

REWIRING MENTAL HEALTH: LEGAL AND REGULATORY SOLUTIONS FOR THE EFFECTIVE IMPLEMENTATION OF TELEPSYCHIATRY AND TELEMENTAL HEALTH CARE

Allison N. Winnike¹ and Bobby Joe Dale III²

I. INTRODUCTION..... 22

II. WANDERING IN THE WILDERNESS: A CRITICAL NEED FOR MENTAL HEALTH CARE ACCESS 25

 A. Prevalence of Mental Illness 26

 B. Cost of Mental Illness 28

 C. Barriers to Access: Stigma and Health Disparities..... 31

 D. Shortage of Mental Health Professionals 40

 E. Access to Telecommunications 41

¹ Research Assistant Professor and Research Director, Health Law & Policy Institute, University of Houston Law Center; B.A., Rice University; J.D., Georgetown University Law Center. I express deep appreciation and gratitude to my co-author Bobby Joe Dale III for his excellent work. I wish to thank the Honorable Mignon Clyburn, Lex Frieden, Leonard Baynes, Dr. Francisco Fernandez, Karen Onyeije, and all at the Connect2Health^{FCC} Task Force and University of Houston Law Center who assisted with Broadband Prescriptions for Mental Health: A Policy Conference. Special thanks to Jessica Roberts, Jessica Mantel, and the editors of the *Houston Journal of Health Law & Policy* for their support, comments, and assistance. Thank you, my dear family and friends, for your enduring love and encouragement.

² Doctor of Jurisprudence candidate, University of Houston Law Center, 2017.

III. ENTERING THE MAZE OF FEDERAL AND STATE REGULATIONS: THE STRUGGLE OF EMERGING MENTAL HEALTH TECHNOLOGIES	42
A. Is Telepsychiatry the Answer? Arguments from the Broadband Prescriptions for Mental Health: A Policy Conference	43
B. Legal and Regulatory Framework for Telepsychiatry.....	46
C. Theseus Confronts the Regulatory Minotaur: Mental Health Technology Innovators	83
IV. THREADING THE LABYRINTH: POLICY PRESCRIPTIONS TO UTILIZE TELEPSYCHIATRY AND TELEMENTAL HEALTH CARE SERVICES TO IMPROVE MENTAL HEALTH CARE ACCESS AND OUTCOMES	88
A. Reimbursement.....	89
B. Geographic Disparities in Access to Care.....	90
C. Privacy and Confidentiality	92
D. Broadband Availability and Access.....	93
E. Standard of Care	94
F. Mental Health Physician Shortage	95
G. Provider Training.....	97
H. Licensure	97
I. Collaborative Care	99
J. Regulation of Mental Health Apps as Medical Devices	100
CONCLUSION	102

I. INTRODUCTION

Telepsychiatry and telemental health care services, which use broadband technology to connect patients with health care providers, provide an opportunity to address growing concerns³ over mental

³ See, e.g., Brianna Ehley, *Obamacare and Mental Health: An Unfinished Story*, POLITICO (July 13, 2016, 5:33 AM), <http://www.politico.com/story/2016/07/obamacare-mental-health-225445> (observing, “America’s mental health system is having a breakdown. Suicide rates are at a record high; drug addiction is epidemic. There aren’t enough therapists, particularly not enough who accept insurance. And too often the most vulnerable and severely ill end up on the streets, or fill our prisons and jails.”); see also Sarah Chamberlin, *Delivering Action on Mental*

health care access and appropriate care in the United States. This technology shatters conventional geographic and temporal barriers by giving patients in-home access to mental health professionals the moment their health care needs arise.⁴ By reducing geographic barriers and eliminating transportation costs and lost work time, telepsychiatry improves access for a range of patients, such as residents of rural and underserved areas, patients with mobility issues, and patients with inadequate resources.⁵ Telepsychiatry promises to improve the quality of and access to mental health care; enhance the efficient use of mental health care resources; and save money for patients, providers, and insurers.⁶

Despite years of safe and effective use of telemedicine and telehealth⁷ technology, an array of inharmonious federal and state laws and regulations, as well as a thicket of unresolved policy issues,⁸ hamper its effective implementation. In the telemedicine and telehealth narrative, the use of such remote broadband technology in the mental and behavioral health care sphere is unique. Telepsychiatry⁹—the use of telecommunications technologies to

Health, HILL (June 13, 2016), <http://thehill.com/blogs/pundits-blog/healthcare/283254-delivering-action-on-mental-health>.

⁴ Mignon Clyburn, Comm'r, Fed. Comm'ns Comm'n, Remarks at Broadband Prescriptions for Mental Health: A Policy Conference 35 (May 18, 2016) (transcript available at <https://www.fcc.gov/file/4029/download>).

⁵ *Id.*

⁶ *Id.*

⁷ There are numerous definitions of telemedicine and telehealth and the terms are often used interchangeably. We define telemedicine as the use of telecommunications technologies to remotely connect patient and physician. We define telehealth more broadly to include remote connections between a patient and a variety of health care providers beyond physicians, encompassing such health professionals as nurses, psychologists, social workers, pharmacists and others. For a discussion on varying definitions of telehealth and telemedicine, see Rene Y. Quashie & Ross K. Friedberg, *Navigating the Telehealth Landscape: Legal & Regulatory Issues*, BLOOMBERG BNS HEALTH L. & BUS. SERIES 1050 (2014); WORLD HEALTH ORG., TELEMEDICINE: OPPORTUNITIES AND DEVELOPMENTS IN MEMBER STATES: REPORT ON THE SECOND GLOBAL SURVEY ON EHEALTH 8–9 (2010), http://www.who.int/goe/publications/goe_telemedicine_2010.pdf.

⁸ See Piper Ranallo et al., *Behavioral Health Information Technology: From Chaos to Clarity*, 35 HEALTH AFFS. 1106, 1106 (2016).

⁹ *Telepsychiatry*, AM. PSYCHIATRIC ASS'N, <https://www.psychiatry.org/psychiatrists/practice/telepsychiatry> (last visited Mar. 24, 2017).

remotely connect patient and psychiatrist – and telemental health care services¹⁰ – the use of such technologies to connect a patient with a broad array of mental health professionals – are sometimes subject to distinct rules to reflect differences in care delivery. Mental health care services can be delivered without physical manipulation of the patient by a health care provider. This significant difference in care delivery allowed mental health professionals to utilize telemedicine and telehealth to a greater extent than in other medical fields.¹¹ As a result, a patchwork of rules and exceptions for telepsychiatry exist at the state and federal level.¹²

This article examines the policy issues surrounding effective telepsychiatry adoption and use, with particular care given to issues discussed at the Broadband Prescriptions for Mental Health: A Policy Conference, presented by the Federal Communications Commission Connect2Health^{FCC} Task Force and the University of Houston Law Center Health Law & Policy Institute on May 18, 2016. The policy conference convened a diverse array of experts and stakeholders who identified emerging issues and opportunities in using the transformative power of broadband to connect consumers with mental health services.¹³ This article begins with a discussion of the critical need to improve mental health care access with an illustration of gaps and disparities in the mental health care delivery system in the United States. Part III confronts the complex legal and regulatory framework impacting telepsychiatric care at the federal and state levels. We discuss the impact of recent legal battles, the Federal Communications Commission (FCC) Connect2Health^{FCC} Task Force's efforts to use the transformative power of broadband to connect consumers with mental health services, and emerging mental health technologies unveiled at the Broadband Prescriptions for Mental Health: A Policy Conference

¹⁰ Univ. of Colo. Denver, *What is Telemental Health?*, TELEMENTAL HEALTH GUIDE, http://www.tmhguide.org/site/epage/87548_871.htm (last visited Mar. 24, 2017).

¹¹ See Brian Grady, *Promises and Limitations of Telepsychiatry in Rural Adult Mental Health Care*, 11 *WORLD PSYCHIATRY* 199 (2012).

¹² See *Telehealth Policy Trend and Considerations*, NAT'L CONF. ST. LEGISLATURES, <http://www.ncsl.org/documents/health/telehealth2015.pdf> (last visited Mar. 24, 2017).

¹³ Program materials, including a transcript and video, are available online at <http://www.law.uh.edu/fcchealth/> and <https://www.fcc.gov/news-events/events/2016/05/broadband-prescriptions-mental-health-policy-conference>.

on mental health care access. Part IV addresses potential legal and regulatory hurdles impacting effective adoption of telemedicine and telehealth services for mental health patients with a targeted range of policy prescriptions to facilitate effective implementation of telepsychiatry and telemental health care services to improve mental health care access and outcomes.

II. WANDERING IN THE WILDERNESS: A CRITICAL NEED FOR MENTAL HEALTH CARE ACCESS

The United States faces a mental health care crisis of unprecedented proportions, with nearly one in five adults experiencing some type of mental illness.¹⁴ Despite significant policy modifications to increase mental health parity and integrate mental and physical care,¹⁵ patients continue to experience stigmatization and barriers to access as a result of mental health professions shortages and inadequately funded mental health programs.¹⁶ Disparities in broadband access, Internet subscription rates, and digital literacy hamper efforts to deploy telemental health services to address the crisis.¹⁷ Subpart A describes the prevalence of mental illness in the United States. Subpart B details the cost of mental illness in the United States. Subpart C analyzes disparities of access to identify target populations for policy intervention. Subpart D then examines the national, regional, and state shortages of physicians that contribute to

¹⁴ In 2015, an estimated 43,421,000 adults had a diagnosable mental, behavioral, or emotional disorder, which comprises 17.9% of the population. *See* CTR. FOR BEHAVIORAL HEALTH STATISTICS & QUALITY, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., RESULTS FROM THE 2015 NATIONAL SURVEY ON DRUG USE AND HEALTH: DETAILED TABLES, 2503-2504 tbls.8. 1A & 8.1B (Sept. 8, 2016), <http://www.samhsa.gov/data/sites/default/files/NSDUH-DefTabs-2015/NSDUH-DefTabs-2015/NSDUH-DefTabs-2015.pdf>.

¹⁵ See discussion of ACA essential health benefits and MHPAEA parity below 15-16.

¹⁶ *See, e.g.*, Brian Henry, Dir. of Telehealth, Univ. of Tex. Med. Branch, Remarks at Broadband Prescriptions for Mental Health: A Policy Conference 107-09 (May 18, 2016) (transcript available at <https://www.fcc.gov/file/4029/download>).

¹⁷ *See, e.g.*, Sharon Stroker, Professor & Dir., Univ. of Tex., Tech. & Info. Policy Inst., Remarks at Broadband Prescriptions for Mental Health: A Policy Conference 88-89 (May 18, 2016) (transcript available at <https://www.fcc.gov/file/4029/download>).

the current mental health care crisis. Subpart E highlights disparities in broadband access, subscription, and digital literacy.

A. Prevalence of Mental Illness

More than forty-three million Americans—approximately eighteen percent of the population—experienced some type of mental illness in the past year.¹⁸ Of these, one in twenty-five adults, or four percent, suffer from mental illness so severe that it seriously impairs their daily life activities.¹⁹ Among the most prevalent illnesses are anxiety disorders, including panic disorder, post-traumatic stress disorder (PTSD), obsessive-compulsive disorder (OCD), and phobias; major depression; bipolar disorder; and schizophrenia.²⁰ Many patients experience co-occurring mental illnesses, spanning into behavioral health issues; forty-one percent of the 19.5 million U.S. adults with a substance use disorder also suffer from a co-occurring mental illness.²¹

In our case study examining the state of Texas, over 500,000 adults and 250,000 children suffer from serious mental illness.²² Among adults, 1.7 million of Texas' veterans have been identified as

¹⁸ In 2015, an estimated 43,421,000 adults had a diagnosable mental, behavioral, or emotional disorder, which comprises 17.9% of the population. See CTR. FOR BEHAVIORAL HEALTH STATISTICS & QUALITY, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., *supra* note 14.

¹⁹ In 2015, an estimated 9,765,000 adults had a diagnosable mental, behavioral, or emotional disorder resulting in serious functional impairment, which comprises 4 percent of the population. See CTR. FOR BEHAVIORAL HEALTH STATISTICS & QUALITY, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., *supra* note 14, at 2509–2510 tbls.8.4A & 8.4B.

²⁰ See *Burden of Mental Illness*, CTR. FOR DISEASE CONTROL & PREVENTION (Oct. 4, 2013), <https://www.cdc.gov/mentalhealth/basics/burden.htm>; *Mental Health by the Numbers*, NAT'L ALLIANCE ON MENTAL ILLNESS, <http://www.nami.org/Learn-More/Mental-Health-By-the-Numbers> (last visited Nov. 23, 2016).

²¹ In 2015, an estimated 19,577,000 adults had a diagnosable substance use disorder involving alcohol or illicit drugs, which comprises 8.1% of the population. An estimated 8,069,000 adults have co-occurring substance use disorder and a diagnosable mental, behavioral, or emotional disorder, which is 41.2% of adults with substance abuse disorder. See CTR. FOR BEHAVIORAL HEALTH STATISTICS & QUALITY, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., *supra* note 14, at 1504–05 tbls.5.3A & 5.3B, 2545–46 tbls.8.22A & 8.22B.

²² *Overview of Mental Health: Hearing Before House Select Committee on Mental Health*, 84th Sess. 3 (Tex. 2016) (presentation of Sonja Gaines, Assoc. Comm'r, Tex. Health & Human Servs. Comm'n), <http://www.legis.state.tx.us/tlodocs/84R/handouts/C3822016021810001/bbf3829e-f919-49e3-aafa-f18bcd16833.PDF>.

potentially requiring mental health treatment.²³ Among children in the Texas Department of Family Protective Services' custody, over fifty percent of the 32,000 children suffer from a diagnosed mental illness.²⁴ Roughly fifty percent of young adults in Texas' juvenile justice system require mental health treatment.²⁵ Further, an estimated eighty percent of these young adults require substance use treatment.²⁶ Among Texas' children placed in special education, over 26,000 have been diagnosed with an emotional disturbance.²⁷

Mental illness may occur at higher rates for some communities, including distinct geographic regions, racial and ethnic minority groups, and prison populations. For example, among the 400,000 predominantly Hispanic individuals living in the over 2,290 *colonias*²⁸ along the Texas-Mexico Border,²⁹ common mental and behavioral health issues include depression, compulsive behaviors, and family and domestic violence.³⁰ In addition, harsh and dehumanizing immigration enforcement actions contribute to higher rates of PTSD among families living in border areas.³¹

Prisons are increasingly becoming default psychiatric treatment centers, at great cost to the public and inmates, and that trend is seen in our case study examination of telemental health care in Texas,

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ See *What is a Colonia*, TEX. SECRETARY STATE, http://www.sos.state.tx.us/border/colonias/what_colonia.shtml (last visited Sept. 3, 2016) (defining a *colonia* as "a residential area along the Texas-Mexico border that may lack some of the most basic living necessities, such as potable water and sewer systems, electricity, paved roads, and safe and sanitary housing.").

²⁹ *Colonias FAQs (Frequently Asked Questions)*, TEX. SECRETARY STATE, <http://www.sos.state.tx.us/border/colonias/faqs.shtml> (last visited Sept. 3, 2016).

³⁰ Francisco Fernandez, Dean, Univ. of Tex. Rio Grande Valley Med. Sch., Remarks at Broadband Prescriptions for Mental Health: A Policy Conference 79-80 (May 18, 2016) (transcript available at <https://www.fcc.gov/file/4029/download>).

³¹ Cecelia Ayon, *Economic, Social, and Health Effects of Discrimination on Latino Immigrant Families*, MIGRATION POL'Y INST. 13 (2014), <http://www.migrationpolicy.org/sites/default/files/publications/FCD-Ayon.pdf>.

whose prison system is the largest in the country.³² “Texas has among the worst records in the country for jailing people who are mentally ill rather than helping them in treatment centers.”³³ An estimated twenty-three percent of Texans with involvement in the criminal justice system have a mental illness.³⁴ Alarming, the Harris County Jail, “[where] about 2,400 inmates are taking psychotropic medications[,] . . . is the largest mental institution in Texas”³⁵ and holds more mentally ill inmates than the state mental hospital.³⁶ Among incarcerated Texans, forty-one percent suffer from bipolar disorder, thirty-one percent from a major depressive disorder, and twenty-five percent from schizophrenia and related disorders.³⁷

B. Cost of Mental Illness

Ultimately, failure to address the U.S. mental health crisis imposes significant economic, health care, and social costs on the country. In total, the United States loses almost a trillion dollars each year in combined mental health care costs and lost earnings as a result of serious mental illness.³⁸ According to Department of Justice estimates, the United States spends \$15 billion annually to incarcerate the mentally ill.³⁹ In Texas, incarcerating a prisoner with mental illness

³² KIDEUK KIM ET AL., URBAN INST., THE PROCESSING AND TREATMENT OF MENTALLY ILL PERSONS IN THE CRIMINAL JUSTICE SYSTEM 11 (2015), <http://www.urban.org/sites/default/files/alfresco/publication-pdfs/2000173-The-Processing-and-Treatment-of-Mentally-Ill-Persons-in-the-Criminal-Justice-System.pdf>.

³³ Nancy Churnin, *Texas Leading Country in Putting More Mentally Ill in Jails than Treatment Centers, We Can and Must Change That*, DALL. MORNING NEWS (Apr. 8, 2014), <http://healthblog.dallasnews.com/2014/04/from-the-we-can-do-better-file-texas-has-more-mentally-ill-in-jails-than-treatment-centers.html/>.

³⁴ DECISION SUPPORT UNIT, TEX. DEP'T. OF STATE HEALTH SERVS., ANOTHER LOOK AT MENTAL ILLNESS AND CRIMINAL JUSTICE INVOLVEMENT IN TEXAS: CORRELATES AND COSTS 5 (2010).

³⁵ Brandi Grissom, *As Mental Health Cuts Mount, Psychiatric Cases Fill Jails*, N.Y. TIMES (Feb. 24, 2011), http://www.nytimes.com/2011/02/25/us/25tmentalhealth.html?_r=0.

³⁶ *Texas Failing Inmates with Mental Illness, New Study Finds*, NAT'L ALLIANCE ON MENTAL ILLNESS AUSTIN (Apr. 8, 2014), <http://www.namiaustin.org/2014/04/texas-failing-inmates-with-mental-illness-new-study-finds/>.

³⁷ DECISION SUPPORT UNIT, TEX. DEP'T. OF STATE HEALTH SERVS., *supra* note 34, at 6.

³⁸ Clyburn, *supra* note 4, at 34.

³⁹ TREATMENT ADVOCACY CTR., JAILS AND PRISONS 2, Apr. 2009, http://www.treatmentadvocacycenter.org/storage/documents/jails_and_prisons-apr_09.pdf.

costs between \$30,000 and \$50,000 per year, which is a 36% to 127% increase over the cost of incarceration for an inmate without mental illness.⁴⁰

Lack of adequate mental health resources contributes to overall health care costs. Individuals with serious mental illness are more likely to have a chronic medical condition⁴¹ and to seek care in emergency departments.⁴² In fact, sixty-eight percent of individuals with a mental illness have another co-occurring medical condition.⁴³ Additionally, individuals with mental illness tend to use emergency rooms more than the general populations and to make multiple visits.⁴⁴ In 2007 alone, almost twelve million emergency room visits in the United States were for adults suffering from mental illness or substance use.⁴⁵

Additionally, the U.S. mental health crisis imposes significant social costs.⁴⁶ These costs manifest in unacceptably high rates of suicide, incarceration, and homelessness. Every year, more than 40,000 people commit suicide.⁴⁷ Suicide is the second highest cause of death for people between ages fifteen and twenty-four and the tenth highest cause of death overall.⁴⁸ Veterans are particularly susceptible to

⁴⁰ OFF. OF RES. & PUB. AFFS., TREATMENT ADVOCACY CTR., SERIOUS MENTAL ILLNESS (SMI) PREVALENCE IN JAILS AND PRISONS 3, Sept. 2016, <http://www.treatmentadvocacycenter.org/storage/documents/backgrounders/smi-in-jails-and-prisons.pdf>.

⁴¹ Benjamin G. Druss & Elizabeth Reisinger Walker, *Mental Disorders and Medical Comorbidity*, 21 RES. SYNTHESIS REP. 4, Feb. 2011, http://www.integration.samhsa.gov/workforce/mental_disorders_and_medical_comorbidity.pdf.

⁴² BAZELON CTR. FOR MENTAL HEALTH LAW, INCREASED EMERGENCY ROOM USE BY PEOPLE WITH MENTAL ILLNESSES CONTRIBUTES TO CROWDING AND DELAYS 1, <http://www.bazelon.org/LinkClick.aspx?fileticket=Epvwc7WBOHg%3D&tabid=386> (last visited Sept. 4, 2016).

⁴³ Druss & Walker, *supra* note 41.

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ Clyburn, *supra* note 4, at 34.

⁴⁷ Clyburn, *supra* note 4, at 33.

