
COMMENTS

POVERTY, MENTAL HEALTH, AND TECHNOLOGY: USING MEDICAID § 1315A INNOVATION GRANTS TO TEST OUT OWN-TIME TELEMENTAL HEALTH TECHNOLOGY*

“I never thought of myself as depressed so much as paralyzed by hope.”

– Maria Bamford¹

I. INTRODUCTION

The behavioral health crisis looms, but popular culture teaches us that technology can heal all woes. Americans retain unfettered access to technologies that “solve” nonexistent problems. Terrified by the possibility of out-of-focus photos of your gerbil? Fear no more! Buy a smartphone app designed to take the perfect pet photo.² Worried about putting one too many crystals of salt on your baked potato? Your new Bluetooth-enabled salt dispenser will measure out the precise amount.³ Though enchanting and readily available, most would agree that pet photo apps and Bluetooth salt dispensers do not serve necessary functions in our lives. The National Institute of Health has yet to declare a blurry cat photo crisis. The United States has, however, recognized a serious public health emergency around the availability of adequate behavioral health care⁴ for low-income people.⁵

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1. *Maria Bamford: The Special Special Special!* (Brady Oil Entertainment 2012).

2. Karissa Bell, *BarkCam Helps the Pet-Obsessed Take Better Dog Portraits*, MASHABLE (July 16, 2014), <http://mashable.com/2014/07/16/barkcam-app/#AtcLtlsmYSqG> [perma: <http://perma.cc/8SXS-AETJ>].

3. SMALT, <http://www.mysmalt.com> [perma: <http://perma.cc/6MFP-FG72>] (last visited May 29, 2018) (“Features mood-lighting to set the ambiance and a Bluetooth speaker to play music!”).

4. This Comment will use the term “behavioral health” to include mental health and substance use disorder diagnoses.

5. This Comment will use “low-income” to mean qualifying for Medicaid. In general, this means income at or below 133% of the federal poverty level (FPL). See ELICIA J. HERZ, CONG. RESEARCH SERV., RL33202, MEDICAID: A PRIMER 2–3 (2012).

Low-income people are almost one-and-a-half times more likely to be diagnosed with a behavioral health disorder in comparison to their more affluent peers,⁶ yet low-income people are far less likely to receive adequate treatment.⁷ This lack of access to treatment is the result of many factors, including fewer providers are willing to treat low-income people, travelling to appointments presents expensive logistical issues, and many low-income people face considerable provider discrimination.⁸ However, technology, specifically telemental health (TMH), presents a practical solution to surmount this problem.

TMH is the “use of telecommunications technology to connect patients and health care providers, permitting effective diagnosis, education, treatment, consultation, transfer of medical data, research, and other health care activities.”⁹ It is typically separated into two categories based on the technology used: synchronous and asynchronous.¹⁰ Synchronous TMH, or “real-time,” entails a provider, such as a therapist, treating the patient over videoconference or other similar technology.¹¹ Patients use asynchronous TMH, or “own-time” technology to work through a premade treatment module, much like a videogame. In own-time TMH, patients only need their therapist to approve them advancing through the module or to answer any questions over email.¹² Own-time TMH allows patients tremendous flexibility, has a strong evidence base supporting its treatment efficacy, and presents considerable cost savings.¹³ However, Medicaid—the biggest insurer of low-income people—does not cover own-time TMH, leaving millions of low-income Americans without needed care.¹⁴

The body of statutes governing Medicaid contains various vehicles for experimentation,¹⁵ and the Secretary of Health and Human Services (Secretary)¹⁶ possesses broad legislatively granted power to experiment with

6. See *infra* notes 23–24 and accompanying text.

7. See *infra* notes 34–3638 and accompanying text.

8. See *infra* notes 34–39 and accompanying text.

9. Frank W. Brown, *Rural Telepsychiatry*, 49 *PSYCHIATRIC SERVICES* 964, 964 (1998).

10. This Comment refers to synchronous TMH as “real-time” or “traditional” TMH because patients must receive treatment in a more traditional manner in real time, and this Comment refers to asynchronous TMH as “own-time” or “store-and-forward” because patients can receive treatment on their own time, when it is convenient for them.

11. See *infra* note 77 and accompanying text.

12. See *infra* notes 78–79, 91 and accompanying text.

13. See *infra* Part II.C.1 and accompanying text.

14. See *infra* notes 187–88 and accompanying text.

15. See *infra* Part III.C.2. See also *infra* note 227 mentioning Section 1915 waivers.

16. The Centers for Medicare & Medicaid Services (CMS) are ultimately overseen by the Secretary of the Department of Health and Human Services (Secretary). Though technically, the power to experiment ultimately resides in the Secretary, the Center for Medicare and Medicaid Innovation (CMMI) plays an important delegated role in authorizing and funding experimentation. See *infra* note 211 and accompanying text; see also DEP’T HEALTH & HUMAN SERVS., CMS ORGANIZATIONAL CHART (2015).

different models of service delivery.¹⁷ But in terms of testing a new approach to service delivery, Section 1115 waivers¹⁸ and § 1315a innovation grants present the most fertile options. Congress enacted both statutory frameworks to give Medicaid the power to allocate funds to states or private providers in order to try new ways of delivering service—all with the hope of developing a knowledge base to replicate those promising experiments in other states.¹⁹ Section 1115 waivers and § 1315a innovation grants each provide their own distinct advantages: Section 1115 waivers give states broad discretion with little accountability,²⁰ whereas § 1315a mandates strict reporting requirements upon individual providers or states to ensure that their results are replicable.²¹

This Comment asserts that own-time TMH presents an effective solution to the behavioral health crisis and that own-time TMH deserves Medicaid coverage. To achieve coverage, it argues that own-time TMH fits neatly into the statutory requirements of the best vehicle to test it out: § 1315a grants issued to individual, nonstate entities. It leverages the extensive literature that explores the virtues of the federalist system and applies that body of scholarship to both the behavioral health crisis and § 1315a grants.

II. BEHAVIORAL HEALTH AND TELEMENTAL HEALTH

The bodies of law governing behavioral health, telemedicine, and Medicaid are individually complex. When combined, their interactions are even more labyrinthine. Section II broadly addresses the context of the behavioral health crisis and treatment from both a historical and forward-looking perspective.

This Section proceeds in four parts. To provide a comprehensive understanding of behavioral health care disparities and current practice trends in behavioral health care, Part II.A begins with a discussion of the relationship between poverty and behavioral health challenges as well as the movement towards patient-centered care and cognitive behavioral therapy. Part II.B provides historical background on TMH with Part II.C detailing the promise of own-time TMH modalities. Part II.D then discusses translating evidence-based treatment into effective care, specifically addressing the use of practice guidelines as regulatory tools.

17. See *infra* Part III.C.2 for an overview of § 1315a innovation grants and Section 1115 waivers.

18. Though Section 1115 of the Social Security Act was incorporated into the Affordable Care Act, see Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 2601, 10201, 124 Stat. 119, 315, 922 (2010) (codified at 42 U.S.C. § 1315(a)), CMMI and commentators continue to refer to the waivers as Section 1115 waivers. See, e.g., *About Section 1115 Demonstrations*, MEDICAID.GOV, <http://www.medicaid.gov/medicaid/section-1115-demo/about-1115/index.html> [perma: <http://perma.cc/L52U-RH5G>] (last visited May 29, 2018); see also Sidney D. Watson, *Out of the Black Box and into the Light: Using Section 1115 Medicaid Waivers to Implement the Affordable Care Act's Medicaid Expansion*, 15 YALE J. HEALTH POL'Y L. & ETHICS 213, 213 (2015). This Comment will also use the Section 1115 designation.

19. See *infra* Part III.C.2 and accompanying text discussing the legislative history of Section 1115 and § 1315a.

20. 42 U.S.C. § 1315(a) (2012).

21. *Id.* § 1315a.

A. *The State of Behavioral Health Care in the United States Today*

Approximately fourteen percent of the global “burden of disease” is attributable to behavioral health disorders, and research suggests that this number underestimates the scale of the problem.²² The United States is no exception; it is estimated that 43.6 million adults eighteen years and older (or eighteen percent of the adult population) live with a mental health diagnosis.²³ For adults on Medicaid, the rate of behavioral health diagnoses skyrockets to twenty-seven percent.²⁴

There is a strong correlation between income level and social determinants of health.²⁵ Relative income determines health outcomes—even within one neighborhood, those who are poorer fare worse than those who are comparatively more affluent.²⁶ Taking the population as a whole, though wealth and income level are not the only predictors of mental health, experts agree that “poverty can be both a determinant and a consequence of poor mental health.”²⁷

22. Martin Prince et al., *No Health Without Mental Health*, 370 LANCET 859, 859 (2007). The “burden of disease” is a composite index of the negative effects caused by all disease and injuries across the world. WORLD HEALTH ORG., THE GLOBAL BURDEN OF DISEASE: 2004 UPDATE 2 (2004), http://www.who.int/healthinfo/global_burden_disease/GBD_report_2004update_full.pdf [perma: <http://perma.cc/RV63-YVLT>].

23. SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN. [SAMHSA], BEHAVIORAL HEALTH TRENDS IN THE UNITED STATES: RESULTS FROM THE 2014 NATIONAL SURVEY ON DRUG USE AND HEALTH 28 (2015), <http://www.samhsa.gov/data/sites/default/files/NSDUH-FRR1-2014/NSDUH-FRR1-2014.pdf> [perma: <http://perma.cc/R3V9-ZC2G>]. The population surveyed includes noninstitutionalized, civilian people living in the United States. *Id.* at 36 n.5. Additionally, 21.5 million American adults were diagnosed with a substance use disorder. *Id.* at 2.

24. MEDICAID & CHIP PAYMENT & ACCESS COMM’N [MACPAC], REPORT TO CONGRESS ON MEDICAID AND CHIP 94 (2015), <http://www.macpac.gov/wp-content/uploads/2015/06/June-2015-Report-to-Congress-on-Medicaid-and-CHIP.pdf> [perma: <http://perma.cc/DPM8-CPLM>] [hereinafter MACPAC, 2015 REPORT TO CONGRESS] (providing the 27% figure for adults between the ages of 21 and 64). Note that all of these figures report diagnosed disorders; there is strong support suggesting that a significant section of the American population has a *diagnosable* (whether actually diagnosed or not) mental health or substance use disorder. KAISER COMM’N ON KEY FACTS, THE ROLE OF MEDICAID FOR PEOPLE WITH BEHAVIORAL HEALTH CONDITIONS 1 (2012), http://kaiserfamilyfoundation.files.wordpress.com/2013/01/8383_bhc.pdf [perma: <http://perma.cc/3T6M-LLUY>]. The Kaiser Commission estimates that more than 60% of adults with a diagnosable disorder do not receive mental health services. *Id.*

25. See Christopher R. Browning & Kathleen A. Cagney, *Moving Beyond Poverty: Neighborhood Structure, Social Processes, and Health*, 44 J. HEALTH & SOC. BEHAV. 553, 565 (2003). See generally Ming Wen et al., *Poverty, Affluence, and Income Inequality: Neighborhood Economic Structure and Its Implications for Health*, 57 SOC. SCI. & MED. 843 (2003). Social determinants of health include the “structural conditions in which people are born, grow, live, work, and age.” HARRY J. HEIMAN & SAMANTHA ARTIGA, KAISER COMM’N ON MEDICAID & THE UNINSURED, BEYOND HEALTH CARE: THE ROLE OF SOCIAL DETERMINANTS IN PROMOTING HEALTH AND HEALTH EQUITY 2 (2015) (quoting Michael Marmot et al., *Closing the Gap in a Generation: Health Equity Through Action on the Social Determinants of Health*, 372 LANCET 1661, 1661 (2008)).

26. Wen et al., *supra* note 25, at 844.

27. Vijaya Murali & Femi Oyebo, *Poverty, Social Inequality and Mental Health*, 10 ADVANCES PSYCHIATRIC TREATMENT 216, 217 (2004) (explaining that poverty causes mental illness). There is disagreement as to whether poverty is the cause of mental illness (that “adversity, stress, and reduced capacity to cope” increased the likelihood of developing mental illness), Jitender Sareen et al.,

Despite the disagreement surrounding the causal relationship between poverty and behavioral health disorders, there is a strong consensus that poverty and its associated deprivations are risk factors.²⁸

Untreated or undertreated behavioral health diagnoses lead to reduced income for individuals and large economic costs to communities. It is estimated that individual workers lose over \$193 billion in wages per year due to mental illness-associated issues,²⁹ and that employers have lost over \$100 billion in lost employee productivity.³⁰ Effective behavioral health treatment, however, has been shown to improve economic outcomes for individuals and their communities.³¹

There is a strong relationship between access to and cost of care in the United States. Approximately thirteen percent of the American adult population lives below the federal poverty level.³² Behavioral health services are expensive,³³ often limiting low-income people from accessing any treatment.³⁴ And where treatment is available to low-income people, it is more likely to be of

Relationship Between Household Income and Mental Disorders: Findings from a Population-Based Longitudinal Study, 68 ARCHIVES GEN. PSYCHIATRY 419, 419 (2011), or whether the consequences of mental illness, such as hospitalizations and the resulting loss of work, cause poverty. Murali & Oyeboode, *supra*, at 216.

28. See A. Kuruvilla & K.S. Jacob, *Poverty, Social Stress & Mental Health*, 126 INDIAN J. MED. RES. 273, 274 (2007); Vikram Patel et al., *Risk Factors for Common Mental Disorders in Women*, 189 BRIT. J. PSYCHIATRY 547, 550 (2006); Scott Weich & Glyn Lewis, *Poverty, Unemployment, and Common Mental Disorders: Population Based Cohort Study*, 317 BMJ 115, 118 (1998). Increases in income, including exits from poverty, have been connected to reductions in psychological symptoms. E. Jane Costello et al., *Relationships Between Poverty and Psychopathology: A Natural Experiment*, 290 J. AM. MED. ASS'N 2023, 2023 (2003).

29. Ronald C. Kessler et al., *Individual and Societal Effects of Mental Disorders on Earnings in the United States: Results from the National Comorbidity Survey Replication*, 165 AM. J. PSYCHIATRY 703, 708 (2008). This includes lost earnings. *Id.*

30. Paolo del Vecchio, *What's Good for Mental Health Is Good for the Economy*, SAMHSA BLOG (Apr. 29, 2016), <http://blog.samhsa.gov/2016/04/29/whats-good-for-mental-health-is-good-for-the-economy/#.WBusBJMrKR> [perma: <http://perma.cc/55WJ-BZSH>]. Additionally, a childhood behavioral health diagnosis, such as oppositional defiance disorder, strongly predicts school dropout, which in turn is a predictor of lost earning potential. Joshua Breslau et al., *Mental Disorders and Subsequent Educational Attainment in a US National Sample*, 42 J. PSYCHIATRIC RES. 708, 708 (2008). See generally, Ronald C. Kessler et al., *Social Consequences of Psychiatric Disorders, I: Educational Attainment*, 152 AM. J. PSYCHIATRY 1026 (1995).

31. Dan Chisholm et al., *Reducing the Global Burden of Depression*, 184 BRIT. J. PSYCHIATRY 393, 397–402 (2004).

32. BERNADETTE D. PROCTOR ET AL., U.S. CENSUS BUREAU, INCOME AND POVERTY IN THE UNITED STATES: 2015, at 13 tbl.3 (2016), <http://www.census.gov/content/dam/Census/library/publications/2016/demo/p60-256.pdf> [perma: <http://perma.cc/DKP6-FQ7W>] (using statistics from 2014 and 2015).

33. David Mechanic & Mark Olfson, *The Relevance of the Affordable Care Act for Improving Mental Health Care*, 12 ANN. REV. CLINICAL PSYCHOL. 515, 518, 530 (2016).

34. Lindsey Wahowiak, *Addressing Stigma, Disparities in Minority Mental Health: Access to Care Among Barriers*, NATION'S HEALTH (2015), <http://thenationshealth.aphapublications.org/content/45/1/1.3.full>. See generally Jeanne Miranda et al., *Mental Health in the Context of Health Disparities*, Commentary, 165 AM. J. PSYCHIATRY 1102 (2008).

lower quality.³⁵ There is a dearth of behavioral health care providers accepting private insurance,³⁶ and the public health system has a “significant” shortage of mental health professionals.³⁷ However, those who are insured, whether publicly or privately, are more likely to obtain needed behavioral health care.³⁸ Though access to care is extremely important, it is not analogous to quality of care. Part II.A.1 discusses the concepts of health care quality, patient-centered care, and their interrelatedness. Part II.A.2 provides background information on cognitive behavioral therapy as a dominant force in modern psychotherapy.

1. Health Care Quality and Patient-Centered Care

In health care, many different definitions have been attached to the word “quality.”³⁹ The Institute of Medicine (IOM) has defined health care quality as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”⁴⁰ Similarly, the Agency for Healthcare Research and Quality (AHRQ) has defined quality as “doing the right thing for the right patient, at the right time, in the right way to achieve the best possible results.”⁴¹ These two definitions attempt to get at the fundamental idea that quality care is individualized, evidence-based, and leads to success.⁴² Quality is a universal

35. Kevin Fiscella & David R. Williams, *Health Disparities Based on Socioeconomic Inequities: Implications for Urban Health Care*, 79 ACAD. MED. 1139, 1139 (2004) (explaining that though socioeconomic level is an important factor, “[r]ace, socioeconomic status, and health have historically been inextricably intertwined in the United States”).

36. Janet R. Cummings, *Rates of Psychiatrists’ Participation in Health Insurance Networks*, 313 J. AM. MED. ASS’N. 190, 190–91 (2015).

37. Wahowiak, *supra* note 34.

38. Sheryl H. Kataoka et al., *Unmet Need for Mental Health Care Among U.S. Children: Variation by Ethnicity and Insurance Status*, 159 AM. J. PSYCHIATRY 1548, 1553 (2002) (noting that “Medicaid and other public insurance programs offer an important safety net” in providing access to behavioral health care for otherwise uninsured children); *see also* Marsha Lillie-Blanton & Catherine Hoffman, *The Role of Health Insurance Coverage in Reducing Racial/Ethnic Disparities in Health Care*, 24 HEALTH AFF. 398, 398–99 (2005). *But see* Steven M. Asch et al., *Who Is at Greatest Risk for Receiving Poor-Quality Health Care?*, 354 N. ENG. J. MED. 1147, 1154 (2006) (“Although having insurance increases the ease of access to the health care system, it is not sufficient to ensure appropriate use of services or content of care.”); Timothy B. Creedon & Benjamin Lê Cook, *Access to Mental Health Care Increased but Not for Substance Use, While Disparities Remain*, 35 HEALTH AFF. 1017, 1020 (2016) (“[G]ains in insurance coverage alone are not likely to push forward meaningful reductions in mental health treatment disparities or increase consistently low overall substance use treatment rates.”).

39. NAT’L COMM. FOR QUALITY ASSURANCE, THE ESSENTIAL GUIDE TO HEALTH CARE QUALITY 6 (n.d.) [hereinafter NCQA REPORT] (noting the various definitions of quality in health care).

40. INST. OF MED., CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY 232 (2001) (quoting INST. OF MED., MEDICARE: A STRATEGY FOR QUALITY ASSURANCE (1990)).

41. NCQA REPORT, *supra* note 39, at 6.

42. *Id.* (“[Health care quality is] based on scientific and medical evidence, it takes the specific details of a patient’s life into consideration and it is aimed at improving the health and life of the patient being treated.”). Unless otherwise noted, this Comment will use “quality” to mean achieving

ideal, unconnected to diagnosis or income level.⁴³

People with behavioral health challenges may be “particularly vulnerable” to receiving low-quality treatment because they are disproportionately low-income, “lack social supports, have cognitive and functional disabilities, and may be reticent to complain about poor-quality care.”⁴⁴ Considerable research has shown that providers’ biases towards certain socioeconomic groups impact the quality of care they provide to those groups, not only in terms of “hard” skills, like diagnosing, but also in terms of “soft” skills, such as patient interaction.⁴⁵

In an effort to foster quality, health care is moving toward patient-centered care.⁴⁶ Patient-centered care requires the provider to approach patients “as persons in context of their own social worlds, listened to, informed, respected, and involved in their care.”⁴⁷ Proponents of patient-centered care argue that it is justifiable on ethical and pragmatic grounds—it is both the *right* thing to do and the *effective* thing to do.⁴⁸ The IOM’s seminal report, *Crossing the Quality Chasm*, listed patient-centered care as one of the core aspects of effective health care.⁴⁹ Various health care accrediting bodies have supported this proposition,⁵⁰ and an ever-increasing amount of research continues to identify the value of

optimal health outcomes for populations served. See HEALTH RES. & SERVS. ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., QUALITY IMPROVEMENT 1 (2011) (citing IOM definition, and defining health care quality as “a direct correlation between the level of improved health services and the desired health outcomes of individuals and populations”). Systems-wide quality is also an incredibly important subject, but to discuss it would exceed the limits of this Comment.

