Texas A&M Law Review

Volume 9 | Issue 1

11-18-2021

A Telehealth Explosion: Using Lessons from the Pandemic to Shape the Future of Telehealth Regulation

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ARTICLES

A TELEHEALTH EXPLOSION: USING LESSONS FROM THE PANDEMIC TO SHAPE THE FUTURE OF TELEHEALTH REGULATION

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DOI: https://doi.org/10.37419/LR.V9.I1.1

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I. INTRODUCTION

From board rooms, to classrooms, to Saturday Night Live skits, the video conferencing app Zoom became a seemingly overnight sensation as a way to connect while businesses were shuttered and individuals were forced to stay at home when the coronavirus pandemic erupted in the United States in March 2020.[1] From 10 million daily users in December 2019 to over 200 million daily users by March 2020, the company founded in 2011[2] became a market leader as the country tried to figure out how to continue business as usual—to the extent possible—during the global pandemic.[3] While hospitals prepared for the onslaught of patients suffering from COVID–19, many physicians and physician offices around the country not tasked with treating patients suffering from COVID–19 shuttered their doors along with other businesses and contemplated ways in which they could still render necessary care to their patients.[4] How could physicians advise or diagnose patients who exhibited coronavirus symptoms without exposing other patients to coronavirus? How could physicians who were themselves immunocompromised or at special risk if they were to contract COVID–19 continue to treat their patients? How could patients feel comfortable seeking care for non-COVID–19 related conditions without feeling like seeking such care could expose them to the virus? In short, providers were facing many of the same dilemmas that other businesses have been facing during the global pandemic, and just like the 200 million fellow Americans who turned to Zoom, the health care industry likewise looked to technology.

Utilizing technology to render necessary healthcare services—often referred to generically as "telehealth"—was neither new nor novel at the time of the coronavirus pandemic in 2020.[5] The concept of

1. Dain Evans, *How Zoom Became So Popular During Social Distancing*, CNBC, https://www.cnbc.com/2020/04/03/how-zoom-rose-to-the-top-during-the-coronavirus-pandemic.html (Apr. 4, 2020, 12:26 PM) [https://perma.cc/S575-UEDC].

2. Taylor Nicole Rogers, *Meet Eric Yuan, the Founder and CEO of Zoom, Who Has Made Over $12 Billion Since March and Now Ranks Among the 400 Richest People in America*, BUS. INSIDER, https://www.businessinsider.com/meet-zoom-billionaire-eric-yuan-career-net-worth-life (Sept. 9, 2020, 10:44 AM) [https://perma.cc/F9YX-5M6F].

3. Evans, *supra* note 1.

4. Gabriela Weigel et al., *Opportunities and Barriers for Telemedicine in the U.S. During the COVID-19 Emergency and Beyond*, KAISER FAM. FOUND. (May 11, 2020), https://www.kff.org/womens-health-policy/issue-brief/opportunities-and-barriers-for-telemedicine-in-the-u-s-during-the-covid-19-emergency-and-beyond/ [https://perma.cc/9GEJ-AL9C].

5. Cynthia LeRouge & Monica J. Garfield, Commentary, *Crossing the Telemedicine Chasm: Have the U.S. Barriers to Widespread Adoption of Telemedicine*

telehealth (the use of closed circuit television at the time) in the broadest sense has existed in health care since the 1960s with projects launched at the National Aeronautics and Space Administration ("NASA") and the Nebraska Psychology Institute.[6] Thus, while the concept of diagnosing and/or treating a patient via technology as opposed to in person has been around for some time, there have been significant barriers that have hindered widespread growth of telehealth more generally.[7] Despite this, telehealth advocates have been doggedly and slowly pushing for expansion and trying to break through the known obstacles for decades in an effort hopefully to achieve the touted gains from telehealth, including enhanced healthcare services to rural and medically underserved populations, more integrated care across platforms to coordinate providers all treating the same episode of care, and greater convenience and efficiency for the patients and providers for the treatment of basic health care needs.[8] Now, just as Zoom was able to grow thirty times in a matter of months due to the increased demand caused by stay-at-home orders, it seems that the global pandemic was just the push that the telehealth industry needed to exhibit the system's advantages and create an ideal environment for understanding whether the fears and barriers that have been holding expansion of telehealth back have been overblown, or at least less extreme than previously thought.[9] Like a set of dominoes, various federal and state restrictions and limitations that have been built up over the years around telehealth were suddenly folded, allowing patients to continue to seek necessary medical care.[10] Patients then found themselves able to access telehealth services from their homes or other places of residence.[11] While some restrictions previously in place are likely to return or have already returned,[12]

Been Significantly Reduced?, 10 INT'L J. ENV'T RSCH. & PUB. HEALTH 6472, 6473 (2013), https://doi.org/10.3390/ijerph10126472 [https://perma.cc/6TN2-LUQY].

6. *Id.*

7. *Id.*; *see also* Miranda A. Moore et al., *Only 15% of FPs Report Using Telehealth; Training and Lack of Reimbursement Are Top Barriers*, AM. FAM. PHYSICIAN (Jan. 15, 2016), https://www.aafp.org/afp/2016/0115/p101.html [https://perma.cc/6SXH-VX5V].

8. *See* LeRouge & Garfield, *supra* note 5, at 6473–74; David Pratt, *Telehealth and Telemedicine in 2015*, 25 ALB. L.J. SCI. & TECH. 495, 508–09 (2015).

9. *See* Weigel et al., *supra* note 4.

10. *See Telehealth: Delivering Care Safely During COVID-19*, U.S. DEP'T HEALTH & HUM. SERVS., https://www.hhs.gov/coronavirus/telehealth/index.html [https://perma.cc/Y54Z-58Y8] [hereinafter *Delivering Care Safely*]; *U.S. States and Territories Modifying Requirements for Telehealth in Response to COVID-19*, FED'N ST. MED. BDS. 1, 1, https://www.fsmb.org/siteassets/advocacy/pdf/states-waiving-licensure-requirements-for-telehealth-in-response-to-covid-19.pdf (July 28, 2021) [https://perma.cc/2ZB4-H9D8].

11. *See Delivering Care Safely*, *supra* note 10; *U.S. States and Territories Modifying Requirements for Telehealth in Response to COVID-19*, *supra* note 10, at 1–2.

12. As discussed in more detail below, certain privacy requirements existed that were lifted to allow patients to use technology that is not compliant with applicable security regulations under the Health Insurance Portability and Accountability Act of

most speculate that the pandemic will be telehealth's "tipping point" and will likely usher in more robust and widespread telehealth use even after the pandemic has passed or at least waned.[13] Indeed, congressional lawmakers submitted a bill titled the Expanded Telehealth Access Act in November 2020 and then reintroduced it in March 2021,[14] aiming to permanently expand Medicaid coverage for certain services for which restrictions were waived during the pandemic.[15] As telehealth services have become more widely available and proven to be useful,[16] it now seems unlikely there will be a return to the previous status quo for the industry. This still leaves the industry, regulators, and enforcers to contemplate what the telehealth industry should look like in a post-pandemic-crisis environment. While the global pandemic has had a devastating effect on society,[17] this is nevertheless a unique and—hopefully—an unable-to-be-replicated moment in time in which the healthcare industry can observe the unfettered use of telehealth. Through this lens, legislators and policymakers have the opportunity to consider regulations and legal limitations anew: which regulations and legal limitations are actually necessary to best protect patients; how effective is the use of telehealth for effective outcomes;

1996 ("HIPAA"). To assure privacy and security of this sensitive data, it is likely desirable to require telehealth services to be conducted utilizing technology that complies with applicable security regulations. Jessica Davis, *Insights into HHS COVID-19 HIPAA Waivers and Lasting Implications*, HEALTH IT SEC. (May 8, 2020), https://healthitsecurity.com/features/insights-into-hhs-covid-19-hipaa-waivers-and-lasting-implications [https://perma.cc/JKR8-4YK5] ("Predictions aside, HHS and OCR have stressed these waivers will only remain in place during the pandemic. As a result, providers must consider any potential privacy, security, or compliance liabilities and obligations to prevent massive complications in the future.").

13. David Nickelson, *The Rapidly Evolving Healthcare Sector: Telehealth, Patient Experience, Data Interoperability During COVID-19 Pandemic*, NERDERY (Mar. 20, 2020), https://www.nerdery.com/insights/the-rapidly-evolving-healthcare-sector-telehealth-patient-experience-data-interoperability-during-covid-19-pandemic/ [https://perma.cc/Y2XL-MWLG]; *see also* Jedrek Wosik et al., *Telehealth Transformation: COVID-19 and the Rise of Virtual Care*, 27 J. AM. MED. INFORMATICS ASS'N 957, 961–62 (2020).

14. The Expanded Telehealth Access Act was first introduced on November 16, 2020, by fourteen U.S. representatives but failed to receive a vote. Expanded Telehealth Access Act, H.R. 8755, 116th Cong. (2020). It was later reintroduced in the 2021 legislative session on March 23, 2021, as H.R. 2168. Expanded Telehealth Access Act, H.R. 2168, 117th Cong. (2021).

15. *See* Eric Wicklund, *Congress to Get Another Shot at Telehealth Coverage for Specialists*, MHEALTH INTEL. (Mar. 26, 2021), https://mhealthintelligence.com/news/congress-to-get-another-shot-at-telehealth-coverage-for-specialists [https://perma.cc/9GFZ-57K3] (proposing expansion for coverage of "telehealth services provided by physical and occupational therapists, audiologists[,] and speech and language pathologists").

16. Weigel et al., *supra* note 4.

17. *See generally* Maria Nicola et al., *The Socio-Economic Implications of the Coronavirus Pandemic (COVID-19): A Review*, 78 INT. J. SURGERY 185, 185 (2020) (noting that at the time the "pandemic ha[d] resulted in over 4.3 million confirmed cases and over 290,000 deaths globally" while "spark[ing] fears of an impending economic crisis and recession").

what barriers are most likely to quell provider participation in telehealth; what previous restrictions have proven inconsequential to combat waste, fraud, or abuse; what previous restrictions have proven essential to combat waste, fraud, or abuse; and what new issues or challenges have emerged as telehealth use has become more widespread. To truly realize the benefits of telehealth while simultaneously providing protection for consumers and payors (commercial and government alike), regulators and enforcers should use this time and its associated data to reconsider the telehealth delivery and its regulatory structure with the goal of enacting practical and workable regulations that advance efficient and effective health care delivery.

To this end, Part II of this Article examines the history of telehealth from its early origins and defines what telehealth means today in all its various forms. Part II further explains the restrictions and regulatory structure, both federal and state, that applied to telehealth before the coronavirus pandemic and the then-current enforcement trends. Next, Part III describes all the various waivers and regulatory changes that went into effect in response to COVID–19 and examines how the pandemic has fueled increased telehealth growth.[18] Part III also analyzes trends realized during the pandemic and other usage data to consider the impact and effect of the waivers and loosening of restrictions on telehealth services. This Article then argues in Part IV that legislators and regulators should avoid either a return to status quo or a permanent adoption of all of the waivers in effect; instead, they should utilize the data and evidence gathered during this time period when restrictions were largely lifted both to understand the true concerns telehealth usage raises and to consider a revised regime that focuses its attention and efforts on those aspects of the regulatory structure that are most detrimental to patients' and consumers' health and safety. It further provides some general recommendations for reconsidering the telehealth regulatory regime once the public health emer-

18. It should be specifically mentioned that while this Article will explain certain waivers that went into effect to ease privacy restrictions, including waivers of HIPAA, its enacting regulations, and other state law privacy protections, the focus for reconsidering telehealth regulations is primarily on the non-privacy related waivers. For telehealth to be successful and potentially transformative, it is of utmost importance that patients and providers feel that the data and all personal interactions are as secure and protected as if the patient was sitting in the office or as if the health records were in a locked file cabinet. Thus, any waivers that were granted during the coronavirus pandemic regarding privacy—usually for the purpose of allowing use of a technology that does not meet security requirements—should not be waived on a permanent basis and regulators should continue to pay increased attention to how, and with what technology, personal health information is best protected. This is not to say that there may not need to be revisions to applicable privacy and security regulations under HIPAA, as such regulations have not been updated to adapt to more modern practices and technologies in some time. Indeed, one outcome of the pandemic might be considering ways in which more common applications and technologies that people use in their everyday lives can be made more secure for telehealth purposes. It is vital, however, that security and protection of the data be a primary consideration.

gency has subsided to promote the use of telehealth in a way that enhances and enriches telehealth benefits without harming patients and consumers. Finally, Part V concludes with thoughts regarding the importance of reimaging the telehealth infrastructure for a sustained and successful future.

II. BACKGROUND

While the World Health Organization traces the origins of telehealth back to the nineteenth century,[19] the modern conception of telehealth first emerged in the 1960s when NASA used it to respond to astronauts' medical issues that presented while in space.[20] Although there was some use of telehealth in the decades following, including for consultations between specialists and general practitioners as well as for use at a state mental hospital and airport medical center,[21] lack of technology hindered widespread use of telehealth until the development of the Internet in the 1990s.[22] The Internet spurred new growth in telehealth's role in the health delivery system across the United States and around the world.[23] As telehealth has expanded, so too have the types of connections and interactions that are possible and have thus become encompassed within the umbrella term "telehealth."[24]

Over the years, the terms "telehealth" and "telemedicine" have sometimes been used interchangeably, and trying to define what exactly telehealth or telemedicine are and do has been one of the challenges to establishing a framework for how to implement a regulatory structure and how to craft regulation of telecommunications tools in health care.[25] There are many definitions of telehealth and telemedicine,[26] and it seems that even state and federal governments cannot agree on a succinct or consistent definition among themselves.[27] Generally, telehealth is understood as "a health care pro-

19. WORLD HEALTH ORG., TELEMEDICINE: OPPORTUNITIES AND DEVELOPMENTS IN MEMBER STATES: REPORT ON THE SECOND GLOBAL SURVEY ON EHEALTH 2, 2 n.4 (2010) (citing John Craig & Victor Patterson, *Introduction to the Practice of Telemedicine*, 11 J. TELEMEDICINE & TELECARE 1, 3–9 (2005)) [hereinafter WHO].

20. Scott A. Borgetti, Philip J. Clapham & Jeremy D. Young, *Telehealth: Exploring the Ethical Issues*, 19 DEPAUL J. HEALTH CARE L. 1, 1 (2017) (noting that NASA developed methods to "monitor vital signs, triage complaints, and diagnose and treat the ailments of American astronauts who were miles above the Earth's surface").

21. WHO, *supra* note 19, at 9.

22. Borgetti et al., *supra* note 20, at 2.

23. *Id.*

24. Rashid Bashshur et al., *The Taxonomy of Telemedicine*, 17 TELEMEDICINE & E-HEALTH 484, 484 (2011).

25. *Id.*

26. WHO, *supra* note 19, at 9 (citing an article from 2007 finding that there were over 104 peer-reviewed definitions of "telemedicine").