⁴⁸ NAT'L CTR. FOR INJURY PREVENTION & CONTROL, CTRS. FOR DISEASE CONTROL & PREVENTION, 10 LEADING CAUSES OF DEATH BY AGE GROUP, UNITED STATES - 2014 (Jan. 28, 2016), https://www.cdc.gov/injury/wisqars/pdf/leading_causes_of_death_by_age_group_2014-a.pdf.

suicide, with an estimated twenty veterans committing suicide each day.⁴⁹

Untreated mental illness also increases criminal justice costs through crime, provision of mental health care to the incarcerated, and recidivism. Individuals with untreated mental illness are eight times more likely to be incarcerated.⁵⁰ By sheer number of confined individuals with mental illness, “the nation’s jails and prisons have become . . . the nation’s largest psychiatric hospitals.”⁵¹ In terms of direct health care costs, state prisons spent between five and forty-three percent of their health care budgets on mental health care in 1998.⁵² At the same time, overall prison health care spending appears to be rising approximately ten percent per year.⁵³

During incarceration, individuals suffering from mental illness exhibit higher likelihoods of misconduct and accidents.⁵⁴ As a result, untreated mental illness costs the criminal justice system in “staff time spent on discipline, physical and pharmaceutical resources spent subduing violent prisoners, and treatment associated with injuries incurred in fights.”⁵⁵ Individuals with mental illness are more likely to reoffend, resulting in re-incarceration and increased criminal justice costs. In a study conducted in Texas, inmates with mental illness were “2.4 times more likely to have four or more repeat incarcerations” than inmates without mental illness.⁵⁶ One study in Utah found that inmates with “severe mental illness returned to prison . . . nearly one full year . . . sooner than offenders without diagnosed mental illness.”⁵⁷ In contrast, some states actively target funding to reduce recidivism costs resulting from mental illness. For example, Washington’s

⁴⁹ VA Suicide Prevention Program Facts About Veteran Suicide, U.S. DEP’T VETERANS AFF., http://www.va.gov/opa/publications/factsheets/Suicide_Prevention_FactSheet_New_VA_Stats_070616_1400.pdf (last visited July 5, 2017).

⁵⁰ *Overview of Mental Health: Hearing Before H. Select Comm. on Mental Health*, *supra* note 22.

⁵¹ TREATMENT ADVOCACY CTR., *supra* note 39, at 1.

⁵² KIM ET AL., *supra* note 32.

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ *Id.* at 12.

⁵⁷ *Id.*

Dangerously Mentally Ill Offender program, which provides treatment during incarceration and for a maximum of five years after release for severely mental ill patients, produces an estimated \$20,000 savings per inmate in terms of crime averted.⁵⁸

Lastly, untreated mental illness creates an increased risk of homelessness. An estimated one-third of all homeless individuals suffer from mental illness.⁵⁹ One study found that in service costs alone, homelessness costs \$20 million annually in mental health care, social services, and criminal justice costs.⁶⁰ Over eighty percent of the chronically homeless individuals in the study suffered from serious mental illness.⁶¹

C. Barriers to Access: Stigma and Health Disparities

Mental illness affects broad swaths of the population who receive health care through a variety of systems,⁶² further highlighting major barriers to access resulting from stigmatization and health disparities in several vulnerable populations. Americans living in the southern United States face some of the lowest rates of access to care for the mentally ill.⁶³ In Texas, access to mental health care is particularly difficult for the elderly, veterans, the incarcerated, those with physical or mental disabilities, those with limited English proficiency, the homeless and housing insecure, and children.⁶⁴ Immigrants and certain racial minorities also face heightened barriers to accessing

⁵⁸ *Id.* at 14.

⁵⁹ OFF. OF RES. & PUB. AFFS., TREATMENT ADVOCACY CTR., SERIOUS MENTAL ILLNESS AND HOMELESSNESS 1 (Sept. 2016), <http://www.treatmentadvocacycenter.org/storage/documents/backgrounders/smi-and-homelessness.pdf>.

⁶⁰ Stephen R. Poulin et al., *Service Use and Costs for Persons Experiencing Chronic Homelessness in Philadelphia: A Population-Based Study*, 61 PSYCHIATRIC SERVS. 1093, 1093 (2010).

⁶¹ *Id.*

⁶² *Overview of Mental Health: Hearing Before H. Select Comm. on Mental Health*, *supra* note 22.

⁶³ *See Ranking the States*, MENTAL HEALTH AM., <http://www.mentalhealthamerica.net/issues/mental-health-america-prevalence-data> (last visited Feb. 1, 2017).

⁶⁴ *Overview of Mental Health: Hearing Before H. Select Comm. on Mental Health*, *supra* note 22.

mental health care.⁶⁵ Lastly, vulnerable populations living in rural⁶⁶ or urban low-income areas⁶⁷ encounter barriers to access to mental health care.

1. Stigma Surrounding Mental Illness

Mental health advocates have long sought to eliminate the stigma surrounding mental illness, which hampers willingness for patients to seek treatment and health benefit plans from providing parity coverage. As a result of stigma against individuals suffering from mental illness, individual, community, and legal and policy barriers have developed that discourage effective treatment.⁶⁸ On an individual level, people suffering from mental illness often avoid seeking treatment or drop out during treatment to avoid being labeled as mentally ill⁶⁹ due to “low perceived need”⁷⁰ or “a desire to handle the problem on one’s own.”⁷¹ Ultimately, more than seventy percent of individuals receiving mental health treatment drop out prematurely.⁷²

Further, community stigma from families and even health care providers discourages individuals with mental illness from seeking care.⁷³ Families of individuals with mental illnesses often experience negative stereotypes and alienation from others within their social

⁶⁵ See Catherine DeCarlo Santiago et al., *Poverty and Mental Health: How Do Low-Income Adults and Children Fare in Psychotherapy?*, 69 J. CLINICAL PSYCH. 115, 118 (2012).

⁶⁶ Alexandra Ginsberg, *The Mental and Behavioral Health Needs of Rural Communities*, AM. PSYCH. ASS’N. (May 13, 2014), <https://www.apa.org/about/gr/issues/gpe/rural-communities.pdf>.

⁶⁷ See LESLIE FOSTER, HEALTH CARE COVERAGE AND ACCESS FOR CHILDREN IN LOW-INCOME FAMILIES: STAKEHOLDER PERSPECTIVES FROM TEXAS 6–8 (Jan. 2016), https://www.packard.org/wp-content/uploads/2016/02/Health-Care-Coverage-and-Access-for-Children_Texas.pdf.

⁶⁸ Patrick W. Corrigan et al., *The Impact of Mental Illness Stigma on Seeking and Participating in Mental Health Care*, 15 PSYCH. SCI. PUB. INT. 37, 37 (2014).

⁶⁹ *Id.* at 43.

⁷⁰ *Id.* at 40.

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.* at 47.

groups.⁷⁴ Because families often experience stress due to this alienation, it decreases the quality of family interaction and an individual's coping abilities.⁷⁵ When front-line health care providers often hold stereotypes of or lack knowledge about specific mental illnesses, they reduce access to care.⁷⁶

Lastly, structural stigma expressed in law and policy discourages individuals from accessing health care.⁷⁷ For example, public and private insurers impose high cost-sharing and lifetime limits on access to mental health services to discourage their overuse.⁷⁸ As a result of high cost-sharing or lifetime service caps, individuals with mental illness often forgo care.⁷⁹ Individuals suffering from severe mental illness reported finances, service-availability, and transportation as major structural barriers to accessing mental health care.⁸⁰ Further, over a third of counties in the United States lack "outpatient mental health facilities that accept Medicaid."⁸¹

Recent policy modifications have been hailed as important steps in reducing stigmatization and increasing parity. Most recently, the Patient Protection and Affordable Care Act (ACA) of 2010 added mental and substance use disorder services to the list of ten essential health benefits that plans in the ACA Exchange Marketplace are required to offer.⁸² This builds on requirements in the Mental Health Parity and Addiction Equity Act (MHPAEA) of 2008, which require plans that offer mental and behavioral health coverage to do so in parity with their medical and surgical benefits.⁸³ However, long-standing stigma against mental illness at the individual, community,

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ *Id.* at 47-48.

⁷⁷ *Id.* at 49.

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² Patient Protection and Affordable Care Act of 2010 § 1302, 42 U.S.C. § 18022 (2015).

⁸³ Mental Health Parity and Addiction Equity Act of 2008, Pub. L. No. 110-343, 122 Stat. 3881 (2008) (codified as amended 26 U.S.C. § 9812, 29 U.S.C. § 1185a, & 42 U.S.C. § 300gg-5).

and structural levels has produced barriers that continue to discourage access to mental health care.

2. Individuals Living in the Southern United States

The southern states, except North Carolina, all rank in the bottom quarter of the United States in terms of access to mental health care services.⁸⁴ According to a ranking of states by Mental Health America on access factors, seven of the bottom ten states were in the south.⁸⁵ Among these, Texas ranked 45th in terms of access to mental health care.⁸⁶ As a result, individuals living in the south face greater difficulties in accessing mental health care than those in other regions of the country.

3. The Elderly

An estimated one in four elderly individuals has mental illness.⁸⁷ Factors reducing elderly individuals' access to mental health services include "inadequate insurance coverage and access barriers such as transportation."⁸⁸ In addition, a 2012 report by the Institute of Medicine found that "Medicare and Medicaid reimbursement rules act to deter rather than facilitate access to effective and efficient" mental health and substance use services for the elderly.⁸⁹

⁸⁴ See *Ranking the States*, MENTAL HEALTH AM., <http://www.mentalhealthamerica.net/issues/mental-health-america-prevalence-data> (last visited Mar. 9, 2017).

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ STEPHEN BARTELS ET AL., *SUBSTANCE ABUSE AND MENTAL HEALTH AMONG OLDER AMERICANS: THE STATE OF KNOWLEDGE AND FUTURE DIRECTIONS 7* (2005), <http://gsa-alcohol.fmhi.usf.edu/Substance%20Abuse%20and%20Mental%20Health%20Among%20Older%20Adults-%20The%20State%20of%20Knowledge%20and%20Future%20Directions.pdf>.

⁸⁸ Alexandra Ginsberg & Deborah DiGilio, *Mental and Behavioral Health and Older Americans*, AM. PSYCH. ASS'N, <http://www.apa.org/about/gr/issues/aging/mental-health.aspx> (last visited Feb. 1, 2017).

⁸⁹ INST. OF MED., *THE MENTAL HEALTH AND SUBSTANCE USE WORKFORCE FOR OLDER ADULTS: IN WHOSE HANDS?* 11 (2012).

4. Veterans

Despite high rates of mental illness and suicide among veterans, they face significant barriers in accessing mental health care.⁹⁰ In fact, as many as eighty-seven percent of veterans with mental illness indicate they fail to receive treatment.⁹¹ The American Public Health Association identified three primary barriers to access to mental health care for veterans.⁹² First, veterans are required to have an honorable or general discharge to be eligible for Department of Veterans Affairs (VA) benefits.⁹³ Second, because of provider shortages, “poor scheduling practices,” and interoperability issues between active and veterans care systems, veterans face long wait times to access care.⁹⁴ Lastly, stigma within the military culture discourages veterans from seeking care.⁹⁵

5. Incarcerated Individuals

Among incarcerated individuals in the United States, forty-five percent of federal prisoners, fifty-six percent of state prisoners, and sixty-four percent of state jail inmates suffer from a mental illness.⁹⁶ However, after incarceration, only one in three state prisoners and one in six state jail inmates report receiving mental health care.⁹⁷ Given the ballooning incarcerated population in the United States, the criminal justice system struggles to provide adequate basic health care to the incarcerated.⁹⁸ As a result, incarcerated individuals who suffer from mental illness often fail to receive needed mental health care treatment.

⁹⁰ APHA Policy Statement 201411: *Removing Barriers to Mental Health Services for Veterans*, AM. PUB. HEALTH ASS'N. (Nov. 18, 2014), <https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2015/01/28/14/51/removing-barriers-to-mental-health-services-for-veterans>.

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ KIM ET AL., *supra* note 32, at 8.

⁹⁷ *Id.* at 10.

⁹⁸ *Id.*

6. *Individuals with Disabilities*

Although fifty-four million individuals in the United States had a physical disability by 2005 estimates,⁹⁹ they often face coverage and geographical barriers to accessing any health care, much less mental health care. These barriers largely result from “prohibitive cost, limited availability of services, physical barriers, and inadequate skills and knowledge among health workers.”¹⁰⁰ Long distances between an individual’s home and care provider also deter individuals with disabilities from seeking mental health care.

7. *Ethnic Minorities and Recent Immigrants*

A large body of research shows significant, unaddressed disparities in access to mental health care among African Americans, Asian Americans, Hispanics, and Native Americans/Alaskan Natives,¹⁰¹ as well as recent immigrants.¹⁰²

These access disparities result from “poor education, lack of health insurance coverage, economic challenges, and impoverished environmental conditions.”¹⁰³ Factors affecting Hispanic individuals include “language fluency, cultural differences such as self-reliance, access to Medicaid specialty services in Latino neighborhoods, differences in recognition of mental health problems, and lower quality of mental health care.”¹⁰⁴

In addition, ethnic minorities “may be hesitant to seek care in traditional settings because of mistrust stemming from historical persecution and racism.”¹⁰⁵ In particular, African Americans and

⁹⁹ DISABILITY RIGHTS EDUC. & DEF. FUND, IMPROVING HEALTH AND ACCESS TO HEALTH CARE FOR PEOPLE WITH DISABILITIES (2009), http://dredf.org/TBFHI/Health_policy_recommendations_2_6.pdf.

¹⁰⁰ *Disability and Health*, WORLD HEALTH ORG., <http://www.who.int/mediacentre/factsheets/fs352/en/> (last visited June 19, 2017).

¹⁰¹ Kisha Holden et al., *Toward Culturally Centered Integrative Care for Addressing Mental Health Disparities Among Ethnic Minorities*, 11 PSYCH. SERVS. 357, 358 (2014).

¹⁰² Santiago et al., *supra* note 65, at 118.

¹⁰³ Holden et al., *supra* note 101, at 358.

¹⁰⁴ Margarita Alegria et al., *Inequalities in Use of Specialty Mental Health Services Among Latinos, African Americans, and Non-Latino Whites*, 53 PSYCH. SERVS. 1547, 1550 (2002).

¹⁰⁵ Santiago et al., *supra* note 65, at 118.

Hispanics are “treated poorly or misjudged because of their race or ethnic background.”¹⁰⁶ Further, “lack of cultural competency and bias in service delivery on the part of mental health and medical professionals” may raise another barrier to care for certain ethnic minorities.¹⁰⁷ Among recent immigrants, unease relating to immigration status may discourage individuals from seeking care.¹⁰⁸

8. Individuals with Limited English Proficiency

Despite the potential for enhanced risk of mental illness among foreign-born individuals in the United States, limited English proficiency is a significant barrier to access to care, particularly among Hispanic individuals.¹⁰⁹ One study found that individuals with limited English proficiency have more difficulty in accessing mental care, are less likely to use care, and are more likely to experience miscommunications with providers.¹¹⁰ Specifically, “inadequate numbers of bilingual and ethnic minority providers and a lack of culturally congruent services” may negatively affect access to care.¹¹¹ Given high levels of initial traumatization and retraumatization among recent immigrants living in *colonias* near the Texas-Mexico border,¹¹² access to care for individuals with limited English proficiency is critical.

9. Homeless Individuals

Although over eighty percent of the homeless suffer from severe mental illness,¹¹³ homeless individuals face major barriers to accessing mental health care. One study identified stigma, uncoordinated health

¹⁰⁶ *Id.*

¹⁰⁷ Holden et al., *supra* note 101, at 359.

¹⁰⁸ Santiago et al., *supra* note 65, at 118.

¹⁰⁹ Giyeon Kim et al., *Limited English Proficiency as a Barrier to Mental Health Service Use: A Study of Latino and Asian Immigrants with Psychiatric Disorders*, 45 J. PSYCH. RES. 104, 104 (2010).

¹¹⁰ *Id.*

¹¹¹ Santiago et al., *supra* note 65, at 118.

¹¹² Fernandez, *supra* note 30, at 80.

¹¹³ Stephen R. Poulin et al., *Service Use and Costs for Persons Experiencing Chronic Homelessness in Philadelphia: A Population-Based Study*, 61 PSYCHIATRIC SERVS. 1093, 1093 (2010).

and social services, and “difficulties . . . in obtaining health insurance” as major barriers to care for homeless individuals.¹¹⁴ Even when homeless individuals receive Medicaid, they are often unable to access care due to transportation costs.¹¹⁵

10. Children

Although approximately one in five children suffer from mental illness, only between ten and thirty percent actually receive the mental health care they need.¹¹⁶ Four major access barriers prevent children from obtaining mental health care. First, “parents, school officials, and medical providers [fail] to address the prevention and early identification of” mental illness.¹¹⁷ Second, medical and social service providers and schools inadequately coordinate their services.¹¹⁸ Third, children have either no insurance or insurance with restrictions that deter them from seeking care.¹¹⁹ Lastly, the shortage of mental health professionals, particularly those trained in treating adolescents, reduces access to care for children.¹²⁰

11. Individuals in Rural Areas

Despite higher levels of suicides and lower quality of mental health, individuals living in rural areas often face major barriers in accessing care.¹²¹ Individuals in rural areas largely face three barriers to care: lack of availability, lack of accessibility, and lack of acceptability.¹²² First, mental health provider shortages raise

¹¹⁴ Reamonn Canavan et al., *Service Provision and Barriers to care for Homeless People with Mental Health Problems Across 14 European Capital Cities*, 12 BIOMED CENT. HEALTH SERVS. RES. 22 (2012).

¹¹⁵ INST. OF MED., HOMELESSNESS, HEALTH, AND HUMAN NEEDS 76 (Nat'l Acad. Press 1988).

¹¹⁶ See David Murphy et al., *Access to Mental Health Care*, CHILD TRENDS, Jan. 2013, https://childtrends-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2013/04/Child_Trends-2013_01_01_AHH_MHAccess1.pdf.

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ Ginsberg, *supra* note 66.

¹²² *Id.*

significant barriers to access for individuals in rural areas.¹²³ In fact, sixty percent of rural-dwelling Americans¹²⁴ live in one of the United States' over 3,900 mental health professional shortage areas.¹²⁵ Second, mental health care is inaccessible for rural-dwelling Americans because of unawareness of their options for mental health care, lack of insurance, and long geographic distances to providers.¹²⁶ In sum, many Americans do not know what mental health care services are available to them or how to access them. Further, individuals who are knowledgeable about mental health care services may lack the insurance coverage needed to access them. Rural-dwelling individuals who have health care literacy and insurance coverage also must contend with long geographical distances to meet with their health care provider. Lastly, stigma about mental illness combined with "limited anonymity" often deters rural-dwelling Americans from seeking care.¹²⁷

12. Individuals in Low-Income Urban Areas

While individuals living in low-income areas are at greater risk of developing mental illness, few actually receive mental health care.¹²⁸ In a medical study of mental health in low-income adults, only thirteen percent of individuals with PTSD actually received care.¹²⁹ In Houston, Texas, thirty percent of the population lacks access to care.¹³⁰ Among these barriers are prohibitive health care costs, lack of insurance or underinsurance, long travel distances, the need to secure childcare, inflexible or unpredictable work schedules, and reliance on

¹²³ *Id.*

¹²⁴ *Id.*

¹²⁵ *Mental Health Care Health Professional Shortage Areas (HPSAs)*, KAISER FAM. FOUND., <http://kff.org/other/state-indicator/mental-health-care-health-professional-shortage-areas-hpsas/> (last visited Sept. 4, 2016).

¹²⁶ Ginsberg, *supra* note 66.

¹²⁷ *See id.*

¹²⁸ Santiago et al., *supra* note 65, at 117.

¹²⁹ *Id.*

¹³⁰ Bobby Robbins, President & CEO of the Tex. Med. Ctr., Remarks at Broadband Prescriptions for Mental Health: A Policy Conference 25 (May 18, 2016) (transcript available at <https://www.fcc.gov/file/4029/download>).

public transportation.¹³¹ Further, low levels of providers who accept Medicaid significantly impede access for individuals in urban low-income areas.¹³² Where individuals living in low-income urban areas are actually able to access care, they have higher likelihoods of premature service drop out and overall poorer health outcomes.¹³³

D. Shortage of Mental Health Professionals

Compounding other barriers to access, the United States faces a major shortage of mental health professionals. In fact, as of April 2014, the United States has over 3,900 mental health professional shortage areas (HPSA).¹³⁴ A mental health HPSA is defined in regulations as an area in which the patient-to-provider ratio is at least 30,000 to 1, or 20,000 to 1 in certain areas defined as having high need.¹³⁵ At the current level of supply of mental health professionals, only about fifty percent of Americans' mental health care needs are being met.¹³⁶ Overall, the United States would need over 2,700 additional mental health professionals to alleviate the current shortage.¹³⁷

At a state level, Texas has over 330 mental health HPSAs, second only to California.¹³⁸ Further, only about forty-six percent of Texas' mental health care needs are met.¹³⁹ The state would need 193 additional mental health providers to remove the HPSA designation.¹⁴⁰ Ultimately, the shortage of mental health professionals amplifies the national and Texas mental health crisis by reducing opportunities for access to care.

¹³¹ Santiago et al., *supra* note 65, at 117.

¹³² Foster, *supra* note 67; *Mental Health Care Health Professional Shortage Areas (HPSAs)*, *supra* note 125.

¹³³ Santiago et al., *supra* note 65, at 117.

¹³⁴ *Mental Health Care Health Professional Shortage Areas (HPSAs)*, *supra* note 125.

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ *Id.*

E. Access to Telecommunications

Access to telecommunications raises an additional barrier to responding to the U.S. mental health crisis by hindering the use of telepsychiatry and new technologies to reduce access barriers. Broadband infrastructure, mobile devices, and digital literacy underlie these telecommunications access barriers.¹⁴¹

First, lack of or inadequate broadband infrastructure hampers the use of telemental health services to remove barriers to access, particularly in Texas.¹⁴² In terms of broadband connection, Texas ranks low on ability to receive a broadband connection with just over half of Texans having access to broadband.¹⁴³ Of the top 100 “critical need” counties in the U.S. in terms of broadband access and infrastructure, the Federal Communications Commission (FCC) has identified twenty-one counties in Texas, more than any other state.¹⁴⁴

Among Texans with access to broadband, over a quarter lack an in-home broadband connection.¹⁴⁵ Further, broadband adoption rates are lower for African Americans, Hispanics, the elderly, lower income individuals, and those living in rural areas.¹⁴⁶ Varying download speeds and broadband widths for live video-streaming technologies,¹⁴⁷ raises additional barriers to use of telemental health services to improve mental health care access.¹⁴⁸

Access to mobile devices raises another barrier to accessing telemental health technologies. Although more than ninety percent of the U.S. population owns a mobile phone, estimates place smartphone ownership at only sixty-four percent of all mobile phone owners.¹⁴⁹ Smartphone ownership is lower among the elderly, low-income

¹⁴¹ Stover, *supra* note 17, at 89.

