Structural Determinism Amplifying the Opioid Crisis: It's the Healthcare, Stupid!*

*Nicolas P. Terry***

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** Hall Render Professor of Law, Executive Director, Hall Center for Law and Health, Indiana University Robert H. McKinney School of Law. Email: npterry@iupui.edu, Twitter @nicolasterry.

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He went to work when he'd spent his last dime
And Sammy took to stealing
When he got that empty feeling
For a hundred dollar habit without overtime.
And the gold rolled through his veins
Like a thousand railroad trains,
And eased his mind in the hours that he chose,
While the kids ran around wearin' other peoples' clothe . . .
There's a hole in daddy's arm where all the money goes . . .[1]

I. Introduction

Why are more than two and a half million Americans suffering from substance use disorder ("SUD")?[2] Why did more than half a million die from drug overdose from 1999–2015[3] and an estimated 72,000 in 2017 alone?[4] Why do so few (maybe only 20%) of those suffering from opioids use disorder ("OUD") receive treatment?[5] Why do so many re-entering from prisons relapse and continue their cycles of despair?[6] Should we be tackling a behavioral health services problem, a substance use epidemic, an opioid epidemic or an opioid overdose epidemic, or all of the above?

Sometimes, explanations to hard problems are found hiding in plain sight. Recently, the academy lost Uwe Reinhardt, one of the finest health policy scholars of his generation.[7] Reinhardt, an

1 JOHN PRINE, *Sam Stone, on* JOHN PRINE (Atlantic Records 1971).

2 SUBSTANCE ABUSE & MENTAL HEALTH SERV. ADMIN. CTR. FOR BEHAVIORAL HEALTH STATISTICS & QUALITY, RESULTS FROM THE 2016 NATIONAL SURVEY ON DRUG USE AND HEALTH: DETAILED TABLES 1220, tbl.5.1A (2017), https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2016/NSDUH-DetTabs-2016.pdf.

3 Puja Seth et al., *Overdose Deaths Involving Opioids, Cocaine, and Psychostimulants — United States, 2015–2016*, 67 MORBIDITY & MORTALITY WKLY. REP. 349, 349 (2018).

4 Farida B. Ahmad et al., *Provisional Drug Overdose Death Counts*, NAT'L CTR. FOR HEALTH STATISTICS (Nov. 14, 2018), https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.

5 *See* Olga Khazan, *Why 80 Percent of Addicts Can't Get Treatment*, THE ATLANTIC (Oct. 13, 2015), https://www.theatlantic.com/health/archive/2015/10/why-80-percent-of-addicts-cant-get-treatment/410269/.

6 Ingrid A. Binswanger et al., *Return to Drug Use and Overdose After Release from Prison: A Qualitative Study of Risk and Protective Factors*, ADDICTION SCI. & CLINICAL PRAC., Mar. 15, 2012, at 3, https://ascpjournal.biomedcentral.com/track/pdf/10.1186/1940-0640-7-3.

7 Sam Roberts, *Uwe Reinhardt, 80, Dies; a Listened-to Voice on Health Care Policy*,

economist, wrote extensively about healthcare costs and in one article famously concluded, "It's the prices, stupid!"[8] As we examine the opioid crisis (and other diseases of despair), we should recognize that here, also, there are some causes or accelerants hiding in plain sight. Indeed, enough relate to healthcare access, financing, and delivery that we should conclude, "It's the Healthcare, Stupid!"

In concentrating on the healthcare system, this article is not seeking to oversimplify what is manifestly a wicked problem with multiple, interlocking causes.[9] Specifically, nothing written here should be misunderstood as minimizing the urgent need for evidence-based harm-reducing public health interventions or denying the fundamental role of social determinants of health upon which addictions attach like parasites. Neither is this concentration on healthcare simply a restatement of the evidence-based medicalization-not-criminalization approach to the opioid crisis. Rather, the article invites critical examination of our healthcare "system" seen through an addictions frame; the way in which it supplies context and the role it plays—or in many ways, fails to play—in crises generally and specifically in the case of the opioid epidemic.

The article paints a picture of a healthcare system that not only has been slow to deliver appropriate treatments but also stands as a structural determinant of this crisis. Structural determinants create barriers that stop or slow the remediation of social determinants while perpetuating others. This paper argues that the healthcare system has failed those struggling with OUD and co-morbidities and is itself a structural determinant that creates barriers to effective behavioral health services.

