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Telehealth - Legal & Compliance Considerations and Operationalization for Employers Post-Pandemic

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I. INTRODUCTION

Telehealth has a unique value proposition that can provide safe and effective access for people to connect with their healthcare providers in both rural and urban areas, both domestic and global. With 60 million people living in rural areas in the United States, telehealth is viewed as a critical healthcare tool that depends upon telecommunication and digital technologies to satisfy the needs of underserved areas for healthcare and education.[1] In today's modern healthcare era, telehealth offers healthcare providers and individuals more accessible healthcare; however, there appears to be underutilization of telehealth in employer health plans or programs. Expanding telehealth programs for employers requires a thorough evaluation of transactional relationships and program structures to minimize risk and ensure compliance with applicable laws and regulations. This is especially so as telehealth expands the universe of involved parties from healthcare providers to intermediaries, such as technology service providers. In partnership with telehealth service providers and vendors, employers should work towards improving employees and their family's health and wellbeing, reducing risks, and overcoming known disparities and inequities in healthcare delivery.[2]

While telehealth has been developing since the distant use of the telephone in the 1870s, in modern times the adoption and use of telehealth have largely been shaped and limited by regulation, payment, and technology.[3] For example, Medicare would only pay for telehealth when it was provided at certain medical facilities, such as clinics and hospitals, and in a designated rural area.[4] In March 2020, the Novel Coronavirus Disease (COVID-19) pandemic outbreak was declared in the United States.[5] The Centers for Medicare & Medicaid Services (CMS) aggressively responded to the public health emergency (PHE).[6] CMS under the Trump Administration, enacted blanket waivers to remove restrictions on licensure, locations, enrollments, and communications, which opened the door for Medicare and states to adopt telehealth broadly and on a larger scale in response to the COVID-19 pandemic.[7] During the PHE, all 50 states and the District of Columbia waived some state licensure requirements.[8] States expanded telehealth for access to care and broader coverages, such as using multiple

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[1] National Center for Advancing Translational Sciences (NCATS). (2022, 3 23). NCATS Funds Network to Improve the Use of Telehealth in Children's Health Care. Retrieved from National Institutes of Health (NIH): https://ncats.nih.gov/pubs/features/sprout-ctsa

[2] Byrne, M. D. (2020, 10 1). Telehealth and the COVID-19 Pandemic. INFORMATICS AND HEALTH INFORMATION TECHNOLOGY, 35(5), 548-551. DOI: https://doi.org/10.1016/j.jopan.2020.06.023

[3] Manpreet S. Mundi, O. M. (2021). Use of telehealth in home nutrition support: Challenges and advantages. Nutrition in Clinical Practice, 36, 775-784. DOI:10.1002/ncp.10736

[4] Centers for Medicare & Medicaid Services (CMS). (2020, 3 17). MEDICARE TELEMEDICINE HEALTH CARE PROVIDER FACT SHEET. Retrieved from CMS at: https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet

[5] Centers for Medicare & Medicaid Services (CMS). (2020, 3 20). COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers. Retrieved from CMS at: https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf

[6] *Id.*

[7] *Id.*

[8] Alliance for Connected Care. (2022, 6 15). COVID-19 State Telehealth and Licensure Expansion Dashboard. Retrieved from Alliance for Connected Care https://connectwithcare.org/state-telehealth-and-licensure-expansion-covid-19-chart/

modalities of audio-visual and audio-only for Medicaid programs.[9] The COVID-19 pandemic created a "perfect storm" in the country's healthcare system leading to an 'involuntary laboratory experiment' testing the utility of telehealth.[10] Without question, the COVID-19 pandemic accelerated the adoption of telehealth across the nation.[11]

Post-pandemic, many states are reviewing telehealth scope and reimbursement policies, especially those with concerns about quality care for audio-only telehealth.[12] The government and its agencies have moved to invest more resources and funding in prioritized healthcare areas, which all include telehealth as part of the scope. The House of Representatives passed the Build Back Better Act (BBBA) on November 19, 2021, which would expand funding for home and community-based services (HCBS) and community mental health services[13] CMS under the Biden Administration will invest in behavioral health policy as one key federal Medicare priority.[14] The Consolidated Appropriations Act, 2022,[15] or the omnibus spending package, requires the Medicare Payment Advisory Commission (MedPAC) to study expanding telehealth services, which would mean amending the Social Security Act after June 15, 2023, when its "Report to Congress" is due.[16] The report date is the same as the due date for the U.S. Department of Health and Human Services (HHS) OIG report on fraud prevention measures for telehealth.[17]

Employers incorporating telehealth into their employee benefit programs will continue to face challenges due to a dynamically changing legal and regulatory landscape. Thus, this paper presents a roadmap of considerations for employers as they consider creating a telehealth program for their workforces. Section II provides an overview of telehealth, including definitions, types, and approaches in the delivery of telehealth. Section III discusses the benefits of, limitations on, and barriers to telehealth development. Trends in telehealth before and during the COVID-19 pandemic based on various survey reports are presented in Section IV. Section V reviews legal and compliance aspects of telehealth before the COVID-19 pandemic, and flexibilities and waivers during the pandemic with potential solutions, in response to two key barriers to telehealth development, including data privacy restrictions and cross-state licensure. Telehealth has many new developments and resources to further boost its adoption and usage as explored or practiced by some companies, so several real cases are presented as examples in Section VI. After this review of telehealth in a new post- COVID-19 pandemic era, the biggest challenge for employers is how to operationalize telehealth in providing comprehensive health

[9] Robin Rudowitz, J. T. (2022, January 18). Medicaid: What to Watch in 2022. Retrieved from KAISER FAMILY FOUNDATION (KFF): https://www.kff.org/medicaid/issue-brief/medicaid-what-to-watch-in-2022/

[10] Reed, A. (2022, 3 25). More Telehealth Data Urged Before Making Eased Rules Permanent. Retrieved from Bloomberg Law at: https://news.bloomberglaw.com/coronavirus/more-telehealth-data-urged-before-making-eased-rules-permanent

[11] *Id.*

[12] *Id.*

[13] *Id.*

[14] *Id.*

[15] Law No: 117-103

[16] Reed, A. (2022, 3 25). More Telehealth Data Urged Before Making Eased Rules Permanent. Retrieved from Bloomberg Law at: https://news.bloomberglaw.com/coronavirus/more-telehealth-data-urged-before-making-eased-rules-permanent

[17] *Id.*

plans to their employees and families. Some suggestions with a checklist, are proposed for future telehealth expansion considerations in Section VII.

II. TELEHEALTH OVERVIEW

i. Definitions

a. Telehealth

The Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) defines telehealth as "the use of electronic information and telecommunications technologies to support and promote long-distance clinical health care, patient and professional health-related education, and public health and health administration. Technologies include videoconferencing, the internet, store-and-forward imaging, streaming media, and landline and wireless communications."[18] The American Academy of Family Physicians (AAFP) has a similar definition of telehealth as "a broad collection of electronic and telecommunications technologies and services that support at-a-distance healthcare delivery and services and virtual medical, health and education services."[19] The Center for Connected Health Policy (CCHP) says telehealth is a broad term and "a collection of means to enhance care and education delivery," not a specific clinical service. [20]

There are no consistent definitions and scopes of telehealth at the federal and state levels.[21] As CCHP states, "These varying definitions influence the policies and regulations surrounding how telehealth is allowed to be used, and these policies vary as much across states as the definitions themselves."[22] According to the Medical Board of California, "Telehealth (previously called telemedicine) is seen as a tool in medical practice, not a separate form of medicine. There are no legal prohibitions to using technology in the practice of medicine, as long as the practice is done by a California licensed physician and complies with state and federal privacy laws."[23]

Fortune Business Insights defines telehealth as connected health including the applications of diagnosis and treatment, monitoring applications, wellness and prevention, healthcare management, and others.[24]

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[18] Department of Health and Human Services (HHS). (n.d.). FAQs on Telehealth and HIPAA during the COVID-19 nationwide. Retrieved 6 28, 2022, from HHS: https://www.hhs.gov/sites/default/files/telehealth-faqs-508.pdf

[19] American Academy of Family Physicians (AAFP). (1994 (2021 BOD)). *Telehealth and Telemedicine.* Retrieved from American Academy of Family Physicians: https://www.aafp.org/about/policies/all/telehealth-telemedicine.html

[20] Center for Connected Health Policy. (2022). What is telehealth? Retrieved from National Telehealth Policy Resource Center: https://www.cchpca.org/what-is-telehealth/?category=live-video

[21] *Id.*

[22] Center for Connected Health Policy. (2022). What is telehealth? Retrieved from National Telehealth Policy Resource Center: https://www.cchpca.org/what-is-telehealth/?category=live-video

[23] Medical Board of California. (2022). Practicing Medicine Through Telehealth Technology. Retrieved from Medical Board of California at: https://www.mbc.ca.gov/Resources/Medical-Resources/telehealth.aspx

[24] Fortune Business Insights. (2021). Connected Healthcare Market Report. Fortune Business Insights. Retrieved from https://www.fortunebusinessinsights.com/connected-healthcare-market-106192

b. Telehealth and Telemedicine

The terms "telehealth" and "telemedicine" are often used interchangeably.[25] The American Academy of Family Physicians (AAFP) distinguishes telehealth from telemedicine, as telehealth covers broader remote healthcare services, while telemedicine is more specifically for remote clinical services.[26] Telehealth can "refer to remote non-clinical services such as provider training, continuing medical education or public health education, administrative meetings, and electronic information sharing to facilitate and support assessment, diagnosis, consultation, treatment, education, and care management."[27] AAFP defines telemedicine as "the practice of medicine using technology to deliver care at a distance, over a telecommunications infrastructure, between a patient at an originating (spoke) site and a physician, or other practitioner licensed to practice medicine, at a distant (hub) site."[28] This paper mainly uses "telehealth" with a broad definition and scope in the context below.

c. Proliferation of "Tele" Terms

New applications of "telehealth" have resulted in an array of new terms. For example, the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (NABP Model Act) include the "Practice of Telepharmacy" and define it as "the Practice of Pharmacy by registered Pharmacies and Pharmacists located within US jurisdictions through the use of Telepharmacy Technologies between a licensee and patients or their agents at distances that are located within US jurisdictions."[29] Telerehabilitation, another example, covers a wide range of habilitation and rehabilitation services delivered by information and communication technologies across the lifespan and a continuum of care in a variety of settings from healthcare and community settings to community-based worksites or patients' homes wherever it is convenient for patients.[30] "Telerehabilitation services can include evaluation, assessment, monitoring, prevention, intervention, supervision, education, consultation, and coaching."[31] Information and communication technologies may incorporate "video and audio conferencing, chat messaging, wearable technologies, sensor technologies, patient portals or platforms, mobile health applications, virtual reality, robotics, and therapeutic gaming technologies."[32]

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[25] Reed V. Tuckson, M.E. (2017). Telehealth. New England Journal of Medicine, 377, 1585-1592. DOI: 10.1056/NEJMsr1503323

[26] American Academy of Family Physicians (AAFP). (1994 (2021 BOD)). *Telehealth and Telemedicine.* Retrieved from American Academy of Family Physicians at: https://www.aafp.org/about/policies/all/telehealth-telemedicine.html

[27] *Id.*

[28] *Id.*

[29] National Association of Boards of Pharmacy (NABP). (n.d.). Model State Pharmacy Act and Model Rules. Retrieved 6 22, 2022, from https://nabp.pharmacy/members/board-resources/model-pharmacy-act-rules/

[30] Brennan, D., Tindall, L., Theodoros, D., Brown, J., Campbell, M., Christiana, D., Smith, D., Cason, J., & Lee, A. (2010). A Blueprint for Telerehabilitation Guidelines. *International Journal of Telerehabilitation, 2*(2), 31–34. https://doi.org/10.5195/ijt.2010.6063

[31] *Id.*

[32] Richmond, T. P. (2017). American Telemedicine Association's Principles for Delivering Telerehabilitation Services. International Journal of Telerehabilitation, 9 (2), 63-68. DOI: https://doi.org/10.5195/ijt.2017.6232

ii. Types And Approaches of Telehealth

a. Medicare Reimbursement for Telehealth

Since 2019, CMS has enacted changes in Medicare reimbursement to cover three types of telemedicine for established patients. These include a) Medicare telehealth visits for video routine office visits; b) virtual check-ins for short patient-initiated communications with healthcare providers, such as remote evaluations of patients' recorded video or images; and c) e-visits for "non-face-to-face patient-initiated communications through an online patient portal."[33]

b. Approaches of Telehealth

The American Telemedicine Association (ATA) lists four common telehealth approaches or modes:[34] a) Virtual visits that include "live, synchronous, interactive encounters between a patient and a healthcare provider via video, telephone, or live chat;"[35] b) Chat-based interactions, which refer to "asynchronous online or mobile app communications to transmit a patient's health data, vital signs and other physiologic data or diagnostic images to a healthcare provider to review and deliver a consultation, diagnosis, or treatment plan at a later time;"[36] c) Remote patient monitoring, in connection with artificial intelligence (AI) and machine learning new technologies, that can detect disease at an early stage, improve diagnosis, and enable better disease surveillance;[37] and d) "Technology-Enabled Modalities: Telehealth and virtual care solutions also provide for physician-to-physician consultation, patient education, data transmission, data interpretation, digital diagnostics (algorithm-enabled diagnostic support), and, digital therapeutics (the use of personal health devices and sensors, either alone or in combination with conventional drug therapies, for disease prevention and management)."[38]

The synchronous approach is a real-time session with healthcare providers by phone, text messaging, and video, the most popular type, and the alternative to an in-person office visit.[39]

The asynchronous mode, or store-and-forward, does not have real-time back-and-forth conversations between patients and their healthcare providers.[40] Healthcare providers will review the information submitted by patients, form a diagnosis or treatment plan, and convey

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[33] Centers for Medicare & Medicaid Services (CMS). (2020, 3 17). MEDICARE TELEMEDICINE HEALTH CARE PROVIDER FACT SHEET. Retrieved from CMS: https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet

[34] American Telemedicine Association (ATA). (2020, 9 11). Telehealth: Defining 21st Century Care. Retrieved from The American Telemedicine Association at: https://marketing.americantelemed.org/hubfs/Files/Resources/ATA_Telehealth_Taxonomy_9-11-20.pdf

[35] *Id.*

[36] *Id.*

[37] *Id.*

[38] *Id.*

[39] Brick, M. (2022, 1 13). The Scoop on Telehealth and Insurance Coverage. Retrieved from OpenLoop at: https://openloophealth.com/blog/the-scoop-on-telehealth-and-insurance-coverage/

[40] *Id.*

the results to patients.[41] More often, it takes place among the healthcare providers with a few examples illustrated below by the Center for Connected Health Policy (CCHP).[42]