¹⁴² *Id.* at 95.

¹⁴³ *Id.* at 95–96.

¹⁴⁴ See *Critical Need Counties in Broadband & Health*, FED. COMM. COMMISSION., <https://www.fcc.gov/sites/default/files/Priority-100-Counties.pdf> (last visited Nov. 3, 2016).

¹⁴⁵ Stover, *supra* note 17, at 97.

¹⁴⁶ *Id.* at 99.

¹⁴⁷ *Id.* at 105.

¹⁴⁸ *Id.* at 101.

¹⁴⁹ *Id.* at 90.

populations, and those with lower education levels.¹⁵⁰ Additionally, low-income populations may only have intermittent access to phone service because of uncertain levels of income.¹⁵¹ As a result, access to telemental health services may be less successful among groups who could likely benefit.¹⁵²

Finally, digital literacy hinders effective deployment of telemental health services¹⁵³ because data-caps or lack of in-home broadband lower the number of types of activities for which some individuals use their phones.¹⁵⁴ Coupled with factors such as lack of broadband availability and disparate levels of digital literacy, there are significant technological and infrastructural barriers for consumers desiring to utilize telemental health services to increase access to mental health care.¹⁵⁵

The current state of mental health care delivery reflects a bleak picture of great need, high costs, inadequate funding, stigmatization, provider shortages, and infrastructural access barriers. Telepsychiatry has long promised to address these formidable problems, but has not been utilized on the scale proponents advocate. While the efforts to persuade skeptics on the benefits of telemental health services have fared well in recent years, a larger battle for widespread implementation is being fought in statehouses across the country.

III. ENTERING THE MAZE OF FEDERAL AND STATE REGULATIONS: THE STRUGGLE OF EMERGING MENTAL HEALTH TECHNOLOGIES

We cannot say whether increased use of telepsychiatry and telemental health services is the solution to the crumbling mental health care system in the United States. Situating ourselves from a good vantage point, like Pierre Bezukhov at the Battle of Borodino, we

¹⁵⁰ *Id.* at 92–93.

¹⁵¹ *Id.* at 93.

¹⁵² *Id.* at 92–93.

¹⁵³ *Id.* at 101.

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

recount the various conflicts upon the many fronts: legal and regulatory, state and federal.

A. Is Telepsychiatry the Answer? Arguments from the Broadband Prescriptions for Mental Health: A Policy Conference

Until recently, developments in telemedicine policy have been the concern primarily of those in the health care industry. However, given the recognized need for technological solutions for the health care system, the FCC recently undertook an initiative to examine the role of telecommunications in improving health outcomes. In 2014, the FCC formed the Connect2Health^{FCC} Task Force to “identif[y] regulatory barriers [and] incentives . . . build stronger partnerships with public and private stakeholders in the areas of telehealth, mobile applications, and telemedicine . . . to accelerate the adoption of advanced health care technologies.”¹⁵⁶ Recently, the Connect2Health^{FCC} Task Force organized a series of “Beyond the Beltway” conferences to examine use of health communications technologies “to improve access to health and care services throughout the country, especially in rural and underserved areas.”¹⁵⁷

As part of this series, the Connect2Health^{FCC} Task Force partnered with the University of Houston Law Center’s Health Law & Policy Institute to convene a policy conference entitled “Broadband Prescriptions for Mental Health” on May 18, 2016. As part of the conference, federal and state policymakers, academics, consumers, industry, and other mental health stakeholders discussed legal, regulatory, and policy issues stemming from the use of telepsychiatry and other broadband mental health technologies. Ultimately, the conference served to spark a conversation among stakeholders to encourage meaningful telepsychiatry policy change.

Telepsychiatry is the use of telemedicine to provide mental health services. Telemedicine is “the [use] of a telecommunication device in the diagnosis and overall care of patients that are separated from

¹⁵⁶ *Connect2HealthFCC Mission and Vision*, FED. COMM. COMMISSION, <https://www.fcc.gov/general/connect2healthfcc-mission-and-vision> (last visited Aug. 21, 2016).

¹⁵⁷ *Beyond the Beltway Series*, FED. COMM. COMMISSION, <https://www.fcc.gov/health/beyond-beltway-series> (last visited Aug. 21, 2016).

providers by a distance.”¹⁵⁸ Research has shown that telepsychiatry improves patient satisfaction and health outcomes, reduces health disparities, increases access to care, and results in cost, travel, and time savings.¹⁵⁹ In fact, the Agency for Healthcare Research and Quality (AHRQ) has found telepsychiatry to be among the most effective forms of telehealth.¹⁶⁰

1. Telepsychiatry Improves Patient Health Outcomes and Satisfaction

The body of medical research demonstrates telepsychiatry's effectiveness at improving patients' mental health for a variety of conditions and their satisfaction with these services.¹⁶¹ Telepsychiatry improves patient health outcomes and mental health states for multiple serious mental health conditions across a wide variety of measures.¹⁶² Telepsychiatry has proven effective at improving mental health when used to treat individuals suffering from depression,¹⁶³ developmental disabilities,¹⁶⁴ panic disorder,¹⁶⁵ PTSD,¹⁶⁶ and schizophrenia.¹⁶⁷ Further, medical research has found telepsychiatry to reduce the severity of mental health disorder symptoms, improve adherence to treatment regimens, and decrease the length of

¹⁵⁸ Stacie Deslich et al., *Telepsychiatry in the 21st Century: Transforming Healthcare with Technology*, 10 PERSPS. HEALTH INFO. MGMT. 1 (2013).

¹⁵⁹ Clyburn, *supra* note 4.

¹⁶⁰ Matlin Gilman & Jeff Stensland, *Telehealth and Medicare: Payment Policy, Current Use, and Prospects for Growth*, 3 MEDICARE & MEDICAID RES. REV. E2 (2013).

¹⁶¹ See Donald M. Hilty et al., *The Effectiveness of Telemental Health: A 2013 Review*, 19 TELEMEDICINE & E-HEALTH 444, 451 (2013).

¹⁶² See *id.* at 445-51.

¹⁶³ Ines Hungerbuehler et al., *Home-Based Psychiatric Outpatient Care Through Videoconferencing for Depression: A Randomized Controlled Follow-Up Trial*, 3 J. MED. INTERNET RES. MENTAL HEALTH e36 (2016).

¹⁶⁴ Hilty et al., *supra* note 161, at 448.

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

¹⁶⁷ See John Kasckow et al., *Telepsychiatry in the Assessment and Treatment of Schizophrenia*, CLINICAL SCHIZOPHRENIA & RELATED PSYCHOSES 21 (2014).

hospitalizations.¹⁶⁸ In addition, this research shows that patient satisfaction with telepsychiatry often meets or exceeds their satisfaction with in-person consultations. Use of telepsychiatry in pediatric, adult, and geriatric settings produce high satisfaction with results.¹⁶⁹ In fact, patient satisfaction with telepsychiatry “is so high that it *de facto* precludes study.”¹⁷⁰

2. Telepsychiatry Increases Access to Care and Reduces Disparities

Because telepsychiatry bridges geographical distances by reducing travel time and costs, reduces stigma, and maximizes the reach of the existing mental health providers, it increases access to care and reduces health disparities. Telepsychiatry increases access to care and reduces health disparities across a variety of social and ethnic groups. Research has demonstrated telepsychiatry’s effectiveness at increasing utilization and access to culturally relevant care among Asian Americans,¹⁷¹ individuals of Hispanic origin,¹⁷² and Native Americans.¹⁷³ Because it reduces stigma, it may increase access for those whose mental health conditions, like autism-related disorders, make them less likely to seek in-person care.¹⁷⁴ By reducing travel time, cost, and distance, telepsychiatry increases access to care and reduces disparities for individuals living in rural areas, veterans, and the incarcerated.¹⁷⁵

¹⁶⁸ Hilty et al., *supra* note 161, at 445.

¹⁶⁹ *Id.* at 447–48.

¹⁷⁰ *Id.* at 451.

¹⁷¹ See Jiali Ye et al., *Telepsychiatry Services for Korean Immigrants*, 18 *TELEMEDICINE & E-HEALTH* 797, 797–802 (2012).

¹⁷² Ines Hungerbuehler et al., *Home-Based Psychiatric Outpatient Care Through Videoconferencing for Depression: A Randomized Controlled Follow-Up Trial*, 3 *J. MED. INTERNET RES. MENTAL HEALTH* e36 (2016).

¹⁷³ Hilty et al., *supra* note 161, at 449.

¹⁷⁴ *Id.* at 445.

¹⁷⁵ *Id.* at 445.

3. Telepsychiatry Saves Money

Compared to both in-person and video consultations, telepsychiatry is a cost-effective method of providing mental health services. The body of research, including studies performed in Australia,¹⁷⁶ the United States,¹⁷⁷ and Canada¹⁷⁸ reiterate these savings.¹⁷⁹ Further, one study found telehealth consultations ultimately decreased costs by \$12,000 compared to in-person consultations, despite initially costing more than in-person consultations.¹⁸⁰ Another study on cost-savings produced by the provision of telepsychiatry to children in Kansas found that telepsychiatry reduced travel costs and expenses for attending a single consultation by \$137.62.¹⁸¹ When utilized in a correctional setting, telepsychiatry produced savings in excess of \$1 million.¹⁸² In sum, patients, providers, and payers all largely support the use of telepsychiatry because it is an “effective, credible, and legitimate” method of providing mental health treatment.¹⁸³

B. Legal and Regulatory Framework for Telepsychiatry

Proponents of increased use of telepsychiatry and telemental health services have struggled to navigate a maze of federal and state laws and regulations spanning the health care, occupations, and

¹⁷⁶ See, e.g., A. C. Smith et al., *The Costs and Potential Savings of a Novel Telepaediatric Service in Queensland*, 7 BIOMED CTR. HEALTH SERVS. RES. 35 (2007).

¹⁷⁷ See, e.g., R. Spaulding et al., *Cost Savings of Telemedicine Utilization for Child Psychiatry in a Rural Kansas Community*, 8 J. TELEMEDICINE & E-HEALTH 867 (2010).

¹⁷⁸ See, e.g., D. D. Persaud et al., *An Incremental Cost Analysis of Telehealth in Nova Scotia from a Societal Perspective*, 11 J. TELEMEDICINE & TELE CARE 77, 77–84 (2005); see also M. Jong, *Managing Suicides via Videoconferencing in a Remote Northern Community in Canada*, 63 INT'L J. CIRCUMPOLAR HEALTH 422, 422–28 (2004).

¹⁷⁹ See Hilty et al., *supra* note 161, at 444–45.

¹⁸⁰ Jay Shore et al., *An Economic Evaluation of Telehealth Data Collection with Rural Populations*, 58 J. PSYCHIATRIC SERVS. 830, 830–35 (2007).

¹⁸¹ See Spaulding et al., *supra* note 177, at 870.

¹⁸² Stacie Anne Deslich et al., *Telepsychiatry in Correctional Facilities: Using Technology to Improve Access and Decrease Costs of Mental Health Care in Underserved Populations*, 17 PERMANENTE J. 80 (2013).

¹⁸³ Quashie & Friedberg, *supra* note 7, at 3501.

technology sectors. Against a backdrop of telepsychiatry's ability to address the U.S. mental health crisis, improve individual and public health outcomes, and reduce health care costs, this Subpart provides an overview of federal and state involvement in the area of telepsychiatry.

1. Federal Level

The federal government plays an important role in telepsychiatry through federal health care programs and telecommunications systems. This section provides a history of federal involvement in telepsychiatry. It then gives an overview of governing federal telepsychiatry law and regulations. Lastly, it turns to an update of federal legislative and policy developments.

a. History of Federal Involvement in Telepsychiatry

Among one of the first telemedicine technologies in use, telepsychiatry has existed in one form or another since at least the end of the 1950s.¹⁸⁴ During this time, the first telepsychiatric patient encounters occurred between Dr. Cecil Wittson of Omaha, Nebraska and his rural patients seeking mental health services.¹⁸⁵ Federal funding for telemedicine began as early as the 1960s by agencies including the National Aeronautics and Space Administration (NASA) and National Library of Medicine.¹⁸⁶

b. Overview of Federal Law and Policy

The federal government's role in regulating the practice of telepsychiatry derive largely from Congress' powers to tax and spend for the general welfare and to regulate interstate commerce.¹⁸⁷

¹⁸⁴ U.S. DEP'T OF HEALTH & HUMAN SERVS., PANDEMIC AND ALL HAZARDS PREPAREDNESS ACE TELEHEALTH REPORT TO CONGRESS 14 (Jan. 2009).

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ U.S. Const. art. I § 8, cl. 1; U.S. Const. art. I, § 8, cl. 3; *see also* Lawrence Gostin, *Public Health Law in a New Century: Part II: Public Health Powers and Limits*, 283 J. AM. MED. ASS'N 2979, 2979 (2000); CONTROL MEASURES AND PUBLIC HEALTH EMERGENCIES: A TEXAS BENCH BOOK 11 (Allison N. Winnike ed., 2016); CONFERENCE OF CHIEF JUSTICES PANDEMIC TASK FORCE, PREPARING FOR A PANDEMIC: AN EMERGENCY RESPONSE BENCHBOOK AND OPERATIONAL

Although the federal authority to regulate telepsychiatry is limited to these explicitly granted powers, the federal government is active in setting nationwide standards through federal policies impacting funding for telemedicine projects to reduce disparities, reimbursement of Medicare patients, and privacy and security of protected health information. This section analyzes federal agencies and their responsibilities relating to telepsychiatry regulation. It then details specific areas of federal involvement.

i. Federal Agencies and Their Responsibilities

Despite its more limited role in the telepsychiatry regulatory structure, federal regulation of telepsychiatry spans several agencies in a number of departments with approximately ten federal agencies involved in funding telemedicine or telehealth-related activities in recent years.¹⁸⁸ Agencies most involved in telemedicine include the Centers for Medicare and Medicaid Services (CMS) and Health Resources and Services Administration (HRSA) within the Department of Health and Human Services (HHS), the Department of Veterans Affairs (VA), and Drug Enforcement Administration (DEA). A Federal Telemedicine Working Group works to coordinate funding for telemedicine across over twenty federal agencies.

(1) Centers for Medicare and Medicaid Services (CMS)

Most directly, CMS regulates telepsychiatry reimbursement in the Medicare program.¹⁸⁹ CMS also promulgates the federal floor minimum requirements with which state Medicaid programs must comply.¹⁹⁰ In addition, CMS provides innovation grants to incentivize

GUIDEBOOK FOR STATE COURT JUDGES AND ADMINISTRATORS 7 (2016).

¹⁸⁸ Memorandum from Bernice Reyes-Akinbileje and Ada Cornell, Congressional Research Service to Senate Special Committee on Aging (Sept. 12, 2014) (on file with the author).

¹⁸⁹ See MEDICARE PAYMENT ADVISORY COMM'N, MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM 235 (2016), <http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0>.

¹⁹⁰ See *Telemedicine*, MEDICAID.GOV, <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/delivery-systems/telemedicine.html> (last visited Sept. 13, 2016).

the innovative use of telemedicine projects to improve health outcomes and save money.¹⁹¹

(2) Health Resources and Services Administration (HRSA)

HRSA administers the Office of Rural Health Policy, which is responsible for administering grants to state rural health agencies “to expand access to, coordinate, and improve the quality of essential health care services, and enhance the delivery of health care in rural areas.”¹⁹²

(3) Federal Communications Commission (FCC)

In addition to its Connect2Health^{FCC} Task Force, the FCC’s involvement in telemedicine and telepsychiatry includes funding telecommunications services to support health care¹⁹³ and regulating the nation’s broadband infrastructure.¹⁹⁴ In particular, the FCC oversees the Rural Health Care Program, which funds certain health care providers to ensure the availability of telecommunications and broadband to support their provision of health care services.¹⁹⁵ Overall, the Rural Health Care Program seeks “to improve the quality of health care available to patients in rural communities by ensuring that eligible health care professionals have access to telecommunications and broadband services.”¹⁹⁶

(4) Department of Veterans Affairs (VA)

As the main provider of health care services to U.S. veterans, including through telemental health technology, the VA has

¹⁹¹ See, e.g., *Health Care Innovation Awards: Louisiana*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://innovation.cms.gov/initiatives/health-care-innovation-awards/louisiana.html> (last updated Oct. 19, 2016).

¹⁹² Public Health Service Act, 42 U.S.C. 254c-14(d)(2)(A) (2016).

¹⁹³ See *Funding Broadband-Enabled Health Care*, FED. COMM. COMMISSION, <https://www.fcc.gov/general/funding-broadband-enabled-health-care> (last visited Oct. 22, 2016).

¹⁹⁴ See, e.g., *FCC Health IT Actions and Activities Timeline*, FED. COMM. COMMISSION, <https://www.fcc.gov/general/fcc-health-it-actions-and-activities-timeline> (last visited Oct. 22, 2016).

¹⁹⁵ *Id.*

¹⁹⁶ *Id.*

significant involvement in setting nationwide telemental health policy.¹⁹⁷ In May 2016, the VA announced an expansion of its telehealth initiatives through four centers located in three cities and a consortium bridging three additional cities to provide telemental health services to veterans in areas experiencing reduced access to mental health care.¹⁹⁸ As noted in the press release, the VA provides care to an estimated twelve percent of all veterans through telehealth technologies.¹⁹⁹ As of 2011, the VA was coordinating with the Department of Defense (DoD) to “develop technical, business, and clinical processes for implementing joint DoD and VA telemental health services.”²⁰⁰

(5) Drug Enforcement Administration (DEA)

The DEA is responsible for implementing and enforcing the Ryan Haight Act of 2008, which prohibits prescribing medications via the Internet.²⁰¹ Despite statutory, regulatory, and subsequent enforcement action implementing the Act, specific provisions providing for a special regulatory registration for telepsychiatry providers remains outstanding.²⁰² For example, at least one DEA field office has taken enforcement action against telepsychiatry providers who prescribe

¹⁹⁷ See DEP'T OF VETERANS AFFS., UNIFORM MENTAL HEALTH SERVICES IN VA MEDICAL CENTERS AND CLINICS 17 (Nov. 16, 2015), http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=1762.

¹⁹⁸ Press Release, U.S. Dep't of Veterans Aff., VA Announces Telemental Health Clinical Resources Centers During Telemedicine Association Gathering (May 16, 2016), <https://www.va.gov/opa/pressrel/pressrelease.cfm?id=2789>.

¹⁹⁹ *Id.*

²⁰⁰ DOD/VA INTEGRATED MENTAL HEALTH STRATEGY, STRATEGIC ACTION SUMMARIES, DEP'TS. OF DEFENSE AND VETERANS AFF. 6 (2011), http://www.mentalhealth.va.gov/docs/VA-DoD_IMHS_Action_Summaries_040814.pdf.

²⁰¹ Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Pub. L. No. 110-425, 122 Stat. 4820 (2008).

²⁰² See David Pittman, *Forthcoming DEA Telemedicine Rule Under Question*, POLITICO (Nov. 9, 2015, 10:00 AM), <http://www.politico.com/tipsheets/morning-ehealth/2015/11/politics-morning-ehealth-forthcoming-dea-telemedicine-rule-under-question-waiting-for-senate-help-bill-continues-meaningful-use-action-in-the-house-211166> (mentioning DEA's meeting with stakeholders to initiate development of a “special registration list” that would permit registered doctors to issue prescriptions legally through a telemedicine encounter).

medications²⁰³ in spite of the Act's explicit exemption for providers engaged in the practice of telemedicine.

(6) Federal Trade Commission (FTC)

Through the Health Breach Notification Rule and the FTC Act, the FTC regulates and enforces patient privacy on Internet and smartphone technologies. For entities not subject to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the FTC regulates the privacy of "personal health records" through the Health Breach Notification Rule. In the event of a breach involving more than 500 people, an entity subject to the Health Breach Notification Rule must report the breach to the individuals whose information was subsequently compromised, the FTC, and the news media.²⁰⁴ In addition, the FTC Act allows the FTC to regulate "unfair or deceptive acts or practices in or affecting commerce."²⁰⁵ Because the FTC holds that poor privacy practices deprive consumers of privacy protections, the FTC enforces against them as "unfair or deceptive."²⁰⁶ As a result, the FTC is highly active in regulation of patient privacy in areas touching on telepsychiatry.

(7) Federal Telemedicine Working Group (FedTel)

Lastly, the Federal Telemedicine Working Group (FedTel), housed within HRSA, is a working group of over twenty federal agencies²⁰⁷ which works to "reduce organizational silos with respect to telehealth, facilitate telehealth education and information sharing amongst the

²⁰³ See TEX. DEP'T. OF STATE HEALTH SERVS., THE MENTAL HEALTH WORKFORCE SHORTAGE IN TEXAS 11, Sept. 2014, http://liberalarts.utexas.edu/iupra/_files/pdf/Mental%20Health%20Workforce%20Shortage%20Texas.pdf. (describing at Footnote 6 DSHS's receipt of "numerous comments" observing "due to a discrepancy between allowable telemedicine practices under state and federal law, regional DEA agents' strict enforcement of this law is negatively impacting telemedicine programs in East Texas, including those of halfway homes, Local Mental Health Authorities, community centers, and state Delivery System Reform Incentive Payment (DSRIP) Projects.").

