from one provider to another (right of portability), and, additionally, rights surrounding automated processing of their data.[29] The regulation places the onus of data protection on entities that gather and use individuals' data, rather than relying upon the individual to enforce their own data privacy rights.[30]

The GDPR requires that businesses provide a legal basis for processing patient data, one of which includes obtaining the consent of the data subject prior to the processing of their data.[31] Consent is obtained on an 'opt-in' basis, requiring that informed and unambiguous consent is freely given by an individual.[32] In addition to requiring that businesses have at least one of six legal bases for processing data, the GDPR also imposes high fines for noncompliance.[33] Further, the regulation requires that companies processing data that present a high risk to the rights of persons must conduct data protection impact assessments, the results of which are shared with regulators.[34] The data auditing and related impact assessment requirements ensure the adequate involvement of citizens in managing their data, and

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[28] Jones, *supra* note 25, at 109.
[29] *See generally* GDPR, *supra* note 1; Gilman, *supra* note 16, at 413.
[30] Gilman, *supra* note 16, at 412.
[31] Ben Wolford, *What are the GDPR consent requirements?*, GDPR.EU, https://gdpr.eu/gdpr-consent-requirements/ (last visited Oct. 20, 2021).
[32] *GDPR consent must be actively given by the data subject,* GDPR EU, https://www.gdpreu.org/the-regulation/key-concepts/consent/ (last visited Oct. 20, 2021).
[33] Jones, *supra* note 25, at 95.
[34] *Id.* at 118.

promote corporate accountability of data processing.[35] Despite these data protections and individual consent safeguards, the regulation does not allow an individual to opt-*out* of the processing of their data, since consent is only one of six ways businesses can establish a legal basis for the processing of an individual's information.[36] Under the GDPR, unlike under related U.S. state laws, if a business relies on one of the other legal bases to further process data, the business does not need to provide data subjects with an opportunity to opt-out of the sale of their personal information.[37]

REGULATORY GUIDANCE AND NOTABLE STATE LAWS

Unlike the EU, which has defined data protection and privacy frameworks through GDPR, there is not yet comprehensive data protection regulation within the U.S. at a federal level.[38] Where federal regulation exists, it is often divided by sector and is not applicable to all industries, as is the GDPR.[39] Moreover, there is no protected right to informational privacy within the United States Constitution, though various provisions do promote autonomy in bodily integrity and family matters.[40]

The current regulatory framework in the U.S. surrounding digital health technology – including devices, wearables, combination products, and software development – is fragmented between the Food & Drug

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[35] *Id.*; Gilman, *supra* note 16, at 431-433.
[36] Carol Umhoefer, *CCPA vs. GDPR: the same, only different*, DLA PIPER (Apr. 11, 2019), https://www.dlapiper.com/en/us/insights/publications/2019/04/ipt-news-q1-2019/ccpa-vs-gdpr/.
[37] Robert B., *How the CCPA is Different from the GDPR,* TERMSFEED (Aug. 15, 2020), https://www.termsfeed.com/blog/ccpa-different-gdpr/#Summary_Of_Key_Differences.
[38] Gilman, *supra* note 16, at 400.
[39] *See* Paul M. Schwartz, *Preemption and Privacy*, 118 YALE L. J. 902, 908-912 (2009), https://digitalcommons.law.yale.edu/cgi/viewcontent.cgi?article=5155&context=ylj (comparing comprehensive data protection laws in EU with state and sectoral data protection laws within U.S.).
[40] Michele Gilman, *The Class Differential in Privacy Law,* 77 BROOK. L. REV. 1389, 1417 (2017), https://brooklynworks.brooklaw.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=1140&context=blr.

Administration (FDA), the Federal Communication Commission, the U.S. Department of Commerce, and other regulatory bodies.[41] The FDA has provided guidance to help manufacturers of such products ensure that their use of data is secure, and has issued an Action Plan and Proposed Regulatory Framework for Software as Medical Device (SaMD) products, though further guidance is forthcoming.[42] This guidance defines the FDA's preliminary approach to premarket review of machine learning driven software modifications, including risk management principles relating to patient safety and change control provisions.[43] The guidance also emphasizes the FDA's commitment to the development and harmonization of Good Machine Learning Practice, which promotes using best practices to ensure continued compliance with regulatory expectations surrounding machine learning, cybersecurity, and medical devices.[44]

In response to the lack of overarching federal regulation, as of 2020, nearly forty-five states have reviewed or introduced cybersecurity resolutions and three states have enacted consumer data protection/privacy laws which include user access and deletion rights, provisions regarding the sale of health data, and other provisions similar to the GDPR.[45]

To be in compliance with individual states' data security and protection laws, companies must first determine the applicability of the various laws to

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[41] *See generally* Kim Theodos & Scott Sittig, *Health Information Privacy Laws in the Digital Age: HIPAA Doesn't Apply*, 18 PERSP. HEALTH INFO. MGMT. 1, 4-7 (Dec. 07, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7883355/ (describing lack of overarching legislation regarding data protection and defining applicable regulations).
[42] CTR. FOR DEVICES & RADIOLOGICAL HEALTH, U.S. FOOD & DRUG ADMIN., *Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan* (Jan. 2021), https://www.fda.gov/media/145022/download.
[43] *Id.*
[44] *Id.* at 3-4.
[45] *Cyber Security Legislation 2021*, NAT'L CONF. OF STATE LEGISLATURES (Jun. 22, 2021), https://www.ncsl.org/research/telecommunications-and-information-technology/cybersecurity-legislation-2021.aspx.

their organizations. Smaller digital or telehealth organizations that do not process large amounts of data or are not yet bringing in revenue beyond a threshold amount may not have to comply with the state laws.[46] State privacy laws often impose civil penalties on organizations of all sizes for violations of their provisions and may include escalation procedures to ensure that any violation is communicated to the individuals or parties affected.[47]

In the case of the California Consumer Protection Act (CCPA), companies must do business in California to be subject to the act.[48] The CCPA does not apply to all medical information outright, but rather covers a multitude of datapoints relating to health care services gathered by organizations beyond clearinghouses, providers, or insurance companies (which are typically covered by HIPAA and state medical record laws).[49] Similar to the GDPR, under the CCPA, companies that collect health data must allow consumers to opt-out of the sale of their data.[50] Further, the CCPA recommends that companies implement privacy policies which describe the data subject's rights, and should allow subjects to request the erasure or portability of their

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[46] Cynthia Brumfield, *12 new state privacy and security laws explained: Is your business ready?*, CSO ONLINE (Dec. 28, 2020, 2:00 AM) https://www.csoonline.com/article/3429608/11-new-state-privacy-and-security-laws-explained-is-your-business-ready.html.

[47] *State Laws Related to Digital Privacy,* NAT'L CONF. OF STATE LEGISLATURES (Jul. 22, 2021), https://www.ncsl.org/research/telecommunications-and-information-technology/state-laws-related-to-internet-privacy.aspx; *California Consumer Privacy Act Guide,* JONES DAY 1, 25 (JUL. 2020), https://www.jonesday.com/en/insights/2019/01/california-consumer-privacy-act-guide. As an example of escalation procedures relating to notification of data breaches, California's CCPA indicates that data subjects may pursue a limited private right of action when their data is subject to unauthorized access, theft, or disclosure as a result of the business' failure to implement and maintain reasonable data security procedures and practices. To bring such a suit, affected individuals must first give notice to the organization (defendant), and must allow for a thirty day period in which the organization may correct and 'cure' the violation prior to filing a lawsuit.

[48] *California Consumer Privacy Act (CCPA)*, ROB BONTA ATT'Y GEN., https://oag.ca.gov/privacy/ccpa#sectiona (last visited Sep. 16, 2021).

[49] Andrea Musker & Anne Brendel, *The California Consumer Privacy Act's Applicability to the Health Care Industry*, BUCHALTER CLIENT ALERT (Nov. 11, 2019), https://www.buchalter.com/wp-content/uploads/2019/11/CCPA-Applicability-Healthcare.Musker.Brendel.pdf.

[50] CAL. CIV. CODE § 1798.100.

data.[51] The CCPA and related California Privacy Rights Act (CPRA),[52] like the GDPR, require that companies perform Data Impact Assessments.[53] The CPRA requires businesses to perform these assessments where data processing may result in high risk to data subjects, and subsequently report the results to the Consumer Privacy Protection Agency.[54] Both the CCPA/CPRA and GDPR authorize enforcement through the imposition of fines for noncompliance, and include data minimization provisions that require companies to limit the collection of an individual's personal data.[55]

Whereas California implemented its data protection act in 2018, Virginia's Consumer Data Protection Act (CDPA) will come into effect as of 2023 alongside recent amendments to California's CCPA.[56] The CDPA establishes an opt-in requirement for any entity to collect or process a user's 'sensitive data,' including diagnostic information, genetic and biometric data, or anything else uniquely identifying to the individual.[57] Apart from language shared with the CCPA and GDPR, Virginia's CDPA requires data protection assessments, and exempts certain entities or types of data from

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[51] *Id.*
[52] IAPP, *The California Privacy Rights Act of 2020,* INT'L ASS'N OF PRIVACY PROFESSIONALS (Mar. 2021), https://iapp.org/resources/article/the-california-privacy-rights-act-of-2020/.
[53] GDPR, *supra* note 1, at Art. 35; Adoriel Bathishou, *8 Things California's New CRPA Law Has in Common With GDPR*, TEVORA (Jan. 12, 2021), https://www.tevora.com/8-things-californias-new-cpra-law-has-in-common-with-gdpr/. Data Processing Impact Assessments, required by both the GDPR and CCPA, are periodic and regular risk assessments that help an organization identify risks related to the handling of an individual's personal information.
[54] Steven Millendorf, et al., *California Votes Pass the California Privacy Rights Act,* FOLEY LARDNER, (Nov. 12, 2020), https://www.foley.com/en/insights/publications/2020/11/voters-pass-california-privacy-rights-act. The CCPA goes beyond the requirements of the GDPR, mandating that where a data privacy impact assessment is completed, it is sent to the regulatory agency. If as a result of the assessment, it is determined that the risks of data processing outweigh the benefits to the business, the businesses may be required to restrict their processing activities.
[55] IAPP, *supra* note 52.
[56] Karin McGinnis, *Virginia Passes Comprehensive Data Privacy Law*, JD SUPRA (Mar. 11, 2021), https://www.jdsupra.com/legalnews/virginia-passes-comprehensive-data-3456920/.
[57] *Id.*

coverage, including data related to human subjects research and data de-identified per requirements under HIPAA.[58] Health care and digital health entities may appreciate the broad exemptions under Virginia's CDPA despite their collection of sensitive data, unlike organizations subject to California's CCPA.[59] If digital health technology companies utilize and process data derived from health care information or that was previously de-identified per HIPAA, they will not need to conduct data impact assessments regarding that data.[60] The CDPA also excludes many health care organizations as well as the use of data for the purposes of medical research; two categories of exceptions that emerging digital health companies may fall within.[61]

The Colorado Privacy Act (CPA), also set to take effect in 2023, tracks closely with the CCPA, GDPR, and CDPA, although it does not contain a monetary threshold like California's CCPA.[62] Unlike the CCPA, the Colorado Privacy Act defines 'sale' of personal information as requiring monetary or similar consideration, and does not consider a consumer's intentional disclosure of information to the general public or to a third party as a sale.[63] Consumers, however, can still opt out of the sale of their data

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[58] Matthew M. Shatzkes & Julia K. Kadish, *What Virginia's New Privacy Law Means for Organizations in the Healthcare Industry*, NAT'L L. REV.: HEALTHCARE LAW BLOG (Mar. 08, 2021), https://www.natlawreview.com/article/what-virginia-s-new-privacy-law-means-organizations-healthcare-industry.

[59] Sarah Rippy, *Virginia passes the Consumer Data Protection Act*, INT'L ASS'N OF PRIVACY PROFESSIONALS (Mar. 03, 2021), https://iapp.org/news/a/virginia-passes-the-consumer-data-protection-act/.

[60] *Id.*

[61] Edward McNicholas et al., *Step Aside California: Virginia Consumer Data Protection Act Becomes Law*, ROPES & GRAY (Mar. 03, 2021), https://www.ropesgray.com/en/newsroom/alerts/2021/March/Step-Aside-California-Virginia-Consumer-Data-Protection-Act-Becomes-Law.

[62] *See generally* Joe Rubino, *Colorado's New Consumer Data Protection Law Among the Most Demanding in the Country*, DENVER POST (Sept. 4, 2018), https://www.denverpost.com/2018/09/04/colorado-businesses-consumer-data-protection-law/ (listing requirements of CPA, noting it as the strongest data protection law in U.S.).

[63] F. Paul Pittman et al., *Colorado Privacy Act: US Consumer Data Privacy Framework Continues Expansion*, WHITE & CASE (Jul. 09, 2021),

despite this narrower definition and must provide consent for the processing of sensitive data (any medical, physical, and genetic data that is uniquely identifying).[64]

Although California, Virginia, and Colorado are the only states that have enacted and signed laws, nearly all fifty states have proposed individual bills regarding the protection of consumer data.[65] In light of these state statutes, digital health and telehealth organizations will need to simultaneously bolster in-house information technology infrastructures and adapt to changing data protection regulations.[66] Contractual agreements and clauses that manage the sharing and distribution of health data will need to reflect best practices in both the technology and healthcare sectors.[67] Technology organizations and digital health companies must have adaptive and dynamic information technology and information security infrastructures that are capable of benefiting from data generated via digital health technologies.[68] Because the end users of digital health products include patients, health care organizations, insurers, and public or private entities among others, digital health companies

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https://www.whitecase.com/publications/alert/colorado-privacy-act-us-consumer-data-privacy-framework-continues-expansion.

[64] Brandon P. Reilly & Carlyle E. Bruemmer, *Colorado's Consumer Data Protection Act Has Passed: What's in It?*, MANATT (Jul. 08, 2021), https://www.manatt.com/insights/newsletters/privacy-and-data-security/colorados-consumer-data-protection-act-has-passed.

[65] NCSL, supra note 47.

[66] *See generally* Shinjoung Yeo, *Tech Companies and Public Health Care in the Ruins of COVID*, 15 INTL J. COMMC'N 1617, 1624 (2021), https://ijoc.org/index.php/ijoc/article/view/16023/3401 (discussing Google's entry into health care and adjustments to information technology infrastructures).

[67] *See generally* Laura Bradford, et al. *Standard contractual clauses for cross-border transfers of health data after Schrems II*, J. L. AND THE BIOSCIENCES (Jun. 21, 2021), https://academic.oup.com/jlb/article/8/1/lsab007/6306998?login=true (reviewing utilization of Standard Contractual Clauses as safeguards for health data in absence of full protection of the law in the EU).

[68] *Id.* at 31.

are subject to an increased risk of data breach and resulting criminal or civil liability under various state laws.[69] To avoid potential large fines associated with the misuse of data, and to stay ahead of changing state regulations, organizations should adopt a policy of 'privacy by design,' embedding privacy and data protection controls into the design of their digital health products from the point of inception.[70] The CCPA is most similar to the GDPR, when compared to both Colorado's and Virginia's respective laws, and it surpasses and more precisely defines the provisions regarding the sale of data as noted in the GDPR. Digital health companies seeking to be in front of evolving U.S. state laws and the increasing focus on data subjects' control over their data should align their internal policies with the provisions set forth in the CCPA.

CONSIDERATIONS FOR DIGITAL HEALTH COMPANIES AND STATE LEGISLATION

As devices begin to utilize more augmented intelligence and machine learning, health care providers and institutions may find themselves removed from the practice of providing in-person care. At the core of healthcare is the understanding that patients trust their physicians. This trust is the basis of clinical decisions, institutional data protection policies, and clinical or medical ethics.[71] Thus, frameworks governing the use and processing of health data should include elements of compliance with national privacy and

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[69] Jovan Stevovic, *GDPR Compliance for Digital Health Startups*, HEALTHWARE GROUP 1, 3 (May 17, 2018), https://www.healthwaregroup.com/blog/gdpr-compliance-for-digital-health-startups-445.
[70] *Id.* at 7.
[71] Camille Nebecker et al., *Building the case for actionable ethics in digital health research supported by artificial intelligence*, BMC MED., 1, 2 (Jul. 17, 2019), https://doi.org/10.1186/s12916-019-1377-7.

security laws and adoption of best practices for information security and database validation.[72]

As the data protection and regulatory landscape continues to develop, both established and innovative digital health companies should continue to monitor developments relating to data privacy and protection even after the pandemic subsides. Compliance issues and ethical concerns alike should be taken into consideration throughout the research and development process, as organizations that plan for a changing regulatory landscape upfront can avoid the downstream costs associated with changing IT infrastructures, contractual obligations, and privacy obligations.