In some ways (such as poor preventative care and over-prescribing) the healthcare system justifiably can be viewed as a cause of the opioid epidemic. However, its true failing is the way it has amplified the crisis; seemingly unable or unwilling to identify appropriate points of intervention or deliver the necessary services. The root causes of the opioid epidemic must be treated with improved education, better surveillance, and generally addressing

N.Y. Times (Nov. 15, 2017), https://www.nytimes.com/2017/11/15/obituaries/uwe-reinhardt-a-listened-to-voice-on-health-care-policy-dies-at-80.html.

8 Gerard F. Anderson et al., *It's the Prices, Stupid: Why the United States is So Different From Other Countries*, 22 Health Affairs 89, 103 (2003).

9 *See generally* Jonathan C. Lee, *The Opioid Crisis is a Wicked Problem*, 27 Am. J. on Addictions 51, 51 (2017).

the social determinants of health. However, the U.S. healthcare system is responsible for many of the symptoms of the opioid crisis and several of the barriers to effective solutions.

The article proceeds as follows. Section II provides context for the current opioid crisis, identifying morphing drug sources to shifting at-risk populations. Section III discusses social and structural determinants of health, arguing that the healthcare system is one of the latter. Section IV is a deeper dive into some of healthcare's flaws relevant to this analysis, critically examining access and benefit stratification, the changing role of Medicaid, and problems associated with fragmentation of care and the lack of wraparound services. Section V provides a brief overview of the extreme healthcare-related structural determinants present in our jails and prisons.

II. Inconvenient Truths

The public health (harm reduction) and medical (treatment) frames for understanding disorders or addictions are widely held.[10] However, many policymakers still cling to a "moral defect" framing.[11] Furthermore, although recognized by some as ineffective or worse,[12] many still believe in continuing or reviving the supply-side criminalization seen in the "war on drugs." The opioid epidemic also pushes some powerful psychological buttons; some of its causes (drug over-prescription by physicians and misleading promotion

10 Scott Burris, *Where Next for Opioids and the Law? Despair, Harm Reduction, Lawsuits, and Regulatory Reform*, 133 PUB. HEALTH REP. 29, 29–33 (2017); Nabarun Dasgupta et al., *Opioid Crisis: No Easy Fix to Its Social and Economic Determinants*, 108 AM. J. OF PUB. HEALTH 182 (2018).

11 Nicole L. Henderson & William W. Dressler, *Medical Disease or Moral Defect? Stigma Attribution and Cultural Models of Addiction Causality in a University Population*, 41 CULTURE, MED., & PSYCHIATRY 480, 492 (2017).

12 *See, e.g.*, Mona Chalabi, *The 'War on Drugs' in Numbers: A Systematic Failure of Policy*, THE GUARDIAN (Apr. 19, 2016), https://www.theguardian.com/world/2016/apr/19/war-on-drugs-statistics-systematic-policy-failure-united-nations; CHRISTOPHER J. COYNE & ABIGAIL R. HALL, CATO INSTITUTE, FOUR DECADES AND COUNTING: THE CONTINUED FAILURE OF THE WAR ON DRUGS (2017), https://object.cato.org/sites/cato.org/files/pubs/pdf/pa-811-updated.pdf; Altaf Rahamatulla, *The War on Drugs has failed. What's next?*, FORD FOUND. (Mar. 23, 2017), https://www.fordfoundation.org/ideas/equals-change-blog/posts/the-war-on-drugs-has-failed-what-s-next/; George P. Shultz & Pedro Aspe, *The Failed War on Drugs*, N.Y. TIMES (Dec. 31, 2017), https://www.nytimes.com/2017/12/31/opinion/failed-war-on-drugs.html.

by pharmaceutical manufacturers) are identifiably blameworthy,[13] sometimes leading to bad actors being shamed in front of Congressional committees.[14] And, at root there are, according to the "moral defect" frame, junkies and their drug lords or kingpins, although this crisis' kingpins are quite different from those seen before.[15]

As befits a "'wicked' problem,"[16] reality is somewhat more complicated. An evolving view of the opioid use crisis is that there exists not just one crisis, but two. Shanoor Seervai and colleagues label the first as a "prescription-drug epidemic," typically impacting older rural whites, but identify the second "emerging epidemic" as impacting non-medical users (increasingly urban communities of color) of heroin and fentanyl.[17]

The line drawn connecting these two epidemics is controversial. The so-called "vector model" assigns causality to drug users and suppliers—overprescribing leads to opioid abuse and overdoses caused by whichever opiate is easiest to acquire.[18] Of course, the two crises (prescription and street drugs) are intertwined[19] and it is not hard to conjure up a mental diagram illustrating how changes in supply and prices of (frequently diverted) prescription

13 Barry Meier, *3 Executives Spared Prison in OxyContin Case*, N.Y. TIMES (July 21, 2017), https://www.nytimes.com/2007/07/21/business/21pharma.html.