²⁰⁴ Quashie & Friedberg, *supra* note 7.

²⁰⁵ *Id.*

²⁰⁶ *Id.*

²⁰⁷ Memorandum from Bernice Reyes-Akinbileje and Ada Cornell, Congressional Research Service to Senate Special Committee on Aging (Sept. 12, 2014) (on file with the author).

members, coordinate funding opportunity announcements and other programmatic materials, and summarize the key telehealth activities of the participants.”²⁰⁸ FedTel also coordinates spending on telehealth initiatives “through appropriations, obligations, payments, and other types of funding.”²⁰⁹ FedTel member agencies include the Department of Agriculture; International Trade Administration, National Institute of Standards and Technology within the Department of Commerce; the Department of the Army’s Telemedicine and Advanced Technology Research Center, U.S. Army Medical Department, Department of the Navy, and National Center for Telehealth and Technology within the Department of Defense; AHRQ, the Centers for Disease Control and Prevention, CMS, the Food and Drug Administration, HRSA, the Indian Health Service, the National Institutes of Health, the Office of the Assistant Secretary for Preparedness and Response, the Office of the National Coordinator for Health Information Technology, the Substance Abuse and Mental Health Services Administration within HHS; the Federal Bureau of Prisons and National Institute of Justice within the Department of Justice; the Department of Labor; the Department of Transportation; the Veterans Health Administration within the VA; and independent agencies including the FCC, NASA, and the National Science Foundation.²¹⁰

c. Areas of Federal Involvement

Although federal involvement in telepsychiatry is subject to constitutional constraints, this section explores federal law and regulation governing reimbursement. It then turns to the federal role in ensuring the privacy and security of health information. Lastly, it details federal governance of online prescribing.

²⁰⁸ *Fed-Tel Face to Face Meeting*, AM. TELEMEDICINE ASS’N., <http://dev.americantelemed.org/ata-2013/partner-meetings/fed-tel#.WObctfnyu00> (last visited Apr. 6, 2017).

²⁰⁹ Memorandum from Bernice Reyes-Akinbileje and Ada Cornell, Congressional Research Service to Senate Special Committee on Aging (Sept. 12, 2014) (on file with the author).

²¹⁰ *Id.* (observing involvement by the Departments of Agriculture, Commerce, Defense, Health and Human Services, Justice, Labor, Transportation, Veterans Affairs, as well as the Federal Communications Commission, National Aeronautics and Space Administration, and National Science Foundation in FedTel).

i. Reimbursement

The federal government sets reimbursement rates for telepsychiatry services provided to Medicare beneficiaries. As a result of highly restrictive reimbursement requirements, Medicare provides limited coverage for telemedicine services. Medicare limits coverage based on requirements in four areas: location of a facilities, type of facilities, providers, and services.²¹¹

Reimbursement based on facility location is the first area where the Medicare program limits reimbursement. Although Medicare imposes no limitations on the location of the provider, it does require a facility providing a telehealth service to be located in a rural HPSA or in a county that falls outside of a Metropolitan Statistical Area (MSA).²¹² A HPSA includes “an area in an urban or rural area . . . which the Secretary [of Health & Human Services] determines has a health manpower shortage and which is not reasonably accessible to an adequately served area.”²¹³ A MSA is a geographical area “with at least one urbanized area that has a population of at least 50,000.”²¹⁴ As of January 2014, the definition of HPSA was expanded to include rural areas within an MSA, increasing access to telehealth services for individuals living in these areas.²¹⁵

Limiting reimbursement to certain facility types is a second area of restriction in the Medicare program. For purposes of telepsychiatry services, eligible locations where a telepsychiatry service may be provided to a Medicare beneficiary include an office of a physician or practitioner, a critical access hospital, a skilled nursing facility, a

²¹¹ Quashie & Friedberg, *supra* note 7.

²¹² 42 U.S.C. § 1395m(m)(4)(C)(i).

²¹³ 42 U.S.C. § 254(e)(a)(1); Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model, 81 Fed. Reg. 46, 161, 46, 179 (July 15, 2016).

²¹⁴ 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas, 75 Fed. Reg. 37246, 37252 (June 28, 2010).

²¹⁵ See Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014, 78 Fed. Reg. 74,229 (Dec. 10, 2013); see also Quashie & Friedberg, *supra* note 5.

community mental health center, a federally qualified health center, or a rural health clinic.²¹⁶

Third, the Medicare program limits reimbursement to certain providers. Providers who are eligible for reimbursement for providing a telepsychiatry service to a Medicare beneficiary include physicians, clinical psychologists, nurse practitioners, physician assistants, clinical nurse specialists, and clinical social workers.²¹⁷

Lastly, the Medicare program limits reimbursement to certain services. An eligible Medicare service “must involve an interactive real-time communication between the physician or a practitioner at the distant site and the Medicare Beneficiary at the originating site.”²¹⁸ Specific services eligible for reimbursement include “consultations, office visits, individual psychotherapy, and pharmacological management delivered via a telecommunications system.”²¹⁹

Considering these four types of Medicare reimbursement restrictions, Medicare’s restrictive stance towards reimbursement of telehealth services may discourage effective implementation of telepsychiatry.

ii. Privacy and Security of Protected Health Information

The federal government is active in regulating the privacy and security of protected health information, which impacts telepsychiatry and telemental health care services. The Health Information Technology for Economical and Clinical Health Act of 2009 (HITECH)²²⁰ and HIPAA²²¹ along with their implementing regulations

²¹⁶ 42 U.S.C. § 1395m(m)(4)(C)(ii); 42 C.F.R. § 410.78(b)(3).

²¹⁷ 42 U.S.C. §§ 1395m(m)(4)(C)(ii), 1395u(b)(18)(C); 42 C.F.R. § 410.78(b)(2).

²¹⁸ Quashie & Friedberg, *supra* note 5.

²¹⁹ *Id.*

²²⁰ See Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, 123 Stat. 226 (2009) (enacted as part of the American Recovery and Reinvestment Act of 2009, Pub. L. 111-5, 123 Stat. 115).

²²¹ See Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, 110 Stat. 1936 (1996).

in the Privacy Rule,²²² Security Rule,²²³ and Omnibus Rule,²²⁴ are the preeminent sources of federal law for patient health information privacy and security.²²⁵ This section analyzes requirements under HIPAA, HITECH, and their implementing regulations.

(1) Health Insurance Portability and Accountability Act (HIPAA) of 1996

Enacted in 1996, congressional intent behind HIPAA was “to improve the portability and continuity of health insurance coverage, to combat waste, fraud and abuse in health care, to promote the use of medical savings accounts, to improve access to long term care, and to simplify the administration of health insurance.”²²⁶ HIPAA provided only general guidance and was implemented into two regulations: the HIPAA Privacy Rule and the HIPAA Security Rule. This subsection analyzes the HIPAA Privacy Rule. It then details the HIPAA Security Rule.

HIPAA Privacy Rule

The HIPAA Privacy Rule provides the “foundation for the regulation of health information privacy and security”²²⁷ and governs the use and disclosure of patients’ “protected health information” by “covered entities” and their “business associates.”²²⁸ For purposes of the rule, “protected health information” is “information that relates to

²²² See Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462 (Dec. 28, 2000); Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53,182 (Aug. 14, 2002), 45 C.F.R. pts. 160, 164.

²²³ See Health Insurance Reform: Security Standards, 68 Fed. Reg. 8334 (Feb. 20, 2003), 45 C.F.R. pts. 160, 162, 164.

²²⁴ See Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, 78 Fed. Reg. 5566 (Jan. 25, 2013) (45 C.F.R. pts. 160, 164).

²²⁵ See also CONTROL MEASURES AND PUBLIC HEALTH EMERGENCIES: A TEXAS BENCH BOOK, *supra* note 187, at 35–37.

²²⁶ GINA MARIE STEVENS, CONG. RES. SERV., RS20934, A BRIEF SUMMARY OF THE HIPAA MEDICAL PRIVACY RULE 2 (2003).

²²⁷ Quashie & Friedberg, *supra* note 7.

²²⁸ *Id.*

an individual's health, condition, or the provision of health care to the individual, and identifies the individual, which could reasonably be used to identify the individual."²²⁹ The rule defines a "covered entity" as "health care providers, health plans, health care clearinghouses, and business associates."²³⁰ A "business associate" is subsequently defined as an "organization that uses, maintains, or discloses [protected health information] on behalf of a covered entity."²³¹ Without patient authorization, a covered entity may disclose an individual's protected health information only in certain cases. For example, a covered entity may disclose an individual's protected health information for "treatment, payment, or healthcare operations."²³² Additionally, a covered entity may disclose protected health information for "public health, judicial, law enforcement, and other specialized purposes."²³³ The HIPAA Privacy Rule also imposes requirements on covered entities relating to the maintenance of "reasonable and appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information."²³⁴

HIPAA Security Rule

Similarly, the HIPAA Security Rule establishes a national framework for the security of personally identifiable electronic protected health information (EPHI).²³⁵ In 2003, HHS implemented HIPAA's security provisions into the HIPAA Security Rule.²³⁶ Under the HIPAA Security Rule, a covered entity must "ensure the confidentiality, integrity, and availability of all EPHI the covered entity creates, receives, maintains, or transmits."²³⁷ Further, the

²²⁹ *Id.*

²³⁰ See 45 C.F.R. § 164.104 (2013).

²³¹ Quashie & Friedberg, *supra* note 7.

²³² 45 C.F.R. § 164.506; GINA STEVENS, CONG. RES. SERV., R42475, DATA SECURITY BREACH NOTIFICATION LAWS 12 (2012).

²³³ 45 C.F.R. § 164.512(a)(1); STEVENS, *supra* note 232.

²³⁴ 45 C.F.R. § 1320(d)(2) & (d)(4); STEVEN, *supra* note 232.

²³⁵ See STEVENS, *supra* note 232.

²³⁶ See *id.*

²³⁷ 45 C.F.R. § 164.306(a); STEVENS *supra* note 232, at 12-13.

HIPAA Security Rule requires a covered entity to “protect against any reasonably anticipated threats or hazards to the security or integrity of such information”²³⁸ and against any “reasonably anticipated uses or disclosures of such information that are not permitted or required under the Privacy Rule.”²³⁹ Lastly, covered entities must “ensure compliance by their workforces.”²⁴⁰ This requirement also extends to “business associates who create, receive, maintain, or transmit EPHI on their behalf,” with whom a covered entity must enter into agreements to protect EPHI.²⁴¹

Specifically, the HIPAA Security Rule requires covered entities to create Administrative, Physical, and Technical standards.²⁴² In creating these standards, covered entities must take into account “the cost of a particular security measure, the size of the covered entity involved, the complexity of the approach, the technical infrastructure and other security capabilities in place, and the nature and scope of potential security risks.”²⁴³

Following the general tendency for telemedicine practitioners, telepsychiatry practitioners are more likely to create electronic health records. As a result, the HIPAA Security Rule raises special concerns for the practice of telepsychiatry.

(2) Health Information Technology for Economical and Clinical Health Act (HITECH) Act of 2009

Because HIPAA was enacted before the major technological advances of the early 2000s, it required significant enhancements to encompass these new innovations more effectively. As a result, Congress enacted the HITECH Act in 2009. Most importantly, HITECH directly applied HIPAA’s privacy and security rules to

²³⁸ STEVENS, *supra* note 232, at 13 (citing to *Security 101 for Covered Entities*, U.S. DEP’T OF HEALTH & HUM. SERVS., <https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/securityrule/security101.pdf> (last visited July 30, 2017)).

²³⁹ *Id.*

²⁴⁰ *Id.*

²⁴¹ *Id.*

²⁴² *Id.*

²⁴³ *Id.*

business associates.²⁴⁴ HITECH enhanced penalties for violations, granted enforcement authority to states, imposed new reporting obligations for security breaches, expanded patients' access to and control of their health records, and limited the uses of protected health information by entities subject to the rule.²⁴⁵ The HITECH amendments were implemented in the 2013 Omnibus Rule.²⁴⁶ This rule extended compliance responsibilities to business associates and enhanced privacy and security by amending certain regulatory definitions.²⁴⁷

Ultimately, federal regulation provides robust protection of the privacy and security of patients' protected health information. Further, federal law preempts state law that is less stringent, while allowing states to enact laws that are more stringent than federal standards. This federal floor approach enhances patient protections, but it also increases the complexity of the regulatory framework for privacy and security.

Online Prescribing

The federal government also regulates the prescribing of controlled substances over the Internet. Specifically, the Ryan Haight Act of 2008 prohibits the distribution or prescribing of medications via the Internet.²⁴⁸ However, a provider who prescribes medications via the Internet is exempt from this prohibition if the provider meets three criteria.²⁴⁹ First, a primary provider must have conducted at least one physical, in-person meeting with the patient prior to prescribing a medication.²⁵⁰ Alternatively, a "covering provider" may conduct a medical evaluation in a manner other than in-person evaluation, so long as the evaluation is at the request of a provider who has evaluated

²⁴⁴ Quashie & Friedberg, *supra* note 7.

²⁴⁵ *Id.*

²⁴⁶ *Id.*

²⁴⁷ *Id.*

²⁴⁸ Ryan Haight Online Pharmacy Consumer Protection Act of 2008, 21 U.S.C. § 829(e)(1) (2016).

²⁴⁹ Ryan Haight Online Pharmacy Consumer Protection Act of 2008, 21 U.S.C. §§ 829(e)(2)(A)(ii) & (e)(2)(B)(i).

²⁵⁰ Ryan Haight Online Pharmacy Consumer Protection Act of 2008, 21 U.S.C. § 829.

the patient in-person at least once in the past twenty-four months, and the requesting provider is “temporarily unavailable” to evaluate the patient.²⁵¹ Similarly, the Act explicitly exempts telemedicine providers from the prohibition.²⁵²

c. Federal Legislative and Policy Developments

At the federal level, there has been modest regulatory action, as well as a single piece of legislation and one Supreme Court case with significant implications for telepsychiatry. This section details federal legislative developments. It then briefly highlights federal regulatory developments. Lastly, it examines a precedent-setting Supreme Court decision.

i. Federal Legislative Developments

During the 114th Congress, over thirty-five bills relating to telemedicine were introduced, including two bills relating to telepsychiatry specifically. As the 114th Congress entered the lame duck session after the 2016 elections, a deal was struck to include one bill – the Helping Families in Mental Health Crisis Act of 2016²⁵³ – into a section of the 21st Century Cures Act²⁵⁴ in an effort to achieve passage of both bills.²⁵⁵ Further, the 114th Congress included several million dollars to support grants for rural telehealth²⁵⁶ and telemedicine and rural broadband services in its appropriation for fiscal year 2016.²⁵⁷ Below we examine legislative telemental health

²⁵¹ Ryan Haight Online Pharmacy Consumer Protection Act of 2008, 21 U.S.C. § 829(e)(2)(C)(i)-(ii).

²⁵² Ryan Haight Online Pharmacy Consumer Protection Act of 2008, 21 U.S.C. § 829(e)(3)(A).

²⁵³ The Helping Families in Mental Health Crisis Act of 2016, H.R. 2646, 114th Cong. (2nd Sess. 2016).

²⁵⁴ See 21st Century Cures Act, H.R. 6, 114th Cong. (1st Sess. 2015).

²⁵⁵ See 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (2016) (Modified versions of H.R. 6 and H.R. 2626 were included as an amendment to H.R. 34, the Tsunami Warning, Education, and Research Act of 2015).

²⁵⁶ Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, 129 Stat. 2601, div. H, tit. II (2015).

²⁵⁷ Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, 129 Stat. 2242, 2265, div. A, tit. III (2015).

provisions of the 21st Century Cures Act. To determine the 21st Century Cures Act's overall impact and likelihood of success, this section analyzes its effectiveness,²⁵⁸ efficiency,²⁵⁹ manageability,²⁶⁰ and political feasibility.²⁶¹

Although the 21st Century Cures Act takes meaningful steps to encourage the use of telemental health technology to address the U.S. mental health crisis, its redirection of funding from preventive care could diminish its effectiveness. For example, the 21st Century Cures Act establishes grant programs to increase the number of psychiatrists,²⁶² mental health practitioners,²⁶³ and access to pediatric telemental health care²⁶⁴ and maternal depression screening and treatment.²⁶⁵ These grants support programs that emphasize telehealth technology training²⁶⁶ and grants preference to applicants with experience in the use of telemental health.²⁶⁷ In addition, the 21st Century Cures Act opens the door to increased application of telehealth services in the Medicare program by requiring CMS to report to the House and Senate committees with jurisdiction over health care by December 2017 on Medicare populations who could benefit from the expansion of telehealth services, the types of services that could be furnished through telehealth technology, barriers preventing the use of telehealth technology, and action by the Centers for Medicare and Medicaid Innovation on telehealth demonstrations under Section 1115 waivers.²⁶⁸ Lastly, the 21st Century Cures Act

²⁵⁸ Effectiveness means "the extent to which an activity achieves its objectives . . . independent of cost." Lester Salamon, *The New Governance and the Tools of Public Action: An Introduction*, 28 *FORDHAM URB. L. J.* 1611, 1647 (2000).

²⁵⁹ Efficiency means "the optimum balance between benefits and costs." *Id.* at 1648.

²⁶⁰ Manageability means "the ease or difficulty of operating [a] program[]." *Id.* at 1649.

²⁶¹ Political feasibility means both "political support or opposition" and "broader public perceptions of the legitimacy of public action." *Id.* at 1649.

²⁶² 21st Century Cures Act, Pub. L. No. 114-255, § 9022, 130 Stat. 1033 (2016).

²⁶³ *Id.*

²⁶⁴ 21st Century Cures Act, Pub. L. No. 114-255, § 10002, 130 Stat. 1033 (2016).

²⁶⁵ *Id.*

²⁶⁶ 21st Century Cures Act, Pub. L. No. 114-255, § 9022, 130 Stat. 1033 (2016).

²⁶⁷ *Id.*

²⁶⁸ 21st Century Cures Act of 2016, Pub. L. No. 114-255, § 4012, 130 Stat. 1033 (2016).

establishes a Health Information Technology Advisory Committee within the Office of the National Coordinator for Health Information Technology and charges the advisory committee with making a variety of recommendations,²⁶⁹ including those related to expanded use of telemedicine.²⁷⁰

After reviewing the above five factors, the mental health provisions of the 21st Century Cures Act may fail to fully address the mental health crisis, because portions of funding used to offset the cost of the legislation is taken from current public health streams.²⁷¹ As a result of redirection of funds away from preventive care, the 21st Century Cures Act may increase the prevalence of other diseases and decrease opportunities to detect and treat them at their earliest onset.²⁷² Taken in terms of effectiveness alone, providing grant funding, establishing reporting requirements, and creating an advisory committee will have varying levels of success at reducing mental illness. In addition, because these approaches will have mixed success at addressing mental health using funding redirected from other sources, their overall efficiency is lowered. Given the varying administrative costs and burdens required to run grant programs, report on federal data collection, and establish and run an advisory committee, manageability of these programs will be moderate. Lastly, given that many of the top public health organizations in the country expressed significant concerns at the diversion of preventive care funding to pay for new programs under the 21st Century Cures Act,²⁷³ political feasibility may also be somewhat diminished. While the 21st Century Cures Act brought much-needed fixes to the U.S. mental health system, it may experience a lower level of success due to redirection of existing funds to pay for its reforms.

²⁶⁹ 21st Century Cures Act of 2016, Pub. L. No. 114-255, § 4003(e), 130 Stat. 1033 (2016).

²⁷⁰ *Id.*

²⁷¹ 21st Century Cures Act of 2016, Pub. L. No. 114-255, § 5009, 130 Stat. 1033 (2016).

²⁷² *See, e.g.*, Letter from Georges C. Benjamin, President, American Public Health Association to U.S. House of Representatives (Nov. 23, 2016), http://healthyamericans.org/health-issues/wp-content/uploads/2016/11/161123_APHA_PPHF_House.pdf.

²⁷³ *See, e.g.*, *Letters Opposing Using the Prevention and Public Health Fund as an Offset for the 21st Century Cures Package*, TRUST FOR AM.'S HEALTH (Dec. 5, 2016), <http://healthyamericans.org/health-issues/letters-opposing-using-the-prevention-and-public-health-fund-as-an-offset-for-the-21st-century-cures-package/>.

ii. Federal Regulatory Developments

Since 2008, approximately three regulations relating to telepsychiatry have been published in the Federal Register.²⁷⁴ Most critically, while the DEA appears to have contemplated a special registration pathway for telepsychiatry providers, the agency has failed to progress this pathway beyond regulatory review by the Office of Management and Budget.

(1) 2015: DEA Proposed Telemedicine Prescriber Exemption from Ryan Haight Online Prescribing Prohibition

Most critically, the DEA has taken small steps towards regulating and enforcing the prescribing of medications via telemedicine. In the preamble to its interim final rule implementing the Ryan Haight Act, the DEA observed that it “will, with the concurrence of the Secretary of Health and Human Services, promulgate regulations governing the issuance to practitioners of a special registration relating to the practice of telemedicine. Those regulations will be issued separately at a later date.”²⁷⁵ In 2015, the DEA proposed this special regulatory pathway to allow providers of telepsychiatry services to register to for exemption from the Ryan Haight Act’s in-person examination requirements.²⁷⁶ This proposal was supported by the American Telemedicine Association.²⁷⁷ Currently, this proposed rule still appears to be under Office of Management and Budget review, despite being cleared for publishing in the Federal Register in October 2015.²⁷⁸ Despite the

²⁷⁴ FED. REG., <https://www.federalregister.gov> (last visited Sept. 4, 2016) (input “telepsychiatry” into “Search Documents” bar and press enter).