- "In radiology, physicians at small rural hospitals can forward X-rays or MRIs to specialists at major medical centers for review."[43]
- "In dermatology, primary care providers can take digital photos of their patients' skin conditions and forward the images to dermatologists for review and determination of treatment if needed."[44]
- "In ophthalmology, eye screenings for diabetic retinopathy, a disease that is a major cause of blindness among individuals with diabetes, can be captured digitally by retinal cameras and transmitted to a specialist for review."[45]
- "A Urology Times article notes, 'In our specialty, a relevant example might involve receiving a computed tomography image or a photo of a genital lesion for expert opinion. Obtaining CME hours via a downloadable course is another example of asynchronous telehealth services.' "[46]
- "Finally, an article in The Lancet Oncology states, 'Store-and-forward communication is practical in fields that require imaging. As an example, the nonprofit organization ORBIS links clinicians in developing countries with mentors in developed countries to improve the diagnosis and management of ocular diseases, including cancer.' "[47]

iii. Delivery of Telehealth

The American Telemedicine Association (ATA) expanded the delivery methodology in a broader format in their 2010 guideline, including but "not limited to video and audio conferencing, chat messaging, wearable technologies, sensor technologies, patient portals or platforms, mobile health applications, virtual reality, robotics, and therapeutic gaming technologies." [48]

The U.S. Food & Drug Administration (FDA) regulates device software functions based on the risk levels, including Class II as moderate risk and Class III as high risk, and oversees the mobile medical applications, including approval of premarket applications, to assure safety and

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[41] *Id.*
[42] Center for Connected Health Policy. (2022). What is telehealth? Retrieved from National Telehealth Policy Resource Center: https://www.cchpca.org/what-is-telehealth/?category=live-video
[43] *Id.*
[44] *Id.*
[45] *Id.*
[46] *Id.*
[47] *Id.*
[48] Richmond, T., Peterson, C., Cason, J., Billings, M., Terrell, E. A., Lee, A., Towey, M., Parmanto, B., Saptono, A., Cohn, E. R., & Brennan, D. (2017). American Telemedicine Association's Principles for Delivering Telerehabilitation Services. *International journal of telerehabilitation*, *9*(2), 63–68. https://doi.org/10.5195/ijt.2017.6232

effectiveness for medical devices.[49] Software developers may need to check with the FDA about their software risk levels and whether a premarket application is required.[50]

The U.S. Department of Health and Human Services (HHS) allowed certain non-public-facing applications to be used by healthcare providers as delivery channels during the COVID-19 pandemic, while public-facing applications such as Facebook Live and Twitch are not allowed.[51] Non-public facing applications may include: a) "Video chat applications: Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, Zoom, Skype"; and b) "Text-based applications: Signal, Jabber, Facebook Messenger, Google Hangouts, WhatsApp, iMessage." [52]

According to GoodRx's survey of 624 healthcare providers' experience with telehealth, the following Chart 1 depicts the third-party platforms used by healthcare providers.[53] Some platforms are popular for all kinds of business, and not unique to the healthcare industry, while some others are uniquely offered by healthcare vendors, such as Teladoc or EHR providers.[54] From Chart 1, Zoom, EHR provider, and Facetime are the top three widely used platforms by healthcare providers, each with an over 25% usage rate.[55] The GoodRx survey report also shows that 65% of healthcare providers offered telehealth services for the diagnosis of new health issues, 51% for medication prescriptions for new patients, and 41% for electronic prescriptions for ongoing issues.[56]

[49] Food & Drug Administration (FDA). (2019, 11 5). Device Software Functions Including Mobile Medical Applications. Retrieved from FDA at: https://www.fda.gov/medical-devices/digital-health-center-excellence/device-software-functions-including-mobile-medical-applications

[50] *Id.*

[51] Health Resources & Services Administration (HRSA). (2021, 1 28). HIPAA flexibility for telehealth technology. Retrieved from HHS: https://telehealth.hhs.gov/providers/policy-changes-during-the-covid-19-public-health-emergency/hipaa-flexibility-for-telehealth-technology/

[52] *Id.*

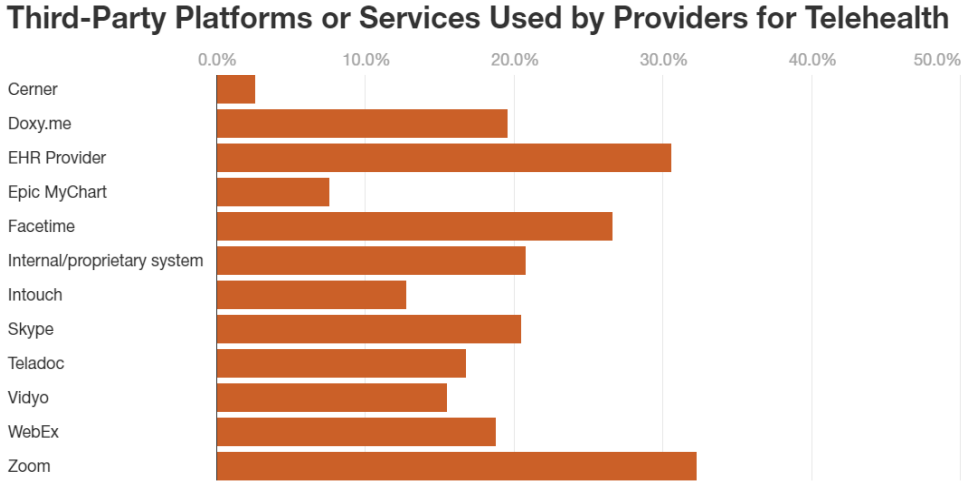
[53] Guttentag, S. (2021, 11 15). The State of Telehealth, According to Healthcare Providers and Patients. Retrieved from GoodRx, Inc. at:
https://www.goodrx.com/healthcare-access/telehealth/state-of-telehealth-survey-2021?source=email

[54] *Id.*

[55] *Id.*

[56] *Id.*

Chart 1



III. BENEFITS OF AND BARRIERS TO TELEHEALTH DEVELOPMENT

i. Benefits of Telehealth

Telehealth can provide access to healthcare and improve healthcare services for underserved communities, such as "people of color, immigrants, people who identify as LGBTQ, people with disabilities, older patients," in addition to rural communities.[57] According to the American Telemedicine Association (ATA), the benefits of telehealth include improved access, cost efficiencies, improved quality care, and meeting consumers' demands.[58] Telehealth has consistently proven to deliver improved quality care, especially in mental health and ICU care, to reduce or contain costs by efficiently managing chronic diseases, sharing healthcare staff, and reducing travel times with fewer hospital visits and shorter stays.[59]

A GoodRx 2021 report shows that over 43% of healthcare providers thought telehealth care was better or much better than in-person care, while 37% felt the same for both types of care, and only 20% thought in-person care was better. [60] Over 70% of healthcare providers think telehealth is better for patients' continuity of care and medication adherence.[61] Some healthcare providers believe telehealth with videoconferencing can help patients to engage easier and show non-verbal cues when young patients are more relaxed. [62]

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[57] Health Resources & Services Administration (HRSA). (n.d.). Health equity in telehealth. Retrieved 7 10, 2022, from HHS: https://telehealth.hhs.gov/providers/health-equity-in-telehealth/

[58] American Telemedicine Association (ATA). (2020, 9 11). Telehealth: Defining 21st Century Care. Retrieved from: The American Telemedicine Association at: https://marketing.americantelemed.org/hubfs/Files/Resources/ATA_Telehealth_Taxonomy_9-11-20.pdf

[59] *Id.*

[60] Guttentag, S. (2021, 11 15). The State of Telehealth, According to Healthcare Providers and Patients. Retrieved from GoodRx, Inc.: https://www.goodrx.com/healthcare-access/telehealth/state-of-telehealth-survey-2021?source=email

[61] *Id.*

[62] Assistant Secretary for Planning and Evaluation (ASPE). (2020, 5 15). Report to Congress: Reducing Barriers To Furnishing Substance Use Disorder (SUD) Services Using Telehealth And Remote Patient Monitoring For

American Well issued the physician index survey in 2019 and reflected a few benefits points from specialists, including Urology, Emergency Medicine, Infectious Disease, Psychiatry, Pediatrics, Oncology, and Neurology.[63] Many specialists have various levels of burnout rates, ranging from 39% separately for Psychiatry and Oncology to 54% for Urology, which correlates to specialists' willingness to use telehealth, ranging from 80% and 76% separately for Psychiatry and Oncology to 91% for Urology.[64] The benefits may include consultation, pre- and post-operation appointments for Urologists, reducing patients' wait time and increasing patients' satisfaction with Emergency Department, bridging the gap between Urologists' aging and Psychiatrists' shortage issues, and allowing Neurologists to practice the leading edge of medicine.[65]

ii. Drawbacks and Limitations of Telehealth

The Medicare Payment Advisory Commission (MedPAC) released the "Report to the Congress" in March 2022 and revealed telehealth patients' feedback that telehealth visits were not thorough or appropriate for all healthcare needs.[66] Healthcare providers explained that certain services were more suitable for in-person visits, such as services requiring checking blood pressure, hearing heart conditions, assessing pulmonary function, or ordering lab tests.[67] While telehealth is suitable for other situations, including "stable medical conditions; medication refills; chronic disease management; remote monitoring, such as continuous glucose monitoring for patients with diabetes; and psychiatry visits."[68] Of course, it would be ideal if both services are provided in combination.[69]

According to Mayo Clinic, telehealth may cause fragmented care, which "may lead to gaps in care, overuse of medical care, inappropriate use of medications, or unnecessary or overlapping care."[70] Other drawbacks to telehealth may include a higher no-show rate.[71]

Pediatric Populations Under Medicaid. Retrieved from Centers for Medicare & Medicaid Services (CMS): https://www.medicaid.gov/medicaid/benefits/downloads/rtc-reducing-barriers-may-2020.pdf

[63] American Well. (2019). Telehealth Index: 2019 Physician Survey. American Well. Retrieved from https://static.americanwell.com/app/uploads/2019/04/American-Well-Telehealth-Index-2019-Physician-Survey.pdf

[64] *Id.*

[65] *Id.*

[66] MedPAC Report to the Congress. (2022). March 2022 Report to the Congress: Medicare Payment Policy. Washington D.C.: MedPAC. Retrieved from https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_SEC.pdf

[67] *Id.*

[68] *Id.*

[69] *Id.*

[70] Mayo Clinic. (2020, 5 15). Telehealth: Technology meets health care. Retrieved from Mayo Foundation for Medical Education and Research (MFMER): https://www.mayoclinic.org/healthy-lifestyle/consumer-health/in-depth/telehealth/art-20044878

[71] Guttentag, S. (2021, 11 15). The State of Telehealth, According to Healthcare Providers and Patients. Retrieved from GoodRx, Inc.at: https://www.goodrx.com/healthcare-access/telehealth/state-of-telehealth-survey-2021?source=email

iii. Barriers to the Use of Telehealth

The barriers to using telehealth and its further expansion can come from both healthcare providers and patients. According to findings of the Robert Graham Center in 2016, the following percentages of family physicians identified three major barriers: lack of training (54%), lack of reimbursement (53%), and cost of equipment (45%).[72]

A 2021 Ernst & Young survey report reveals that the top barriers from a healthcare provider's perspective include increasing administrative burden, losing interactions with telehealth patients, relying on data more than professional judgment, adapting health IT with interoperability, reimbursement issues for telehealth services, and missing overall strategy of telehealth.[73]

a. Infrastructure & Technology

The lack of digital literacy for patients in rural and frontier areas is one challenge. [74] Over 14 million urban homes and four million rural homes have no broadband.[75] Broadband is one of many social determinants of health, so the infrastructure of broadband at a speed to support telehealth platforms and usage can help improve health care and telehealth development.[76] Necessary devices, systems, and equipment can be a huge burden for healthcare providers.

b. Interstate Medical Licensure

Telehealth care across state borders implicates state health professional licensing rules.[77] Healthcare providers are required to have licenses in any state where they provide telehealth services.[78] For example, the Medical Board of California requires by law that physicians must have a license in California to provide telehealth care to patients in California.[79] The National Association of Boards of Pharmacy (NABP) Model State Pharmacy Act requires any licensed pharmacies or pharmacists located out of state to be licensed within the same state where

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[72] Robert Graham Center. (2016, January 15). *Widespread Telemedicine Adoption Blocked by Training, Payment Barriers.* Retrieved from Robert Graham Center: https://www.graham-center.org/press-events/press/all-releases/011516-telemedicine-blocked.html

[73] Thompson, D. (2021). Embracing digital: is COVID-19 the catalyst for lasting change? Imperial College London, Institute of Global Health Innovation (IGHI). London: Ernst & Young Global Ltd (EY). Retrieved from https://assets.ey.com/content/dam/ey-sites/ey-com/en_gl/topics/government-and-public-sector/ey-embracing-digital-is-covid-19-the-catalyst-for-lasting-change.pdf

[74] Health Resources & Services Administration (HRSA) (2022, 5 13). Telehealth for rural areas. Retrieved from HHS at: https://telehealth.hhs.gov/providers/telehealth-for-rural-areas/preparing-rural-patients-for-telehealth/

[75] Siwicki, B. (2022, 7 12). The key relationship between health equity and telemedicine. Retrieved from Healthcare IT News: https://www.healthcareitnews.com/news/key-relationship-between-health-equity-and-telemedicine

[76] *Id.*

[77] Byrne, M. D. (2020, 10 1). Telehealth and the COVID-19 Pandemic. INFORMATICS AND HEALTH INFORMATION TECHNOLOGY, 35(5), 548-551. DOI: https://doi.org/10.1016/j.jopan.2020.06.023

[78] COVID-19 Healthcare Coalition. (2022, 3 3). TELEHEALTH Impact Study: Claims Data Analysis Executive Summary. Retrieved from https://c19hcc.org/static/catalog-resources/telehealth-claims-data-analysis-v3-c19hcc.pdf

[79] Medical Board of California. (2022). Practicing Medicine Through Telehealth Technology. Retrieved from Medical Board of California at: https://www.mbc.ca.gov/Resources/Medical-Resources/telehealth.aspx

pharmacist care services are provided, including through the use of telepharmacy technologies.[80] Some nurses need to have multistate licensure to serve multistate telehealth practices.[81] However, some argue that the investment to gain and keep multistate licensure may not be worth the return, particularly because in many states telehealth is not ready for many nurses and care providers to practice.[82]

c. Reimbursement & Funding

Reimbursing services for healthcare providers is the primary focus of telehealth financing.[83] On the other hand, most of the time healthcare providers' professional training via telehealth connections and programs is outside of the scope of federal and state programs.[84] Without reimbursement and funding incentives, healthcare providers are unwilling to invest in telehealth applications or provide training via telehealth programs.[85]

d. Workflow Challenges

According to the 2022 Telehealth Impact Study, healthcare providers' workflow challenges consist of 30.3% from the integrity of electronic health records (EHRs), with 58% advising no access to telehealth from EHRs, 27.9% from other technology, 25.7% without specific telehealth workflows, and 25.3% from lack of technical support.[86] "Under the EHR Reporting area, HHS focused on evaluating regulatory, administrative, financial, and other burdens for physicians and hospitals related to participation in and use of health IT as part of federal quality reporting, value-based payment, and EHR programs."[87] Healthcare providers noted excessively burdensome program requirements, and "overly complex and for disincentivizing innovative approaches to health IT use," especially considering the investment of financial and human resources.[88] "2016 study in Health Affairs analyzed data from a November 2014 Medical Group Management Association (MGMA) survey and found that practices reported spending 15.1 hours per physician per week—or 785.2 staff and physician hours per physician year—tracking measure specifications, developing and implementing data collection processes, entering information into the medical record, and collecting and