14 *See* Katie Zezima & Scott Higham, *Drug Executives to Testify Before Congress About Their Role in U.S. Opioid Crisis*, WASH. POST (Apr. 12, 2018), https://www.washingtonpost.com/national/drug-executives-to-testify-before-congress-about-their-role-in-us-opioid-crisis/2018/04/12/89e7ccf2-3db6-11e8-974f-aacd97698cef_story.html?.

15 Esmé E. Deprez et al., *Deadly Chinese Fentanyl Is Creating a New Era of Drug Kingpins*, BLOOMBERG (May 22, 2018), https://www.bloomberg.com/news/features/2018-05-22/deadly-chinese-fentanyl-is-creating-a-new-era-of-drug-kingpins.

16 *See generally* Horst W. J. Rittel & Melvin M. Webber, *Dilemmas in a General Theory of Planning*, 4 POL'Y SCI. 155 (1973).

17 Shanoor Seervai et al., *The U.S. Has Two Opioid Epidemics: The Federal Response Should Consider Both*, THE COMMONWEALTH FUND: TO THE POINT (Mar. 22, 2018), http://www.commonwealthfund.org/publications/blog/2018/mar/federal-response-to-opioids.

18 *See* Dasgupta et al., *supra* note 10, at 183.

19 "And so it went. Oxycontin first, introduced by reps from Purdue Pharma over steak and dessert and in air-conditioned doctors' offices. Within a few years, black tar heroin followed in tiny uninflated balloons held in the mouths of sugarcane farm boys from Xalisco driving old Nissan Sentras to meet-ups in McDonald's parking lots." SAM QUINONES, DREAMLAND: THE TRUE TALE OF AMERICA'S OPIATE EPIDEMIC 269 (2016).

drugs lead to increases in the demand for street drugs.

However, the vector model for comprehending and reacting to the opioid crises cannot stand.[20] More closely examined, these two increasingly diverging crises exhibit other and more complicated similarities and differences. White middle-class persons with OUD are more likely to have private insurance, unlike the rural and urban poor, who are more likely to rely on Medicaid. Persons of color are more likely to have been the subject of law enforcement and face additional problems associated with societal re-entry from corrections. Finally, and true to its internal (albeit flawed) logic, the vector model emphasizes supply-side interventions such as limitations on prescribing,[21] opioid reimbursement reforms,[22] and the expansion of Prescription Drug Monitoring Programs ("PDMPs").[23] Some of these reforms may impact the prescription drug epidemic.[24] However, they are likely to be of limited help regarding the second epidemic and, obviously, do nothing to address underlying social determinants of health.

A further inconvenience is that the nature of the problem we face is hard to define or, even when defined, is muddied by inconsistent labelling. According to The Diagnostic and Statistical Manual of Mental Disorders ("DSM-5") "[t]he essential feature of a substance use disorder is a cluster of cognitive, behavioral, and physiological symptoms indicating that the individual continues using the substance despite significant substance-related problems."[25] Opioids are included in the list of substances. The core diagnostic criterion for OUD is "[a] problematic pattern of opioid use leading

20 *See* Dasgupta et al., *supra* note 10 (rejecting "prescribing as the causative vector" and arguing that economic and social upheaval are the primary causes).

21 Deborah Dowell et al., *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, 65 MORBIDITY & MORTALITY WKLY. REP. 1 (2018), https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf.

22 *See* Dasgupta et al., *supra* note 10; *see also 2019 Medicare Advantage and Part D Advance Notice Part II and Draft Call Letter*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Feb. 1, 2018), https://www.cms.gov/newsroom/fact-sheets/2019-medicare-advantage-and-part-d-advance-notice-part-ii-and-draft-call-letter.

23 *See generally* Rebecca L. Haffajee et al., *Mandatory Use of Prescription Drug Monitoring Programs*, 313 JAMA 891 (2015).

24 *See generally* Kelly K. Dineen, *Addressing Prescription Opioid Abuse Concerns in Context: Synchronizing Policy Solutions to Multiple Complex Public Health Problems*, 40 LAW & PSYCHOL. REV. 1 (2016).