43. See INST. OF MED., *supra* note 40, at 53 (“[T]he quality of care should not differ because of such characteristics as gender, race, age, ethnicity, income, education, disability, sexual orientation, or location of residence.”).

44. Julie Seibert et al., *Use of Quality Measures for Medicaid Behavioral Health Services by State Agencies: Implications for Health Care Reform*, 66 PSYCHIATRIC SERVICES 585, 585 (2015) (noting that concerns about “stigma” often dissuade people with behavioral health issues from complaining about poor-quality care).

45. See generally Janice A. Sabin et al., *Physician Implicit Attitudes and Stereotypes About Race and Quality of Medical Care*, 46 MED. CARE 678 (2008) (discussing other studies). For example, one study measuring the impact of race on patient-centered care found that doctors were twenty-three percent more verbally dominant and participated in thirty-three percent less patient-centered communication with African-Americans than with white patients. Rachel L. Johnson et al., *Patient Race/Ethnicity and Quality of Patient-Physician Communication During Medical Visits*, 94 AM. J. PUB. HEALTH 2084, 2084 (2004).

46. Ronald M. Epstein et al., *Why the Nation Needs a Policy Push on Patient-Centered Health Care*, 29 HEALTH AFF. 1489, 1489 (2010).

47. Ronald M. Epstein & Richard L. Street, Jr., *The Values and Value of Patient-Centered Care*, 9 ANNALS FAM. MED. 100, 100 (2011). The medical model of health care, which is often viewed as the opposite of a patient-centered model, “limit[s] its attention to the finitude of human bodies” as opposed to “the needs of whole human persons.” Daniel P. Sulmasy, *A Biopsychosocial-Spiritual Model for the Care of Patients at the End of Life*, 42 GERONTOLOGIST 24, 24 (2002).

48. Epstein et al., *supra* note 46, at 1489.

49. INST. OF MED., *supra* note 40, at 6. Similarly, the National Committee for Quality Assurance (NCQA) reported that patient-centered care is effective care. NCQA REPORT, *supra* note 39, at 10.

50. E.g., NAT’L COMM. FOR QUALITY ASSURANCE, NCQA PATIENT-CENTERED MEDICAL HOME: IMPROVING EXPERIENCES FOR PATIENTS, PROVIDERS AND PRACTICE STAFF (2014), <http://www.ncqa.org/Portals/0/PCMH%20brochure-web.pdf> [perma: <http://perma.cc/PVV3-3XTR>].

patient-provider communication in achieving desired health care outcomes.⁵¹

Patient-centered care comprises three key dimensions: relational, clinical, and structural.⁵² The relational dimension prioritizes the use of multidisciplinary teams, effective patient-provider communication, and the development of patient knowledge.⁵³ The clinical dimension focuses on the way that care is provided, specifically the process for making clinical decisions (such as the need for evidence-based treatment), the coordination of care, the reimbursement structure, and the types of encounters allowed.⁵⁴ This dimension focuses on the way that clinical decisions are made as well as how the service is delivered.⁵⁵ The clinical dimension also embraces questions about how to use technology to address people's needs or preferences⁵⁶—for some patients with long commutes, for example, the benefits of receiving therapy services using own-time technology may outweigh the potential drawbacks. The structural dimension addresses the physical space in which the service is provided, the ease of access to care, and the use of information technology.⁵⁷

Patient-centered care places a strong focus on the promotion of patient agency and personal autonomy.⁵⁸ It draws from an understanding that people who feel control over their actions and what is happening to them are generally more successful in achieving their goals, whether health related or otherwise.⁵⁹ This is consistent with modern approaches to psychotherapy, specifically cognitive behavioral therapy.

2. Modern Psychotherapy's Embrace of Cognitive Behavioral Therapy

Since 1976, cognitive behavioral therapy (CBT) has become one of the most widely employed forms of psychotherapy in the United States.⁶⁰ CBT has been

51. Francesca Dwamena et al., *Interventions for Providers to Promote a Patient-Centred Approach in Clinical Consultations*, COCHRANE DATABASE SYSTEMATIC REVIEWS, no. 12, 2012, at 3–4 (“A growing consensus . . . identifies provider-patient communication as a key to . . . achieving patient-centred care.”).

52. Sarah M. Greene et al., *A Framework for Making Patient-Centered Care Front and Center*, PERMANENTE J., Summer 2012, at 49, 50.

53. *Id.*; see also Marissa K. Constand et al., *Scoping Review of Patient-Centered Care Approaches in Healthcare*, BMC HEALTH SERVICES RES., no. 14, 2014, at 271, 271.

54. Greene et al., *supra* note 52, at 50.

55. *Id.* at 52. For example, this might include a shared decisionmaking model where providers and patients use structured tools to determine the best course of action for that patient. *Id.*

56. *Id.*

57. *Id.* at 50. This aspect of patient-centeredness examines the use of infrastructure to facilitate better patient outcomes. *Id.* at 52–53. In terms of telemedicine, the structural dimension and clinical dimension of patient-centeredness may be difficult to separate because telemedicine can be considered both a clinical intervention and a method of service delivery. See *id.* at 50–52.

58. Kathleen Montgomery & Miles Little, *Enriching Patient-Centered Care in Serious Illness: A Focus on Patients' Experiences of Agency*, 89 MILBANK Q. 381, 382 (2011).

59. *Id.* at 382.

60. Brandon A. Gaudiano, *Cognitive-Behavioural Therapies: Achievements and Challenges*, 11 EBMH 5, 5 (2008); John C. Norcross et al., *Clinical Psychologists Across the Years: The Division of Clinical Psychology from 1960 to 2003*, 61 J. CLINICAL PSYCHOL. 1467, 1471 tbl.1 (2005) (explaining

successfully used to treat mood disorders, anxiety disorders, and chronic pain, among other diagnoses.⁶¹ In short, CBT focuses on helping us to improve the way we perceive events in order to help us react differently toward them, which in turn helps us to feel differently about them.⁶²

Since its inception, CBT practitioners and proponents believed the methodology should be built on scientific principles that were testable and replicable.⁶³ As CBT has evolved, it has continued to focus on proving (and improving) its value through ongoing empirical evaluation.⁶⁴ Of all therapeutic interventions, CBT possesses the largest evidentiary body of support.⁶⁵

B. TMH History and Current Usage

Telemedicine is broadly defined as “the use of advanced telecommunications technologies to exchange health information and provide healthcare services across geographic, time, social and cultural barriers.”⁶⁶ TMH, a specialty within telemedicine, employs telecommunications technology to link

that as of 2003, twenty-eight percent of therapists reported their primary therapeutic orientation as using behavioral therapy, which was second only to “eclectic/integrative” orientation).

61. Gaudiano, *supra* note 60, at 5 (explaining in an examination of sixteen meta analyses, CBT produced “large effect size improvement” in adults and teenagers with emotional disorders, and that CBT has been shown to be more effective than antidepressants for adult depression). CBT can be understood as “the class of interventions that are based on the basic premise that emotional disorders are maintained by cognitive factors, and that psychological treatment leads to changes in these factors through cognitive . . . and behavioral . . . techniques.” Stefan G. Hofmann & Jasper A. J. Smits, *Cognitive-Behavioral Therapy for Adult Anxiety Disorders: A Meta-Analysis of Randomized Placebo-Controlled Trials*, 69 J. CLINICAL PSYCHIATRY 621, 622 (2008).

62. Courtney L. Benjamin et al., *History of Cognitive-Behavioral Therapy in Youth*, 20 CHILD & ADOLESCENT PSYCHIATRY CLINICS N. AM. 179, 180–81 (2011); see also *What Is Cognitive Behavioral Therapy (CBT)?*, BECK INST. FOR COGNITIVE BEHAV. THERAPY, <http://www.beckinstitute.org/get-informed/what-is-cognitive-therapy/> [perma: <http://perma.cc/5GE2-FZ7E>] (last visited May 29, 2018) (“CBT is a psychotherapy that is based on the cognitive model: the way that individuals perceive a situation is more closely connected to their reaction than the situation itself. One important part of CBT is helping clients change their unhelpful thinking and behavior that lead [sic] to enduring improvement in their mood and functioning.”).

63. Steven C. Hayes, *Acceptance and Commitment Therapy, Relational Frame Theory, and the Third Wave of Behavioral and Cognitive Therapies*, 35 BEHAV. THERAPY 639, 640 (2004). Today, this may seem to be a “no-brainer”; however, in contrast to the preexisting clinical methodologies that “had a very poor link to scientifically established basic principles,” the underlying empiricism of CBT was revolutionary. *Id.* Those who practiced in the classical Freudian psychoanalytical school employed “convoluted” analytical schemes to determine the origins of the patient’s problem, whereas early CBT practitioners employed simple methods of analysis, with a focus on reducing problematic behavior and emotion. See *id.* at 641 (comparing, in hilarious detail, the Freudian and behaviorist approaches in the tale of “Little Hans”).

64. See generally *id.* CBT, though often referred to as a singular modality, is not monolithic. Gaudiano, *supra* note 60, at 5 (explaining that though it “is possible to describe the main elements of CBT, one should recognise that the actual application can and does vary somewhat in practice”).

65. Cf. Gaudiano, *supra* note 60, at 5 (noting CBT’s “impressive amount of empirical support”).

66. ADAM WILLIAM DARKINS & MARGARET ANN CARY, *TELEMEDICINE AND TELEHEALTH: PRINCIPLES, POLICIES, PERFORMANCE, AND PITFALLS 2* (2000) (providing four definitions of the term).

providers with patients in order to facilitate diagnosis and treatment.⁶⁷ TMH includes “all mental health applications including telepsychiatry and telemental health-care.”⁶⁸ After teleradiology, telepsychiatry, a subset of TMH, is the “most practiced form of telemedicine in the world.”⁶⁹

TMH has been provided in a diversity of settings and clinical encounters,⁷⁰ and to serve a diversity of populations.⁷¹ Though TMH services have been touted as a solution to the dearth of mental health care in rural communities,⁷² they are also used in urban settings.⁷³ A variety of services can be provided using TMH, including assessments, diagnoses, evaluations, and psychosocial interventions.⁷⁴

TMH services are often defined in terms of the types of technology employed: synchronous versus asynchronous communication.⁷⁵ Synchronous or “real-time” technology includes videoconferencing or telephone-based services.⁷⁶ Asynchronous or “own-time” technologies “involve acquiring medical

67. Brown, *supra* note 9, at 964.

68. Subho Chakrabarti, *Usefulness of Telepsychiatry: A Critical Evaluation of Videoconferencing-Based Approaches*, 5 WORLD J. PSYCHIATRY 286, 288 (2015).

69. *Id.* It has also been in existence since 1958 when the University of Nebraska began performing telepsychiatry experiments. Christina Hernandez Sherwood, *Telepsychiatry as a Growing Frontier in Mental Health*, MEDCITY NEWS (Aug. 8, 2016, 5:21 PM), <http://medcitynews.com/2016/08/telepsychiatry-growing-frontier-mental-health/> [perma: <http://perma.cc/MQ65-TTS2>].

70. Chakrabarti, *supra* note 68, at 289 (noting the diversity of settings such as inpatient facilities, outpatient facilities, emergency rooms, prisons, schools, and even patients’ own homes); *see also* Meera Narasimhan et al., *Impact of Telepsychiatry Program at Emergency Departments Statewide on the Quality, Utilization, and Costs of Mental Health Services*, 66 PSYCHIATRIC SERVICES 1167, 1167–68 (2015) (discussing the South Carolina pilot program that used telepsychiatry to reduce the frequency and duration of emergency room admissions for psychiatric patients).

71. Chakrabarti, *supra* note 68, at 289 (including children, adults, elderly, prison populations, and military personnel among those served by TMH).

72. *E.g.*, Sy Atezaz Saeed et al., *Use of Telepsychiatry to Improve Care for People with Mental Illness in Rural North Carolina*, 72 N.C. MED. J. 219, 219 (2011).

73. Chakrabarti, *supra* note 68, at 289.

74. *Id.*

75. *E.g.*, EPSTEIN BECKER GREEN, 50-STATE SURVEY OF TELEMENTAL/TELEBEHAVIORAL HEALTH 4 (2016). Remote monitoring, which uses technology to collect data about a patient (imagine a patient wearing heart-rate monitor that reports information to the patient’s cardiologist), is also a third type, though it is outside the scope of this Comment. *See Remote Patient Monitoring*, CTR. FOR CONNECTED HEALTH POL’Y, <http://www.cchpca.org/remote-patient-monitoring> [perma: <http://perma.cc/F8PY-3LWW>] (last visited May 29, 2018).

76. Chakrabarti, *supra* note 68, at 288. Videoconferencing is the form of TMH that shares the most similarities with traditional face-to-face mental health counseling. Its similarities and “multisensory experience make it an attractive alternative to other technologies” in providing mental health services. Lisa K. Richardson et al., *Current Directions in Videoconferencing Tele-Mental Health Research*, 16 CLINICAL PSYCHOL. 323, 323 (2009). CBT is a commonly used modality in real-time TMH with considerable success. *See* Gemma Kok et al., *The Three-Month Effect of Mobile Internet-Based Cognitive Therapy on the Course of Depressive Symptoms in Remitted Recurrently Depressed Patients: Results of Randomized Controlled Trial*, 84 PSYCHOTHERAPY & PSYCHOSOMATICS 90, 91 (2015) (explaining that a large body of evidence has shown that CBT prevents relapse into a major depressive period); *see also* Per Carlbring et al., *Long-Term Outcome of Internet-Delivered Cognitive Behavioral Therapy for Social Phobia: A 30-Month Follow-Up*, 47 BEHAV. RES. & THERAPY 848, 848

data, and then transmitting this clinical information . . . for later review by a specialist.”⁷⁷ Own-time communication allows for the transfer of text, biometric information, audio-video clips, or recordings.⁷⁸ Both real-time and own-time technologies have been used either on their own, in tandem, or paired with some sort of face-to-face encounter.⁷⁹ Though videoconferencing may create a more familiar environment, interventions using own-time technologies have also proven effective.

C. *The Promise of Own-Time TMH Modalities*

A nascent, yet growing, body of research shows that own-time TMH is highly effective. Part II.C.1 discusses support for own-time TMH and provides concrete illustrations of how it works. Part II.C.2 discusses the research limitations associated with such a new type of practice.

1. Own-Time TMH: Why and How It Works

Own-time modes for delivering behavioral health services provide a vehicle for increasing access to evidence-based therapeutic interventions, such as CBT.⁸⁰ Unlike real-time TMH technologies like videoconferencing, own-time TMH can feel quite different from traditional mental health services, in that communication with a mental health professional is delayed, and the patient is doing a considerable amount of the therapeutic intervention on her own.⁸¹ For many people who are accustomed to traditional therapeutic modalities, this can be a difficult adjustment.⁸² However, a growing body of evidence shows that own-time TMH is as effective as traditional face-to-face therapy,⁸³ and it may also present distinct advantages over real-time TMH.⁸⁴ Though there are a

(2009) (noting that “internet-delivered . . . cognitive behaviour therapy for social anxiety disorder has been found to generate promising short-term results, up to one year posttreatment”); Gretchen J. Diefenbach et al., *Changes in Quality of Life Following Cognitive-Behavioral Therapy for Obsessive-Compulsive Disorder*, 45 BEHAV. RES. & THERAPY 3060, 3060 (2007).

77. Chakrabarti, *supra* note 68, at 288.

78. *Id.*

79. See, e.g., Benjamin W. Van Voorhees et al., *Randomized Clinical Trial of an Internet-Based Depression Prevention Program for Adolescents (Project CATCH-IT) in Primary Care: 12-Week Outcomes*, 30 J. DEVELOPMENTAL & BEHAV. PEDIATRICS 23 (2009) (discussing intervention using both own-time and real-time components).

80. Jesper Enander et al., *Therapist Guided Internet Based Cognitive Behavioural Therapy for Body Dysmorphic Disorder: Single Blind Randomised Controlled Trial*, 352 BMJ 2016, at i241 (explaining the program used student therapists as the primary provider with a supervising experienced therapist).

81. *E.g., id.*

82. See *infra* notes 109–12 and accompanying text discussing provider and patient reservations.

83. Gerhard Andersson et al., *Guided Internet-Based vs. Face-To-Face Cognitive Behavior Therapy for Psychiatric and Somatic Disorders: A Systematic Review and Meta-Analysis*, 13 WORLD PSYCHIATRY 288, 288 (2014) [hereinafter Andersson et al., *A Systematic Review*].

84. Own-time TMH is “convenient, flexible, and reduces traveling time, costs, and waiting lists, enabling more patients to be reached and treated.” Sylvia van Beugen et al., *Internet-Based Cognitive Behavioral Therapy for Patients with Chronic Somatic Conditions: A Meta-Analytic Review*, 16 J. MED.

variety of own-time TMH modalities available, Internet-based cognitive behavioral therapy (ICBT) is one of the most widely adapted and has received a large amount of meta-analysis.⁸⁵

Though there is considerable variation based on the needs of the populations being served, in general, “ICBT takes the form of an online self-help program, guided by a therapist who gives feedback and answers questions.”⁸⁶ For example, BDD-NET, a treatment modality for adults diagnosed with body dysmorphic disorder, entails a twelve-week-long program in which participants guide themselves through eight interactive modules in an online platform.⁸⁷ The platform records their interactions with the module as well as the communication between provider and patient.⁸⁸ Each module provides psychoeducation about their diagnosis, cognitive restructuring, and relapse prevention.⁸⁹ In order to progress through each module, participants are required to complete module-specific homework assignments, which are automatically submitted to their therapists.⁹⁰ Participants are able to contact their therapists using email at any time throughout the twelve-week course of treatment.⁹¹ Often, each specific module corresponds to what would be a face-to-face therapy session.⁹² In a sense, BDD-NET functions much like a videogame with an email component.

Own-time TMH is attractive because it provides cost savings and is highly flexible. For example, own-time ICBT requires far less of each therapist’s time, which directly translates to reduced costs and increased access to behavioral

INTERNET RES., no. 3, 2014, at e88, 2; *see also* Erik Andersson et al., *Cost-Effectiveness of Internet-Based Cognitive Behavior Therapy for Irritable Bowel Syndrome: Results from a Randomized Controlled Trial*, 11 BMC PUB. HEALTH, 2011, at 215, 215 (concluding that ICBT provides effective treatment for irritable bowel syndrome and generates cost savings in the form of patients missing fewer days of work).

85. Gerhard Andersson & Pim Cuijpers, *Pros and Cons of Online Cognitive-Behavioural Therapy*, 193 BRIT. J. PSYCHIATRY 270, 270 (2008); *see, e.g.*, Gerhard Andersson & Pim Cuijpers, *Internet-Based and Other Computerized Psychological Treatments for Adult Depression: A Meta-Analysis*, 38 COGNITIVE BEHAV. THERAPY 196 (2009); van Beugen et al., *supra* note 84. In the scientific community, and especially those who study mental health, the process of “[m]eta-analysis has gained increasing recognition as a useful way to evaluate the efficacy of a treatment and has certain advantages as well as limitations as a review method.” Andrew C. Butler et al., *The Empirical Status of Cognitive-Behavioral Therapy: A Review of Meta-Analyses*, 26 CLINICAL PSYCHOL. REV. 17, 18 (2006).

86. van Beugen et al., *supra* note 84, at 2.

87. Enander et al., *supra* note 80, at 3.

88. *Id.*

89. *Id.*

90. *Id.*

91. *Id.* As BDD-NET was conscientiously self-guided, the therapist served to “guide and coach the participant throughout the treatment, provide feedback on homework assignments, answer questions from the participants, and consecutively grant access to the next treatment module.” *Id.*

92. Andersson et al., *A Systematic Review*, *supra* note 83, at 288. ICBT, however, is not monolithic. *See, e.g.*, Björn Meyer et al., *Effects of an Internet Intervention (Deprexis) on Severe Depression Symptoms: Randomized Controlled Trial*, 2 INTERNET INTERVENTIONS 48, 50–51 (2015) (explaining that the studied treatment modality employs “simulated dialogues” with a computer and regular reminder text messages to reinforce the course content).

health care, especially for specialized populations.⁹³ A diversity of populations is served by ICBT and CBT-based interventions employing own-time TMH in both adults⁹⁴ and children.⁹⁵

Unsurprisingly, many studies have shown that patient engagement with treatment is a strong predictor of the therapeutic benefit of treatment.⁹⁶ Own-time TMH may be uniquely positioned to engage patients because it allows patients to access therapy on their own terms.⁹⁷ For example, chronically ill patients may be unable to drive themselves to a clinic to receive much-needed CBT; by providing them with the ability to engage in CBT “anytime and anywhere,” own-time methods facilitate patient access and its consequential engagement without the inconveniences associated with obtaining face-to-face therapy or even real-time TMH.⁹⁸ Similarly, for adults with body dysmorphic disorder, in the early stages of treatment, many are afraid to leave their homes for fear of ridicule.⁹⁹ ICBT may present a uniquely accessible option for this group who may not be able go outside to seek treatment.¹⁰⁰

93. Enander et al., *supra* note 80. The cost savings and efficacy have been recognized by many other developed countries. *Id.* (explaining that in some countries, such as “Sweden, Australia, . . . the Netherlands, and the United Kingdom,” ICBT has been widely implemented and recognized as a highly effective treatment modality).