27. *See generally* Ken Kozlowski, *The Internet Guide to Telehealth. . .or Telemedicine. . .or Telecare*, 20 INTERNET L. RESEARCHER 1 (2015) (noting that the Federal Communications Commission provides a definition of telehealth,

vider's use of information and communication technology ("ICT") in the delivery of clinical and nonclinical health care services."[28] In contrast, telemedicine is generally understood to be "a health care provider's use of ICTs in the delivery of only clinical health services."[29] Thus, the distinction between the two terms is generally understood to be that "telehealth" broadly indicates the use of technology for health *and health-related* services whereas "telemedicine" is limited to the use of technology for the rendering of clinical services.[30] Industry professionals typically divide telehealth technologies into the following general categories: (1) mobile health ("mHealth"); (2) video and audio technologies (including digital photography); (3) remote patient monitoring ("RPM"); and (4) store-and-forward technologies.[31] Different technologies create different compliance concerns, so understanding all of the various technologies through which telehealth can be administered is critical for understanding the regulatory structure.

mHealth is the use of healthcare applications and programs accessible on a smartphone, tablet, laptop, or other mobile device.[32] These applications and programs range according to their functions, including the tracking of health measurements (such as the Apple Health app), reminders and calendaring of appointments or medications, and provider health portals to enable sharing of patient data such as test results or provider-patient communication.[33] While all these programs may be included in a general definition of telehealth, only some of these interactions might be subject to regulations or privacy restrictions.[34]

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telemedicine, and telecare as do other federal agencies, including the Health Resources and Services Administration, although none of these definitions are necessarily identical to definitions set forth in federal regulations or by state statutes or state agencies).

28. CONG. RSCH. SERV., TELEHEALTH AND TELEMEDICINE: FREQUENTLY ASKED QUESTIONS 1 (2020) (noting that the Health Care Safety Net Amendments of 2002 (P.L. 107-251) define telehealth as "[t]he use of electronic information and telecommunications technologies to support long distance clinical health care, patient and professional health-related education, public health, and health administration").

29. *Id.* at 2 (finding that unlike telehealth, telemedicine is defined in three separate sections of the United States Code, each with slightly different definitions: (a) the Indian Health Care Improvement Act (P.L. 94-437); (b) the Honoring America's Veterans and Caring for Camp Lejeune Families Act of 2012 (P.L. 112-154); and (c) the National Defense Authorization Act for Fiscal Year 2014 (P.L. 113-66)).

30. *What Is Telehealth?*, NEJM CATALYST (Feb. 1, 2018), https://catalyst.nejm.org/doi/full/10.1056/CAT.18.0268 [https://perma.cc/QED9-8FLV] [hereinafter NEJM Catalyst].

31. *Id.*

32. *Id.*

33. *Id.*; *What Is Telehealth?*, CCHP, https://www.cchpca.org/what-is-telehealth/ [https://perma.cc/LW47-FE6K] (follow the page down to "Key components of telehealth," then choose the tab "Mobile Health").

34. *The U.S. FDA's Regulation and Oversight of Mobile Medical Applications*, UL 2 (2013), https://legacy-uploads.ul.com/wp-content/uploads/sites/40/2015/02/UL_WP_Final_The-US-FDAs-Regulation-and-Oversight-of-Mobile-Medical-Applications_v6_HR.pdf [https://perma.cc/VC5A-GNWH].

Video and audio technologies are more commonly used for telemedicine purposes and include videoconferencing tools "such as Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, Zoom, or Skype."[35] This is a frequently utilized telehealth resource, as it is largely viewed as a substitute for an in-person encounter when an in-person visit is either not possible or ill advised.[36] Traditionally, this has been utilized most frequently when the patient was in a rural or remote location and was unable to travel, but during the pandemic it has been used to avoid in-person visits when such would be compromising for either the patient or the provider.[37]

A third type of technology, RPM, involves wearable or implantable devices or computers to report, collect, transmit, and evaluate patient health data.[38] Distinct from mHealth, this technology is typically ordered or recommended by a physician who is then responsible for monitoring the data and utilizing it to identify patterns of concern or for detecting potential complications earlier.[39]

The last type of telehealth is phrased "store-and-forward" technology because, unlike RPM, which might transmit data in real time, "store-and-forward" refers to the process of capturing, storing, and transmitting patient health information for a specialist's consultation or review—usually not in real time.[40] For example, a physician treating a patient at a community hospital might send an MRI or a CT-scan to a specialist at a specialty hospital to have the specialist review the images and provide advice regarding treatment.[41]

A. *Historical and Current Telehealth Legal Barriers*

The varied and broad-ranging technologies that constitute telehealth generally pose different benefits, risks, and concerns to patients, yet many of them are subject to the same rules and regulations because of their general categorization as telehealth activities.[42] The

35. *See Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency*, U.S. DEP'T HEALTH & HUM. SERVS., https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html (Jan. 20, 2021) [https://perma.cc/C4J3-MQBJ] [hereinafter *OCR Notification*].

36. *What is Telehealth?*, *supra* note 33 (follow the page down to "Key components of telehealth," then choose the tab "Live Video").

37. Marjorie S. Rosenthal, *The New Language of Telehealth*, N.Y. TIMES (May 5, 2020), https://www.nytimes.com/2020/05/05/well/live/doctors-patients-mother-baby-pediatrics-telemedicine-computers.html [https://perma.cc/B9ND-J932] (noting that telehealth was a necessity during the pandemic because the provider was being treated for metastatic colon cancer and was thus immunocompromised).

38. NEJM Catalyst, *supra* note 30.

39. *Id.*

40. *Id.*

41. *Id.*

42. Avery Schumacher, Note, *Telehealth: Current Barriers, Potential Progress*, 76 OHIO ST. L.J. 409, 439 (2015).

regulations and legal limitations imposed on telehealth technologies and services are diverse and complex—a web of federal regulations and reimbursement restrictions, state statutes and regulations, and commercial contracting limitations.[43]

1. State Licensure Laws

As a starting matter, the practice of telehealth meets its first legal obstacle at the state level under applicable licensing regulations, which typically require that any state resident receive medical services rendered, remotely or otherwise, by a practitioner who is duly licensed to practice in that state.[44] Historically, citing concerns regarding the economic loss from licensing fees and revenues, the risk of market saturation, and the desire to maintain control and authority over standards necessary for maintaining quality and safety of the medical profession, many states have maintained the requirement that physicians rendering services to a state's residents in any manner be licensed in that state.[45] Even in states that have created specific licensure exceptions for the practice of telehealth, such as a special license, these exceptions are sometimes limited to second opinions or situations in which telehealth services are rendered on an infrequent basis.[46] Thus, licensure restrictions have contributed to sluggish telehealth expansion as the cost of licensing fees and ongoing compliance has proved to show an inadequate return on investment for most providers.[47]

More recently, perhaps out of pressure to provide more flexibility and access to necessary medical services,[48] twenty-nine states, the District of Columbia, and the territory of Guam have joined the Interstate Medical Licensure Compact ("Compact") in some capacity.[49]

43. *See generally id.* at 419–20, 439.

44. Kyle Y. Faget, *Telemedicine Compliance: The Practice Requirements*, 22 J. HEALTH CARE COMPLIANCE 27, 28 (2020).

45. Schumacher, *supra* note 42, at 422.

46. *See* Jeremy Sherer & Amy Joseph, *Physician Law Evolving Trends and Hot Topics: Telehealth*, 32 HEALTH L. 20, 23 (2020) (noting that nine states have special licenses or certificates that permit the practice of telehealth and discussing how the specific licensure exceptions vary across jurisdictions).

47. *See* Mary K. Wakefield, U.S. Dep't of Health & Hum. Servs., Health Res. & Servs. Admin., *Health Licensing Board Report to Congress*, HRSA.GOV 25, https://www.hrsa.gov/sites/default/files/ruralhealth2/about/telehealth/licenserpt10.pdf [https://perma.cc/TA3F-58TX] (noting that as of 2010 only 22% of physicians maintain licenses in multiple states).

48. *See A Faster Pathway to Physician Licensure*, INTERSTATE MED. LICENSURE COMPACT, https://www.imlcc.org/a-faster-pathway-to-physician-licensure/ [https://perma.cc/5YHK-M5WH].

49. *U.S. State Participation in the Compact*, INTERSTATE MED. LICENSURE COMPACT, https://www.imlcc.org/ [https://perma.cc/86CG-UMSQ] (showing that twenty-four states and the Territory of Guam are members of the Compact and serve as State of Principal License to process applications and issue licenses, including Alabama, Arizona, Colorado, Idaho, Illinois, Iowa, Kansas, Nevada, Maine, Maryland, Michi-

Under the Compact, which became effective in April 2017, physicians meeting applicable eligibility requirements can complete a single application to become licensed in any state in which the physician would like to practice medicine so long as that state is also a Compact member state.[50] To maintain quality control, a physician must first hold a "full, unrestricted medical license in a Compact member-state that can serve as a declared State of Principal License ("SPL")."[51] For a state to serve as a physician's SPL, the physician must be a primary resident of the state, render at least 25% of the physician's practice of medicine in the state, be employed to practice medicine by an entity located in the state, *or* the state serves as the physician's place of residence for purposes of paying federal income tax.[52] There are other additional criteria that are similar to those typical of state licensure laws, including graduating from an accredited medical school or foreign equivalent and completing applicable graduate medical education requirements along with other disciplinary criteria such as disclosure of past or present disciplinary actions.[53] Compact legislation has been introduced in either 2019 or 2020 in six other states.[54] Thus, in the three years since the Compact became operational, over half of the states are participating in some manner, and others are still in active discussions regarding joining the Compact.[55] With approximately 80% of physicians seeking licensure meeting applicable criteria, the Compact may ease some of the historical licensure challenges that physi-

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gan, Minnesota, Mississippi, Montana, Nebraska, New Hampshire, North Dakota, South Dakota, Tennessee, Utah, Washington, West Virginia, Wisconsin, and Wyoming). An additional three states (Oklahoma, Georgia, and Vermont) are currently members of the Compact but do not serve as States of Principal License. *Id.* Also, Pennsylvania, Kentucky, and the District of Columbia have passed legislation to join the Compact but are still in the process of implementation or implementation has been delayed. *Id.*

50. *A Faster Pathway to Physician Licensure*, *supra* note 48.

51. *Id.*

52. *Id.*

53. *Id.* The complete requirements are that the physician must "[h]ave graduated from an accredited medical school, or a school listed in the International Medical Education Directory[;] [h]ave successfully completed ACGME- or AOA-accredited graduate medical education[;] [p]assed each component of the USMLE, COMLEX-USA, or equivalent in no more than three attempts for each component . . . [;] [h]old a current specialty certification or time-unlimited certification by an ABMS or AOABOS board" and must also demonstrate that the physician does "[n]ot have any history of disciplinary actions towards their medical license[;] [n]ot have any criminal history[;] [n]ot have any history of controlled substance actions toward their medical license[;] [and] [n]ot currently be under investigation." *Id.*

54. *Id.*

55. Note that there are similar nurse compacts and physical therapy compacts across the country that allow the practice of nursing or physical therapy across state lines. *See* Schumacher, *supra* note 42, at 423; *Physical Therapy Compact. . . Increasing Access, Improving Mobility*, PT COMPACT, www.ptcompact.org [https://perma.cc/47D2-6NNC].

cians faced when even considering the possibility of engaging in telehealth or telemedicine services.[56]

2. Practitioner-Patient Relationship and State and Federal Prescribing Practices

Once a physician is licensed in the state, it is still necessary that the physician establish a physician-patient relationship before rendering treatment or prescribing any medication.[57] While no state specifically prohibits telehealth being the means by which a physician-patient relationship can be established, there has been consistent confusion and disagreement among states regarding whether telehealth services are sufficient to establish this necessary physician-patient relationship, and many states have very specific criteria for how such relationship can be established.[58] Moreover, the American Medical Association ("AMA") advocates for the establishment of a physician-patient relationship before the rendering of telehealth services either through a face-to-face examination, if such would typically be required without telemedicine, or a consultation through another physician who has an ongoing physician-patient relationship.[59] The reason that establishing a physician-patient relationship via telemedicine can sometimes be called into question is multifaceted.[60] First, from a medical perspective, a face-to-face visit, in contrast with a visit utilizing technology (either by phone or other means of communication), allows for (1) verifying and authenticating the patient, (2) disclosing physician identity and credentials, and (3) obtaining necessary consents.[61] It is not that these verifications, disclosures, and consents cannot take place via telemedicine, but such communication might be more complex and less reliable.[62] Second, from the perspective of state regulators, requiring an in-person visit or creating strict controls around a telehealth visit allows the state to control competition and supply of services in the state by preventing (in large part) online-only practitioners, who are not located in the state and have no intention to relocate to the state, from providing services in the state, and by preventing online-

56. *A Faster Pathway to Physician Licensure*, *supra* note 48.

57. Faget, *supra* note 44, at 3.

58. *See id.* at 29–30.

59. Advoc. Res. Ctr., *50-State Survey: Establishment of a Patient-Physician Relationship via Telemedicine*, Am. Med. Ass'n 1 (2018), https://www.ama-assn.org/system/files/2018-10/ama-chart-telemedicine-patient-physician-relationship.pdf [https://perma.cc/2DFG-H9DL] [hereinafter *AMA Survey*].

60. *See Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine*, Fed'n St. Med. Bds. 3 (Apr. 2014), https://www.fsmb.org/siteassets/advocacy/policies/fsmb_telemedicine_policy.pdf [https://perma.cc/S5N8-AAWV] [hereinafter *FSMB*].

61. *Id.*

62. *How to Approach Telehealth Policy*, CCHP, https://www.cchpca.org/policy-101/ [https://perma.cc/6NW2-MQYQ] (follow the page down to "A deeper dive into telehealth policy," then select the tab "Informed Consent").

only pharmacies domiciled out of state or in foreign jurisdictions from competing with in-state pharmacies.[63] Although the foundation for putting limitations on the ability of telehealth services to form a physician-patient relationship makes sense for purposes of controlling services within the state and protecting against fraud at both the state and federal levels (and is likely effective at both goals),[64] it has also served as a hindrance toward allowing widespread use of telehealth services.[65] Requiring an in-person or face-to-face visit as part of establishing a physician-patient relationship (even if not the initial appointment) necessitates physicians use telehealth for primarily local patients, but the cost of investing in technology for patients who could otherwise come to the office can be prohibitive.[66] Thus, although states do not prohibit the use of telehealth to establish a physician-patient relationship, state laws and regulations continue to create limitations and restrictions on how telehealth could establish such a relationship for the purported benefit of controlling telehealth services in the state and protecting against its abuses.[67]

In the context of prescribing practices, historically many state regulations limited or prohibited practitioners from prescribing medicine to patients without a face-to-face encounter.[68] This was true even in jurisdictions that had specific regulations permitting telehealth services.[69] Thus, in some jurisdictions, even if a practitioner was duly licensed and rendering services to an individual living within the state, the practitioner might nevertheless be in violation of applicable regulations if the practitioner prescribed medication through telehealth services without conducting an in-person encounter.[70] In *Teladoc, Inc. v. Texas Medical Board*, a Texas court questioned the necessity for an in-person visit in the context of using telehealth services for prescribing.[71] The *Teladoc* court found a sufficient showing that a Texas administrative rule requiring all physicians to render a face-to-face visit or in-person evaluation before issuing a prescription violated the Sherman Act because it effectively prohibited telehealth services.[72] Similar requirements in other states have been correspondingly de-

63. *Intro to Telehealth Policy*, CCHP, https://www.cchpca.org/policy-101/ [https://perma.cc/5C65-RZXV] (follow the page down to "A deeper dive into telehealth policy," then choose the tab "FTC & Professional Licensure Boards").

64. *See id.*; *FSMB*, *supra* note 60.