25 AMERICAN PSYCHIATRIC ASSOCIATION, DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS 483 (5th ed. 2013).

to clinically significant impairment or distress."[26] Diagnosis of OUD and its severity depends upon the presence of certain criteria, for example "[r]ecurrent opioid use in situations in which it is physically hazardous" or "[c]ontinued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by substance."[27]

Notwithstanding the discrete diagnosis of OUD, government agencies such as the Substance Abuse and Mental Health Services Administration ("SAMHSA") or the Centers for Medicare & Medicaid Services ("CMS") tend not to break out OUD from SUD, tending to refer more to the latter, although clearly accepting there *is* an opioid epidemic.[28] When it comes to treatment, the broader phrase "behavioral health services" often is employed referring to both mental health and substance use disorder services.[29] The Affordable Care Act ("ACA") uses the phrase "[m]ental health and substance use disorder services, including behavioral health treatment" to define one of its "essential health benefits."[30] The linkage to mental health is not accidental. As noted in DSM-5, "[a]n important characteristic of substance use disorders is an underlying change in brain circuits that may persist beyond detoxification, particularly in individuals with severe disorders."[31] Finally, some refer to the current epidemic as an opioid overdose crisis,[32] a term that is both accurate and perhaps telling in that overdoses, particularly overdose deaths, have elevated this crisis in both public and political consciousnesses.[33]

In this article SUD will be used when describing a broader addiction epidemic or when that language is used by agencies.

26 *Id.* at 541.

27 *Id.* In total DSM lists 11 such diagnostic/severity criteria.

28 *See* MEDICAID INNOVATION ACCELERATOR PROGRAM, *infra* note 211.

29 *See, e.g., Behavioral Health Services,* MEDICAID.GOV, https://www.medicaid.gov/medicaid/benefits/bhs/index.html (last visited Dec. 9, 2018); *see also Behavioral Health Treatments and Services,* SUBSTANCE ABUSE & MENTAL HEALTH SERV. ADMIN. (Sept. 20, 2017), https://www.samhsa.gov/treatment.

30 Patient Protection and Affordable Care Act, 42 U.S.C. § 18022(b)(1)(E) (2018).

31 AM. PSYCHIATRIC ASS'N, *supra* note 25, at 483.

32 *See, e.g., Opioid Overdose Crisis,* NAT'L INST. ON DRUG ABUSE, https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis (last updated Mar. 2018).

33 *See* German Lopez, *The Opioid Epidemic: Explained,* VOX (Dec. 21, 2017), https://www.vox.com/science-and-health/2017/8/3/16079772/opioid-epidemic-drug-overdoses.

However, the article is concerned primarily with OUD, particularly at the severe end of the scale involving opioid intoxication, withdrawal, or overdose.[34]

Those definitional issues lead into another inconvenient truth: that our current opioid epidemic is not unique. It *is* an addiction crisis but is neither the only one we have faced nor likely the last one we will face. Herzberg and colleagues have explained how, at root, the opioid epidemic is part of an addiction problem that stretches back over a century, with each crisis, (methamphetamine in the 1980s, crack cocaine in the early 1990s, and so on) tending to recycle "supply-side and criminal-justice approaches" rather than "an expanded public health response."[35] Until we solve the broader addiction problem, we will be treating somewhat varying symptoms, not root causes.

These root causes *do* require public health responses such as improved education, better surveillance, and tackling social determinants of health. However, many of the adverse *symptoms* of the crisis (its co-morbidities if you like), and barriers to effective solutions, should be laid at the feet of the U.S. healthcare system. The opioid crisis does present as a "wicked problem,"[36] however "[e]very wicked problem can be considered to be a symptom of another problem."[37] On a daily basis, many of our fellow citizens must confront problems with our healthcare system. Those with OUD must deal with an amplified problem: a healthcare system that is particularly poor at providing access to, or delivering appropriate and necessary, healthcare services.

III. Structural Determinants and Overlapping Frames

Multiple frames are used to explain the opioids crisis. For example, the linear (or vector) model begins with prescription opioids and their over-prescription causing the crisis, followed by some of the users transitioning over to illegal drugs as the supply

34 *See* AM. PSYCHIATRIC ASS'N, *supra* note 25, at 546–47; Ayman Fareed et al., *Illicit Opioid Intoxication: Diagnosis and Treatment*, SUBSTANCE ABUSE: RES. & TREATMENT, 2011, at 17.

35 David Herzberg et al., *Recurring Epidemics of Pharmaceutical Drug Abuse in America: Time for an All–Drug Strategy*, 106 AM. J. PUB. HEALTH 408, 409 (2016).