²⁷⁵ Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, 74 Fed. Reg. 15596-15625, 15597 (Apr. 6, 2009) (to be codified at 21 C.F.R. pts. 1300, 1301, 1304, and 1306).

²⁷⁶ DEP’T OF JUSTICE, SPECIAL REGISTRATION TO ENGAGE IN THE PRACTICE OF TELEMEDICINE RIN: 1117-AB40 UNIFIED AGENDA (Fall 2015), <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201504&RIN=1117-AB40> (last visited Nov. 28, 2016).

²⁷⁷ Letter from Jonathan Linkous, Chief Exec. Officer, American Telemedicine Association, to Imelda Paredes, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration (Oct. 6, 2015) (on file with the author).

²⁷⁸ See DEP’T OF JUSTICE, *supra* note 276.

DEA's failure to act on the telepsychiatry permitting pathway, recent enforcement action by the agency highlights need for action. Although the Ryan Haight Act exempts qualifying telemedicine providers from online prescribing prohibitions, the DEA has reportedly taken enforcement action against telemedicine practitioners in Texas.²⁷⁹ Because this enforcement action has specifically targeted practitioners in rural East Texas, it reduces access to care for some of the most vulnerable populations in a particularly hard-hit area of the state.²⁸⁰

(2) 2016: CMS Medicaid Face-to-Face Requirements for Home Health Services Rule

CMS promulgated a final rule entitled "Medicaid Program; Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health" on February 2, 2016, which implements portions of the Patient Protection and Affordable Care Act of 2010 (ACA) and Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) "to add requirements that, for home health services, physicians document, and, for certain medical equipment, physicians or certain authorized non-physician practitioners (NPP) document the occurrence of a face-to-face encounter (including through the use of telehealth) with the Medicaid eligible beneficiary within reasonable timeframes" and harmonize the timing requirements for Medicaid

²⁷⁹ See DEP'T. OF STATE HEALTH SERVS., *supra* note 203 (describing at Footnote 6 DSHS's receipt of "numerous comments" observing "due to a discrepancy between allowable telemedicine practices under state and federal law, regional DEA agents' strict enforcement of this law is negatively impacting telemedicine programs in East Texas, including those of halfway homes, Local Mental Health Authorities, community centers, and state Delivery System Reform Incentive Payment (DSRIP) Projects.").

²⁸⁰ See *The Mental Health Care Workforce in Texas: Hearing Before the House Select Comm. on Health Care Education and Training*, 83rd Reg. Sess. (Tex. 2014), <http://www.legis.state.tx.us/tlodocs/83R/handouts/C2872014091610001/58f4558a-0c66-412c-b168-7c6fac8b703a.PDF> (statement of Andrew Harper, MD, Tex. Med. Ass'n & Fed. of Tex. Psychiatry) (noting, "the current DEA position is significantly impacting initial access to care, disrupting continuity of care, and is imposing a barrier to provide services to both vulnerable and underserved populations by a variety of medical disciplines across the state of Texas.").

home telehealth services requirements with those of the Medicare program.²⁸¹ The rule took effect on July 1, 2016.²⁸²

(3) 2016: CMS Medicare and Medicaid Electronic Health Record Incentive Rule

Lastly, CMS published a proposed rule entitled “Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3” in March 2015.²⁸³ This rule allows eligible professionals (EP) to count patients seen in real-time through telepsychiatry as “seen by the EP” for purposes of calculating incentive payments under the Meaningful Use program.²⁸⁴ The rule also allows providers discretion to include asynchronous telepsychiatry consults in their calculations.²⁸⁵ As a result, this may show increased receptiveness to the recognition of telepsychiatry as an equivalent to in-person care.

iii. Federal Judicial Developments

In February 2015, the United States Supreme Court issued a critical decision affecting state agencies’ regulatory and enforcement powers and their ability to claim state-action immunity from antitrust actions brought pursuant to state agencies’ regulations. This case is highly salient to ongoing litigation relating to the Texas Medical Board’s (TMB) restrictive regulation of telemedicine.

In *North Carolina Board of Dental Examiners v. Federal Trade Commission*, the United States Supreme Court held that a state regulatory body may not invoke state-action immunity where “a controlling number of the board’s decision makers [are] active . . . market participants and the board [is] not subject to active state

²⁸¹ Medicaid Program; Face-to-Face Requirements for Home Health Services; Policy Changes and Clarifications Related to Home Health, 81 Fed. Reg. 5530 (Feb. 2, 2016) (to be codified at 41 C.F.R. pt. 440).

²⁸² *Id.*

²⁸³ Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3, 80 Fed. Reg. 16,732 (Mar. 30, 2015) (to be codified at 42 C.F.R. pt. 495).

²⁸⁴ *Id.*

²⁸⁵ *Id.*

supervision.”²⁸⁶ *North Carolina Board of Dental Examiners* involved interpretation of the North Carolina Dental Practice Act by the state’s dental regulatory body to include tooth whitening services and subsequent enforcement action against non-dentists engaged in the practice.²⁸⁷ As early as 2003, despite tooth whitening being previously offered only by dentists, non-dentists began to offer services in the state. Apparently motivated by lower cost competition, several dentists filed complaints to the Board highlighting “possible harm to consumers.”²⁸⁸ In response, the Board then brought several enforcement actions.²⁸⁹ First, the Board sent approximately forty-seven cease-and-desist letters to tooth whitening product manufacturers and non-dentists engaged in tooth whitening indicating that unlicensed practice of dentistry was a criminal offense and insinuating that tooth whitening involved the practice of dentistry.²⁹⁰ Second, the Board successfully encouraged the North Carolina Board of Cosmetologists to dissuade licensed cosmetologists from providing tooth whitening services.²⁹¹ Lastly, the Board contacted mall operators encouraging them to expel non-dentists who were providing tooth whitening services “in violation of the Dental Practice Act.”²⁹² Ultimately, these enforcement actions halted the offering of tooth whitening services by non-dentists in the state.²⁹³

In response, the Federal Trade Commission (FTC) brought an administrative complaint against the Board’s enforcement action.²⁹⁴ Specifically, the FTC alleged “that the Board’s concerted action to exclude non-dentists from the market for teeth whitening services in North Carolina constituted an anticompetitive and unfair method of

²⁸⁶ *N.C. Bd. of Dental Exam’rs v. Fed. Trade Comm’n*, 135 S. Ct. 1101 (2015).

²⁸⁷ *Id.* at 1107–08.

²⁸⁸ *Id.* at 1101.

²⁸⁹ *Id.* at 1108.

²⁹⁰ *Id.*

²⁹¹ *Id.*

²⁹² *N.C. Bd. of Dental Exam’rs v. Fed. Trade Comm’n*, 135 S. Ct. 1101, 1108 (2015).

²⁹³ *Id.*

²⁹⁴ *Id.* at 1108–09.

competition” as defined by the Federal Trade Commission Act.²⁹⁵ An administrative hearing found the Board to have “unreasonably restrained trade in violation of antitrust law.”²⁹⁶ Next, the FTC required the Board to halt issuing cease-and-desist letters and notify previous letter recipients of “their right to seek declaratory rulings in state court.”²⁹⁷ The Board unsuccessfully appealed this ruling to the Fourth Circuit.²⁹⁸

In upholding the lower court’s ruling, the United States Supreme Court held that a state agency asserting state-action immunity must satisfy two factors to prevail: clear articulation and active supervision.²⁹⁹ First, clear articulation requires “displacement of competition [as] the inherent, logical, or ordinary result of the exercise of authority delegated by the state legislature.”³⁰⁰ To satisfy the clear articulation requirement, the “State must have foreseen and implicitly endorsed the anticompetitive efforts as consistent with its policy goals.”³⁰¹

Second, active supervision requires “that state officials have and exercise power to review particular anticompetitive acts of private parties and disapprove those that fail to accord with state policy.”³⁰² To satisfy the active supervision requirement, the State must “review and approve interstitial policies made by the entity claiming immunity.”³⁰³

The Court declined to accept the Board’s argument that it was exempt from the active supervision requirement as a State-designated agency.³⁰⁴ Instead the Court observed that, “the need for supervision turns not on the formal designation given by States to regulators but

²⁹⁵ *Id.* at 1109.

²⁹⁶ *Id.*

²⁹⁷ *Id.* at 1101.

²⁹⁸ N.C. Bd. of Dental Exam’rs v. Fed. Trade Comm’n, 135 S. Ct. 1101, 1109 (2015).

²⁹⁹ *Id.* at 1110–11.

³⁰⁰ *Id.* at 1112.

³⁰¹ *Id.*

³⁰² *Id.*

³⁰³ *Id.*

³⁰⁴ N.C. Bd. of Dental Exam’rs v. Fed. Trade Comm’n, 135 S. Ct. 1101, 1113 (2015).

on the risk that active market participants will pursue private interests in restraining trade.”³⁰⁵ Further, although the Board was empowered to regulate dentistry, the Dental Practice Act failed to address the specific practice of tooth whitening.³⁰⁶ Because the Board failed “to rely on any of the powers at its disposal that would invoke oversight by a politically accountable official,” the Court ultimately found “no evidence . . . of any decision by the State to initiate or concur with the Board’s actions against non-dentists.”³⁰⁷

To survive review under the Court’s standard, state supervision must “provide ‘realistic assurance’ that a non-sovereign actor’s anticompetitive conduct ‘promotes state policy, rather than merely the party’s individual interests.’”³⁰⁸ Factors the Court considers to indicate active supervision include: substantive (not merely procedural) review of an anticompetitive policy by a supervisor, supervisory veto or modification power over regulatory decisions, and status of the state supervisor as “not itself . . . an active market participant.”³⁰⁹

Ultimately, because of the active supervision requirement, the Supreme Court’s decision in *North Carolina Board of Dental Examiners* holds major implications for ongoing telemedicine litigation at the state level in Texas.

3. State Level

This section provides a history of state involvement in telepsychiatry. It then gives an overview of governing state telepsychiatry law and regulations. Lastly, it turns to an update of state legislative and policy developments.

a. History of State Involvement in Telepsychiatry: Texas

Telepsychiatry programs have been used in the states for years, notably in our case study examination of Texas. Since 1989, Texas has

³⁰⁵ *Id.* at 1101.

³⁰⁶ *Id.* at 1116.

³⁰⁷ *Id.*

³⁰⁸ *Id.*

³⁰⁹ *Id.*

been formally involved in telemedicine and telepsychiatry.³¹⁰ That year both the Texas Telemedicine Project (Project Bluebonnet)³¹¹ and the Texas Tech University Telemedicine Project were established³¹² to serve rural central and west Texas, respectively. Beginning in 1993, the University of Texas Medical Branch at Galveston (UTMB) began contracting with the Texas Department of Criminal Justice (TDCJ) “to provide medical-specialty diagnosis and treatment of state prison inmates through telemedicine.”³¹³ In addition, TDCJ also began contracting with the Texas Tech University Health Sciences Center to offer similar services.³¹⁴ The number of telemedicine or telehealth encounters in the TDCJ system, including those for telepsychiatry services, grew from approximately 10,000 in fiscal year 1999 to over 136,000 encounters by fiscal year 2015.³¹⁵

The Texas Legislature took notice of the success of these programs and their incorporation into the health care delivery model. In 1997, Texas established its current law requiring parity, or equal reimbursement, for telehealth services. House Bill 2033, authored by Representative Patricia Gray, took effect on September 1, 1997.³¹⁶ The law requires private insurance providers “to cover telemedicine services as part of a health benefit plan.”³¹⁷ The law provided the state’s first definition of telemedicine.³¹⁸ It also established informed consent requirements for physicians.³¹⁹

³¹⁰ Jack Moncrief, *Telemedicine: The Slow Revolution*, 30 *ADVANCES PERITONEAL DIALYSIS* 125, 125-27 (2014).

³¹¹ *Id.*

³¹² *The History of Telemedicine at Texas Tech*, TEX. TECH UNIV. HEALTH SCI. CTR., <https://www.ttu.hsc.edu/telemedicine/generalhistory.aspx> (last visited Oct. 1, 2016).

³¹³ KRISTIE ZAMRAZIL, TEX. HOUSE RESEARCH ORG., *TELEMEDICINE IN TEXAS: PUBLIC POLICY CONCERNS* 4 (2000).

³¹⁴ *Id.*

³¹⁵ See TEX. HOUSE RESEARCH ORG., *EMERGING ISSUES IN TEXAS TELEMEDICINE REGULATION* 3 (2017).

³¹⁶ Bill Lookup H.B. 2033, Texas Legislature Online, <http://www.capitol.state.tx.us/BillLookup/History.aspx?LegSess=75R&Bill=HB2033> (last visited Oct. 1, 2016).

³¹⁷ Tex. H. Comm. on Public Health, Bill Analysis, Tex. H.B. 2033, 75th Reg. Sess. (1997).

³¹⁸ *Id.*

³¹⁹ *Id.*

In 1997, the Texas Legislature also established the initial Medicaid benefit for telemedicine.³²⁰ House Bill 2017 directed the Commissioner of the Texas Health and Human Services Commission (HHSC) to “develop and implement a system of reimbursement for Medicaid services performed using telemedicine and to encourage certain providers to participate as providers of telemedicine.”³²¹ The bill also prohibited HHSC from requiring the provision of services via telemedicine.³²² The bill also directed the Texas State Board of Medical Examiners to establish a standard of care for the provision of telemedicine services and promulgate rules to deter fraud and abuse in the new program.³²³ In 2011, the Texas Legislature established an expanded Medicaid benefit for telemedicine medical services, telehealth services, and home telemonitoring services with Senate Bill 293,³²⁴ which took effect on September 1, 2011.³²⁵

b. Overview of State Law and Policy

Acting pursuant to their police power,³²⁶ the states exercise significant authority to regulate nearly every facet of telepsychiatry including licensure, standards of care, delivery, privacy and security, and reimbursement.³²⁷ This section highlights Texas state agencies

³²⁰ Bill Lookup H.B. 2017, Tex. Legislature Online, <http://www.capitol.state.tx.us/BillLookup/History.aspx?LegSess=75R&Bill=HB2017> (last visited Oct. 1, 2016).

³²¹ Tex. Legislature, Enrolled Bill Summary, Tex. H.B. 2017, 75th Reg. Sess. (1997).

³²² *Id.*

³²³ *Id.*

³²⁴ Tex. House Comm. on Public Health, Bill Analysis, Tex. S.B. 293, 75th Reg. Sess. (1997).

³²⁵ Bill Lookup S.B. 293, Tex. Legislature Online, <http://www.legis.state.tx.us/billlookup/History.aspx?LegSess=82R&Bill=SB293> (last visited Oct. 1, 2016).

³²⁶ See, e.g., *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) (defining states’ police powers to include “such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety . . . subject only to the condition that no rule prescribed by a state, nor any regulation adopted by a local governmental agency acting under the sanction of state legislation, shall contravene the Constitution of the United States or infringe any right granted or secured by that instrument”); CONTROL MEASURES AND PUBLIC HEALTH EMERGENCIES: A TEXAS BENCH BOOK, *supra* note 187, at 12.

³²⁷ See U.S. CONST., amend. X; see also *Gonzales v. Oregon*, 546 U.S. 243 (2006) (observing states possess “great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.”).

with jurisdiction over telepsychiatry issues and their responsibilities. It then details specific areas of state involvement.

Given significant state authority to protect the public health, Texas is highly active in regulating nearly every area of telepsychiatry. This section analyzes the state's licensure of telepsychiatry providers. It then examines Texas law governing the privacy and security of protected health information. Next, it details state law governing the reimbursement of providers for telepsychiatry services. Lastly, it discusses state law relating to online prescribing.

i. Licensure

Because states have authority to regulate the practice of medicine within their jurisdictions, a telepsychiatry provider must obtain a license in each state in which the provider wishes to practice.³²⁸ The TMB has authority to promulgate and enforce regulations governing the practice of medicine in Texas and to license physicians to practice medicine in the state.³²⁹ Texas defines the practice of medicine as "the diagnosis, treatment, or offer to treat a mental or physical disease or disorder or a physical deformity or injury by any system or method, or the attempt to effect cures of those conditions."³³⁰

Although this definition clearly includes the practice of telepsychiatry, Texas law explicitly expands the state's regulatory jurisdiction to include an individual located outside of the state who "performs an act that is part of a patient care service initiated" within Texas.³³¹ However, the law exempts four categories of telemedicine providers and allows for the provision of a special telemedicine license.³³² First, the law exempts out-of-state providers who "provide only episodic consultation services on request to a physician licensed [in Texas] who practices in the same medical specialty."³³³ Second, the law exempts out-of-state providers who provide consultations to a

³²⁸ Quashie & Friedberg, *supra* note 7.

³²⁹ TEX. OCC. CODE § 153.001; TEX. OCC. CODE § 155.001.

³³⁰ TEX. OCC. CODE § 151.002(3).

³³¹ TEX. OCC. CODE § 151.056(a).

³³² 22 TEX. ADMIN. CODE § 172.12; TEX. OCC. CODE § 151.056.

³³³ TEX. OCC. CODE § 151.056(b)(1).

medical school.³³⁴ Third, the law exempts out-of-state providers who provide consultations to the University of Texas M.D. Anderson Cancer Center or University of Texas Health Science Center at Tyler.³³⁵ Lastly, the law exempts a physician licensed by and subject to the jurisdiction of a neighboring state “who is the treating physician of a patient and orders home health or hospice services for a resident of this state to be delivered by a home and community support services agency licensed in this state.”³³⁶

ii. Privacy and Security

Although the federal government preempts less stringent state regulations governing health information privacy and security, Texas has enacted an array of additional protections for protected health information.³³⁷ Taking effect in 2012, the Texas Medical Records Privacy Act significantly enhanced penalties for disclosure of protected health information.³³⁸ It also sped up a patient’s access to his or her health records by shortening a provider’s timeline to provide access from thirty days to fifteen days.³³⁹ It added additional employee training requirements that mandate employee training within sixty days of hire and at least every two years thereafter.³⁴⁰ Lastly, it prohibited the sale of protected health information.³⁴¹

iii. Reimbursement

Texas law governs the reimbursement of telepsychiatry services by the state’s Medicaid program and private payers. This section analyzes Texas Medicaid reimbursement requirements. It then examines reimbursement requirements for private payers.

³³⁴ TEX. OCC. CODE § 151.056(b)(2).

³³⁵ TEX. OCC. CODE § 151.056(b)(3).

³³⁶ TEX. OCC. CODE § 151.056(b)(4).

³³⁷ 2011 Tex. Gen. Laws 1126; *see* Quashie & Friedberg, *supra* note 7.; CONTROL MEASURES AND PUBLIC HEALTH EMERGENCIES: A TEXAS BENCH BOOK, *supra* note 187, at 37.

³³⁸ 2011 Tex. Gen. Laws 1126 § 8(b)(1)–(3).

³³⁹ 2011 Tex. Gen. Laws 1126 § 6.

³⁴⁰ *Id.*

³⁴¹ 2011 Tex. Gen. Laws 1126 § 7.

(1) State Medicaid

Texas law limits the types of services, methods, providers, and sites for which the state Medicaid program will provide reimbursement for telepsychiatry. Texas reimburses only for direct, face-to-face telemedicine services, telehealth services, or home telemonitoring services.³⁴² As such, reimbursement for a telepsychiatry service depends on which statutory definition it triggers. First, Texas law defines “telemedicine medical services” as:

[A] health care service that is initiated by a physician or provided by a health professional acting under physician delegation and supervision, that is provided for purposes of patient assessment by a health professional, diagnosis or consultation by a physician, or treatment, or for the transfer of medical data, and that requires the use of advanced telecommunications technology, other than telephone or facsimile technology, including compressed digital interactive video, audio, or data transmission; clinical data transmission using computer imaging by way of still-image capture and store and forward; and other technology that facilitates access to health care services or medical specialty expertise.³⁴³

Texas law defines “telehealth services” as:

[A] health service, other than a telemedicine medical service, that is delivered by a licensed or certified health professional acting within the scope of the health professional’s license or certification who does not perform a telemedicine medical service and that requires the use of advanced telecommunications technology.³⁴⁴

Next, it defines “home telemonitoring services” as “scheduled remote monitoring of data related to a patient’s health and transmission of the data to a licensed home health agency or a hospital.”³⁴⁵

³⁴² TEX. GOV’T CODE § 541.0216 (West 2017); 1 TEX. ADMIN. CODE § 354.1432 (2017); TEX. MEDICAID & HEALTHCARE P’SHIP, TEX. MEDICAID PROVIDER PROCEDURES MANUAL: TELECOMM. SERVS. HANDBOOK: 2 PROVIDER HANDBOOKS 4-6, 8 (Dec. 2016), http://www.tmhpc.com/TMPPM/TMPPM_Living_Manual_Current/2_Telecommunication_Srvs.pdf.

³⁴³ TEX. GOV’T CODE § 531.001(8) (West 2017); TEX. MEDICAID & HEALTHCARE P’SHIP, *supra* note 342, at 5.

³⁴⁴ TEX. GOV’T CODE § 531.001(7) (West 2017); 1 TEX. ADMIN. CODE § 354.1430(10) (2017); TEX. MEDICAID & HEALTHCARE P’SHIP, *supra* note 342, at 6.

³⁴⁵ TEX. GOV’T CODE § 531.001(4-a) (West 2017); 1 TEX. ADMIN. CODE § 354.1434(b) (2017); TEX.