94. For adults, this includes people diagnosed with chronic somatic conditions, immigrants with anxiety, and those diagnosed with severe “unipolar” depression. van Beugen et al., *supra* note 84, at 1 (somatic conditions); Rony Kayrouz et al., *A Feasibility Open Trial of Guided Internet-Delivered Cognitive Behavioural Therapy for Anxiety and Depression Amongst Arab Australians*, 2 INTERNET INTERVENTIONS 32, 32 (2015) (immigration-related anxiety); Meyer et al., *supra* note 92, at 51 (depression).

95. Richard O’Kearney et al., *A Controlled Trial of a School-Based Internet Program for Reducing Depressive Symptoms in Adolescent Girls*, 26 DEPRESSION & ANXIETY 65, 65 (2009) (in-school interventions); Van Voorhees et al., *supra* note 79, at 23 (primary-care-based interventions). Project CATCH-IT is not a strictly ICBT treatment modality in that it calls itself an “Internet-based behavior change/resiliency building intervention,” though it uses motivational interviewing, which is an important aspect of CBT. Van Voorhees et al., *supra* note 79, at 24; *see also* Viviana M. Wuthrich et al., *A Randomized Controlled Trial of the Cool Teens CD-ROM Computerized Program for Adolescent Anxiety*, 51 J. AM. ACAD. CHILD & ADOLESCENT PSYCHIATRY 261, 262 (2012) (teenagers with anxiety).

96. *E.g.*, Kayrouz et al., *supra* note 94, at 32 (explaining that in immigrant communities, “increasing the compatibility between a psychological treatment protocol and a client’s value and meaning base is thought to enhance an individual’s engagement with treatment”).

97. *See* van Beugen et al., *supra* note 84, at 1.

98. *Id.* (noting, additionally, that ICBT may also reduce the stigma associated with behavioral health treatment).

99. *See id.*

100. *See id.* In addition to these accessibility benefits, own-time TMH provides distinct advantages over other interventions because asynchronous technology involves less real-time provider interaction (and presumably less room for error). Kathleen Myers & Jonathan S. Comer, *The Case for Telemental Health for Improving the Accessibility and Quality of Children’s Mental Health Services*, 26 J. CHILD & ADOLESCENT PSYCHOPHARMACOLOGY 186, 187 (2016). A “particular advantage of such asynchronous interventions is that they ensure fidelity in the delivery and dissemination of an intervention that can be difficult to achieve with traditional forms of treatment.” *Id.*

2. Own-Time TMH: Limits to the Knowledge Base

Though various meta-analyses have shown that own-time therapy is equally effective to traditional face-to-face therapy,¹⁰¹ there are some limitations to the knowledge base and drawbacks to the use of own-time therapy.¹⁰² A majority of the meta-analyses evaluate only CBT and ICBT¹⁰³ and thus omit other evidence-based therapies.¹⁰⁴ These other therapies may also be effective—perhaps even more so than ICBT—but there is a lack of meta-analysis to support this. Additionally, these same studies define CBT broadly, and only certain outcomes were compared.¹⁰⁵ Finally, as ICBT is relatively new, and compared with CBT possesses a smaller evidence base, fewer studies have shown its efficacy.¹⁰⁶

Own-time TMH studies are also limited. The studies that discuss roadblocks to TMH interventions only address real-time TMH.¹⁰⁷ The comparative lack of data about own-time TMH itself presents a problem as it shows that the specific practical obstacles to ensuring widespread use of own-time TMH are somewhat unknown.¹⁰⁸ On the provider side, some obstacles defy the most up-to-date scientific evidence regarding the efficacy of TMH.¹⁰⁹ Providers report having reservations about the effectiveness of services delivered through TMH.¹¹⁰ Both patients and providers agreed in focus group settings that in order to surmount the perceived belief that TMH does not work, providers need to give special attention to developing a relationship with the patient.¹¹¹ Older providers report being less comfortable using TMH technology and also cite lack of insurer reimbursement as barriers to more widespread use.¹¹²

101. See, e.g., Pim Cuijpers et al., *Is Guided Self-Help as Effective as Face-To-Face Psychotherapy for Depression and Anxiety Disorders? A Systematic Review and Meta-Analysis of Comparative Outcome Studies*, 40 PSYCHOL. MED. 1943, 1943 (2010).

102. Andersson et al., *A Systematic Review*, *supra* note 83, at 293.

103. *Id.*; see, e.g., Cuijpers et al., *supra* note 101.

104. Andersson et al., *A Systematic Review*, *supra* note 83, at 288 (explaining that psychodynamic therapy or acceptance and commitment therapy may be studied less than ICBT).

105. *Id.* Broadly defining CBT may present a problem because it creates comparisons that are not one-to-one.

106. *Id.* at 293.

107. John Paul Jameson et al., *VA Community Mental Health Service Providers' Utilization of and Attitudes Toward Telemental Health Care: The Gatekeeper's Perspective*, 27 J. RURAL HEALTH 425, 430 (2011).

108. However, there may be provider and patient apprehension to using technology to provide mental health services, regardless of whether they are provided synchronously or asynchronously. *Id.*

109. See *id.* (“[P]roviders appear to have some reservations about the effectiveness of . . . services delivered via TMH . . . despite promising research evidence to the contrary.”).

110. See, e.g., *id.*

111. Jonathan Swinton et al., *Telehealth and Rural Depression: Physician and Patient Perspectives*, 27 FAMILIES SYSTEMS & HEALTH 172, 179 (2009). *But cf.* Cuijpers et al., *supra* note 101, at 1953 (finding “the patient-therapist relationship can be realized with minimal contact” between the two, suggesting “it is not so much the intensity of the contact . . . but more the contact between the two in itself”).

112. Elizabeth Brooks et al., *Provider Barriers to Telemental Health: Obstacles Overcome, Obstacles Remaining*, TELEMEDICINE & E-HEALTH, June 2013, at 433, 436 (noting that anecdotal evidence suggests younger providers are unlikely to feel uncomfortable with technology in the same

Patients have reported being receptive to receiving psychiatric care using telehealth, but in a study by Professor Anouk Grubaugh (Grubaugh study) over two-thirds of patients believed that telepsychiatry would be less helpful than traditional face-to-face psychiatry.¹¹³ The Grubaugh study contextualizes this apparent reservation with a reminder that TMH is not necessarily intended to supplant regular face-to-face care; instead it is intended to supplant inferior care or no care at all.¹¹⁴ Participants in the study reinforced Grubaugh's eventual conclusion as only approximately six percent reported believing that TMH would be of no help.¹¹⁵ As with providers, the Grubaugh study noted a generational difference—younger patients were more receptive to trying telepsychiatry.¹¹⁶

Low-income patients face the additional obstacle of being less likely to have access to a computer in their home.¹¹⁷ As many people who use own-time TMH do so in their homes,¹¹⁸ this lack of access to home computers could present an obstacle to dissemination of own-time TMH to those who most need it. Though the increased prevalence of mobile devices, such as smartphones and tablets, may serve as an effective substitute to a home computer,¹¹⁹ only fifty-two percent of adults with an annual household income of less than \$30,000 own smartphones.¹²⁰

D. Evidence-Based Care Translated into Effective Care

Because CBT has been studied so thoroughly since its introduction, and because CBT provides a framework of flexible concepts, it has been adapted and adopted as an evidence-based practice for the treatment of various diagnoses in various populations. Evidence-based health care uses “current best evidence in making decisions about the care of individual patients” and it integrates the provider’s “individual clinical expertise with the best available external clinical evidence.”¹²¹ The practice of evidence-based care requires providers to base their recommendations about patient care on the best evidence about the

way); *see also id.* at 433 (discussing reimbursement as a barrier).

113. Anouk L. Grubaugh et al., *Attitudes Toward Medical and Mental Health Care Delivered via Telehealth Applications Among Rural and Urban Primary Care Patients*, 196 J. NERVOUS & MENTAL DISEASE 166, 169 (2008).

114. *Id.*

115. *Id.*

116. *Id.* Professor Grubaugh also noted that more educated patients were more receptive to telepsychiatry than those who were less educated. *Id.*

117. *See generally* Mary Keegan Eamon, *Digital Divide in Computer Access and Use Between Poor and Non-Poor Youth*, 31 J. SOC. & SOC. WELFARE 91, 91 (2004) (discussing the “digital divide” resulting in low-income youth’s comparative lack of access to home computers).

118. *See* van Beugen et al., *supra* note 84, at 1.

119. Andersson et al., *A Systematic Review*, *supra* note 83, at 293.

120. MONICA ANDERSON, PEW RESEARCH CTR., TECHNOLOGY DEVICE OWNERSHIP: 2015, at 7 (2015). *But cf. id.* (noting smartphone ownership continues to rise irrespective of income levels).

121. David L. Sackett et al., *Evidence Based Medicine: What It Is and What It Isn't*, 312 BMJ 71, 71 (1996).

condition and the unique characteristics about their individual patients.¹²² Developing an evidence-based practice and implementing it to serve those who need it most are two different things; one approach to bridge this gap, and perhaps the most recognized approach, has been the use of practice guidelines.¹²³

Practice guidelines include practical approaches for using the best available research as well as methods for the provider to tailor the treatment plan to the specific needs of their unique patient.¹²⁴ CBT has been added to numerous American Psychiatric Association (APA) practice guidelines for various disorders, including providing treatment for people with eating disorders,¹²⁵ major depressive therapy,¹²⁶ and obsessive compulsive disorder,¹²⁷ among many others.¹²⁸ Practice guidelines, which are often privately developed by organizations like the APA or the Institute for Clinical Systems Improvement,¹²⁹ however, have been criticized as being too narrow, with their “parameters simply . . . reflect[ing] the practice customs of the developers,” as opposed to the specific needs of the provider-user.¹³⁰

Because public and private insurers rely on practice guidelines “as a template to determine” provider payment, this mismatch can become a serious problem for providers whose patient population, facilities, or niche specialty do not resemble those of the developers.¹³¹ On a larger scale, guidelines that

122. Bonnie Spring, *Evidence-Based Practice in Clinical Psychology: What It Is, Why It Matters, What You Need to Know*, 63 J. CLINICAL PSYCHOL. 611, 611–13 (2007).

123. APA Presidential Task Force on Evidence-Based Practice, *Evidence-Based Practice in Psychology*, 61 AM. PSYCHOLOGIST 271, 271 (2006) (“One approach to implementing evidence-based practice in health care systems has been through the development of guidelines for best practice.”).

124. Spring, *supra* note 122, at 611.

125. *E.g.*, WORK GRP. ON EATING DISORDERS, AM. PSYCHIATRIC ASS’N, PRACTICE GUIDELINE FOR THE TREATMENT OF PATIENTS WITH EATING DISORDERS 18 (3d ed. 2006).

126. *E.g.*, WORK GRP. ON MAJOR DEPRESSIVE DISORDER, AM. PSYCHIATRIC ASS’N, PRACTICE GUIDELINE FOR THE TREATMENT OF PATIENTS WITH MAJOR DEPRESSIVE DISORDER 17 (3d ed. 2010).

127. *E.g.*, WORK GRP. ON OBSESSIVE-COMPULSIVE DISORDER, AM. PSYCHIATRIC ASS’N, PRACTICE GUIDELINE FOR THE TREATMENT OF PATIENTS WITH OBSESSIVE-COMPULSIVE DISORDER 11 (2007).

128. *See, e.g.*, WORK GRP. ON SCHIZOPHRENIA, AM. PSYCHIATRIC ASS’N, PRACTICE GUIDELINE FOR THE TREATMENT OF PATIENTS WITH SCHIZOPHRENIA 14 (2d ed. 2004) (explaining that for the treatment of adults with a diagnosis of schizophrenia, a “number of psychosocial treatments have demonstrated effectiveness during the stable phase,” which includes “cognitive behaviorally oriented psychotherapy”); WORK GRP. ON SUBSTANCE USE DISORDERS, AM. PSYCHIATRIC ASS’N, PRACTICE GUIDELINE FOR THE TREATMENT OF PATIENTS WITH SUBSTANCE USE DISORDERS 10 (2d ed. 2006) (recommending CBT as an evidence-based psychosocial treatment for substance use disorders).

129. *See, e.g.*, *Depression, Adult in Primary Care*, INST. FOR CLINICAL SYSTEMS IMPROVEMENT, http://www.icsi.org/guidelines__more/catalog_guidelines_and_more/catalog_guidelines/catalog_behavi_oral_health_guidelines/depression/ [perma: <http://perma.cc/K8XU-BSLM>] (last updated Mar. 2016) (noting that to obtain the guidelines, one must purchase them or become a member).

130. *See* John D. Ayres, *The Use and Abuse of Medical Practice Guidelines*, 15 J. LEGAL MED. 421, 430 (1994).

131. *See id.* at 422–24; *see also* *Behavioral Health Clinical Practice Guidelines 2018-2019*, BLUECROSS BLUESHIELD ILL., http://www.bcbsil.com/provider/clinical/clinical_practice_guidelines.

recommend against an intervention, without strong empirical support for doing so, can “lead providers to drop access to or coverage for services” that would otherwise be highly effective for needy patients.¹³²

Though reliance on practice guidelines certainly serves valuable interests, critics have argued that reliance on practice guidelines can be especially problematic when there is an opportunity for an effective innovation.¹³³ Own-time TMH exemplifies this issue. As of the publication of this Comment, neither the APA nor the American Telemedicine Association (ATA) has developed any practice guidelines for own-time TMH,¹³⁴ despite the considerable evidence base supporting its efficacy¹³⁵ and despite a demonstrated need.¹³⁶

III. MEDICAID, THE STATE LABORATORY, § 1315A INNOVATION GRANTS, AND SECTION 1115 WAIVERS

The prior Section provided an overview of behavioral health, detailing the crisis, trends in treatment, and the promise of own-time TMH. This Section shifts into a discussion of Medicaid and its role in the system of state laboratories, especially as applied to own-time TMH.

Section III comprises three Parts. Part III.A provides a history of Medicaid, including a discussion of the payment system, changes made by the Affordable Care Act (ACA), and the lack of behavioral health care providers for Medicaid enrollees. Part III.B explains Medicaid’s policies on TMH coverage. Broadly

html [perma: <http://perma.cc/E88P-V5R4>] (last visited May 29, 2018) (connecting user to four different practice guidelines for treating depression). One of these BlueCross Guidelines was authored by the APA, another by the American Academy of Child and Adolescent Psychiatry, and the other two were authored by the American Academy of Child and Adolescent Psychiatry and the Anxiety and Depression Association of America, respectively. *Id.* Though practice guidelines provide considerable value in ensuring that care is consistent from one patient to another, guidelines that are rigid have the potential to harm patients “by leaving insufficient room for clinicians to tailor care to patients’ personal circumstances and medical history.” Steven H. Woolf et al., *Potential Benefits, Limitations, and Harms of Clinical Guidelines*, 318 *BMJ* 527, 529 (1999).

132. Woolf et al., *supra* note 131, at 529. For a more sinister explanation of why practice guidelines should not be trusted, see generally, Jeanne Lenzer, *Why We Can’t Trust Clinical Guidelines*, *BMJ*, June 14, 2013, at f3830. Jeanne Lenzer explains that not only are practice guidelines subject to poor use of data but also to the improper influence of pharmaceutical and medical device companies. *See id.*

133. Tony Delamothe, *Wanted: Guidelines That Doctors Will Follow*, 307 *BMJ* 218, 218 (1993).

134. The ATA calls itself “the largest telehealth-focused organization” in the world. *About ATA*, AM. TELEMEDICINE ASS’N, <http://www.americantelemed.org/main/about/about-ata> [perma: <http://perma.cc/X97B-NSLG>] (last visited May 29, 2018). The ATA has, however, developed practice guidelines for TMH delivered via videoconferencing. *See AM. TELEMEDICINE ASS’N, PRACTICE GUIDELINES FOR VIDEO-BASED ONLINE MENTAL HEALTH SERVICES* (2013).

135. *See supra* notes 82–101 and accompanying text for a discussion about the strong evidence base supporting the efficacy of own-time TMH. This is true as of the publication of this Comment.

136. *See supra* notes 33–37 and accompanying text discussing the need for and lack of behavioral health care for low-income people. *See also* Michelle M. Mello et al., *Critical Opportunities for Public Health Law: A Call for Action*, 103 *AM. J. PUB. HEALTH* 1979, 1980 (2013) (“In pressing matters of population health and safety, there may be opportunities for legal reform that should be advanced even before voluntary best practices have been fully deployed.”).

speaking, Part III.C discusses state health care laboratories from a theoretical perspective and then delves into their practical application under Medicaid grants and waivers.

A. *Enter Medicaid*

Medicaid is the largest U.S. health insurer, with its most important qualification being income level.¹³⁷ The following Parts provide background on Medicaid's structure, policies, and behavioral health coverage. Part III.A.1 explains Medicaid's history and payment structure. Part III.A.2 discusses Medicaid's fundamental policies. Part III.A.3 briefly addresses Medicaid's coverage of behavioral health services.

1. Medicaid: Federal-State Cooperative

Congress enacted Medicaid as Title XIX of the 1965 Amendments to the Social Security Act,¹³⁸ and the program now insures over 71.1 million Americans.¹³⁹ Like Medicare, Congress enacted Medicaid as part of President Johnson's Great Society.¹⁴⁰ As a component of the "War on Poverty,"¹⁴¹ eligibility has always been predicated on income.¹⁴² Unlike Medicare, which is fully run by the federal government, Medicaid is a joint federal and state cooperative program¹⁴³ in which the federal government sets broad parameters for eligibility, coverage, and the services for which it will match funds allocated by the state.¹⁴⁴ States have no obligation to provide Medicaid to their

137. See HERZ, *supra* note 5, at 1.

138. LAURA KATZ OLSON, *THE POLITICS OF MEDICAID* 25 (2010). This statute is a labyrinth, having once been called "an aggravated assault on the English language [and] resistant to attempts to understand it." *Friedman v. Berger*, 409 F. Supp. 1225, 1225–26 (S.D.N.Y. 1976). Medicaid has been retrospectively called an "afterthought" to Medicare. OLSON, *supra*, at 23. Catering primarily to senior citizens and the chronically disabled, Medicare insures 56.5 million Americans. CMS, *FAST FACTS* (2016).

139. CMS, *supra* note 138. This number is accurate as of June 2016. *Id.*

140. OLSON, *supra* note 138, at 24. However, the concept of assistance to the poor was not a new idea as federal, state, and municipal governments have been providing assistance for specific categories of the "blameless" poor since the late nineteenth century. Nicole Huberfeld, *Federalizing Medicaid*, 14 U. PA. J. CONST. L. 431, 439–41 (2011). Medicaid built off of other federal welfare programs, such as Social Security. *Id.*

141. John D. Blum & Gayland O. Hethcoat II, *Medicaid Governance in the Wake of National Federation of Independent Business v. Sebelius: Finding Federalism's Middle Pathway, from Administrative Law to State Compacts*, 45 J. MARSHALL L. REV. 601, 610 (2012).

142. See OLSON, *supra* note 138, at 26. Some scholars, however, argue that Medicaid is increasingly becoming a middle-class entitlement because it is one of the largest payers of nursing home care. Jill Quadagno, *The Transformation of Medicaid from Poor Law Legacy to Middle-Class Entitlement?*, in *MEDICARE AND MEDICAID AT 50: AMERICA'S ENTITLEMENT PROGRAMS IN THE AGE OF AFFORDABLE CARE* 77, 77, 86 (Alan B. Cohen et al. eds., 2015) (explaining that Medicaid pays for over forty percent of all nursing home care and that though sixty percent of patients enter as privately paid, they leave as Medicaid-paid).

143. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 624, 630 (2012) (Ginsburg, J., concurring in part and dissenting in part).

144. Nicole Huberfeld et al., *Plunging into Endless Difficulties: Medicaid and Coercion in*

citizens,¹⁴⁵ and if a state does decide to operate a Medicaid program, there are strong incentives to loosen eligibility requirements and expand benefits, within the broad boundaries of federal regulations.¹⁴⁶

States have considerable latitude in how they operate their Medicaid programs, though this prerogative is not absolute. One of the strongest, if not *the* strongest, incentives provided in federal legislation is its matching provision: if the federal law covers a health care service, then the federal government will pay at least fifty percent of its cost.¹⁴⁷ In addition to possessing broad leeway in defining eligibility and covered benefits, states are also able to choose whether they operate state-run Medicaid programs or if they employ managed care organizations to take over this responsibility.¹⁴⁸ Though states have wide discretion in determining the precise eligibility criteria, since its inception, Medicaid has generally covered people who are poor.¹⁴⁹ The ACA expanded eligibility to people with income levels of up to 133% of the federal poverty line (FPL)¹⁵⁰ and simplified the prior eligibility determination.¹⁵¹

National Federation of Independent Business v. Sebelius, 93 B.U.L. REV. 1, 15–16 (2013).