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[80] National Association of Boards of Pharmacy (NABP). (n.d.). Model State Pharmacy Act and Model Rules. Retrieved 6 22, 2022, from https://nabp.pharmacy/members/board-resources/model-pharmacy-act-rules/

[81] Byrne, M. D. (2020, 10 1). Telehealth and the COVID-19 Pandemic. INFORMATICS AND HEALTH INFORMATION TECHNOLOGY, 35(5), 548-551. DOI:https://doi.org/10.1016/j.jopan.2020.06.023

[82] *Id.*

[83] Assistant Secretary for Planning and Evaluation (ASPE). (2020, 5 15). Report to Congress: Reducing Barriers To Furnishing Substance Use Disorder (SUD) Services Using Telehealth And Remote Patient Monitoring For Pediatric Populations Under Medicaid. Retrieved from Centers for Medicare & Medicaid Services (CMS): https://www.medicaid.gov/medicaid/benefits/downloads/rtc-reducing-barriers-may-2020.pdf

[84] *Id.*

[85] Byrne, M. D. (2020, 10 1). Telehealth and the COVID-19 Pandemic. INFORMATICS AND HEALTH INFORMATION TECHNOLOGY, 35(5), 548-551. DOI: https://doi.org/10.1016/j.jopan.2020.06.023

[86] COVID-19 Healthcare Coalition. (2022). Telehealth Impact Study: Physician Survey. Survey report. Retrieved from https://c19hcc.org/static/catalog-resources/telehealth-physician-survey-analysis-c19hcc.pdf

[87] Office of the National Coordinator (ONC) for Health Information Technology. (2020, 2). Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs. Retrieved from Health IT: https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf

[88] *Id.*

transmitting data." [89] "It amounted to an 'average cost of $40,069 per physician per year, or a combined total of $15.4 billion annually for general internists, family physicians, cardiologists, and orthopedists in the United States.' " [90]

e. Challenges Faced by Patients

Challenges faced by patients include lack of access to technology or internet or data access, patients' awareness or understanding of telehealth offerings, health insurance, community-based resources, or patients' preference for in-person visits. According to a J.D. Power 2019 United States Telehealth Satisfaction Study, 29% of consumers indicated that telehealth was not available and 37% did not know whether their healthcare providers offered telehealth services.[91] Other barriers for patients may include a lack of private space for telehealth visits or support to people with disabilities, and patients' language difficulties to communicate virtually.[92]

IV. TRENDS OF TELEHEALTH BEFORE AND DURING THE COVID-19 PANDEMIC

i. Trends Before The COVID-19 Pandemic

Over decades preceding the pandemic, telehealth programs were developed by many healthcare providers; however, the overall utilization of telehealth was quite small. According to CMS, Medicare covered certain telehealth services under restricted circumstances before March 2020; for instance, "beneficiaries were only eligible for telemedicine services if they lived in a rural area and had an established relationship with the provider." [93] The qualification of healthcare providers for telehealth was confined and more information on this aspect is available in Section V Legal Reviews I Medicare & Medicaid Programs Before COVID-19 Pandemic.[94]

In 2019, FAIR Health's "FH Healthcare Indicators and FH Medical Price Index 2019" reported that telehealth claims increased across the nation and states.[95] The national growth of claim lines for telehealth was greater in the period 2012-2017 (1,202%) than in the period of 2011-2016 (643%).[96] The rural increase in telehealth claim lines from 2012 to 2017 was 482%

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[89] *Id.*
[90] *Id.*
[91] J.D. Power. (2019, 10 28). Telehealth: Best Consumer Healthcare Experience You've Never Tried, Says J.D. Power Study. Retrieved from J.D. Power: https://www.jdpower.com/business/press-releases/2019-us-telehealth-satisfaction-study
[92] Health Resources & Services Administration (HRSA). (n.d.). Health equity in telehealth. Retrieved 7 10, 2022, from HHS: https://telehealth.hhs.gov/providers/health-equity-in-telehealth/
[93] CMS. (2022, 3 29). Medicare Telemedicine Snapshot. Retrieved from Centers for Medicare & Medicaid Services (CMS): https://www.cms.gov/medicare-telemedicine-snapshot
[94] *Id.*
[95] FAIR Health, Inc. (2019, 04). FH Healthcare Indicators and FH Medical Price Index 2019: An Annual View of Place of Service Trends and Medical Pricing. Retrieved from FAIR: https://s3.amazonaws.com/media2.fairhealth.org/whitepaper/asset/FH%20Healthcare%20Indicators%20and%20FH%20Medical%20Price%20Index%202019%20-%20A%20FAIR%20Health%20White%20Paper.pdf
[96] *Id.*

and the urban increase was 1,289%.[97] In the single year from 2016 to 2017, rural growth was 29%, and urban growth was 55%, with an overall national growth of 53%.[98]

The top three cause categories for telehealth in 2017 were "injury (e.g., contusions, open wounds), acute respiratory infections, and digestive system issues (e.g., gastroesophageal reflux disease, abdominal and pelvic pain, nausea, and vomiting)", each with 13% of the distribution of claim lines (Chart 2 - Figure 24).[99] General signs and symptoms (e.g., fever, headache, general malaise) and mental health-related illness (e.g., anxiety disorders, stress reactions, obsessive-compulsive disorder) were next at 9% and 7% of the distribution.[100]

Chart 2

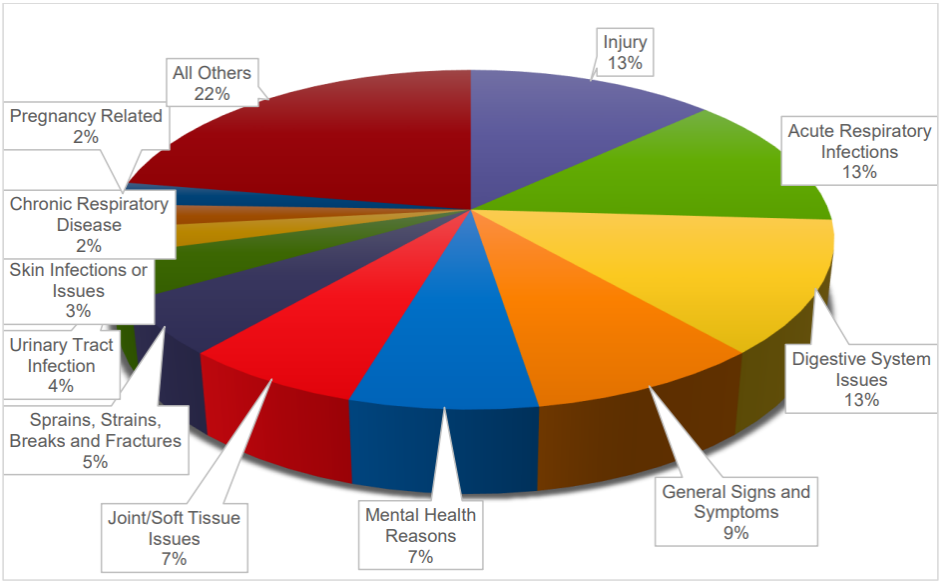

Figure 24. Distribution of claim lines with telehealth usage by diagnostic category, 2017

In 2017, patients ages 31 to 60 were treated through telehealth more than other age groups, accounting for 44% of the distribution of claim lines, while pediatric and young adult age groups comprised a significant portion of telehealth patients, with patients aged 0-10 accounting for 10% and those in the age group 23-30 accounting for 12% of total patients.[101] However, the telehealth usage situation of both the top five and bottom five states in the reports from 2016 and 2017 fluctuated a lot even just comparing the claim line data in those two years.[102] In 2017, the top five states for telehealth claim lines, as a percentage of all medical claim lines in each state, were Oklahoma, Wyoming, Ohio, Hawaii, and West Virginia, none of which were the top five in 2016.[103] The bottom five states were New Jersey, Rhode Island, Nebraska, Connecticut, and South Dakota, and South Dakota was among the top five in 2016.[104]

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[97] *Id.*
[98] *Id.*
[99] *Id.*
[100] *Id.*
[101] *Id.*
[102] *Id.*
[103] *Id.*
[104] *Id.*

In 2019, J.D. Power also undertook a consumer survey on telehealth, which fielded 8,296 consumers with a past year of telehealth experience in August-September 2019.[105] It revealed the following key findings: A) 65% of telehealth consumers received positive references from others, including their employers, colleagues, friends, health plan, and health care providers;[106] B) 73% of telehealth consumers did not struggle with the technology, 87% enrolled in telehealth easily and 84% resolved their medical concerns;[107] C) the total telehealth experience on average takes 44 minutes, including 17 minutes of enrollment, 9 minutes of a waiting period, and 18 minutes of consultation.[108] The survey also scored various organizations' consumer satisfaction based on telehealth consumers' experiences from "customer service (45%); consultation (28%); enrollment (19%); and billing and payment (9%)."[109] In the direct-to-consumer brand category, Teladoc ranked the highest in consumer satisfaction with a score of 870, with the next two ranking as Doctor on Demand (867) and MDLIVE (847).[110] In the category of consumer satisfaction with payers of health plan provided telehealth services, Humana, Kaiser Foundation, and Cigna were the top three with close scores of 864-862.[111]

A 2019 Employer Health Benefits Survey undertaken by Peterson-KFF revealed that most large employers cover telemedicine in their employee benefits programs, and this trend increased from 27% in 2015 to 82% in 2019.[112] The coverage rate of telemedicine for various sizes of employers ranges from 65% for smaller size employers with 50 to 199 employees to 90% for the largest employers with 5,000 and above employees.[113] However, the enrollees' usage rate is very low, with a similar low usage rate of 2.1% for rural areas and 2.4% for urban area.[114]

Other key trends with a positive influence on telehealth development include: a) further innovation of the technology with more capital investments in telehealth, including applications and wearable monitoring devices;[115] b) integration of telehealth with the care-delivery process in electronic or soft health records and clinical decision support systems for efficiency for healthcare providers;[116] c) growth of consumerism with convenient and real-time access to

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[105] J.D. Power. (2019, 10 28). Telehealth: Best Consumer Healthcare Experience You've Never Tried, Says J.D. Power Study. Retrieved from J.D. Power: https://www.jdpower.com/business/press-releases/2019-us-telehealth-satisfaction-study

[106] *Id.*

[107] *Id.*

[108] *Id.*

[109] *Id.*

[110] *Id.*

[111] *Id.*

[112] Matthew Rae, C. C. (2020, 03 03). Coverage and utilization of telemedicine services by enrollees in large employer plans. Retrieved from:
PETERSON-KFF Health System Tracker at https://www.healthsystemtracker.org/brief/coverage-and-utilization-of-telemedicine-services-by-enrollees-in-large-employer-plans/#Share%20of%20enrollees%20in%20large%20employer%20health%20plans%20with%20at%20least%20one %20telehealth%20service,%20by%20age%20group,%202018

[113] *Id.*

[114] *Id.*

[115] Reed V. Tuckson, M. E. (2017). Telehealth. New England Journal of Medicine, 377, 1585-1592. :DOI: 10.1056/NEJMsr1503323

[116] *Id.*

healthcare, personal health information and prescription refills;[117] and d) value-based reimbursement as incentives for affordable healthcare service delivery as per the Affordable Care Act and as incentives in the private sector of healthcare services.[118]

ii. Trends During The COVID-19 Pandemic

a. US Telehealth Market

According to the "Report to the Congress" in March 2022 by the Medicare Payment Advisory Commission (MedPAC), telehealth was mainstream in US healthcare by mid-2021, with 37% of elderly Medicare patients using audio-only telephone visits, 23% using interactive video visits, and an 89% satisfaction rate.[119] KPMG 2021 outlook report showed that in the first six months of the pandemic 55 US-based telehealth companies received the majority of the funding in the digital health sector, which is a record high of $6.5 billion, including platforms such as Doctor on Demand and Heartbeat Health.[120] Telehealth would be the largest investment sector in healthcare IT in the following 1-2 years and "the most disruptive technology trend for the healthcare market".[121]

a) Pandemic Telehealth Flexibilities

During the pandemic, Medicare telehealth services were expanded, with more categories of healthcare providers, services, and locations, such as federally qualified health centers (FQHCs) and rural health clinics (RHCs), 140 additional healthcare services, audio-only interactions, all within urban areas and at patients' locations.[122]

According to EY's 2021 Medical Technology Report, the Acute Hospital Care at Home program, which was introduced by the US Centers for Medicare & Medicaid Services (CMS), was "adopted by 53 health systems and 116 hospitals across 29 states" until April 2021, allowing hospitals to provide flexible treatment at patients' homes.[123] "Humana's alliance with DispatchHealth to offer around-the-clock, on-call care team services is a notable indicator of the shift in care delivery."[124]