36 Jonathan C. Lee, *The Opioid Crisis is A Wicked Problem*, 27 AM. J. ON ADDICTIONS 51, 51 (2017).

37 Horst W.J. Rittel & Melvin M. Webber, *Dilemmas in a General Theory of Planning*, 4 POL'Y SCI. 155, 165 (1973).

of prescription drugs is slowed.[38] In fact, only 3.6% of prescription opioid users transition to heroin, but 79.5% of heroin users previously had used prescription opioids.[39] As already noted, concentrating on supply fails to factor in the reasons for demand and tends to over-focus interventions on the supply side.[40]

Increasingly, the opioids crisis has been identified as a "disease of despair,"[41] akin to the "deaths of despair" detailed by Anne Case and Angus Deaton: an increase in mortality and morbidity among non-Hispanic white Americans without college degrees caused in part by "an increasingly difficult labor market."[42] Case and Deaton themselves posit the view that "the prescription of opioids for chronic pain added fuel to the flames, making the epidemic much worse than it otherwise would have been."[43] Dayna Matthew takes a similar approach arguing, "social determinants contribute to hopelessness and social trauma that 'set the stage' for opioid abuse and dependency."[44]

Social determinants of health, the "complex, integrated, and overlapping social structures and economic systems that are responsible for most health inequities," are broadly and correctly identified as causative with regard to diseases of despair including the opioid crisis.[45] Paula Braveman and colleagues define "health

38 *See generally* Dasgupta et al., *supra* note 10.

39 Pradip K. Muhuri et al., *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, CBHSQ Data Rev., Aug. 2013, at 2–3.

40 Dasgupta et al., *supra* note 10, at 182–83.

41 Jeff Guo, *The Disease Killing White Americans Goes Way Deeper than Opioids*, Wash. Post (Mar. 24, 2017), https://www.washingtonpost.com/news/wonk/wp/2017/03/24/the-disease-killing-white-americans-goes-way-deeper-than-opioids/?noredirect=on&utm_term=.734ce9f859c2; Michael Meit et al., *Appalachian Diseases of Despair*, Appalachian Regional Commission (Aug. 2017), https://www.arc.gov/research/researchreportdetails.asp?REPORT_ID=139.

42 Anne Case & Angus Deaton, *Mortality and Morbidity in the 21st Century*, 2017 Brookings Papers on Econ. Activity 397, 399 [hereinafter Case & Deaton, *Mortality and Morbidity*]; *see also* Anne Case & Angus Deaton, *Rising Morbidity and Mortality in Midlife Among White Non–Hispanic Americans in the 21st Century*, 112 Proc. Nat'l Acad. Sci., Dec. 2015, at 15078 [hereinafter Case & Deaton, *Rising Morbidity*].

43 Case & Deaton, *Rising Morbidity*, at 15078.

44 Dayna Bowen Matthew, Un-Burying the Lead: Public Health Tools Are the Key to Beating the Opioid Epidemic 4 (2018), https://www.brookings.edu/wp-content/uploads/2018/01/es_20180123_un-burying-the-lead-final.pdf.

45 *NCHHSTP Social Determinants of Health*, Ctrs. for Disease Control

equity" as "the ethical and human rights principle that motivates us to eliminate health disparities, which are differences in health or its key determinants (such as education, safe housing, and freedom from discrimination) that adversely affect marginalized or excluded groups."[46]

Structural determinants include architectural, economic, or political frameworks that create barriers to remediating social determinants or perpetuate social determinants such as health inequities. This paper argues that the healthcare system has failed those struggling with OUD and co-morbidities and is itself a structural determinant that creates barriers to effective behavioral health services.

Flaws in the U.S. healthcare system are clearly not the only structural determinants at play in the opioid crisis. As Dayna Matthew notes, "[s]ocial determinants such as poor housing conditions are often accompanied by neighborhood-level conditions that limit access to health care, risk-reduction information, and treatment alternatives, which are protective resources and can disrupt behaviors that ultimately lead to opioid addiction."[47] A far more specific example would be adverse policing practices in the vicinity of syringe exchanges.[48]

Two well-known frameworks may help to pinpoint the areas where the healthcare system has failed the opioid epidemic. First, and at a macro level, the Institute for Healthcare Improvement's *Triple Aim* identifies the key goals of our healthcare system: "Improving the patient experience of care (including quality and satisfaction); Improving the health of populations; and Reducing the per capita cost of health care."[49]

& PREVENTION, https://www.cdc.gov/nchhstp/socialdeterminants/definitions.html (last updated Mar. 21, 2014); *see e.g.*, Dasgupta et al., *supra* note 10, at 182–86.

46 Paula Braveman et al., *What Is Health Equity? And What Difference Does a Definition Make?*, ROBERT WOOD JOHNSON FOUND. 3 (May 2017), https://www.rwjf.org/content/dam/farm/reports/issue_briefs/2017/rwjf437393 (emphasis omitted).