145. Harris v. McRae, 448 U.S. 297, 301 (1980) (“Although participation in the Medicaid program is entirely optional, once a State elects to participate, it must comply with the requirements of Title XIX.”); *see also* Sebelius, 567 U.S. at 578 (plurality opinion) (“Permitting the Federal Government to force the States to implement a federal program would threaten the political accountability key to our federal system.”).

146. Huberfeld et al., *supra* note 144, at 17.

147. *See* 42 U.S.C. §§ 1396b(a)(1), § 1396d(b) (2012).

148. HERZ, *supra* note 5, at 9. It is not accidental that this allocation of power tips strongly in states’ favor. *See* Sebelius, 567 U.S. at 630 (Ginsburg, J., concurring in part and dissenting in part) (“Instead, Congress gave the States the opportunity to partner in the program’s administration and development. Absent from the nationalized model, of course, is the state-level policy discretion and experimentation that is Medicaid’s hallmark; undoubtedly the interests of federalism are better served when States retain a meaningful role in the implementation of a program of such importance.”). Medicaid was developed to “undergird what was traditionally a state—indeed a local—function: taking care of the medical needs of the poor.” Sara Rosenbaum, *Medicaid at Forty: Revisiting Structure and Meaning in a Post-Deficit Reduction Act Era*, 9 J. HEALTH CARE L. & POL’Y 5, 9 (2006) (quoting TIMOTHY STOLTZFUS JOST, *DISSENTMENT?: THE THREATS FACING OUR PUBLIC HEALTH-CARE PROGRAMS AND A RIGHTS-BASED RESPONSE* 162 (2003)).

149. Federal law requires states participating in Medicaid to cover the “categorically needy,” and gives them the option to cover those who are “medically needy.” *See* 42 U.S.C. § 1396a(a)(10)(A).

150. *Id.* § 1396a(a)(10)(A)(i)(VIII).

151. Letter from Cindy Mann, Dir., CMS, to State Health Official and Medicaid Dir. (Dec. 28, 2012) (on file with author) (addressing modified adjusted gross income (MAGI)); *Medicaid and CHIP Eligibility Levels*, MEDICAID.GOV, <http://www.medicaid.gov/medicaid/program-information/medicaid-and-chip-eligibility-levels/index.html> [perma: <http://perma.cc/Z6GE-KEM7>] (last visited May 29, 2018). The ACA’s determination of eligibility is now based on individuals’ modified adjusted gross income. *Medicaid and CHIP Eligibility Levels*, *supra*. Except for people who are blind or disabled, coverage of people who have serious medical problems but whose income is too high to meet the MAGI requirements is at the states’ discretion. *Eligibility*, MEDICAID.GOV, <http://www.medicaid.gov/medicaid/eligibility> [perma: <http://perma.cc/PPH8-895J>] (last visited May 29, 2018). For a comprehensive discussion of groups that states have the option to cover under the ACA’s Medicaid expansion, see Sidney D. Watson, *Embracing Justice Roberts’ “New Medicaid”*, 6 ST. LOUIS U. J. HEALTH L. & POL’Y 247, 250 (2013).

2. Policy Underpinnings

One of the guiding principles in Medicaid is the “triple aim”—improving population health, enhancing population health outcomes, and reducing per-patient costs.¹⁵² Under the triple aim, when a state covers a service that is not mandatory under federal law, it is typically required to meet four conditions¹⁵³: (1) the comparability rule, which requires all benefits to be equivalent in “amount, duration, and scope” for all enrollees;¹⁵⁴ (2) the “statewideness” rule, which requires that benefits be the same throughout the state, regardless of geographic distinctions;¹⁵⁵ (3) freedom of choice, which requires that all “beneficiaries may obtain services from any qualified Medicaid provider that undertakes to provide the services to them”;¹⁵⁶ and (4) efficiency, economy, and quality of care, which requires that the services must be of an amount, duration, and scope to achieve their purpose.¹⁵⁷ Though all of these requirements are grounded in the federal statutory scheme, case law has thoroughly developed their meanings and nuances.¹⁵⁸

3. Medicaid and Behavioral Health

Medicaid is the single largest payer of mental health services in the United

152. ALEXANDRA GATES ET AL., KAISER COMM'N ON MEDICAID & THE UNINSURED, AN OVERVIEW OF DELIVERY SYSTEM REFORM INCENTIVE PAYMENT (DSRIP) WAIVERS 3 (2014), <http://kff.org/report-section/an-overview-of-delivery-system-reform-incentive-payment-waivers-issue-brief/> [perma: <http://perma.cc/C4QZ-VH7C>].

153. HERZ, *supra* note 5, at 5.

154. 42 C.F.R. § 440.240(a) (2017).

155. See 42 U.S.C. § 1396a(a) (“A State plan for medical assistance must— (1) provide that it shall be in effect in all political subdivisions of the State”); 42 C.F.R. § 431.50(b)(1); see also *Masterman v. Goodno*, Civil No. 03-2939 (JRT/FLN), 2004 U.S. Dist. LEXIS 354, at *15 (D. Minn. Jan. 8, 2004); HERZ, *supra* note 5, at 5.

156. 42 C.F.R. § 431.51(a)(1); 42 U.S.C. § 1396a(a)(23) (“[A] Medicaid managed care organization, or a similar entity shall not restrict the choice of the qualified person from whom the individual may receive services”). Despite the statewideness rule, access to care has never been an explicit Medicaid policy. Frank J. Thompson, *Medicaid Rising: The Perils and Potential of Federalism, in MEDICARE AND MEDICAID AT 50: AMERICA’S ENTITLEMENT PROGRAMS IN THE AGE OF AFFORDABLE CARE*, *supra* note 142, at 191, 200. In 1989, Representative Henry Waxman introduced an amendment requiring Medicaid payment rates to be “sufficient to enlist enough providers so that care and services are available . . . at least to the extent that such care and services are available to the general population in [the] geographic area.” *Id.* (omission in original) (quoting MACPAC, REPORT TO THE CONGRESS ON MEDICAID AND CHIP 126 (2011), <http://www.macpac.gov/publication/report-to-the-congress-on-medicaid-and-chip-311/> [perma: <http://perma.cc/58KX-3QND>])). This access provision has never been passed, and states are not required to preserve access when they submit changes in payment rates for the purpose of federal review. *Id.*

157. 42 C.F.R. § 440.230(b) (“Each service must be sufficient in amount, duration, and scope to reasonably achieve its purpose.”); see also HERZ, *supra* note 5, at 5; SAMHSA, HHS PUB. NO. SMA-13-4773, MEDICAID HANDBOOK: INTERFACE WITH BEHAVIORAL HEALTH SERVICES MODULE 2, at 2–6 (2013) [hereinafter SAMHSA, MEDICAID HANDBOOK].

158. *E.g.*, *Masterman*, 2004 U.S. Dist. LEXIS 354, at *15 (elaborating on “statewideness”); *Bell v. Thornburgh*, 420 A.2d 443, 448–49 (Pa. 1980) (describing “freedom of choice” as “the right to choose among a range of qualified providers”).

States.¹⁵⁹ The Substance Abuse and Mental Health Services Administration (SAMHSA) estimated Medicaid (combining both federal and state funds) paid over \$51 billion for mental health services in that year alone.¹⁶⁰ This figure is estimated to represent twenty-six percent of *all* behavioral health spending, including privately insured and other non-Medicaid public insurers.¹⁶¹ Behavioral health services accounted for about ten percent of Medicaid's total FY2014 spending, with Medicaid projected to increase its behavioral health care spending through 2020.¹⁶²

Medicaid enrollees' demand for care is greater than the behavioral health market's supply.¹⁶³ This mirrors the larger behavioral health care market but is also compounded by problems unique to the Medicaid payment structure and population.¹⁶⁴ As of 2014 only fifty-five percent of psychiatrists accepted private insurance, and only forty-three percent accepted Medicaid.¹⁶⁵ Similarly, only thirty-two percent of all psychologists participated in Medicaid.¹⁶⁶ Two cited reasons for the provider shortage are Medicaid's lower reimbursement rates and slow processing time, compared to private insurers and even Medicare.¹⁶⁷ These act as disincentives to providers.¹⁶⁸

159. *Behavioral Health Services*, MEDICAID.GOV, <https://www.medicaid.gov/medicaid/benefits/bhs/index.html> [perma: <https://perma.cc/manage/create>] (last visited May 29, 2018) ("Medicaid is the single largest payer for mental health services in the United States and is increasingly playing a larger role in the reimbursement of substance use disorder services.").

160. SAMHSA, HHS PUB. NO. SMA-14-4883, PROJECTIONS OF NATIONAL EXPENDITURES FOR TREATMENT OF MENTAL AND SUBSTANCE USE DISORDERS, 2010–2020, at 19 (2014) [hereinafter SAMHSA, PROJECTIONS OF NATIONAL EXPENDITURES]. This figure does not even include the \$7.75 billion in substance use disorder treatment spending in 2014. *Id.* at 31; *see also Total Medicaid Spending*, KAISER FAM. FOUND., <http://kff.org/medicaid/state-indicator/total-medicaid-spending/> [perma: <http://perma.cc/N49U-5CW9>] (last visited May 29, 2018) (providing figures for 2016).

161. MACPAC, 2015 REPORT TO CONGRESS, *supra* note 24, at xvii.

162. SAMHSA, PROJECTIONS OF NATIONAL EXPENDITURES, *supra* note 160, at 19; *id.* at 24 (explaining that Medicaid projected to increase 2014 spending levels from \$179 billion to \$238 billion in 2020).

163. *E.g.*, Virgil Dickson, *Medicaid Plans Struggle to Provide Mental Health Services*, MOD. HEALTHCARE (July 4, 2015), <http://www.modernhealthcare.com/article/20150704/MAGAZINE/307049979> [perma: <http://perma.cc/N6J9-PDK3>]. *See generally* Mark Olfson, *Building the Mental Health Workforce Capacity Needed to Treat Adults with Serious Mental Illnesses*, 35 HEALTH AFF. 983 (2016).

164. Tara F. Bishop et al., *Acceptance of Insurance by Psychiatrists and the Implications for Access to Mental Health Care*, 71 JAMA PSYCHIATRY 176, 176–81 (2014) (explaining that only fifty-five percent of psychiatrists accepted private insurance, and only forty-three percent accepted Medicaid in 2009–2010).

165. *Id.* (providing data for 2009 and 2010).

166. Olfson, *supra* note 163, at 986. Though social workers and other mental health professionals also provide mental health services under Medicaid, research suggests that there is an inadequate number of mental health professionals to address the needs of the Medicaid population. Mechanic & Olfson, *supra* note 33, at 532–33.

167. Olfson, *supra* note 163, at 986.

168. *See* Bishop et al., *supra* note 164, at 180 (explaining that “administrative hurdles” around billing insurers is often cited by psychiatrists who do not accept insurance). Another issue may be the acuity of behavioral health needs present in the Medicaid population. With poverty having been

B. Medicaid's Coverage of Telemedicine: TMH Is Left Out

On a federal level, Medicaid gives states the option of providing telemedicine services, meaning, federal law authorizes the federal government to pay for “telemedicine” as defined by the federal rule.¹⁶⁹ The federal Medicaid rule uses Medicare’s definition of telemedicine,¹⁷⁰ describing telemedicine as the use of technology “permitting two-way, real time interactive communication between the patient, and the [provider] [using] . . . telecommunications equipment that includes, at a minimum, audio and video equipment.”¹⁷¹ Despite Medicaid’s stated purpose in covering telemedicine services—to facilitate a “cost-effective alternative to the more traditional face-to-face way of providing medical care”—in general, Medicaid only covers real-time services,¹⁷² which are “face-to-face,” albeit using a computer monitor.¹⁷³ Medicaid also has expanded coverage of own-time services under certain circumstances.¹⁷⁴ Because Medicaid borrows its telemedicine definition from Medicare, it is necessary to briefly address Medicare’s construal of the term “telemedicine.”

Though it separates telehealth into synchronous and asynchronous, Medicare strictly interprets the two. Real-time, or synchronous, technology is used for videoconferencing encounters, and own-time, or asynchronous, technology is used for the transfer of images.¹⁷⁵ The regulation, first promulgated

shown to exacerbate mental health conditions, and, for example, transportation roadblocks making travel to treatment difficult, providers who accept Medicaid may also suffer higher rates of burnout. Quadagno, *supra* note 142, at 84.

169. *Telemedicine*, MEDICAID.GOV, <http://www.medicaid.gov/medicaid/benefits/telemed/index.html> [perma: <http://perma.cc/TV6X-8JJW>] (last visited May 29, 2018); *see also* 42 U.S.C. § 1396a (2012) (defining conditions of state reimbursement for Medicaid services).

170. *See Telemedicine*, *supra* note 169.

171. *Id.*; *see also* 42 C.F.R. § 410.78(a)(3) (2017).

172. *Telemedicine*, *supra* note 169 (“Asynchronous or ‘store and forward’ applications would not be considered telemedicine but may be utilized to deliver services.”).

173. Paul Luff et al., *Embedded Reference: Translocating Gestures in Video-Mediated Interaction*, 49 RES. ON LANGUAGE & SOC. INTERACTION 342, 342–43 (2016) (explaining that “face-to-face” is a *model* of interaction, as opposed to a *medium* of interaction). *But see* Yiting Emily Guo et al., *Assessment of Aphasia Across the International Classification of Functioning, Disability and Health Using an iPad-Based Application*, TELEMEDICINE & E-HEALTH, Apr. 2017, at 1, 1 (defining “face-to-face” as a medium for communication, that is, synonymous with “in-person”).

174. For example, Medicaid allows California’s Medicaid program to reimburse providers for own-time telehealth, such as teleophthamology. MEDI-CAL, PROVIDER MANUAL: TELEHEALTH 2 (2013), http://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/mednetele_m01o03.doc [perma: <http://perma.cc/FZ7H-QRBK>]. Medicaid defines “telehealth” as “the use of telecommunications and information technology to provide access to health assessment, diagnosis, intervention, consultation, supervision and information across distance.” *Telemedicine*, *supra* note 169. This appears very similar to Medicaid’s definition of telemedicine, but Medicaid clarifies that telehealth services are not considered “telemedicine” (which is reimbursed as a traditional service), but that telehealth services “may nevertheless be covered and reimbursed as part of a Medicaid coverable service, such as laboratory service, x-ray service or physician services (under section 1905(a) of the Social Security Act).” *Id.*

175. *E.g.*, Medicare Program; Payment for Teleconsultations in Rural Health Professional Shortage Areas, 63 Fed. Reg. 33,882, 33,882–83 (proposed June 22, 1999) (codified at 42 C.F.R. § 410.78).

in 1998 and still in effect, explains asynchronous technology “is used to transfer video images from one location to another,” and it does not even conceive of other applications for own-time technology.¹⁷⁶ By only giving the example of “[p]hotographs visualized by a telecommunications system” in its regulatory guidance,¹⁷⁷ Medicare still appears to construe own-time technology as monolithic, encompassing only the transmission of images, as opposed to facilitating a diversity of services. Medicaid, though less restrictive than Medicare,¹⁷⁸ has stated in its online guidance that its “definition is modeled on Medicare’s definition of telehealth services.”¹⁷⁹ And Medicaid follows Medicare’s lead in denying coverage of most own-time technologies.¹⁸⁰ However, despite its narrow view of telemedicine, the Center for Medicare and Medicaid Innovation (CMMI) directs states to be creative about telemedicine reimbursement; they are “encouraged to use the flexibility inherent in federal law to create innovative payment methodologies” for services using telemedicine.¹⁸¹

The Medicaid programs in all but three states cover some form of telemedicine.¹⁸² Of the forty-seven states that do cover telemedicine, there are currently nine states that provide Medicaid reimbursement for own-time telehealth services.¹⁸³ This coverage extends only to payment for physician-to-

176. *Id.*

177. 42 C.F.R. § 410.78 (2017).

178. Medicare will only cover telehealth services for patients in rural locations, *see id.*, whereas Medicaid has not put this restriction on distribution of matching funds. *Telemedicine, supra* note 169.

179. *Telemedicine, supra* note 169.

180. *Id.* (“Asynchronous or ‘store and forward’ applications would not be considered telemedicine but may be utilized to deliver services.”). Medicaid does make exceptions for coverage of own-time services, such as teledermatology and teleradiology imaging, for rural patients, *see supra* note 174 (discussing Medi-Cal), and under limited circumstances, specifically in demonstration programs in Alaska and Hawaii. 42 C.F.R. § 410.78(d).

181. *Telemedicine, supra* note 169. This flexibility may extend so far as to permit states to ignore the statewideness, freedom of choice, and comparability rules in their innovation processes. *Id.*

182. CTR. FOR CONNECTED HEALTH POLICY, STATE TELEHEALTH LAWS AND MEDICAID PROGRAM POLICIES 5–6 (2016), <http://www.cchpca.org/sites/default/files/resources/50%20State%20FINAL%20April%202016.pdf> [perma: <http://perma.cc/56ME-L6Q3>] (noting all states but Massachusetts, Rhode Island, and Utah have some sort of written policy for telemedicine reimbursement).

183. For example, New Mexico Medicaid will cover some own-time services. N.M. CODE R. § 8.310.2.12 (LexisNexis 2018) (“[New Mexico Medicaid] will reimburse for services delivered through store-and-forward. To be eligible for payment under store-and-forward, the service must be provided through the transference of digital images, sounds, or previously recorded video from one location to another . . .”); *see also* CTR. FOR CONNECTED HEALTH POLICY, *supra* note 182, at 6–7 (listing Alaska, Arizona, California, Illinois, Minnesota, Mississippi, New Mexico, Virginia, and Washington). A tenth state, New York, has passed legislation to allow reimbursement, yet the specifics of the reimbursement requirements have not yet been developed. CTR. FOR CONNECTED HEALTH POLICY, *supra* note 182, at 6–7. *But see* Am. Telemedicine Ass’n, *Medicaid*, ATAKWIKI.ORG, <http://atawiki.org.s161633.gridserver.com/wiki/index.php?title=Medicaid> [perma: <http://perma.cc/H9W2-8Q8K>] (last visited Mar. 2, 2017) (explaining that twelve states are authorized by Medicaid to reimburse for store-and-forward technology). *Id.*

physician consultations,¹⁸⁴ for which the patient need not be present.¹⁸⁵

A considerable number of states that provide Medicaid reimbursement for telemedicine generally also provide reimbursement for TMH.¹⁸⁶ However, none of these states provide coverage for own-time TMH services; they only provide reimbursement for real-time TMH.¹⁸⁷ In failing to recognize own-time technology, at both the state and federal level, the Medicaid program's understanding of telehealth aspires to recreate the traditional health care encounter where a patient speaks to her provider about her issues face-to-face.¹⁸⁸

C. The State Health Care Laboratory—State Options when Federal Law Prevents Coverage of New Models of Care

One of the oft-cited benefits of a federalist system is its ability to facilitate state innovation for the welfare of its own citizens in ways that can later be applied to the rest of the country.¹⁸⁹ The Tenth Amendment allocates all police powers not granted to the federal government to the states—including the power to regulate the health and welfare of the states' citizens.¹⁹⁰ Under this system, a state may test out a novel policy, leading states to be referred to as the “laboratories of democracy.”¹⁹¹ Part III.C.1 discusses the characteristics of an

184. *E.g.*, ALASKA ADMIN. CODE tit. 7, § 110.625(a) (2018).

185. *E.g.*, *Physician and Professional Services*, MINN. DEP'T HUM. SERVICES, http://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=ID_008926 [perma: <http://perma.cc/RUZ4-CNAK>] (last revised Feb. 13, 2017). These permit, for example, a non-dermatologist or non-radiologist referring doctor to send images to a consulting dermatologist or radiologist to obtain a diagnosis. *E.g.*, ARIZ. HEALTH CARE COST CONTAINMENT SYS., FEE-FOR-SERVICE PROVIDER MANUAL, at 10-37 to -38 (last revised Oct. 5, 2016) (providing no requirement that the patient be present while reviewing doctor examines images).

186. *E.g.*, ARIZ. HEALTH CARE COST CONTAINMENT SYS., *supra* note 185, at 10-37 to -38.

187. *See, e.g.*, MEDI-CAL PROVIDER MANUAL, *supra* note 174, at 2–3.

188. Michael A. Cassidy & Tucker Arensberg, *Chapter 6: Introduction to Telehealth*, in 2015 HEALTH LAW HANDBOOK (Alice G. Gosfield ed., 2015), Westlaw HTHLHB.

189. *See* Brian Galle & Joseph Leahy, *Laboratories of Democracy? Policy Innovation in Decentralized Governments*, 58 EMORY L.J. 1333, 1335 (2009).

190. *See* *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905) (“[T]he police power of a State . . . embrace[s], at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety.”).