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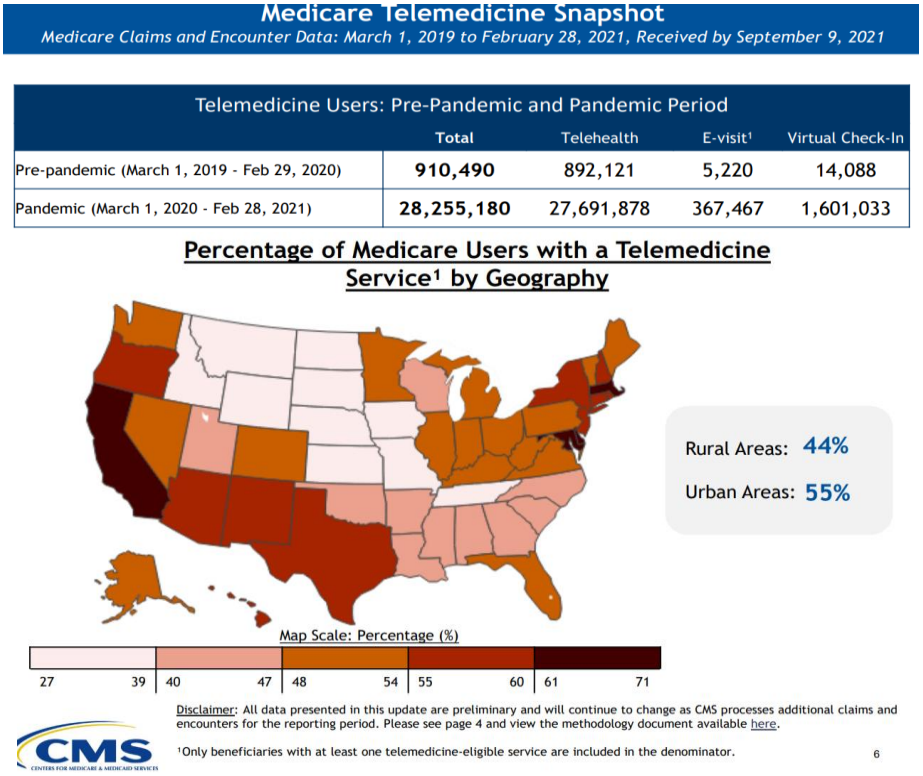
[117] *Id.*
[118] *Id.*
[119] MedPAC Report to the Congress. (2022). March 2022 Report to the Congress: Medicare Payment Policy. Washington D.C.: MedPAC. Retrieved from: https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_SEC.pdf
[120] Brett Glover, S. L. (2021). Opportunities and challenges in an evolving market: 2021 healthcare and life sciences investment outlook. Retrieved from KPMG LLP: https://institutes.kpmg.us/content/dam/institutes/en/healthcare-life-sciences/pdfs/2021/2021-hcls-investment-outlook.pdf
[121] *Id.*
[122] Lok Wong Samson, W. T. (2021). Medicare Beneficiaries' Use of Telehealth in 2020: Trends by Beneficiary Characteristics and Location. Washington, D.C.: Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health, and Human Services. Retrieved from: https://aspe.hhs.gov/sites/default/files/documents/a1d5d810fe3433e18b192be42dbf2351/medicare-telehealth-report.pdf
[123] Jim Welch, H. M. (2022, 05 01). Pulse of the industry - Medical technology report 2021. Retrieved from Ernst & Young Global Limited: https://www.ey.com/en_us/life-sciences/pulse-of-the-industry
[124] *Id.*

CMS released the Medicare claim data received on September 9, 2021, which were collected from March 31, 2020 to February 28, 2021, in their Medicare Telemedicine Snapshot as per Chart 3 below.[125] It shows the Medicare telemedicine claim amounts to a total of $28,255,180, compared to the total Medicare telemedicine claim amount of $910,490 for the same period before the pandemic.[126]

Chart 3 – CMS Medicare Telemedicine Snapshot [127]



As per the MedPAC "Report to the Congress" in March 2022, Medicare telehealth services under physician fee schedule (PFS) were a total of 4.2 billion USD in 2020, 5 percent of total PFS spending, in comparison with $59 million in 2019 of less than 1 percent.[128] Almost all were evaluation and management services charges.[129] "14.3 million FFS Medicare beneficiaries received at least 1 telehealth service (40 percent of FFS beneficiaries with Part B)."[130] The trend of monthly Medicare telehealth services changed from 5.7 million at its peak

[125] CMS. (2022, 3 29). Medicare Telemedicine Snapshot. Retrieved from Centers for Medicare & Medicaid Services (CMS): https://www.cms.gov/medicare-telemedicine-snapshot
[126] *Id.*
[127] *Id.*
[128] MedPAC Report to the Congress. (2022). March 2022 Report to the Congress: Medicare Payment Policy. Washington D.C.: MedPAC Retrieved from: https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_SEC.pdf
[129] *Id.*
[130] *Id.*

in April 2020 to 2.6 million in October, and back to 3.3 million towards the year-end of 2020 due to the wave of the COVID-19 pandemic.[131]

The EY's 2021 survey report shows various levels of uptake when using phone and video consultations, including phone consultations increasing from 39% offered by the U.S. Department of Health and Human Services (HHS) organizations before the pandemic to 81% during the pandemic, and video ones increasing from 22% before the pandemic to 71% during the pandemic.[132] The report shows a dramatic increase in user support tool usage, such as patient portals, patients' self-assessment online, and disease management, as well as an increase in other tools used, such as mobile sensors or wearables.[133] Urban health centers provided over 30% of virtual care more than rural ones.[134]

In Section IV(i), Trends Before the COVID-19 Pandemic, we discussed the data of trends from the J.D. Power 2019 consumer survey result. Now we will discuss the J.D. Power 2021 survey results as a comparison. The 2021 survey fielded 4,676 consumers with a past year of telehealth experience from June 2020 to July 2021.[135] Some key findings include: a) Telehealth access spiked from 7% in 2019 to 36% in 2021; b) Convenience (57%), speed (47%), and safety (36%) drive utilization; and c) Patient satisfaction decreased as the following barriers of telehealth services presented, including "limited services (24%), lack of awareness of costs (15%), unclear technology requirements (15%), and lack of information about providers (15%)."[136] In telehealth satisfaction survey, Teladoc ranked the highest of direct-to-consumer category, consistent with the 2019 result, with the next top two ranking companies as MDLIVE (previously No. 3 in 2019) and MyTelemedicine.[137] UnitedHealthcare ranked the highest (previously No.4) among payers of health plan-provided telehealth services, with Humana and Kaiser Foundation second in a tie (previously No.1 and 2).[138]

b) In-State vs Out-of-State

The COVID-19 Healthcare Coalition's Telehealth Impact Study Work Group analyzed claims data and found the in-state versus out-of-state trend as shown in Chart 4 below.[139] In 2019, a majority of telehealth claims arose from in-state providers, while 28.5% of telehealth

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[131] *Id.*

[132] Thompson, D. (2021). Embracing digital: is COVID-19 the catalyst for lasting change? Imperial College London, Institute of Global Health Innovation (IGHI). London: Ernst & Young Global Ltd (EY). Retrieved from: https://assets.ey.com/content/dam/ey-sites/ey-com/en_gl/topics/government-and-public-sector/ey-embracing-digital-is-covid-19-the-catalyst-for-lasting-change.pdf

[133] *Id.*

[134] Demeke HB, P. L. (2020, 12 18). Telehealth Practice Among Health Centers During the COVID-19 Pandemic-United States, July 11–17, 2020. DOI: http://dx.doi.org/10.15585/mmwr.mm6950a4external icon

[135] J.D. Power. (2021, 9 30). Telehealth Usage Surging but Service Issues and Barriers to Access Strain Patient Experience, J.D. Power Finds. Retrieved from J.D. Power: https://www.jdpower.com/business/press-releases/2021-us-telehealth-satisfaction-study

[136] *Id.*

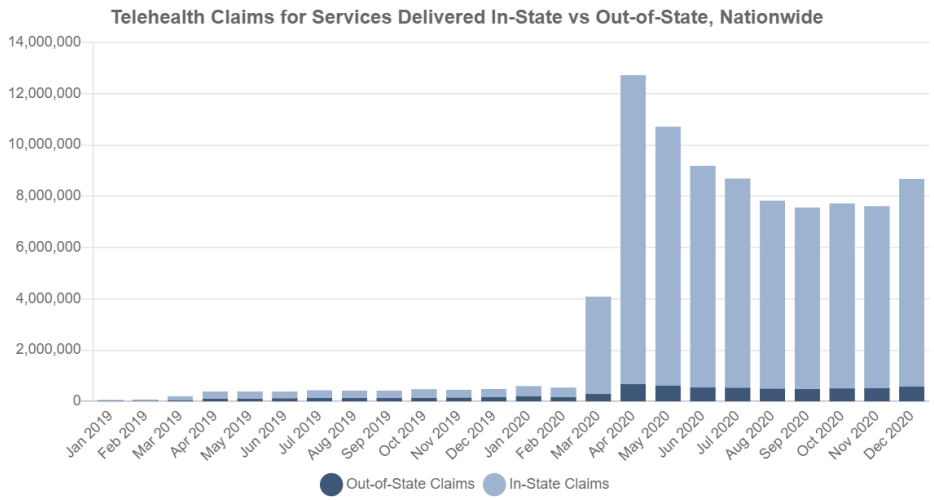
[137] *Id.*

[138] *Id.*

[139] COVID-19 Healthcare Coalition. (2022, 3 3). TELEHEALTH Impact Study: Claims Data Analysis Executive Summary. Retrieved from https://c19hcc.org/static/catalog-resources/telehealth-claims-data-analysis-v3-c19hcc.pdf

claims were provided by healthcare providers out of state.[140] During the pandemic, all telehealth claims grew sharply, with an increased out-of-state telehealth claim of 6.5% in Q4 2020.[141]

Chart 4



c) Top Diagnosis Categories

"Behavioral and mental health disorders" were the top diagnosis category before the pandemic and grew rapidly during the pandemic.[142] In the month of April 2020, over 5 million telehealth claims fell within this category, reaching the peak of telehealth usage and claims, in comparison with one million telehealth claims of circulatory system conditions and less than one million claims of endocrine and metabolism disorders.[143] The Medicare Payment Advisory Commission (MedPAC) reported that telehealth played a key role in treating behavioral and mental health (25% of Medicare fee-for-service spending), and treating circulatory system conditions (e.g., hypertension and heart disease) (14%) during the COVID-19 pandemic.[144]

d) Telehealth Trend for Employers

The Society for Human Resource Management undertook the annual benefits survey with 3,129 responses, revealing that "mental health and telehealth services" are two of the most

[140] *Id.*
[141] *Id.*
[142] COVID-19 Healthcare Coalition. (2022, 3 3). TELEHEALTH Impact Study: Claims Data Analysis Executive Summary. Retrieved from https://c19hcc.org/static/catalog-resources/telehealth-claims-data-analysis-v3-c19hcc.pdf
[143] *Id.*
[144] MedPAC Report to the Congress. (2022). March 2022 Report to the Congress: Medicare Payment Policy, Washington D.C.: MedPAC Retrieved from: https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_SEC.pdf

important benefits that employers offer in 2022, and 93% of respondents already offered telehealth to employees, which increased by 20% from 2019. [145]

After the Consolidated Appropriations Act of 2022, the Business Group on Health undertook a quick survey of employers in April 2022, and the key findings from 70 employers' responses include: "A) 25% of employers will cover telehealth services before the deductible for their high deductible health plan (HDHP) employees; B) 50% of those employers will not require any cost sharing for telehealth services, and; C) only 32% of employers with copay-only health plans cover telehealth services before the deductible."[146]

b. Global Market

According to the EY survey report, several factors largely contributed to making telehealth happen, including: "the alleviation of practitioner concerns, rapid leadership buy-in, strategic plan adoption, improvements in digital literacy, availability of funding and reimbursement for new ways of working, improvements in IT operability, alleviation of ethical and privacy concerns, and regulation and governance changes." [147]

The North American connected health market grew from $16.87 billion in 2019 to $27.20 billion in 2020.[148] The globally connected health market was $62.29 billion in 2020 and "is projected to grow from $51.68 billion in 2021 to $297.95 billion in 2028 at CAGR of 28.4% in the forecast period." [149]

New technology, for mobile phones and "wearable devices such as trackers, blood pressure monitors, glucose meters", makes self-monitoring sustainable for patients to examine self-medical parameters and upload the results for healthcare providers to review and reduce regular in-person exams and medical costs.[150] According to Sensor Tower's reports, among the top categories by year-over-year consumer download growth in Q1 to Q3 2021, medical app downloads are ranked Number 2 with 29% growth, leading the growth trend more than that of finance, sports, utilities, and other app categories.[151] The downloads and installations of Health

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[145] Alliance for Connected Care. (2022, 6 22). Mental health, telehealth benefits are post-pandemic priorities. Retrieved from Alliance for Connected Care: https://connectwithcare.org/mental-health-telehealth-benefits-are-post-pandemic-priorities/

[146] Business Group on Health. (2022, 4). HDHP Telehealth Accommodation in 2022. Retrieved from Business Group on Health at: https://www.businessgrouphealth.org/resources/hdhp-telehealth-accommodation-2022-quick-survey

[147] Thompson, D. (2021). Embracing digital: is COVID-19 the catalyst for lasting change? Imperial College London, Institute of Global Health Innovation (IGHI). London: Ernst & Young Global Ltd (EY). Retrieved from https://assets.ey.com/content/dam/ey-sites/ey-com/en_gl/topics/government-and-public-sector/ey-embracing-digital-is-covid-19-the-catalyst-for-lasting-change.pdf

[148] Fortune Business Insights. (2021). Connected Healthcare Market Report. Fortune Business Insights. Retrieved from https://www.fortunebusinessinsights.com/connected-healthcare-market-106192

[149] *Id.*

[150] Fortune Business Insights. (2021). Connected Healthcare Market Report. Fortune Business Insights. Retrieved from https://www.fortunebusinessinsights.com/connected-healthcare-market-106192

[151] Sensor Tower Inc. (2022). Mobile App Market Overlook 2022. Retrieved from https://go.sensortower.com/rs/351-RWH-315/images/mobile-app-market-outlook-2022.pdf

& Fitness apps in Europe were 290 million in 2021 and this trend continues growing, with an estimated 13% increase from Q1 2019 to 80 million downloads in Q1 2022.[152]

V. LEGAL & COMPLIANCE REVIEWS

i. Medicare & Medicaid Programs Before COVID-19 Pandemic

Telehealth providers and employers need to carefully navigate all legal and compliance requirements, including technical compatibility and liabilities.[153]

The Medicare program defines originating sites mainly located in rural areas as qualified locations. "The patient must go to the originating site for the services located in either a County outside a Metropolitan Statistical Area (MSA) or Rural Health Professional Shortage Area (HPSA) in a rural census tract. The Health Resources and Services Administration (HRSA) designates HPSAs, and the Census Bureau designates MSAs."[154] Or a site may qualify as an originating site "if they (providers) participate in a federal telemedicine demonstration project approved by (or getting funding from) HHS."[155]

As CCHP explains, most telehealth policies from federal and state levels focus on reimbursement, with 4 key elements, including eligibility of services being covered (What), the healthcare providers who can offer telehealth services and get reimbursed (Who), locations of the patients receiving telehealth services (Where), and the delivery of telehealth out of 4 modalities as discussed in section I (How).[156] There are no two states with the same policy, definition, and application scope.[157] "All states cover synchronous telehealth in some shape or form. Only 22 states cover asynchronous telehealth services. Remote patient monitoring is covered in 29 states."[158] According to the American Telemedicine Association (ATA) 2019 report on telehealth coverage and reimbursement, some key findings include:[159] A) "36 states and D.C. have parity policies for private payer coverage; only 21 states and D.C. have coverage parity policies in Medicaid."[160] B) "28 states have Medicaid payment parity policies; only 16 mandate payment parity for private payers."[161] and C) "The majority of states have no restrictions

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[152] Sensor Tower Inc. (2022). State Of Health Fitness Apps Europe 2022. Retrieved from: https://go.sensortower.com/rs/351-RWH-315/images/state-of-health-fitness-apps-europe-2022.pdf

[153] Byrne, M. D. (2020, 10 1). Telehealth and the COVID-19 Pandemic. INFORMATICS AND HEALTH INFORMATION TECHNOLOGY, 35(5), 548-551. DOI: https://doi.org/10.1016/j.jopan.2020.06.023

[154] Centers for Medicare & Medicaid Services (CMS). (2021, 6). Telehealth Services. Retrieved from CMS: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/TelehealthSrvcsfctsht.pdf

[155] *Id.*

[156] Center for Connected Health Policy (CCHP). (n.d.). Telehealth Policy 101. (Public Health Institute) Retrieved 7 2, 2022, from CCHP: https://www.cchpca.org/policy-101/

[157] *Id.*

[158] Brick, M. (2022, 1 13). The Scoop on Telehealth and Insurance Coverage. Retrieved from OpenLoop at: https://openloophealth.com/blog/the-scoop-on-telehealth-and-insurance-coverage/

[159] American Telemedicine Association. (2019, 7 18). 2019 State of the States Report: Coverage and Reimbursement. Retrieved from American Telemedicine Association at: https://www.americantelemed.org/initiatives/2019-state-of-the-states-report-coverage-and-reimbursement/

[160] *Id.*

[161] *Id.*

around eligible provider types; ten states have authorized six or more types of providers to treat patients through telehealth."[162]

ii. CMS Waivers & Flexibilities During The COVID-19 Pandemic

According to CMS, "on March 13, 2020, the President issued an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5207 (the "Stafford Act") to declare a national public health emergency."[163] Blanket waivers for certain program requirements and conditions for Medicare, Medicaid, and Children's Health Insurance Program (CHIP) programs were declared by CMS, the U.S. Department of Health and Human Services (HHS) under Section 1135 of the Social Security Act, in response to the COVID-19 pandemic emergency, retroactive from March 1, 2020, through the end of the emergency declaration.[164] The following are the abstracts from 1135 Waivers relating to telehealth and lifts of certain health care restrictions.