Health care and health technology organizations within the United States must comply with a series of federal and state laws pertaining to data privacy, data security, and data protection. Digital health companies and related healthcare organizations may already be subject to the GDPR if they process sensitive data from individuals from the EU. The most comprehensive state law, mirroring and exceeding the provisions of the GDPR, is the CCPA. Whereas the GDPR creates affirmative rights of individuals and procedures for organizations to follow, California's CCPA similarly establishes individual rights and terms of corporate governance. Additionally, the state law defines a robust and strict opt-out procedure, where data subjects can select to prevent the sale or processing of their personal data whereas the GDPR does not directly provide for this right, instead providing EU data

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[72] *See generally* Farah Aninha Fernandes & Georgi V. Chaltikyan, *Analysis of Legal and Regulatory Frameworks in Digital Health: Comparison of Guidelines and Approaches in the European Union and United States*, J. INT'L. SOC'Y TELEMED EHEALTH, 1, 9, (Dec. 14, 2020) https://journals.ukzn.ac.za/index.php/JISfTeH/article/view/1935 (defining aspects of meaningful regulation of digital health and liabilities surrounding adoption of digital health tools).

subjects with broad, generalized user rights that can be used to achieve the same effect.[73]

The CCPA has gone beyond the provisions as defined in the GDPR, requiring that covered health care entities report the findings of impact assessments to the state regulatory agency.[74] Though companies will not come into full compliance with both the GDPR and CCPA by choosing to work under either a strictly opt-out or an opt-in regime, digital health companies operating in the U.S. which handle European subject data would be able to maintain the focus on protection of the data, users' consent to data processing, and promotion of data subject autonomy by adhering to the principles set forth in the CCPA.

Organizations within the United States that handle either EU subject data or health data relating to California residents, regardless of the location of treatment or service provisioning, should look to the CCPA to simultaneously come into compliance with the various state laws and international regulations.

CONCLUSION

It is not expected that the U.S. will develop a comprehensive, omnibus data protection regulation at this time, and states will continue to promulgate their own (often sector-specific) data protection and security regulations.[75] In light of the piecemeal regulations coming from states, digital health companies should focus their privacy and protection policies on the CCPA and GDPR due to the similarity between the two regulations. The GDPR requires data protection by design, and many U.S.-based companies

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[73] Sarah Rippy, *Opt-in vs. opt-out approaches to personal information processing*, INT'L ASS'N OF PRIVACY PROFESSIONALS (May 10, 2021), *see* Laura Jehl & Alan Friel, *CCPA and GDPR Comparison Chart,* Practical Law https://iapp.org/news/a/opt-in-vs-opt-out-approaches-to-personal-information-processing/.
[74] GDPR, *supra* note 1, at Art. 35; *see* Millendorf, *supra* note 54.
[75] NCSL, *supra* note 47.

processing health data are already subject to the Regulation. Until a more comprehensive, federal data protection regulation is promulgated within the U.S., companies would most benefit from adhering to the principles of the CCPA.

Though compliance with the CCPA may seem daunting, because the CCPA is over-inclusive when compared to the GDPR, digital health companies would benefit from tailoring their data governance programs to California's current law. Crafting internal data governance policies to reflect the requirements of the CCPA would simultaneously allow organizations to comply with the strictest of the effective laws at the time, while also ensuring their processing of individual's data meets the standards in both the United States and the European Union's GDPR. By doing so, companies will be well-positioned to face changing domestic and international regulations surrounding data protection and can better allocate business resources to the development of innovative digital health technologies and therapies.

Keeping Pace with Advancing Artificial Intelligence in Healthcare: A Call for Increased Regulation and Legislative Action to Avoid the Deflection of Liability

Danny Maher

INTRODUCTION

Artificial Intelligence (AI) and Machine Learning (ML) are emerging areas of technology incorporated by healthcare organizations for a growing range of applications including clinical, administrative, and research purposes.[1] In health care, "approximately 86 percent of providers utilize at least one form of artificial intelligence in their practices."[2] This highlights a continued effort to improve the efficiency and quality of patient care by incorporating advancements in medical research and technology.[3] Both AI and ML have the opportunity to be transformative in the health care technology space.[4] Vast amounts of data generation and analysis can provide new and important insights to further the effective delivery of health care to individuals.[5]

The U.S. Food and Drug Administration (FDA) defines artificial intelligence as "the science and engineering of making intelligent machines, especially intelligent computer programs."[6] Machine learning is defined by the FDA as a subset or specific technique within artificial intelligence that implements the use of software algorithms that are designed and trained to

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[1] *How FDA Regulates Artificial Intelligence in Medical Products*, THE PEW CHARITABLE TRUSTS (Aug. 5, 2021), https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2021/08/how-fda-regulates-artificial-intelligence-in-medical-products.
[2] Sarah Kamensky, Note, *Artificial Intelligence and Technology in Health Care: Overview and Possible Legal Implications*, 21 DEPAUL J. HEALTH CARE L. 1, 1 (2020).
[3] *See id.* at 1 (noting efforts to improve patient care using medical research and technology).
[4] *Artificial Intelligence and Machine Learning in Software as a Medical Device*, FDA, https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device (Sept. 22, 2021).
[5] *Id.*
[6] *Id.* (quoting John McCarthy, *What Is Artificial Intelligence?*, http://jmc.stanford.edu/articles/whatisai/whatisai.pdf).

learn from and act on data that is collected and analyzed on a continued rolling basis.[7]

The FDA has taken steps to advance the management and regulation of artificial intelligence in medical software and products through the implementation of the January 2021 Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan.[8] The path to safe and robust development of AI/ML requires that important regulatory questions be addressed in a comprehensive manner.[9] The FDA has acknowledged that the rapid pace of innovation in the digital health field poses significant challenges.[10] New regulatory frameworks will be essential to the safe and effective development of devices without slowing innovation.[11]

Legislation and policy intervention must keep pace with technological developments and change the regulatory landscape to ensure safety and accountability when technology fails.[12] It is not enough for the FDA to provide guidance every few years through action plans. Congress needs to take legislative action to provide uniform regulation allowing for the safe application of this new technology. Without concrete legislative action from Congress, continued efforts to deflect liability among physicians and developers will impede consumer trust in the rapidly developing technology.

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[7] *Artificial Intelligence and Machine Learning in Software as a Medical Device, supra* note 4.
[8] FDA, ARTIFICIAL INTELLIGENCE/MACHINE LEARNING (AI/ML)-BASED SOFTWARE AS A MEDICAL DEVICE (SAMD) ACTION PLAN (Jan. 2021), https://www.fda.gov/media/145022/download [hereinafter *FDA Action Plan*].
[9] Jessica Kent, *FDA Evaluations of Medical AI Devices Show Limitations*, HEALTH IT ANALYTICS (Apr. 8, 2021), https://healthitanalytics.com/news/fda-evaluations-of-medical-ai-devices-show-limitations.
[10] *How FDA Regulates Artificial Intelligence in Medical Products*, *supra* note 1.
[11] *Id.*
[12] *Id.*

BACKGROUND OF ARTIFICIAL INTELLIGENCE IN HEALTHCARE

AI/ML in the healthcare industry involves technology that is used to collect health data, analyze it, and make informed decisions across a variety of different disciplines and subcategories.[13] AI/ML learns through data and observations, becoming more accurate with increased collection and interpretation of data.[14] Through the recognition of patterns and probabilities, AI/ML is able to simulate the mind processes of humans.[15] This technology provides a powerful tool in comparison to traditional programming and is becoming an important tool for improving healthcare.[16] The growth in the AI/ML market in healthcare is expected to reach $6.6 billion by 2021, a compounded annual growth rate of nearly 40 percent.[17]

The FDA faces unique challenges in developing a framework that sufficiently regulates these technologies, given how AI/ML-based devices change and adapt over time.[18] Many AI/ML devices use what the FDA describes as adaptive algorithms, which are constantly developing based on new input data.[19] The current regulatory framework is not set up to easily accommodate these adaptive, changing models.[20] Because the outputs associated with any AI/ML model are dynamic, AI/ML presents unique challenges that are atypical from other medical devices.[21] There is no ability

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[13] Richard Jenkins, *Artificial Intelligence in Medical Devices: The Future*, ATL TECHNOLOGY (Mar. 10, 2021), https://atltechnology.com/blog/artificial-intelligence-in-medical/.
[14] Megan Sword, Comment, *To Err is Both Human and Non-Human*, 88 UMKC L. Rev. 211, 213 (2019).
[15] *Id.*
[16] *Id.* at 214.
[17] *Id.* at 215.
[18] Jenkins, *supra* note 13.
[19] *Artificial Intelligence and Machine Learning in Software as a Medical Device*, *supra* note 4.
[20] Benjamens et al., *The state of artificial intelligence-based FDA approved medical devices and algorithms*, NATURE: NPJ DIGITAL MEDICINE (Sept. 11, 2020), https://www.nature.com/articles/s41746-020-00324-0.
[21] Charlotte A. Tschider, *Medical Device Artificial Intelligence: The New Tort Frontier*, 46 BYU L. REV. 1551, 1555 (2021).

for a programmer to assess the code and determine how the AI/ML system arrived at the new algorithm.[22] Invariably, this presents difficulty in FDA regulation and assignment of liability.[23]

The legal concept of preemption reduces some of the risk manufacturers and commercial developers take on when they develop AI/ML models for healthcare applications that are approved by the FDA.[24] Preemption ensures that federal law prevails when state and federal law conflicts, avoiding the need to meet safety requirements in each state separately.[25] AI/ML models in medical devices are constantly evolving.[26] This calls into question the application of preemption to AI/ML, as the initial FDA-approved algorithm does not remain static and undergoes constant change.[27] So far, the FDA has approved or cleared only devices using "locked" algorithms that change via manual update, hindering the impact AI technology and capabilities can have on devices and innovation.[28] Despite the FDA's attempts to provide guidance, gaps still exist to ensure the safety and effectiveness of AI/ML products in the healthcare field.[29]

ARTIFICIAL INTELLIGENCE & LIABILITY

Artificial intelligence and machine learning have the power to take the doctor training and treatment experience to new levels.[30] AI/ML provides physicians with vast amounts of medical knowledge.[31] In some cases, AI/ML

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[22] Sword, *supra* note 14, at 214.
[23] *Id.*
[24] Saurabh Jha, *Can you Sue an Algorithm for Malpractice? It Depends*, STAT (Mar. 9, 2020), https://www.statnews.com/2020/03/09/can-you-sue-artificial-intelligence-algorithm-for-malpractice/.
[25] *Id.*
[26] *Id.*
[27] *Id.*
[28] Susan Kelly, *FDA Issues Action Plan for Regulating AI in Medical Devices*, MEDTECH DIVE (Jan. 13, 2021), https://www.medtechdive.com/news/fda-issues-action-plan-for-regulating-ai-in-medical-devices/593280/.
[29] Tschider, *supra* note 21, at 1584.
[30] Sword, *supra* note 14, at 216.
[31] *Id.*

has engendered more accurate differential and clinical diagnoses than any human physician.[32] However, some physicians are skeptical about the implementation of this technology because it lacks physician intuition and evidence-based solutions, which they feel are essential tools not incorporated in the machine learning.[33] In addition, the incorporation of AI/ML into medical decision-making complicates physician liability when patients are harmed.[34] If physicians feel they may be liable for the unpredictable behavior of AI/ML models, they may be hesitant about implementing such models into their clinical practice.[35]

When AI/ML is used in a clinical context and a patient is harmed, assigning responsibility between the model or the physician may prove difficult.[36] The assignment of liability is an important issue when it comes to implementation of these models because patients deserve accountability.[37] A lack of clear responsibility can allow for mistakes to continue to flourish.[38] When a misdiagnosis or mistreatment occurs because a physician misused AI/ML information to treat the patient, the physician may deflect liability by shifting blame onto the developer.[39] On the other hand, developers may look to limit their liability for machine learning in medical devices using software exemption under products liability doctrines.[40] Since products are defined as tangible personal property, the application of products liability doctrine to software has been questioned on the grounds that software is not truly a product.[41] This provides manufacturers and developers with a software

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[32] *Id.* at 215.
[33] *Id.* at 216.
[34] *Id.* at 218.
[35] *Id.*
[36] Olivia Goldhill, *When AI in Healthcare Goes Wrong, Who is Responsible?*, QUARTZ (Sept. 20, 2020), https://qz.com/1905712/when-ai-in-healthcare-goes-wrong-who-is-responsible-2/.
[37] *Id.*
[38] *Id.*
[39] Sword, *supra* note 14, at 218.
[40] Harned et al., *Machine Vision, Medical AI, and Malpractice*, HARV. J.L. & TECH. DIG. 1, 8 (2019), https://jolt.law.harvard.edu/assets/digestImages/PDFs/Harned19-03.pdf.
[41] *Id.*

exemption under products liability.[42] Alternatively, developers may have physicians engage in an active role when using ML systems to provide manufacturers with the opportunity for a learned intermediary defense to liability.[43] The learned intermediary doctrine asserts that once a physician has received adequate warning of the products risks, they have a duty to relay this warning to the patient.[44] Regardless, AI developers must demonstrate how AI justifies its actions and decision-making before society trusts AI/ML in the clinical context.[45]

Today, policymakers are struggling to keep pace with the rapid technological development of AI and robotics into the expanding healthcare industry.[46] As the technology continues to develop, public demand for protection will continue to grow.[47] While some legislators remain fearful of inhibiting technological innovation, it is difficult for this new technology to gain traction if consumers are not assured that someone will be responsible when it fails.[48] Congress must develop standard government regulation to ensure that developers and physicians cannot unfairly deflect liability. This will allow the courts to employ a regulatory framework to help solve the liability issues associated with these models and assure patients of its quality.[49]

ARTIFICIAL INTELLIGENCE IN SURGICAL DECISION-MAKING & ROBOTICS

Preventable medical errors are the fourth leading cause of death in the United States, with twenty-six percent of these deaths being attributed to

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[42] *Id.* at 10.
[43] *Id.* at 9.
[44] *Id.*
[45] Sword, *supra* note 14, at 233.
[46] Frank Pasquale, *When Medical Robots Fail: Malpractice Principles for an Era of Automation*, BROOKINGS (Nov. 9, 2020), https://www.brookings.edu/techstream/when-medical-robots-fail-malpractice-principles-for-an-era-of-automation/.
[47] *Id.*
[48] *Id.*
[49] See *id*. (explain that a strong regulatory framework will allow courts to properly assign liability).

surgical errors that cost nearly $36 billion.[50] AI/ML can effectively combine the best of human decision-making from surgeons with new and exceptional technology tools.[51] Although fully automated robotic surgery may be a distant concept, the use of AI/ML as a tool to effectively augment situational, surgical decision-making could be transformative in the healthcare space.[52] The field of surgical decision-making is "dominated by hypothetical-deductive reasoning, individual judgment, and heuristics."[53] Because these factors are such driving forces in the field, bias, error, and preventable harm may result.[54]

The first examples of AI in surgical-decision making have entered the commercial market, as Activ Surgical debuted its ActivEdge™ platform, an AI/ML application designed to provide critical real-time intelligence and visualization to surgeons in the U.S.[55] The company has plans to commercialize globally in 2021, following an initial launch of the platform and associate products in the U.S. market.[56]

AI/ML technology can be an effective tool to aid in the decision-making process and secure better outcomes for patients.[57] The use of this technology raises important questions in regard to liability when errors are made.[58] Increased Congressional input and policy intervention on a federal level will help supplement FDA action, and solidify the regulatory landscape of artificial intelligence as the technology continues to develop.[59] This will allow for further incorporation of AI into surgical decision-making in an

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[50] Greg Nichols, *Should AI Assist in Surgical Decision-Making*, ROBOTICS (May 18, 2020), https://www.zdnet.com/article/should-ai-assist-in-surgical-decision-making/.
[51] *Id.*
[52] *Id.*
[53] *Id.*
[54] *Id.*
[55] *Id.*
[56] *Id.*
[57] *Id.*
[58] Pasquale, *supra* note 46.
[59] *How FDA Regulates Artificial Intelligence in Medical Products*, *supra* note 1.

effort to drive down the number of preventable deaths due to medical errors using technology that has already been developed.[60]

Robotic software incorporating AI and ML is the next generation of tools that can aid surgeon skills and improve surgical outcomes.[61] By analyzing thousands of previous cases in real time, AI advice derived from ML algorithms can be incorporated into surgery to provide instantaneous guidance.[62] One potential application for this AI-delivered advice involves real-time visual overlays, suggesting to surgeons that they steer clear from certain areas or critical blood vessels while operating.[63] These warnings and guidance can augment the work being done by the surgeons, and could lead to better surgical outcomes.[64] Implementation of AI will improve the robotic surgery landscape by providing surgeons with information to help prevent mistakes and provide suggestions based on previously successful alternatives.[65]

The incorporation of artificial intelligence in medicine has taken on both physical and virtual applications.[66] While virtual examples include the development of AI for use in surgical robots, virtual informatics have used AI to control health management systems, electronic health records, and to provide guidance to physicians on treatment decision-making.[67] Surgical robots use technology known as "haptics," which increase resistance to movement at the borders of safe zones to give surgeons feedback during surgical procedures.[68] If the surgeon deviates from the zone provided by

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[60] Nichols, *supra* note 50.
[61] Roger Smith, *How Robots and AI are Creating the 21st-Century Surgeon*, ROBOTICS BUSINESS REVIEW, (Feb. 7, 2019), https://www.roboticsbusinessreview.com/health-medical/how-robots-and-ai-are-creating-the-21st-century-surgeon/.
[62] *Id.*
[63] *Id.*
[64] *Id.*
[65] *Id.*
[66] Frank Griffin, *Artificial Intelligence and Liability in Health Care*, 31 HEALTH MATRIX 65, 68 (2021).
[67] *Id.*
[68] *Id.* at 70.

preoperative planning, auditory and visual notifications will alert the surgeon.[69] The use of this technology in surgical robots could theoretically lead to fully automated robotic invasive procedures, although they are currently not being performed due to existing technological constraints.[70] Fully-automated robotic medical procedures would likely not be introduced until a regulatory framework has been well established and the safety and efficacy of robotic surgery has experienced robust development.[71]