191. *See* *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting). The experimentation has been beneficial for many, but as the general belief in human rights has evolved over the last century, critics have raised concerns that the laboratory of democracy brings up important issues of government-sponsored experimentation on human subjects. *See, e.g.*, Sara Rosenbaum, *Mothers and Children Last: The Oregon Medicaid Experiment*, 18 AM. J.L. & MED. 97, 118–19 (1992) [hereinafter Rosenbaum, *Mothers and Children*]. This is especially important in light of the American government's poor track record of using marginalized groups for human subject experimentation. *Id.* Testing out new ways of delivering care to Medicaid beneficiaries does not escape this ethical issue, though it may escape legal consequences. The United States' long history of experimentation on marginalized groups cannot be ignored. *See* FRED D. GRAY, *THE TUSKEGEE SYPHILIS STUDY: THE REAL STORY AND BEYOND* 23–24 (1998). However, the regulatory framework protecting human subjects in federally funded experiments from harm—the so-called “Common Rule”—exempts research or demonstration projects subject to the approval of an agency head and

effective state laboratory. Part III.C.2 surveys Medicaid's practical, statutory channels that facilitate health care experimentation at state and local levels.

1. Federalism and the State Laboratory

The concept of the state as the laboratory of democracy is a fundamental tenet of federalism. Under their Tenth Amendment powers, states have had wide discretion to innovate in areas of health care payment and delivery.¹⁹² The federal government has supported this innovation through regulatory and financial incentives,¹⁹³ in part with the goal of applying the effective innovations developed in one state to other states.¹⁹⁴ Proponents have touted the benefits of the states-as-laboratories concept, noting that it allows for smaller risks to be taken without generating negative externalities to the rest of the country,¹⁹⁵ in comparison to federal experimentation, states can more narrowly tailor experiments to their needs;¹⁹⁶ and states are more accountable to their constituents, encouraging them to find quick solutions.¹⁹⁷

The success of a state experiment depends on how closely a state is able to

designed to study or examine “[p]ublic benefit or service programs.” 45 C.F.R. § 46.101(b)(5) (2017). The case law informing these regulations does not generally address issues of, for example, testing out new services such as own-time TMH. For example, in *Crane v. Mathews*, 417 F. Supp. 532 (N.D. Ga. 1976), Medicaid beneficiaries sued the State of Georgia arguing that the State's new requirements that beneficiaries pay copayments (granted under Section 1115 waiver authority) constituted experimentation on human subjects. *Id.* at 545. *Crane* was brought prior to the Common Rule exemption. *Id.* The Secretary has interpreted the Common Rule to mean that public welfare experiments which test out changes in benefits are generally exempted from review by the institutional review board and that informed consent is not necessary. See *C.K. v. Shalala*, 883 F. Supp. 991, 1009 (D.N.J. 1995), *aff'd sub nom.* *C.K. v. N.J. Dept. of Health & Human Servs.*, 92 F.3d 171 (3d Cir. 1996). Courts have affirmed this interpretation finding that “public benefits programs would be hamstrung to the point of paralysis if every reduction in benefits for economically vulnerable populations violated” the Common Rule. *Newton-Nations v. Betlach*, 660 F.3d 370, 382–83 (9th Cir. 2011); *Spry v. Thompson*, CV–03–121–ST, 2003 WL 23411996, at *26 (D. Or. Dec. 8, 2003), *report and recommendation adopted*, 03–121–ST, 2004 WL 1050867 (D. Or. Apr. 6, 2004), *aff'd in part, rev'd in part*, 487 F.3d 1272 (9th Cir. 2007). However, there may be specific situations when changes in public benefits may present a danger to the beneficiary that would trigger the protections of the Common Rule. *C.K.*, 883 F. Supp. at 1009; *Beno v. Shalala*, 853 F. Supp. 1195, 1210 (E.D. Cal. 1993), *rev'd*, 30 F.3d 1057 (9th Cir. 1994). This, however, is outside the scope of this Comment as the law seems relatively settled.

192. E.g., Kristin Madison, *Building a Better Laboratory: The Federal Role in Promoting Health System Experimentation*, 41 PEPP. L. REV. 765, 768 (2014).

193. See *supra* notes 144–47 and accompanying text discussing the strong financial incentive for states to get federal matching funds. See generally Madison, *supra* note 192.

194. E.g., Kavita Patel & John McDonough, *From Massachusetts to 1600 Pennsylvania Avenue: Aboard the Health Reform Express*, 29 HEALTH AFF. 1106, 1106–08 (2010) (discussing Massachusetts's health reform law—made possible only through a federal waiver—as the model for the ACA's health insurance expansion).

195. Keith Cunningham-Parmeter, *Forced Federalism: States as Laboratories of Immigration Reform*, 62 HASTINGS L.J. 1673, 1692–93 (2011).

196. See Doni Gewirtzman, *Complex Experimental Federalism*, 63 BUFF. L. REV. 241, 243 (2015).

197. *Id.*

mirror an empirical experiment.¹⁹⁸ The state must be willing to experiment; it must go through a process of testing or evaluating; the experimental results must be transmitted;¹⁹⁹ the experiment must be replicable; and the costs of the experiment must be internalized to the state.²⁰⁰ There have been notable successes employing the states-as-laboratories concept, such as the ACA health insurance expansion, which was modeled after Massachusetts's health reform law.²⁰¹ But opponents have criticized the idea as a poor and imperfect analogy.²⁰²

One of the biggest criticisms made is that states do not often undertake changes in policies in an empirical, replicable way; they are incapable of doing so in many cases because they comprise complex systems.²⁰³ Moreover, scientific experiments are able to control variables (like, say, researcher bias)²⁰⁴ to demonstrate channels of likely causation,²⁰⁵ while states, by contrast, are intricate systems whose variables cannot be controlled.²⁰⁶

The nominal purpose of an empirical experiment is to advance the general corpus of scientific knowledge, whereas the state policy experiments are undertaken to achieve subjective social goods.²⁰⁷ This haphazard, nonempirical approach leads to another problem inherent in the concept: because there is a lack of controls, state "laboratory" innovations may not apply broadly to other states.²⁰⁸ Critics of the analogy have argued, however, that the concept of regional health care delivery laboratories is a valuable idea, and they have put forth a solution that addresses some of the issues inherent in a lack of state empiricism.²⁰⁹ This solution has been codified in the ACA as § 1315a innovation

198. Cf. Madison, *supra* note 192, at 777–78 (distinguishing between a physical laboratory, with controlled variables and scientists formulating a hypothesis, and a state "laboratory," where the political body "does not systematically test its hypothesis").

199. *Id.*

200. Cunningham-Parmeter, *supra* note 195, at 1692–93.

201. See Patel & McDonough, *supra* note 194, at 1106.

202. E.g., James A. Gardner, *The "States-as-Laboratories" Metaphor in State Constitutional Law*, 30 VAL. U. L. REV. 475, 480 (1996) (explaining that a "scientific experiment involves . . . a systematic program of trials, . . . control groups, . . . and a host of methods that clearly have no equivalent in the actual political practices of the state or national governments"). See *infra* Part III.C.2 discussing the specific mechanisms available to states seeking to experiment in health care delivery.

203. Gewirtzman, *supra* note 196, at 252.

204. Michael Abramowicz, Ian Ayres & Yair Listokin, *Randomizing Law*, 159 U. PA. L. REV. 929, 949 (2011).

205. Cf. *id.* at 940.

206. Gardner, *supra* note 202, at 480.

207. *Id.* at 480–82; see also Galle & Leahy, *supra* note 189, at 1370 (explaining that because states undertake "experiments" with the purpose of achieving a specific goal, they may be dissuaded from reporting failures because unlike scientists, states are not disinterested observers).

208. Galle & Leahy, *supra* note 189, at 1347 (noting also that experiments that are well performed still may not apply to other states due to regional variations); see also Cunningham-Parmeter, *supra* note 195, at 1692–93 (explaining that the cost of state experimentation may be externalized such that states do not suffer the negative repercussions of their experimental failures, or the so-called "free rider problem").

209. E.g., Madison, *supra* note 192, at 781.

grants.²¹⁰

The ACA created the Center for Medicare and Medicaid Innovation (CMMI) which provides grants to states in order to test out state-level innovations, and CMMI also provides service-delivery innovation grants, which can be awarded to individual health systems, individual provider entities, and occasionally state or municipal governments.²¹¹ These awards are called health care innovation awards (HCIAs).²¹² In most instances, HCIAs are awarded to individual providers, such as a health care system, that partner with state governments.²¹³ When HCIAs have been awarded to states, they have tended to focus on testing out new ways of providing health insurance coverage.²¹⁴ Provider awardees, on the other hand, experiment with innovative health care services and delivery systems.²¹⁵ These different focuses may be the result of the structural differences between a state and a health care delivery system, such as a hospital network.

Health care delivery systems are designed to deliver medical care and services.²¹⁶ Because they are staffed by medical professionals with a twofold professional responsibility that entails providing high-quality care at a low cost, hospital staff are interested in medical advancements that save money.²¹⁷ Health care delivery systems are also usually staffed with scientific professionals or affiliated with academic institutions.²¹⁸ These factors have led commentators to observe that “the parallels between delivery systems and scientific laboratories may be closer than the parallels between states and scientific laboratories, given the nature of medical practice.”²¹⁹ Delivery-system laboratories—manned by providers—foster distinct advantages over state laboratories, especially with regard to their ability to control variables;²²⁰ however, as market participants, they face different issues than state laboratories.

As with the problems inherent in the concept of a state laboratory, competition among health systems may also hinder delivery-system innovation. Because similarly situated delivery systems must compete with one another for patients (and the consequential revenue coming from payment for services), a

210. 42 U.S.C. § 1315a (2012).

211. See, e.g., BOYD GILMAN ET AL., MATHEMATICA POLICY RESEARCH, EVALUATION OF THE ROUND TWO HEALTH CARE INNOVATION AWARDS (HCIA R2): FIRST ANNUAL REPORT (2016). See *infra* Part III.C.2.a for a full discussion of this grant structure.

212. GILMAN ET AL., *supra* note 211, at xi. HCIA's include delivery-system innovation grants (DSIM's), discussed *infra* in Part III.C.2.a.

213. See, e.g., GILMAN ET AL., *supra* note 211, at 4 (discussing Wisconsin Department of Health Services' partnership with two children's hospitals).

214. See Madison, *supra* note 192, at 774.

215. See *infra* Part III.C.2.a.ii for two examples of provider grantees.

216. Madison, *supra* note 192, at 774–75.

217. *Id.* at 785.

218. *Id.* at 775 (noting that scientific professionals may “be more attentive than state governments to the need to systematically study the impact of their reforms”).

219. *Id.* at 774–75.

220. Cf. *id.* at 781 (explaining that states' size produces many uncontrolled variables).

health system that successfully innovates may be unwilling to share with its competitors cost-saving, quality-enhancing changes derived therefrom.²²¹ Such a health system may view sharing the details of its innovation as increasing competition, and consequentially a threat to their profits.²²² Thus, delivery-system laboratories may lack an incentive to transmit their data and knowledge—a necessary step in achieving replicable results and additional testing.²²³ Delivery-system laboratories may face additional disincentives to innovate in a free, or relatively free, market. As many patients may be unable to determine whether they are actually receiving superior care, the classic market-based problem of “imperfect consumer knowledge” may thwart providers’ incentive to innovate because their improvements in quality “may not be rewarded with an influx of patients.”²²⁴ In a country with privatized health care, market competition and its concomitant knowledge hoarding may thwart the upsides of delivery-system laboratories.

2. Medicaid Innovation and Experimentation

Medicaid has historically fostered innovation in payment and service delivery through two primary channels: providing innovation grants and issuing waivers of reimbursement conditions to states. Grants may be provided to states seeking to experiment with new ways of paying for or delivering services.²²⁵ The ACA has also permitted Medicaid to award grants to individual deliverers of services, such as hospitals, community-based providers, and even some municipal governments that directly deliver services.²²⁶ Waivers are awarded only to states because waivers exempt state Medicaid administrators from complying with certain otherwise mandatory conditions in exchange for the state testing out new approaches to payment or service delivery that will either maintain or increase

221. *Id.* at 787.

222. *Id.* at 785–87.

223. Cunningham-Parmeter, *supra* note 195, at 1697 (“[E]ven if the results are clear, sister states still require additional information to distinguish successful policies from failures.”).

224. As consumers, like all other economic actors, cannot predict the future with complete accuracy, they are said to be operating “in a world of imperfect knowledge . . . [where] they can comprehend neither ‘the full range of possible [market] outcomes’ nor their likelihoods.” ROMAN FRYDMAN & MICHAEL D. GOLDBERG, *IMPERFECT KNOWLEDGE ECONOMICS: EXCHANGE RATES AND RISK* 3 (2007) (second alteration in original) (quoting Alan Greenspan, Chairman, Fed. Reserve Bd., Remarks at the Meeting of the American Economic Association (Jan. 3, 2004)); *see also* Madison, *supra* note 192, at 786. Because insurers may be primarily interested in reduced costs as opposed to improved quality (as the insurance company is not being treated by a doctor, only paying for it) improvements in quality may not result in insurance companies paying higher fees to providers. David M. Cutler, *Where Are the Health Care Entrepreneurs? The Failure of Organizational Innovation in Health Care*, in 11 *INNOVATION POLICY AND THE ECONOMY* 1, 3 (Josh Lerner & Scott Stern eds., 2010).

225. CMMI, *STATE INNOVATION MODELS: FUNDING FOR MODEL DESIGN AND TESTING ASSISTANCE* 3 (2012).

226. GILMAN ET AL., *supra* note 211, at 4 (discussing Wisconsin Department of Health Services’ partnership with two children’s hospitals).

quality without additional cost.²²⁷ Innovation grants and waivers both permit states to spend money and to receive federal Medicaid reimbursement for services and groups for which they may not otherwise receive reimbursement.²²⁸ Part III.C.2.a discusses § 1315a innovation grants, and Part III.C.2.b details Section 1115 waivers.

a. Section 1315a Innovation Grants

Section 3021 of the ACA established the Center for Medicare and Medicaid Innovation (CMMI).²²⁹ CMMI has various statutory powers to promote innovation in health care delivery,²³⁰ including the ability to give grants to individual organizations as well as states.²³¹ Section 1315a, as enacted by the ACA, establishes the criteria for innovation grants,²³² of which there are two types: delivery-system innovation model grants (DSIMs) and state innovation model grants (SIMs). DSIMs focus on the way in which health care is provided,²³³ whereas SIMs focus on the broader state system of payment.²³⁴ For example, a DSIM was awarded to HealthLink Now, a private company, to use telemedicine to provide behavioral health care services to people in rural areas who lacked access to care.²³⁵ CMMI awarded the State of Minnesota a SIM to facilitate the State's delivery system reform by changing payment incentives and structures.²³⁶ DSIMs, a type of HCIA, address a specific population, and they are usually awarded to individual private organizations, though states and municipal governments also have been award recipients or have collaborated with private

227. 42 U.S.C. § 1315(a) (2012) (referencing the criteria in § 1396a). There are also other types of waivers, such as Section 1915 which can either limit enrollee's "freedom of choice," *see supra* notes 156–58 accompanying text, or authorize states to provide home and community services to various vulnerable groups, such as the elderly and people with intellectual disabilities. *See* JANE PERKINS, NAT'L HEALTH LAW PROGRAM, FACT SHEET: FEDERAL AUTHORITY TO APPROVE MEDICAID DEMONSTRATION PROGRAMS 2 (2005); *see also* § 1396n (codifying Title XIX, Section 1915 of the Social Security Act).

228. KAISER COMM'N ON KEY FACTS, FIVE KEY QUESTIONS AND ANSWERS ABOUT SECTION 1115 MEDICAID DEMONSTRATION WAIVERS 2 (2011), <http://kff.org/health-reform/issue-brief/five-key-questions-and-answers-about-section/> [perma: <http://perma.cc/JFF4-NTEL>] [hereinafter KAISER COMM'N, FIVE KEY QUESTIONS].

229. Now codified at 42 U.S.C. § 1315a.

230. *Id.* This has been interpreted to allow CMMI to issue various types of grants, provide reports, and provide training. *CMS Innovation Center*, CMS.GOV, <http://innovation.cms.gov/> [perma: <http://perma.cc/M56K-B2Y3>] (last visited May 29, 2018).

231. *See supra* notes 210–13 and accompanying text.

232. 42 U.S.C. § 1315a. Though the original legislation was an amendment to the Social Security Act—Section 1115A—for ease of reading, I will refer to this section under its ACA subtitle.

233. *See* HENRY IREYS ET AL., MATHEMATICA POLICY RESEARCH, EVALUATING HCIA—BEHAVIORAL HEALTH/SUBSTANCE ABUSE AWARDS: SECOND ANNUAL REPORT 2 tbl.I.1 (2016) (listing the interventions for which organizations were awarded grant monies).

234. RTI INT'L, STATE INNOVATION MODELS (SIM) INITIATIVE EVALUATION: MODEL TEST YEAR TWO ANNUAL REPORT, at ES-1 (2016) (noting that the goals of SIMs is to move away from volume-based payment to value- or quality-based payment).

235. IREYS ET AL., *supra* note 233, at 2 tbl.I.1.

236. RTI INT'L, *supra* note 234, at 207.

recipients.²³⁷ Only states can be granted SIMs, as their purpose is to allow states to test out wide-scale systematic changes on a statewide level.²³⁸

i. The Statutory Framework for § 1315a Grants

Despite the differences between DSIMs and SIMs, awardees must meet similar criteria, and the evaluation structures are similar. CMMI has the ability to provide grants to states and specific providers or health systems under § 1315a as enacted by the Social Security Act (and other subsequent legislation) to promote the development and testing of “new payment and service delivery models,” as well as other categories for innovation.²³⁹ The innovation grant model is typically broken into two phases: testing in one location in Phase I and broader geographic expansion in Phase II.²⁴⁰

In the first phase of the innovation grant (Phase I), CMMI provides awardees with grants to be used to test “payment and service delivery models” where the Secretary determines that the “model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures.”²⁴¹ The contours of the grant requirements are broad. The models should balance a reduction in costs with preservation or enhancement of the quality of the services.²⁴² There are twenty-four model types listed, and they address innovations in three big areas: approaches to payment,²⁴³ service delivery,²⁴⁴ and quality improvement.²⁴⁵ One of the model categories includes approaches to promote “greater efficiencies and timely access to outpatient services . . . through models that do not require a physician or other health professional to refer the service or be involved in establishing the plan of care for the service.”²⁴⁶ The Secretary will also give preference to models which include, among others, the following criteria: patient-centeredness,²⁴⁷ the use of

237. See, e.g., GILMAN ET AL., *supra* note 211, at 20.

238. CMMI, *supra* note 225, at 1.

239. *Innovation Models*, CMS.GOV, [http://innovation.cms.gov/initiatives/#views=Health Care Innovation Awards](http://innovation.cms.gov/initiatives/#views=Health%20Care%20Innovation%20Awards) [perma: <http://perma.cc/V22F-GMR8>] (last visited May 29, 2018).

240. 42 U.S.C. § 1315a (2012).

241. *Id.*

242. *Id.*

243. *E.g., id.* § 1315a(b)(2)(B)(ii) (preferring approaches that contract “directly with groups of providers of services and suppliers to promote innovative care delivery models, such as through risk-based comprehensive payment or salary-based payment”).

244. *E.g., id.* § 1315a(b)(2)(B)(xix) (giving preference to approaches that “[u]tiliz[e], in particular in entities located in medically underserved areas . . . telehealth services . . . in treating behavioral health issues”).

245. *E.g., id.* § 1315a(b)(2)(B)(xv) (preferring approaches that promote “improved quality and reduced cost by developing a collaborative of high-quality, low-cost health care institutions that is responsible for . . . providing assistance to other health care institutions on how best to employ such best practices and proven care methods to improve health care quality and lower costs”).

246. *Id.* § 1315a(b)(2)(B)(xvii).

247. *E.g., id.* § 1315a(b)(2)(C)(ii) (listing as a criterion whether “the model places the applicable individual . . . at the center of the care team”).

technology,²⁴⁸ and coordination of care.²⁴⁹ Phase I under the ACA is not required to be budget neutral,²⁵⁰ and the Secretary must conduct an “evaluation of each model” tested.²⁵¹

The statute itself does not condition grants on the presentation of a strong evidence base to support the efficacy of the proposed innovation.²⁵² This is perhaps a tacit acknowledgement of the “practical paradox” inherent in public health innovations: cutting-edge models may lack a strong evidence base precisely *because* they are so new.²⁵³ Section 1315a’s focus on evaluation effectively develops an evidence base through the grant process.²⁵⁴ The Secretary must make the results of each evaluation available to the public and reserves the power to establish reporting requirements for the grantees participating in the model demonstration.²⁵⁵ The Secretary may also “terminate or modify the design and implementation of a model,” unless the model is expected to improve quality of care without increasing spending, decrease spending, or improve quality of care and reduce spending.²⁵⁶ If the model is expected to meet any of these goals, then the Secretary has discretion to move the project to Phase II: geographic expansion.²⁵⁷

Phase II provides the Secretary with the authority to expand the “duration and the scope” of a model being tested if, taking into account the evaluation metrics, the Secretary determines that the expansion will reduce spending without reducing the quality of care or improve the quality of care without

248. *E.g., id.* § 1315a(b)(2)(C)(iv) (listing as a criterion whether “the model utilizes technology, such as electronic health records and patient-based remote monitoring systems, to coordinate care over time and across settings”).