"Telemedicine. CMS is waiving the provisions related to telemedicine at 42 CFR §482.12(a) (8)–(9) for hospitals and §485.616(c) for CAHs, making it easier for telemedicine services to be furnished to hospital patients through an agreement with an off-site hospital. This allows for increased access to necessary care for hospital and CAH patients, including access to specialty care."[165]

"CAH Staff Licensure. CMS is deferring to staff licensure, certification, or registration to state law by waiving 42 CFR §485.608(d) regarding the requirement that staff of the CAH is licensed, certified, or registered per applicable federal, state, and local laws and regulations."[166]

"CAH Status and Location. CMS is waiving the requirement at 42 CFR §485.610(b) that the CAH be located in a rural area or an area being treated as being rural, allowing the CAH flexibility in the establishment of surge site locations. CMS is also waiving the requirement at §485.610(e) regarding the CAH's off-campus and co-location requirements, allowing the CAH flexibility in establishing temporary off-site locations. To facilitate the establishment of CAHs without walls, these waivers will suspend restrictions on CAHs regarding their rural location and their location relative to other hospitals and CAHs."[167]

"Practitioner Locations. CMS is temporarily waiving requirements that out-of-state practitioners be licensed in the state where they are providing services when they are licensed in another state. CMS will waive the physician or non-physician practitioner licensing requirements when the following four conditions are met…"[168]

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[162] *Id.*
[163] Centers for Medicare & Medicaid Services (CMS). (2020, 3 20). COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers. Retrieved from CMS at: https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf
[164] *Id.*
[165] *Id.*
[166] *Id.*
[167] *Id.*
[168] *Id.*

"Provider Enrollment. Allow licensed providers to render services outside of their state of enrollment…Allow physicians and other practitioners to render telehealth services from their home without reporting their home address on their Medicare enrollment while continuing to bill from their currently enrolled location."[169]

During the COVID-19 pandemic, states applied for Medicaid Section 1135 Waivers for greater use with flexibility. As of April 21, 2020, CMS had approved "53 COVID-related emergency waivers, 39 state amendments, 16 COVID-related Medicaid Disaster Amendments, and one CHIP COVID-related Disaster Amendment in record time."[170] According to KFF's tracker, "between March 2020 and July 2021, all 50 states and DC received approval to make changes through Disaster-Relief state plan amendments (SPAs), Section 1135 waivers and Section 1915(c) Appendix K waivers."[171] "Twelve states received approval for changes through a Section 1115 waiver and six states made changes through regular SPAs."[172]

The Alliance for Connected Care has been tracking and updating the legislation relating to "significant telehealth or remote patient monitoring provisions", including 43 newly introduced legislation between March and December 2020 for 116th Congress, and 59 new ones between January 2021 and June 2022 for 117th Congress.[173]

In June 2022, "based on interviews with federal officials and a review of federal statutes, regulations, and approved section 1135 waivers and section 1115 demonstrations, the CMS Coverage Learning Collaborative team compiled this detailed inventory of available strategies, some of which are available without needing approval from CMS."[174] The "Inventory of Medicaid and CHIP flexibilities and authorities in the event of a public health emergency or disaster" covers a broad scope with Medicaid and CHIP state exceptional examples during the COVID-19 pandemic, including "eligibility and enrollment, beneficiary cost sharing and premiums, benefits, adverse actions, and fair hearings, managed care, provider enrollment, and participation, telehealth, Medicaid finance and reimbursement, reporting and oversight, HIPAA compliance, emergency IT systems funding" and more.[175]

The extension in the Consolidated Appropriations Act 2022, five months after the end of the public health emergency (PHE), relieved most concerns about the sudden cut-off of coverage

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[169] *Id.*

[170] Centers for Medicare & Medicaid Services (CMS). (2020, 4 21). CMS NEWS ALERT APRIL 21, 2020. Retrieved from CMS at: https://www.cms.gov/newsroom/press-releases/cms-news-alert-april-21-2020

[171] Rachel Dolan, M. G. (2021, 8 26). How Have States Used Medicaid Emergency Authorities During COVID-19 and What Can We Learn? Retrieved from KAISER FAMILY FOUNDATION (KFF) at: https://www.kff.org/medicaid/issue-brief/how-have-states-used-medicaid-emergency-authorities-during-covid-19-and-what-can-we-learn/

[172] *Id.*

[173] Alliance for Connected Care. (n.d.). Federal Legislation. Retrieved 7 23,2022, from Alliance for Connected Care at: https://connectwithcare.org/telehealth-legislation/

[174] Center for Medicaid and CHIP Services (CMCS), CMS. (2022, 6). Preparedness and Response Toolkit for State Medicaid and CHIP Agencies in the Event of a Public Health Emergency or Disaster. Retrieved from CMCS, CMS: https://www.medicaid.gov/state-resource-center/downloads/mac-learning-collaboratives/medicaid-chip-disastertoolkit.pdf#page=42&zoom=100,93,96

[175] *Id.*

of most virtual care or the "telehealth cliff."[176] Telehealth laws and regulations will continue developing and the telehealth industry needs to keep tracking the dynamic changes in telehealth.

iii. Data Privacy & Cyber Security

Telehealth technology and telecommunications require extensive and thorough reviews of the Health Insurance Portability and Accountability Act (HIPAA), the Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule"), cybersecurity, data privacy and management, and patient consent.[177] The goal is to protect individuals' identifiable health information and their rights, and to allow the "flow of health information needed to provide and promote high-quality health care and protect the public's health and wellbeing."[178] HIPAA and the Privacy Rule protect the privacy of individuals seeking healthcare services and permit important use of health information.[179] HIPAA includes the detailed requirements for group health plans for the parties, including "plan sponsor, health insurance issuer, or HMO", or "a covered entity that performs multiple covered functions that would make the entity any combination of a health plan, a covered health care provider, and a health care clearinghouse."[180] HIPAA guides "Security Standards for the Protection of Electronic Protected Health Information" with a matrix as per Table 1 "Appendix A to Subpart C - Security Standards for the Protection of Electronic Protected Health Information" of Part 164 - Security Standards: Matrix in the Appendix.[181]

Worldwide, healthcare providers, employers, and any organizations that work with individual patients, employees, and consumers, must comply with all jurisdictional laws and regulations relating to data privacy and data security, such as the European Union's (EU's) General Data Protection Regulation (GDPR) and Canada's Personal Information Protection and Electronic Documents Act (PIPEDA), to protect personally identifiable information (PII) such as IP addresses, email addresses, date of birth, personal contacts, or company information.[182] [183]

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[176] Reed, A. (2022, 3 25). More Telehealth Data Urged Before Making Eased Rules Permanent. Retrieved from Bloomberg Law at: https://news.bloomberglaw.com/coronavirus/more-telehealth-data-urged-before-making-eased-rules-permanent

[177] Byrne, M. D. (2020, 10 1). Telehealth and the COVID-19 Pandemic. INFORMATICS AND HEALTH INFORMATION TECHNOLOGY, 35(5), 548-551. DOI: https://doi.org/10.1016/j.jopan.2020.06.023

[178] The Joint Commission. (2011, 10). Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care for the Lesbian, Gay, Bisexual, and Transgender (LGBT) Community: A Field Guide. Retrieved from Joint Commission at: https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/health-equity/lgbtfieldguide_web_linked_verpdf.pdf?db=web&hash=FD725DC02CFE6E4F21A35EBD839BBE97&hash=FD725DC02CFE6E4F21A35EBD839BBE97

[179] *Id.*

[180] 45 C.F.R. § 164.102-164.534. Title 45 was last amended on 7/15/2022.

[181] 45 C.F.R. § 164.302-164.318

[182] Regulation (EU) 2016/679

[183] One Trust Data Guidance & Edwards, Kenny & Bray LLP. (n.d.). Comparing Privacy Laws: GDPR v. PIPEDA. Retrieved 7 23, 2022, from:
One Trust Data Guidance: https://www.dataguidance.com/sites/default/files/gdpr_v_pipeda.pdf

a. HIPAA Flexibilities During the Pandemic [184]

HIPAA Compliance Flexibilities & Exceptions were compiled by the Center for Medicaid and CHIP Services (CMCS) in 2022 as below in Chart 5 Table K HIPAA Compliance.[185]

Chart 5

Table K: HIPAA Compliance

Available flexibilities and exceptions	Authorities and sources	Notes on implementation and necessary state action
Temporarily suspend application of sanctions and penalties arising from non-compliance with HIPAA requirements to/related to: • Obtain a patient's agreement to speak with family members or friends; • Honor a request to opt out of the facility directory; • Distribute a notice; • The patient's right to request privacy restrictions; • The patient's right to request confidential communications; • Use existing permissions and flexibilities in the HIPAA Rules that apply in emergencies and other circumstances.	section 1135 waiver 1135 Waiver - At A Glance HIPAA Special Topics (Emergency Situations: Preparedness, Planning, and Response) 45 CFR 160 and 164, 85 FR 19392 (Apr. 7, 2020) HHS Office for Civil Rights, Guidance on HIPAA, Health Information Exchanges, and Disclosures of Protected Health Information for Public Health Purposes, Dec. 18, 2020 HHS OCR guidance, HIPAA and Contacting Former COVID-19 Patients about Plasma Donation, Aug. 20, 2020 HHS OCR guidance, COVID-19 and HIPAA: Disclosures to law enforcement, paramedics, other first responders and public health authorities, March 24, 2020	Seek section 1135 waiver. Waivers for HIPAA requirements are limited to the 72-hour period beginning upon implementation of a hospital disaster protocol.

During the COVID-19 pandemic, Illinois, Louisiana, North Carolina, and Washington applied for Medicaid Section 1135 Waivers to allow healthcare providers to use non-HIPAA-compliant modes, such as Facetime, WhatsApp, and Skype.[186]

b. Potential Solutions

One effective solution is for healthcare providers to sign a Business Associate Agreement (BAA) with associated parties to hold the parties responsible for patients' data when the data are "tampered with, misused, lost or stolen."[187] [188] During the COVID-19 pandemic, the U.S. Department of Health and Human Services (HHS) directed healthcare providers to use HIPAA-

[184] Department of Health and Human Services (HHS). (n.d.). FAQs on Telehealth and HIPAA during the COVID-19 nationwide. Retrieved 6 28, 2022, from HHS at: https://www.hhs.gov/sites/default/files/telehealth-faqs-508.pdf
[185] Center for Medicaid and CHIP Services (CMCS), CMS. (2022, 6). Preparedness and Response Toolkit for State Medicaid and CHIP Agencies in the Event of a Public Health Emergency or Disaster. Retrieved from CMCS, CMS at: https://www.medicaid.gov/state-resource-center/downloads/mac-learning-collaboratives/medicaid-chip-disastertoolkit.pdf#page=42&zoom=100,93,96
[186] *Id*
[187] 45 C.F.R. § 164.504 (e)
[188] Pexip Holding ASA. (2020). How Video is Shaping the Future of Telemedicine. Oslo, Norway: Pexip Holding ASA. Retrieved from https://www.pexip.com/hubfs/20201229_Pexip_WhitePaper_Telemedicine_final.pdf

compliant technology vendors, who can provide "HIPAA-compliant video communication products" and who will "enter into a HIPAA business associate agreement."[189]

The U.S. Department of Veterans Affairs (VA) uses telehealth-approved programs, secure connections, and encrypted data to protect veterans' and their family members' medical and personal data.[190] The VA has a privacy policy, including some key features that the VA "will never sell or rent personal information to outside parties", and uses "web analysis tools (e.g., cookies) for limited uses authorized in this policy."[191]

According to Fortune Business Insights, blockchain technology is a good opportunity for healthcare providers to guard patients' data for safe and proficient data management, storage, and access control.[192] In May 2018, a telehealth platform, MyClinic.com, was launched, where MedTokens can be used for payment.[193] Data and software companies like BurstIQ, now provide data management platforms for healthcare providers, using blockchain technology while strictly complying with HIPAA rules, such as "the right to control your health information disclosures."[194]

iv. Cross State Line or Multi-State Licensing

As discussed in Section III Barriers, multi-state licensing is one of the barriers to telehealth, and in Section V Legal Reviews we discussed the flexibilities during the COVID-19 pandemic, including licensure flexibilities. As of June 15, 2022, 39 states and Washington D.C. ended the PHE, while 13 states kept licensure flexibilities in place until a later date.[195] For example, the Vermont legislation extends waivers through June 30, 2023, and Indiana extends out-of-state healthcare registration through the duration of the federal PHE.[196] Minnesota's legislation permits out-of-state healthcare providers to perform telemedicine services after they register in the state.[197] California still has waivers on both telehealth and licensure.[198]