In terms of method limitations on reimbursement for telepsychiatry services, Texas law excludes email, fax, telephone, and chart review from the telemedicine or telehealth services from eligibility for reimbursement.³⁴⁶ Significantly, although Texas law contemplates the use of store-and-forward technology,³⁴⁷ Texas Medicaid policy excludes telemedicine or telehealth services provided through store-and-forward technology from reimbursement.³⁴⁸ Although Texas law requires parity for home telemonitoring services,³⁴⁹ state law imposes significant eligibility restrictions on patients, and approval and documentation requirements on providers.³⁵⁰ Specifically, if the Texas HHS determines it is cost-effective and feasible to provide home telemonitoring for mental illness, a patient with mental illness may receive home telemonitoring services if the patient meets two or more statutorily defined risk factors.³⁵¹ These factors are:

[T]wo or more hospitalizations in the prior twelve month period, frequent or recurrent emergency room admissions, a documented history of poor adherence to ordered medication regimens, a documented history of falls in the prior six month period, limited or absent informal support system, living alone or being home alone for extended periods of time, and a documented history of access to care challenges.³⁵²

If a patient does not meet two or more of these conditions, the patient will not be eligible for home telemonitoring reimbursement.

MEDICAID & HEALTHCARE P'SHIP, *supra* note 342, at 8.

³⁴⁶ TEX. MEDICAID & HEALTHCARE P'SHIP, *supra* note 342, at 4.

³⁴⁷ TEX. GOV'T. CODE § 531.001 (West 2017) (including within the definition of telemedicine medical services and telehealth services "clinical data transmission using computer imaging by way of still-image capture and store and forward.").

³⁴⁸ TEX. MEDICAID & HEALTHCARE P'SHIP, *supra* note 342, at 4 (observing "only those services that involve direct face-to-face interactive video communication between the client and the distant-site provider constitute a telemedicine or telehealth service.").

³⁴⁹ See 1 TEX. ADMIN. CODE § 355.7001 (2017).

³⁵⁰ 1 TEX. ADMIN. CODE § 354.1434 (2017); TEX. MEDICAID & HEALTHCARE P'SHIP, *supra* note 336, at 8.

³⁵¹ 1 TEX. ADMIN. CODE § 354.1434 (2017).

³⁵² 1 TEX. ADMIN. CODE § 354.1434(d)(2)(A)-(G) (2017).

In addition, Texas limits the types of providers eligible for reimbursement under the state Medicaid program. Texas allows for reimbursement of telepsychiatry telemedicine medical services when provided by a physician, nurse practitioner, or physician assistant.³⁵³ Texas allows for reimbursement of telepsychiatry telehealth services provided by: a licensed professional counselor; a licensed marriage and family therapist; a licensed clinical social worker; a psychologist; a licensed psychological associate; or a provisionally licensed psychologist.³⁵⁴

Lastly, Texas limits the types of patient sites from which telepsychiatry telemedicine medical services and telehealth services may be provided. These services may only be provided from an established medical site, a state mental health facility, or a state supported living center. Texas law defines an “established medical site” as the

[L]ocation where clients will present to seek medical care. There must be a patient-site presenter and sufficient technology and medical equipment to allow for an adequate physical evaluation, as appropriate for the client’s presenting complaint. A defined physician-client relationship is required. A client’s private home is not considered an established medical site.³⁵⁵

It defines a “state mental health facility” as “a hospital with an inpatient component funded or operated by [Department of State Health Services (DSHS)].”³⁵⁶ It defines a “state-supported living center” as:

A state-supported and structured residential facility operated by [the Texas Department of Aging and Disability Services (DADS)] to provide individuals with intellectual and developmental disabilities a variety of

³⁵³ TEX. MEDICAID & HEALTHCARE P’SHIP, *supra* note 342, at 5.

³⁵⁴ TEX. MEDICAID & HEALTHCARE P’SHIP, *supra* note 342, at 7.

³⁵⁵ 1 TEX. ADMIN. CODE § 354.1432(1)(C)(i), (2)(C)(i) (2017); TEX. MEDICAID & HEALTHCARE P’SHIP, *supra* note 342, at 5-7.

³⁵⁶ 1 TEX. ADMIN. CODE § 354.1432(1)(C)(ii), (2)(C)(ii) (2017); TEX. MEDICAID & HEALTHCARE P’SHIP, *supra* note 342, at 5-7.

services, including medical treatment, specialized therapy, and training in the acquisition of personal, social, and vocation skills.³⁵⁷

In short, Texas' complicated and often-changing Medicaid reimbursement policies discourage the effective use of telepsychiatry to address the state's mental health crisis.

(2) Private Payers

Similarly, Texas has enacted laws governing the reimbursement of telepsychiatry services by private insurers. Specifically, Texas prohibition of a private insurer from excluding telepsychiatry service from reimbursement is the sole reason that the service is not provided in person.³⁵⁸ Texas Department of Insurance regulations implementing this statute allows a private insurer to "provide enrollees the option to access covered health care services through a telehealth service or a telemedicine medical service."³⁵⁹

iv. Online Prescribing

Lastly, Texas law also governs the prescribing of medications online. Specifically, Texas applies "the same standards of appropriate practice" to in-person and online prescribing.³⁶⁰ Texas law explicitly prohibits a physician from prescribing medications based on an online or phone questionnaire.³⁶¹ Further, in order for a physician to prescribe medications, state law requires an in-person evaluation or telepsychiatry evaluation with the patient located at an established medical site.³⁶² Prescriptions for mental health services are specifically exempted from these requirements, unless the patient is experiencing a behavioral emergency.³⁶³

³⁵⁷ 1 TEX. ADMIN. CODE § 354.1432(1)(C)(iii), (2)(C)(iii) (2017); 1 TEX. ADMIN. CODE § 354.1432(1)(C)(ii), (2)(C)(ii) (2017); TEX. MEDICAID & HEALTHCARE P'SHIP, *supra* note 340, at 5-7.

³⁵⁸ TEX. INS. CODE § 1455.004 (West 2017).

³⁵⁹ 28 TEX. ADMIN. CODE § 11.1607(m) (2017).

³⁶⁰ 22 TEX. ADMIN. CODE § 174.8 (2017).

³⁶¹ *Id.*

³⁶² 22 TEX. ADMIN. CODE § 190.8 (2017).

³⁶³ *Id.*

c. State Legislative/Policy Developments

The Texas Legislature, TMB, and judiciary have seen significant action relating to telemedicine in the past two years. This section analyzes Texas legislative developments. It then provides an overview of recent regulatory developments. Lastly, it examines judicial developments.

i. State Legislative Developments

As the 85th Regular Session of Texas Legislature begins, it faces lingering health disparities in the state's rural, urban low-income, veteran, and homeless populations, in addition to a dire economic outlook. To inform the upcoming legislative session, the 84th Texas Legislature has proactively studied the state's mental health challenges during the interim session by appointing a Select Committee on Mental Health and significant legislative action on bills addressing mental health from a variety of policy perspectives. This section highlights the Texas Legislature 84th Regular Session. It then discusses the 84th Interim Session. It concludes with a summary of the recently concluded 85th Regular Session.

(1) Texas Legislature 84th Regular Session

During the 84th Regular Session, the Texas Legislature saw action on 150 bills relating to telemedicine and mental health.³⁶⁴ These bills sought to improve mental health in the state largely by allowing for reimbursement of providers, addressing health care disparities and increasing access to care, reducing the mental health professional shortage, and enhancing broadband access. Two of these bills were particularly notable. First, Texas House Bill (H.B.) 1623 and Texas Senate Bill (S.B.) 1177 would have provided for reimbursement for providers for telemedicine services under Medicaid.³⁶⁵ H.B. 1623 by Representatives Laubenberg, Burkett, Coleman, Guerra, and Greg

³⁶⁴ See H.B. 1623, 2015 Leg., 84th Reg. (Tex. 2015).

³⁶⁵ See S.B. 1177, 2015 Leg., 84th Reg. (Tex. 2015).

Bonnen passed the House and died in the Senate Health and Human Services committee.³⁶⁶

Similarly, H.B. 3476 would have expanded conditions eligible for home telemonitoring and provided for pilot project to test broader use of in-home telemedicine services.³⁶⁷ Because the bill provided for broad coverage for individuals with special health care needs,³⁶⁸ it could have opened the door for telepsychiatry. H.B. 3476 by Representatives Coleman, Guillen, and Walle unanimously passed the House, but died in the Senate Health and Human Services Committee.³⁶⁹

(2) Texas Legislature 84th Interim Session

Although the Texas Legislature is in session for 140 days in odd numbered years,³⁷⁰ the Legislature has taken two steps affecting telepsychiatry in the state. First, both the House Public Health Committee³⁷¹ and the Senate Health and Human Services Committee³⁷² studied telemedicine as part of their interim charges. Second, in November 2015, Texas House Speaker Joe Straus announced the appointment of a Select Mental Health Committee to examine broadly the state's mental health systems and needs.³⁷³ Between February and August 2016, the Select Committee on Mental Health held seven hearings and took testimony from over 100

³⁶⁶ See *Bill Search*, TEX. LEG. ONLINE, <http://www.capitol.state.tx.us/BillLookup/History.aspx?LegSess=84R&Bill=HB1623> (last visited Sept. 3, 2016).

³⁶⁷ See H.B. 3476, 2015 Leg., 84th Reg. Sess. (Tex. 2015).

³⁶⁸ *Hearing on H.B. 3476 Before the Public Health Committee*, 2015 Leg., 84th Reg. 2-4 (Tex. 2015) (testimony of Bobby Joe Dale III).

³⁶⁹ *Bill Search*, TEX. LEG. ONLINE, <http://www.capitol.state.tx.us/BillLookup/History.aspx?LegSess=84R&Bill=HB3476> (last visited Mar. 21, 2017).

³⁷⁰ TEX. CONST. ART. III, § 5(a) (amended 1999).

³⁷¹ House Pub. Health Comm., *Interim Report to the 85th Legislature*, TEX. HOUSE OF REPRESENTATIVES 21, 28, Dec. 5, 2016, http://www.house.state.tx.us/_media/pdf/committees/reports/84interim/Public-Health-Committee-Interim-Report-2016.pdf.

³⁷² Senate Health & Human Servs. Comm., *Interim Report to the 85th Legislature*, TEX. SENATE 92-101, Nov. 2016, <http://www.senate.texas.gov/cmtes/85/c610/c610.InterimReport2016.pdf>.

³⁷³ Jason Embry, *House Will Take Comprehensive Look at Mental Health Care*, TEX. HOUSE REPRESENTATIVES (Nov. 9, 2015), <http://www.house.state.tx.us/news/press-releases/?id=5741>.

witnesses.³⁷⁴ In its interim report, the Select Committee specifically recommended increased use of telemedicine and mobile health applications to address the state's mental health crisis.³⁷⁵ Lastly, a diverse working group of stakeholders produced a draft telemedicine reform bill during the interim.³⁷⁶ The bill would significantly expand the practice of telemedicine in Texas.

(3) Texas Legislature 85th Regular Session

In spite of the state's meager revenue projections,³⁷⁷ the 85th Texas Legislature saw a flurry of telemedicine legislation filed.³⁷⁸ Most significantly, major telemedicine reform legislation which modernizes the definitions of telemedicine, telehealth, and the provider-patient relationship and continues the telemental health exemption passed through both houses of the Texas Legislature, was signed by the governor, and largely took immediate effect, with certain provisions impacting the Texas Insurance Code taking effect on January 1, 2017.³⁷⁹ In addition, a bill to provide an expedited licensure process for psychiatrists who hold an unrestricted out-of-state license that passed both Houses of the Legislature and signed by the governor may also boost the state's workforce and potentially increase access to telepsychiatric services.³⁸⁰ At the same time, the Legislature made

³⁷⁴ See House Comm. on Mental Health, *House Committee Meetings*, TEX. HOUSE REPRESENTATIVES, <http://www.legis.state.tx.us/Committees/MeetingsByCmte.aspx?Leg=84&Chamber=H&CmteCode=C382> (last visited Mar. 21, 2017).

³⁷⁵ House Select Comm. On Mental Health, *Interim Report to the 85th Tex. Leg. 26*, TEX. HOUSE REPRESENTATIVES (Dec. 29, 2016), http://www.house.state.tx.us/_media/pdf/committees/reports/84interim/Mental-Health-Select-Committee-Interim-Report-2016.pdf.

³⁷⁶ Darius Tahir, *Texas Telemedicine Tussle Seeks Legislative Solution*, POLITICO (July 10, 2016, 10:00 AM), <http://www.politico.com/tipsheets/morning-ehealth/2016/07/texas-telemedicine-tussle-seeks-legislative-solution-theranos-world-turns-again-usds-dod-va-how-about-some-acronyms-215457>.

³⁷⁷ Edgar Walters, *Hegar Gives Lawmakers Dour Revenue Estimate for 2017 Session*, TEX. TR. (Jan. 9, 2017, 10:04 AM), <https://www.texastribune.org/2017/01/09/hegar-gives-lawmakers-dour-revenue-estimate-2017-s/>.

³⁷⁸ *Bill Search*, TEX. LEG. ONLINE, <http://www.capitol.state.tx.us/Search/BillSearch.aspx> (under Legislature, select "85(R) - 2017"; under "Subjects", select "telemedicine"; then press "search") (last visited May 7, 2017).

³⁷⁹ See H.B. 2697, 2017 Leg., 85th Reg. (Tex. 2017); S.B. 1107, 2017 Leg., 85th Reg. (Tex. 2017).

³⁸⁰ See S.B. 674, 2017 Leg., 85th Reg. (Tex. 2017).

deep budget cuts, while contending with a multitude of issues that contribute both directly and indirectly to the state's mental health crisis.³⁸¹ Thus, legislative proposals that sought to expand the application of telemental health technology had to navigate an even more complex gauntlet—the Appropriations process—with those proposals that successfully survived the legislative process potentially failing to receive the funding necessary for effective implementation. Regardless of funding, the Legislature nonetheless enacted lasting changes to the Texas telemedicine landscape.

ii. State Regulatory Developments

Texas has also seen regulatory changes. In March 2017, HHSC amended its Medicaid regulations to allow a physician to conduct the required initial patient evaluation through a telemedicine encounter and exempt telepsychiatry and telemental health services from the initial evaluation requirement.³⁸² Prior to the HHSC rule amendment and passage of SB 1107, the TMB and Texas State Board of Examiners of Professional Counselors (TBEPC) have actively proposed rules to limit the practice of telemedicine in the state. Since 2010, the TMB has attempted through its rulemaking authority to control the expansion of telemedicine use in the state.³⁸³ Acting pursuant to these regulations, the TMB has brought enforcement action against Teladoc. This enforcement action has resulted in litigation in which a court ultimately found in favor of Teladoc. In response, TMB promulgated an emergency rule which was the subject of litigation in the United States Court of Appeals for the Fifth Circuit. Recently, the FTC announced it has opened an investigation into potential federal antitrust law violations by TMB in promulgating the rules.

³⁸¹ Marissa Evans, *House Panel Warns of "Peril" in Texas Mental Health System*, TEX. TRIB. (Jan. 5, 2017, 5:46 PM), <https://www.texastribune.org/2017/01/05/house-panel-warns-peril-texas-mental-health/>.

³⁸² 42 Tex. Reg. 1245 (Mar. 17, 2017) (to be codified at 1 TEX. ADMIN. CODE §354.1432).

³⁸³ Joey Berlin, *Telemedicine Company's Suit Claims TMB Rules Are Not Immune from Antitrust Challenge*, TEX. MED., Apr. 2016, <https://www.texmed.org/SeekingInvalidation/> (noting "since 2010, TMB rules have defined telemedicine as using advanced telecommunications technology that allows the distant site provider to see and hear the patient in real time") (internal quotations omitted).

(1) 2015: TMB Emergency Rule Requiring Initial In-Person Visit

In January 2015, the TMB proposed an emergency rule restricting the practice of telemedicine by requiring a face-to-face or in-person visit to establish a physician-patient relationship.³⁸⁴ In response to a December 2014 ruling by the Third Court of Appeals of Texas striking down³⁸⁵ a previous rule by TMB requiring a face-to-face visit between a physician and patient to prescribe medications,³⁸⁶ the emergency rule updated violation guidelines to require a face-to-face, in-person visit to prescribe medications.³⁸⁷ Although the emergency rule exempts telemental health services from the face-to-face requirement, it does require a physical examination to be prescribed drugs in situations involving behavioral emergencies.³⁸⁸ This case will be discussed further in State Judicial Developments below. Despite significant pushback from stakeholders,³⁸⁹ the Board voted thirteen to one to finalize the emergency rule.³⁹⁰ Ultimately, Teladoc, Inc., a major opponent of the rule, brought suit in the United States District Court for the Western District of Texas and won an injunction against the rule.³⁹¹ In light of recognized mental health professional shortages of

³⁸⁴ TEX. MED. BD., BOARD MEETING MINUTES 3 (Jan. 16, 2015), <http://www.tmb.state.tx.us/dl/B588BAC1-6EB6-56E6-D854-A26F646D68DD>.

³⁸⁵ *Teladoc, Inc. v. Tex. Med. Bd.*, 453 S.W.3d 606, 2 (Tex. App—Austin 2014, *pet. denied*).

³⁸⁶ See 35 Tex. Reg. 9003, 9090 (Oct. 8, 2010) (codified at 22 TEX. ADMIN. CODE §174.8)); see also 35 Tex. Reg. 3345, 392–93 (Apr. 30, 2010) (codified at 22 TEX. ADMIN. CODE §174.8); see also 35 Tex. Reg. 6133, 6183 (July 16, 2010) (codified at 22 TEX. ADMIN. CODE §190.8).

³⁸⁷ TEX. MED. BD., *supra* note 384.

³⁸⁸ 22 TEX. ADMIN. CODE § 190(L)(i)(II)(c) (2017).

³⁸⁹ See, e.g., Abby Goodnough, *Texas Medical Panel Votes to Limit Telemedicine Practices in the State*, N.Y. TIMES (Apr. 10, 2015), http://www.nytimes.com/2015/04/11/us/texas-medical-panel-votes-to-limit-telemedicine-practices-in-state.html?_r=0; see also Mary Ann Roser, *Texas Medical Board Overwhelmingly Adopts New Telemedicine Rules*, AUSTIN AM.-STATESMAN (Apr. 10, 2015, 8:18 PM), <http://www.mystatesman.com/news/news/state-regional-govt-politics/texas-medical-board-overwhelmingly-adopts-new-tele/nkrZL/>.

³⁹⁰ 40 Tex. Reg. 993, 1016 (2015) (codified at 22 TEX. ADMIN. CODE §174.6); see also, Press Release, Tex. Med. Bd., TMB Adopts Rules Expanding Telemedicine Opportunities (Apr. 14, 2015).

³⁹¹ *Federal Court Rules in Favor of Teladoc, Blocking Texas Medical Board Rule and Preserving Telehealth in Texas Teladoc Service to Millions of Texas Continues Uninterrupted*, TELADOC (May 29, 2015), <https://www.teladoc.com/news/2015/05/29/federal-court-rules-in-favor-of-teladoc/>.

207 of Texas' 254 counties³⁹² and significant geographic distances,³⁹³ the rule raises significant barriers to the effective deployment of telepsychiatry.

(2) 2016: TBEP Rule Requiring In-Person Visit for Professional Counselors

In January 2016, the TBEP proposed a similar rule that would have required an in-person visit before a professional counselor could use telemental health services to provide counseling to a patient.³⁹⁴ After receiving significant outcry from practitioners, the TBEP ultimately rejected the rule.³⁹⁵

iii. A State Judicial Developments

Despite a significant ruling by the Texas Court of Appeals awarding a victory to Teladoc in December 2011, the TMB's emergency rule has resulted in additional on-going litigation in federal court between Teladoc and the TMB. Although the recent U.S. Supreme Court ruling in *North Carolina State Board of Dental Examiners* likely tilted the balance in favor of Teladoc, the TMB dropped its appeal and the parties appear to be pursuing settlement.

In October 2010, the TMB finalized a telemedicine rule requiring face-to-face, in-person examinations to establish a physician-patient relationship for the purposes of providing telemedicine medical services.³⁹⁶ In June 2011, the Board sent a violation letter to Teladoc, Inc. accusing the company of violating the newly promulgated rules. Teladoc argued that the letter violated the Texas Administrative Procedure Act because it was an unpublished regulation. Ultimately,

³⁹² TEX. DEP'T OF STATE HEALTH SERVS., *supra* note 203, at 7.

³⁹³ Stroker, *supra* note 17, at 107-08

³⁹⁴ 41 Tex. Reg. 547, 570 (2016) (codified at 22 TEX. ADMIN. CODE §681.41) (proposed on Jan. 15, 2016).

³⁹⁵ Mary Ann Roser, *Texas Board Rejects Rule Restricting 'Distance' Counseling*, AUSTIN AM.-STATESMAN (Mar. 2, 2016, 5:47 PM), <http://www.mystatesman.com/news/news/state-regional-govt-politics/texas-board-rejects-rule-restricting-distance-coun/nqCLX/>.

³⁹⁶ 35 Tex. Reg. 9003, 9091 (Oct. 8, 2010) (codified at 22 TEX. ADMIN. CODE §174.7).