249. *E.g., id.* § 1315a(b)(2)(C)(v) (listing as a criterion whether “the model provides for the maintenance of a close relationship between care coordinators, primary care practitioners, specialist physicians, community-based organizations, and other providers of services and suppliers”).

250. *Id.* § 1315a(b)(3). Commentators have applauded this provision of nonneutrality because “neutrality requirements had hampered previous demonstrations” in the past. Madison, *supra* note 192, at 792–94.

251. 42 U.S.C. § 1315a(b)(4).

252. *Id.* § 1315a(b)(2)(A) (“The Secretary shall select models to be tested from models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care . . .”).

253. See Evan Anderson & Scott Burris, *Researchers and Research Knowledge in Evidence-Informed Policy Innovation*, in REGULATING TOBACCO, ALCOHOL AND UNHEALTHY FOODS: THE LEGAL ISSUES 36, 41–42 (Tania Voon et al., eds. 2014) (explaining “a practical paradox confronts exponents of evidence-based public health law: if a legal intervention is truly innovative, there will not yet be direct evidence of its impact”).

254. 42 U.S.C. § 1315a(b)(4). The evaluation focuses on an analysis of the quality of care, with a specific eye to patient-level outcomes, patient-centeredness, and any changes in spending. *Id.*

255. *Id.*

256. *Id.* § 1315a(b)(3)(B). Scholars have noted that demonstration projects were possible prior to the ACA, but the Secretary’s broad power has the potential to make them even more effective. Madison, *supra* note 192, at 792 (noting historical challenges by citing intractability of malpractice liability demonstration projects prior to the ACA in William M. Sage, *Why Are Demonstrations of Comprehensive Malpractice Reform So (at All) Controversial?*, 37 U. MEM. L. REV. 513 (2007)).

257. 42 U.S.C. § 1315a(c).

increasing spending.²⁵⁸ Additionally, the Secretary must determine that the expansion would not “deny or limit the coverage or provision of benefits” of Medicaid-eligible individuals.²⁵⁹ Though the Secretary’s power is broad, the ACA requires the Secretary to provide Congress with an annual report of the grantee activities.²⁶⁰

ii. Practical Application of § 1315a Grants

Since its inception, CMMI has given some of the ten billion dollars in grants²⁶¹ to groups that include renowned hospitals and health systems, such as Beth Israel Deaconess in Boston, Massachusetts and the Mayo Clinic in Rochester, Minnesota.²⁶² Innovations in service delivery include programs that have created a “community paramedic” who, instead of responding to emergencies after they have occurred, visits patients to prevent emergencies from occurring.²⁶³ The Community Paramedics program (CP) was designed to combat high rates of emergency room utilization in a community experiencing high rates of obesity, cholesterol, diabetes, stroke, and other chronic conditions.²⁶⁴ Another grant has gone to community-based providers to implement PREP, an evidence-based treatment to prevent the development of full psychosis and to help reduce the symptoms of people experiencing full psychosis.²⁶⁵ Because § 1315a is so new, in order to understand the statutory expectations and interpretation, it may be useful to look to the specific details of each grant recipient program.

CP and PREP have both targeted underserved populations with expensive yet preventable health needs. CP identified “at least 100 patients who had multiple hospital visits in the preceding 18 months.”²⁶⁶ They were categorized into three groups based on risk for hospital admission.²⁶⁷ PREP similarly focused

258. *Id.*

259. *Id.* Thus, Phase II requires either budget neutrality or savings. *Id.*

260. *Id.* § 1315a(g). The evaluation results are also readily available to the public. *See, e.g.,* IREYS ET AL., *supra* note 233.

261. 42 U.S.C. § 1315a(f).

262. *Innovation Models*, *supra* note 239.

263. *Prosser Public Hospital District*, CMS.GOV: INNOVATION CTR., <http://innovation.cms.gov/initiatives/participant/Health-Care-Innovation-Awards/Prosser-Public-Hospital-District.html> [perma: <http://perma.cc/ZX4U-PS9L>] (last visited May 29, 2018).

264. Ed Mund, *What a Rural CP Program Is Revealing*, EMSWORLD (May 1, 2013), <http://www.emsworld.com/article/10932227/prosser-washington-community-paramedic-program-yields-results> [perma: <http://perma.cc/3VUL-93F5>] (last visited May 29, 2018).

265. *Family Service Agency of San Francisco*, CMS.GOV: INNOVATION CTR., <http://innovation.cms.gov/initiatives/participant/Health-Care-Innovation-Awards/Family-Service-Agency-Of-San-Francisco.html> [perma: <http://perma.cc/E4Q5-3K4C>] (last visited May 29, 2018); *see also History of Development*, PREPWEALTHNESS.ORG, <http://prepwellness.org/history-of-development/> [perma: <http://perma.cc/2P5H-MKS7>] (last visited May 29, 2018).

266. Mund, *supra* note 264.

267. *Id.* These groups were as follows: (1) “more than five visits for conditions other than pain relief”; (2) “open surgeries with risk of infection”; and (3) “patients with the potential to fall into” the first group. *Id.*

on a group of people for prevention. The PREP program targets people who have been diagnosed with their first episode of psychosis or people who have been diagnosed with psychosis and additional issues, such as substance abuse.²⁶⁸ The implied goal of CP and PREP is twofold: to enhance patients' quality of life through effective health care outcomes, and to reduce their utilization of expensive health care services.²⁶⁹

CP's and PREP's populations both have the potential to be heavy users of the emergency room, which is expensive for patients, taxpayers, and hospitals.²⁷⁰ CP seeks to reduce emergency room utilization by providing follow-up and education to patients who may be at risk of rehospitalization due to complications arising from failure to follow discharge instructions.²⁷¹ PREP also takes a preventative approach because, similar to CP's target population, hospitalization of people due to mental illness is expensive due to the cost of care and the loss of wages.²⁷²

Unlike CP, PREP has a considerably larger evidence base to draw upon, so even at the time the CMMI grant was awarded, PREP could demonstrate that due to involvement in PREP, its participants reduced their number of hospitalizations by seventy-one percent, which saved \$15,450 per participant per year.²⁷³ PREP enrollment also corresponded with a reduction in symptomology, which for people living with psychosis may be the difference between being able to keep a job and being fired.²⁷⁴ Though PREP's additional evidence base likely was useful in obtaining a grant, Phase I does not require grantees to provide extrinsic evidence of the efficacy of their program in order to move on to Phase II; if the internal evaluation data allow the Secretary to infer either sustained quality at reduced cost or improved quality at the same cost, then a CMMI-grant-funded innovation project should be able to move to Phase II.²⁷⁵ Cost savings can also be achieved through promoting efficiencies in outpatient care without the need to use a doctor.

CP and PREP limit the use of physicians on both a chronic and acute basis: by expanding the roles of nonphysicians as primary providers and also by reducing emergency-room admissions. CP achieves this goal by employing paramedics as the main provider.²⁷⁶ Paramedics, who require far less training

268. *Learn More About Training in the Felton Early Psychosis Programs Approach*, PREPWELLNESS.ORG, <http://prepwellness.org/training/> [perma: <http://perma.cc/C7QV-UWXG>] (last visited May 29, 2018).

269. See Mund, *supra* note 264; see also *Felton Early Psychosis Programs Results*, PREPWELLNESS.ORG, <http://prepwellness.org/results/> [perma: <http://perma.cc/8XLF-LYTW>] (last visited May 29, 2018) (mentioning "improvements in social functioning").

270. E.g., *Felton Early Psychosis Programs Results*, *supra* note 269.

271. Mund, *supra* note 264.

272. Chisholm et al., *supra* note 31, at 397–402.

273. *Felton Early Psychosis Programs Results*, *supra* note 269.

274. *Id.*

275. 42 U.S.C. § 1315a(c) (2012).

276. Mund, *supra* note 264.

than physicians, make home visits to help patients with their follow-up care.²⁷⁷ Physicians become involved only when emergencies arise or when a patient's needs are outside the scope of the paramedic's license.²⁷⁸ PREP limits the role of psychiatrists to primarily that of medication management, and psychiatric nurse practitioners are interchangeable with doctors under the PREP approach.²⁷⁹

Section 1315a does not call its preference "patient-centered care"; however, by noting that there is a preference for models that "place[] the applicable individual, including family members and other informal caregivers of the applicable individual, at the center of the [individual's] care team,"²⁸⁰ it effectively uses the IOM's definition.²⁸¹ These two awardees fit into the patient-centered paradigm because whether physically or clinically, CP and PREP prioritize patient accessibility and ease. CP facilitates patients receiving the care they need because the paramedics actually provide patients with treatment in their homes, which is likely a more accessible approach than forcing people to commute to a hospital.²⁸² PREP similarly facilitates ease of access as it focuses on developing a "one-stop shop" where patients and their families can get everything they need in one place.²⁸³

Though § 1315a notes that grants using technology are preferred,²⁸⁴ CP does not detail its use of technology as an integral aspect of its program.²⁸⁵ PREP's focus is on early intervention and the use of care teams to reduce symptoms; however, PREP also touts its use of algorithm-based medication management.²⁸⁶ The benefits of this approach include consistency and the removal of provider bias arising from pressure to prescribe certain medications.²⁸⁷

Section 1315a does not explicitly require that models demonstrate a strong evidence base in order to receive funding; however, the Secretary determined

277. *Id.*

278. *Id.*

279. *Learn More About Training in the Felton Early Psychosis Programs Approach*, *supra* note 268.

280. 42 U.S.C. § 1315a(b)(2)(C).

281. *See supra* note 40 and accompanying text.

282. Mund, *supra* note 264.

283. *Why Felton Early Psychosis Programs Are Different*, PREPWEALTHNESS.ORG, <http://prepwellness.org/why-prep-is-different/> [perma: <http://perma.cc/ART2-EBMY>] (last visited May 29, 2018).

284. 42 U.S.C. § 1315a(b)(2)(C).

285. However, HealthLinkNow, a DSIM awardee, used real-time telemedicine to allow clinicians to provide behavioral health services to rural patients who otherwise would not have access to behavioral health. IREYS ET AL., *supra* note 233, at 65.

286. *Learn More About Training in the Felton Early Psychosis Programs Approach*, *supra* note 268. This can be a computer program that computes the proper medication and dosage for individuals based on the results of their physical attributes as well as their reported preferences. *See* Madhukar H. Trivedi et al., *Clinical Results for Patients with Major Depressive Disorder in the Texas Medication Algorithm Project*, 61 ARCHIVES GEN. PSYCHIATRY 669, 669-71 (2004); Jennifer P. Wisdom et al., *Preparing to Implement Medication Algorithms: Staff Perspectives and System Infrastructure*, 14 J. PSYCHIATRIC PRAC. 209, 209 (2008).

287. Wisdom et al., *supra* note 286, at 212.

that both CP and PREP have demonstrated evidence of their efficacy. CP and PREP seem to have to meet a relatively low standard of proof as neither CP nor PREP has readily available practice guidelines.²⁸⁸ PREP possesses a considerable, readily accessible evidence base because it has been studied and used with success in other countries, and PREP also draws from CBT and other interventions with strong bodies of evidentiary support.²⁸⁹ Organizations appear to receive grants more often than states when it comes to developing innovative treatment delivery systems.²⁹⁰ States, however, have another tool which effectively allows them to test out new methods of payment and service delivery: Section 1115 waivers.²⁹¹

b. Section 1115 Waivers

Section 1115 was added to the Social Security Act in 1962 and thus predates Medicaid.²⁹² It provides the Secretary with broad authority to waive certain requirements of the Social Security Act, in order to “encourage experimental, pilot, or demonstration projects” that would promote the objectives of the Act.²⁹³ This provision was incorporated into the ACA and codified in § 1315 of the U.S. Code.²⁹⁴ It gives the Secretary authority to waive provisions of § 1396a (providing Medicaid coverage requirements)²⁹⁵ in order to establish state-based demonstration, experimental, or pilot programs that are “likely to assist in

288. When the CP program went live in January 2013, there were no practice guidelines developed. To date, there does not appear to be any conclusive set of CP guidelines; however, the Health Resources & Services Administration (HRSA) developed an evaluation tool, published in 2012, that CP programs can use to determine their own fidelity to the CP model. *See* OFFICE OF RURAL HEALTH POLICY, HRSA, COMMUNITY PARAMEDICINE EVALUATION TOOL (2012).

289. *Why Felton Early Psychosis Programs Are Different, supra* note 283.

290. *See* CMS, HEALTH CARE INNOVATION AWARDS ROUND ONE PROJECT PROFILES (2013) (listing awardees, all of which are organizations, as opposed to states). However, § 1315a does not limit grants to organizations alone. *Cf.* 42 U.S.C. § 1315a(b)(2)(B)(x) (2012) (providing criteria by which states may “test and evaluate”).

291. Public Welfare Amendments of 1962, Pub. L. No. 87-543, § 122, 76 Stat. 172, 192 (codified as amended at 42 U.S.C. § 1315).

292. *Id.* (creating Section 1115 of the Social Security Act of 1935). President John F. Kennedy “urged Congress in 1962 to amend the Social Security Act of 1935 to include a waiver provision permitting experimentation with methods of delivering benefits to beneficiaries of then-existing and future programs provided under the” Social Security Act. Judith M. Rosenberg & David T. Zaring, Recent Developments, *Managing Medicaid Waivers: Section 1115 and State Health Care Reform*, 32 HARV. J. ON LEGIS. 545, 547 (1995); 108 CONG. REC. 1,489 (1962) (message from Pres. Kennedy) (“I recommend that amendments be made to encourage experimental, pilot, or demonstration projects that would promote the objectives of the assistance titles and help make our welfare programs more flexible and adaptable to local needs.”).

293. 108 CONG. REC. 1,489 (1962) (message from Pres. Kennedy).

294. 42 U.S.C. § 1315(a).

295. Section 1396a provides the requirements that a state plan must meet in order to receive federal Medicaid funds. *Id.* § 1396a. The ACA gives CMS “comprehensive waiver authority starting in 2017.” Thompson, *supra* note 156, at 206. Comprehensive means authority to grant program administration waivers. *See infra* notes 305–08 and accompanying text.

promoting the objectives” of the Medicaid Act.²⁹⁶

When enacted, Congress billed Section 1115 as a way to “test out new ideas and ways of dealing with the problems of public welfare recipients.”²⁹⁷ Section 1115 waivers were intended to facilitate one of the main policies underlying federalism: employing states as laboratories of democracy.²⁹⁸ Scholars have pointed to the fact that aside from a few statements, “[t]here is virtually no legislative history to section 1115”²⁹⁹ to provide a basis under which states have justified the use of Section 1115 waivers to reduce benefits.³⁰⁰

The Secretary has broad authority to grant states permission to waive conditions in § 1396a including “statewideness,” “freedom of choice,” enrollment criteria, and the covered benefits for specific populations.³⁰¹ Section 1115 also gives the Secretary broad authority to waive otherwise mandatory conditions in § 1396b, which provides the criteria under which the federal government will pay matching funds to states.³⁰² By giving the Secretary the ability to waive coverage requirements for eligibility and service types, all while treating the experiment as part of the Medicaid program, Section 1115 provides the Secretary with considerable discretion and power to allow states to mold federal regulations to meet their own needs.³⁰³

Like their § 1315a innovation grant counterparts, Section 1115 waivers are

296. 42 U.S.C. § 1315(a). The Secretary will also grant waivers for the purposes of promoting the objectives of other parts of the Social Security Act, *id.*, but that extends beyond the scope of this Comment.

297. S. REP. NO. 87-1589, at 19–20 (1962); *see also* Social Security Amendments of 1965, Pub. L. No. 89–97, 79 Stat. 286.

298. *See* Madison, *supra* note 192, at 767. Contemporary scholars have pointed out that this is an example of “negotiated federalism,” where states and the federal government bargain for the benefit of the deal. Erin Ryan, *Negotiating Federalism*, 52 B.C. L. REV. 1, 6 (2011); *see, e.g.*, ROBIN RUDOWITZ ET AL., KAISER COMM’N ON MEDICAID & THE UNINSURED, MEDICAID EXPANSION WAIVERS: WHAT WILL WE LEARN? 13 (2016) (discussing Indiana’s Section 1115 plan in which the state traded a reduction in coverage of non-emergent care in exchange for expanding eligibility).

299. Rosenbaum, *Mothers and Children*, *supra* note 191, at 111 (noting that the “small amount [of legislative history] that does exist suggests that the intent of Congress was to authorize demonstrations that improve the performance of Social Security Act programs for *beneficiaries*” (emphasis added)).

300. Jonathan R. Bolton, Note, *The Case of the Disappearing Statute: A Legal and Policy Critique of the Use of Section 1115 Waivers to Restructure the Medicaid Program*, 37 COLUM. J.L. & SOC. PROBS. 91, 111 (2003). State creativity has expanded considerably with over twenty percent of federal Medicaid spending being governed by Section 1115 demonstrations. Quadagno, *supra* note 142, at 80–81. Critics have also charged that Section 1115 waivers subvert the legislative process by allowing states to make broad changes to their programs through executive action. *Id.* at 80. They have also been criticized as circumventing the democratic process at the state level because of the wide scope of power allotted to the Secretary. Thompson, *supra* note 156, at 197. Section 1115 waivers have also been called examples of “executive federalism” under which appointed members of the executive branch (i.e., the Secretary) “facilitate[] transformations in Medicaid without congressional authorization.” *Id.*

301. 42 U.S.C. § 1315(a) (referencing the criteria in § 1396a).

302. *Id.* (referencing the criteria in § 1396b).

303. Sidney D. Watson, *Premiums and Section 1115 Waivers: What Cost Medicaid Expansion?*, 9 ST. LOUIS U. J. HEALTH L. & POL’Y 265, 269 n.19 (2016).

generally classified as either comprehensive or specific.³⁰⁴ Comprehensive waivers make broad changes in “eligibility, benefits and cost sharing, and provider payments,”³⁰⁵ while specific waivers focus on particular services, such as family planning, or certain populations,³⁰⁶ such as people with unique diseases.³⁰⁷ Unlike § 1315a demonstration *grants*, Section 1115 *waivers* have been used less for obtaining permission to deliver specific (otherwise uncovered) types of care and more for the purpose of obtaining permission to change the broader system of delivery.³⁰⁸ Prior to the enactment of the ACA, states had used waivers to obtain federal matching funds to cover populations that were otherwise uncovered by Medicaid.³⁰⁹

Critics and neutral observers alike have noted that Section 1115 waivers have been used less for purposes of trial and experimentation in service delivery and more for the purpose of reducing costs.³¹⁰ Section 1115 waivers have been used by states to reduce the type or amount of benefits covered³¹¹ or place otherwise unauthorized cost-sharing requirements on Medicaid beneficiaries.³¹² For example, when the ACA provided a mechanism by which states could expand Medicaid (and receive federal funding), of the thirty-two states that chose to expand Medicaid, six implemented expansion under waiver provisions.³¹³ They reasoned that in exchange for reducing costs, they should be permitted to reduce coverage of otherwise required services.³¹⁴ Waivers have

304. KAISER COMM’N, FIVE KEY QUESTIONS, *supra* note 228, at 2. Under Section 1115, there are also grants called “delivery system reform incentive pool” grants (DSRIPs). GATES ET AL., *supra* note 152, at 3. They provide block grants to states; the states, in turn, can use these funds to reward individual providers that meet certain quality goals. *See generally id.* DSRIPs exceed the scope of this Comment because they focus on payment innovations as opposed to service-delivery innovations.

305. KAISER COMM’N, FIVE KEY QUESTIONS, *supra* note 228, at 2.

306. *Id.*

307. *See, e.g.*, MD. DEP’T OF HEALTH & MENTAL HYGIENE, MARYLAND HEALTHCHOICE PROGRAM § 1115 WAIVER RENEWAL APPLICATION 7 (2016) (proposed draft) (discussing rare and expensive disease case management program).

308. *See infra* notes 304–15 and accompanying text for a comprehensive discussion of the use of waivers.

309. *See generally* KAISER COMM’N ON MEDICAID & THE UNINSURED, THE ROLE OF SECTION 1115 WAIVERS IN MEDICAID AND CHIP: LOOKING BACK AND LOOKING FORWARD (2009), <http://kff.org/medicaid/issue-brief/the-role-of-section-1115-waivers-in/> [perma: <http://perma.cc/RL27-W2PC>] [hereinafter KAISER COMM’N, THE ROLE OF SECTION 1115 WAIVERS]. Massachusetts famously used Section 1115 waivers to obtain near-universal coverage; this approach, tested in one state laboratory, later became the model for the ACA. Thompson, *supra* note 156, at 198; *see also supra* Part III.C.2.b and accompanying text.