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[189] Health Resources & Services Administration (HRSA). (2021, 1 28). *HIPAA flexibility for telehealth technology.* Retrieved from HHS at: https://telehealth.hhs.gov/providers/policy-changes-during-the-covid-19-public-health-emergency/hipaa-flexibility-for-telehealth-technology/

[190] U.S. Department of Veterans Affairs. (n.d.). What Is Telehealth? Retrieved 6 23, 2022, from U.S. Department of Veterans Affairs at: https://telehealth.va.gov/what-telehealth

[191] U.S. Department of Veterans Affairs. (n.d.). Privacy, policies, and legal information Retrieved 6 26, 2022, from U.S. Department of Veterans Affairs: https://www.va.gov/privacy-policy/

[192] Fortune Business Insights. (2021). Connected Healthcare Market Report. Fortune Business Insights. Retrieved from https://www.fortunebusinessinsights.com/connected-healthcare-market-106192

[193] *Id.*

[194] *Id.*

[195] Alliance for Connected Care. (2022, 6 15). COVID-19 State Telehealth and Licensure Expansion Dashboard. Retrieved from Alliance for Connected Care at: https://connectwithcare.org/state-telehealth-and-licensure-expansion-covid-19-chart/

[196] *Id.*

[197] Minnesota Statute §147.032

[198] *Id.*

a. Potential Solutions

Some states have offered special telemedicine licenses; for example, New Mexico had issued around 250 telemedicine licenses, mainly to teleradiologists till 2014.[199] New Mexico issues telemedicine licenses to out-of-state healthcare providers, who "hold a full license in another state and meet New Mexico standards for good moral character."[200] Service companies and platforms are now hired to handle the paperwork for healthcare providers in all the states with reasonable fees.[201]

In 2018, the Department of Veterans Affairs released final regulation for VA healthcare providers only, excluding VA contractors, to expand telehealth services within their scope of practice to veterans and families, without state limitations.[202] This allows VA healthcare providers to offer telehealth services across states by preempting state licensing requirements.[203]

The other solution is via various interstate licensure compacts, as depicted by Chart 6 below from the Center for Connected Health Policy (CCHP).[204] It allows healthcare providers to practice in another state through a licensure compact via different approaches.[205] The Interstate Medical Licensure Compact makes the medical licensing process expedited for physicians.[206] The Physical Therapy Compact and the Recognition of EMS Personnel Licensure Interstate Compact (REPLICA) both allow "Compact Privilege" to physical therapists or EMS personnel.[207] The Psychology Interjurisdictional Compact (PSYPACT) gives psychologists the authority to practice inter-jurisdictional telepsychology.[208]

The Nurse Licensure Compact (NLC) allows nurses with multi-state licenses to practice in 37 states.[209] According to the most updated information from NCSBN, 39 Jurisdictions now have enacted NLC legislation, and four states have pending NLC legislation.[210] The APRN Compact is another compact allowing advanced nurses interstate practice privileges, being newly adopted in August 2020, and waiting for seven states to activate it.[211]

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[199] Ronald S. Weinstein, M. L. (2014, 3). Telemedicine, Telehealth, and Mobile Health Applications That Work: Opportunities and Barriers. The American Journal of Medicine, 127(No. 3), 183-187. DOI: https://doi.org/10.1016/j.amjmed.2013.09.032

[200] eVisit. (2019, 10). New Mexico Telemedicine Information. Retrieved from eVisit: https://evisit.com/state-telemedicine-policy/new-mexico/#:~:text=While%20New%20Mexico%20is%20not,for%20%E2%80%9C good%20moral%20character.%E2%80%9D

[201] Ronald S. Weinstein, M. L. (2014, 3). Telemedicine, Telehealth, and Mobile Health Applications That Work: Opportunities and Barriers. The American Journal of Medicine, 127(No. 3), 183-187. DOI: https://doi.org/10.1016/j.amjmed.2013.09.032

[202] Center for Connected Health Policy (CCHP). (n.d.). Telehealth Policy 101. (Public Health Institute) Retrieved 7 2, 2022, from CCHP: https://www.cchpca.org/policy-101/

[203] *Id.*

[204] *Id.*

[205] *Id.*

[206] *Id.*

[207] *Id.*

[208] *Id.*

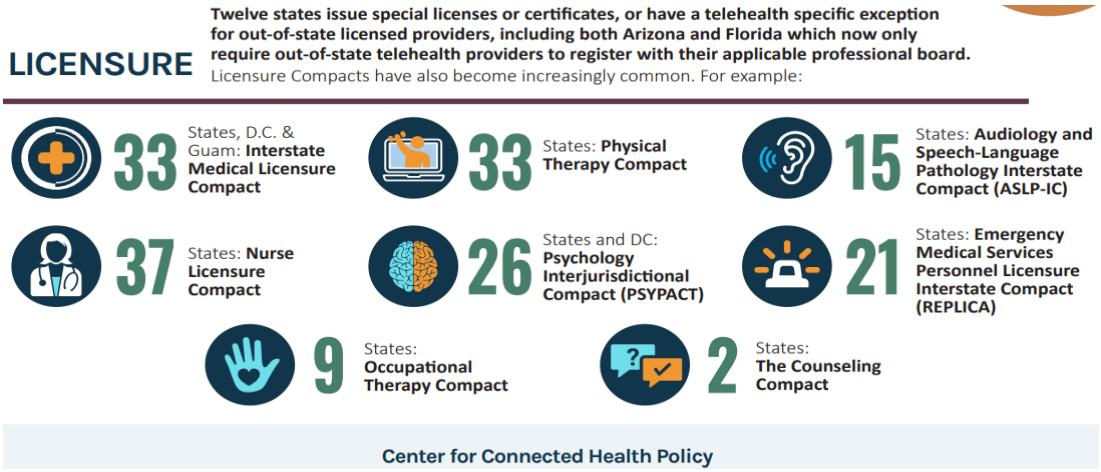
[209] NCSBN. (n.d.). Nurse Licensure Compact (NLC). Retrieved 7 17, 2022, from NCSBN: https://www.ncsbn.org/nurse-licensure-compact.htm

[210] *Id.*

[211] *Id.*

Some compacts are waiting for more states to activate them, including the Occupational Therapy Compact, and Audiology and Speech-Language Pathology Interstate Compact (ASLP-IC), while other compacts are in development, such as the ones for Licensed Marriage and Family Therapists and Licensed Professional Counselors.[212]

Chart 6 – Licensure Compacts from CCHP [213]



VI. NEW TRENDS AND RESOURCES

"The Coronavirus Aid, Relief, and Economic Security Act (CARES Act), a part of the federal response to the COVID-19 pandemic, ear-marked 29 million dollars per year for 4 years in grant funding to expand telehealth infrastructure, while the Federal Communications Commission identified $200 million in funds available for the purchasing of telehealth hardware and software. "[214] Payers and employers are increasingly aware of the long-term costs of behavioral health issues so more grants and public funding are available, especially for the transition to telehealth.[215] The KPMG 2022 investment outlook report showed investors' strong confidence that telehealth will be widely used, especially in behavioral health.[216] Through acquisitions of smaller platforms, mega platforms are available in telehealth, especially with

[212] Center for Connected Health Policy (CCHP). (n.d.). Telehealth Policy 101. (Public Health Institute) Retrieved 7 2, 2022, from CCHP: https://www.cchpca.org/policy-101/
[213] Center for Connected Health Policy (CCHP). (2021, Fall). State Telehealth Medicaid Policy Trends. Retrieved from CCHP: https://www.cchpca.org/2021/10/Fall2021_Infographic_FINAL.pdf
[214] Byrne, M. D. (2020, 10 1). Telehealth and the COVID-19 Pandemic. INFORMATICS AND HEALTH INFORMATION TECHNOLOGY, 35(5), 548-551. doi: https://doi.org/10.1016/j.jopan.2020.06.023
[215] Kristin Ciriello Pothier, R. N. (2022). Investing in a future transformed by the pandemic: 2022 Healthcare and Life Sciences Investment Outlook. Retrieved from KPMG LLP: https://institutes.kpmg.us/content/dam/institutes/en/healthcare-life-sciences/pdfs/investing-future-transformed-by-pandemic-hcls-2022.pdf?cm_ven=ExactTarget&cm_cat=7014W000001G20eQAC+NS1_HC+JPM+Outlook+Autoresp+Email1+2-7-2022+28001&cm_pla=All+Subscribers
[216] *Id.*

more connected devices for virtual healthcare, including the new investment in ambulatory, post-acute, and acute care, in addition to wearables and home-monitoring equipment.[217]

i. Enhancing Coordination Across HHS

In May 2021, the U.S. Department of Health and Human Services (HHS) formed a new Behavioral Health Coordinating Council (BHCC) to serve as a coordinating body across the Department.[218] One of the five BHCC focus areas includes child and youth behavioral health: "$10 million for the Pediatric Mental Health Care Access Program, which will continue to support the development or improvement of statewide or regional pediatric mental health care telehealth access programs." [219] "These programs provide teleconsultations, training, technical assistance, and care coordination for pediatric primary care providers to assist in their work in managing children with behavioral health conditions." [220]

As stated in the 2023 Payment Notice, starting in the 2023 plan year, CMS will collect data from QHPs on which of their in-network providers offer telehealth services.[221] For this purpose, CMS defines telehealth as "professional consultations, office visits, and office psychiatry services through brief communication technology-based service/virtual check-in, remote evaluation of pre-recorded patient information, and inter-professional internet consultation."[222]

ii. Target Groups for Telehealth Delivery

In Section III Limitations of Telehealth, we mentioned that not all healthcare services are suitable to use telehealth. The GoodRx 2021 report shows that patients have been using telehealth for behavioral or mental healthcare, chronic care treatment, acute emergency care, skin care or dermatology, and others. [223] Anthem describes the following situation as more suitable for virtual care, available 24/7 without an appointment and with a shorter waiting time of an average of 10 minutes, including "flu-like symptoms, allergies, fever, sinus infection, diarrhea, eye infection, skin infection, rash, urinary tract infection (UTI)." [224]

Here are two examples of how telehealth benefits target groups with the trend of telehealth delivery, including veterans and youth with two successful or groundbreaking programs: a) Indiana Behavioral Health Access Program ("Be Happy") and b) Colorado "I

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[217] *Id.*
[218] White House. (2021, 10 19). FACT SHEET: Improving Access and Care for Youth Mental Health and Substance Use Conditions. Retrieved from White House: https://www.whitehouse.gov/briefing-room/statements-releases/2021/10/19/fact-sheet-improving-access-and-care-for-youth-mental-health-and-substance-use-conditions/
[219] *Id.*
[220] *Id.*
[221] HHS. (2022, 4 28). 2023 Final Letter to Issuers in the Federally Facilitated Exchanges. Retrieved from CMS: https://doi.sc.gov/DocumentCenter/View/13796/2023-Final-Letter-to-Issuers
[222] *Id.*
[223] Guttentag, S. (2021, 11 15). The State of Telehealth, According to Healthcare Providers and Patients. Retrieved from GoodRx, Inc.:
https://www.goodrx.com/healthcare-access/telehealth/state-of-telehealth-survey-2021?source=email
[224] Anthem Insurance Companies, Inc. (n.d.). Where To Go When You Need Care. Retrieved 7 20, 2022, from Anthem at: https://www.anthem.com/member-resources/urgent-care#PatientCare

Matter" Program. They are important groups for employers to consider providing more support. This demonstrates how much state and federal governments and various organizations can help promote the health and well-being of broader populations via telehealth.

a. Veterans

The U.S. Department of Veterans Affairs (VA) is one of the largest telehealth providers in the US.[225] In 2021, over 2 million veterans received care through VA telehealth.[226] The VA offers telehealth services via Facility Telehealth Coordinators in local facilities from community-based outpatient clinics (CBOC) to VA medical centers, and by VA specialists from regional telehealth hubs.[227] It partners with vendors to offer digital health tools including My HealtheVet and VA Mobile Apps.[228] Via the My HealtheVet website, veterans patients can fill prescriptions, track appointments, message non-emergency situations and questions, access VA medical records, and get educational and health promotion information on mental health and healthy living from Healthy Living Centers.[229]

b. The Youth

As per the U.S. surgeon general, mental health has been the leading concern of youth, whose ages range from 3 to 17 years old, who have mental, emotional, developmental, or behavioral disorders with 1 in 5 ratios.[230] Reports state high school students have persistent feelings of sadness or hopelessness at a higher ratio of 1 to 3, increased by 40% from 2009 to 2019.[231] From 2009 to 2019 suicidal behaviors of high school students increased by 36% with 19% seriously considering attempting suicide, and increased by 44% with 16% making suicide plans.[232] Suicide is the second main cause of death among youth aged from 10 to 24.[233] The National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH) awarded $3.6 million to researchers for the "Supporting Pediatric Research on Outcomes and Utilization of Telehealth (SPROUT) Collaborative" from the American Academy of Pediatrics.[234] The SPROUT-Clinical & Translational Science Awards (CTSA) is "to create a network to develop, test and broadly disseminate an evidence-based pediatric telehealth research

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[225] U.S. Department of Veterans Affairs. (n.d.). What Is Telehealth? Retrieved 6 23, 2022, from U.S. Department of Veterans Affairs: https://telehealth.va.gov/what-telehealth

[226] *Id.*

[227] *Id.*

[228] *Id.*

[229] *Id.*

[230] Indiana University. (2021, December 16). $2.7M grant will help pediatric primary care providers address youth mental health needs. Retrieved from Indiana University: https://news.iu.edu/stories/2021/12/iu/releases/16-grant-pediatric-primary-care-providers-youth-mental-health.html

[231] *Id.*

[232] *Id.*

[233] Guttentag, S. (2021, 11 15). The State of Telehealth, According to Healthcare Providers and Patients. Retrieved from GoodRx, Inc.:
https://www.goodrx.com/healthcare-access/telehealth/state-of-telehealth-survey-2021?source=email

[234] National Center for Advancing Translational Sciences (NCATS). (2022, 3 23). NCATS Funds Network to Improve the Use of Telehealth in Children's Health Care. Retrieved from National Institutes of Health (NIH) at: https://ncats.nih.gov/pubs/features/sprout-ctsa

model."[235] It will evaluate pediatric telehealth services, determine the impact on healthcare quality, identify best practices, remove barriers to the future success of telehealth in pediatric healthcare, and establish a network for research in this area.[236]

a) Indiana's Behavioral Health Access Program ("Be Happy")

Healthcare providers lack training and support from behavior specialists or mental health consultations to properly address the social, emotional, and behavioral needs and development of youth, which may even go in an opposite direction to rely on "punitive and exclusionary forms of discipline (e.g., suspensions and expulsions)." [237] In Indiana, the availability of child psychiatrists is lower than in most other states in the United States, ranking number 48.[238]