FDA REGULATION OF ARTIFICIAL INTELLIGENCE

The importance of regulating digital health products, and more specifically AI/ML, was first recognized by the FDA in July 2017 with the release of guidance in the form of the Digital Health Innovation Action Plan.[72] The agency released additional guidance in April 2019 and again in January 2021, proposing a regulatory framework for modifications to AI/ML-learning-based software as a medical device (SaMD).[73] The FDA action plan outlined five actions that the agency intended to take, including further developing the proposed regulatory framework through issuance of draft guidance on a predetermined change control plan for software's learning over time.[74] Other action points included supporting development of good AI/ML practices to evaluate and improve algorithms, fostering a patient-centered approach with device transparency, developing methods to evaluate and improve ML algorithms, and advancing real world performance monitoring pilots.[75] The FDA's goal was to appropriately tailor regulatory oversight for AI/ML-based SaMD that will deliver safe and effective

[69] *Id*. at 70.
[70] *Id.* at 71.
[71] *Id.*
[72] FDA, DIGITAL HEALTH INNOVATION PLAN (2017), https://www.fda.gov/media/106331/download.
[73] *FDA Action Plan*, *supra* note 8, at 1.
[74] *FDA Action Plan*, *supra* note 8, at 3.
[75] *FDA Action Plan*, *supra* note 8, at 3-6.

software functionality to improve patient care.[76] However, this action plan did not go far enough in establishing a regulatory framework that sufficiently clarified products liability issues for medical device manufacturers and developers.[77]

The action plan outlined the FDA's steps towards furthering AI/ML oversight via a total product lifecycle-based oversight approach.[78] The proposed framework is described as a "Predetermined Change Control Plan" in premarket submissions.[79] The plan would include anticipated modifications used to implement changes in a controlled manner that manages risks to patients, referred to as an "Algorithm Change Protocol."[80] With an expectation of transparency and real-world performance monitoring by manufacturers, it would allow the FDA to evaluate and monitor the software product from premarket development through post-market performance to provide a reasonable assurance of safety and effectiveness.[81]

The FDA has recognized that the plan will need to evolve to address patient safety issues as they arise, but the agency has not developed a regulatory approach enacted through policy or legislation.[82] Currently, there is no specific regulatory pathway for AI/ML-based medical devices in the U.S. or Europe, but a less rigorous evaluation process of medical devices in Europe has led to earlier approval of devices.[83] To improve public trust,

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[76] FDA, PROPOSED REGULATORY FRAMEWORK FOR MODIFICATIONS TO ARTIFICIAL INTELLIGENCE/MACHINE LEARNING (AI/ML) – BASED SOFTWARE AS A MEDICAL DEVICE (SAMD*)* 1 (2020), https://www.fda.gov/media/122535/download.
[77] *Id.*
[78] *FDA Action Plan*, *supra* note 8, at 1.
[79] *Id*.
[80] *Id*.
[81] *Id*.
[82] *Id*. at 7.
[83] Muehlematter et al., *Approval if Artificial Intelligence and Machine Learning-Based Medical Devices in the USA and Europe (2015-20): A Comparative Analysis*, THE LANCET DIGITAL HEALTH (Jan. 18, 2021), https://www.thelancet.com/action/showPdf?pii=S2589-7500%2820%2930292-2.

safety, overall efficacy, and quality of AI/ML-based medical devices in the U.S., more transparency into their approval and regulation is needed.[84]

Medical devices are currently cleared by the FDA through three pathways based on the risk of the devices, intended use, indications for use, technological characteristics, and necessary regulatory controls.[85] The premarket approval pathway is the most stringent review for high-risk devices, the de-novo premarket review is used for low and moderate-risk devices, and the 510(k) pathway makes up the third regulatory path.[86] Despite these regulatory paths and action plans implemented in the U.S., the lack of laws that specifically regulate the use of AI/ML-enabled medical devices presents challenges that will likely need to be addressed through federal legislation.[87] Manufacturers must spend substantial effort and resources to understand the application of the current regulatory framework as it struggles to keep up with development, leading to much uncertainty and risk.[88] If the current regulatory regime continues without a more structured pathway, developers may slow innovation for fear of liability.[89] Establishing clear and specific laws on the federal level will limit attempts to deflect liability among various parties involved in the development and implementation of AI/ML technology.

In an effort to improve the existing regulatory structure, a more expansive and multi-faceted regulatory model must be implemented by healthcare stakeholders.[90] Regulation focused on narrow standards of evaluation of device safety or physician licensure will not adequately account for the

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[84] *Id.*
[85] Minssen et al., *Regulatory Responses to Medical Machine Learning*, 7 J.L. & BIOSCIENCES 1, 4 (Jan.-June 2020).
[86] Muehlematter et al., *supra* note 83.
[87] Minssen et al., *supra* note 85, at 17.
[88] *Id.* at 17.
[89] Pasquale, *supra* note 46.
[90] Nicolas Terry, *Of Regulating Healthcare AI and Robots*, 21 YALE J. L. & TECH. 133, 189-90 (2019).

evolution of devices and technology powered by AI and ML.[91] In addressing the deficiencies in the existing regulatory structure, it is necessary to account for how the technological and human domains intertwine in AI and ML.[92]

Current regulatory models are ill-equipped to harness the technological power of AI/ML devices which are continually evolving while incorporating new data.[93] These models separately assess the safety of the healthcare product or device and the conduct of the medical professionals who interact with the device.[94] Finding a way to integrate these separate features is imperative to implementing evolving technology in the realm of augmenting surgical decision-making.[95] Without action to improve the cohesiveness of the existing regulatory model, physicians and AI/ML developers will continue to be at odds regarding responsibility when errors are made.

CONCLUSION

Given the rapid expansion of artificial intelligence into medical devices and the healthcare industry, Congress must engage in legislative efforts to keep pace with the regulation required to ensure safe application of this new technology. Although the United States regulatory system for medical devices involves a centralized process through a single agency, the lack of specific laws on a federal level present challenges for assigning liability and limiting manufacturer risk.[96] While technological advancements in artificial intelligence can improve human health, it is inevitable that mistakes will be made, and responsibility must be assigned. Physicians and developers will continue to attempt to deflect liability away from themselves when

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[91] *Id.* at 190.
[92] *Id.* at 173.
[93] *Id.*
[94] *Id.*
[95] *Id.*
[96] Magali Contardi, *Changes in the Medical Device's Regulatory Framework and Its Impact on the Medical Device's Industry: From the Medical Device Directives to the Medical Device Regulations*, 2 ERASMUS LAW REVIEW 166, 169 (2019).

incorporating this new technology into their practice. The existing gap in regulation leads to stifled innovation and a lack of consumer trust in the application of artificial intelligence in the healthcare field. An unfortunate consequence is that this potentially transformative technology may begin to fizzle.

Medical Device Regulation and Coverage: How CMS' Medicare Coverage of Innovative Technology Rule Would Promote Equity and Innovation

Kelly McDunn

INTRODUCTION

Determining insurance coverage for medical technology and devices involves a difficult balancing act—weighing the desire to provide rapid access to innovation against concerns related to paying for technology with insufficient evidence of safety and effectiveness.[1] While this balancing act is a required undertaking of any insurance provider, in late 2020, the adequacy of the Centers for Medicare & Medicaid Services' (CMS) execution came under fire following its rule on a new Medicare coverage pathway for certain medical devices.[2] A federal agency within the United States Department of Health & Human Services, CMS administers the Medicare program, which provides health insurance for individuals aged over sixty-five, as well as others with certain disabilities and end-stage renal disease.[3] CMS commonly covers drugs immediately upon Food & Drug Administration (FDA) approval, in stark contrast to limited access to most FDA approved and authorized devices for Medicare beneficiaries, which require participation in additional clinical studies sanctioned by CMS.[4]

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[1] Peter J. Neumann & James D. Chambers, *Eroding Progress on Evidence and Outcomes: CMS's New Proposed Pathway for Medical Device Coverage*, HEALTH AFFAIRS: HEALTH AFFAIRS BLOG (Dec. 2, 2020), https://www.healthaffairs.org/do/10.1377/hblog20201130.767638/full/.

[2] *Id.*

[3] *Medicare Program - General Information*, CENTERS FOR MEDICARE & MEDICAID SERVICES (Jan. 14, 2021, 9:55 AM), https://www.cms.gov/Medicare/Medicare-General-Information/MedicareGenInfo.

[4] Anand Shah, *Op-Ed: Medicare Needs to OK Rule Giving Seniors Access to FDA-Approved Medical Devices*, CNBC: OP. (May 6, 2021, 1:26 PM), https://www.cnbc.com/2021/05/06/op-ed-medicare-needs-to-ok-rule-giving-seniors-access-to-fda-approved-medical-devices.html.

In the Trump administration's final week,[5] CMS finalized the *Medicare Coverage of Innovative Technology (MCIT)* rule, which would have granted expedited coverage for FDA-designated breakthrough devices.[6] Touted as promoting CMS' continued initiative of bringing new and innovative technologies to beneficiaries, the MCIT rule provided national Medicare coverage as early as the same day as FDA market authorization for breakthrough devices.[7] This coverage would last up to four years, during which time manufacturers could voluntarily develop clinical studies to demonstrate the long-term value of the device for the Medicare population, and thereafter receive continued national coverage.[8]

After being delayed twice by the Biden administration, the final MCIT rule was set to go into effect in December of 2021.[9] However, on September 15, 2021, CMS published a new proposed rule which, if finalized, would repeal the final MCIT rule.[10] CMS now claims that the MCIT rule may not be "in the best interest of Medicare beneficiaries," specifically referring to the fact that there is no FDA requirement that Medicare beneficiaries be included in the clinical studies necessary for market authorization.[11] On November 12, 2021, CMS officially rescinded the MCIT rule, stating that although the agency is in favor of enhancing access to new technologies, the

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[5] *CMS Proposed Rule Repeals MCIT Final Rule,* ASSOC. OF AM. MED. COLLEGES (Sept. 17, 2021), https://www.aamc.org/advocacy-policy/washington-highlights/cms-proposed-rule-repeals-mcit-final-rule.
[6] Centers for Medicare & Medicaid Services, 42 C.F.R. pt. 405 (2021).
[7] *Fact Sheet: Medicare Coverage of Innovative Technology (CMS-3372-F),* CENTERS FOR MEDICARE & MEDICAID SERVICES, (Jan. 12, 2021), https://www.cms.gov/newsroom/fact-sheets/medicare-coverage-innovative-technology-cms-3372-f.
[8] *Id.*
[9] Christopher Hanson & Konnor Owens, *Changing Course, CMS Proposes to Repeal Medicare Coverage Pathway for FDA-Designated "Breakthrough Devices"*, XI NAT'L L. REV. 293 (Sept. 21, 2021), https://www.natlawreview.com/article/changing-course-cms-proposes-to-repeal-medicare-coverage-pathway-fda-designated.
[10] *Id.*
[11] *Id.*; *see also* Centers for Medicare & Medicaid Services, 42 Fed. Reg. 3372 (proposed September 15, 2021) (to be codified as 42 C.F.R. pt. 405)(proposing a repeal of the MCIT rule).

Medicare program needs to implement policies that balance access and appropriate safeguards.[12]

This article argues that the final MCIT rule *was* in the best interest of Medicare beneficiaries, by weighing the benefits of access to breakthrough medical devices against the risks of new technology. First, the article will present an overview of the FDA's Breakthrough Device Program,[13] as well as CMS' general regulatory standards for medical devices.[14] Second, it will evaluate CMS' chief, yet weak, justification in repealing the MCIT rule.[15] Finally, the article will demonstrate how the MCIT rule was in the best interest of Medicare beneficiaries for several reasons—it would provide patients with more choices,[16] play a role in preventing inequitable access to medical treatments and technologies,[17] and promote future innovation.[18]

FDA Regulatory Standards For Breakthrough Devices

Medical devices, which range from common medical supplies such as bandages and tongue depressors to complex instruments such as artificial heart valves and mechanical ventilators, play a crucial role in the treatment and diagnosis of illness and disease.[19] While medical devices provide significant benefits, they also present equally substantial risks.[20] It is the responsibility of the FDA to balance these benefits and risks and make well-supported regulatory decisions, permitting only those devices that are

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[12] Press Release, Centers for Medicare & Medicaid Services, CMS Repeals MCIT/R&N Rule; Will Consider Other Coverage Pathways to Enhance Access to Innovative Medical Devices (Nov. 12, 2021), https://www.cms.gov/newsroom/press-releases/cms-repeals-mcitrn-rule-will-consider-other-coverage-pathways-enhance-access-innovative-medical.
[13] *See infra* FDA Regulatory Standards For Breakthrough Devices.
[14] *See infra* CMS Regulatory Standards For Medical Devices.
[15] *See infra* CMS' Concerns.
[16] *Id.*
[17] *See infra* Eliminating Inequitable Access.
[18] *See infra* Incentivizing Innovation.
[19] U.S. Food & Drug Admin., Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health 1 (2018), https://www.fda.gov/files/about%20fda/published/Medical-Device-Safety-Action-Plan--Protecting-Patients--Promoting-Public-Health-%28PDF%29.pdf.
[20] *Id.*

deemed "safe and effective" to reach the market.[21] Ensuring the safety and efficacy of medical devices also necessitates promoting innovation to develop even safer and more effective devices.[22]

In recent years, the FDA has taken several steps to promote innovation, including finalizing its Breakthrough Devices Program.[23] Established by the 21st Century Cures Act,[24] the "Breakthrough Devices Program" is intended to advance the development of innovative devices, and help give patients more timely access to products that effectively diagnose or treat "life-threatening or irreversibly debilitating diseases or conditions."[25]

In the voluntary program, any manufacturer that wishes to submit an application must demonstrate that its device (1) provides more effective treatment or diagnosis for life-threatening or irreversibly debilitating diseases or conditions; and (2)(A) represents a breakthrough technology; (B) with no existing approved or cleared alternatives; (C) that offers a significant improvement over available alternatives; or (D) the availability of which is in the best interest of patients.[26] If granted breakthrough designation, the FDA and device manufacturer will work closely together in "sprints," with the FDA providing various flexibilities related to interactive communication, priority review, modified clinical studies, and lenient manufacturing considerations.[27]

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[21] *Id.* at 3–4.
[22] *Statement from FDA Comm'r Scott Gottlieb, M.D. & Dir. of the Ctr. For Devices and Radiological Health Jeff Shuren, M.D., on new steps to promote innovations in medical devices that help advance patient safety,* U.S. FOOD & DRUG ADMIN. (Dec. 18, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-jeff-shuren-md-director-center-devices-and-0 [hereinafter *Statement from FDA*].
[23] *Id.*
[24] 21st Century Cures Act, S. 3051, 114th Cong. (2017).
[25] *Statement from FDA*, *supra* note 22.
[26] U.S. FOOD & DRUG ADMIN., BREAKTHROUGH DEVICES PROGRAM: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF, U.S. FOOD & DRUG ADMIN 8. (2018), https://www.fda.gov/media/108135/download [hereinafter *Guidance for Industry and FDA Administration Staff*]; *see*, 21 U.S.C. § 360e–3(b) (providing program for devices representing breakthrough technologies).
[27] *Id.* at 3–8.