47 MATTHEW, *supra* note 44.

48 *See generally* Leo Beletsky et al., *Police Encounters Among Needle Exchange Clients in Baltimore: Drug Law Enforcement as a Structural Determinant of Health*, 105 AM. J. PUB. HEALTH 1872 (2015).

49 *The IHI Triple Aim*, INST. FOR HEALTHCARE IMPROVEMENT, http://www.ihi.org/Engage/Initiatives/TripleAim/Pages/default.aspx (last visited Dec. 8, 2018). *See generally* Donald M. Berwick et al., *The Triple Aim: Care, Health, and Cost*, 27 HEALTH AFF. 759 (2008).

Second, and at the micro opioid treatment level, SAMHSA[50] and the American Society of Addiction Medicine ("ASAM") are clear that the standard of care is comprised of the three Food and Drug Administration-approved medication-assisted treatments ("MAT").[51] Additionally, ASAM recommends certain levels of treatment services for those suffering from OUD: level 1 (outpatient services), level 2 (intensive/partial hospitalization services), level 3 (residential/inpatient services), and level 4 (medically managed intensive inpatient services).[52]

Failures and frequent barriers to effective interventions are as rampant as they are obvious. At the macro level, they involve familiar health policy tropes: limited access to care, high costs, and failures in healthcare delivery. More specifically, our healthcare system is not providing quality care to those with OUD, failing at the levels of access and the standard of care. Population health (preventative care and public health) continues to be put on a back burner compared to expensive clinical interventions, such as surgery, and our policymakers have completely missed the overwhelming cost-benefit argument for preventative care and wraparound services for those at OUD risk. At the micro level, MAT and appropriate levels of treatment are still unavailable for vast swaths of the population. Moreover, for some cohorts, such as rural populations and those in jails and prisons, the level of neglect is extraordinary.

The healthcare system deserves to be called out as a problem: primarily because of its role in causing the crisis and, more importantly, because for so many affected by opioids the healthcare system should have been a solution while in practice it has failed them and frequently amplified their problems.

Foremost, the healthcare system must take some responsibility for the opioids crisis. There is nothing new about opiate-based treatment for pain; it dates back to the 19th century.[53] However, in the

50 *Medication Assisted Treatment (MAT)*, SAMHSA, https://www.samhsa.gov/medication-assisted-treatment (last updated Feb. 7, 2018).

51 *Information About Medication–Assisted Treatment (MAT)*, U.S. Food & Drug Admin., https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm600092.htm (last updated Oct. 3, 2018).

52 *What are the ASAM Levels of Care?*, ASAM Continuum (May 13, 2015), https://www.asamcontinuum.org/knowledgebase/what-are-the-asam-levels-of-care. These levels of care are expanded upon at *infra* text accompanying note 92.

53 *See generally* Marcia L. Meldrum, *A Capsule History of Pain Management*, 290 JAMA 2470 (2003).

1990s clinicians were persuaded by the "non-addictive" marketing of Oxycontin.[54] Meanwhile, the greater expenses associated with multidisciplinary approaches likely led to their disfavor among providers and insurers, even though such methods can be highly useful.[55] Simultaneously, healthcare organizations were responsible for designating pain as the "fifth vital sign"[56] and introducing pain management into reimbursement-impacting patient satisfaction scores.[57]

Whatever the specific cause, there was a more liberal outlook with regards to opioid prescribing, particularly for nonmalignant pain.[58] That prescribing trajectory continued almost as though the 2007 guilty pleas of Purdue Pharma, and three senior executives, to accusations of misleading doctors never happened.[59] As already noted, the prescribing vector model for explaining the opioid crisis is both flawed as to causation and tends to lead to over-reliance on supply-side interventions.[60] Notwithstanding this flawed hypothesis, the healthcare system, together with those in the opioid prescription drug supply chain, continues to deserve our disapprobation for doing more to cause a problem than solve it.[61]

More fundamentally, the healthcare system has simply failed those who need it most. Persons with SUD face acute problems in accessing healthcare services. In 2016, 19.9 million adults needed substance use treatment but only 10.8% received specialty treatment; 26.9% of those who did not receive specialty treatment,

54 *See* QUINONES, *supra* note 19, at 124–27.

55 *Id.* at 86–87, 97–98; *see also* Marcia L. Meldrum, *The Ongoing Opioid Prescription Epidemic: Historical Context*, 106 AM. J. PUB. HEALTH 1365 (2016) [hereinafter Meldrum, *Historical Context*].