Indiana University School of Medicine now offers the Indiana Behavioral Health Access Program ("Be Happy") to youth and their families in Indiana.[239] The program guides healthcare providers with resources from psychiatric specialists to provide the best practices of pediatric behavioral healthcare within local communities at no cost.[240] The program includes "assessment, diagnostic clarification, medication management, treatment planning, and other pediatric mental health questions", and referral services to find evidence-based treatment programs available locally.[241]

The Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) awarded $2.6 million to this program, as part of "the American Rescue Plan Act's Pediatric Mental Health Care Access New Area Expansion."[242] The new grant will use telehealth consultations to increase statewide healthcare providers' accessibility and provide online education sessions through the "Child and Adolescent Mental Health ECHO program".[243] Until 2021, 570 healthcare providers across Indiana registered with the "Be Happy" Program, and 1,079 consultation calls were arranged for various services relating to "anxiety disorders, attention deficit hyperactivity disorder and depression", including "medication questions, therapy/behavioral intervention questions, and diagnostic questions/evaluations."[244]

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[235] *Id.*
[236] *Id.*
[237] Department of Education. (n.d.). Supporting Child and Student Social, Emotional, Behavioral, and Mental Health Needs. Retrieved 6 27, 2022, from:
Department of Education: https://www2.ed.gov/documents/students/supporting-child-student-social-emotional-behavioral-mental-health.pdf
[238] Indiana University School of Medicine. (n.d.). Indiana Behavioral Health Access Program for Youth. Retrieved 6 27, 2022, from Indiana University School of Medicine: https://medicine.iu.edu/psychiatry/clinical-care/integrated/behavioral-health
[239] Indiana University School of Medicine. (n.d.). Indiana Behavioral Health Access Program for Youth. Retrieved 6 27, 2022, from Indiana University School of Medicine: https://medicine.iu.edu/psychiatry/clinical-care/integrated/behavioral-health
[240] *Id.*
[241] *Id.*
[242] Indiana University. (2021, December 16). $2.7M grant will help pediatric primary-care providers address youth mental health needs. Retrieved from Indiana University at: https://news.iu.edu/stories/2021/12/iu/releases/16-grant-pediatric-primary-care-providers-youth-mental-health.html
[243] *Id.*
[244] *Id.*

b) Colorado "I Matter" Program

Colorado's Governor Polis signed the Behavioral Health Administration (BHA) bill (House Bill 22-1278) into law, officially establishing BHA to launch on July 1, 2022.[245] BHA as a new state agency will offer the "I Matter" program to "provide access to free mental health and substance use disorder services for youth…such as heightened anxiety and fear and constant transitions between online and in-person classes."[246] The groundbreaking program provided over 1,300 therapy sessions since the fall of 2021 and has already scheduled hundreds more appointments.[247] Youth and their families can do everything online, including brief mental health screenings, therapist selection, scheduling, three to six free 45-minute therapy sessions, and additional support by care navigators, so they do not need to drive far to attend in-person sessions.[248]

iii. Development, Resources & Emerging Business Models

According to Ernst & Young Global Limited (EY), the future forecast is that connected health applications and telehealth will play a broadened role in effectively managing and overseeing chronic conditions including diabetes and mental health for certain United States healthcare consumers, probably between 30% and 45%.[249] In 2021, there were three large merger and acquisition deals in MedTech companies relating to the expansion of digital health and telehealth capabilities with enhanced remote care options, including a) "Philips purchased BioTelemetry, a maker of digital patient monitoring platforms and AI-based analytics, for US$2.8 billion;"[250] b) "Boston Scientific announced a US$1.3 billion buy-out of Preventice Solutions, which designs remote monitoring services and mobile health solutions for cardiac arrhythmia patients;"[251] and, c) in December 2021 Baxter International Inc. (Baxter) acquired Hillrom for $12.5 Billion, using "its combined expertise in connectivity technology and integration, digital health solutions, data visualization and analytics, therapy development, and monitoring and sensing to build a connected system that surrounds the patient and their care team."[252] Recent mergers and acquisitions demonstrate that healthcare delivery will be transformed by companies that lead collaboration between connectivity and technology.

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[245] Colorado Department of Human Services. (2022, 5 25). Bill to establish Behavioral Health Administration signed into law. Retrieved from State of Colorado: https://cdhs.colorado.gov/press-release/bill-to-establish-behavioral-health-administration-signed-into-law

[246] Colorado Department of Human Services. (2022, 1 26). I Matter program gains momentum, addresses growing stress and anxiety facing youth. Retrieved from State of Colorado: https://cdhs.colorado.gov/press-release/i-matter-program-gains-momentum-addresses-growing-stress-and-anxiety-facing-youth

[247] *Id.*

[248] *Id.*

[249] Jim Welch, H. M. (2022, 05 01). Pulse of the industry - Medical technology report 2021. Retrieved from Ernst & Young Global Limited: https://www.ey.com/en_us/life-sciences/pulse-of-the-industry

[250] *Id.*

[251] *Id.*

[252] Baxter International Inc. (2021, 12 13). Baxter Completes Acquisition of Hillrom, Creating ~$15 Billion Global Medtech Leader. Retrieved from Baxter International Inc. (NYSE: BAX): https://www.baxter.com/baxter-newsroom/baxter-completes-acquisition-hillrom-creating-15-billion-global-medtech-leader

The telehealth industry has been developing rapidly with dynamic changes in healthcare services, new technologies, and new participants entering the market or engaging in mergers and acquisitions. One development in 2022 is for companies to engage with other companies' platforms or devices to provide virtual healthcare services more conveniently. Here, we will explore some projects, developments, and resources in the telehealth arena, among many other rapid developments in connection with new technology deployment. Examples include a) Project ECHO as a global telementoring and training center with a speak-and-hub model,[253] b) SteadyMD as a Business-to-Business (B2B) telehealth provider for 50-state clinicians and licensing and credentialing platform,[254] c) Teladoc Health as a direct-to-consumer (D2C) or whole-person virtual care model,[255] and d) Hinge Health in the employer musculoskeletal (MSK) market.

a. Project ECHO

Project ECHO uses video conferencing and telementoring to educate and train healthcare professionals in rural, underserved, and under-resourced areas on the best ways to provide high-quality specialty care.[256] Project ECHO was launched in 2003 for New Mexicans' needs and now covers global communities in Africa, Latin America, India, and more.[257] Project ECHO created over 3,000 programs, covering over 600 training centers, with participants from over 180 countries, and now hopes to reach one billion people by 2025.[258]

Project ECHO's knowledge-sharing model offers a learning framework for continuous learning, mentoring, and peer support.[259] The model studies cases in the real world, shares best practices to reduce disparity, uses technology for more resources, and analyzes data for result monitoring.[260] Now Project ECHO focuses on global healthcare, education, and climate change.[261]

b. SteadyMD

SteadyMD provides a tech-enabled and board-certified clinician workforce, legal and regulatory guidance, and telehealth software as a partner to organizations (Business to Business or B2B model), including "employers, healthcare organizations, labs and diagnostics companies,

[253] Project ECHO. (n.d.). About Project ECHO. Retrieved 6 22, 2022, from The University of New Mexico: https://hsc.unm.edu/echo/about-us/
[254] Landi, H. (2022, 6 21). SteadyMD snags BlocHealth to bolster clinician licensing, and credentialing services. Retrieved from FIERCE Healthcare: https://www.fiercehealthcare.com/health-tech/steadymd-snags-blochealth-bolster-clinician-licensing-credentialing-services
[255] Teladoc Health, Inc. (n.d.). Who we are. Retrieved from Teladoc: https://www.teladochealth.com/about/
[256] Project ECHO. (n.d.). About Project ECHO. Retrieved 6 22, 2022, from The University of New Mexico: https://hsc.unm.edu/echo/about-us/
[257] *Id.*
[258] *Id.*
[259] *Id.*
[260] *Id.*
[261] *Id.*

pharmacies, payers, and digital health brands."[262] SteadyMD recently announced its acquisition of BlocHealth in June 2022 to increase the capability of providing clinician licensing and payer enrollment with medical credentialing.[263] After the acquisition, SteadyMD will provide "state license registration, payer enrollment, renewals, DEA/CSR registration, primary source verification, ongoing monitoring, and smart notifications."[264] This deal will make SteadyMD "the first telehealth infrastructure provider to offer both a 50-state clinician workforce and a full-service licensing and credentialing platform" as an end-to-end solution for healthcare administrations.[265]

c. Teladoc

Teladoc Health, Inc. (Teladoc) is the world leader in whole-person virtual care, and now it has over 5,000 employees with a global footprint in over 20 countries.[266] According to the J.D. Power 2019 and 2021 surveys, Teladoc ranked Number 1 in the direct-to-consumer (D2C) brand category.[267] Teladoc serves more than 100 United States health plans and over half of the Fortune 500 companies.[268] In October 2020, Teladoc acquired Livongo for $18.5 billion to accelerate remote monitoring and other telehealth deliveries.[269] In February 2022, Teladoc announced they would be launching their service on Amazon Echo products so American patients who have Echo products at home can now easily receive calls back from Teladoc doctors for non-emergency health needs, at an affordable cost of $75 without insurance or $0 with insurance.[270] This recent collaboration between Teladoc and Amazon demonstrates the companies' willingness to share platforms and devices to provide virtual healthcare services more conveniently to more populations.

d. Hinge Health in Employer MSK Market

According to the 2020 Business Group on Health employer survey, "one in two people in the United States is experiencing musculoskeletal (MSK) pain and this consumes 1 in 6 healthcare dollars for large employers and $600 billion for the U.S. economy overall."[271] MSK

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[262] Landi, H. (2022, 6 21). SteadyMD snags BlocHealth to bolster clinician licensing, credentialing services. Retrieved from FIERCE Healthcare: https://www.fiercehealthcare.com/health-tech/steadymd-snags-blochealth-bolster-clinician-licensing-credentialing-services

[263] *Id.*

[264] *Id.*

[265] *Id.*

[266] Teladoc Health, Inc. (n.d.). Who we are. Retrieved from Teladoc: https://www.teladochealth.com/about/

[267] Teladoc Health, Inc. (2022). *Virtual Care Transformation Study: Insights from organizations at every stage in the virtual care journey.* Purchase, NY: Teladoc Health, Inc. Retrieved from https://assets.ctfassets.net/l3v9j0ltz3yi/6Q0hA0muWRcElhEahIXQRJ/967cbe4eee238c8caa9d14745673ed0c/Virtual_Care_Transformation_Study-_Insights_from_organizations_at_every_stage_in_the_virtual_care_journey.pdf

[268] Teladoc Health, Inc. (n.d.). Who we are. Retrieved from Teladoc: https://www.teladochealth.com/about/

[269] Fortune Business Insights. (2021). Connected Healthcare Market Report. Fortune Business Insights. Retrieved from https://www.fortunebusinessinsights.com/connected-healthcare-market-106192

[270] Teladoc Health, Inc. (2022, 2 28). Teladoc Health and Amazon Team Up to Launch Teladoc on Alexa. Retrieved from GlobeNewswire: https://www.globenewswire.com/news-release/2022/02/28/2393250/0/en/Teladoc-Health-and-Amazon-Team-Up-to-Launch-Teladoc-on-Alexa.html

[271] Heather, L. (2022, 7 14). Bucking the economic downturn, Hinge Health charts strong growth, stretching its reach in the employer MSK market. Retrieved from Fierce Healthcare: https://www.fiercehealthcare.com/health-tech/bucking-economic-downturn-hinge-health-charts-strong-growth-stretching-its-reach

is one of the top three drivers of healthcare costs, as per the Centers for Disease Control & Prevention (CDC) and the National Health Interview Survey.[272] According to FIERCE Healthcare, 10% of employers have an MSK solution, and 70% plan to adopt a digital MSK solution in the following years.[273] Hinge Health operates digital MSK clinics and physical therapy services, and provides services to over 750 employers while working with new employers and health plans from various industries "across the e-commerce, home improvement, technology and automotive sectors as well as many retirement and state health systems."[274]

VII. OPERATIONALIZING TELEHEALTH FOR EMPLOYERS

i. Health Plans for Employees with Telehealth

As of 2016, there were around "5,600 registered hospitals, two hundred health plans, and thousands of large employers" in the United States.[275] With respect to incorporating telehealth into employer-sponsored health insurance, there are three key transactional convergence areas: health systems with their plans, health plans with their providers, and employers directly contracting with providers.[276] According to the Business Group on Health, during the COVID-19 pandemic, large employers tried to offer accessible and affordable healthcare to employees, with 74% eliminating cost sharing for telemedicine.[277]

Insurance programs offered by employers to their employees and families vary greatly, based on many factors: the size of the company, the number of employees, the type of industry and the location of operations, to name a few. Plan design and benefits offerings can take many forms and require continual changes to coverage and offerings to make employers competitive in the area of human resource retention and recruitment. Thus, renewed interest and acceptance of telehealth coverage offers individuals and employees additional coverage options.

a. High Deductible Health Plan (HDHP)

Employers' health plans could impact the fee structures with telehealth providers.[278] Employee deductibles must be met before medical services can be covered and reimbursed under high deductible health plans (HDHP).[279] If preferred provider organization plans (PPO) as another type of employers' health plan, there is no fee structure restriction without high deductible requirements.[280] During the COVID-19 pandemic, "Section 3701 of the CARES Act

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[272] *Id.*
[273] *Id.*
[274] *Id.*
[275] Scott, B. C. (2016). Convergence in Healthcare: Providers, Employers, and Health Plans. Am Health Drug Benefits, 9 (2), 66–67. Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4856231/
[276] *Id.*
[277] Business Group on Health. (2020, 8 18). 2021 Plan Design Survey: Employer Perspectives on the Health Care Landscape. Retrieved from Business Group on Health: https://www.businessgrouphealth.org/resources/2021-plan-employerdesign-survey-employer-perspectives-on-the-health-care-landscape
[278] Nick J. Welle, T. B. (2020, 3 31). COVID-19: New Law Allows Free Telehealth without Blowing Tax Benefits of Health Savings Accounts. Retrieved from Foley & Lardner LLP: https://www.foley.com/en/insights/publications/2020/03/covid19-law-free-telehealth-tax-benefits-hsa
[279] *Id.*
[280] *Id.*

creates a temporary safe harbor allowing HDHPs to cover telehealth services and other remote care without cost to plan members before plan members' deductibles are met" before January 1, 2022.[281] The IRS provided "Covid-19 Guidance Under § 125 Cafeteria Plans And Related To High Deductible Health Plans."[282]

b. FMLA

In December 2020, the Department of Labor (DOL) released Field Assistance Bulletin (FAB) No. 2020-8 relating to "Telemedicine and Serious Health Conditions under the Family and Medical Leave Act (FMLA)."[283] "The FMLA provides eligible employees of covered employers with unpaid, job-protected leave for specified family and medical reasons" for up to 12 work weeks within 12 months.[284] FAB No. 2020-8 confirmed that employees can use FMLA leave for telehealth as in-person visits under 29 C.F.R. §825.115 with criteria of "an examination, evaluation, or treatment by a health care provider; be permitted and accepted by state licensing authorities; and, generally, should be performed by video conference."[285]

ii. Telehealth Considerations for Employers

a. Mature IT Integration and Governance

As discussed in Section III, "Barriers to Telehealth Development," infrastructure and technology are areas worth funding to develop telehealth and expand its utilization. How will employers and healthcare providers consider IT integration and governance with investment strategy and how can they bring governance along for future IT in the digital era?[286] There are five critical factors for mature IT governance in the digital era, including 1) cross-organizational engagement; 2) strategic prioritization of investment; 3) integration of technology, business systems, and processes, and customer experience to emphasize simplification, automation, and measurement to align organizationally shared accountability; 4) optimization of oversight, by evaluating regulation, risks, and opportunities, and stakeholders' interest; and, 5) a balance of "trust, value contribution, and measurable progress toward future IT strategies."[287] It is important to balance the strategies with a focus on data by optimizing analytics and utilizing artificial intelligence (AI), emerging social environments and issues, and affordable and economic ways.[288]