CMS REGULATORY STANDARDS FOR MEDICAL DEVICES

Medical devices deemed "safe and effective" by the FDA are not always covered by CMS, which requires device manufacturers to overcome an additional hurdle, proving devices to be "reasonable and necessary."[28] CMS has long grappled with the reasonable and necessary clause.[29] Determining what level of care is "necessary" is contingent on the strength of the supporting clinical evidence, but these judgments are invariably complex.[30] Further, determining "reasonableness" can be even more difficult, as it implies figuring out whether spending money on a particular medical technology is a wise allocation of resources.[31] In addition to providing for same-day coverage of FDA-designated breakthrough devices, the MCIT rule modified the "reasonable and necessary" standard.[32] Specifically, moving forward, officials would consider whether a device is: (1) safe and effective; (2) non-experimental or investigational; and (3) appropriate for Medicare patients.[33] However, these changes to the necessary and reasonable criteria would do little to alleviate the previously existing ambiguities.[34] While all medical devices should arguably be "appropriate," this term's vagueness established one of the grounds for CMS' repeal of the MCIT rule.[35]

CMS' CONCERNS

CMS' chief justification in its decision to repeal the MCIT rule is that Medicare beneficiaries are not adequately represented in FDA clinical trials,

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[28] Shah, *supra* note 4.
[29] Joshua Cohen, *Medicare Reverse Course On Decision to Universally Cover Breakthrough Medical Devices for 4 Years*, FORBES (Oct. 4, 2021, 11:34 AM), https://www.forbes.com/sites/joshuacohen/2021/10/04/medicare-reverses-course-on-decision-to-universally-cover-breakthrough-medical-devices-for-4-years/?sh=2d4e0a5e28fd.
[30] *Id.*
[31] *Id.*
[32] *Id.*; *see also* Centers for Medicare & Medicaid Services, 42 C.F.R. pt. 405 (2021) (providing modification of CMS' reasonable and necessary standard).
[33] *Id.*
[34] Cohen, *supra* note 29.
[35] *Id.*

and due to beneficiaries' advanced ages and additional comorbidities, this could lead to coverage of devices that are inappropriate or unsafe for the population.[36] However, it is the responsibility of the FDA to make well-supported regulatory decisions, permitting only devices deemed "safe and effective" to reach the market.[37] The Breakthrough Devices Program is not a new form of FDA approval, and does not provide an alternative to the existing FDA approval pathways.[38] FDA-designated breakthrough devices progress to market via one of three existing pathways: premarket approval, 501(k) clearance, or De Novo marketing authorization.[39] The Breakthrough Devices Program preserves all of the statutory standards of these pathways,[40] while assisting manufactures in getting their medical devices on the market faster, by means of an interactive program with various flexibilities.[41]

While the FDA's Breakthrough Devices Program does provide concessions when it comes to risk-benefit analysis, namely allowing for post-market data collection and the amount of uncertainty that may be appropriate at approval, such risks are necessary considering the critical patient population the devices are intended to serve.[42] In fact, in all FDA approval decisions there exists some level of uncertainty.[43] For all medical devices,

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[36] Lee A. Fleisher, *Medicare Coverage of Innovative Technologies (MCIT)*, CENTERS FOR MEDICARE & MEDICAID SERVICES: BLOG (Sept. 13, 2021), https://www.cms.gov/blog/medicare-coverage-innovative-technologies-mcit.; *see* Centers for Medicare & Medicaid Services, 42 Fed. Reg. 3372 (proposed Sept. 15, 2021) (to be codified at 42 C.F.R. pt. 405) (proposing a repeal of the MCIT rule).
[37] Joseph Grogan, *Medicare Coverage of Innovative Technologies: The U.S. Should do More to Speed Entry of Breakthrough Devices to Market*, USC DORNSIFE: CTR. FOR ECON. POL'Y AND SOC. RSCH. (Sept. 23, 2021), https://healthpolicy.usc.edu/evidence-base/medicare-coverage-of-innovative-technologies-the-u-s-should-do-more-to-speed-entry-of-breakthrough-devices-to-market/.
[38] *The FDA's Breakthrough Devices Program*, JOHNER INSTITUTE, https://www.johner-institute.com/articles/regulatory-affairs/fda/breakthrough-devices/.
[39] *Breakthrough Devices Program*, U.S. FOOD & DRUG ADMIN. (Jan. 5, 2021), https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program; *see also* Madelyn Lauer et al., *FDA Device Regulation*, 114(4) MO. MED. 283, 285 (2017) (providing background on medical device pathways to market).
[40] *Id.*
[41] *The FDA's Breakthrough Devices Program, supra* note 38.
[42] U.S. DEP'T. OF HEALTH AND HUMAN SERVICES & FOOD AND DRUG ADMIN., *REPORT TO CONGRESS: BREAKTHROUGH DEVICES PROGRAM,* 6–7 (2019).
[43] *Guidance for Industry and FDA Administration Staff, supra* note 26 at 4.

the appropriate level of uncertainty is carefully calculated based on the specific circumstances surrounding a device, including the probable benefits of the device, and relevant non-clinical and clinical information.[44]

Devices, which have been authorized through the FDA's Breakthrough Devices Program, are narrowly defined as devices that assist in the diagnosis or treatment of life-threatening and irreversibly debilitating diseases.[45] The Medicare beneficiaries who would utilize these devices may be harmed just as much by refusals to grant approvals, or delays to approvals, as they may be devices that come with risks, or are not entirely effective.[46] Examples of recent FDA-designated breakthrough devices include an implantable pulse generator for patients with advanced heart failure,[47] as well as a liquid biopsy assay designed to provide early detection for pancreatic ductal adenocarcinoma cancer (PDAC).[48] Both of these patient populations face exceptionally poor prognoses and limited alternative treatment options, factors that both outweigh the invariable risks of new technology.[49] Specifically, by 2040, PDAC is projected to become the second leading cause of cancer-related death, primarily because the disease is asymptomatic in the early stages, which further emphasizes the importance of capitalizing on innovative technology solutions.[50] Medicare patients with life-threatening conditions should, in consultation with their doctors, be provided with the

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[44] *Id.*
[45] *Id.* at 8.
[46] *The FDA's Breakthrough Devices Program*, *supra* note 38.
[47] Press Release, U.S. FOOD & DRUG ADMIN., *FDA approves new device to improve symptoms in patients with advanced heart failure* (Aug. 16, 2019), https://www.fda.gov/news-events/press-announcements/fda-approves-new-device-improve-symptoms-patients-advanced-heart-failure [hereinafter *Advanced Heart Failure*].
[48] Press Release, BIOLOGICAL DYNAMICS, INC., *FDA Grants Breakthrough Device Designation for Biological Dynamics' Early stage Pancreatic Cancer Detection Test* (Oct. 20, 2021), https://biologicaldynamics.com/news-all/2021/10/13/biological-dynamics-awarded-fda-breakthrough-device-designation-for-early-stage-pancreatic-cancer-detection-test [hereinafter *Early stage Pancreatic Cancer Detection Test*].
[49] *Id.*; *Advanced Heart Failure*, *supra* note 47.
[50] *Early stage Pancreatic Cancer Detection Test, supra* note 48.

option to utilize breakthrough devices.[51] At the end of the day, recommending, prescribing and utilizing a breakthrough medical device should be within the discretion of the patient and their provider, not CMS.[52]

The MCIT rule maintains the safeguards built into the FDA authorization process, and if at any point analytical or clinical data suggest device utilization side effects or other risks, the FDA requires identification of those risks on the product's label.[53] Further, if new risks are identified through clinical adoption of a breakthrough device, the FDA has the authority to require label changes.[54] Providing an additional safeguard, the MCIT rule also allows CMS to terminate coverage in instances where the FDA has issued a safety warning or rescinded market authorization of a device.[55] Concerns raised by CMS stem from patient safety; however, with existing statutory standards and added safety provision within MCIT rule, risks are mitigated and the weighing of any remaining risks and benefits becomes a conversation between physician and patient.

ELIMINATING INEQUITABLE ACCESS

There are three primary pathways for CMS coverage of medical devices: National Coverage Determination (NCD), Local Coverage Determinations (LCD) made by regional contractors, and claim-by-claim determinations.[56] The processes to establish NCDs and LCDs consider clinical evidence obtained through CMS-sanctioned studies, public comment periods and input from independent experts to establish that devices are reasonable and

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[51] Glenn G. Lammi, *CMS Should Offer Immediate Reimbursement Coverage To FDA-Approved Breakthrough Devices*, FORBES (Apr. 29, 2021, 10:23 AM), https://www.forbes.com/sites/wlf/2021/04/29/cms-should-offer-immediate-reimbursement-coverage-to-fda-approved-breakthrough-devices/?sh=2f15b87e476e.
[52] *Id.*
[53] *Id.*
[54] *Id.*
[55] Grogan, *supra* note 37.
[56] *Id.*

necessary.[57] Due to the rigorous nature of these processes, local and national coverage determinations may come years after FDA authorization.[58] For example, it was nearly sixty-seven months after gaining FDA approval that SCULPTRA, a medical device for HIV patients, finally gained CMS coverage.[59] Similarly, the Independence Ibot Motility System, an advance powered wheelchair, did not receive CMS coverage until thirty-five months after FDA approval.[60]

Additionally, LCDs create a patchwork of, rather than uniform, coverage.[61] At the time of the MCIT rule's finalization, of the sixteen existing FDA-designated breakthrough devices, ten experienced coverage variability depending on the jurisdiction.[62] This slow and patchy coverage of breakthrough devices results in inequitable access for patients who could benefit from immediate and consistent coverage of these devices.[63] Following CMS' initial delay of the MCIT rule, numerous comments were filed calling on the agency to effectuate the rule.[64] One comment came from a cardiologist in rural Maine, who noted that, "given the lack of trained people to administer legacy services and the large gap in services available in rural versus urban centers, the promise of MCIT is the promise that emerging technologies built on strong evidence can suture our healthcare fabric together."[65] The MCIT rule would be an initial step towards

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[57] Vinay K. Rathi et al., *Medicare's New Device-Coverage Pathway – Breakthrough or Breakdown?*, 384; 12 N. ENGL. J. MED. 1–2 (Mar. 25, 2021).
[58] *Id.*
[59] Grogan, *supra* note 37.
[60] *Id.*
[61] *Id.*
[62] *Id.*
[63] *Id.*
[64] Lammi, *supra* note 51.
[65] *Id.*; *see* Centers for Medicare & Medicaid Services*, Comment on CMS-2020-0098-0371*, REGULATIONS.GOV (Apr. 7, 2021), https://www.regulations.gov/comment/CMS-2020-0098-0371 (providing physician's support of MCIT implementation to alleviate inequitable access in rural areas).

alleviating inequitable access due to geography, and would allow all Medicare beneficiaries access to the same medical devices.[66]

Breakthrough designation has been awarded to a wide variety of devices, from in vitro diagnostics and imaging platforms, to implants and portable devices, and covering a range of ailments, including Ebola, traumatic brain injury, heart disease, and cancer.[67] However, there are patients who are unable to access cutting-edge testing, such as advanced DNA sequencing as part of a cancer workup, because CMS does not provide coverage.[68] The same product can often be obtained by the patient through commercial insurance; however, after aging into the Medicare program many patients forgo other insurance options.[69] As a last resort, patients have no choice but to pay out of pocket.[70] Unfortunately, not all patients have this ability, and these individuals miss out on opportunities for improvements in their conditions and independence solely due to an inability to pay.[71] In the aforementioned comment period, a sixty-seven year old stroke survivor expressed not only appreciation for the rehabilitation opportunities he received, but also concern regarding the high out-of-pocket costs.[72] He noted that, "many stroke survivors are just scraping by, and spending even a hundred dollars on their care each month – let alone the out of pocket costs of these breakthrough devices – becomes untenable quickly."[73] The MCIT rule would help alleviate such inequitable access related to prohibitive out-

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[66] Robert King, *CMS Rule Aims to Reduce Lag Time between FDA Approval and Medicare Coverage of New Devices*, FIERCE HEALTHCARE (Aug. 31, 2020, 12:06PM), https://www.fiercehealthcare.com/payer/cms-rule-aims-to-reduce-lag-time-between-fda-approval-and-medicare-coverage-new-devices.
[67] Shah, *supra* note 4.
[68] *Id.*
[69] *Id.*
[70] *Id.*
[71] Lammi, *supra* note 51.
[72] *Id.*; *see* Centers for Medicare & Medicaid Services*, Comment on CMS-2020-0098-0347*, REGULATIONS.GOV (Apr. 22, 2021), www.regulations.gov/comment/CMS-2020-0098-0376 (demonstrating patient's support of MCIT implementation as related to out-of-pocket costs) [hereinafter *Comment on CMS-2020-0098-0347]*.
[73] *Comment on CMS-2020-0098-0347, supra* note 72.

of-pocket costs and variations between commercial insurance and Medicare.[74]

INCENTIVIZING INNOVATION

Providing a pathway for medical devices to reach patients more quickly creates incentives for innovators, manufactures and investors to continue work on, as well as invest in, these types of technologies.[75] The delay that usually accompanies CMS' consideration post-FDA approval of Medicare coverage, slows device companies' risk-taking, as well as the willingness of investors to make financial commitments.[76] This time period, where safe and effective technologies have been fully developed, yet are not available to patients, is referred to by many innovators as the "valley of death."[77] On average, the FDA approval process, alone, can take up to ten years, depending on the nature of a medical device and its related clinical trials.[78] Even after the FDA approves a medical device, the technology will still be subject to years of additional scrutiny by CMS, before earning coverage under Medicare.[79] This entire medical device approval process is both time- and capital- intensive.[80]

Medical device innovation almost always occurs in the private sector, primarily through venture capital investment in smaller companies.[81] While the ultimate motive of medical device innovation is to improve patients' qualities of life, investment generally relies on the prospect of financial

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[74] Lammi, *supra* note 51.
[75] *Id.*
[76] *Id.*
[77] *Id.*
[78] Press Release, Patient Care, Advanced Medical Technology Association, *Top Medtech Venture Investor Says MCIT Rule Would Be "Transformative" for Seniors* (Sept. 15, 2021), https://www.advamed.org/industry-updates/news/medtech-pov-podcast-top-medtech-venture-investor-says-mcit-rule-would-be-transformative-for-seniors-patient-care/ [hereinafter *Top Medtech Venture Investor Says MCIT Rule Would Be "Transformative"*].
[79] *Id.*
[80] *Id.*
[81] Emily P. Zeitler et al., *How Is Medical Device Innovation Currently Supported in the U.S.?: From the Heart Failure Collaboratory*, 9 J. AM. COLL. CARDIOLOGY 855, 855 (2021).

gain.[82] In recent years, new device development has slowed, and the proportion of venture capital investment in medical device technology has drastically declined, notably by more than two-thirds from 1992 to 2016.[83] Not only would the MCIT rule speed up the approval process, but it would also allow for a four-year window of time to validate cost effectiveness along the way, which appeals to venture capital and investment firms.[84]

Further, the MCIT rule functions as a subsidy for truly innovative medical devices, specifically those that are FDA-designated breakthrough devices.[85] These devices would gain reimbursement earlier than others and reimbursement would be ensured for at least four years.[86] Some critics have noted that companies already seldom generate enough data for CMS to assess value for its beneficiaries.[87] They claim that the MCIT rule would drain any remaining motivation that these companies have to study their treatments in the patients who are likely to receive them, particularly Medicare beneficiaries.[88] However, the four-year limitation to coverage, absent voluntary submission of additional clinical support, serves as an incentive for device manufactures to either timely collect real-world evidence on health outcomes specific to the Medicare population,[89] or develop even more advanced technology.[90]

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[82] *Id.*
[83] *Id.*
[84] *Top Medtech Venture Investor Says MCIT Rule Would Be "Transformative," supra* note 78.
[85] Abe Sutton, *In Defense of Medicare Coverage of Innovative Technologies*, HARVARD L. PETRIE FLOM CTR.: BILL OF HEALTH (Feb. 1, 2021), https://blog.petrieflom.law.harvard.edu/2021/02/01/medicare-coverage-of-innovative-technologies/.
[86] *Id.*
[87] Peter Bach, *After 4 Years of Trump, Medicare and Medicaid Badly Need Attention: Science and Objective Analysis Need to be Revived*, N.Y. TIMES: OP. (Dec. 1, 2020), https://www.nytimes.com/2020/12/01/opinion/trump-medicare-medicaid.html?action=click&module=Opinion&pgtype=Homepage.
[88] *Id.*
[89] Shah, *supra* note 4.
[90] Sutton, *supra* note 85.

CONCLUSION

In determining coverage for medical devices, it is essential that benefits and risks are adequately weighed. To do so requires taking into account not only the potential benefits and risks, but also the complexity of the patient populations being served. The FDA's Breakthrough Device Program provides an expedited pathway to FDA authorization for devices aiding in the treatment and diagnosis of life-threatening diseases.[91] The MCIT rule would allow for Medicare beneficiaries to have access to these devices the same day that the devices are granted FDA approval, potentially years sooner than they would have received access otherwise.[92] Although CMS has expressed concerns about the FDA not requiring the Medicare population be included in clinical studies, the beneficiaries utilizing these devices are generally willing to assume more risk given the gravity of their conditions.[93] Further, in providing for nationwide coverage of FDA-designated breakthrough devices, the MCIT rule would support more equitable access to healthcare treatments in technology, from both geographic and economic standpoints. Above all, the MCIT rule would promote medical device innovation, incentivizing both investors to finance new technology and medical device companies to focus on innovation. The MCIT rule's benefits to beneficiaries, and the general public, far outweigh the possibility of harm and the potential risks, and therefore, its passage *was* in the best interst of Medicare beneficiares.

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[91] *Guidance for Industry and FDA Administration Staff, supra* note 26 at 4.
[92] Rathi, *supra* note 57.
[93] *The FDA's Breakthrough Devices Program, supra* note 38.

"Can You Repeat That?": Why AI Speech Discrimination Should Decelerate the Use of Automated Speech Recognition as a Medical Record Tool

Mackenzie Pike

INTRODUCTION

Automated speech recognition (ASR) is a type of artificial intelligence (AI) that uses machine learning to translate speech into written word.[1] Similar to how the brain uses experiences to learn, machine learning takes large datasets and runs them through an algorithm to continuously improve.[2] Specifically, ASR uses machine learning to listen to speech and convert it to text at an increasingly better rate, and therefore largely relies on the datasets available to it.[3] ASR is used in translation applications, to generate closed captions, and in smart devices such as "Alexa."[4] For example: ASR is typically used to receive and direct phone calls when a person dials the phone number on the back of a gift card to check its balance.[5]

In their quest to enter the health care field, Big Tech companies have developed ASR with goals of employing it in doctors' offices to transcribe patient-provider conversations into medical records.[6] Facebook, Amazon,

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[1] *What is Speech ASR? The Guide to Automatic Speech Recognition Technology*, REV (May 24, 2021), https://www.rev.com/blog/what-is-automatic-speech-recognition-technology-the-ultimate-guide-to-asr.
[2] *Id.*; *see* Sara Brown, *Machine Learning, Explained*, MIT SLOAN SCH. MGMT. (Apr. 21, 2021), https://mitsloan.mit.edu/ideas-made-to-matter/machine-learning-explained (explaining how machine learning allows "computers to program themselves through experience").
[3] *The Importance of Machine Learning Data*, ALGORITHMIA (Mar. 26, 2020), https://algorithmia.com/blog/the-importance-of-machine-learning-data.
[4] *What is Speech ASR? The Guide to Automatic Speech Recognition Technology*, *supra* note 1; *What Is Automatic Speech Recognition?*, AMAZON, https://developer.amazon.com/en-US/alexa/alexa-skills-kit/asr (last visited Oct. 26, 2021).
[5] *What is Automatic Speech Recognition (ASR)?*, NICE, *https://www.niceincontact.com/call-center-software-company/glossary/what-is-contact-center-asr-automatic-speech-recognition* (last visited Dec. 7, 2021).
[6] Jennifer Bresnick, *Has Google Cracked EHR Speech Recognition for Medical Conversations?*, HEALTH IT ANALYTICS (Dec. 27, 2017),

Apple, Microsoft, and Google have all made a push into the health care sector by developing such technologies or purchasing start-ups that have done so.[7] ASR is seen as the future of medical record keeping in the face of the argument that doctors spend so much time focused on accurate notetaking that the patient is no longer their center focus.[8] For example, start-ups such as Abridge offer providers software that will save them time "simply by recording your patient visits."[9]

The capability of technology to listen and understand language is already worrisome, and the implications of employing such devices in doctors' offices take it a step further. Through misunderstood speech, ASR technology unfairly harms people of color, people with nonnormative dialects, people with atypical articulation and pitch generally associated with gender, and people with disabilities, among others. First, this paper will explore the harms of utilizing ASR technology in doctors' offices as a medical record transcription tool for people with language differences. Next, this paper will discuss the serious consequences that might arise from implementing ASR technology into doctors' offices prematurely. Finally, this paper will posit that although ASR innovation provides many benefits, federal regulation and impactful corporate policies are needed to ensure that the technology does not become widespread until it is equally accessible to all.