310. *See generally* KAISER COMM’N, THE ROLE OF SECTION 1115 WAIVERS, *supra* note 309.

311. *See supra* note 298 discussing Indiana’s Section 1115 waiver which traded coverage of non-emergent services in exchange for expanding eligibility.

312. *E.g.*, CMS, 11-W-00245/5, SPECIAL TERMS AND CONDITIONS: HEALTHY MICHIGAN SECTION 1115 DEMONSTRATION 96 (2015); Letter from Andrew M. Slavitt, Acting Admin., U.S. Dep’t of Health & Human Servs., to Chris Priest, Dir., Mich. Med. Servs. Admin. (Dec. 17, 2015).

313. RUDOWITZ ET AL., *supra* note 298, at 1. The six states that used Section 1115 waivers were Arkansas, Indiana, Iowa, Michigan, New Hampshire, and Montana. *Id.* at 2.

314. *See supra* note 298 discussing Indiana’s Section 1115 waiver.

been criticized as a pretense used to reduce benefits, often justified under the guise of expansion of services.³¹⁵

Section 1115 waivers have many purposes; they can be used to deliver new services, but states most often use them to deliver old services in new ways or treat “old” conditions in new ways. States typically bundle these new services in with changes to program administration; it is atypical that they simply apply for a Section 1115 waiver for a single new service.³¹⁶ However, despite their normal usage, states also occasionally use Section 1115 to obtain funding for new services, which is similar to states’ and municipalities’ use of § 1315a DSIMs.³¹⁷

Section 1115 waivers are generally approved for a period of five years,³¹⁸ and most can be renewed beyond that period.³¹⁹ As demonstration projects, Section 1115 waivers are meant to be evaluated by the Secretary, and States are also supposed to report their data on a periodic basis.³²⁰ The volume of Section 1115 waivers has increased dramatically, which in turn has constrained federal research budgets, forcing states to do their own evaluations.³²¹ States have been criticized for not making these evaluation reports available.³²² This lack of focus on evaluations and their unavailability “restricts the ability for researchers, policymakers, and other stakeholders to identify the impacts of and lessons learned from Section 1115 waivers to date.”³²³ However, the Secretary does have minimal congressional reporting requirements.³²⁴ Like § 1351a grants, the Secretary must report the “actions taken . . . with respect to applications for

315. *E.g.*, Lucy A. Williams, *The Abuse of Section 1115 Waivers: Welfare Reform in Search of a Standard*, 12 YALE L. & POL’Y REV. 8, 24 (1994) (focusing on Aid to Families and Dependent Children benefits, but discussing waiver abuse in general). *But see* Ryan, *supra* note 298, at 64 (highlighting a waiver program that successfully expanded services).

316. *E.g.*, R.I. EXEC. OFFICE OF HEALTH & HUMAN SERVS., 11-W-00242/1, RHODE ISLAND COMPREHENSIVE SECTION 1115 DEMONSTRATION, at attachment A (2015). Rhode Island recently amended its broad Section 1115 waiver, and requested a change so that it could cover a new, cutting-edge treatment called cortical integrative therapy, a “non-invasive diagnostic and treatment program for brain-based disorders.” *Id.*

317. *See supra* notes 232–35 and accompanying text.

318. 42 U.S.C. § 1315 (2012); *see also* KAISER COMM’N, FIVE KEY QUESTIONS, *supra* note 228, at 3.

319. 42 U.S.C. § 1315; *see also* KAISER COMM’N, FIVE KEY QUESTIONS, *supra* note 228, at 3. Despite this five-year policy, some waivers have been renewed continuously since their inception. *See, e.g.*, OKLAHOMA SOONERCARE SECTION 1115 DEMONSTRATION FACT SHEET 3 (1995) (outlining Waiver 11-E-00048/6, which began in 1995, and has been continuously renewed through 2015). Like Phase II of § 1315a innovation grants, Section 1115 waivers must also be budget neutral and, though neutrality is not statutorily mandated, it is the long-standing policy. KAISER COMM’N, FIVE KEY QUESTIONS, *supra* note 228, at 2, 4.

320. KAISER COMM’N, FIVE KEY QUESTIONS, *supra* note 228, at 2; *see also* 42 U.S.C. § 1315(d)(2)(D)–(E).

321. KAISER COMM’N, FIVE KEY QUESTIONS, *supra* note 228, at 4; *see also* 42 U.S.C. § 1315(e)(6) (“[E]xtension of a waiver project . . . shall be on the same terms and conditions . . . including applicable terms and conditions relating to . . . budget neutrality.”).

322. KAISER COMM’N, THE ROLE OF SECTION 1115 WAIVERS, *supra* note 309, at 2–3.

323. KAISER COMM’N, FIVE KEY QUESTIONS, *supra* note 228, at 2.

324. 42 U.S.C. § 1315(d)(3).

demonstration projects under this section.”³²⁵ However, these requirements are far less strict than those of § 1315a innovation grants.³²⁶

IV. DISCUSSION

Own-time TMH presents a high-quality, low-cost solution to providing behavioral health services to those who are most likely to need it—the low-income or Medicaid population. Despite the growing evidence base supporting own-time TMH’s efficacy, Medicaid does not cover it. If federal Medicaid funds cannot be used to match state Medicaid funds, it is unlikely that any state will ever implement it. Though a state could pay for the service on its own, without the assistance of federal Medicaid funds, this course of action is expensive for states and does not guarantee that the “experiment” will be replicable. Federal Medicaid law, however, provides a few viable channels through which a state seeking to test own-time TMH could serve as a laboratory of democracy to not only reap the benefits within its own borders but also to provide data to support other states’ future implementation of own-time TMH.

The two available vehicles for testing novel innovations to service delivery are Section 1115 waivers and § 1315a innovation grants. Because they truly foster innovation, as opposed to just being a guise for cost savings, § 1315a innovation grants provide a superior vehicle for experimenting with policy changes. They also provide a structure conducive to replication. Unlike waivers, the goal of innovation grants is to experiment with a new approach in one state, and then, when proven effective, replicate that model across the country.³²⁷ Replicability is built into all experiments funded by innovation grants, and states functioning as laboratories of democracy are not excluded. States, however, may not be in the best position to conduct an effective experiment, and own-time technology may be better tested out with individual providers using DSIM.³²⁸

Own-time TMH is an effective, low-cost solution to address the Medicaid population’s behavioral health needs. Because Medicaid does not match state payments, states seeking to address a lack of behavioral health providers by experimenting with own-time TMH should partner with a private entity to obtain a DSIM grant to test out this innovative and much-needed approach to

325. *Id.* The Secretary’s reporting requirements to Congress are less strict than those of § 1315a innovation grants, which require the Secretary to describe the models tested . . . , the number of individuals . . . participating in such models and payments made . . . , any models chosen for expansion . . . , and the results from evaluations. . . . [E]ach . . . such report shall provide such recommendations as the Secretary determines are appropriate for legislative action to facilitate the development and expansion of successful payment models.

Id. § 1315a(g).

326. *Compare id.*, with *id.* § 1315(d)–(e), and 42 C.F.R. § 431.420 (2017). Note that innovation grants possess detailed *statutory* evaluation and reporting requirements whereas waivers possess *regulatory* evaluation and reporting requirements. *See* 42 U.S.C. § 1315a(g); *id.* § 1315(d)–(e); 42 C.F.R. § 431.420. Historically, the Secretary has not enforced waiver evaluation. Watson, *supra* note 18, at 214–15.

327. *See supra* note 240 and accompanying text discussing geographic expansion.

328. *See, e.g., supra* Part III.C.2.a.ii.

service delivery. Part IV.A asserts that own-time TMH fills the behavioral health treatment gap for Medicaid enrollees because it has been proven effective, is evidence based, and is patient centered. Part IV.B shows that own-time TMH squarely fits into the CMMI grant criteria because it meets all the statutory requirements, best practices in behavioral health, and surmounts the public health innovation paradox. Part IV.C compares innovation grants and waivers, ultimately concluding that innovation grants facilitate the replication of health care quality whereas waivers provide only cost savings.

A. Own-Time TMH Provides an Evidence-Based, Patient-Centered Solution to the Dearth of Behavioral Health Care for Medicaid Enrollees

The economic and social costs of untreated behavioral health problems are expensive for everyone.³²⁹ They lead to missed work for adults.³³⁰ And children with undertreated behavioral health issues have reduced income later in life in comparison to their treated or unaffected peers.³³¹

The poor are disproportionately in need of behavioral health care, and there is a considerable lack of providers who will treat the poor, even the poor on Medicaid.³³² Own-time TMH has the potential to ameliorate this problem because it is a patient-driven approach to behavioral health care delivery. Patients are able to work through the treatments themselves—much like playing a videogame—and only require a behavioral health professional in order to progress to the next level.³³³ In comparison to a therapist treating patients using traditional, face-to-face behavioral health services, or even a therapist treating patients through real-time TMH, one therapist may be able to treat relatively more patients because her time is spent responding to emails and checking quiz results.³³⁴ For example, if a typical therapy session lasts for fifty minutes, plus ten minutes to document the session, then one treatment session requires a full hour of the therapist's time. In an own-time module, like BDD-NET, the patient herself may spend a few hours per module, but the therapist only needs to take the necessary time to check the quiz results and respond to any of the patient's questions.³³⁵ The patient receives more treatment yet requires less of the therapist's time.

Own-time TMH may increase the likelihood that people with behavioral health challenges will obtain their desired health outcomes. First, own-time TMH may address unmet needs by simply providing more than nothing—namely by providing access to care for those who have none. Second, a growing body of evidence is showing that own-time TMH is much more than nothing—it is highly

329. See *supra* notes 29–31 and accompanying text.

330. See *supra* notes 29–30 and accompanying text.

331. See *supra* notes 29–31 and accompanying text.

332. See *supra* notes 36–37 and accompanying text.

333. See *supra* notes 88–92 and accompanying text.

334. See *supra* note 93 and accompanying text.

335. See *supra* notes 87–93 and accompanying text.

effective.³³⁶ Because own-time TMH requires minimal therapist intervention and the program records all the patient's and therapist's activities, own-time TMH possesses an unparalleled dual ability to be verified for model fidelity as well as ongoing efficacy.³³⁷

Because own-time TMH is fully recorded in the module in which it is delivered,³³⁸ as compared to traditional face-to-face mental health counseling, there is a greater ability to both monitor the delivery of service and ensure that services are provided, thus helping to combat fraud. Because there is less therapist interaction,³³⁹ own-time TMH may also make it easier for less skilled therapists to provide higher quality therapy as the patient relies on the computer module as the primary therapeutic intervention. Furthermore, own-time TMH is uniquely person centered, which may be an additional reason for its efficacy.

Own-time TMH succeeds along the three key dimensions of patient-centered care.³⁴⁰ The relational dimension prioritizes the use of multidisciplinary teams, effective patient-provider communication, and the development of patient knowledge.³⁴¹ Own-time TMH addresses this dimension most obviously in terms of effective patient-provider communication by the use of stored communication that can be later referenced if either the patient or provider needs to recall information.³⁴² Additionally, patient knowledge is developed by the use of objective data—by either correctly or incorrectly answering knowledge comprehension questions—to confirm that the patient understands her diagnosis.³⁴³

Own-time TMH is clinically person centered in that the time and place of the delivery of the service are fully at the discretion of the patient. Patients in need are able to access care when and where it is most convenient for them, without worrying about the availability of the therapist.³⁴⁴ Similarly, own-time TMH is structurally patient centered because the physical space in which the patient receives care is decided by the patient.³⁴⁵ Though hospitals may attempt to design rooms to be inviting, there is no place like home.

Not all own-time TMH modalities are created equally, of course, and this Comment is not meant to convey that. There are certainly important obstacles that need to be addressed. Despite strong support to the contrary, patients and providers perceive TMH to be less effective than in-person therapy.³⁴⁶ Comfort with technology increases, however, with increased exposure, which in turn

336. See *supra* notes 83–84 and accompanying text.

337. See *supra* note 88 and accompanying text.

338. See *supra* note 88 and accompanying text.

339. See *supra* notes 86–90 and accompanying text.

340. See *supra* note 52 and accompanying text.

341. See *supra* note 53 and accompanying text.

342. See *supra* note 88 and accompanying text.

343. See *supra* note 90 and accompanying text.

344. See *supra* notes 97–100 and accompanying text.

345. See *supra* notes 97–100 and accompanying text.

346. See *supra* notes 109–13 and accompanying text.

improves people's beliefs about the efficacy of TMH.³⁴⁷ Access to technology presents the biggest challenge to the practical efficacy of TMH.³⁴⁸

Lack of personal computers in private locations, such as the home, presents a serious obstacle in terms of solving a lack of access to mental health care. Mobile devices, such as cell phones and tablets, may function as effective substitutes for full-sized computers, and smartphone ownership among low-income people is steadily increasing.³⁴⁹ This increase suggests that access to own-time TMH is within reach.³⁵⁰

Though other modalities of therapy may be useful, current evidence supports cognitive-based therapy—specifically ICBT—as an effective intervention.³⁵¹ ICBT, however, is relatively new, which means that compared to older modalities (or perhaps even new approaches to delivery that appear similar to older modes) there is less research supporting its efficacy. The public health innovation paradox, however, can be overcome by pointing to the promise of current ICBT research as well as grounding ICBT in CBT. As one of the most studied treatment modalities,³⁵² CBT has one of the strongest evidence bases supporting its usefulness in treating a variety of ailments. Policymakers seeking to fill the behavioral health treatment gap for low-income patients would be wise to begin with a modality such as CBT because of its strong evidence base. As such, instead of framing ICBT as a completely new model of treatment, programs such as BDD-NET can be framed as new ways of providing access to evidence-based interventions, such as CBT.³⁵³

One of the biggest reported barriers to the adoption of own-time TMH, and perhaps a force stifling additional studies into the efficacy of own-time TMH, is the fact that public insurers will not reimburse providers for it.³⁵⁴ Showing viability with the exact population that would be served if this were reimbursable would provide a necessary first step to obtain payment for this valuable service.

B. DSIM Grants Provide the Best Structure for Testing Own-Time TMH as a Model of Service Delivery

Using own-time TMH to provide much-needed behavioral health services

347. See *supra* notes 112–16 and accompanying text.

348. See *supra* notes 117–20 and accompanying text.

349. See *supra* notes 117–20. Schools and public libraries may also provide semiprivate locations in which people can access own-time TMH.

350. Access can also be thought of as problematic in terms of ability to engage with the technology; low levels of literacy may be a barrier to effectively engaging with own-time TMH. These challenges, though important, are outside the scope of this Comment. In recognizing the importance of literacy levels, the health care community is increasingly tailoring their text to the literacy levels of individuals. See, e.g., OFFICE OF DISEASE PREVENTION & HEALTH PROMOTION, PLAIN LANGUAGE: A PROMISING STRATEGY FOR CLEARLY COMMUNICATING HEALTH INFORMATION AND IMPROVING HEALTH LITERACY (2005).

351. See *supra* notes 85–86 and accompanying text.

352. See *supra* notes 85–86 and accompanying text.

353. See *supra* notes 61–63, 85–87 and accompanying text.

354. See *supra* note 167 and accompanying text.

to the Medicaid population is really a proposal to innovate in the way that services are delivered. Regardless of whether a state, city, or private organization (or some combination of the three) undertakes an own-time TMH demonstration project, a DSIM would be the proper type of grant to pursue.³⁵⁵ Even though this Comment advocates for own-time TMH in the broad sense—as own-time TMH presents a wide range of specific approaches—it is fundamentally advocating for reimbursement for a new approach to service *delivery*.

DSIM grants provide the most flexibility because they allow municipal and private entities to obtain a grant independently of one another, or the two can partner in obtaining the grant.³⁵⁶ Because own-time TMH is a relatively targeted intervention, a SIM would be an inappropriate vehicle because SIMs focus on experimenting and innovating within the entire health care system of the state.³⁵⁷ Alternatively, if neither a private entity nor a municipal government wishes to pursue a DSIM to test own-time TMH, then an application to test own-time TMH could easily be bundled into a SIM,³⁵⁸ as part of a state’s broader initiative to reform delivery systems through experimental payment structures.

This Part proceeds in five smaller segments, in parallel with the statutory requirements by which the Secretary may select grantees. Part IV.B.1 addresses the statute’s requirement that the own-time TMH’s population be defined. Part IV.B.2 illustrates own-time TMH’s cost-neutrality. Part IV.B.3 shows how own-time TMH neatly fits into the physician-reduction model type. Part IV.B.4 explains how own-time TMH meets other preferential requirements, including patient-centeredness. Part IV.B.5 reconciles own-time TMH with the public health innovation paradox.

1. Defined Population

Examining the statutory language and its interpretation, own-time TMH fits squarely into the criteria for receipt of a Phase I innovation grant.³⁵⁹ The first criterion of Phase I tackles the specific population: the model must address “a defined population for which there are deficits in care leading to poor clinical

355. The selection of grantees under programs administered by executive agencies, such as CMMI, is a highly discretionary process. This Comment assumes that CMMI is a “black box” and that it is impossible to examine the Center’s decisionmaking processes. See Mark Seidenfeld, *Cognitive Loafing, Social Conformity, and Judicial Review of Agency Rulemaking*, 87 CORNELL L. REV. 486, 486 (2002); see also Sydney A. Shapiro, *The Failure to Understand Expertise in Administrative Law: The Problem and the Consequences*, 50 WAKE FOREST L. REV. 1097, 1098 (2015). This Comment does not suggest that an own-time TMH program would definitely be chosen for a grant. Rather, it only offers that own-time TMH neatly meets statutory criteria and historical awardee precedent associated with § 1315a grants.

356. See *supra* notes 211–13 and accompanying text.

357. See *supra* notes 235–37 and accompanying text.

358. See *supra* note 316 and accompanying text.

359. This Comment assumes that an own-time TMH demonstration grant would move to Phase II.

outcomes or potentially avoidable expenditures.”³⁶⁰ This requirement is relatively broad. Looking to previous grantees, CP defined its population by the number of hospitalizations in the preceding eighteen months and further categorized participants by their types of visits.³⁶¹ PREP is only designed for people who have either been diagnosed with a single episode of psychosis or who have been diagnosed with psychosis as well as additional issues.³⁶² However, consider HealthLink Now—a DSIM grantee that provided real-time TMH to rural residents.³⁶³ The HealthLink Now population is extremely broad: people living in rural communities who need, yet lack access to, behavioral health.³⁶⁴

Though own-time TMH serves diverse populations, a program such as BDD-NET—designed for people diagnosed with body dysmorphic disorder—could easily meet this criterion because, like PREP, its population is defined by diagnosis.³⁶⁵ Thus, a program such as BDD-NET might need to further refine its population to include either prior episodes of treatment (as in CP) or even lack of access (as in HealthLink Now) to enhance its prospects at obtaining a grant.

2. Cost-Neutrality

The second criterion of Phase I requires models to balance a reduction in costs while preserving or enhancing the quality of the services.³⁶⁶ Selection of models is based on whether the Secretary expects the model to reduce program costs while preserving or enhancing the quality of care received by the targeted population.³⁶⁷ Again, this criterion depends on the targeted population; if it is broadly defined to include all Medicaid-eligible individuals who need yet lack adequate behavioral health treatment, then a large corpus of compelling data exists showing that low-income people are most in need of behavioral health treatment and are also the least likely to receive it.³⁶⁸

The Medicaid population, on the whole, presents a chronically underserved group in need of behavioral health treatment.³⁶⁹ As many Medicaid enrollees receive zero behavioral health treatment, own-time TMH, with its promising evidence base, is certainly better than no treatment at all.³⁷⁰ Even if own-time TMH is only nominally better than no treatment at all—though studies show it to be highly effective³⁷¹—then it provides an increase in quality. Furthermore, because much less provider time is required per patient, own-time TMH

360. 42 U.S.C. § 1315a(b)(2)(A) (2012).

361. *See supra* notes 266–67 and accompanying text.

362. *See supra* note 268 and accompanying text.

363. *See supra* note 235 and accompanying text.

364. *See supra* note 235 and accompanying text.

365. *See supra* note 87 and accompanying text.

366. 42 U.S.C. § 1315a (2012).

367. *Id.*

368. *See supra* notes 23–24, 163 and accompanying text.

369. *See supra* notes 23–24, 163 and accompanying text.

370. *See supra* notes 107–11 and accompanying text.

371. *See supra* Part II.C.1.

provides savings over traditional face-to-face therapy.³⁷² In the long term, like CP and PREP, treatment for most behavioral health conditions reduces the likelihood that an individual would be admitted to the hospital for some sort of psychiatric emergency,³⁷³ which provides an additional reduction in costs because hospital stays are expensive.