65. *See* Matlin Gilman & Jeff Stensland, *Telehealth and Medicare: Payment Policy, Current Use, and Prospects for Growth*, 3 MEDICARE & MEDICAID RSCH. REV. E1, E3 (2013).

66. *See id.*

67. *See generally AMA Survey*, *supra* note 59.

68. *See* Teladoc, Inc. v. Tex. Med. Bd., 112 F. Supp. 3d 529, 534 (W.D. Tex. 2015).

69. *Id.*

70. *See* Sherer & Joseph, *supra* note 46, at 24.

71. *See generally Teladoc, Inc.*, 112 F. Supp. 3d at 534.

72. *Id.* at 540.

feated, and it is now settled in all fifty states that electronic means can establish the necessary relationship.[73]

Not all states have expanded their definitions of telehealth or telemedicine enough, however, to encompass all the various technologies that fall under the telehealth umbrella. Therefore, while states have softened their positions regarding physicians' prescribing as part of real-time online visits using video and audio technologies, some of the other telehealth technologies are not afforded the same allowances.[74] Many states have further limited the distribution chain by order type.[75] For example, certain states require that any type of prescription fulfilled from an online order, including prescriptions ordered in response to an online questionnaire, necessitate an in-person visit with the ordering prescriber or a previous physician-patient relationship.[76]

In addition to regulation at the state level, the federal government has also actively regulated telemedicine through the Drug Enforcement Agency ("DEA") and its authority regarding the prescribing of controlled substances.[77] As with telehealth generally, the advent of the Internet brought about the new business of online pharmacies, which have been hard to control and difficult to police since many pharmacies on the Internet are extraterritorial and difficult to trace.[78] States and the federal government have been challenged to try and control the pharmaceutical supply chain and prescribing practices of

73. *Compare* TENN. COMP. R. & REGS. 0880-02-.16(1)(f), (g) (2016) (including a definition of "store-and-forward technology" individually and also as an aspect of the definition of "telemedicine"), *with* ARK. CODE ANN. § 17-80-403 (West 2021) (limiting the "professional relationship" that can be established via telemedicine to not include "(1) an internet questionnaire, (2) [a]n email message, (3) [p]atient-generated medical history, (4) [a]udio-only communication . . . , (5) [t]ext messaging, (6) [a] facsimile machine, or (7) [a]ny combination [thereof]"). Consistent with the approach of Arkansas, the CMS defines telehealth as being real-time interaction where the patient is at an originating site and, like Arkansas, excludes communication via telephone, fax, or email. 42 C.F.R. § 410.78(b)(3), (f) (noting that these are some of the regulations that have been modified during the pendency of the Public Health Emergency).

74. *See* Sherer & Joseph, *supra* note 46, at 24–25.

75. *Id.*

76. *Id.*

77. *See id.* at 27. Prescribing practices have historically been governed by both the states and federal government; states largely govern non-controlled substances, and the federal government governs controlled substances. Note that in recent years, states have also begun enacting regulations that govern not only the prescribing of non-controlled substances (such as standard antibiotics) but also have taken an increased role in control over the prescribing of controlled substances. *See* Corey S. Davis et al., *Laws Limiting the Prescribing or Dispensing of Opioids for Acute Pain in the United States: A National Systematic Legal Review*, 194 DRUG & ALCOHOL DEPENDENCE 166, 166–67 (2019).

78. *See* Tim K. Mackey & Gaurvika Nayyar, *Digital Danger: A Review of the Global Public Health, Patient Safety and Cybersecurity Threats Posed by Illicit Online Pharmacies*, 118 BRIT. MED. BULL. 115, 123–24 (2016), https://doi.org/10.1093/bmb/ldw016 [https://perma.cc/XUY4-ZYMH].

controlled substances.[79] To guard against the increased risks of online pharmacies and virtual-only prescribing practices, Congress enacted the Ryan Haight Online Pharmacy Consumer Protection Act ("Ryan Haight Act").[80] The Ryan Haight Act requires any person dispensing controlled substances to do so only pursuant to a "valid prescription" obtained via an in-person evaluation.[81] There is an applicable exception for telemedicine, but the exception is narrow and provides few instances in which the standard in-person visit does not apply.[82] For example, the Ryan Haight Act establishes a special registration process for the provision of telemedicine services, which is intended to provide training and extend specific permission from the DEA to telemedicine providers when prescribing controlled substances.[83] The DEA, however, never promulgated any rules enabling this registration process to take place.[84] Thus, the intended mechanism has not been implemented. Other exceptions set forth under the law require that the telemedicine visits occur at particular facilities—such as a hospital or clinic—or with particular providers and in the physical presence of a practitioner or with an employee or contractor of the Department of Veterans Affairs or the Indian Health Services (or at such facility).[85] Importantly, there is a broad exception that applies to the extent that the Department of Health and Human Services ("HHS") has declared a public health emergency.[86] Although the Ryan Haight Act hinders only the *prescribing* of controlled substances via telehealth, the requirements and limitations constrict the prescriber's ability to prescribe substances as necessary to treat the patient and may further quell practitioners from utilizing telehealth at all, which possibly limits treatment options. Thus, even in situations in which telehealth service exceptions have been contemplated, the actual implementation of these exceptions and their applicability to common uses of telehealth are obstacles to the industry's growth.

The Center for Medicare and Medicaid Services ("CMS") has also enacted regulations aimed at accomplishing the same policy goals as requiring the establishment of a physician-patient relationship—that

79. *Id.* at 124–28.

80. Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Pub. L. No. 110-425, 122 Stat. 4820 (2008) (codified in 21 U.S.C.A. §§ 829(e)(2)(A)(i) (West 2018)); 42 U.S.C.A. § 1395m(m)(1) (West 2020); 42 C.F.R. § 410.78(a)(3) (2020)). The Act is named after Ryan Haight, an eighteen-year-old who was prescribed Vicodin online from a physician he had never met and later died due to an overdose. Marlene Maheu, *Telehealth Opioids and Ryan Haight Act: Update*, TELEHEALTH.ORG (May 21, 2021), https://telehealth.org/ryan-haight-act/ [https://perma.cc/YWM6-J5SS].

81. 21 U.S.C.A. §§ 829(e)(2)(A)(i) (West 2018); 42 U.S.C.A. § 1395m(m)(1) (West 2020).

82. 21 U.S.C.A. § 802(54)(A)–(G) (West 2018).

83. 21 U.S.C.A. § 831(h) (West 2018).

84. Sherer & Joseph, *supra* note 46, at 28.

85. 21 U.S.C.A. § 831(h) (West 2018).

86. 21 C.F.R. § 1300.04(d)(4) (2020).

is, verification of the provider's and patient's identity and confirmation of the necessity for medical services.[87] Under CMS's billing and collection requirements, federal telehealth rules under the Medicare program have traditionally been limited by the site of service for both the patient at the "originating site" and the provider at the "distant site."[88] CMS first established regulations in 1999 that required telehealth services be provided at an originating site—such as practitioner's offices, hospitals, critical access hospitals, rural health clinics ("RHCs"), or federally qualified health centers ("FQHCs")—that was located within a rural health professional shortage area.[89] Further, regulations required that the practitioner render the telehealth visit at a specific distant site.[90] Due to slow growth and reimbursement challenges (discussed in more detail below), certain restrictions were loosened over time.[91] The "originating site" rules that prohibit a patient from utilizing telehealth services from the patient's home remain intact today under the current regulations with limited exceptions for home dialysis, end-stage renal disease ("ESRD")-related clinical assessment, or treatment of a substance use disorder or co-occurring mental health disorder.[92] In almost all circumstances, telehealth services under the Medicare program have been limited to originating sites that are considered to be located in rural settings.[93] The most recent relaxation of these geographic limitations went into effect in 2019, permitting telehealth services at a geographically unrestricted originating site: if the telehealth services were for monthly home dialysis treatments; if for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke; or if for services and treatment to individuals diagnosed with substance use disorders.[94] Other than those limited exceptions, telehealth services are limited to certain areas, conducted from certain specific originating sites, and limited only to certain distant sites.[95]

87. *See generally* 42 C.F.R. § 410.78 (2020).

88. 42 C.F.R. § 410.78(b)(3) (2020).

89. *See* Gilman & Stensland, *supra* note 65, at E5.

90. *See id*.

91. *Id.* at E7 (summarizing initial regulations and subsequent changes).

92. 42 C.F.R. § 410.78(b)(4).

93. 42 C.F.R. § 410.78(b)(4)(i)–(iii) (specifying that an originating site must be "(i) [l]ocated in a health professional shortage area (as defined under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A)) that is either outside of a Metropolitan Statistical Area (MSA) as of December 31st of the preceding calendar year or within a rural census tract of an MSA . . . as of December 31st of the preceding calendar year, or (ii) [l]ocated in a county that is not included in a [MSA] . . . as of December 31st of the preceding year, or (iii) [a]n entity participating in a Federal telemedicine demonstration project that has been approved by, or receiving funding from, the Secretary as of December 31, 2000, regardless of its geographic location").

94. 42 C.F.R. § 410.78(b)(4)(iv).

95. 42 C.F.R. § 410.78(b)(2) (indicating that control at the distant site is not dictated by the location site, but by the qualifications of the practitioner). A practitioner

While a number of limitations on telehealth services remain, over time Medicare has expanded the types of telehealth and technologies that beneficiaries can use.[96] For example, Medicare has covered RPM since 2018 and permits RPM data transmission from a patient's home.[97] Further, since 2019, Medicare has covered "virtual check-ins,"[98] store-and-forward communication,[99] and consultations regardless of where there the patient is located.[100] Thus, there has been movement to expand coverage to technologies already in use that were not previously covered and to provide reimbursement in hopes to incentivize continuing such practices.

B. *Historical and Current Economic Barriers*

Independent of specific legal limitations such as licensing and prescribing practices, lack of reimbursement for telehealth services has likely been the biggest barrier to broader and more rapid expansion of telehealth.[101] In a study of healthcare executives, the majority of those surveyed planned to expand their telehealth services in some way, as they found real promise in the ability for telehealth to enhance patient experience and patients' lives.[102] However, they also expressed concern about the lagging reimbursement response that could hinder adoption.[103] These reimbursement challenges span both government and commercial payors and encompass not only payment but also cov-

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at a distant site must be one of the following: physician, physician assistant, nurse practitioner, clinical nurse specialist, nurse-midwife, clinical psychologist, clinical social worker, registered dietician or nutrition professional, or a certified registered nurse anesthetist. *Id.*

96. *See* Sherer & Joseph, *supra* note 46, at 32.

97. *Id.* at 32–33.

98. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019, 83 Fed. Reg. 59,452, 59,683–84 (Nov. 23, 2018) (allowing a practitioner to bill and collect for a "virtual check-in" when "a physician or non-physician practitioner has a brief (5 to 10 minutes), non-face-to-face check in with a patient via communication technology to assess whether the patient's condition necessitates an office visit").

99. *Id.* at 59,684 (allowing payment for a pre-recorded "store-and-forward" video or image in which a practitioner reviews the video or image and then follows up verbally with the patient within twenty-four business hours).

100. *See* Sherer & Joseph, *supra* note 46, at 33.

101. *KLAS-CHIME Study: Healthcare Industry Moving Ahead with Telehealth Despite Concerns*, CHIME (Oct. 10, 2017), https://chimecentral.org/klas-chime-study-healthcare-telehealth-concerns/ [https://perma.cc/6D95-PHDA] (noting that a study conducted in 2017 found that half of the respondents listed reimbursement as a limitation, despite all the benefits executives felt telehealth could hold for the industry).

102. *Id.*

103. *Id.* (finding that health care organizations were using virtual care already (or seeking expansion from their vendor) in three instances: "to increase patient access by allowing patients to schedule and conduct a clinical visit virtually[;] . . . to decrease the costs for patients and providers by dealing with urgent/nonemergency medical needs of patients on-demand[; and] . . . to improve the clinical outcomes of patients by increasing their access to needed specialists").

erage issues.[104] This section will explore pre-public health emergency reimbursement policies under Medicare, Medicaid, and commercial payors and the impact that such policies have had on widespread adoption of telehealth services.

1. Reimbursement Under Medicare

Medicare generally provides coverage and reimbursement for telehealth services that take place between a patient who lives in a rural community and a licensed practitioner and that utilize "audio and video equipment permitting two-way, real-time interactive communication."[105] Despite technological advancements and the level of sophistication that is possible when utilizing telehealth resources, the reimbursement rules under Medicare have made few substantive changes since coverage was first established in 1997.[106] Striking the right reimbursement balance has been a challenge over the years, leading policy makers to ask a number of questions: How much should payors reimburse the distant practitioner? How much, if any, should payors reimburse the originating site?[107] Should the amount be the same as for a standard, in-person visit? If not, how much more or less? Should the fee vary based on specialty? In considering these questions, Medicare's current regulations contemplate that the practitioner at the distant site who is providing the medical service receive the same amount as would have been paid if the visit had occurred in the office with a small facility fee paid to the originating site.[108]

In a 2013 report, the Medicare Payment Advisory Commission noted that of the limited telehealth services that occurred at the time of the report, approximately half the distant practitioners who submitted claims were mental health practitioners, and just one-third of the claims were from physicians for specialties other than mental

104. *See* Sherer & Joseph, *supra* note 46, at 30–36.

105. 42 C.F.R. § 410.78 (2020).

106. *Id.*; 42 U.S.C.A. § 1395m(m)(1) (West 2020). Telehealth services first appeared as part of the Medicare program pursuant to an amendment to the Social Security Act in 1997, but regulations were not promulgated and effective until 1999. *See* Gilman & Stensland, *supra* note 65, at E5.

107. Gilman & Stensland, *supra* note 65, at E5 (noting that in the beginning, the distant practitioner was paid 75% of the fee (based on the physician fee schedule), and the originating site was paid 25%; however, to encourage more use of telehealth services, this was amended in 2001 to instead require Medicare to pay 100% of the fee that would be owed in person to the distant practitioner, with the originating site receiving a facility fee payment).

108. *Medicare Claims Processing Manual: Chapter 12 - Physicians/Nonphysician Practitioners*, CTRS. FOR MEDICARE & MEDICAID SERVS. (May 3, 2021), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf [https://perma.cc/3SK8-UC8D]. This is effectively a facility fee for use of space and equipment.

health.[109] While the lack of medical and/or surgical specialties participating in telehealth services surprised the authors, they attributed telehealth's slow adoption to reimbursement:

> Yet these findings are consistent with the economic-model explanations for the low uptake of telehealth mentioned earlier: the theory that specialist physicians already have sufficient in-person patient populations and therefore consider telehealth, which involves added time for them, to be financially unattractive. In other words, specialist physicians' opportunity cost of providing telehealth services may be too high . . . .[110]

In addition to low reimbursement for the distant practitioners, the report further found that the billing by the distant practitioner and originating site were not proportionate; that is, a little less than half of claims submitted in 2009 by distant practitioners had a corresponding claim from the originating site.[111] The report speculated two primary reasons for this discrepancy; some of the claims were likely due to errant billing,[112] but others were likely the result of the distant site choosing not to bill due to the expense of claims processing relative to the amount actually reimbursed.[113]

The answer to which of these is likely the larger driver of the billing discrepancy may be identified based on findings from a 2018 Office of the Inspector General ("OIG") report.[114] The OIG reviewed 191,118 distant site claims that Medicare paid in 2014 and 2015 that did not have corresponding originating claims.[115] The OIG then audited a random sample of 100 claims and concluded that 31 claims did not meet Medicare billing requirements for telehealth services.[116] The bulk of the discrepancies related to errors regarding the eligibility of the site itself: Twenty-four of the claims were unallowable because the beneficiaries received services at a non-rural originating site, seven were billed by sites that were ineligible as an originating site, and three were billed by sites that were not authorized as originating

109. *See* Gilman & Stensland, *supra* note 65, at E8–E9 (noting that non-mental-health-related specialties included family practice and internal medicine specialists, nephrologists, and neurologists).