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https://healthitanalytics.com/news/has-google-cracked-ehr-speech-recognition-for-medical-conversations.

[7] Nicole Angelica, *Alexa's Artificial Intelligence Paves the Way for Big Tech's Entrance into the Health Care Industry–The Benefits to Efficiency and Support of the Patient-Centric System Outweigh the Impact on Privacy*, 21 N.C. J.L & TECH. 59, 62 (2020).

[8] Bresnick, *supra* note 6.

[9] Abridge, https://www.abridge.com/clinicians (last visited Sept. 15, 2021).

AUDIO-BASED AI DISCRIMINATION EXACERBATES HISTORICAL HEALTHCARE DISCRIMINATION

Using biased ASR technology in healthcare would just add to the already long list of explicit and implicit discrimination tactics used by the medical field against vulnerable communities. Discrimination in the medical field is documented throughout history, and prematurely implementing biased ASR in doctors' offices will further contribute to the harm it has caused. For example, racism in healthcare has deep roots. In the 19th century, phrenology—a pseudoscience purporting character traits could be determined by reading skull shapes—was used to justify slavery and remove Native Americans from their land.[10] Racism in health care was also on display in the Tuskegee study, where hundreds of African American men were deceived into participating in a medical experiment by promising free treatment for syphilis.[11] Four hundred men died because they were actually being observed in the Tuskegee study and did not receive any treatment.[12] Neither these men, nor their families, were ever told the truth; instead, it took decades for the study to be exposed.[13] In 1951, an African American woman named Henrietta Lacks experienced medical racism when her cells were taken and experimented on without her or her family's consent.[14] Considering this history, it is not surprising that these issues still infiltrate the health care industry; now they are just hidden behind innovative algorithms and complex technologies.[15] Currently, algorithmic discrimination based on race is rampant in the health care industry.[16] For example, one study found that an algorithm was less likely to refer African American people than white

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[10] Harry Kretchmer, *A Brief History of Racism in Healthcare*, WORLD ECON. F. (July 23, 2020), https://www.weforum.org/agenda/2020/07/medical-racism-history-covid-19/.
[11] *Id.*
[12] *Id.*
[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] Heidi Ledford, *Millions of Black People Affected by Racial Bias in Health-Care Algorithms*, NATURE, https://www.nature.com/articles/d41586-019-03228-6 (Oct. 26, 2019).

people to improvement programs despite both populations being equally sick.[17]

Because artificial intelligence functions similarly to a brain in how it learns from what it is exposed to, it is helpful to imagine a person exclusively hearing white, American English their entire childhood.[18] Consequently, when this person first hears voices that differ from this dialect, they will likely misunderstand words due to the extremely narrow exposure. Artificial intelligence has had a very similar childhood. ASR machine learning depends on the data sets funneled into their algorithms, and this data heavily relies on the narrow exposure of the English language spoken by white Americans.[19] A recent Stanford study found ASR technology from Amazon, IBM, Google, Microsoft, and Apple erred in transcribing African American voices at almost double the error rate of white voices.[20] Specifically, the study found that ASR misunderstood speech in only 19 percent of words spoken by white people, but 35 percent of words spoken by African Americans.[21] To remedy the divergent error rates, the researchers suggested including a more diverse set of data in the software; however, this has not been accomplished yet.[22] Another study similarly found that ASR word error rates for white speakers were the lowest, while the word error rates for African American and mixed-race speakers were higher.[23] This clear gap in efficiency demonstrates that deploying audio-based artificial intelligence without federal regulation to

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[17] *Id.*
[18] *See What is Speech ASR? The Guide to Automatic Speech Recognition Technology*, *supra* note 1 (discussing how ASR loosely mimics the brain's architecture and becomes progressively better with more data).
[19] *See* Allison Koenecke et al., *Racial Disparities in Automated Speech-Recognition*, 117 PNAS 7684, 7684 (2020) (discussing the performance gap in acoustic models underlying ASR systems and corresponding need for more inclusive data including nonstandard English and AAVE).
[20] *Id.*
[21] *Id.*
[22] *Id.*
[23] RACHAEL TATMAN & CONNOR KASTEN, EFFECTS OF TALKER DIALECT, GENDER & RACE ON ACCURACY OF BING SPEECH AND YOUTUBE AUTOMATIC CAPTIONS 937 (INTERSPEECH, 2017), https://aclanthology.org/W17-1606.pdf.

ensure that it can accurately transcribe the voices of non-white races may render it yet another racially biased tenet of the healthcare system.[24]

SERIOUS CONSEQUENCES FOR OTHER COMMUNITIES

The lack of diverse data in audio-based AI not only risks racial bias, but also risks prejudice against anyone with a dialect that differs from traditional American English. Because the creators of speech-recognition technologies have accent and language biases that surface in ASR, it effectively censors "voices that are not part of the "standard" languages or accents used to create these technologies."[25] In particular, the Washington Post describes ASR technology as "inattentive, unresponsive, [and] even isolating" for people with accents that differ from traditional American English.[26] Their research led to findings that indicated people with a Spanish accent were understood six percent less often than people who grew up on the West Coast.[27] Moreover, another study found that a person with a Scottish accent had a reliably higher word error rate in ASR technology compared to someone from California.[28] One person censored by a dialect barrier sadly explains that "either you assimilate, or you are not understood."[29] Cultural dialects are an important and meaningful part of an individual's identity, and therefore, asking someone to assimilate to lower the amount of time spent

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[24] *See* Khiara M. Bridges, *Implicit Bias and Racial Disparities in Health Care*, A.B.A.: HUMAN RIGHTS, https://www.americanbar.org/groups/crsj/publications/human_rights_magazine_home/the-state-of-healthcare-in-the-united-states/racial-disparities-in-health-care/ (last visited Sept. 15, 2021) (discussing how already-existing racial biases in health care, both structural and implicit in individuals practicing medicine, compromise the health of people of color).
[25] Claudia Lopez Lloreda, *Speech Recognition Tech is Yet Another Example of Bias*, SCI. AM.: POL'Y OP. (July 5, 2020), https://www.scientificamerican.com/article/speech-recognition-tech-is-yet-another-example-of-bias/.
[26] Drew Harwell, *The Accent Gap*, WASH. POST (July 19, 2018) https://www.washingtonpost.com/graphics/2018/business/alexa-does-not-understand-your-accent/.
[27] *Id.*
[28] RACHAEL TATMAN, GENDER AND DIALECT BIAS IN YOUTUBE'S AUTOMATIC CAPTIONS (2017), http://www.ethicsinnlp.org/workshop/pdf/EthNLP06.pdf.
[29] Lopez Lloreda, *supra* note 25.

chronicling medical records is wrong.[30] Further, the medical records of those who choose not to assimilate their speech will unfairly incorporate disproportionate inaccuracies.

Another example of the problematic biases appearing in artificial intelligence is ASR's unequal accuracy rates in transcribing the voices of females compared to males. A conscious decision was made in the early days of voice recording technology to limit the vocal range of the technology to one that serves the average male speaker better than the average female speaker.[31] Later, automobile manufacturers who utilized ASR acknowledged the inequalities but suggested the remedy was for women to "sit through lengthy training," to "be taught to speak louder, and direct their voices toward the microphone."[32] Recently, a study found that Google's ASR technology was 13 percent more accurate for men than it was for women.[33] One explanation may be that young women tend to use linguistics as a tool for social connection by adapting their speech patterns to the context of the situation, which creates diversity in speech that ASR has likely not been trained to identify.[34] Additionally, a mere six percent of professional software developers in AI are women, and only around 12 percent of artificial intelligence researchers are female, so the field that is "reshaping society" is controlled by those who do not adequately represent it.[35] This extensive lack

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[30] *See id.* (explaining that forcing someone to change their speech to be able to be recognized by AI is "inherently cruel").
[31] Sam Zegas, *Is There an ASR Gender Gap?*, DEEPGRAM (Mar. 31, 2021), https://deepgram.com/blog/is-there-an-asr-gender-gap/.
[32] Graeme McMillan, *It's Not You, It's It: Voice Recognition Doesn't Recognize Women*, TIME (June 1, 2011), https://techland.time.com/2011/06/01/its-not-you-its-it-voice-recognition-doesnt-recognize-women/.
[33] Joan Palmiter Bajorek, *Voice Recognition Still Has Significant Race and Gender Biases*, HARV. BUS. REV. (May 10, 2019), https://hbr.org/2019/05/voice-recognition-still-has-significant-race-and-gender-biases.
[34] Zegas, *supra* note 31.
[35] Anu Madgavkar, *A Conversation on Artificial Intelligence and Gender Bias*, MCKINSEY & CO. (April 7, 2021), https://www.mckinsey.com/featured-insights/asia-pacific/a-conversation-on-artificial-intelligence-and-gender-bias; *see also* Tom Simonite, *AI is the Future- But Where Are the Women?*, WIRED (Aug. 17, 2018), https://www.wired.com/story/artificial-intelligence-researchers-gender-imbalance/.

of representation for females in AI companies explains the early disregard of ASR's gender bias. Accordingly, the implementation of this technology into doctors' offices without proper representation for the speech patterns of females will likely lead to more inaccuracies in medical records where either the patient or provider is female.

The problem of discrimination in healthcare also extends to people who are transgender. A troubling 2015 study found that 33 percent of transgender people had at least one negative experience when they sought medical treatment.[36] Adding audio-based technology discrimination into the mix could exacerbate the ubiquitous mistreatment of transgender patients and providers.[37] If a transgender patient or provider seeks access to ASR for transcribing medical records, they might find the technology unable to transcribe their voice due to pitch and articulation fluctuations from potential voice therapy for their transition. AI technology is not yet developed with enough diverse data to appropriately recognize and respond to the speech patterns of transgender individuals.[38] Further, asserted solutions involve collecting data from people who may be extremely uncomfortable with medical data collection due to the historical mistreatment of the transgender community.[39] Because patients and providers may be subject to incorrect medical records based on indicators generally associated with gender, it is unfair to implement this technology in doctors' offices until federal regulation makes certain it is developed enough to effectively understand people, irrespective of gendered voice differences.

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[36] JAMES ET AL., THE REPORT OF THE 2015 U.S. TRANSGENDER SURVEY 3 (2016).
[37] Jessica Cerretani, *Transgender Discrimination in Health Care: What Families Should Know*, BOSTON CHILDREN'S HOSPITAL (July 1, 2020), https://answers.childrenshospital.org/transgender-discrimination/ (explaining the extensive mistreatment of the transgender community by the medical field).
[38] *See* Sigal Samuel, *Some AI Just Shouldn't Exist*, VOX (Apr. 19, 2019), https://www.vox.com/future-perfect/2019/4/19/18412674/ai-bias-facial-recognition-black-gay-transgender (discussing how AI offensively identifies some individuals due to lack of diverse data but debiasing AI might be harmful to transgender individuals).
[39] *Id.*

In addition to racial, cultural, and gender biases, voice-to-text software may also be harmful to patients with speech-related disabilities.[40] ASR technology often cannot recognize the speech of people with neurological speech disorders like dysarthria or individuals suffering from motor conditions affecting their speech (such as those resulting from a stroke).[41] Additionally, patients and healthcare providers that lack the ability to speak in any capacity cannot benefit from the purported promises of the innovation.[42] Thus, while ASR can be an important accessibility tool for some disabled populations, using the software in doctors' offices as a medical record tool may cause more harm than good for others.[43]

Lastly, age also factors into whether ASR technology accurately transcribes speech.[44] A 2021 study found that teenage speech is the most accurately transcribed, followed by seniors, with children's speech being the least accurate.[45] The researchers explained that discrimination against children's speech is not surprising, since the acoustic models used to train ASR are adult-focused.[46] Thus, the speech of young patients will not be adequately transcribed to reflect their visits and they, too, will likely suffer from inaccurate medical records. Additionally, pediatric providers might forego the use of ASR in light of the discrimination, unfairly excluding them from the benefits that their colleagues who treat adults will receive solely based on the age of their patients.

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[40] Lopez Lloreda, *supra* note 25.
[41] Madeline Jefferson, *Usability of Automatic Speech Recognition Systems for Individuals with Speech Disorders: Past, Present, Future, and A Proposed Model*, UN. MINN. DIGIT. CONSERVANCY (2019), https://hdl.handle.net/11299/202757.
[42] *See* Guo et al., *Towards Fairness in AI for People with Disabilities: A Research Roadmap*, ARXIV (Aug. 2, 2019), https://arxiv.org/abs/1907.02227 (discussing how speech-related disabilities adversely impact speech recognition systems).
[43] *Id.*
[44] Feng et al., Quantifying Bias in Automatic Speech Recognition, ARXIV (Apr. 1, 2021), https://arxiv.org/pdf/2103.15122.pdf.
[45] *Id.*
[46] *Id.*

Like the example of the child who grew up in a linguistic echo-chamber having trouble understanding differences in speech, the lack of diverse data driving ASR software causes it to misunderstand patients whose speech differs from traditional American English, specifically that which is non-white, non-male, and non-adult. Therefore, anyone outside this demographic is at risk of ASR technology recording inaccurate medical records for them, putting them at greater risk for misdiagnoses or incorrect prescriptions.[47]

Further, utilizing this technology in healthcare as is might create a serious risk of medical malpractice for health care providers if it inaccurately transcribes their speech.[48] For example, if a provider diagnoses a patient with ischemic colitis, but the ASR technology wrongly transcribes it as ischemia instead, the patient may later be given medication or surgical treatment based on the incorrect medical record, creating liability for medical malpractice against the provider. The structural complexity of many medical terms make this possibility even greater. The risk of incorrect interpretation of vital medical information might also shift the burden onto patients. Providers may be less motivated to make positive diagnoses when being recorded by the software due to the possibility of incorrect interpretation creating malpractice liability for them.[49] Providers might also be less willing to efficiently send medical records to their patients or other providers for fear there are misrepresentations that could implicate them.[50] Further, patients may exclude necessary information if they are uncomfortable being recorded, which can negatively affect the provider's ability to accurately diagnose.[51]

In this way, word-for-word transcription of a provider's conversation with their patient might also hinder the natural discussion necessary to provide

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[47] Koenecke et al., *supra* note 19.
[48] *See id.*
[49] *See id.*
[50] *See* Tim Lahey and Glyn Elwyn, *Go Ahead and Hit 'Record' in the Doctor's Office*, STAT (July 10, 2017), https://www.statnews.com/2017/07/10/record-doctors-office-patient-visit/ (describing the fears providers feel about recording patient visits).
[51] *Id.*

adequate medical care. One of the proposed promises of ASR as a medical record tool is that it allows the doctor to focus on the patient instead of notetaking, leading to a more natural conversation.[52] However, the inverse could easily occur. If every single word the patient and provider say is being recorded, they could become hyper-aware of what they are saying and alter aspects of the conversation to ensure the software correctly interprets the speech; in turn, creating an unnatural conversation. Effective patient-provider communication is pivotal to building a trustful relationship, and this supposed solution might actually obstruct this relationship's formation.

The positives associated with implementing ASR into doctors' offices include improving health literacy for underserved communities; keeping physicians' focus patient-centric; minimizing the extensive hours needed for health providers to ensure correct records are taken; and the possibility of easily holding physicians accountable for malpractice through a written record of their words.[53] While these possibilities are exciting, federal regulation and efficient corporate policies are needed to address bias in ASR to ensure that these benefits are experienced equally by patients and providers and dispersed equitably across the healthcare spectrum.