56 David W. Baker, *History of The Joint Commission's Pain Standards: Lessons for Today's Prescription Opioid Epidemic*, 317 JAMA 1117 (2017); *see also* Natalia E. Morone & Debra K. Weiner, *Pain as the 5th Vital Sign: Exposing the Vital Need for Pain Education*, 35 CLINICAL THERAPEUTICS 1728 (2013).

57 *See generally* Jay. S. Lee et al., *Postoperative Opioid Prescribing and the Pain Scores on Hospital Consumer Assessment of Healthcare Providers and Systems Survey*, 317 JAMA 2013 (2017).

58 *See id.*; *see also* Meldrum, *Historical Context*, *supra* note 55, at 1365–66.

59 Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, N.Y. TIMES (May 10, 2007), https://www.nytimes.com/2007/05/10/business/11drug-web.html.

60 *See* Rittel, *supra* note 37.

61 *See, e.g.*, Michael E. Schatman & Lynn R. Webster, *The Health Insurance Industry: Perpetuating the Opioid Crisis Through Policies of Cost-Containment and Profitability*, 8 J. PAIN RES. 153, 155–56 (2015).

but perceived that they did need it, cited no healthcare coverage and not being able to afford the cost of treatment as reasons for non-treatment.[62] The history is plain to see, with the healthcare system (from policymakers, to insurers, to healthcare institutions and clinicians) failing those requiring behavioral healthcare services. It was not until the 2008 passage of The Mental Health Parity and Addiction Equity Act ("MHPAEA")[63] that health insurers had to treat behavioral health benefits on a par with medical or surgical benefits. The ACA[64] continued its work by, for example, including behavioral health as one of the statute's essential health benefits ("EHBs").[65] However, while there have been modest increases in behavioral health spending,[66] there have been numerous complaints about its impact and, in particular, its enforcement.[67]

Some of healthcare's failings are better understood as fundamental systems problems. Nabarun Dasgupta and colleagues catalog some of healthcare's failures: a system ill-equipped to coordinate a combination of social and clinical ills, fragmentation (and sometimes cessation) of care, limited access to MAT, and an inability to provide wraparound services.[68] Other issues that may create barriers to treatment range from a lack of culturally competent

62 Eunice Park-Lee et al., Substance Abuse & Mental Health Serv. Admin., Receipt of Services for Substance Use and Mental Health Issues Among Adults: Results from the 2016 National Survey on Drug Use and Health (2017).

63 Emergency Economic Stabilization Act of 2008, Pub. L. 110-343, § 511, 122 Stat. 3765 (2008). *See generally Implementation of the Mental Health Parity and Addiction Equity Act (MHPAEA)*, Substance Abuse & Mental Health Serv. Admin., https://www.samhsa.gov/health-financing/implementation-mental-health-parity-addiction-equity-act (last updated Jan. 24, 2017).

64 Patient Protection and Affordable Care Act, 42 U.S.C. § 180001 (2018).

65 *Id. See generally* Richard G. Frank et al., *Behavioral Health Parity and the Affordable Care Act*, 13 J. Soc. Work Disability & Rehabilitation 31 (2015).

66 Sarah Friedman et al., *The Mental Health Parity and Addiction Equity Act Evaluation Study: Impact on Specialty Behavioral Healthcare Utilization and Spending Among Enrollees with Substance Use Disorders*, 80 J. Substance Abuse Treatment 67 (2017).

67 Jenny Gold, *Advocates Say Mental Health 'Parity' Law is Not Fulfilling its Promise*, Kaiser Health News (Aug. 3, 2015), https://khn.org/news/advocates-say-mental-health-parity-law-is-not-fulfilling-its-promise/.

68 *See* Dasgupta et al., *supra* note 10, at 184. Wraparound services are considered to be "non-clinical services that facilitate patient engagement and retention in treatment as well as their ongoing recovery." U.S. Dep't of Health & Human Servs., Office of the Surgeon Gen., Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health 5–6 (2016).

health services, or professionals, when dealing with the poor, the addicted, or the mentally ill; to concerns about cost; the likelihood of experiencing stigma; or even apprehension about sub-optimal "care" that focuses on detox and potentially painful withdrawal.[69]

IV. Healthcare Structural Determinants Versus Opioid Responses

Most systems, be they industrial, technological, or social services, are designed primarily to function for average use; to respond to the mean. As a result, systems will experience outlying events as stressors. Most will survive such an event, and some are even capable of temporary ramp-ups to handle the outliers. However, the U.S. healthcare ecosystem is uniquely fragile. In large part, because it is not a single "system," it seems to have particular difficulties responding to stressors whether they be pandemics, syndemics, or natural disasters. For example, problems with healthcare delivery were quite apparent in the aftermath of Hurricane Katrina and during the Ebola outbreak.[70]