Teladoc won on appeal, and the Texas Supreme Court denied petition from the TMB for review.³⁹⁷

As a result, the TMB deemed the court's ruling an "emergency," and proceeded to promulgate an emergency rule requiring face-to-face visit to establish a physician-patient relationship for the purposes of telemedicine.³⁹⁸ Although this rule exempted telemental health services from the face-to-face requirement, it did subject behavioral health emergencies to the requirement.³⁹⁹

In April 2016, Teladoc sued in the United States District Court for the Western District of Texas alleging that the TMB violated federal antitrust law and the Commerce Clause of the Constitution.⁴⁰⁰ In July 2016, the TMB filed a motion to dismiss, claiming state-action immunity from antitrust liability, running of the statute of limitations for filing a claim, and failure to state a claim under the Commerce Clause.⁴⁰¹ The Court ultimately denied this motion.⁴⁰² In August 2016, the TMB filed a motion to certify order for appeal to allow the Fifth Circuit to consider its state-action immunity claim.⁴⁰³ On August 15, 2016, the TMB's motion to certify appeal was denied.⁴⁰⁴

Currently, the case is still pending appeal in the Fifth Circuit only on the issue of whether Teladoc's antitrust claim can be dismissed on state-action immunity grounds.⁴⁰⁵ However, given the U.S. Supreme Court's requirement in *North Carolina State Board of Dental Examiners* that state regulatory agencies composed of active market participants be subject to active state supervision to claim state-action immunity,⁴⁰⁶ the TMB's January 2015 emergency rule is potentially vulnerable. In

³⁹⁷ Tex. Med. Bd. v. Teladoc, Inc., No. 1:15-CV-343-RP, 2016 U.S. Dist. LEXIS 107443, at *15 (W.D. Tex. Aug. 15, 2016).

³⁹⁸ TEX. MED. BD., *supra* note 384.

³⁹⁹ 22 TEX. ADMIN. CODE §190(L)(i)(II)(c) (2017).

⁴⁰⁰ Teladoc Inc. v. Tex. Med. Bd., No. 1:15-CV-343-RP, U.S. Dist. LEXIS 107443, at *3-4 (W.D. Tex. Aug. 15, 2016).

⁴⁰¹ *Id.* at *4.

⁴⁰² *Id.*

⁴⁰³ *Id.*

⁴⁰⁴ *Id.* at *14.

⁴⁰⁵ Teladoc Inc. v. Tex. Med. Bd., 2016 U.S. Dist. Lexis 107443.

⁴⁰⁶ N.C. Bd. of Dental Exam'rs v. Fed. Trade Comm'n, 135 S. Ct. 1101 (2015).

fact, on September 9, 2016, the FTC filed an amicus brief with the U.S. Fifth Circuit Court of Appeals arguing that the court should dismiss the appeal for “lack of appellate jurisdiction.”⁴⁰⁷ In the alternative, the FTC argues that the court should affirm the lower court on state action grounds because the TMB “is composed of active market participants” and failed to show active state supervision of its proposed rule.⁴⁰⁸

Although the TMB abruptly dropped its appeal without explanation in October 2016,⁴⁰⁹ the U.S. Supreme Court’s ruling in *North Carolina State Board of Dental Examiners* and the substantial amount of support for Teladoc may have influenced the Board’s decision. While legal commentators speculated that Teladoc and the Board are pursuing settlement agreements,⁴¹⁰ comments from the Board indicate it will continue to fight.⁴¹¹

C. Theseus Confronts the Regulatory Minotaur: Mental Health Technology Innovators

Technology developments and innovative initiatives in both the public and private sectors are rapidly working to reduce access disparities, enhance telecommunications access for first-responders, and increase evidence-based treatment options available to individuals suffering from a mental illness. As constant technological innovations in mobile health applications revolutionize the delivery of mental health care and reduce access disparities, they collide with outdated and slow-moving legal and regulatory frameworks that hamstring change. This section highlights the Theseus of mental health technological innovation as they attempt to overcome the Minotaur of outdated regulation.

⁴⁰⁷ Brief for the Federal Trade Commission as Amici Curiae Supporting Plaintiffs-Appellees, *Teladoc, Inc. v. Tex. Med. Bd.*, No. 16-50017 (5th Cir. filed Sept. 9, 2016).

⁴⁰⁸ *Id.*

⁴⁰⁹ See, e.g., Erica Teichert, *Texas Drops Appeal Against Teladoc Lawsuit*, MOD. HEALTHCARE (Oct. 18, 2016), <http://www.modernhealthcare.com/article/20161018/NEWS/161019900>.

⁴¹⁰ See, e.g., Rebekah Hudgins, *Part 3 of 3: The Telemedicine Debate in Texas: Federal Judge Halts the TMB’s Revised Rule*, LEXOLOGY (Jan. 25, 2017), <http://www.lexology.com/library/detail.aspx?g=b51b419a-52a0-4a98-bb49-c30d76967dc3>.

⁴¹¹ See Teichert, *supra*, note 409.

This section provides an overview of specific technology, apps, and developments in the field of telemental health. First, this section discusses the ETHAN Project, the City of Houston's Emergency Tele-Health and Navigation Project. Next, it highlights the First Responders Network Authority. It then examines the Big White Wall mobile health application and details the Valera mobile health application. Next, it discusses the AT&T Foundry for Connected Health initiative. Lastly, it highlights the Telemedicine Wellness Intervention Triage and Referral Project.

At the local level, the ETHAN Project improves the efficiency of emergency medical services by equipping first responders in the City of Houston Fire Department with telehealth technology that allows a provider to remotely triage a patient's medical needs and direct them to the most appropriate source of care.⁴¹² The City of Houston Fire Department responds to over 250,000 emergency calls per year, at a rate of over 300 ambulance trips per day.⁴¹³ As applied in a mental health context, the ETHAN Project can be instrumental in helping individuals with mental illness seek necessary care and adhere to treatment.⁴¹⁴ For example, the ETHAN Project allows a provider to access health records and vital signs for an individual suffering from schizophrenia whose prescription supply is extremely low, triage their need for health services, and schedule for an appointment with the nearest mental health provider.⁴¹⁵ The provider can also schedule transportation to and from the appointment, eliminating the patient's reliance on the ambulance and emergency room as a source of care.⁴¹⁶ In cases where emergency care is not required, the provider can refer the patient to a social worker in the City of Houston Health Department to help identify and resolve the issue that caused the

⁴¹² See David Persse, Physician Dir., Emergency Med. Servs., City of Hous. Fire Dep't Pub. Health Auth., City of Houst. Dep't. of Health & Human Servs., Remarks at Broadband Prescriptions for Mental Health: A Policy Conference 118-23 (May 18, 2016) (transcript available at <https://www.fcc.gov/file/4029/download>).

⁴¹³ Michael Gonzalez et al., *In Houston, Telemedicine is Bringing the Doc to the Field*, TELEMEDICINE, <http://www.telemedmag.com/current-scope-section/2016/3/10/kwem5i8i3w3yd3zdudz8eq6npr9hw0> (last visited Sept. 17, 2016).

⁴¹⁴ See Persse, *supra* note 411, at 127-33.

⁴¹⁵ *Id.*

⁴¹⁶ *Id.*

patient to call 911.⁴¹⁷ The ETHAN Project could provide an estimated \$200 million in cost-savings by reducing unnecessary use of ambulances and emergency departments.⁴¹⁸ While the ETHAN Project must treat seven patients every five years to remain cost-neutral, in its first year alone, the project treated 135 patients.⁴¹⁹ Ultimately, the ETHAN Project improves collaboration among the City of Houston Health Department and community stakeholders to address proactively the underlying health disparities at the root of 911 calls.⁴²⁰

On a national scale, the U.S. Congress created the First Responder Network Authority or “FirstNet,” a special wireless broadband network for use by first responders, in response to the need for stronger bandwidth speeds and better public safety connectivity during emergencies. Prior to the creation of FirstNet in 2012, first responders’ reliance on commercial broadband networks to communicate during disasters and emergencies limited their ability to communicate.⁴²¹ By providing a high-speed network solely for public safety communication, FirstNet addresses first responders’ need for high bandwidth and speeds.⁴²² Further, the explicit statutory purpose of FirstNet is to provide a unified conduit for first-responder communications that “evolves with technological advancements.”⁴²³ As a result, it can significantly improve the use of telemental health services like the previously mentioned ETHAN Project among first responders.⁴²⁴

⁴¹⁷ See Carrie Feibel, *Doctors Make House Calls on Tablets Carried by Houston Firefighters*, NAT’L PUB. RADIO (Apr. 9, 2015), <http://www.npr.org/sections/health-shots/2015/04/09/396583624/doctors-make-house-calls-on-tablets-carried-by-houston-firefighters>.

⁴¹⁸ *Id.*

⁴¹⁹ See Persse, *supra* note 409, at 127.

⁴²⁰ *Id.* at 124.

⁴²¹ Gabrielle Banks, *Harris County to Be First in Nation with Public-Safety Broadband Network*, HOUST. CHRON. (Aug. 2, 2015), <http://www.houstonchronicle.com/news/houston-texas/houston/article/Harris-County-to-be-first-in-nation-with-6420785.php>.

⁴²² *Id.*

⁴²³ LINDA MOORE, CONG. RESEARCH SERV., R42543, THE FIRST RESPONDER NETWORK (FIRSTNET) AND NEXT-GENERATION COMMUNICATIONS FOR PUBLIC SAFETY: ISSUES FOR CONGRESS 1 (2014).

⁴²⁴ Banks, *supra* note 419.

Similarly, Big White Wall is an online community in the United Kingdom that is accessible by all devices where individuals with mental health concerns can anonymously seek professionally guided support and share coping strategies.⁴²⁵ Big White Wall offers anonymous, 24-hour access to mental health support and services is compliant with both HIPAA and U.K. privacy standards.⁴²⁶ Because of the promise of anonymous, professionally guided, peer-led support, Big White Wall reduces stigma.⁴²⁷ Since its founding in 2007, Big White Wall has served more than 35,000 people⁴²⁸ and seventy percent of Big White Wall members report using the program “improved their wellbeing in at least one way.”⁴²⁹ Lastly, Big White Wall could help boost health care savings. Use of Big White Wall generates an estimated “£38,000 in direct healthcare savings for each 100 six-month subscriptions.”⁴³⁰

Utilizing digital capabilities in a different way, Valera Health works to apply data analytics and digital technology to take a precision-based approach to mental health care.⁴³¹ Valera’s technologies specifically collect data through a mobile phone from patients suffering from depression on factors shown to correlate to reduced mental health state.⁴³² The application then uses this information to sort individuals based on the severity of depression and determine a patient’s mental state and develop a care plan for the patient, and collect pre- and post-care data.⁴³³ Additionally, Valera is

⁴²⁵ *About Big White Wall*, BIG WHITE WALL, <https://www.bigwhitewall.com/landing-pages/landingV3.aspx#.V96nLOmmdUQ> (last visited Sept. 18, 2016).

⁴²⁶ *History of Big White Wall*, BIG WHITE WALL, <https://www.bigwhitewall.com/info/history-of-big-white-wall/#.V96omemmdUQ> (last visited Sept. 18, 2016).

⁴²⁷ *Frequently Asked Questions*, BIG WHITE WALL, <https://www.bigwhitewall.com/info/faqs/#.V96t5ummdUQ> (last visited Sept. 18, 2016).

⁴²⁸ *Research and Outcomes*, BIG WHITE WALL, <https://www.bigwhitewall.com/info/research-and-outcomes/#.V96wCemmdUQ> (last visited Sept. 18, 2016).

⁴²⁹ *About Big White Wall*, *supra* note 425.

⁴³⁰ *Research and Outcomes*, *supra* note 428.

⁴³¹ See Thomas Tsang, Chief Operating Officer & Co-Founder, Valera Health, Remarks at Broadband Prescriptions for Mental Health: A Policy Conference 262 (May 18, 2016), <https://www.fcc.gov/file/4029/download>.

⁴³² *Id.*

⁴³³ *Id.* at 258.

establishing a HIPAA-compliant telemedicine pilot program focused on providing care to individuals suffering from schizophrenia.⁴³⁴ Finally, Valera is piloting partnerships to speed the release of correctional patients with dual diagnoses for mental health conditions, as well as address mental health issues among young adults in Texas.⁴³⁵

Further, AT&T has established a Foundry for Connected Health to be located in the Texas Medical Center to serve as help to collaboratively address healthcare issues.⁴³⁶ While technology innovation in the healthcare space can take significant periods of time, the AT&T Foundry will seek to identify problems and pilot solutions within weeks.⁴³⁷ Among projects created by AT&T's other health foundries are a smart "connected wheelchair" and a headband capable of detecting a patient's pain levels, which could be applied to determine the effect of mental health disorders on a patient's brain function.⁴³⁸

Lastly, the Texas Tech University Health Sciences Center has developed the Telemedicine Wellness, Intervention, Triage, and Referral (TWITR) Project to provide a school-based intervention to middle school and high school students at high risk of harm to themselves or others.⁴³⁹ The TWITR Project serves nine school districts in metropolitan and non-metropolitan settings.⁴⁴⁰ As part of the project, students receive in-school screening and referral to the program from a licensed professional counselor. Once referred to the program, the counselor manages telemedicine sessions for the

⁴³⁴ *Id.*

⁴³⁵ *Id.* at 258–59.

⁴³⁶ See Judi Manis, Regional Vice President-Business Development and Strategic Relations, Internet of Things-Healthcare, AT&T, Presentation at Broadband Prescriptions for Mental Health: A Policy Conference (May 18, 2016), <https://www.fcc.gov/file/3996/download>.

⁴³⁷ *Id.* at 245.

⁴³⁸ *Id.* at 251.

⁴³⁹ *Telemedicine Wellness, Intervention, Triage, and Referral Project (TWITR)*, TEX. TECH UNIV. HEALTH SCI. CTR., <https://www.ttuhs.edu/ruralhealth/researchgroup/TWITR.aspx> (last visited Sept. 18, 2016).

⁴⁴⁰ *Id.*

students.⁴⁴¹ The telemedicine sessions are provided by one of four psychiatric residents at the Texas Tech University's Health Sciences Center Department of Psychiatry.⁴⁴² Remarkably, truancy and discipline referrals have declined by thirty-seven percent for students receiving mental health services through TWITR.⁴⁴³

IV. THREADING THE LABYRINTH: POLICY PRESCRIPTIONS TO UTILIZE TELEPSYCHIATRY AND TELEMENTAL HEALTH CARE SERVICES TO IMPROVE MENTAL HEALTH CARE ACCESS AND OUTCOMES

Because of the rapid pace of technological development, existing legal and regulatory frameworks struggle to remain current and adapt to new technologies. In order to implement telepsychiatry effectively, policymakers will need to travel to the heart of the regulatory labyrinth, grapple with the several large issues at its center, and return unscathed. Like Ariadne's thread, this section demystifies the tricky policy turns and pitfalls surrounding mental health technologies.

First, policymakers must ensure adequate reimbursement of providers for the provision of telemental health services. Second, policymakers must address geographic disparities in access. Third, policymakers must ensure robust privacy and confidentiality of patient mental health information. Fourth, policymakers must ensure adequate broadband access and connectivity to support deployment of telemental health services in all geographic locations. Fifth, policymakers must address the mental health physician shortage. Sixth, policymakers must ensure adequate provider training in the use of emerging telemental health technologies. Seventh, policymakers must address the issue of licensure of telemental health providers both within and outside of state lines. Eighth, policymakers must ensure the current standard of care facilitates the effective treatment of mental health issues via telemental health services. Ninth, federal policymakers must decide which regulatory path applies to emerging

⁴⁴¹ *Id.*

⁴⁴² *Id.*

⁴⁴³ *Id.*

mobile mental health technologies and applications. Lastly, policymakers must address the provision of collaborative care across the health care provider and professional spectrum.

A. Reimbursement

Because reimbursement rates act to incentivize or deter providers' adoption of telepsychiatry,⁴⁴⁴ they are a crucial piece of any strategy for effective telepsychiatry implementation. However, the current patchwork of differing reimbursement rates and policies across the states impede the effective implementation of telepsychiatry.⁴⁴⁵ Determining the rate at which payers will reimburse the provision of telepsychiatry services is a critical issue in effective implementation of telepsychiatry.⁴⁴⁶ Although telemental health services were among the first telemedicine services to receive reimbursement,⁴⁴⁷ the issue of reimbursement rates for telemental health care remains unsettled.

Although the cost savings resulting from telepsychiatry fuel debate on reimbursement rates, we urge maintaining the same reimbursement rates, or parity, for mental health services provided through telepsychiatry as those provided for in-person care. Because of its cost savings and effectiveness, proponents argue that telepsychiatry should be reimbursed at the same rate as other mental health services.⁴⁴⁸ Opponents argue that because telepsychiatry results in cost-savings, it should be reimbursed at a lower rate.⁴⁴⁹ However, lower reimbursement rates ultimately fail to incentivize greater use of telepsychiatry.⁴⁵⁰ Ultimately, lower reimbursement rates may even increase health care costs by deterring providers from providing cost-

⁴⁴⁴ See Henry, *supra* note 16.

⁴⁴⁵ NAT'L. CONF. OF STATE LEGISLATURES, TELEHEALTH POLICY TRENDS AND CONSIDERATIONS 4 (2015), <http://www.ncsl.org/documents/health/telehealth2015.pdf>.

⁴⁴⁶ See Henry, *supra* note 14, at 108.

⁴⁴⁷ *Id.*

⁴⁴⁸ See Tony Yang, *Health Policy Brief: Telehealth Parity Laws*, HEALTH AFF. 4 (Aug. 2016).

⁴⁴⁹ *Id.*

⁴⁵⁰ *Id.*; Peter Cunningham and Len Nichols, THE EFFECT OF MEDICAID REIMBURSEMENT ON THE ACCESS TO CARE OF MEDICAID ENROLLEES: A COMMUNITY PERSPECTIVE, 62 MED. CARE & RES. REV. 677, 693-94 (Dec. 2005) (observing that "physicians' willingness to accept Medicaid patients increases along with higher fee levels.").

effective care through telepsychiatry. Any dollars saved through lower reimbursement rates would be consumed by travel, time, and treatment costs relating to delayed or un-provided mental health care. Therefore, maintaining parity, or equal reimbursement rates, between mental health care services provided in-person or via telepsychiatry is critical to stimulating uptake of telemental health technology.

B. Geographic Disparities in Access to Care

Though geographic disparities in access to care underlie many of the other policy issues discussed throughout this paper,⁴⁵¹ we advise policymakers to emphasize rural and low-income urban areas, rather than taking a uniform geographical approach, in any policy intervention to ensure the most effective response to the mental health crisis. Such emphasis may include research examining the specific workforce needs of rural mental health shortage areas⁴⁵² or testing value-based alternative payment models.⁴⁵³

One approach to reducing geographic disparities is to prioritize studies examining the specific needs of mental health shortage areas. One study indicates that more specific research to collect information on workforce needs may help policymakers refine interventions to most effectively address geographic disparities.⁴⁵⁴ Specifically, this research should take into account five key areas. First, research should examine “workforce capacity in publicly-funded mental health agencies that provide the bulk of care.”⁴⁵⁵ Second, research should analyze “variations in workforce capacity across functional mental

⁴⁵¹ Henry, *supra* note 14, at 108.

⁴⁵² Richard L. Hough et al., *Workforce Capacity for Reducing Rural Disparities in Public Mental Health Services for Adults with Severe Mental Illness*, 35 J. RURAL MENTAL HEALTH 35, 36 (2011).

⁴⁵³ INST. OF MED., VARIATION IN HEALTH CARE SPENDING: TARGET DECISION MAKING, NOT GEOGRAPHY 2 (July 2013), http://www.nationalacademies.org/hmd/~media/Files/Report%20Files/2013/Geographic-Variation2/geovariation_rb.pdf/ (recommending that “CMS should continue to test payment reforms that offer incentives to providers to share clinical data, coordinate patient care, and assume some financial risk for the care of their patients” rather than “adjusting payments geographically based on any aggregate or composite measure of spending or quality” to avoid penalizing “high-value providers” and to account for geographic variation).

⁴⁵⁴ Hough et al., *supra* note 452.

⁴⁵⁵ *Id.*

health shortage areas, rather than larger geographic units such as states.”⁴⁵⁶ Third, research should probe “disparities in workforce capacity in relation to the size of the specific target populations.”⁴⁵⁷ Fourth, research should look at “workforce capacity types of specialty and non-specialty providers.”⁴⁵⁸ Lastly, research should quantify “workforce capacity in full-time equivalent (FTE) positions rather than estimates of the number of providers from professional association registries or other sources.”⁴⁵⁹

Similarly, the Institute of Medicine has recommended the continued testing of value-based payment methods that encourage care coordination, data sharing, and accountable care.⁴⁶⁰ This approach would take into account geographic variation within mental health shortage areas and avoid penalizing successful providers.⁴⁶¹

Lastly, policymakers could seek geographically targeted funding through the state’s Section 1115 Medicaid Waiver.⁴⁶² As of 2013, all twenty of the state’s Regional Healthcare Partnerships used Delivery System Reform Incentive Payment demonstrations within Texas’ Section 1115 Waiver “to increase the number of” mental health providers in rural areas.⁴⁶³ Including telepsychiatry incentives within these demonstration projects could further boost the number of mental health care providers in high-need geographic regions.⁴⁶⁴

⁴⁵⁶ *Id.*

⁴⁵⁷ *Id.*

⁴⁵⁸ *Id.*

⁴⁵⁹ *Id.*

⁴⁶⁰ INST. OF MED., *supra* note 453 (recommending that “CMS should continue to test payment reforms that offer incentives to providers to share clinical data, coordinate patient care, and assume some financial risk for the care of their patients” rather than “adjusting payments geographically based on any aggregate or composite measure of spending or quality” to avoid penalizing “high-value providers” and to account for geographic variations).

⁴⁶¹ *Id.*

⁴⁶² *The Mental Health Care Workforce in Texas: Hearing Before the House Select Comm. on Health Care Education and Training, supra* note 280 (noting, “the current DEA position is significantly impacting initial access to care, disrupting continuity of care, and is imposing a barrier to provide services to both vulnerable and underserved populations by a variety of medical disciplines across the state of Texas.”).

⁴⁶³ *Id.*

⁴⁶⁴ *Id.*

Because geographic disparities in access to mental health remain at the heart of the U.S. mental health crisis, policymakers must sharpen the focus of any telemental health policy intervention on high-need geographic regions.