PROPOSED SOLUTIONS

Currently, there is a gap in federal regulation against bias in ASR transcription technology. In general, the Food and Drug Administration (FDA) regulates medical devices.[54] The FDA defines a medical device as intended to treat, diagnose, cure, mitigate, or prevent disease or other

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[52] Abridge, *supra* note 9.
[53] *Id.*; *Increasing Health Literacy with AI Drives Better Health Outcomes and Lower Costs*, MEDIUM: SANA LABS (June 26, 2020), https://medium.com/@sanalabs/increasing-health-literacy-with-ai-drives-better-health-outcomes-and-lower-costs-ee4cefd5b800.
[54] Changes to Existing Medical Software Policies Resulting From Section 3060 of the 21st Century Cures Act; Guidance for Industry and Food and Drug Administration Staff; Availability, 84 Fed. Reg. 51165 (Sept. 27, 2019).

conditions.[55] However, section 3060(a) of the Cures Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to exclude certain products from the definition of "device."[56] Among the excluded are software products intended for administrative support and software products intended to serve as electronic patient records.[57] Therefore, an AI product meant to provide administrative support by transcribing patient visits and not interpreting the medical record for treatment purposes does not qualify as a medical device and, therefore, is not under the purview of the FDA.[58] The only federal regulation that reaches this technology, then, is the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH), both of which only focus on the privacy and security implications of electronic health record systems.[59] Thus, the FDA's inadequate regulation against bias in ASR transcription technology is likely caused by its absence from the conversation.[60] As long as this technology is excluded from conversations about bias in FDA regulation, its use as a widespread medical recordkeeping tool will further exacerbate historical discrimination. To prevent this result, the FDA should revise its definition of medical "device" to explicitly include ASR transcription technology. Doing so will ensure that the technology is encompassed in the FDA's ongoing efforts to mitigate medical AI bias broadly.[61]

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[55] 21 C.F.R. § 520(o)(1)(E) (2021).
[56] *Supra* note 54.
[57] *Id*.
[58] *See id.*
[59] *HIPAA for Professionals*, HHS, https://www.hhs.gov/hipaa/for-professionals/index.html (Dec. 6, 2021); *What is the HITECH Act?*, HIPAA J., https://www.hipaajournal.com/what-is-the-hitech-act/ (Dec. 6, 2021).
[60] *See* Soleil Shah & Abdul El-Sayed, *The FDA Should Better Regulate Medical Algorithms*, SCI. AM. (Oct. 7, 2021), https://www.scientificamerican.com/article/the-fda-should-better-regulate-medical-algorithms/ (explaining how the FDA does not adequately regulate medical AI products because many products can avoid FDA approval).
[61] *See How FDA Regulates Artificial Intelligence in Medical Products*, PEW CHARITABLE TRUSTS (Aug. 5, 2021), https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2021/08/how-fda-regulates-artificial-intelligence-in-medical-products (describing the FDA proposals for mitigating bias in medical devices); *See* Liz Richardson, *FDA Review*

Federal regulation could also demand that health technology companies and healthcare systems implement internal policies that promote education and transparency around ASR transcription technology. Customers, patients, and health providers should be aware of the shortcomings of this new technology and the risks its widespread use presents for patient outcomes. Thus, regulation should require health tech companies to be transparent with healthcare systems interested in employing ASR for medical recordkeeping and require providers to be transparent with their patients about their use of such technology. Healthcare systems that do decide to apply this technology should enact internal policies that safeguard against its deficiencies. For example, a policy might require that providers offer patients an opt-out option after they describe the technology and its weaknesses, or a policy might mandate that providers read through the transcribed records and note any inaccuracies to filter the mistakes the technology may have made.

Unfortunately, a paradox exists between AI demanding as much data as possible to train it to be inclusive and AI opponents arguing for stricter protection of patient health data.[62] These protections innately make access to diverse data more difficult for AI companies.[63] Likewise, the lack of access to sensitive health data makes researching whether AI presents biased particularly difficult.[64] Therefore, the technological solution will likely come from either creating AI that does not need large data sets to be inclusive, or medical data sharing becoming more common.[65] As one scientist explained,

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Can Limit Bias Risks in Medical Devices Using Artificial Intelligence, PEW CHARITABLE TRUSTS (Oct. 7, 2021), https://www.pewtrusts.org/en/research-and-analysis/articles/2021/10/07/fda-review-can-limit-bias-risks-in-medical-devices-using-artificial-intelligence (describing FDA efforts to improve health equity in medical devices).

[62] *See* Blake Murdoch, *Privacy and Artificial Intelligence: Challenges for Protecting Health Information in a New Era*, 22 BMC MED. ETHICS 122, 123 (2021) (discussing patient data privacy concerns for AI technology).

[63] Kaushal et al., *Health Care AI Systems Are Biased*, SCI. AM.: POLICY (Nov. 17, 2020), https://www.scientificamerican.com/article/health-care-ai-systems-are-biased/.

[64] Ledford, *supra* note 16.

[65] Kaushal et al., *supra* note 63.

any purported solution is not straightforward because it is difficult to solve problems when bias and injustice is still inherent in our society.[66]

CONCLUSION

Without federal regulation and intentional corporate policies, the widespread use of ASR as a medical record tool will perpetuate existing discrimination against vulnerable communities in healthcare. Continuing to develop AI without utilizing diverse data sets in its training will prevent this software from true progress and will likely cause more harm than good. Ignoring the possible harm caused by such technology in the name of innovation will be detrimental to both patients and providers. Therefore, ASR technology as a medical record transcription tool should not be implemented without the aforementioned safeguards. To prevent further harm to vulnerable communities, federal guidance and policy efforts by health technology companies and healthcare systems are needed before widespread application can occur. Hopefully, the future yields creativity from diverse engineers who understand the dire need for an innovative solution that protects vulnerable communities from further discrimination.

[66] Ledford, *supra* note 16.

Technology Access Alone Won't Solve the Health Care Gap: How the Focus on Access to Technology Misses the Mark

Marisa Polowitz

INTRODUCTION

Health disparities across the United States are not new.[1] COVID-19 both highlighted and deepened the disparities that have arisen from long-running, systemic inequities in our healthcare structure.[2] Historically, under-resourced populations, already subject to health disparities, are experiencing disproportionate impacts due to the COVID-19 pandemic, an issue compounded by the broken promise of technological solutions.[3] As the quote famously attributed to William Gibson goes: "The future is already here – it's just not evenly distributed."[4] Those who do not spend their workday or personal time accessing a computer or connected smartphone experience and utilize technology differently than those who regularly and consistently access the internet – this is commonly referred to as the technology gap or the digital gap.[5] In 2019, more than 40% of older Americans did not have internet access in their homes, and lower-income, minority, and rural

[1] See *Disparities*, OFF. OF DISEASE PREVENTION & HEALTH PROMOTION, https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities (stating statistical information of various disparities in the United States).
[2] *Covid-19 Shines Light on Health Disparities*, NAT'L CONF. OF STATE LEGISLATORS (July 30, 2021), https://www.ncsl.org/blog/2020/07/30/covid-19-shines-light-on-health-disparities.aspx.
[3] *See* Alexander Seifert et al., *A Double Burden of Exclusion? Digital and Social Exclusion of Older Adults in Times of COVID-19*, JOURNALS OF GERONTOLOGY: SOC. SCIS., July 16, 2020, at 1, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7454901/ (discussing the exclusion of older adults and other vulnerable communities during the COVID-19 pandemic).
[4] QUOTE INVESTIGATOR, https://quoteinvestigator.com/2012/01/24/future-has-arrived/ (last visited Sep. 10, 2021).
[5] PC MAG, https://www.pcmag.com/encyclopedia/term/technology-gap (last visited Sep. 10, 2021).

communities were most likely to be affected by broadband and cellular dead zones.[6] While not everyone regularly utilizes technology on a day-to-day basis, technology nonetheless plays a role in everyone's daily life.[7] The COVID-19 pandemic clearly demonstrates how a tunnel-visioned focus on user adoption of technological tools exacerbates preexisting health disparities.[8]

Technological redlining, the perpetuation of preexisting inequities in society through technology, is a concerning byproduct of a society with an increasing dependence on technology to obtain access to basic services and exposure to opportunities.[9] Accessing a COVID-19 test or even scheduling a routine medical appointment now requires a use of technology that goes beyond mere access to the tool itself – it takes time, internet access, technological and health literacy, and sometimes even access to transportation.[10] Throughout the COVID-19 vaccine roll-out, this gap was so apparent that people volunteered their time and technical knowledge to find and schedule vaccine appointments for the technologically disinclined, disadvantaged, and disempowered.[11] As of May 2020, more than a third of American households with a head of the household age 65 or older do not

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[6] Valerie G. Press, et al., *Inequities in Technology Contribute to Disparities in COVID-19 Vaccine Distribution*, J. OF THE AMERICAN MEDICAL ASSOCIATION HEALTH FORUM, March 19, 2021, at 1.

[7] Jack Turner, *The 7 Main Ways Technology Impacts Your Daily Life*, TECH.CO (May 5, 2021, 12:01 AM), https://tech.co/vpn/main-ways-technology-impacts-daily-life.

[8] Amanda Pederson, *Is Digital Technology Addressing Healthcare Disparities or Widening the Gap?*, MEDICAL DEVICE AND DIAGNOSTIC INDUSTRY (April 13, 2021), https://www.mddionline.com/digital-health/digital-technology-addressing-healthcare-disparities-or-widening-gap.

[9] Anh Nguyen, *Technological redlining: how algorithms are tearing communities apart.*, MEDIUM (Nov. 20, 2019) https://atnd.medium.com/technological-redlining-how-algorithms-are-dividing-the-country-6939dcc88659.

[10] *See* Press, *supra* note 6 at 1.

[11] *See* Rachel Monahan, *I Spent the Past Six Weeks Finding COVID-19 Vaccine Appointments. Here's How You Can Obtain One While Keeping Your Chill*, WILLAMETTE WEEKLY (April 14, 2021, 5:40 AM), https://www.wweek.com/news/state/2021/04/14/i-spent-the-past-six-weeks-finding-covid-19-vaccine-appointments-heres-how-you-can-obtain-one-while-keeping-your-chill/ (explaining the experience a volunteer had scheduling vaccine appointments for others).

have a computer or laptop, and more than 50% do not have a smartphone.[12] Only 14% of white children do not have a computer at home, while over 30% of Hispanic or Black households with children do not have a computer.[13] Further, over 21 million individuals in the United States do not have access to broadband internet.[14] While the issue of access to technology itself is a substantial factor impacting the adoption and use of health technologies, it is far from the only issue deepening the health care access gap.[15]

Society's growing reliance on technological and data-oriented tools in the healthcare space and beyond is a hindrance to closing the health care access gap. The near-ubiquitous demand for the adoption of increasingly sophisticated, inaccessible, and regularly evolving technology is the problem for many, rather than the solution. This paper will highlight some of the complex issues foundational to the experience of health technology redlining in under-resourced communities. This paper will then discuss the ways in which that experience perpetuates harm within the context of health care, health services, and health outcomes. Finally, this paper will propose potential legal, regulatory, and legislative remedies to decrease the detrimental impacts of health technology redlining and to possibly mitigate the damage of future harms.

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[12] David Velasquez & Ateev Mehrotra, *Ensuring The Growth Of Telehealth During COVID-19 Does Not Exacerbate Disparities In Care*, HEALTH AFFAIRS BLOG (MAY 8, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200505.591306/full/.

[13] *Id.*

[14] Chukwuma N. Eruchalu et al., *The Expanding Digital Divide: Digital Health Access Inequities during the COVID-19 Pandemic in New York City*, 98 J. OF URB. HEALTH, 183, 183 (2021).

[15] *See* Fitzpatrick et al., *The Digital Divide in Healthcare: It's Not Just Access*, HEALTHCARE INFO. AND MGMT. SYS. SOC'Y (Feb. 24, 2021), https://www.himss.org/resources/digital-divide-healthcare-its-not-just-access (discussing the digital divide and its expansion during the COVID-19 pandemic).

CONTRIBUTORY ELEMENTS OF TECHNOLOGICAL REDLINING IN HEALTH CARE

Through the lens of COVID-19, obstacles to accessing care and services caused by the growing digital divide were stark.[16] But merely improving access to health technologies is not the comprehensive solution needed to increase access to health care and improve health outcomes.[17] Rather, cost and technological literacy are continually deemed the driving forces preventing individuals from leveraging technological tools.[18] Health technology-related policy focuses on proliferation of health applications, exchange of patient data between providers, and patient portals as the solutions to increasing patient access to care and empowering their health information and choices.[19] However, attention to building accessible and culturally inclusive platforms is lacking, creating additional obstacles for those already less likely to benefit from their proposed advantages.[20] This is evidenced by statistics revealing that older, Black, and Hispanic patients are less likely to use a medical site rather than younger and white patients.[21] Further, the rapid pace of technology development cycles ages older hardware out, meaning those without the newer versions of phones and computers are less likely to be able to use the full-functioning versions of those tools.[22] The ever increasing costs of technology, the rapid cycles of

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[16] *Id.*
[17] *Id.*
[18] Madelynn Valu, *Understanding the Digital Divide and Ensuring Access for All,* HEALTHCARE INFO. AND MGMT. SYS. (Mar. 30, 2021), https://www.himss.org/resources/understanding-digital-divide-and-ensuring-access-all.
[19] *See Health Care Access and Quality*, OFF. OF DISEASE PREVENTION & HEALTH PROMOTION, https://health.gov/healthypeople/objectives-and-data/browse-objectives/health-care-access-and-quality (Last visited Sep. 10, 2021) (listing health care access and quality objectives).
[20] *Id.*
[21] Velasquez et al., *supra* note 12.
[22] Jeffrey Vagle, *Technological Redlining*, THE CTR. FOR INTERNET & SOC'Y (Jul. 19, 2016, 2:56 PM), http://cyberlaw.stanford.edu/blog/2016/07/technological-redlining.

technological evolution that require constant hardware and software updates, tech literacy or proficiency, and time to dedicate to developing a proficiency in technology use are all contributory factors in addition to access that feed the growing digital divide.[23] Obstacles preventing access are just one technologically-induced element perpetuating the cycle of health disparities, much like lack of access to quality education, housing, food, or healthcare services.[24] While access obstacles are paramount, access-focused remedies alone will not combat the myriad of issues exacerbating the care divide.

Additional contributory issues center around the growing interconnectedness of technology vis-a-vis The Internet of Things, the objects connected to the internet that share information or "talk" to one another and track, leverage, and store user data.[25] In health care, the Internet of Health Things refers to all of the connected tools utilized to promote, facilitate, monitor, track, and deliver health services.[26] Merely going to the doctor, or even making a dinner reservation, means entering personal information into a technological system. It is not an option to opt into the services and benefits that society offers, declining the collection and use of data used to *define* you.[27] As data use increases, so does its value and the value of data analytics. In turn, the volume of attacks aimed at accessing user data increases as well.[28] The collection and sale of user data, including but not limited to health information to third parties such as pharmaceutical

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[23] *Id.*
[24] *Id*.
[25] Matt Burgess, *What is the Internet of Things? WIRED Explains,* WIRED (Feb. 16, 2018, 12:40 PM), https://www.wired.co.uk/article/internet-of-things-what-is-explained-iot.
[26] Nicolas P. Terry, *Will the Internet of Things Transform Healthcare?*, 19 VAND. J. OF ENT. & TECH. L. 327 (2020).
[27] *See* Mary Madden, *Need medical help? Sorry, not until you sign away your privacy.,* MIT TECH. REV., Oct. 23, 2018, https://www.technologyreview.com/2018/10/23/66429/need-medical-help-sorry-not-until-you-sign-away-your-privacy/ (describing the author's personal experience providing health data at doctor's office).
[28] *Id.*

companies, insurance providers, and diagnostic tool developers, is a rapidly growing and highly lucrative marketplace.[29] For those with a distrust of health systems, the requirement of using technology, which collects and potentially shares your data, plays a role in the decision to seek care.[30]

A deeper, and arguably larger, contributing issue is *how* that technology functions.[31] Layered on top of basic access to internet, computers, or smartphones exists a panoply of more complex and hidden issues. Algorithms, or sets of instructions for how to perform a task, are coded into every piece of technology and are fundamental to the functional capabilities of technological tools.[32] Algorithmic tools perform based on data input from the humans that create them, and the humans that build the tools are fallible.[33] Societal inequities, then, produce inequities in the algorithms employed in technology.[34] There is a wealth of information and studies pertaining to the reproduction of societal disparities in algorithms.[35] Historically, societal disparities perpetuated through profiling occurred offline, but have now become widespread across the digital space, including within the realm of health care.[36]

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[29] *Id.*
[30] Sarah Heath, *COVID-19 Pushed Health IT Adoption, Now Patient Trust Must Follow,* PATIENT ENGAGEMENT HIT (Aug. 12, 2020), https://patientengagementhit.com/news/covid-19-pushed-health-it-adoption-now-patient-trust-must-follow.
[31] *See* Fitzpatrick, *supra* note 15 (discussing the digital divide and its expansion during the COVID-19 pandemic).
[32] TECHTERMS, https://techterms.com/definition/algorithm (Last visited Sep. 5, 2021); Jorry Denny, *What is an algorithm? How computers know what to do with data,* THE CONVERSATION (Oct. 16, 2020, 7:00 AM), https://theconversation.com/what-is-an-algorithm-how-computers-know-what-to-do-with-data-146665.
[33] *See* Nguyen, *supra* note 9 (discussing technological redlining and its impact on vulnerable communities).
[34] *Id.*
[35] Ziad Obermeyer et. al., *Dissecting racial bias in an algorithm used to manage the health of populations*, SCIENCE, Oct. 25, 2019, at 1–7.
[36] *See* Seeta Peña Gangadharan, *Digital inclusion and data profiling*, FIRST MONDAY, May 2012, https://firstmonday.org/ojs/index.php/fm/article/download/3821/3199?inl#author (discussing surveillance impact on political freedom and commercial data profiling).