110. *Id.* at E9–E10.

111. *Id.* at E8.

112. While specific errors were not identified, it is presumed that this could be due to any number of errors on either the distant site or the originating site. For example, perhaps the distant site submitted a claim for the services rendered not realizing that the originating site at which the services were provided was not actually located within a qualifying rural community.

113. *Id.*

114. *See generally* GLORIA J. JARMON, OFF. OF INSPECTOR GEN., CMS PAID PRACTITIONERS FOR TELEHEALTH SERVICES THAT DID NOT MEET MEDICARE REQUIREMENTS, U.S. DEP'T OF HEALTH & HUM. SERVS. 1 (Apr. 2018).

115. *Id.* at 5.

116. *Id.*

sites.[117] Although the focus of the report was on the claims that were paid in error, perhaps just as significant is the finding that 69 of the 100 claims did not identify any type of billing error but nevertheless did not involve a claim by the originating site.[118] Thus, the originating site *could* have billed for the service but did not. By reading the report from the Medicare Advisory Payment Commission together with the OIG's 2018 report, it appears that the primary driver for lack of billing from the originating site is disincentive due to low reimbursement.[119]

For many years, Medicare Advantage Plans largely tracked traditional Medicare, and reimbursement for telehealth services under Medicare Advantage plans were not hugely distinct.[120] Beginning in 2020, however, Medicare Advantage Plan beneficiaries have the benefit of receiving additional telehealth benefits beyond those offered under traditional Medicare.[121] The benefits vary based on particular plans' offerings and are limited to certain value-based demonstrations.[122] Depending on how commercial payors embrace telehealth services, the limitations and restrictions that currently hamper more rapid growth under the Medicare program could cause a wider chasm between Medicare Advantage Plan beneficiaries and traditional Medicare beneficiaries.

117. *Id.* (noting that CMS reported the total number of errors exceeded thirty-one because some of the claims had more than one error). There were four additional errors other than the ones listed above, which included two claims for services provided using an unallowable means of communication, one claim for a noncovered service, and one claim for a physician located outside the U.S. *Id.* The report identified both a lack of sufficient oversight and a lack of sufficient education of the regulations as some of the reasons for the billing discrepancy. *Id.* at 6. In a cited example, one claim originated from Lynchburg, Virginia—a city with a population of 82,168 as of the July 1, 2019, census estimate. *Id.*; *QuickFacts: Lynchburg City, Virginia (County)*, U.S. CENSUS BUREAU, https://www.census.gov/quickfacts/lynchburgcityvirginiacounty [https://perma.cc/8MZG-ZXXR]. Lynchburg is within its own MSA (Lynchburg, Virginia, Metro Area) with an estimated population of 263,566 in 2019. *Metropolitan and Micropolitan Statistical Areas Population Totals and Components of Change: 2010-2019*, U.S. CENSUS BUREAU, https://www.census.gov/data/tables/time-series/demo/popest/2010s-total-metro-and-micro-statistical-areas.html [https://perma.cc/PJE5-JB7Q] (Follow the page down to "Tables: Annual Estimates of the Resident Population: April 1, 2010[,] to July 1, 2019," then select "Metropolitan Statistical Area; and for Puerto Rico."). The MSA is inclusive of Amherst, Appomattox, Bedford, and Campbell counties. *Lynchburg MSA, Virginia: Community Profile*, CNTY. AMHERST, https://www.countyofamherst.com/egov/documents/1213287955_268646.pdf [https://perma.cc/8FCD-X9JX].

118. JARMON, *supra* note 114, at 5.

119. *See generally id.*

120. Katie Horton, Mary-Beth Malcarney & Naomi Seiler, *Medicare Payment Rules and Telemedicine*, 129 PUB. HEALTH REPS. 196, 196 (2014).

121. *Telehealth*, MEDICARE.GOV, https://www.medicare.gov/coverage/telehealth [https://perma.cc/QB4N-85WY]; 42 C.F.R. § 422.135 (2019).

122. *See, e.g.*, 42 C.F.R. § 510.605 (2017).

2. Reimbursement Under Medicaid

Unlike Medicare, the federal government has not created similar restrictions for Medicaid reimbursement when it comes to telehealth.[123] Rather, consistent with many Medicaid programs, telehealth coverage and reimbursement is largely left to the states for establishment of their own telehealth rules.[124] Recognizing the value of utilizing telehealth to bridge transportation and access challenges, many states had already implemented some sort of telehealth program, but the scope of what was covered and reimbursed varied widely.[125] Like originating site restrictions under the Medicare program, less than half of states across the country allow a Medicaid beneficiary's home to serve as an originating site.[126] Complicating the reimbursement picture under Medicaid is how to address conflicting originating or distant site rules between the state in which the patient is located and the state in which the practitioner is providing services.[127] Moreover, Medicaid managed care further obfuscates the variability between states, as some states may defer to their contracted, managed care organizations for telehealth reimbursement policies and coverage decisions.[128] Thus, a distant site might have coverage for a wide variety of services provided in multiple locations (including across state lines), but there may be no corresponding coverage for the originating site in another state.

Like Medicare, while live video telehealth services are reimbursed in all fifty states, state laws vary greatly as to reimbursement for other telehealth technologies.[129] Only sixteen states have Medicaid programs that reimburse for store-and-forward telehealth services, and only twenty-three states have Medicaid programs that reimburse for

123. Madeline Guth & Elizabeth Hinton, *State Efforts to Expand Medicaid Coverage & Access to Telehealth in Response to COVID-19*, KAISER FAM. FOUND. (June 22, 2020), https://www.kff.org/coronavirus-covid-19/issue-brief/state-efforts-to-expand-medicaid-coverage-access-to-telehealth-in-response-to-covid-19/ [https://perma.cc/N33G-VH73] (citing *Telemedicine*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/benefits/telemedicine/index.html [https://perma.cc/7X63-C4TT]).

124. *Id.*

125. *Id.* ("All states had some form of Medicaid coverage for services delivered via telehealth, but reimbursement and regulation policies varied widely. As of February 2020, Medicaid programs in all fifty states and Washington, DC reimbursed some type of live video telehealth service delivery in FFS Medicaid programs; however, the scope of this coverage was inconsistent across states and many included restrictions on the type of services, providers, and originating sites.").

126. *Id.*

127. *See* Sherer & Joseph, *supra* note 46, at 34.

128. *See, e.g.*, *Tennessee: Current State Laws & Policy*, CTR. FOR CONNECTED HEALTH POL'Y, https://www.cchpca.org/telehealth-policy/current-state-laws-and-reimbursement-policies/tennessee-medicaid-summary [https://perma.cc/35F8-6AJB].

129. *State Telehealth Laws & Reimbursement Policies*, CTR. FOR CONNECTED HEALTH POL'Y 15 (2020), https://www.cchpca.org/sites/default/files/2020-05/CCHP_%2050_STATE_REPORT_SPRING_2020_FINAL.pdf [https://perma.cc/TA84-RFDQ] [hereinafter *Reimbursement Report*].

RPM.[130] In short, the advantage that telehealth services might be able to provide by allowing for remote care provided across jurisdictions is hindered by the inconsistent and sometimes conflicting approaches among state Medicaid programs.

3. Reimbursement Under Commercial Insurance

Just as government payors have slowly expanded reimbursement for telehealth, so too have private payors—some due to requirements under state law and some for their own business reasons.[131] Over the last few years, many states have enacted telehealth "parity" laws, which generally require private payors to offer coverage for telehealth services in parity with in-person services (coverage parity) and/or payment for telehealth services in parity with in-person services (payment parity).[132] As of the spring of 2020, forty-two states and Washington, D.C., have a law that requires some form of coverage parity for telehealth services, but only a handful of states have a meaningful payor parity law that would require reimbursement by private payors for telehealth services, at least at the same level as in-person services.[133] Thus, while states have made great strides in recent years in at least increasing coverage for telehealth services from private insurers, only a few states have actually provided the necessary reimbursement parity to spur growth.[134] Further, even in states with coverage parity, many state statutes or regulations retain some of the same legal barriers referenced above; that is, restrictions on the type of reimbursable telehealth technology or requirements surrounding the estab-

130. *Id.* (acknowledging that some states have laws that require reimbursement for store-and-forward technology or RPM but do not have official written policies implementing such reimbursement).

131. *See* Weigel et al., *supra* note 4.

132. *See* Sherer & Joseph, *supra* note 46, at 35.

133. *Reimbursement Report*, *supra* note 129, at 11, 15–16 (reporting that Alabama, Alaska, Idaho, North Carolina, Pennsylvania, South Carolina, West Virginia, Wisconsin, and Wyoming do not have laws providing for coverage parity in telehealth, but only Delaware, Georgia, Hawaii, Minnesota, and New Mexico have payment parity laws); *see also* Jared Augenstein et al., *Executive Summary: Tracking Telehealth Changes State-by-State in Response to COVID-19*, MANATT (July 22, 2020), https://www.manatt.com/insights/newsletters/covid-19-update/executive-summary-tracking-telehealth-changes-stat [https://perma.cc/GS9A-QY8S]. It should be noted that according to the Manatt reports, prior to COVID–19, nine states had laws with existing telehealth payment parity provisions, which were listed as Arkansas, Delaware, Georgia, Hawaii, Kentucky, Minnesota, Missouri, New Mexico, and Utah. *Id.* Based on a review of those state laws, the list from Manatt appears most accurate, but it should be noted that Utah did not have a payment parity statute before the COVID–19 pandemic. The Utah legislature did enact a law during the pandemic that would require coverage parity for telehealth services and payment for telehealth services to be "commercially reasonable." UTAH CODE ANN. § 31A-22-649.5(2)(b) (West 2021).

134. *See Reimbursement Report*, *supra* note 129, at 13–14.

lished relationship between the patient and practitioner.[135] All of these make implementation of robust telehealth services disparate and inconsistent for private payors among the various states.

With all this taken together, it is not necessarily surprising that while the concept of telehealth has been around since the 1960s and efforts to potentially develop more widespread use of telehealth services began in the late 1990s, the actual use and implementation of telehealth services across the country and for all types of payors have been slow and fragmented. Despite telehealth's potential benefits, including increased access, increased efficiencies, lower costs, more consistent monitoring (utilizing real-time data), and reduction of exposure to infectious disease, the fear of the potential for fraud and abuse of online services and the effects of protectionary tactics to reduce competition for services seems to have been considered a greater concern over the last twenty years. Now that telehealth has become more of a necessity than a convenience because of the coronavirus pandemic, some previous restrictions and limitations will be tested to determine their need or effectiveness.

III. Public Health Emergency Waivers for Telehealth Services

On January 31, 2020, Alex Azar, Secretary of Health and Human Services, declared a public health emergency as a result of confirmed cases of the "2019 Novel Coronavirus (2019-nCoV)," now known as COVID–19.[136] This declaration, subsequently renewed multiple times,[137] set off a chain of events around the country in connection with healthcare delivery, including widespread and broad waivers of telehealth restrictions and limitations then in place.[138] Federal and state agencies as well as private payors involved in implementation and regulation of telehealth services effectuated the changes necessary to keep patients and practitioners safe and to comply with government orders for individuals to stay at home, which required a multi-layered approach. Not all changes have been complete waivers of existing laws; rather, some have created narrower or more targeted exceptions to existing laws. This part explains the waivers and other legislative and regulatory changes that were enacted because of the declaration of the public health emergency and analyzes how such

135. *See* Carl Benjamin Lewis, Note, *Private Payer Parity in Telemedicine Reimbursement: How State-Mandated Coverage Can Be the Catalyst for Telemedicine Expansion*, 46 U. Mem. L. Rev. 471, 484–485 (2015).

136. *Determination That a Public Health Emergency Exists*, PHE.gov, https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx (Jan. 31, 2020) [https://perma.cc/42M5-ZY6B].

137. *Renewal of Determination That a Public Health Emergency Exists*, PHE.gov, https://www.phe.gov/emergency/news/healthactions/phe/Pages/COVID-15April2021.aspx (Apr. 16, 2021) [https://perma.cc/7PLH-PA3C].

138. *OCR Notification*, *supra* note 35.

waivers and changes have impacted the utilization of telehealth services and its role in the healthcare delivery system.

A. *Federal Changes to Telehealth Policy*

At the federal level, there are various agencies that touch and regulate telehealth, and thus no single agency could issue a waiver or enact an exception that would create the desired effect for all telehealth services. The affected agencies include the Office for Civil Rights (in connection with the enforcement of HIPAA and other privacy-related concerns),[139] the DEA (in connection with the enforcement of prescribing controlled substances utilizing telehealth),[140] CMS (in connection with administration of Medicare and Medicaid and oversight of Medicare Advantage),[141] and even the Department of the Treasury (in connection with the distribution of funding under the Corona Aid, Relief, the Economic Security Act of 2020 ("CARES Act")), and the American Rescue Plan of 2021.[142] Likewise, states and their agencies add another layer of regulation and enforcement for telehealth services through state Medicaid programs and state insurance laws governing third-party payors operating within each state. Each of these federal and state agencies represents a different limitation on or regulation of telehealth services and thus a different concern regarding the purpose behind existing laws or regulations surrounding telehealth services. To understand the existing telehealth framework, it is critical to examine the action steps that all agencies—state and federal—took in response to the COVID–19 public health emergency.

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139. Press Release, U.S. Dep't Health & Hum. Servs., OCR Announces Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency, https://www.hhs.gov/about/news/2020/03/17/ocr-announces-notification-of-enforcement-discretion-for-telehealth-remote-communications-during-the-covid-19.html (Mar. 26, 2020) [https://perma.cc/54TF-PFZ6] [hereinafter OCR Press Release]; *OCR Issues Guidance on Telehealth Remote Communications Following Its Notification of Enforcement Discretion*, U.S. DEP'T HEALTH & HUM. SERVS., https://www.hhs.gov/about/news/2020/03/20/ocr-issues-guidance-on-telehealth-remote-communications-following-its-notification-of-enforcement-discretion.html (Mar. 20, 2020) [https://perma.cc/2YMF-VS5G].

140. *COVID-19 Information Page*, DIVERSION CONTROL DIV., https://www.deadiversion.usdoj.gov/coronavirus.html [https://perma.cc/4QYQ-JEGB] ("On March 16, 2020, the Secretary, with the concurrence of the Acting DEA Administrator, designated that the telemedicine allowance under section 802(54)(D) applies to all schedule II-V controlled substances in all areas of the United States.").

141. *COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers*, Ctrs. for Medicare & Medicaid Servs., https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf (May 24, 2021) [https://perma.cc/VN5G-8TZG].

142. *See generally* CARES Act, Pub. L. 116-136, 134 Stat. 281 (2020); American Rescue Plan Act of 2021, H.R. 1319, 117th Cong. (2021).