3. Model Type

Among the various model types, an own-time TMH demonstration would promote “greater efficiencies and timely access to outpatient services” because it does not “require a physician or other health professional to refer the service or be involved in establishing the plan of care for the service.”³⁷⁴ This type of model also serves to reduce costs by empowering typically lower-paid health care professionals—such as paramedics in CP³⁷⁵—to provide services without the explicit authorization of a higher-paid health professional—such as a heart surgeon. This model, exemplified by CP, allows a nonphysician to be the lead clinician for the patient, while relying on support (when needed) from higher-paid health care professionals.³⁷⁶

In CP, the paramedic is the patient’s main provider; instead of requiring the patient to go to the hospital (or, even more expensively, have a specialist physician make a house call), the paramedic provides education to the patient and checks her vital signs in her own home.³⁷⁷ This approach is far less expensive than admitting a patient to a hospital for observation,³⁷⁸ and the paramedic does not require express authorization from the doctor to check on the patient or provide education as this plan of care is built into the CP model.³⁷⁹

Treatment programs employing own-time TMH, such as (but not limited to) BDD-NET, provide a similar structure to CP because the plan of care is effectively prepackaged. Thus, a physician or other health care professional does not need to develop the plan of care for each patient. All that is required is that the patient meets the criteria and agrees to engage in the treatment, and that the therapist approves the patient’s progress from one level to the next.³⁸⁰ In the event that the patient communicates with the therapist using email, the therapist also must respond.³⁸¹ Like a CP paramedic who cannot perform certain medical functions, if there is an issue that the therapist does not feel comfortable

372. See *supra* note 93 and accompanying text. The author, however, was unable to find the exact costs of implementing the modules discussed.

373. See *supra* notes 30–31 and accompanying text.

374. 42 U.S.C. § 1315a(b)(2)(B)(xvii) (2012). This Comment also assumes that state licensing issues and other reimbursement requirements do not propose a practical impediment to implementation.

375. See *supra* notes 276–78 and accompanying text.

376. See *supra* notes 276–78 and accompanying text.

377. See *supra* notes 263–64 and accompanying text.

378. See *supra* notes 269–72 and accompanying text.

379. See *supra* notes 27, 276–78 and accompanying text.

380. See *supra* notes 87–92 and accompanying text.

381. See *supra* note 91 and accompanying text.

addressing, then she can ask her supervising therapist for help determining the course of action.³⁸² The CP model and models like BDD-NET are highly structured and require little decisionmaking by the administering health care professional. Additionally, both are effectively provided in outpatient settings by being provided in the patient's home as opposed to requiring a hospital admission and overnight stay.

4. Patient-Centered, Integrates Technology, and Interdisciplinary Care

The Secretary of the Department of Health and Human Services (HHS) will also give preference to models that include the following criteria (among others): patient centeredness,³⁸³ the use of technology,³⁸⁴ and coordination of care.³⁸⁵ Examining own-time TMH under all three elements of the definition of patient-centered care³⁸⁶ reveals that own-time TMH provides a uniquely patient-centered approach to treatment. The relational dimension of patient-centered care requires effective patient-provider communication;³⁸⁷ for some individuals, having a written record of their provider conversations may be very helpful. Even though both providers and patients have expressed concerns about TMH negatively affecting the therapeutic alliance, there is considerable evidence that supports to the idea that in own-time TMH, the depth of the relationship is not predictive of treatment outcomes. Instead, the *mere presence* of a relationship is predictive of successful treatment results.³⁸⁸

Both the clinical and structural dimensions present the strongest examples of the patient-centered design of own-time TMH. These dimensions address the way in which service is provided and its logistical aspects, such as the location in which service is provided.³⁸⁹ Because the patient does not have to coordinate her schedule with a provider, as in traditional or even real-time TMH, a patient is fully in control of when and where she receives treatment.³⁹⁰ As with CP, many patients may be most amenable to receiving treatment or engaging in therapy in their own homes. Patients with certain conditions, such as body dysmorphic disorder or chronic pain, may be completely unable to leave their homes and, thus, *require* home treatment.³⁹¹ Own-time TMH also meets § 1315a's statutory

382. See *supra* notes 276–78 and accompanying text.

383. E.g., 42 U.S.C. § 1315a(b)(2)(C)(ii) (2012) (listing as a factor for consideration whether “the model places the applicable individual . . . at the center of the care team”).

384. *Id.* § 1315a(b)(2)(C)(iv) (listing as a factor for consideration whether “the model utilizes technology . . . to coordinate care over time and across settings”).

385. E.g., *id.* § 1315a(b)(2)(C)(v) (listing as a factor for consideration whether “the model provides for the maintenance of a close relationship between care coordinators, primary care practitioners, specialist physicians, community-based organizations, and other providers of services and suppliers”).

386. See *supra* notes 52–57 and accompanying text.

387. See *supra* note 53 and accompanying text.

388. See *supra* note 111.

389. See *supra* notes 99–100 and accompanying text.

390. See *supra* notes 97–100 and accompanying text.

391. See *supra* notes 99–100 and accompanying text.

preference for technology because, like HealthLink Now's real-time TMH program, it requires a computer or other mobile device.³⁹²

5. Reconciling the Public Health Innovation Paradox

Notably absent in § 1315a is the requirement that the model be evidence based. It only requires that "there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures."³⁹³ It may initially appear that because own-time TMH does not possess a set of practice guidelines, like its real-time counterpart,³⁹⁴ own-time TMH lacks the necessary general acceptance required to even be considered for a DSIM grant. However, neither CP nor PREP possessed practice guidelines prior to being awarded a grant.³⁹⁵ As own-time TMH has been used with success in other countries and has also been the subject of various meta-analyses addressing its efficacy,³⁹⁶ it possesses an evidence base analogous to that of PREP. Prior to receiving a DSIM grant, PREP had been successfully employed in other countries (and counties),³⁹⁷ and like BDD-NET, there was a strong evidence base supporting its efficacy.³⁹⁸

Furthermore, the structure of the DSIM grant addresses the very paradox inherent in public health innovations: such approaches often lack a comprehensive evidence base precisely because they are so new.³⁹⁹ By requiring (and enforcing) systematic, ongoing evaluation by an external evaluator, § 1315a facilitates the development of an evidence base and may encourage a culture of data use by the program.

C. Innovation Grants Facilitate Health Care Quality While Waivers Facilitate Fewer Services

Though Section 1115 waivers were originally designed to "test out new ideas and ways of dealing with the problems of public welfare recipients,"⁴⁰⁰ they have in fact been used to test out new ways for states to save money and cut services. Like SIM grants, waivers were created to address systems-level changes and redesigns that states attempt to test;⁴⁰¹ however, the history and statutory language of Section 1115 waivers belie this purpose.

In order to obtain a waiver, states must prove to the Secretary that the

392. See *supra* notes 86–92 and accompanying text.

393. 42 U.S.C. § 1315a(b)(2)(A) (2012).

394. See *supra* notes 133–36 and accompanying text.

395. However, there are practice guidelines for real-time TMH, which was used by awardee HealthLink Now. See *supra* note 134 and accompanying text discussing real-time TMH practice guidelines. See also *supra* note 235 and accompanying text discussing HealthLink Now.

396. See, e.g., *supra* notes 83–85, 93.

397. See *supra* note 289.

398. See *supra* notes 273–74, 289 and accompanying text.

399. See *supra* note 253 and accompanying text discussing the public health innovation paradox.

400. S. REP. NO. 87-1589, at 19–20 (1962).

401. See *supra* notes 310–16 and accompanying text.

state's proposed plan would promote the objectives of Medicaid.⁴⁰² In contrast, to obtain an innovation grant (a DSIM or a SIM), the governing statute explicitly requires a prospective awardee (whether private or public entity) to demonstrate that quality will be enhanced or preserved.⁴⁰³ The Secretary also gives preference to models that are patient centered and employ technology.⁴⁰⁴ Section 1315a innovation grants have the twofold goal of quality and cost savings.⁴⁰⁵ In stark contrast, Section 1115 waivers allow for reductions in benefits if the state is able to show, under a relatively squishy standard, that the waiver helps meet the goals of the Medicaid program.⁴⁰⁶ Where waivers allow for benefits to be reduced, Phase II of the innovation grant program explicitly prohibits the expansion of any model denying or limiting benefits.⁴⁰⁷

Innovation grants are statutorily designed to improve quality while waivers are designed to reduce costs. This is not to say that innovation grants do not account for fiscal savings; in fact, to move to Phase II, successful demonstrations must show that quality is preserved with cost reductions or that quality is improved while maintaining costs.⁴⁰⁸ However, the fact that waivers must be budget neutral, whereas Phase I grants are not required to be budget neutral⁴⁰⁹ provides further evidence of the true focus of Section 1115 waivers.

The history of state governments' waiver use also contradicts the waiver program's stated purpose of developing innovative approaches to payment and service delivery. For example, states that obtained a waiver in the early 2000s were encouraged to expand Medicaid coverage to uncovered groups in exchange for reducing benefits and requiring otherwise impermissible cost sharing for beneficiaries.⁴¹⁰ The financial benefits to the states and federal government are

402. 42 U.S.C. § 1315a(b)(2)(A) (2012).

403. *Id.*

404. *See id.* § 1315a. This is, of course, in addition to other criteria. *See id.*

405. *Id.* § 1315a(a)(1) ("The purpose of the C[M]MI is to test innovative payment and service delivery models to reduce program expenditures . . . while preserving or enhancing the quality of care furnished to individuals . . .").

406. *See supra* notes 300–03 and accompanying text.

407. *See supra* note 258–59 and accompanying text. The Phase II requirement effectively means that if any innovation program intends to move beyond Phase I, it cannot be structured to reduce benefits.

408. *See supra* note 258 and accompanying text. *But see* Richard Daly, *No Savings from CMS Innovations Program: Study*, HFMA (Mar. 28, 2017), <http://www.hfma.org/Content.aspx?id=53516> [perma: <http://perma.cc/9B8N-WBQB>] (discussing study by Kevin W. Smith and his collaborators that found no savings over the first two years of CMMI's existence). The study also found that with the telemedicine grantees, there was actually increased spending. *Id.* *See generally* Kevin W. Smith et al., *Impact of Health Care Delivery System Innovations on Total Cost of Care*, 36 HEALTH AFF. 509 (2017). However, all the tested approaches employed real-time modalities; the lack of savings from real-time telehealth was attributed to the "wide variation" in provider use—effectively a nonissue in own-time TMH. *Daly, supra*; *see supra* Part IV.B.3; *cf.* Smith et al., *supra*, at 514. Moreover, it is important to note that the study did not find quality deficits. It only found reduced savings. Smith et al., *supra*, at 510 (noting the study "estimate[d] the impact of specific delivery system components on federal expenditures for medical care" (emphasis added)).

409. *See supra* note 250 and accompanying text.

410. KAISER COMM'N, FIVE KEY QUESTIONS, *supra* note 228, at 5 (discussing President Bush's

clear—fewer dollars spent per beneficiary—but the experimental value of this initiative is more opaque. This is due, in large part, to a lack of publicly available evaluations of waiver projects.⁴¹¹ If waivers were designed to foster replicable innovation, then the ongoing failure of states to make their evaluations available—and of HHS to enforce publication—violates the first tenet of effective state laboratories: the state must be willing to experiment.

Even if we assume that states are willing to experiment, as opposed to just cutting costs, then failure to publish evaluations and provide comparative evaluation of waiver programs defies another key principle of the state laboratory concept: transmission of the innovation.⁴¹² Sharing the process and results of state experimentation allows other states to scrutinize the innovation and, if desired, replicate the experiment.⁴¹³ In addition to defeating the replicability of the so-called experiment, the lack of a transmission-of-results requirement makes it impossible to determine whether federal expenditures were used in not only an empirical way but also a fiscally responsible, legal way.

It is important to remember that Medicaid waivers allow federal Medicaid funds to be used by states to pay for services for which federal dollars could not be used. Not requiring states to transmit the results of their experiments poses another problem in experimental design: states are able to externalize their costs. This means that states force the federal government—specifically the resources provided by taxpayers from other states—to pay for testing they “do not control and cannot effectively evaluate”⁴¹⁴ without suffering the full brunt of negative repercussions associated with their failed experiments.⁴¹⁵ States that do not internalize experimental risk effectively destroy one of the key purposes underlying the concept of states as “laboratories of democracy” because instead of the experimenting state suffering the repercussions of its own failures, the entire country suffers.

The problem of externalization occurs where any entity receives grant money, or an expenditure, as grants are not the direct result of labor; rather, they are almost like gifts from the grantor to the grantee. Grantors often get around this problem by conditioning funding on rigid reporting requirements by the grantee and making grants time-limited.⁴¹⁶ These requirements allow grantors to internalize costs to grantees because a grantee will lose funding if it does not meet the reporting requirements, and it only has a certain amount of time in which to effect change using the grant money.

If we think of the federal spending created by Section 1115 waivers as

HIFA plan).

411. *Id.* at 2. The lack of obvious experimental value is also caused by the unavailability of comparative, multistate evaluations.

412. *See supra* notes 199, 221–22 and accompanying text.

413. *See supra* notes 200, 221–22 and accompanying text.

414. Cunningham-Parmeter, *supra* note 195, at 1693.

415. Externalization of risk is said to be problematic because if an actor does not stand to suffer negative consequences as a result of her actions, then she has less of an incentive to act carefully. *See supra* note 195–97, 200 and accompanying text.

416. *See supra* notes 241–60 and accompanying text.

analogous to grants,⁴¹⁷ then state waivers present a high likelihood of externalization of costs because there are very few conditions placed upon states to receive federal monies. It is possible that states are all achieving their goals and spending federal monies responsibly. However, because it cannot be determined whether they were effectively using the funds, states do not suffer any negative repercussions because they are not practically required to report their findings.⁴¹⁸ And though waivers last for five years, nonrenewal of waivers almost never occurs.⁴¹⁹ Waivers do not guarantee externalization, but they dramatically facilitate it.⁴²⁰

In short, waivers do not incentivize innovation in the delivery of quality services, nor do they protect people from the possible harms associated with being subjects of a service-delivery experiment. Waivers allow states to reduce benefits, sometimes in the interest of serving more people,⁴²¹ without ensuring that these “experiments” do not harm beneficiaries.⁴²² Because it is a new approach to service delivery, own-time TMH faces possible opposition from critics charging that it has not been proven effective or that it presents dangers to those who use it. As such, an own-time TMH implementation that is effectively tested within a laboratory of democracy must provide safeguards to ensure strong outcomes reporting.

There may be a temptation to test such promising technology as own-time TMH on a statewide scale, and thus to apply for an SIM. However, entire states rarely function as true laboratories of democracy;⁴²³ their notable successes have not been in service delivery so much as payment reform.⁴²⁴ Individual entities, such as hospitals or even health networks, serve as better vehicles to test out new approaches to service delivery.⁴²⁵ As such, a private entity, state, or municipal government responsible for Medicaid enrollees should apply for a DSIM grant.

Those who study the concept of federal laboratories have criticized the concept of states functioning as laboratories of democracy. Perhaps the most significant criticism is that states are unable to control the plethora of variables inherent in a diverse polity.⁴²⁶ This lack of controls makes state “experiments”

417. Though Section 1115 and § 1315a distinguish between grants and waivers, commentators have noted that waivers function as grants because their use allows a state government to receive effectively unchecked funds. See, for example, *supra* notes 320–318–19 and accompanying text discussing the continuous renewal of Section 1115 waivers.

418. See *supra* notes 321–23 and accompanying text.

419. See *supra* notes 319–20.

420. The lack of readily available evaluation data not only brings into question the value of state “experimentation,” but it also brings into question the ethics of federally funded human-subject experimentation. See *supra* note 191 for a discussion of the implication of the Common Rule in public benefits programs’ experimentation.

421. See *supra* note 302 and accompanying text.

422. See *supra* note 191 for a discussion of the Common Rule implications; see also notes 321–23 for a discussion of the minimal reporting requirements associated with waivers.

423. See *supra* notes 203–06 and accompanying text.

424. See *supra* note 194 discussing Massachusetts’s seminal health care reform law.

425. See *supra* notes 209–11 and accompanying text.

426. See *supra* notes 203–06 and accompanying text.

unable to be replicated by other states, thus defeating the purpose. Individual entities, also thought to serve as laboratories, may suffer from similar shortcomings as their state counterparts.⁴²⁷ By testing out new approaches to service delivery, neither states nor health care systems approach their “experiments” with the disinterest of a scientist.⁴²⁸ Innovation with the goal of cost savings and increased quality is an inherently *interested* endeavor, and both states and individual entities present difficult issues of researcher bias that do not comport with a traditionally empirical approach to experimentation.⁴²⁹ Individual entities also face their own unique innovation roadblocks that states do not face. In testing new approaches to service delivery, individual entities, however, provide distinct advantages that make them closer to the ideal of a laboratory of democracy.

The problems inherent in using individual entities as laboratories of democracy are connected to the fact that health care is provided through markets, and thus providers must compete with one another to stay afloat as businesses. This, in turn, leads to individual health care entities closely guarding information about effective approaches to enhancing quality while saving money.⁴³⁰ Thus, individual entities may be unwilling to transmit successful experiments because it may increase competition with their peers.⁴³¹ States also struggle with the transmission element of successful experimentation. But this arises less from a concern about market competition (a disincentive to health care entities) and more from a lack of affirmative incentive to do so. As funding is not tied to disseminating data, states “experimenting” using waivers do not stand to lose anything from not sharing their data. Innovation grants, however, provide various affirmative incentives for recipients to share their data.⁴³² Innovation grants reward entities that can collect data, supporting the replicability of their models in three distinct ways.

First, as a condition of spending, innovation awardees must collect data and be subject to an independent, cross-program evaluation.⁴³³ Waiver awardees are also technically required to collect data about their activities, but § 1315a provides a statutory requirement that the Secretary make the results available whereas Section 1115 is silent on the public availability of such data.⁴³⁴ The second is unique to truly new programs. By requiring new approaches to delivery, such as own-time TMH, to collect data throughout Phase I of experimentation, innovation grants help cutting-edge service delivery models overcome the so-called practical paradox of evidence supporting innovation.⁴³⁵

427. See *supra* note 220 and accompanying text discussing the “interest” of cost savings.

428. See *supra* note 204 and accompanying text.

429. See *supra* notes 203–06 and accompanying text.

430. See *supra* notes 221–22 and accompanying text.

431. See *supra* notes 221–22 and accompanying text.

432. See *supra* notes 240251–57 and accompanying text.

433. See, e.g., GILMAN ET AL, *supra* note 211.

434. See *supra* notes 319–25 and accompanying text.

435. See *supra* note 253 and accompanying text.

Thus, even if an own-time TMH grantee did not move from Phase I to Phase II, the grantee can use the data gathered during Phase I to apply for private grant funding or even partner with the state to negotiate for federal funds under a waiver program.⁴³⁶ Third, innovation grants incentivize strong data collection. Unlike waivers, whose continued funding is not conditioned on any showing of efficacy, moving an innovation program from Phase I to Phase II requires an awardee to produce a robust body of data showing the efficacy of their program.⁴³⁷

Innovation grants overcome the market incentive to guard experimental results by mandating that not only are evaluation results shared with the Secretary, but the Secretary must also

make the results of each evaluation . . . available to the public . . . and may establish requirements for . . . entities participating in the testing of models . . . to collect and report information that the Secretary determines is necessary to monitor and evaluate such models.⁴³⁸

Collection and transmission of data are inextricably intertwined; by mandating public sharing of the data, innovation grants facilitate the replication of successes and avoidance of failures, thus truly serving their purpose in acting as laboratories of democracy.

V. CONCLUSION

Own-time TMH presents an effective solution to the behavioral health crisis facing poor Americans. Medicaid should cover own-time TMH to incentivize its further development. However, if advocates and policymakers are truly interested in ending the crisis, own-time TMH must be available to all Americans in all states. Though Section 1115 waivers may fund innovation on a state-by-state level, during which many states may be testing out the same approach in parallel, the waiver system, with its lack of transparency, is simply not equipped to foster replicable innovation. In contrast, § 1315a innovation grants are available to private entities, which serve as more contained laboratories in comparison to states, mandate data reporting and publication of results, and focus on quality.

The arguments made in this Comment are not unique to own-time TMH. At its heart, this Comment proposes a set of criteria policymakers should consider in deciding how to test out new approaches to service delivery for the Medicaid population.⁴³⁹ This determination requires choosing between one of the two vehicles for testing out new approaches to service delivery—Section 1115 or § 1315a. In comparing the two statutory approaches, the beneficiaries of each become clear, giving rise to the ultimate question: is the goal of the experiment to give states free rein to cut costs or to get people much-needed treatment?

436. See *supra* notes 239–50 and accompanying text.

437. See *supra* notes 241–51 and accompanying text.

438. 42 U.S.C. § 1315a(b)(4)(B) (2012).

439. Many of these ideas also apply to testing out new approaches to service delivery on the Medicare population.