Systemic healthcare inequalities are inextricably intertwined with social inequalities.[37] The same tools that make life easier for many, often negatively impact the well-being of others and exacerbate the racial, economic, and social divides currently plaguing society.[38] Instead of lifting people out of poverty, connecting communities, and creating opportunity, the narrow focus on accessing technology without attention to its building will continue to deepen the schisms already present in society.[39]

More and more aspects of life are driven by the use of technology and influenced by, if not wholly dependent on, the algorithms coded into those tools.[40] How technology is built, and by whom, shapes our lives.[41] In particularly chilling examples, predictive technology has consistently shown that harms exacerbated by societal inequities are magnified when unintentionally – but thoughtlessly – built into algorithms.[42] Technologists tasked with creation of these technologies are often oblivious to how harms may be perpetuated through their creation, or how populations may disproportionally experience the benefits afforded by those tools.[43] Data collected from outside of regulated relationships such as purchasing habits, or fitness devices, is analyzed and can be used for a host of healthcare

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[37] Robert David Hart, *If you're not a white male, artificial intelligence's use in healthcare could be dangerous,* QUARTZ (August 1, 2018), https://qz.com/1023448/if-youre-not-a-white-male-artificial-intelligences-use-in-healthcare-could-be-dangerous/?linkId=43834429.
[38] Jason Hiner, *Why tech made racial injustice worse, and how to fix it*, CNET (Jun. 25, 2020, 10:00 AM), https://www.cnet.com/news/why-tech-made-racial-injustice-worse-and-how-to-fix-it/.
[39] *See* Vagle, *supra* note 22 (discussing how Pokémon Go demonstrates a larger issue of technological redlining).
[40] *See* Nguyen, *supra* note 9 (discussing how algorithms cause technological redlining of vulnerable communities. Specifically highlighting banks and mortgages, internet service providers, employment opportunities, and housing options).
[41] *Id*.
[42] Salon Barocas et al., *Data & Civil Rights: Technology Primer,* DATA & SOC'Y RSCH. INST., (Oct. 30, 2014), https://datasociety.net/library/data-civil-rights-technology-primer/.
[43] *Id*.

applications.[44] But these applications can have harmful effects when misapplied.[45] Technology may provide a potential remedy for the health care access gap, but the focus on patients neglects a major obstacle in technological tool adoption – the tools themselves.

CASCADING HARMS OF TECHNOLOGICAL REDLINING IN HEALTH CARE

The use of telemedicine increased by over 50% in the first quarter of 2020, according to the Centers for Disease Control and Prevention.[46] A study analyzing sociodemographic association with telemedicine usage during the early phase of the pandemic found that the elderly, female, Black, Latinx, those with Medicaid, and those who did not speak English as their primary language were less likely to utilize telehealth technology.[47] Conversely, the increased offerings of telehealth and telemedicine appointments disproportionately benefit middle or upper-middle class white males and those with robust health insurance plans.[48]

The Office of Disease Prevention and Health Promotion (ODPHP) includes a focus on Health Care IT amongst its priorities for Health Care Access and Quality Objectives as a part of the Healthy People 2030 initiative.[49] Every goal listed under Health IT includes increasing the proportions of people leveraging health technology tools both on the provider

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[44] Alex Rosenblat et al., *Data & Civil Rights: Health Primer,* DATA & SOC'Y RSCH. INST., (Oct. 30, 2014), https://datasociety.net/library/data-civil-rights-health-primer/.
[45] *Id*.
[46] Lisa M. Koonin et al., *Trends in the Use of Telehealth During the Emergence of the COVID-19 Pandemic*, CDC: MORB. MORTAL WKLY (October 30, 2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6943a3.htm.
[47] Lauren A. Eberly, et al., *Patient Characteristics Associated With Telemedicine Access for Primary and Specialty Ambulatory Care During the COVID-19 Pandemic*, J. OF THE AMERICAN MEDICAL ASSOCIATION HEALTH FORUM, Feb 19, 2021, at 1.
[48] *Id*.
[49] *See Health Care Access and Quality*, OFF. OF DISEASE PREVENTION & HEALTH PROMOTION, https://health.gov/healthypeople/objectives-and-data/browse-objectives/health-it (Last visited Oct. 27, 2021) (outlining objectives pertaining to access and utilization of health care technology).

and patient side, and increasing the general use of telehealth in the effort towards increasing health care access.[50] Increasing inclusion of systemically disadvantaged populations into an already inequitable, biased, and under-monitored world of technology will further harm those already vulnerable and will only compound the disparities – not fix them.[51] It has become unambiguously clear that the unintended consequences of technology are harmful, especially to those already chronically under-resourced.

So long as government entities continue to approach the adoption of health technologies through the lens of user/patient and provider/system, without addressing the way those technologies are built, whether systemically underserved demographics could/should trust these technologies, the *accessibility* of technologies (rather than simply *access to* technology), the rapid technology advancement cycles which render older tech outdated or incompatible, the health care access schism will only deepen.

PROPOSED SOLUTIONS

Without concerted, directed, and meaningful work to remedy the inequities at the root of technological development, the problems will only multiply. Addressing the nuanced, complex, and layered contributory factors will require a wide range of solutions and approaches.[52] To advance health equity, a critical and intentional lens needs to be applied regarding how, why and for what goal all technology is being created and utilized. An urgent assessment of what these tools aim to solve and for whom is essential.[53] The

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[50] *Id.*
[51] *See* Gangadharan, *supra* note 36 (discussing surveillance impact on political freedom and commercial data profiling).
[52] *See* Press, *supra* note 6 (discussing technologies' contribution to inequity in vaccine distribution).
[53] Amanda Lenhart & Kellie Owens, *Good Intentions, Bad Inventions: The Four Myths of Healthy Tech*, DATA & SOC'Y RSCH. INST., (Oct. 7, 2020), http://datasociety.net/pubs/Good-Intentions-Bad-Inventions.pdf.

impacts and issues pertaining to technology-exacerbated health disparities are many and growing. At their core, these issues are societal – technology reflects what society values. As such, there is no singular fix. Understanding the limitations of technology will empower us to make intelligent, informed, and intentional decisions about how to use technology in service to society.[54] Many of the solutions do not require a technical fix – they require a human one.

First and foremost, accessibility needs to be placed on the same level of importance as access. Access pertains to the question of whether a tool is available to a user, while accessibility pertains to whether that tool is meaningfully usable for different users with different needs.[55] Currently, health platforms and applications are rarely designed with a focus on underserved populations and accessibility.[56] Health centric apps should be required to meet a federal baseline for inclusion and accessibility. Much of the discussion about how mobile technologies can positively impact health outcomes centers on developing technology with those specific communities in mind.[57] The Office of the National Coordinator (ONC), in addition to its focus on access, should place a premium on digital health equity efforts focused on intentional and inclusive development of health technologies. The ODPHP should include accessibility and inclusive development in its

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[54] *See* Review of *Artificial Unintelligence, How Computers Misunderstand the World*, MIT PRESS, https://mitpress.mit.edu/books/artificial-unintelligence (Last visited Sep. 8, 2021) (discussing *Artificial Unintelligence* and the importance of understanding the limits of technology).

[55] Karen McCall, *Digital Access vs Accessibility*, KARLEN COMMUNICATIONS, https://www.karlencommunications.com/AccessVersusAccessibility.htm (last visited Nov. 16, 2021).

[56] Jorge A. Rodriguez et al., *Digital Health Equity as a Necessity in the 21st Century Cures Act Era*, 323 J. OF THE AM. MED. ASS'N 2381, 2382 (2020) (discussing suggestions for bringing health equity to patient-facing digital health tools).

[57] KAREN M. ANDERSON & STEVE OLSON, THE PROMISES AND PERILS OF DIGITAL STRATEGIES IN ACHIEVING HEALTH EQUITY: WORKSHOP SUMMARY 14 (Gillian Christie et al. eds., 2016) https://www.ncbi.nlm.nih.gov/books/NBK373436/; Kali Durgampudi, *User-Centered Design: The Key to Health IT Innovation*, ELECTRONIC HEALTH REPORTER (Nov. 1, 2019), https://electronichealthreporter.com/user-centric-design-the-key-to-health-it-innovation/.

Health IT Objectives, as well. Guidance at the federal level could set a standard for socio-cultural, linguistic, and literacy sensitive technology development.[58] State health departments should create similar guidance for local and state health departments, leveraging public health systems as a jumping off point.

The increase in utilization, application, and dependence on health technology tools has not spurred equal levels of catalyzation in government guidance and development. But the federal government is where the initiative should begin. Federal mandates should provide guidance for equitable data sharing practices, data sale and use transparency, and technological development.[59]

A less cohesive, but highly essential avenue of approach needs to be through educational training. We need to consider the entire context within which technology is being built and ask who it is serving, and more importantly, who it will harm?[60] Technology is not created in a vacuum; instead, there has continuously been a failure to emphasize the need for those building technologies to fully comprehend the potential consequences of their tools. Leaders of tech-centric, health-focused development should be encouraged to complete educational requirements for equitable technological development. Creators of health technology should be required to complete training for spotting and weeding out bias in data and analytics and for coding with inclusivity as a priority.

Companies operating within the health technology space should be incentivized to surpass the baseline standards of equitable technological

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[58] *See* Rodriguez et al., *supra* note 56 at 2381.
[59] *Id.*
[60] Anna Lauren Hoffmann, *Data violence and how bad engineering choices can damage society*, MEDIUM (APR. 30, 2018), https://medium.com/s/story/data-violence-and-how-bad-engineering-choices-can-damage-society-39e44150e1d4.

development. The use of civil and criminal penalties for violation of requirements laid out in future policy and regulation could serve as motivation for compliance, like the approach taken under the Health Information Portability and Accountability Act's (HIPAA) Privacy Rule.[61] Tiered penalty structures for HIPAA violations create major financial incentives to avoid non-compliance, compounded by potential criminal penalties for willful violations.[62] As in organizations handling data specifically designated as protected under HIPAA, deterrence from misuse of those data through implementation of robust policy and corresponding penalties could be equally beneficial in incentivizing for health technology companies to create more equitable tools.

An additional possibility is the creation of a socially desirable certification program like the Leadership in Energy and Environmental Design (LEED) Certification created by the U.S. Green Building Council for energy efficient building construction.[63] Between 2015 and 2018, LEED-certified buildings boasted an estimated $1.2 billion on energy savings and $149.5 million in water savings through its high-efficiency development framework.[64] Commercial buildings constructed under this framework consume an average of 25% less energy than comparable buildings.[65] And it's impacts are

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[61] *See generally* U.S. DEPT. OF HEALTH & HUM. SERVICES, https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/data/enforcement-highlights/index.html (last visited Sep. 20, 2021).
[62] Steve Alder, *What Happens if You Break HIPAA Rules?*, HIPAA JOURNAL (Apr. 3, 2021), https://www.hipaajournal.com/what-happens-if-you-break-hipaa-rules/.
[63] U.S. GREEN BUILDING COUNCIL, https://www.usgbc.org/about/brand (last visited Sep. 20, 2021).
[64] U.S. GREEN BUILDING COUNCIL, https://www.usgbc.org/leed/why-leed (last visited Nov. 16, 2021).
[65] Joel Makower, *The Environmental Impacts of Green Buildings*, GREENBIZ (Nov. 19, 2008), https://www.greenbiz.com/article/environmental-impacts-green-buildings.

desirable – from 2017 to 2019, residential LEED certification increased by 19%.[66]

A program designed to establish and promote companies going above and beyond to create equitable technology could further incentivize companies to pursue meaningful change to the way they develop technology. Development within a defined, vetted, known, and trusted framework, could not only create social capital (and benefits), but may be more cost-effective – rather than companies creating their own, individual standards, on an ad-hoc basis, requiring both financial and human capital to do so. The program framework would provide structure and direction, reducing individual upstart cost and variation across organizations, as well as a reliable baseline standard with clear definition.

CONCLUSION

Systemic inequalities across society have been built into a nearly mandatory reliance on technology, without an intentional dismantling of preexisting inequities. This has resulted in wide-spread health technology redlining with detrimental impacts on already underserved and marginalized populations. To ameliorate the negative and inequitable impacts associated with technological solutions we must look beyond user adoption. To truly address the many and layered issues of health technology redlining and its associated negative health outcomes, there needs to be a multi-faceted, concerted focus on requiring that the technological tools we allow to shape our lives are created with the protection and interests of the most vulnerable

[66] Sarah Stanley, *U.S. Green Building Council Report Reveals a 19% Growth in LEED Residential Market*, USGBC (Aug. 7, 2019), https://www.usgbc.org/articles/us-green-building-council-report-reveals-19-growth-leed-residential-market.

among us in mind. Government needs to be at the forefront of this initiative, working to promote accessibility rather than merely increase access.

Investing in Health Care Informatics and IT: How the January 2021 Proposed Modifications to the Privacy Rule Will Impact Covered Entities and Facilitate EHR Access and Transfer[1]

Shivani Thakker, MPH

INTRODUCTION

As technology advances, it is quickly integrated into a wide variety of industries.[2] As of 2019, 89.9% of office-based physicians used a type of electronic medical record (EMR) or electronic health record (EHR) system.[3] With this extensive usage comes the need to protect and streamline access to that health information. The Health Insurance Portability and Accountability Act (HIPAA), signed into law in 1996, allowed the Department of Health and Human Services (HHS) to create standards for safeguarding Protected Health Information (PHI).[4] In 2002, HHS issued the Privacy Rule to protect all "individually identifiable health information" held or transferred by a covered entity or its business associate.[5] In 2003, HHS added the Security Rule to explicitly protect "electronic protected health information" (e-PHI).[6]

Congress further defined and expanded the privacy standards through the Health Information Technology for Economic and Clinical Health Act (HITECH Act) in 2009.[7] The purpose of the HITECH Act was not only to

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[1] At the time of writing this article, the proposed modifications to the Privacy Rule are pending and have not been adopted into a Final Rule.
[2] Hecht, *How Technology is Driving Change in Almost Every Major Industry*, Forbes (Nov. 30, 2018). https://www.forbes.com/sites/jaredhecht/2018/11/30/how-technology-is-driving-change-in-almost-every-major-industry/?sh=6902a57b2f6f.
[3] Nat'l Ctr. for Health Stat., *Electronic Medical Records/Electronic Health Records (EMRs/EHRs)*, CTR. FOR DISEASE CONTROL AND PREVENTION (Oct. 14, 2021).
[4] Benjamin Elmore, *What is HIPAA Compliance? Complete HIPAA Compliance Guide*, ACCOUNTABLE (Feb. 5, 2021), https://www.accountablehq.com/post/the-basics-of-hipaa-compliance.
[5] Office of Civil Rights, *Summary of the HIPAA Privacy Rule*, U.S. DEPT. OF HEALTH & HUM. SERV. (July 26, 2013) at 2.
[6] Office of Civil Rights, *Summary of the HIPAA Security Rule*, U.S. DEPT. OF HEALTH & HUM. SERV. (July 26, 2013).
[7] Benjamin Elmore, *The HITECH Act: Putting the "Force" into HIPAA Enforcement*, ACCOUNTABLE (July 19, 2021), https://www.accountablehq.com/post/the-hipaa-hitech-act.

encourage healthcare providers to adopt EHR and supporting technology, but to anticipate the impact of exchanging electronically protected health information (ePHI) between doctors, hospitals, and vendors that store ePHI.[8] The HITECH Act also aimed to strengthen enforcement of HIPAA regulations by increasing penalties for noncompliance and mandating similar rules to apply to business associates as covered entities.[9]

The last monumental change to HIPAA regulations occurred in 2012 when The Office of Civil Rights (OCR) finalized the HIPAA Omnibus Rule.[10] Nearly a decade later, on January 21, 2021, The OCR proposed modifications to the Privacy Rule which were published in the Federal Register.[11] The critical goals of the 2021 rule modifications are to add definitions for the terms "EHR" and "personal health application," and to modify provisions related to individuals' right to access PHI.[12] HHS proposed these modifications to increase permissible disclosures of PHI and to improve care coordination and case management.[13] Multiple studies show that "improved patient access to their health information increases patient engagement, improves medication adherence, and allows patients to more actively participate in their care."[14]

In the age of COVID-19, reliance upon digital access has transformed how health care services are delivered.[15] As the nation navigates the uncertainty of the pandemic and its impacts on the health care system, there is strong support for increased access to health information for patients and

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[8] *Id.*
[9] *Id.*
[10] Hurt, *The History of HIPAA*, ACCOUNTABLE (April 7, 2021), https://www.accountablehq.com/post/history-of-hipaa.
[11] *Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement*, 86 FED. REG. 6446 (Jan. 21, 2021).
[12] *Id.* at 6447.
[13] *Id.*
[14] John Schieszer, *Proposed HIPAA Changes Promise to Improve Health Care Delivery*, MPR (Jan. 14, 2021), https://www.empr.com/home/features/hipaa-privacy-rule-changes-patient-access-records-health-care-coordination/.
[15] John Glaser, et al., *What the Pandemic Means for Health Care's Digital Transformation*, HARV. BUS. REV. (Dec. 4, 2020).

providers.[16] Most Americans want their data to be better protected and, across party lines, there is support for additional federal measures to improve the accurate exchange of records between health care providers.[17]

This article will first address the background pieces of legislation that directly impact the exchange of records between health care providers and patient access to ePHI. Next, this article will advocate for the enactment of the proposed HHS modifications from early 2021 to facilitate EHR access and transfer. This article will also discuss why facilitating EHR access and transfer will improve care coordination, and why prioritizing care coordination is crucial. Then, this article will recommend a feasible method of implementation and enforcement for both larger and smaller covered entities to comply with these rules. Specifically, this paper proposes that larger covered entities should invest financially in health informatics and health IT teams to head the implementation of these rules while proposing alternatives for smaller covered entities that would likely find such a solution financially unfeasible. This article will also address concerns regarding enforcement issues between large-scale and small-practice health care organizations. Finally, this article will provide recommendations in the event these proposed modifications to the Privacy Rule do not become part of a Final Rule for implementation.