1. Office for Civil Rights

The Office for Civil Rights is responsible for the protection and security of personal health information and enforcement of violations of HIPAA, the Health Information Technology for Economic and Clinical Health ("HITECH") Act,[143] and their respective enacting regulations.[144] Thus, under its telehealth auspices are restrictions and limitations on which technology platforms or applications can be used that will ensure compliance with existing security regulations.[145] Before COVID–19, platforms like FaceTime or Zoom were not approved applications for telehealth live video consultations because they did not contain the necessary encryption capability or privacy protections that complied with existing privacy laws.[146] To facilitate increased use of telehealth as COVID–19 began spreading across the United States, HHS permitted the use of "everyday communications technologies"—even if the service itself was for medical concerns unrelated to COVID–19.[147] This action did not eliminate, without additional waivers, any state law privacy restrictions that were in effect.[148]

While necessary to facilitate greater use of telehealth during the pandemic, there are some risks associated with broad waivers that have paved the way for more expansive use of more common technologies. For example, one recent study by Sermo, a "doctors-only social networking platform," found that Zoom was the most commonly used technology for telehealth visits.[149] Further, technology communication tools embedded within electronic health records ("EHRs"), which are most likely HIPAA compliant, constituted only 16% of those telehealth technologies currently in use.[150] Although the convenience and ease of using Zoom is obvious, the potential downsides of using a

143. *Summary of the HIPAA Security Rule*, U.S. DEP'T HEALTH & HUM. SERVS., https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html (July 26, 2013) [https://perma.cc/7LS8-YS9M]; *see also HIPAA Enforcement*, U.S. DEP'T HEALTH & HUM. SERVS., https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/index.html [https://perma.cc/79Zh-UHWG].

144. *About Us*, U.S. DEP'T HEALTH & HUM. SERVS., https://www.hhs.gov/ocr/about-us/index.html (Oct. 8, 2019) [https://perma.cc/27QU-DWFS].

145. *Delivering Care Safely*, *supra* note 10.

146. *OCR Notification*, *supra* note 35.

147. OCR Press Release, *supra* note 139; *see also OCR Notification*, *supra* note 35 (noting that although most video chat applications, such as Apple FaceTime, Facebook Messenger, Google Hangouts, Zoom, and Skype, were specifically permitted, HHS did exempt from use Facebook Live, Twitch, and TikTok, which are considered public facing).

148. *See* Weigel et al., *supra* note 4.

149. Deborah Borfitz, *Zoom and Skype Rule Telemedicine World of Physicians*, DIAGNOSTICS WORLD (June 30, 2020), https://www.diagnosticsworldnews.com/news/2020/06/30/zoom-and-skype-rule-telemedicine-world-of-physicians [https://perma.cc/9WUZ-76DP] (citing Sermo HCP Sentiment Studies, which surveyed adoption by physicians between April and May 2020, and noting that 34% of providers used Zoom, 22% used Skype, and 16% used an existing EHR platform).

150. *Id.*

less secure source was laid bare as the company has been plagued during the pandemic by privacy and security concerns ranging from compromised passwords and email sharing to Zoom "bombs."[151] Nevertheless, telehealth visits and utilization has soared with the expansion to more commonly utilized programs; the Sermo survey found that 90% of physician respondents worldwide were treating patients remotely and that 48% of those physicians were first-time telehealth users.[152] The simplicity and ease of existing applications along with the minimal financial investment that is required from providers to utilize these programs make their popularity clear. What is not as clear is whether these more mainstream technology companies or even EHR vendors will be able to create a product or tool that provides the necessary encryption and security without overcomplicating the product's use and still maintaining cost effectiveness.

2. Centers for Medicare and Medicaid Services ("CMS")—Medicare

In addition to loosening privacy restrictions, HHS, through CMS, has waived many of the limitations set forth in the Medicare program for the delivery of telehealth services, including waivers to allow (1) patients to participate in visits located in their homes or outside a rural area, (2) providers to practice remote care across state lines, (3) providers to deliver services to established patients or new patients,[153] and (4) providers to bill and collect for telehealth services in the same manner as if they were provided in person.[154] Moreover, CMS has adjusted reimbursement rules to change certain coverage restrictions.[155] Such adjustments include coverage for audio-only interaction (not requiring video) for particular services such as virtual check-in services and other evaluations, along with behavioral health services

151. *See* Allen St. John, *At Zoom, New Privacy and Security Problems Keep Emerging*, CONSUMER REPS., https://www.consumerreports.org/privacy/at-zoom-new-privacy-and-security-problems-keep-emerging/ (Apr. 2, 2020) [https://perma.cc/5G24-MTNR]. Zoom "bombs" were incidents that occurred during Zoom meetings in which uninvited attendees would "bomb" the meeting and disrupt whatever was taking place. *Id.* That this could occur and that unauthorized individuals could join the meeting caused many to question the privacy and confidentiality of virtual meetings using the platform. *Id.*

152. Borfitz, *supra* note 149.

153. *Delivering Care Safely*, *supra* note 10. Previous restrictions required that the provider have treated the Medicare beneficiary within the previous three years. Wyatt Koma, Juliette Cubanski & Tricia Neuman, *Medicare and Telehealth: Coverage and Use During the COVID-19 Pandemic and Options for the Future*, KAISER FAM. FOUND. (May 19, 2021), https://www.kff.org/medicare/issue-brief/medicare-and-telehealth-coverage-and-use-during-the-covid-19-pandemic-and-options-for-the-future/ [https://perma.cc/68XY-HP4D].

154. *Delivering Care Safely*, *supra* note 10.

155. Wyatt Koma et al., *supra* note 153.

and patient education services.[156] CMS also waived the requirement that a provider be licensed in the state in which the telehealth services are delivered, although such waiver is one of reimbursement and coverage only and does not waive or supersede state licensure laws.[157] While Medicare Advantage Plans were already permitted to offer greater telehealth benefits than traditional Medicare,[158] CMS further stated under the issuance of the public health emergency that Medicare Advantage beneficiaries do not have to pay cost sharing amounts for COVID–19 testing and that plans may offer more telehealth services than those services already approved in the 2020 benefit plans.[159]

Like the observations made regarding the use of common technologies, the loosening of these restrictions has, not surprisingly, spurred huge growth among Medicare beneficiaries for telehealth services.[160] According to CMS, the weekly use of telemedicine services in one week jumped from 13,000 beneficiaries before the pandemic to 1.7 million beneficiaries during the pandemic.[161] When tracking total usage from mid-March through mid-June, over nine million beneficiaries had received some telehealth service, including audio-video visits as well as audio-only visits and virtual check-ins.[162] Interestingly, easing the rural restrictions prompted much of the growth, as 30% of beneficiaries living in urban areas utilized telehealth services compared to 22% of beneficiaries living in rural areas.[163] While use did seem to vary based on the particular geographic location within the country,[164] telehealth utilization spanned various demographics, including males and females, beneficiaries under and over the age of sixty-five, and

156. *Additional Background: Sweeping Regulatory Changes to Help U.S. Healthcare System Address COVID-19 Patient Surge*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Mar. 30, 2020), https://www.cms.gov/newsroom/fact-sheets/additional-background-sweeping-regulatory-changes-help-us-healthcare-system-address-covid-19-patient [https://perma.cc/MWS5-J9UB].

157. *See* Weigel et al., *supra* note 4.

158. Medicare and Medicaid Programs; Policy and Technical Changes, 84 Fed. Reg. 15,680, 15,680–15,681 (Apr. 16, 2019) (summarizing the expansion of telehealth services available to Medicare Advantage Plans).

159. *Id.* at 15,683.

160. Seema Verma, *Early Impact of CMS Expansion of Medicare Telehealth During COVID-19*, HEALTH AFFS. (July 15, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200715.454789/full/ [https://perma.cc/P5UW-MNKV].

161. *Id.* (citing to the weekly numbers for the last week of April 2020).

162. *Id.*

163. *Id.* Some of this discrepancy might be related to access to technology necessary to utilize telehealth services, including an internet connection, a smart phone, or a computer. *See* Sara Heath, *75% of Patients Still Not Using Telehealth Due to Access Barriers*, PATIENT ENGAGEMENT HIT (Aug. 1, 2019), https://patientengagementhit.com/news/75-of-patients-still-not-using-telehealth-due-to-access-barriers [https://perma.cc/F8AP-W9X5].

164. *See* Verma, *supra* note 160. Telehealth use was more common in the Northeast than in the Midwest, which might be due to the volume of telehealth services offered or whether patients sought out telehealth services. *Id.* Certainly, during the early months of the pandemic, COVID–19 was much more prevalent and rampant in the Northeast than in the Midwest. *Id.*

racial and ethnic groups.[165] There was a greater utilization of telehealth services by dual-eligible beneficiaries (those who qualify for both Medicare and Medicaid programs) than Medicare-only beneficiaries,[166] which could be due at least in part to previous experience with telehealth in a Medicaid program with more expansive telehealth coverage. Just as in previous years, mental health services remain some of the most frequently utilized services for telehealth, but during the pandemic, the most common use for telehealth was a standard office visit, referred to as an evaluation and management ("E/M") visit, with 5.8 million beneficiaries receiving such a visit during the public health emergency.[167] Additionally, the waiver allowing for audio-only services—usually through the telephone—was accessed by over three million beneficiaries.[168] While these numbers make clear that the waivers enacted to loosen telehealth restrictions for the Medicare population were effective at increasing use and allowing necessary services to be received remotely, it is likely necessary to gather more data about the reasons for seeking treatment and ease of use to determine how to continue to promote and support telehealth services in the future.

3. Drug Enforcement Agency ("DEA")

To treat patients who utilize telehealth services appropriately, the DEA also implemented certain waivers to adjust prescribing practices during the public health emergency. The COVID–19 public health emergency declared in January 2020 triggered an exception for the prescribing of controlled substances via telemedicine under the Ryan Haight Act.[169] As a result, effective March 16, 2020, DEA-registered providers are permitted to prescribe controlled substances (Schedule II-V) without an in-person visit subject to the meeting of certain conditions.[170] It should be noted that there are also specific limitations on the prescribing of buprenorphine for maintenance or detoxification

165. *Id.* (reporting that females utilized services at a slightly higher percentage than men (30% compared to 25%, respectively), that a slightly higher percentage of beneficiaries under the age of sixty-five utilized telehealth services compared to older beneficiaries, and that among racial and ethnic groups, telehealth utilization was statistically similar).

166. *Id.*

167. *Id.*

168. *Id.*

169. *See* Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Pub. L. No. 110-425, 122 Stat. 4820 (2008).

170. To issue a prescription via the Internet (including telemedicine), the prescriber must meet the following conditions: (a) "[t]he prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice;" (b) "[t]he telemedicine communication is conducted using an audio-visual, real-time, and two-way interactive communication system;" and (c) "[t]he practitioner is acting in accordance with applicable Federal and State laws." *COVID-19 Information Page*, *supra* note 140.

treatment of an opioid use disorder and an outright prohibition of the prescribing of methadone.[171] As with other federal waivers, the waivers do not supersede or negate any state laws or regulations.[172]

Anecdotally, the ability to prescribe following a telemedicine visit may have had less of an effect on prescribing practices during the pandemic than the ability to order a ninety-day supply of medication.[173] In reviewing statistics regarding the filling of prescriptions during the pandemic, researchers found that the filling of prescriptions has largely decreased overall and that the filling of the most commonly prescribed medications continues to remain below pre-pandemic levels—with a few exceptions.[174] For some individuals, the increased ninety-day supply reduced the need to fill orders as frequently, but observers are also concerned that the pandemic is causing individuals not to prioritize medications in the same way as they did before the pandemic.[175] Some critics have stated that the waivers, while laudable, do not actually go far enough to truly increase the ability for prescribing via telehealth systems, including for palliative care patients,[176] or have not really eased any burdens when it comes to medication changes or the distribution of samples.[177] Thus, it is difficult to assess based on current data whether the relaxation of the prescribing limita-

171. *FAQs: Provision of Methadone and Buprenorphine for the Treatment of Opioid Use Disorder in the COVID-19 Emergency*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf (Apr. 21, 2020) [https://perma.cc/63UE-Q74Y] (specifying different treatment for buprenorphine and methadone).

172. *COVID-19 Information Page*, *supra* note 140. As stated in Part II, while controlled substances are typically under the jurisdiction of the DEA and non-controlled substances are regulated at the state level, some states have in recent years enacted laws further restricting the prescribing of controlled substances, primarily for opioid prescriptions. *See infra* Part III.B.

173. Regina Schaffer, *Filling Prescriptions Becomes Easier for Some, Harder for Others During COVID-19*, HEALIO (May 22, 2020), https://www.healio.com/news/endocrinology/20200522/filling-prescriptions-becomes-easier-for-some-harder-for-others-during-covid19 [https://perma.cc/ LX4Q-RMZH].

174. Tori Marsh, *Live Updates: How Is COVID-19 Affecting Prescription Fills?*, GOODRX (June 16, 2020, 3:10 PM), https://www.goodrx.com/blog/medication-fills-rise-during-coronavirus-covid-19-pandemic/ [https://perma.cc/T84M-FVB4] (noting spikes in drugs for asthma and type 2 diabetes in mid-March with the remainder more common prescriptions dipping below previous fill levels).

175. *Id.*

176. Patrice Villars, Eric Widera & Chad D. Kollas, *To Protect Palliative Care Patients During the COVID-19 Pandemic, Allow More Flexibility to Prescribe Controlled Substances by Phone*, HEALTH AFFS. (Apr. 26, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200422.989316/full/ [https://perma.cc/JDQ7-NMYJ] (finding that too few patients who are receiving palliative care have access to video capability or an Internet connection to utilize the exceptions).

177. *See* Schaffer, *supra* note 173 (" 'The issue has been that, sometimes, when we initiate a new therapy, we give people some samples,' [Satish K. Garg, M.D., professor of medicine and pediatrics at the Barbara Davis Center for Diabetes, University of Colorado Denver,] told *Endocrine Today*. 'For example, if I start someone on semaglutide . . . , I don't know if they are going to tolerate the drug, so I will give them the medication to try . . . . So now, we conduct the telehealth visit, and we ask

tions under the Ryan Haight Act is driving increased prescribing as a result of a telehealth visit or service.

4. Centers for Medicare and Medicaid Services ("CMS")—Medicaid

While HHS's public health emergency declaration did not necessarily require states to take any action or issue any waivers of state law provisions, many states also waived certain telehealth restrictions under their Medicaid programs or for commercial insurance companies operating in-state. The Kaiser Family Foundation summarized ways in which states have expanded telehealth in their Medicaid programs into four general categories: (1) population expansion, by increasing the number of Medicaid beneficiaries who can utilize telehealth services; (2) service and payment rate expansion, by adding additional coverage for services rendered via telehealth that are reimbursable and adjusting the payment or lowering the cost sharing obligations; (3) technology expansion, by increasing the types of technology that can be used for telehealth services and the originating and distant sites at which such services can be rendered; and (4) provider expansion, by adding to the types of providers who are eligible to deliver telehealth services.[178] Thus, many of the changes imposed at the state level for Medicaid programs mirror changes implemented at the federal level to the Medicare program.[179] Unlike Medicare, however, states have a great deal of discretion with their individual Medicaid programs and thus have an increased the ability to implement none, some, any, or all of these types of changes.[180]

As "telehealth" is not even defined in the federal Medicaid statute,[181] states operating traditional Medicaid programs have broad discretion regarding telehealth services generally, including applicable

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our patients to come to our parking lot where we can give them the necessary [medicinal samples]. That is a little bit of a hurdle.'").