C. Privacy and Confidentiality

Given the “exponential growth” of health care data breaches in recent years,⁴⁶⁵ we recommend policymakers take a thoughtful approach towards protecting the privacy and confidentiality of patient mental health information in spurring the implementation of telemental health technology.⁴⁶⁶ Beyond fostering a positive legal and regulatory environment, addressing privacy and confidentiality may enhance public perception of telepsychiatry.⁴⁶⁷ As a result, ensuring privacy and confidentiality of patients’ mental health information may help pave the way for both effective implementation and widespread acceptance of telepsychiatry.

Ensuring privacy and confidentiality of patient mental health information requires robust security features at “all stages of a telehealth encounter.”⁴⁶⁸ These security features must comply with state and federal privacy and data security laws, including HIPAA.⁴⁶⁹ Further, these features must protect data and privacy on both the patient and provider ends during and after the provision of telepsychiatry services, as well as, by each health care support professional and staff who has access to the patient’s data.⁴⁷⁰ For example, security features must protect and encrypt all “audio, video, and all other data transmissions.”⁴⁷¹ In light of the rise of mobile mental health apps, “security features such as multi-factor

⁴⁶⁵ U.S. GOV’T ACCOUNTABILITY OFF., GAO-16-771, ELECTRONIC HEALTH INFORMATION: HHS NEEDS TO STRENGTHEN SECURITY AND PRIVACY GUIDANCE AND OVERSIGHT (Aug. 2016).

⁴⁶⁶ See Laura Galbreath, Dir., SAMSHA-HRSA Ctr. for Integrated Health Sols., Nat’l. Council on Behavioral Health, Remarks at Broadband Prescriptions for Mental Health: A Policy Conference 164–65 (May 18, 2016), <https://www.fcc.gov/file/4029/download>.

⁴⁶⁷ NAT’L. CONF. OF STATE LEGISLATURES, *supra* note 445.

⁴⁶⁸ *Id.* at 23.

⁴⁶⁹ *Id.*

⁴⁷⁰ *Id.*

⁴⁷¹ *Id.*

authentication and the ability to remotely disable or erase personal health information are also examples of way to protect mobile device use.”⁴⁷²

In regard to privacy and confidentiality, consensus among stakeholders regarding the role of and need for state policy has failed to coalesce.⁴⁷³ Because federal privacy and confidentiality law preempts state law unless a state law is “more stringent” than federal law, “some stakeholders” argue that federal law is sufficient to ensure adequate privacy and confidentiality of patient mental health information.⁴⁷⁴ As a result, policymakers must decide whether federal privacy laws adequately protect the privacy of stakeholders or whether their stakeholders require further state policy action.⁴⁷⁵

D. Broadband Availability and Access

Because the effective implementation of telepsychiatry requires robust broadband availability and access,⁴⁷⁶ we recommend that policymakers also ensure adequate broadband infrastructure in all regions of the state. Using the FCC’s specification of “25 megabytes per second,” just over half of all Texans able to access a broadband connection in the state.⁴⁷⁷ At these levels, Texas’ access to broadband falls far short of the national average.⁴⁷⁸ Further, Texas’ low broadband speeds also hamper effective implementation of telemental health technologies, because these technologies require faster broadband speeds.⁴⁷⁹ As a result, policymakers must significantly expand and enhance broadband access and infrastructure to reap the benefits of telepsychiatry.

⁴⁷² *Id.*

⁴⁷³ *Id.*

⁴⁷⁴ *Id.*

⁴⁷⁵ *Id.*

⁴⁷⁶ Strover, *supra* note 17, at 101.

⁴⁷⁷ *Id.* at 96.

⁴⁷⁸ *Id.* at 95.

⁴⁷⁹ *Id.* at 97.

E. Standard of Care

As use of telemental health technologies becomes more prevalent, the standard of care, or accepted practice by a “similarly trained and equipped provider . . . in a similar situation,”⁴⁸⁰ becomes a salient issue for policymakers.⁴⁸¹ Specifically, we encourage policymakers to weigh “the rapid acceleration of technology and [telepsychiatry] and its potential benefits with the responsibility to ensure safe, quality care for their constituents.”⁴⁸² Across the country, state policymakers have typically taken two routes in this regard: (1) promulgating guidelines and (2) defining requirements for delivery via telemental health technologies.⁴⁸³

First, regulators and industry professional associations have promulgated guidelines covering the standard of care for general provision telehealth.⁴⁸⁴ For example, the American Telemedicine Association, the American Medical Association, and the Federation of State Medical Boards have all promulgated best practices for telemedicine.⁴⁸⁵

Next, state policymakers have defined requirements in statute or regulations that must be met in order for mental health services to be provided via telemental health technologies.⁴⁸⁶ For example, states have acted to define the provider-patient relationship.⁴⁸⁷ Other states have defined requirements for informed consent for patients to receive care via telepsychiatry.⁴⁸⁸ In addition, some states have directly

⁴⁸⁰ NAT'L. CONF. OF STATE LEGISLATURES, *supra* note 445.

⁴⁸¹ See Mari Robinson, Exec. Dir., Tex. Med. Bd., Remarks at Broadband Prescriptions for Mental Health: A Policy Conference 291-301 (May 18, 2016), <https://www.fcc.gov/file/4029/download>.

⁴⁸² NAT'L. CONF. OF STATE LEGISLATURES, *supra* note 445.

⁴⁸³ *Id.*

⁴⁸⁴ *Id.*

⁴⁸⁵ *Id.*

⁴⁸⁶ *Id.*

⁴⁸⁷ *Id.*

⁴⁸⁸ *Id.*

defined what services may or may not be provided via telemental health technology.⁴⁸⁹

Ultimately, while state policymakers must strike a critical balance to protect the public health while fostering the development and effective implementation of new technologies, because the standard of care still applies, it will effectively promote the responsible and effective use of telemental health technologies among the majority of physicians.⁴⁹⁰

F. Mental Health Physician Shortage

The lingering physician shortage in the United States helps drive the U.S. mental health crisis. Thus, we urge policymakers to continue to reduce the mental health physician shortage. Texas' physician shortage is particularly severe, and it impacts the state's mental health crisis by reducing access and fueling existing geographic disparities.⁴⁹¹ In Texas, an estimated 43,000 physicians serve a population of over twenty-three million.⁴⁹² Further, Texas has only 186 physicians for every 100,000 residents,⁴⁹³ compared to a national average of 236 physicians for every 100,000 residents.⁴⁹⁴ Alarming, fifty-seven percent of these physicians practice in one of the states four largest urban areas, compared to only 2.5 percent serving the over two million rural-dwelling Texans.⁴⁹⁵ Based on these statistics, Texas ranks forty-fifth in terms of its physician to patient ratio.⁴⁹⁶ When compared nationally, Texas mental health physician shortage is 58.2% below the nationwide average.⁴⁹⁷

⁴⁸⁹ *Id.*

⁴⁹⁰ *See id.*

⁴⁹¹ *See* Garnet Coleman, State Representative, Tex. House of Representatives, Remarks at Broadband Prescriptions for Mental Health: A Policy Conference 274 (May 18, 2016), <https://www.fcc.gov/file/4029/download>.

⁴⁹² *Why Texas Needs More Physicians*, TEX. MED. ASS'N, <http://www.texmed.org/Template.aspx?id=5427> (last visited Sept. 28, 2016).

⁴⁹³ *Id.*

⁴⁹⁴ *Id.*

⁴⁹⁵ *Id.*

⁴⁹⁶ *Id.*

⁴⁹⁷ *See The Mental Health Care Workforce in Texas: Hearing Before the House Select Comm. on Health*

Further, the number of residents and medical students graduating from Texas eight medical schools has remained nearly constant for approximately a quarter of a century.⁴⁹⁸ For example, each year, 5,400 medical students and 6,000 medical residents receive education through the state's eight medical schools.⁴⁹⁹ Decreased federal graduate medical education (GME) funding and state GME budget cuts contribute to this shortfall.⁵⁰⁰ Specifically, state budget cuts have reduced GME spending by approximately \$127 million in Medicaid support and \$8 million in other funding sources.⁵⁰¹ Further, Texas "is now one of only three states that does not pay for GME through the state Medicaid program."⁵⁰² Statistics support increased funding for GME. For example, physicians who completed medical school and residency are three times more likely to remain in Texas.⁵⁰³

Given the freezing of federal GME funding at 1996 levels,⁵⁰⁴ state funding for GME is crucial. State options include direct funding of GME⁵⁰⁵ and funding loan repayment assistance programs.⁵⁰⁶ Recently, state legislators acted to increase funding for GME.⁵⁰⁷ During the 84th Regular Session, Texas legislators passed Senate Bill 18, which will increase state funding for graduate medical education by \$300 million beginning in 2018.⁵⁰⁸ However, action on loan repayment assistance has been less successful. Specifically, the state established the Texas

Care Education and Training, *supra* note 280.

⁴⁹⁸ *Why Texas Needs More Physicians*, *supra* note 492.

⁴⁹⁹ *Id.*

⁵⁰⁰ *Id.*

⁵⁰¹ *Id.*

⁵⁰² *Id.*

⁵⁰³ *Id.*

⁵⁰⁴ *Id.*

⁵⁰⁵ *Id.*

⁵⁰⁶ *The Mental Health Care Workforce in Texas: Hearing Before the H. Select Comm. on Health Care Education and Training*, *supra* note 280 ("[T]he current DEA position is significantly impacting initial access to care, disrupting continuity of care, and is imposing a barrier to provide services to both vulnerable and underserved populations by a variety of medical disciplines across the state of Texas.").

⁵⁰⁷ *Id.*

⁵⁰⁸ *Id.*

Medicaid Loan Forgiveness plan and defunded it within three years.⁵⁰⁹ To further increase the number of mental health providers in Texas, state policymakers may need to weigh continued or increased state GME funding, with a targeted emphasis on mental health care providers, to fill the federal GME funding gap.

G. Provider Training

Provider training will also significantly impact the effective implementation of telepsychiatry.⁵¹⁰ In order to effectively implement telepsychiatry, we advocate health educators to emphasize training that includes a focus on new technologies and equipment.⁵¹¹ As a result, implementing training in telemental health technologies during providers' education will equip them with the skills to effectively use this technology.⁵¹² In addition, providing continuing education to current providers will bolster their skills and help make them more comfortable employing new technology to address patients' mental health care needs remotely.⁵¹³ At the same time, it is critical that any education keeps pace with the high speed of technological innovation.⁵¹⁴

H. Licensure

In tandem with growing use of telepsychiatry, licensure will become a salient issue for state policymakers as the practice of medicine potentially extends beyond state borders.⁵¹⁵ In response to the issue of licensure, states have taken three paths: (1) temporary or special licensure, (2) reciprocity and endorsement, and (3) adoption of interstate licensure compacts.⁵¹⁶ We propose that state policymakers

⁵⁰⁹ Foster, *supra* note 67, at 8.

⁵¹⁰ See Galbreath, *supra* note 466, at 162.

⁵¹¹ NAT'L. CONF. OF STATE LEGISLATURES, *supra* note 445, at 19.

⁵¹² *Id.* at 16.

⁵¹³ *Id.*

⁵¹⁴ *Id.*

⁵¹⁵ *Id.* at 16-19.

⁵¹⁶ *Id.*

consider at least one licensure pathway that provides for meaningful oversight while encouraging uptake of telemental health technologies.

First, some states have created temporary or special licenses to allow doctors to practice telemental health.⁵¹⁷ Wyoming has created an abbreviated path for physicians and physician assistants to obtain a temporary license to practice telehealth.⁵¹⁸ More commonly, states create special telehealth licenses that permit out-of-state providers to practice telehealth in the licensing state, as long as the licensee refrains from establishing an in-state office.⁵¹⁹ Nine states including Texas have taken this approach.⁵²⁰

Second, states have adopted reciprocity or endorsement policies to automatically grant licenses to practitioners from other states.⁵²¹ Under the reciprocity approach, each state agrees to accept a license from a provider licensed in the other state.⁵²² Alabama and Pennsylvania have opted to take the reciprocity approach.⁵²³ Similarly, states may implement endorsement agreements that allow for an out-of-state licensed provider who has satisfied licensure requirements out of state to obtain a license in a new state,⁵²⁴ as long as the licensee refrains from establishing an in-state office.⁵²⁵ Nine states including Texas have taken this approach.⁵²⁶

Lastly, states have begun to adopt interstate licensure compacts that provide for automatic licensure and more uniform standards among member states.⁵²⁷ In order to adopt an interstate compact, each member state must pass identical legislation that allows for full

⁵¹⁷ *Id.* at 16.

⁵¹⁸ *Id.*

⁵¹⁹ *Id.*

⁵²⁰ *Id.*

⁵²¹ *Id.*

⁵²² *Id.*

⁵²³ *Id.*

⁵²⁴ *Id.*

⁵²⁵ *Id.*

⁵²⁶ *Id.*

⁵²⁷ *Id.* at 16-18.

licensure of providers in member states.⁵²⁸ Most notably, in 2015, the Federation of State Medical Boards proposed Interstate Medical Licensure Compact gained significant approval.⁵²⁹ Although the compact required at least seven states to adopt it in order for it to take effect, twelve states adopted the compact in 2015 alone.⁵³⁰ These states are Alabama, Idaho, Illinois, Iowa, Minnesota, Montana, Nevada, South Dakota, Utah, West Virginia, Wisconsin, and Wyoming.⁵³¹ Although the 84th Texas Legislature saw a number of bills proposing adoption of the Interstate Medical Licensure Compact, none ultimately passed.⁵³²

I. Collaborative Care

In light of the use of other mental health professionals in providing telemental health services to mitigate the mental health provider shortage, collaborative care is another issue that will fuel the effective implementation of telepsychiatry.⁵³³ Studies highlight that collaborative mental health care is “both clinically-effective and cost-effective for a variety of mental health conditions, in a variety of settings, using several different payment mechanisms.”⁵³⁴ One study confirms the effectiveness of collaborative care in the telemental health care setting.⁵³⁵ As a result, combining the collaborative mental health care model with telemental health services will likely amplify the cost-effectiveness of both models of care.

To help effectively implement telepsychiatry, policymakers must incentivize education and training for providers and professionals.⁵³⁶

⁵²⁸ *Id.*

⁵²⁹ *Id.*

⁵³⁰ *Id.*

⁵³¹ *Id.*

⁵³² See, e.g., Tex. H.B. 661, 84th Reg. Sess. (2015).

⁵³³ See Fernandez, *supra* note 30, 73–78.

⁵³⁴ Jurgen Unutzer et al., *The Collaborative Care Model: An Approach for Integrating Physical and Mental Health Care in Medicaid Health Homes*, HEALTH HOME INFO. RESOURCE CTR. 1 (May 2013).

⁵³⁵ See John Fortney et al., *A Randomized Trial of Telemedicine-based Collaborative Care for Depression*, 22 J. GEN. INTERNAL MED. 1086 (2007).

⁵³⁶ See Fernandez, *supra* note 30, at 73–78.

This education and training must facilitate intercommunication, understanding, and familiarity with the role of other professionals in and methods of providing collaborative care using telemental health services.⁵³⁷

J. Regulation of Mental Health Apps as Medical Devices

Given the proliferation of cutting edge telemental health technologies⁵³⁸ and growing rates of use by consumers,⁵³⁹ federal regulators must provide targeted oversight to maximize the benefits of mobile mental health apps and minimize their safety risks.⁵⁴⁰ To achieve these aims, the FDA should provide meaningful oversight to stimulate development of evidence-based apps⁵⁴¹ and equip consumers with information to distinguish these evidence-based apps from others available on the market.⁵⁴² Rather than preempting FDA regulatory authority over mobile health apps, Congress should empower the agency to provide effective oversight.⁵⁴³

Because of the huge number of mobile health apps available and their potential risk to individuals seeking mental health care, we urge regulators to act to protect the public's health. As of October 2016, 259,000 mobile health applications were available on app stores.⁵⁴⁴ Comparatively, the FDA has approved only about 200 mobile health apps, with the vast majority cleared through the FDA's least stringent pathway.⁵⁴⁵ While evidence-based apps improve access and patient

⁵³⁷ *Id.*

⁵³⁸ Bernard Harris, Corporate Exec. Officer & Managing Partner, Vesalius Ventures, Keynote Address at Broadband Prescriptions for Mental Health: A Policy Conference 59 (May 18, 2016), <https://www.fcc.gov/file/4029/download>.

⁵³⁹ Strover, *supra* note 17, at 90-91

⁵⁴⁰ See Nathan G. Cortez et al., *FDA Regulation of Mobile Health Technologies*, 371 N. ENG. J. MEDICINE 372, 372 (2014).

⁵⁴¹ *Id.*

⁵⁴² Tara Donker et al., *Smartphones for Smarter Delivery of Mental Health Programs: A Systematic Review*, 15 J. MED. INTERNET RES. e247 (2013).

⁵⁴³ See Cortez et al., *supra* note 540, at 377.

⁵⁴⁴ Jane Sarasohn Kohn, *The Mobile Health App Glut*, HEALTHCARE IT NEWS (Oct. 21, 2016), <http://www.healthcareitnews.com/blog/mobile-health-app-glut>.

⁵⁴⁵ See *Examples of Pre-Market Submissions that Include MMAs Cleared or Approved by FDA*, U.S.

health outcomes, “the majority of apps that are currently available lack scientific evidence of their efficacy.”⁵⁴⁶ A recent survey of mobile health app developers found remote monitoring, diagnostic, medical condition management, and remote consultation to be the top four app types for market potential over the next five years.⁵⁴⁷ Further, twenty-seven percent of survey respondents found depression among the therapy fields with best market potential.⁵⁴⁸ Because an estimated 1.7 million people could be using mobile health applications by 2018,⁵⁴⁹ the necessity of regulatory action to ensure the safety and effectiveness of these apps and protect vulnerable consumers cannot be overstated.

Currently, the FDA relies on guidance to regulate only certain mobile health apps.⁵⁵⁰ As laid out in guidance, the FDA has decided to exercise regulatory authority over “only those mobile apps that are medical devices and whose functionality could pose a risk to a patient’s safety if the mobile app were to not function as intended.”⁵⁵¹ Rather than relying on unenforceable guidance, the FDA should provide regulatory clarity that strikes a balance between stimulating development of high-quality apps and protecting consumers from apps that are “ineffective or unsafe.”⁵⁵²

To protect the public’s health and stimulate development of evidence-based apps, the FDA must provide meaningful oversight, sufficient information, and regulatory clarity. A report issued by the Office of the National Coordinator for Health Information Technology, FDA, and FCC recommends only limited oversight authority over

FOOD & DRUG ADMIN. (last updated July 20, 2016), <http://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm368784.htm>.

⁵⁴⁶ Donker et al., *supra* note 542.

⁵⁴⁷ RESEARCH2GUIDANCE, MHEALTH APP DEVELOPER ECONOMICS 2016: THE CURRENT STATUS AND TRENDS OF THE MHEALTH APP MARKET 4 (Oct. 2016), <http://research2guidance.com/wp-content/uploads/2016/10/mHealth-App-Developer-Economics-2016-v17-Preview-1.pdf>.

⁵⁴⁸ *Id.*

⁵⁴⁹ Cortez et al., *supra* note 540, at 372.

⁵⁵⁰ See FOOD AND DRUG ADMIN., MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMIN. STAFF (2015), <http://www.fda.gov/downloads/MedicalDevices/./UCM263366.pdf>.

⁵⁵¹ *Id.*

⁵⁵² Cortez et al., *supra* note 540, at 377.

mobile health apps.⁵⁵³ Two recent legislative proposals would have prevented the FDA from regulating this technology⁵⁵⁴ or excluded the technology from FDA regulation.⁵⁵⁵ As part of the 21st Century Cures Act, certain provisions create a special “breakthrough device” pathway that allow a device that meets five statutory criteria to be eligible for an abbreviated approval pathway.⁵⁵⁶

CONCLUSION

Telepsychiatry provides a potent remedy for the U.S. mental health crisis. It delivers mental health care at the precise moment a patient’s need arises, regardless of geographic distance from the provider. Further, it delivers care in an effective manner for a variety of patient populations and mental health conditions. It reduces the impact of the mental health physician shortage and mitigates lingering geographic disparities in mental health provider distribution. Ultimately, telepsychiatry saves money, improves patient health outcomes, and maximizes the efficient use of existing health care resources.

As telemental health technologies continue to evolve and emerge, policymakers can fuel the effective implementation of telepsychiatry by targeted legislation and regulation that incentivizes provider use through fair reimbursement, addresses geographic disparities, tailors the existing standard of care to new technologies, enhances patient privacy and confidentiality, responds to the mental health provider shortage, provides a thoughtful licensure pathway for providers, promotes cutting edge training, facilitates collaborative care, and regulates mobile mental health apps in a thoughtful, measured manner. Successfully navigating this thicket of policy issues will pave

⁵⁵³ See U.S. FOOD & DRUG ADMIN., FDASIA HEALTH IT REPORT: PROPOSED STRATEGY AND RECOMMENDATIONS FOR A RISK-BASED FRAMEWORK 3 (2014).

⁵⁵⁴ The Preventing Reg. Overreach to Enhance Care Tech. (PROTECT) Act of 2014, S. 2007, 113th Cong. (2nd Sess. 2014).

⁵⁵⁵ The Sensible Oversight for Tech. Which Advances Reg. Efficiency (SOFTWARE) Act of 2013, H.R. 3303, 113th Cong. (1st Sess. 2013).

⁵⁵⁶ 21st Century Cures Act, Pub. L. No. 114-255, § 3051, 130 Stat. 1033 (2016).

the path to deploy telepsychiatry effectively to reduce cross-cutting mental health disparities and impact the U.S. mental health crisis.