LEGISLATION IMPACTING PROTECTED HEALTH INFORMATION: 1996 – PRESENT DAY

Enacted in 1996, the intent of HIPAA was to help employees maintain health insurance coverage between jobs and "to combat waste, fraud, and abuse in health insurance and healthcare delivery."[18] However, the federal

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[16] *Most Americans Want to Share and Access More Digital Health Data* (July 2021), https://www.pewtrusts.org/-/media/assets/2021/07/americans_support_federal_efforts_v5.pdf.
[17] *Id.*
[18] *HIPAA History,* HIPAA J. (last visited Sept. 12, 2021), https://www.hipaajournal.com/hipaa-history/.

government has not historically rigorously enforced HIPAA, and the standards for achieving compliance can be confusing.[19] The Act required the Secretary of HHS to issue privacy regulations to govern individually identifiable health information if Congress did not enact legislation within three years of passing HIPAA.[20] When Congress did not enact any privacy legislation, HHS created a proposed rule that eventually became the Standards for Privacy of Individually Identifiable Health Information (the Privacy Rule).[21]

Codified in 45 C.F.R. pts. 160,164, the Privacy Rule established federal standards for protecting individuals' medical records and other PHI.[22] It applies to health plans, health care clearinghouses, and health care providers that conduct certain health care transactions electronically.[23] Under this rule, all "individually identifiable health information" held or transmitted by any applicable entities in any form is protected.[24] "Individually identifiable health information" is any information that is related to (1) an individuals' past, present, or future physical or mental health, (2) health care provided to the individual, (3) the past, present, or future payment for the health care provided to the individual where such information identifies the individual or there is a reasonable belief that it could be used to identify the individual.[25]

HHS also published the Security Standards for the Protection of Electronic Protected Health Information (the Security Rule) in 2003 to further clarify the security standards for protecting PHI.[26] The Security Rule was established to protect PHI while also allowing covered entities to

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[19] Elmore, s*upra* note 7.
[20] OFFICE FOR CIVIL RIGHTS, *supra* note 5 at 1-2.
[21] OFFICE FOR CIVIL RIGHTS, *supra* note 5 at 2.
[22] 45 C.F.R. Subtit. A, Subch. C, §160; 164.
[23] OFFICE OF CIVIL RIGHTS, *The HIPAA Privacy Rule*, U.S. DEPT. OF HEALTH & HUM. SERV. (Dec. 10, 2020).
[24] Elmore, s*upra* note 4.
[25] *Id.*
[26] OFFICE FOR CIVIL RIGHTS, *supra* note 6.

utilize new technologies to improve the quality and efficiency of patient care.[27] Under the Security Rule, covered entities are required to (1) ensure the confidentiality, integrity, and availability of all ePHI they create, receive, maintain, or transmit; (2) identify and protect against reasonably anticipated threats to the security or integrity of the information; (3) protect against reasonably anticipated, impermissible uses or disclosures; and (4) ensure compliance by their workforce.[28]

In 2009, President Obama signed the HITECH Act into law as a part of the American Recovery and Reinvestment Act.[29] This legislation focused on the implementation and use of health information technology with an emphasis on privacy and security.[30] The HITECH Act provided incentives and subsidies for providers and hospitals for the meaningful use of certified qualified EHRs.[31] HITECH also mandated public notification if there was any security breach when PHI was disclosed or used for an unauthorized purpose.[32] If the breach affects more than 500 individuals, the responsible organization must notify the HHS Secretary, and HHS will post the name of the institution on its website.[33] Further, when a healthcare practice or organization utilizes an EHR system, the HITECH Act provides patients that are served by that entity the right to obtain their PHI in an electronic format.[34] Consequently, this makes it easier for patients to access their health records and share those records with other organizations if needed.[35]

While each piece of legislation has further clarified regulatory standards, there are still gaps in care coordination that rely upon EHR and the transfer

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[27] *Id.*
[28] *Id.*
[29] Elmore, *supra* note 7.
[30] Howard Burde, *The HITECH Act: An Overview*, AMA J. OF ETHICS (Mar. 2011), https://journalofethics.ama-assn.org/article/hitech-act-overview/2011-03.
[31] *Id.*
[32] OFFICE FOR CIVIL RIGHTS, *HITECH Breach Notification Interim Final Rule*, U.S. DEPT. OF HEALTH & HUM. SERV. (July 26, 2013).
[33] Burde, *supra* note 30 at 174.
[34] Elmore, *supra* note 7.
[35] *Id.*

of information. As one example of many, a clinical informatics expert in California was able to see that "gaps in care were in part due to standard workflow protocols that were not working as needed in the EHR system."[36] Those gaps have resulted in a lack of interoperability even with the regulations currently in place. Interoperability permits effective information transfer when patients move facilities or multiple providers manage their care or medication regimen.[37] Health information technology can assist with the most significant gaps in care coordination: (1) information transfer; (2) systems to monitor patients; (3) tools to support patient self-management goals; and (4) tools to link patients and their caregivers with community resources.[38]

PATIENT ACCESS REALITY AND THE 2021 CHANGES PROPOSED BY HHS

The different pieces of legislation were all enacted to protect patient access and information. However, patients' experiences are at times different than the expectations of the policies in place.[39] Even though the regulations indicate that patient access to records is a priority, not all of a patient's medical records may be available through a patient portal and not all patients utilize a portal even if it is available.[40] Because HIPAA allows providers to charge patients a "reasonable" cost-based fee for providing paper or electronic copies of medical records, patients may feel discouraged from accessing the information they need.[41]

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[36] Felix Carpio, *Dr. Carpio Optimizes EHR System to Eliminate Gaps in Care*, THE OFF. OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH. (July 7, 2017), https://www.healthit.gov/success-story/dr-carpio-optimizes-ehr-system-eliminate-gaps-care.
[37] Samal et al., *Care coordination gaps due to lack of interoperability in the United States: a qualitative study and literature review*, BMC HEALTH SERV. RES. (Apr. 22, 2016), https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-016-1373-y.
[38] *Id.*
[39] Kim Murphy-Abdouch, *Patient Access to Personal Health Information: Regulation vs. Reality*, PERSP. IN HEALTH INFO. MGMT. (Jan. 1, 2015).
[40] *Id.*
[41] *Id.*

More than half of the survey respondents from a study run by the American Health Information Management Association (AHIMA) Foundation and Texas State University reported that providers charge patients for electronic copies, and nearly two-thirds reported that they charge for paper copies of records.[42] The fees vary from state to state and the time frame for responding to a patient's request for information also varies.[43] The fees providers charge to patients range from "free to hundreds of dollars."[44] Additionally, while HIPAA allows providers up to thirty days to respond to a patient's request, state statutes vary with response times between fifteen and thirty days.[45]

Even though the HITECH Act requires healthcare providers to use EHRs to provide patients with digital versions of their medical records, patient engagement is relatively low.[46] A second study conducted by the AHIMA Foundation and Texas State University explored the perspectives of the healthcare consumer when accessing their health information.[47] The study found that although consumers responded positively to access becoming more manageable, there were still many reservations concerning the security of information, lack of operability for records in different systems, and lack of centralization of information between providers.[48]

On January 21, 2021, HHS submitted proposed rules to the Federal Register to amend the Privacy Rule.[49] HHS proposed many amendments including but not limited to: (1) shortening required response time from covered entities to no later than fifteen calendar days; (2) creating a pathway to direct the sharing of PHI in an EHR among covered health care

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[42] *Id.*
[43] *Id.*
[44] *Id.*
[45] *Id.* at 3.
[46] Kim Murphy-Abdouch et al., *Patient Access to Personal Health Information: An Analysis of the Consumer's Perspective*, PERSP. IN HEALTH INFO. MGMT. (June 22, 2017).
[47] *Id.*
[48] *Id.*
[49] Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement,, *supra* note 11 at 6446.

providers and health plans; (3) requiring covered health care providers and health plans to respond to certain records requests received from other covered health care providers and health plans when directed by individuals under the right of access; and (4) requiring covered entities to post estimate fee schedules on their websites.[50]

PROPOSED METHODS FOR COMPLIANCE

Should the proposed modifications to the Privacy Rule become definitive rules, covered entities have many options for who should lead implementation and enforcement to maintain compliance.[51] It is crucial to remember that to be effective, both implementation and enforcement will require many individuals and teams to communicate with each other. The chief compliance officer and general counsel of a covered entity should continuously be involved to address any compliance or legal issues that may come up. Communication between the individuals in both roles is imperative for coordination and implementation of compliance strategies.

One way for larger-sized covered entities to implement and enforce these rules is to invest in health informatics and healthcare information technology teams. Health informatics professionals create and maintain the systems that allow information exchange and manage the security systems.[52] In contrast, health information management professionals focus on organizing and managing patient data within a medical record, including releasing information and maintaining confidentiality.[53] These teams need not work in isolation; under the HITECH Act, the Office of the National Coordinator for Health Information Technology (ONC) has implemented

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[50] *Id.*
[51] OFFICE FOR CIVIL RIGHTS, *supra* note 5.
[52] USFHealth, *The Difference Between Health Informatics and Health Information Management*, USFHEALTH (Oct. 15, 2021), https://www.usfhealthonline.com/resources/career/differences-between-health-informatics-and-health-information-management/.
[53] *Id.*

five programs to support health care providers in using EHRs.[54] The Regional Extension Centers assist primary care providers in adopting and meaningfully using EHRs, while the Beacon Community Program has funded seventeen selected communities that have already invested in health IT.[55] The Health IT Workforce Development program aims to train new professionals to help providers implement EHRs.[56] The State Health Information Exchange Program funds state efforts to enable secure patient information transfer and the Strategic Health IT Advanced Research Projects Program supports research that will "accelerate the nationwide use of health IT."[57]

To continue the chain of communication, the health informatics team should report to the chief health information officer, or someone with similar responsibilities.[58] Those responsibilities include strategic implementation of EHR and health informatics to streamline the transfer of patient information.[59] This person may report to the chief information officer, who oversees the IT department and can communicate with other C-suite executives regarding the digital data collected.[60] The health IT team would be best suited to report to someone in the role of a chief information security officer, who is responsible for developing the healthcare organization's policy on IT security and can regularly interact with both the chief technology officer and the chief compliance officer.[61]

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[54] *Advancing the Future of Healthcare with Electronic Health Records: A Look at ONC'S HITECH Programs*, THE OFF. OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH. (Apr. 14, 2017), https://www.healthit.gov/sites/default/files/advancing-the-future-of-health-care-with-electronic-health-records-a-look%20-at%20-onc's-hitech-programs-2.pdf.
[55] *Id.*
[56] *Id.*
[57] *Id.*
[58] Laura Dyrda, *38 Hospital and Health System C-level Roles, Defined*, BECKER'S HOSP. REV. (June 13, 2017), https://www.beckershospitalreview.com/hospital-management-administration/38-hospital-and-health-system-c-suite-executive-positions.html.
[59] *Id.*
[60] *Id.*
[61] *Id.*

In addition to improving care coordination, investing in health information technology has a positive effect on hospital revenue.[62] For example, health information exchanges of data access across every major emergency department in the Memphis, Tennessee area in the early 2010s resulted in reduced hospital admissions and an annual cost savings of nearly $2 million.[63] While this proposal may have pushback from individuals who directly determine resource allocation within these healthcare organizations, the case study suggests that the upfront investment saves medical costs and improves care.[64] Indeed, 75% of providers report that their EHR allows them to deliver better patient care.[65]

Smaller covered entities typically lack the resources and expertise required to address the constant changes in compliance rules and regulations.[66] Few have designated privacy, security, or compliance officers who can specifically focus on these issues.[67] Even though HIPAA compliance is a top priority, the attention and engagement required for federal compliance are not always available.[68] Unfortunately, smaller groups or individual providers are at the greatest risk of privacy and security breaches.[69]

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[62] Jinhyung Lee and Jae-Young Choi, *Increased Health Information Technology Investment Decreases Uncompensated Care Cost: A Study of Texas Hospitals*, 27 TECH. AND HEALTH CARE 13-21 (2019) at 14. (Modeling indicated a negative association between IT investment and uncompensated care).
[63] *See* Press Release, Craig Boerner, Vanderbilt University Medical Center, *Financial Impact of Sharing Electronic Health Information Focus of Vanderbilt Study – Savings of Nearly $2 Million Reported Across Memphis Eds*, (Nov. 7, 2011), https://www.mc.vanderbilt.edu/news/releases.php?release=2271.
[64] *Id.* (Case study that indicates investment in technology can save medical costs by improving care).
[65] *Improved Diagnostics & Patient Outcomes*, THE OFF. OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH. (June 4, 2019).
[66] Primeau, *How Small Organizations Handle HIPAA Compliance*, J. OF AHIMA 88, NO.4 18-21 (April 2017) at 18.
[67] *Id.*
[68] *Id.*
[69] *Id.*

Organizations must be proactive to minimize potential data breaches in a practical manner.[70] For smaller organizations, it is prudent to contract with an outside vendor to conduct a privacy and security analysis if the internal resources are not available.[71] This process begins with a risk analysis that can identify weak spots that an organization can address even on a limited budget.[72] Once weak spots are identified, assigning a level of risk for all findings can help develop a plan of action based on priority.[73] Some action items include developing a disaster recovery plan, conducting annual compliance training for all employees who interact with patient data, or ensuring mobile device compliance.[74]

CONCERNS REGARDING COMPLIANCE ENFORCEMENT

Regardless of the size of the covered entity, there is a large gap between the priorities of healthcare compliance officers and regulators when it comes to HIPAA compliance.[75] Many healthcare compliance professionals have stated that compliance with HIPAA Security and Privacy rules is their highest priority.[76] However, regulators at the HHS Office of the Inspector General and the Department of Justice have focused on violations of the anti-kickback statute and Stark laws.[77] Despite providers' focus on compliance, nearly three-quarters of the 2018 Healthcare Compliance Benchmark Survey respondents stated that their compliance offices have five or fewer staff.[78] This report concludes that "many, if not most,

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[70] *Id.*
[71] *Id.*
[72] *Id.* at 19.
[73] *Id.*
[74] *Id.* at 20.
[75] Fred Donovan, *HIPAA Compliance Gap Between Compliance Officers, Regulators*, HEALTHITSECURITY (Apr. 20, 2018), https://healthitsecurity.com/news/hipaa-compliance-gap-between-compliance-officers-regulators.
[76] *Id.*
[77] *Id.*
[78] *Id.*

compliance departments are being stretched thin to meet their obligations."[79]

Compliance offices already face challenges in meeting existing compliance rules; imposing new requirements may add additional barriers to covered entities' efforts to remain compliant with federal statutes and regulations. Additionally, the small and medium-sized covered entities that do not have a sufficiently dedicated budget for compliance offices are at an even bigger disadvantage. Accordingly, this raises questions about the length of time afforded to small and medium-sized covered entities to become compliant with the new regulations. Currently, the effective date of a final rule would be sixty days after publication and the compliance date would be no later than 180 days from the effective date.[80] Although HHS has stated compliance would not require more than the 180-day period,[81] there is a risk that small and medium-sized covered entities will be scrambling to find a way to meet the new regulations. OCR would begin enforcement of the revised standards 240 days after publication of a final rule regardless of the impacts that the COVID-19 pandemic has had on organization budgets.[82]

Even larger covered entities have had significant budget changes due to the pandemic, and there are lasting consequences to that in terms of resource allocation for compliance offices. HHS has established that for certain proposed modifications that would require an extended compliance period, the Department will request information from entities regarding how much time would be needed and the impact of an extended compliance period.[83] Ultimately, without considering the pandemic's impact on all covered entities, compliance with the new proposed modifications may be

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[79] *Id.*
[80] Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement, *supra* note 11 at 6448.
[81] *Id.*
[82] *Id.*
[83] *Id.*

challenging. Despite these challenges, it is necessary to keep pushing forward to protect data privacy and improve patient access to digital records.

CONCLUSION

The proposed modifications were published on January 21, 2021.[84] There was an initial public comment period until March 22, 2021, but on March 9, the OCR announced a forty-five-day extension until May 6, 2021.[85] Since then, there have been no updates about the proposed modifications, but it is essential to not let the momentum surrounding EHR management and care coordination slip. Bolstering healthcare organizations' informatics and IT teams is more important than ever as we continue to navigate a pandemic where all healthcare stakeholders rely upon digital access.

Even if the proposed modifications to the Privacy Rule do not make it into the Biden administration's Final Rule at the end of 2021, it is crucial to continue to address streamlining EHR access and transfer can improve care coordination, and ultimately, patient outcomes. EMR and EHR platforms are here to stay, so it is vital to incorporate the technology into standard medical practice.

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[84] Elmore, *supra* note 7.
[85] *See* Press Release, HHS Press Office, *Extension of the Public Comment Period for Proposed Modifications to the HIPAA Privacy Rule*, (Mar. 9, 2021), https://www.hhs.gov/about/news/2021/03/09/extension-public-comment-period-proposed-modifications-hipaa-privacy-rule.html.