178. *See* Guth & Hinton, *supra* note 123.

179. Amwell, *COVID-19 and Telehealth Regulations in the States*, AMWELL BLOG (Apr. 01, 2020), https://business.amwell.com/covid-19-and-telehealth-regulations-in-the-states/ [https://perma.cc/U4YH-B7U5].

180. In fact, many of the states operate their Medicaid programs off a 1115 waiver and thus have even greater discretion with their operation. Elizabeth Hinton et al., *10 Things to Know About Medicaid Managed Care*, KAISER FAM. FOUND. (Oct. 29, 2020), https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-medicaid-managed-care/ [https://perma.cc/5E8H-J4J7]. In Tennessee, for example, the Medicaid program, known as TennCare, is almost exclusively operated under contract between the state and various managed care companies. *See TennCare Overview*, TENN. DIV. TENNCARE, https://www.tn.gov/tenncare/information-statistics/tenncare-overview.html [https://perma.cc/ERF4-4KTN] [hereinafter *TennCare Overview*]. Thus, any rules or regulations that could be imposed at the federal level may be inapplicable to the extent that the regulations apply to a traditional Medicaid population.

181. Federal Medicaid regulations contain certain mandatory coverage categories and then certain optional coverage categories that states can choose to cover or not cover. *See* Kaiser Comm'n on Medicaid & Uninsured, *Medicaid: A Primer*, KAISER

coverage, limitations, and payment.[182] Moreover, many states operate their Medicaid programs under a waiver from the federal government that permits states to implement a managed care delivery system by contracting with third-party managed care companies to administer benefits for all or a portion of the state's Medicaid beneficiaries.[183] For example, under a Section 1115 waiver, the State of Tennessee operates its Medicaid program, known as TennCare, as an "integrated, full-risk, managed care program" that covers the entire state's Medicaid population.[184] Thus, decisions regarding coverage and reimbursement for telehealth services are largely in the control of managed care companies, subject to any state laws to which such companies are subject.

Due to the variability in the state approaches to telehealth before the coronavirus pandemic, there has not necessarily been broad uniformity in state Medicaid waivers for telehealth. There have, however, been some consistent changes across the states. First, to expand the population that can receive telehealth services during the public health emergency, all the states and the District of Columbia used Section 1135 waivers to permit providers who have equivalent licensure status to provide services across state lines to Medicaid beneficiaries.[185] Some states have authorized additional payments for telehealth, some have included ancillary telehealth delivery costs, and the majority have implemented amendments to enable virtual eligibility assessments for home and community-based services and allow electronic service delivery.[186] To expand the coverage of telehealth services that are offered, nearly all states have issued guidance to expand coverage, including one or more of the following: waiving requirements for an established provider-patient relationship; establishing payment parity for *some* services and waiving or lowering applicable co-payment obligations; permitting FQHCs and RHCs—institutional providers that already treat a disproportionate number of Medicaid patients—to provide telehealth services as the distant site; allowing a patient's home to serve as an originating site for telehealth services; and expanding the types of technologies or modalities that patients and providers can utilize for rendering telehealth services.[187] A number of states have also taken more specific action regarding particular types of medical care to broaden telehealth access, includ-

FAM. FOUND. 5–6 (Mar. 2013), https://www.kff.org/wp-content/uploads/2010/06/7334-05.pdf [https://perma.cc/8EHN-NVTA].

182. *See* Guth & Hinton, *supra* note 123.

183. *See Managed Care Authorities*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/managed-care/managed-care-authorities/index.html [https://perma.cc/RS6U-WZGJ].

184. *See TennCare Overview*, *supra* note 180.

185. *See* Guth & Hinton, *supra* note 123.

186. *Id.*

187. *Id.*

ing behavioral health services, pediatric services, reproductive and maternal health services, COVID–19-specific services, dental services, speech therapy, physical therapy, and occupational therapy services.[188]

These changes, while laudable, will nevertheless be difficult to implement in a way that will spur widespread telehealth use due to continued infrastructure challenges in the Medicaid population. According to data from 2017, about one-quarter of Medicaid eligible adults reported that they never use a computer, and about the same percentage reported that they never use the Internet.[189] Further, according to the Federal Communications Commission, adults in rural areas, who are also more likely to have Medicaid coverage, lack sufficient access to broadband, making many telehealth services that require an Internet connection largely inaccessible during the public health emergency.[190] Although perhaps it is still a bit early to analyze fully and assess comprehensive reports regarding failures and successes or even increased use of telehealth services in Medicaid populations under the relaxed restrictions, the growth in use and adoption of telehealth services in the Medicaid population is likely to lag slightly from the Medicare population or commercial insurers due to the high proportion of Medicaid beneficiaries who live in rural areas (about 24% of all non-elderly adults living in rural areas).[191] Even though rural areas have long been the focus of telehealth efforts as a means to improve access—especially in recent years, as there has been an increase in rural hospital closures and Medicaid beneficiary coverage—reliable Internet access has remained a vexing problem that cannot likely be solved in the immediate future given the ongoing challenges with massive layoffs and an economic downturn.[192] There does appear to be anecdotal evidence that telehealth services in the Medicaid pop-

188. *Id.* For a current map and current status of all actions that states have taken in response to their emergency authority under the COVID–19 public health emergency, see *Medicaid Emergency Authority Tracker: Approved State Actions to Address COVID-19*, KAISER FAM. FOUND. (July 1, 2021), https://www.kff.org/coronavirus-covid-19/issue-brief/medicaid-emergency-authority-tracker-approved-state-actions-to-address-covid-19/ [https://perma.cc/AW3L-LVZW].

189. Rachel Garfield et al., *Understanding the Intersection of Medicaid and Work: What Does the Data Say?*, KAISER FAM. FOUND. (Aug. 2019), https://files.kff.org/attachment/Issue-Brief-Understanding-the-Intersection-of-Medicaid-and-Work-What-Does-the-Data-Say [https://perma.cc/J3S4-28M2].

190. *See* Guth & Hinton, *supra* note 123.

191. *See* Julia Foutz, Samantha Argita & Rachel Garfield, *The Role of Medicaid in Rural America*, KAISER FAM. FOUND. (Apr. 25, 2017), https://www.kff.org/medicaid/issue-brief/the-role-of-medicaid-in-rural-america/ [https://perma.cc/HUD7-YCPT].

192. Matthew Ralls & Lauren Moran, *Telehealth in Rural America: Disruptive Innovation for the Long Term?*, CTR. FOR HEALTH CARE STRATEGIES (June 19, 2020), https://www.chcs.org/news/telehealth-in-rural-america-disruptive-innovation-for-the-long-term/ [https://perma.cc/GPD4-NG9T].

ulation have increased with the waivers, at least in rural areas,[193] but the increased coverage and access provisions under state Medicaid programs will likely only be effective to the extent that reimbursement and payment support their use by providers.[194]

B. *State Changes to Telehealth Policy*

The various federal waivers enacted to enable increased use of telehealth services during the public health emergency did not supersede or override existing state laws and regulations. Therefore, even with all the waivers in place, states also needed to make amendments or changes to their laws to ease the use of telehealth services. Just like waivers under the Medicaid and Medicare programs, nearly all states have moved to temporarily waive licensure obligations, permitting providers with equivalent licenses in other states to practice telemedicine services.[195] To facilitate more visits and enable online prescribing, many states waived the requirement that patients have an in-person visit with the provider before filling an online prescription although some states retained more protections for the prescribing of opioids.[196] Finally, a majority of states have laws or regulations that require providers to document that the patient has provided informed consent regarding the rendering of a telehealth visit, including some states that require such consent to be in writing.[197] Some states that have such written consent requirements have issued waivers permitting the informed consent to be verbal.[198]

In addition to waivers to existing telehealth limitations and restrictions, a number of states have also increased their focus on both coverage parity and payment parity for telehealth services.[199] Before COVID–19, forty-two states and the District of Columbia had some sort of parity law requiring coverage or payment for telehealth services to be at least on par with healthcare services rendered in person.[200] Of those, eight states had telehealth payment parity laws, and

193. *Telehealth and COVID-19 in Rural Areas*, BIPARTISAN POL'Y CTR. (June 4, 2020, 10:00 AM), https://bipartisanpolicy.org/event/telehealth-and-covid-19-in-rural-areas/ [https://perma.cc/9D95-JZC9].

194. *See* Ralls & Moran, *supra* note 192 (noting that funding is key to driving telehealth in rural communities).

195. For a summary of all state approaches, see generally *U.S. States and Territories Modifying Requirements for Telehealth in Response to COVID-19*, *supra* note 10.

196. *Id.*

197. *See e.g.*, Mich. Exec. Order No. 2020-86 (June 29, 2020), https://www.michigan.gov/whitmer/0,9309,7-387-90499_90705-529458—,00.html [https://perma.cc/M762-8XAB]; Cal. Exec. Order N-43-20 (Apr. 3, 2020), https://www.gov.ca.gov/wp-content/uploads/2020/04/4.3.20-EO-N-43-20.pdf [https://perma.cc/M5XB-HAH7].

198. *See* Mich. Exec. Order No. 2020-86, *supra* note 197.

199. Jared Augenstein et al., *supra* note 133.

200. *See Reimbursement Report*, *supra* note 129, at 11 (noting further that some states have enacted laws requiring both payment parity and coverage parity).

an additional three states enacted payment parity laws during the pandemic, which went into effect on January 1, 2021.[201] Further, several states enacted legislation responsive to the pandemic to expand telehealth services and, hopefully, create greater capacity for the administration of healthcare services outside of hospitals and facilities.[202] The newly enacted state laws vary but include coverage and payment parity,[203] increased access to behavioral health services through telehealth,[204] amendments to remove requirements for previously established relationship or in-person visits,[205] altering definitions and adding to permissible services,[206] and licensure changes.[207] Some states enacted these laws to clarify and enhance telehealth services in their states, and others enacted these laws likely out of necessity to allow federal waivers to take effect. At least two states initially enacted telehealth waivers in response to the coronavirus pandemic and have since made such waivers permanent to expand telehealth service access.[208] Idaho's Governor said this of his state's adoption of permanent telehealth waivers:

> Our loosening of healthcare rules since March helped to increase the use of telehealth services, made licensing easier, and strengthened the capacity of our healthcare workforce – all necessary to help our citizens during the global pandemic. We proved we could do it without compromising safety. Now it's time to make those healthcare advances permanent moving forward.[209]

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201. *See id.* at 13–14; *see also* Jared Augenstein et al., *supra* note 133 (California, Arizona, and Washington enacted laws prior to the pandemic to become effective in 2021 that would enact payment parity.). Pursuant to Executive Order 20-29, the Governor of Washington has ordered immediate implementation of the payment parity law during the COVID–19 pandemic to relieve demand on the health care system. Wash. Proclamation 20-29 Telemedicine (Feb. 29, 2020), https://www.governor.wa.gov/sites/default/files/proclamations/20-29%20Coronovirus%20OIC%20%28tmp%29.pdf [https://perma.cc/XD34-QYHE].

202. *See* Jared Augenstein et al., *supra* note 133.

203. SCS HB 29(HSS) am S (Alaska 2020); S.B. 20-212, 73rd Gen. Assemb., Reg. Sess. (Colo. 2020); H.B. 530, 2020 Reg. Sess., 2020 La. Acts 276; H.B. 313, 2020 Gen. Sess. (Utah 2020); H.B. 4003 (W.Va. 2020).

204. S. File 2261, 88th Gen. Assemb. (Iowa 2020); H.B. 449, 2020 Reg. Sess., 2020 La. Acts 191.

205. S.B. 20-212, 73rd Gen. Assemb. (Colo. 2020); S.B. 402, 2020 Gen. Assemb., Reg. Sess (Md. 2020); H.B. 5412, 100th Leg. Reg. Sess., 2020 Mich. Pub. Acts 97; H.B. 5413, 100th Leg. Reg. Sess., 2020 Mich. Pub. Acts 98; H.B. 1682, 100th Gen. Assemb., 2d Reg. Sess. (Mo. 2020).

206. H.B. 348, 150th Gen. Assemb. (Del. 2020); S.P. 676, 129th Me. Leg., 2d Reg. Sess. (2020); H.B. 8416, 2017-2018 Leg. Sess. (N.Y. 2020).

207. S.B. 361, Gen. Assemb., 2020 N.C. Sess. Laws 2020-82; H.B. 1701, Gen. Assemb., 2020 Va. Acts 368.

208. Shelby Livingston, *Some States Cement COVID-19 Telehealth Expansions*, MOD. HEALTHCARE (July 8, 2020, 1:52 PM), https://www.modernhealthcare.com/law-regulation/some-states-cement-covid-19-telehealth-expansions [https://perma.cc/5Y23-ZV8Y].

209. *Id.*

Some state actions have required commercial health insurers to expand or increase telehealth use, and other commercial health insurers have taken action on their own in response to the pandemic to react to their beneficiaries' needs.[210] Like the waivers and actions taken at the federal and state level, commercial insurers have made changes to expand coverage and access by expanding specialties that can utilize telehealth and permitting the number of members who can employ such services.[211] Additionally, they adjusted reimbursement to reduce cost-sharing obligations of beneficiaries and ensure payment parity.[212]

C. *Federal Financing Initiatives (CARES Act)*

Although waivers of existing limitations and restrictions have played a significant factor in reducing barriers to telehealth during the pandemic, funding for technology and other resources to expand telehealth services was also necessary. As part of the CARES Act, Congress appropriated additional funding under the Telehealth Network Grant Program, a program already in place that awards funds to providers and facilities in rural and medically underserved areas to invest in telehealth technology.[213] The law further extends funding for the Telehealth Resource Center Grant Program, which provides federal funds for Telehealth Resource Centers.[214] Reimbursement for telehealth services and funding to support technology and infrastructure to support a telehealth network are critical to the extent that telehealth services will be able to continue to be utilized and expanded—especially in rural and medically underserved communities.

When considering all the actions taken as a whole at the state and federal levels to enable greater access to telehealth services during the coronavirus pandemic, those efforts seemed to have most successfully increased access and capacity. According to a study researchers conducted at Harvard University and Phreesia, a healthcare technology company, the extreme decline in in-person health visits that began at approximately the second week of March 2020 was partially offset by an increase in telehealth visits during that same time.[215] While it did

210. *See generally* Weigel, *supra* note 4.

211. *Id.*

212. *Id.*

213. CARES Act, Pub. L. 116-136, § 3213, 134 Stat. 281, 370 (2020); *HHS Awards Nearly $165 Million to Combat the COVID-19 Pandemic in Rural Communities*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Apr. 22, 2020), https://www.hhs.gov/about/news/2020/04/22/hhs-awards-nearly-165-million-to-combat-covid19-pandemic-in-rural-communities.html [https://perma.cc/6A7C-FHX3].

214. Telehealth Resource Centers were formed for the purpose of providing "assistance, education, and information to organizations and individuals who are actively providing or interested in providing health care at a distance." *Experts in the Field of Telehealth Education and Implementation*, NAT'L CONSORTIUM OF TELEHEALTH RES. CTRS., https://www.telehealthresourcecenter.org/ [https://perma.cc/8VUU-CMVL].