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[281] *Id.*
[282] IRS Notice 2020-29
[283] Department of Labor (DOL). (2021, 12 29). FIELD ASSISTANCE BULLETIN No. 2020-8. Retrieved from DOL: https://www.dol.gov/sites/dolgov/files/WHD/legacy/files/fab_2020_8.pdf
[284] 29 U.S.C. § 2612(a)(1)(C)-(D), and 29 CFR § 825.112(a)(3)-(4)
[285] Department of Labor (DOL). (2021, 12 29). FIELD ASSISTANCE BULLETIN No. 2020-8. Retrieved from DOL: https://www.dol.gov/sites/dolgov/files/WHD/legacy/files/fab_2020_8.pdf
[286] Calder, A. (2022, 3). IDC PlanScape: Mature Governance for Future IT. Retrieved from IDC Corporate USA: https://www.idc.com/getdoc.jsp?containerId.=US48946922&pageType=PRINTFRIENDLY
[287] *Id.*
[288] *Id.*

b. Health Equity in Telehealth

The U.S. Department of Health and Human Services (HHS) states that "Health equity in telehealth is the opportunity for everyone to receive the healthcare they need and deserve, regardless of social or economic status. Providing health equity in telehealth means making changes in digital literacy, technology, and analytics."[289] Several groups who are underserved would need to increase healthcare access and services via telehealth.[290] Here is an example of using telehealth for the group of Lesbian, Gay, Bisexual, Transgender, Queer, Asexual, and other identities (LGBTQ+) for employers' health plan considerations.[291]

Telehealth is a great channel to offer health equity and deliver the necessary healthcare remotely to LGBTQ+ patients from healthcare providers taking health equity into consideration and without discrimination.[292] LGBTQ+ groups may have higher stress, depression, mental health issues, and suicide attempts, especially when they face discrimination or violence.[293] Accordingly, healthcare providers and employers need to consider extra care needs from experts and specialists, without implicit bias and/or assumptions.[294] It may require specialists in certain areas, such as hormone therapy or prescriptions, fertility treatment, HIV/AIDS/STIs prevention, treatment and management, gender affirmation or plastic surgery, and behavioral health specialists and psychiatrists for counseling and therapy.[295] Healthcare providers need to be LGBTQ+ friendly and have subject matter experts to provide LGBTQ+ related information.[296] When it is appropriate, healthcare providers may need to connect individuals with specialists who know their unique needs.[297] LGBTQ+ patients require privacy and confidentiality for healthcare visits.[298] Healthcare providers need to provide a comprehensive enrollment process to identify the needs and provide unique care during virtual visits.[299] Healthcare providers should offer LGBTQ+ health education or training as part of the telehealth workflow.[300]

The Centers for Disease Control & Prevention (CDC) suggests preferred terms for select population groups and communities, such as for sexual orientation and gender identity,

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[289] Health Resources & Services Administration (HRSA). (2022, 6 3). Health equity in telehealth. Retrieved from HHS: https://telehealth.hhs.gov/providers/health-equity-in-telehealth/

[290] *Id.*

[291] Health Resources & Services Administration (HRSA). (2021, 10 8). Telehealth for LGBTQ+ Patients. Retrieved from HHS: https://telehealth.hhs.gov/providers/health-equity-in-telehealth/telehealth-for-lgbtq-patients/

[292] *Id.*

[293] Anthem Insurance Companies, Inc. (2021, 6 16). LGBTQ+ Healthcare: Building a Better Future. Retrieved from Anthem at: https://www.anthem.com/blog/living-healthy/lgbtq-healthcare-building-a-better-future/

[294] *Id.*

[295] *Id.*

[296] *Id.*

[297] *Id.*

[298] The Joint Commission. (2011, 10). Advancing Effective Communication, Cultural Competence, and Patient- and Family-Centered Care for the Lesbian, Gay, Bisexual, and Transgender (LGBT) Community: A Field Guide. Retrieved from Joint Commission at: https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/health-equity/lgbtfieldguide_web_linked_verpdf.pdf?db=web&hash=FD725DC02CFE6E4F21A35EBD839BBE97&hash=FD725DC02CFE6E4F21A35EBD839BBE97

[299] *Id.*

[300] *Id.*

considering gender-neutral language, inclusive of all gender identities, pronouns, and terms (e.g., Singular they or their, or He/she/they), but no gendered and binary language.[301]

c. Vendor Selection & Management

Understanding Health Plans: Employers should know the health plans, what health plans can offer on telehealth, and what healthcare providers can offer in local communities and hospitals.[302] Most cities have some hospitals offering telehealth services.[303] If telehealth is not offered by local hospitals, employers can contract or partner with telehealth providers.[304]

Screening Telehealth Providers: Employers should consider a good average utilization rate from telehealth providers, such as the number of visits divided by the enrollment total, normally between 20% and 30%.[305] Telehealth services from health plan providers should include performance guarantees in the contract, assigned account manager and service teams, monthly reporting, and continual education of telehealth to the employees.[306]

MSK Management: Mix in-person therapy, virtual coaching, and self-care to help employees recover from MSK injuries and pains so digital tools can "supplement in-person therapy to aid injury prevention, recovery, and post-injury maintenance."[307]

Data Security and Privacy: Healthcare providers as selected vendors need to have safeguards in place to ensure de-identification or masking of employees' data.[308] The safeguards also need to protect employees' identity, including security systems for processing personal information, cloud-based computing and analytical tools, and ethical artificial intelligence (AI) tools with usage policies.[309] Healthcare providers need to be trained regularly on "privacy principles and appropriate ways to gather, store, use and ultimately govern this information."[310]

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[301] Centers for Disease Control and Prevention (CDC). (n.d.). Preferred Terms for Select Population Groups & Communities. Retrieved 7 10, 2022, from CDC: https://www.cdc.gov/healthcommunication/Preferred_Terms.html

[302] Roundstone Insurance. (n.d.). How to Screen a Telemedicine Provider. Retrieved 7 20, 2022, from Roundstone Insurance: https://roundstoneinsurance.com/wp-content/uploads/2020/05/Screening-a-Telemedicine-Provider_may2020.pdf

[303] *Id.*

[304] *Id.*

[305] *Id.*

[306] *Id.*

[307] Bardavon Health Innovations. (2022, 7 7). Why a Mix of In-person Therapy, Virtual Coaching, and Self Care Are Key to Helping Workers Recover from Musculoskeletal Injuries. Retrieved from Risk & Insurance: https://riskandinsurance.com/sponsored-why-a-mix-of-in-person-therapy-virtual-coaching-and-self-care-are-key-to-helping-workers-recover-from-musculoskeletal-injuries/

[308] Kelly, A. (2022, 2 16). 4 Questions for a Data Science Innovator. Retrieved from Johnson & Johnson Services, Inc.: https://www.jnj.com/innovation/questions-for-a-healthcare-data-scientist

[309] *Id*

[310] *Id.*

d. Checklist Template for Employers

While this checklist is designed to consider the normal workflow of vendor selection, setup, and management by healthcare facilities and provider organizations, and as a guide for their implementation of digital health solutions, it can serve as a template for employers who want to incorporate telehealth in employee benefit plans, with reference to the American Medical Association (AMA) Telehealth Implementation Playbook.[311]

- Evaluate employees' and families' needs, including groups for veterans, youth, LGBTQ+, and others with chronic conditions such as diabetes patients.
- Sign confidentiality agreement/non-disclosure agreement with vendors.
- Define vendors' service scope and key performance indicators (KPIs), including health outcomes, employee experience, reduced costs, and healthcare providers' satisfaction. [312]
- Check vendors' financials, including year-end audited financial reports and bonds.
- Check vendors' compliance management and if any red flags or the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) exclusions.
- Check vendors' credentialing and licensing with cross-state licensing.
- Check vendors' IT setup and process for cyber security and data privacy, including risk assessment and resilience plans.
- Check vendors' apps and platforms for 510(k) clearance: Authorization from the FDA that a device is safe and effective or at least "substantially equivalent" to what is already on the market. [313]
- Check vendors' reputations, business partners, and insurance.
- Check vendors' network, workflow, and process flow, especially the integration of digital technology into the clinical workflow. [314]
- Set up vendors – sign master service agreement (MSA) and business associate agreements (BAA) for HIPAA compliance to protect employees' and families' private health information (PHI), and for liabilities, if any data breach. [315]
- Design policies and process flows.
- Audit both employers' telehealth programs and vendors' telehealth services for validation of compliance with HIPAA rules and data security and privacy practices, e.g., HITRUST.[316]
- Identify common use cases of telehealth and the situations not suitable for telehealth.
- Communicate regularly with employees, including the announcement of telehealth programs coverage and fees, information on network and billing and payment structure, registration, and enrollment, annual usage satisfaction surveys, etc.
- Provide education and training to employees and their families, including telehealth knowledge and information sharing, hotlines, and online training programs.

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[311] American Medical Association (AMA). (2020). Telehealth Implementation Playbook. Retrieved from AMA: https://www.ama-assn.org/system/files/2020-04/ama-telehealth-implementation-playbook.pdf
[312] *Id.*
[313] *Id.*
[314] *Id.*
[315] *Id.*
[316] *Id.*

- Ongoing vendor management and regular data collection and evaluation for telehealth usage trends for employers to continue seeking improvement of telehealth programs and better coverage, including the number of visits, type of services, and top causes.

VIII. CONCLUSIONS

Telehealth is a great combination of healthcare providers' specialties and technology development to offer healthcare to consumers and patients in broad areas. This paper has explored recent developments impacting telehealth legal and compliance considerations, especially during the COVID-19 pandemic, compared the trend of telehealth usage before and during the pandemic, and explored the new market direction for telehealth with emerging business models. It has proposed some practical approaches and a checklist for employers to consider when implementing or expanding telehealth programs in their health plan benefits. It has also highlighted telehealth legal and compliance considerations for employers to consider as they embrace a new decade of changes in healthcare.

Telehealth is a great platform and approach. Now, right after the pandemic and during the PHE wind down, is the time to analyze the data and evaluate where and how telehealth can be utilized and maximized. The telehealth industry still needs new laws and regulations to maintain telehealth flexibilities, remove key barriers, and support further development and adoption. The legal and regulatory environment is ready and ripe for changes and employers have the opportunity to create new partnerships, offerings, and collaborations.

Due to the COVID-19 pandemic and associated public health emergencies, the United States and worldwide businesses have identified and accepted that a broadened healthcare delivery system, one which embraces and covers telehealth services, is a positive improvement to employee health and wellbeing. Employers must now encourage employees to take advantage of covered telehealth services and telehealth offerings.

Employers should collaborate with healthcare providers to discuss plan design that integrates telehealth programs and services into standard plan designs. Working with health plan designers, employers can collect aggregated information and data that support advanced health plan design. Health plan vendors who act as partners with employers can design plans and incorporate data collection, analysis, and reporting that benefit both the employers and the employees.

Telehealth is a new and renewed approach to healthcare. Employers have the opportunity to lead broad-based improvement in individuals' health and wellbeing by embracing and using new tools and technologies and relying on expert advice on new health plan offerings. Cost savings for employers, convenience for employees, and service for underserved areas have all been shown to improve health and the perception of advanced health insurance offerings.

IX. APPENDIX

Section V Legal & Compliance Reviews iii. Data Privacy & Cyber Security
Table 1 Appendix A to "Subpart C - Security Standards for the Protection of Electronic Protected Health Information" of Part 164 - Security Standards: Matrix [317]
Quote

Standards Sections	Implementation	Specifications (R) = Required, (A) = Addressable
Administrative Safeguards		
Security Management Process	164.308(a)(1)	Risk Analysis (R)
		Risk Management (R)
		Sanction Policy (R)
		Information System Activity Review (R)
Assigned Security Responsibility	164.308(a)(2)	(R)
Workforce Security	164.308(a)(3)	Authorization and/or Supervision (A)
		Workforce Clearance Procedure Termination Procedures (A)
Information Access Management	164.308(a)(4)	Isolating Health care Clearinghouse Function (R)
		Access Authorization (A)
		Access Establishment and Modification (A)
Security Awareness and Training	164.308(a)(5)	Security Reminders (A)
		Protection from Malicious Software (A)
		Log-in Monitoring (A)
		Password Management (A)
Security Incident Procedures	164.308(a)(6)	Response and Reporting (R)
Contingency Plan	164.308(a)(7)	Data Backup Plan (R)
		Disaster Recovery Plan (R)
		Emergency Mode Operation Plan (R)
		Testing and Revision Procedure (A)
		Applications and Data Criticality Analysis (A)
Evaluation	164.308(a)(8)	(R)
Business Associate Contracts and Other Arrangement	164.308(b)(1)	Written Contract or Other Arrangement (R)
Physical Safeguards		
Facility Access Controls	164.310(a)(1)	Contingency Operations (A)
		Facility Security Plan (A)
		Access Control and Validation Procedures (A)
		Maintenance Records (A)
Workstation Use	164.310(b)	(R)
Workstation Security	164.310(c)	(R)

[317] 45 C.F.R. § 164.302-164.318

Device and Media Controls	164.310(d)(1)	Disposal (R)
		Media Re-use (R)
		Accountability (A)
		Data Backup and Storage (A)
Technical Safeguards		
Access Control	164.312(a)(1)	Unique User Identification (R)
		Emergency Access Procedure (R)
		Automatic Logoff (A)
		Encryption and Decryption (A)
Audit Controls	164.312(b)	(R)
Integrity	164.312(c)(1)	Mechanism to Authenticate Electronic Protected Health Information (A)
Person or Entity Authentication	164.312(d)	(R)
Transmission Security	164.312(e)(1)	Integrity Controls (A)
		Encryption (A)

Unquote