215. Ateev Mehrotra et al., *The Impact of the COVID-19 Pandemic on Outpatient Visits: A Rebound Emerges*, COMMONWEALTH FUND (May 19, 2020), https://

not get close to replacing in-person visits—especially for specialties in which telehealth is virtually impossible, such as surgery—it did enable continued and expanded healthcare services.[216] Further, the researchers estimated that the number of telehealth visits during the initial stages of COVID–19 stay-at-home orders was actually underestimated because of systems not initially being set up to schedule and track these types of visits.[217] Because telehealth, as a tool, is not intended ever to wholly replace in-person healthcare services, critics view the value in telehealth services as helping to divert volume from busy emergency rooms, which helps move patients more efficiently and safely to the right specialty and helps avoid exposures to unrelated infectious diseases—including COVID–19.[218] Further, the way in which the pandemic forced telehealth to the forefront prompted both patients *and* providers, some of whom may have been reticent or uncomfortable with telehealth previously, into trying new methods, new approaches, and new technologies.[219] All this will ease future use of telehealth services, as providers and patients have had to learn new methods and technologies out of necessity and, such use may have helped remove some of the stigma or fear that patients and providers may have felt in the past. Researchers have noted the following:

> The impact of telemedicine on COVID-19 response is matched by a likely enduring impact of COVID-19 on telemedicine, and through it on healthcare delivery in general, with a new reality of a broad population of Americans and their providers who are getting a crash course in using telemedicine tools, experiencing their capabilities, and establishing comfort and expectations of their widespread availability.[220]

Thus, while the waivers and amendments to existing federal and state laws and regulations and the enactment of new state laws have been complex, such actions have largely been beneficial and have paved the way for telehealth to lessen the burdens on the healthcare system during a time that any stressors can be devastating.

IV. The Path Forward for Regulation of Telehealth Services

Most observers, including legislators, administrators, and regulators, seem to agree that going back to the previous telehealth regulatory regime once the COVID–19 public health emergency has been

www.commonwealthfund.org/publications/2020/apr/impact-covid-19-outpatient-visits [https://perma.cc/5YG3-CXW4].

216. *Id.*

217. *Id.*

218. Devin M. Mann et al., *COVID-19 Transforms Health Care Through Telemedicine: Evidence from the Field*, 27 J. Am. Med. Informatics Ass'n 1132, 1134 (2020).

219. *Id.* at 1135 (showing the increase in use by providers and patients).

220. *Id.* at 1135–36.

lifted would be a mistake. Indeed, telehealth and its potential ability to improve healthcare access for all Americans at this time—and especially rural Americans in the future—has gotten attention at the highest levels of government. On August 3, 2020, President Trump issued an executive order reiterating the need for improved access to health care through telehealth especially in rural areas.[221] The order proposed establishing new payment models for telehealth in rural areas, increasing investments and funds for physical and communications-related infrastructure in rural areas to enable telehealth services, increasing study regarding policy initiatives for improving the health of Americans living in rural communities, and reviewing the temporary measures in place under the public health emergency to determine which and to what extent such measures should be extended.[222] Similarly, then-CMS Administrator Seema Verma wrote an article in July 2020, stating publicly that CMS was open and willing to embrace the idea of a revised and reimagined telehealth approach.[223] Verma wrote:

> With these transformative changes unleashed over the last several months, it's hard to imagine merely reverting to the way things were before. As the country re-opens, CMS is reviewing the flexibilities the administration has introduced and their early impact on Medicare beneficiaries to inform whether these changes should be made a permanent part of the Medicare program.[224]

Similarly, on June 15, 2020, thirty U.S. legislators—both Republicans and Democrats—sent a letter to then-Senate Majority Leader Mitch McConnell (R-Kentucky) and then-Senate Minority Leader Chuck Schumer (D-New York),[225] asking Congress to adopt—on a permanent basis—the telehealth provisions set forth in the Creating Opportunities Now for Necessary and Effective Care Technologies for Health Act ("CONNECT for Health Act"), which were enacted on a temporary basis as part of the Coronavirus Preparedness and Response Supplemental and Appropriations Act of 2020 and the CARES Act.[226] The CONNECT for Health Act permits the HHS

221. Exec. Order No. 13,941, 85 Fed. Reg. 47,881 (Aug. 6, 2020).

222. *Id.*

223. *See* Verma, *supra* note 160.

224. *Id.*

225. *See generally* Letter from Brian Schatz, Senator, U.S. Senate et al. to Mitch McConnell, Majority Leader, U.S. Senate and Charles Schumer, Minority Leader, U.S. Senate (June 15, 2020), https://www.schatz.senate.gov/imo/media/doc/Letter%20to%20leadership_CONNECT%20for%20Health%20Act_06.12.20.pdf [https://perma.cc/BJA2-K8Z8] [hereinafter, *Ltr. to McConnell and Schumer*].

226. The CONNECT for Health Act was first introduced as legislation in 2016 and reintroduced to the 116th Congress in October of 2019. S. 2741, 116th Cong. (Oct. 30, 2019). It was proposed as bi-partisan legislation by Brian Schatz (D-Hi.) and co-sponsored initially by Roger Wicker (R-Ms.), Benjamin Cardin (D-Md.), John Thune (R-S.D.), Mark Warner (D-Va.), and Cindy Hyde-Smith (R-Ms.). *Id.* Provisions of the bill were adopted in parts of the CARES Act, Pub. L. 116-136, 134 Stat. 281 (2020), and the Coronavirus Preparedness and Response Supplemental and Appropriations Act of 2020, Pub. L. 116-123, 134 Stat. 146 (2020).

Secretary to waive certain telehealth requirements under the Medicare program and the FQHCs and RHCs to serve as distant sites for telehealth services, and it allows for telehealth to constitute the necessary face-to-face visit required to recertify a patient for hospice care.[227] The letter implored congressional action to expand the use of telehealth to realize known benefits of increasing access and coverage.[228] It acknowledged, however, that more data and analytics were necessary to determine the best course of action for the future:

> [W]e believe now is an important time to measure the impact of telehealth on Medicare. Specifically, the federal government should collect and analyze data on the impact of telehealth on utilization, quality, health outcomes, and spending during the COVID-19 pandemic. There is currently a scarcity of data available regarding the impact of telehealth on the Medicare program. This data would assist Congress in crafting additional policies to improve health outcomes and use resources more effectively.[229]

President Biden has largely stayed the course when it comes to telehealth, and Congress has pending bills that seek to make at least some of the current waivers permanent.[230]

In addition to executives, regulators, and legislators, providers have also made calls for extending the relaxed telehealth regime into the future, as it has ushered in increased flexibility and effectiveness in the delivery of care.[231] For example, the American College of Physicians suggested to CMS to make the following temporary changes permanent: facility fee payments for provider-based hospital departments when the patient is located at home; flexibility regarding direct supervision requirements for physicians at teaching hospitals; waivers of geographic restrictions on originating sites; continued relaxation of requirements that would allow physicians to provide telehealth services across state lines; payment parity for audio-only and audio-video telehealth services as comparable to E/M visits; continued access to RPM services for new patients (as well established patients); and allowances for physicians to reduce or waive telehealth-related, cost-sharing requirements for patients.[232]

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227. *Ltr. to McConnell and Schumer*, *supra* note 225, at 1.

228. *Id.*

229. *Id.* at 2.

230. Temporary Reciprocity to Ensure Access to Treatment Act (TREAT Act), H.R. 708, 117th Cong. (2021); Telehealth Modernization Act, S. 368, 117th Cong. (2021).

231. Revenue Cycle Advisor, *Providers Push to Extend Telehealth Policies and Waivers Beyond COVID-19*, HEALTHLEADERS (June 15, 2020), https://www.healthleadersmedia.com/innovation/providers-push-extend-telehealth-policies-and-waivers-beyond-covid-19 [https://perma.cc/GBN6-DPPH] (summarizing a letter from the American College of Physicians ("ACP") to Seema Verma recommending that several telehealth waivers remain in place after the public emergency declaration has expired).

232. *Id.*

Similarly, the American Hospital Association ("AHA") came out with its own list of telehealth waivers that it believes should become a permanent mainstay.[233] In AHA's letter to CMS Administrator Verma, the organization stated that the experience with the pandemic has shown its members that many of the "flexibilities" that CMS has allowed during the public health emergency, including telehealth, can "[provide] for a better patient experience and high-quality outcomes in the long term."[234] Regarding telehealth services specifically, the AHA suggested changes in three broad categories: (1) increased access and capacity, (2) increased payment flexibility, and (3) increased administrative flexibility.[235] In connection with increased access and capacity, the AHA called for eliminating the originating and geographic site restrictions (and specifically for permitting patients to conduct visits from their homes), expanding provider eligibility for who can provide telehealth services, allowing hospice and home health providers to deliver telehealth services, allowing FQHCs and RHCs as distant sites, altering direct supervision rules to allow for virtual presence through audio/video real-time communications technology, and permitting continued use of everyday communications technologies such as FaceTime or Skype.[236] As to greater payment flexibility, AHA requested allowing hospital outpatient departments and critical access hospitals to bill for telehealth services, allowing hospitals to bill as an originating site when conducting telehealth visits with patients in their homes, permitting the billing of new visits via telehealth (without initial in-person exam), expanding payment for services covered under the public health emergency, and treating RPM in a similar way to other telehealth technology.[237] Finally, the AHA suggested implementation of administrative flexibilities by allowing providers to provide Medicare telehealth via audio-only communications (such as phone calls) when medically appropriate, permitting hospice and home health face-to-face recertification visits via telehealth, continuing waiver of certain verbal order requirements to enable more frequent telehealth use, not requiring providers who render telehealth services from their homes to update the Medicare enrollment address, allowing virtual check-ins and e-visits for new patients, eliminating the need for a separate informed consent process for the telehealth visit itself (allowing instead the visit to constitute the

233. Jacqueline LaPointe, *AHA's List of COVID-19 Flexibilities That Should Stay and Go*, REVCYCLE INTEL. (July 2, 2020), https://revcycleintelligence.com/news/ahas-list-of-covid-19-flexibilities-that-should-stay-and-go [https://perma.cc/2CBQ-TZ46].

234. Letter from Am. Hosp. Ass'n to Seema Verma, CMS Adm'r, Ctrs. for Medicare & Medicaid Servs. (June 26, 2020), https://www.aha.org/system/files/media/file/2020/06/aha-urge-cms-to-extend-certain-covid-19-flexibilities-letter-6-26-20.pdf [https://perma.cc/3S9J-VU9C].

235. *Id.* at 2–3.

236. *Id.*

237. *Id.* at 3.

informed consent), and allowing for providers who have state licensure reciprocity to obtain DEA registration in any such state.[238]

Lastly, in addition to providers advocating for more permanence in the loosening of restrictions, state agencies and legislatures have also begun focusing on whether waivers should realize more permanence in their state Medicaid programs and commercial insurance products. Several states have taken actions during the pandemic to enact new statutes or amend existing statutes to reduce the barriers for telehealth use, and other states have taken steps to codify what were previously temporary waivers.[239] Still, other states are monitoring the impact of these waivers on the outcomes, effectiveness, and access to their Medicaid and general populations.[240]

Thus, after decades of slow, incremental growth of telehealth services, the coronavirus pandemic has put the need for telehealth services on the fast-track and seemingly provided the necessary momentum for telehealth to become finally more of a mainstay in the U.S. healthcare delivery system. Moreover, after near-constant partisan bickering over the last ten to twenty years about the organization and structure of the U.S. healthcare system, federal and state regulators and legislators agree with industry players and the public that some of the changes that have occurred during the public health emergency in connection with telehealth services *must* extend beyond the pandemic and that there is now no going back to the previous regulatory structure. Even with this agreement, how to accomplish this and what the new telehealth model should look like is still a matter for rigorous debate. Although the waivers have eased many of the structural barriers that plagued the pre-COVID–19 system to usher in more widespread use, concerns remain regarding access, outcomes, quality of care, privacy, and fraud.[241] Therefore, while there may be an inclination to capitalize on the current energy for telehealth expansion and permanently adopt the existing waivers, developing a telehealth structure that will be well-positioned to thrive in the future must be carefully thought out. It must strike the right balance between ease and simplicity of use and establishment of appropriate protections and limitations to safeguard patients, providers, and payors.

238. *Id.* at 3–4.

239. *See* Livingston, *supra* note 203.

240. *Id.*

241. *See generally* Daniel Young & Elizabeth Edwards, *Telehealth and Disability: Challenges and Opportunities for Care*, NAT'L HEALTH L. PROGRAM (May 6, 2020), https://healthlaw.org/telehealth-and-disability-challenges-and-opportunities-for-care/ [https://perma.cc/W4B6-8K98]; Carmel Shachar, Jaclyn Engel & Glyn Elwyn, *Implications for Telehealth in a Postpandemic Future*, JAMA NETWORK (June 16, 2020), https://jamanetwork.com/journals/jama/fullarticle/2766369 [https://perma.cc/Z6QT-56BR]; Maria Castellucci, *Telehealth Explosion Points to Need for More Research on Quality of Care Provided*, MOD. HEALTHCARE (June 18, 2020, 2:57 PM), https://www.modernhealthcare.com/safety-quality/telehealth-explosion-points-need-more-research-quality-care-provided [https://perma.cc/M9DB-LH5S].

Rather than offer suggestions for certain waivers that should become permanent or respond to specific proposals from trade associations, industry groups, or legislators, this Article advocates for a broader approach to telehealth in a post-pandemic world. Any new regulatory regime that emerges should not be a piecemeal adoption of particular regulations or laws or waivers but instead a comprehensive and integrative approach that is responsive to and founded upon evidenced-based data regarding outcomes and usage of telehealth services during the public health emergency. This is not to say that changes and adjustments to a new regulatory structure should be slow; indeed, it will be critical to take advantage of the momentum that the COVID–19 public health emergency has created for telehealth services. Many are studying and reviewing the impact that this newly relaxed regime has made on telehealth services during the public health emergency; but such studying should be continuous and ongoing, and the regulatory regime needs to be sufficiently flexible and nimble such that telehealth services can continue to grow and thrive but have sufficient controls. In considering the role of telehealth services within the U.S. healthcare delivery system in future years, regulators and legislators should weigh five key factors when restructuring and reorganizing existing laws and regulations.

A. *Legislative and Regulatory Coordination and Cooperation*

The first factor to be considered in telehealth regulation is better coordination and cooperation between state and federal regulators regarding defining and regulating telehealth services and a reduction of compliance complexity. As critics have studied telehealth and its successes and failures over the years, one of telehealth's most complex aspects is the multi-layered approach that requires providers to understand an intricate and sometimes conflicting regulatory structure involving state laws and regulations in the domicile state, state laws and regulations in other states, federal laws and regulations, federal reimbursement rules, state reimbursement rules, and all applicable laws, regulations, and contractual provisions of commercial insurers.[242] This aspect of telehealth was true before COVID–19, and the COVID–19 waivers have done little to address these complexities. Moreover, the pandemic revealed the obstacles that these complexities create when the time came to enable increased access to telehealth services across an entire country.

In enacting various federal waivers, HHS and the DEA noted specifically that the federal waivers did not supersede or make ineffective

242. *See supra* Part I (describing all of the various aspects of telehealth with which one would have to comply in order to provide a service and be able to seek reimbursement for such service).

any state laws or regulations that were in place.[243] Hence, even with a federal waiver, telehealth services might be no more accessible before or after the waiver if the state failed to adopt a similar waiver or amend an existing law. For example, as part of the response to the public health emergency, CMS waived any reimbursement restrictions that applied to physicians providing services to Medicare beneficiaries who were residents of another state.[244] If a state required that all providers who provide medical care to residents of the state be duly licensed in that state, then a waiver of certain reimbursement rules does nothing to actually permit such telehealth services to take place without the state relaxing its own licensure restrictions to allow such telehealth services to take place. While efforts to expand telehealth services between the state and federal governments have been surprisingly coordinated during the COVID–19 pandemic, the sheer volume of waivers and legal actions necessary to accomplish such coordination makes plain that the myriad state and federal authorities necessary to accomplish a single action in the telehealth arena has hindered growth and will continue to hamper progress if not ameliorated to some extent.[245] It will therefore be imperative for the federal government and states to work together to create a regulatory regime that is less complex and less confusing for the providers and patients who are trying to operate within its confines.

One potential solution could be for the federal government to create incentives that would encourage states to coordinate with one another and with the federal government on a basic regulatory structure for telehealth. Further, Congress, in coordination with HHS, should establish a definitional framework for telehealth services to ensure that the states and federal government are operating off the same general terms and from the same general premise for purposes of regulating telehealth services. Having an established definition for telehealth and for its various subparts would enable the federal and state governments to better coordinate a basic organizational framework for telehealth services that would give providers and patients a clearer understanding of basic rules. Additionally, programs such as the Compact, in which states coordinate licensure across state lines based on agreed-upon minimum qualifications, would ease the way for federal reimbursement changes that also permit intrastate medical services. With an established framework for telehealth services, states will be better able to engage in legislative redesign that creates consistency between the state and federal governments and among the states. Reducing compliance complexities will likewise decrease the administra-

243. *COVID-19 Information Page*, *supra* note 140; *see supra* text accompanying note 172.

244. *COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers*, *supra* note 141, at 34–35.

245. *See generally id.* (indicating CMS's volume of enacted waivers).

tive burden for providers and enable more providers to invest in telehealth technologies and infrastructure.

B. *Reduce Geographic and Locality Barriers*

The second factor that federal and state regulators need to consider when re-conceptualizing telehealth regulation is reducing the controls at the state and federal levels that continue to tie telehealth services to a physical location in the same way an in-person visit is tied. The very nature of telehealth services implies that it aspires to operate independently of geographic or physical barriers and expects to permit the rendering of services such that two parties can connect without having to be physically together. Restrictions and limitations that create barriers on the location of the patient or the provider hinder telehealth services' benefits. For example, access to care—especially specialty care—in rural communities remains one of the biggest challenges in improving health outcomes in rural communities.[246] Yet Medicare reimbursement rules since their inception have required patients to seek telehealth services at a particular location, typically a facility,[247] and have services rendered at that remote facility, usually in the same state as the patient and provided by a provider licensed in the state.[248] Although there are advantages to making facilities available to serve as originating sites to provide a resource for technology and infrastructure, and although these originating sites can also serve as a means of verifying the necessity and propriety of the service, limiting the services to such locations negates the access and coverage that telehealth is intended to accomplish.[249] Further, any advantages that the establishment of an originating site creates are all but eliminated when reimbursement rates are so low that sites have little incentive to provide the service or to submit the associated claims.[250] It seems clear that untethering virtual services from a specific physical location and permitting such services to occur from a patient's home, whether rural or urban, have made telehealth services more accessible to patients and thus more viable as a robust aspect of the healthcare delivery model.[251]

246. *See* Ralls & Moran, *supra* note 192.

247. 42 C.F.R. §§ 410.78(b)(1),(3) (2021); Gilman & Stensland, *supra* note 65, at E5–7.

248. §§ 410.78(b)(1),(3); *see* Gilman & Stensland, *supra* note 65, at E3.

249. *See* Weigel et al., *supra* note 4.

250. *See* Gilman & Stensland, *supra* note 65, at E5, E9–10.

251. Some states have taken some action in connection with these restrictions, but states have a limited scope of power when it comes to making significant change, as state law is largely limited to either Medicaid or commercial insurance for residents of the state. *See* Weigel et al., *supra* note 4. Also, the limitations in some instances relate to certain types of services. For example, Tennessee enacted a law in the 2021 legislative session that would permit behavioral health visits to occur from a patient's home or location of the patient's choosing for its Medicaid population. S. 429, 112th Gen. Assemb. (Tenn. 2021).

It is possible that the loosening of locality and geographic restrictions will result in greater billing and collection fraud. However, CMS now has months of data from the beginning of the pandemic that should shed light on whether this is true, and such data should be able to help guide CMS and the Department of Justice toward a responsive approach. Even upon finding evidence of some fraud, the benefits of unmooring specific facilities or locations to telehealth services might nevertheless override the fraud concerns and push regulators into considering alternative ways to verify the necessity and propriety of the service.

C. *Reconsidering Fraud, Waste, and Abuse Controls*

Relatedly, the third key factor for regulators to consider is whether existing barriers—presumably established for the purpose of protecting both patients and payors from fraud, waste, and abuse—are in fact successfully controlling such ills or instead creating needless obstacles that stunt innovation. Admittedly, fraud, waste, and abuse will never go away, as these are a harsh reality of any government program. It is not realistic to permit telehealth services to be provided without regulation or wholly unfettered as if fraud, waste, or abuse will never occur. However, for decades, the slow growth of telehealth services has been, at least in part, the result of highly restrictive regulations that create so many controls as to general location, originating site, distant site, and mechanisms for billing and collection that only certain providers have had the resources and capabilities to provide such services.[252] Although initial Medicare billing regulations were enacted in 1999 and the money spent on telehealth services has increased over time,[253] few regulatory changes were implemented between 1999 and 2018 to adjust or react to the existing telehealth billing process. As a result, there has been little testing to see if the strict regulations put in place are necessary to accomplish the goals for which they were set out. At this unprecedented time, however, during which HHS is actively collecting and studying data, there is a new opportunity to consider these restrictions and use the data to determine and address actual fraud as opposed to assumed or potential fraud.

HHS has been gathering such data and considering the impact of current telehealth use to shape telehealth's future.[254] In an Issue Brief

252. *See Information on Medicare Telehealth*, CTRS. FOR MEDICARE & MEDICAID SERVS. 7 (Nov. 15, 2018), https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Information-on-Medicare-Telehealth-Report.pdf [https://perma.cc/85QG-5J9Q].

253. *See* Jarmon, *supra* note 114, at 1 (noting that Medicare had paid claims in excess of $17 million by 2018).

254. Arielle Bosworth et al., *Medicare Beneficiary Use of Telehealth Visits: Early Data from the Start of the COVID-19 Pandemic*, U.S. DEP'T HEALTH & HUM. SERVS. 10 (July 28, 2020), https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//198331/hp-issue-brief-medicare-telehealth.pdf [https://perma.cc/2Z3G-3YKU].

released on July 28, 2020, the Assistant Secretary for Planning and Evaluation noted that after a dip in in-person primary care visits in mid-March following the public health emergency, 43.5% of Medicare primary care visits in April were provided via telehealth in comparison to only 0.1% of all primary care visits provided via telehealth before the public health emergency.[255] While the brief did not address fraud directly, it noted that the "stable and sustained use of telehealth after in-person primary care visits [that] started to resume in mid-April suggests there may be a continued demand for telehealth in Medicare, even after the pandemic ends."[256] Most importantly, it reiterated the importance of and commitment to future research, stating:

> There is broad interest and discussion regarding whether some or all of the Medicare telehealth flexibilities should be made permanent after the pandemic ends. . . . To inform these potential policy changes, evaluation of the impact of the Medicare telehealth flexibilities during the [public health emergency] across the country and for different groups of beneficiaries could be helpful. . . . A key question for future research will be to assess if the Medicare telehealth flexibilities were effective . . . .[257]

This research and data gathering will be critical to assessing the impact of the waivers and should help to highlight vulnerabilities and risks as distinct from necessary easing of restrictions for the purposes of realizing the benefits of what telehealth services can provide.

D. *State Laws Should Be for the Purpose of Promoting Efficiency and Quality Care, Not Protecting Against New Competitors*

Of utmost importance in considering any restructuring or redesign of telehealth services is ensuring quality of care and efficient delivery of care. Historically, many laws and regulations have required an in-person visit take place first to verify the patient's identity, ensure the physician's qualifications and credentials, and obtain necessary consents from the patients about the risks of a virtual visit.[258] Indeed, as telehealth services have increased during the public health emergency, some have voiced fears about quality of care concerns.[259] Geisinger Health's associate vice president for telehealth services expressed excitement about being able to compare, potentially for the first time, the outcomes of a virtual visit against the outcomes from an in-person visit.[260] Geisinger planned to compare "emergency department utilization, readmission rates[,] and overall healthcare usage among patients

255. *Id.* at 1.
256. *Id.* at 10.
257. *Id.*
258. *Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine*, *supra* note 60, at 2.
259. Castellucci, *supra* note 241.
260. *Id.*

with the same conditions who had telehealth and an office visit."[261] Because the usage of telehealth has been so limited in years' past and often restricted to certain populations, it has often been difficult to assess whether concerns and trepidations over quality of care when services are virtual are supposed or actual. Increased volumes and increased usage across a spectrum of patients and specialties should provide a better picture of any true concerns.

Being able to study and assess greater and better data should also guide legislators and regulators in determining what regulations are effectively controlling and addressing quality of care and what regulations are creating barriers that do little to actually promote quality of care. For example, in reviewing existing laws and regulations, especially at the state level, certain laws that might appear to respond to quality of care concerns may instead be only controlling or restricting competition or generating revenue. The primary example of this is licensure restrictions that prohibit or restrict physicians from practicing telehealth services within the state without being fully licensed in the state.[262] As the number of states participating in the Compact has shown, many states have similar licensure obligations and minimum qualification criteria that should adequately protect patients from harmful or inappropriate medical care in any state.[263] Thus, strict licensure rules that require full licensure to render telehealth services seem to be more focused on controlling or suppressing competition in the state and generating fees and taxes tied to licensure and not in fact for the purpose of enacting quality of care controls over medical services. Enacting laws or regulations that protect quality care in theory but not in practice will actually prevent the public from recognizing when real quality care reform may be needed. Further, such laws could prompt the mistaken belief that the existing laws regulate specific issues or create certain controls when the effect of such laws creates no such controls. Thus, as legislators and regulators reconsider how telehealth should look in the future, especially those at the state law level, they should carefully analyze data the pandemic generates to understand where telehealth might actually generate quality of care concerns and enact laws to control for those concerns.

E. *Promoting and Enhancing Reimbursement and Payment Parity*

Finally, any revised regulatory structure must reconsider reimbursement—not only the manner and method for reimbursement—but the actual amounts paid for services provided. Although most public health emergency waivers are focused on removing barriers and easing restrictions, it is critical to remember that one of the primary chal-

261. *Id.*
262. *See* Faget, *supra* note 44, at 2.
263. *See A Faster Pathway to Physician Licensure*, *supra* note 48.

lenges to expansion of telehealth before the COVID–19 pandemic was reimbursement.[264] The bulk of waivers that were issued endeavor to waive particular requirements that hinder and burden telehealth services but have a relatively minimal impact on specific amounts paid for services. At the federal level, while Medicare did expand coverage of the types of services that can be reimbursed for telehealth, it did not increase the amounts paid to providers under existing reimbursement models for telehealth services.[265] At the state level, a small number of states either had laws or enacted laws in 2020 requiring that state Medicaid plans and commercial insurers organized in the state provide payment parity for telehealth services.[266] Still, the number of states with payment parity remains relatively limited.[267]

Given the expenses associated with infrastructure and training for the technology associated with telehealth, at least under the present structure, waivers and increased access will only go so far in promoting increased usage. The pandemic has shown the interest, capacity, and support for utilization of telehealth services, but creating a sustainable future must be accompanied by increased reimbursement that will encourage such use long-term. States are making good strides through enactment of coverage parity and payment parity laws, and such efforts need to continue. Studies and data from before the public health emergency make clear that patient health benefits, practice efficiencies, and triaging care acuity are not sufficient drivers for telehealth services without sufficient financial support.[268] There can be little doubt that the need for increased financial incentives through reimbursement will continue to be true in a post-pandemic environment.

V. Conclusion

In July 2020—four months into the onset of the COVID–19—Seema Verma wrote, "During these unprecedented times, telemedicine has proven to be a lifeline for health care providers and patients. The rapid adoption of telemedicine among providers and patients has shown that telehealth is here to stay."[269] Regulators such as Verma, Congressional representatives, providers, and industry profes-

264. *See KLAS-CHIME Study: Healthcare Industry Moving Ahead with Telehealth Despite Concerns*, *supra* note 101.

265. *See Additional Background: Sweeping Regulatory Changes to Help U.S. Healthcare System Address COVID-19 Patient Surge*, *supra* note 156; *see also* Weigel et al., *supra* note 4; *cf.* Medicare and Medicaid Programs; Policy and Technical Changes, 84 Fed. Reg. 15,680, 15,680–81 (Apr. 16, 2019) (summarizing the previous expansion of telehealth services available to Medicare Advantage Plans to establish a baseline).

266. *See Reimbursement Report*, *supra* note 133, at 4, 11–14.

267. *Id.* at 11–14.

268. *See* Arielle Bosworth et al., *supra* note 254, at 3, 10; Weigel et al., *supra* note 4.

269. *See* Verma, *supra* note 160.

sionals alike all seem to agree that now the benefits and advantages of telehealth have been realized, it is neither desirable nor advisable to return to the same telehealth regulatory regime that was in place before the pandemic. To not lose momentum and instead use this rare moment of bipartisan support, the instinct of many is simply to make the waivers permanent, reducing many of the barriers that have hindered expansion over the years. While being careful to not lose the dynamism that has taken place in the telehealth industry because of COVID–19, there should be some caution in simply adopting immediate waivers and declaring victory. To do so would ignore the enormous opportunity presented to the industry to use this time to study and better understand the true advantages and disadvantages of telehealth. The COVID–19 public health emergency and the relaxation of regulations and laws that have been necessary to ensure health and safety of individuals during the pandemic have provided a unique window into where telehealth services are most needed, most wanted, most effective, most efficient, and best suited. Now is the time to create a more sustainable and workable framework for telehealth services that will be prepared for the future.

It was not until over 200 million users started using Zoom that it was discovered that someone could "bomb" a meeting, causing Zoom and the schools and businesses using its platform to enhance security measures and realize the privacy limitations of the online platform.[270] In that same way, the healthcare industry should use this time to study and analyze telehealth use and telehealth data to consider a new approach. Undoubtedly, aspects of a new approach will involve making permanent some of the waivers and changes that were adopted during the pandemic. Making such changes without a more thoughtful review of the entire infrastructure, however, would be short sighted. Admittedly, a new framework for telehealth needs to focus on removing barriers, but it also needs to reconsider how and why those barriers were in place and, with that information, create a system redesign that involves a better definition of telehealth and telehealth services; improves coordination and cooperation among the state and federal agencies to make regulations less administratively complex; removes physical and geographic barriers; responds to actual fraud, waste, and abuse; promotes quality care; and provides increased reimbursement and funding for services. All of this together will not only permit telehealth growth but will allow telehealth as a component of the healthcare delivery system to thrive and be better poised for any future public health emergencies.

270. Evans, *supra* note 1; St. John, *supra* note 151.