Structural barriers to healthcare access and delivery are deeply seated and path dependent—even once-in-a-generation major legislative and funding efforts, such as the ACA,[71] only make incremental changes to a system populated by persons and institutions who lack incentives to change. The U.S. healthcare system is not a particularly good one when measured against metrics such as access, cost, or outcomes.[72] While it can excel at some tasks

69 Of course, this is something of an oversimplification. Barriers to treatment are multiple, quite complicated, and include a lack of help-seeking behavior. *See, e.g.*, Philip W. Appel et al., *Barriers to Enrollment in Drug Abuse Treatment and Suggestions for Reducing Them: Opinions of Drug Injecting Street Outreach Clients and Other System Stakeholders*, 30 AM. J. DRUG & ALCOHOL ABUSE 129 (2004).

70 *See, e.g.*, Josh Voorhees, *Everything That Went Wrong in Dallas: A Timeline of the Many Missteps Surrounding the First Cases of Ebola Diagnosed in the United States*, SLATE (Oct. 16 2014), http://www.slate.com/articles/health_and_science/medical_examiner/2014/10/dallas_ebola_timeline_the_many_medical_missteps_at_texas_health_presbyterian.html; Alyssa Rege, *How Hurricane Katrina Impacted Healthcare in New Orleans and What That May Mean for Houston*, BECKER'S HOSP. R. (Aug. 29, 2017), https://www.beckershospitalreview.com/patient-flow/how-hurricane-katrina-impacted-healthcare-in-new-orleans-and-what-that-may-mean-for-houston-5-takeaways.html.

71 Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 (2018).

72 *See, e.g.*, Leah A. Burke & Andrew M. Ryan, *The Complex Relationship Between Cost and Quality in US Health Care*, 16 AM. MED. ASS'N J. ETHICS 124, 127 (2014); Cynthia Cox & Bradley Sawyer, *How Does Cost Affect Access to Care?*, KAISER FAMILY FOUND.: PETERSON-KAISER HEALTH SYSTEM TRACKER (Jan. 17, 2018), https://www.healthsystemtracker.org/chart-collection/cost-

such as complex surgeries, its strength does not lie in diagnostics or treating chronic illnesses[73]—areas of great need for those with OUD. The U.S. healthcare system's major operational deficiencies are well known. For example, the U.S. spends more on its healthcare than any other economically advanced country yet receives less both in terms of the percentage of the population receiving care and the quality of the care provided.[74] The list of symptoms and causative factors is long and includes: access problems (particularly for the poor and the near poor), high and increasing costs (including insurance costs, prescription drug costs, and cost-shifting), substandard care coordination, a frequently incoherent healthcare delivery model involving multiple types of entities and or reimbursement models, and severe deficiencies in data management and sharing.[75] These, among many others, are architectural, financing, or implementation flaws that have presented as barriers to effective responses to the opioid crisis.

This article concentrates on only a few of the myriad defects in our healthcare system; those that play out with particular force in the context of the opioid crisis. First, the difficulty of access to healthcare services is illustrated by examining the stratified manner in which persons are provided access to healthcare insurance: the gateway to healthcare in the U.S. Second, and closely related to the first, is the recent whiplash phenomenon associated with Medicaid, the insurance system arguably best positioned to provide preventative care and treatment for those susceptible to diseases of despair but which increasingly is beginning to act more like a problem than a solution. Third, behavioral and non-behavioral health disciplines have developed with differential architectures, both as to treatment models, locations, and data sharing—defects that highlight the healthcare system's fundamental inability to provide care coordination and wraparound services.

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affect-access-care/.

73 *See, e.g., U.S. Spends More on Health Care Than Other High-Income Nations but has Lower Life Expectancy, Worse Health*, COMMONWEALTH FUND (Oct. 8, 2015), http://www.commonwealthfund.org/publications/press-releases/2015/oct/us-spends-more-on-health-care-than-other-nations.

74 *See id.*; Melissa Etehad & Kyle Kim, *The U.S. Spends More on Healthcare Than Any Other Country—But Not with Better Health Outcomes*, L.A. TIMES (July 28, 2017), https://www.latimes.com/nation/la-na-healthcare-comparison-20170715-htmlstory.html.

75 *See* Nicolas P. Terry, *Pit Crews with Computers: Can Health Information Technology Fix Fragmented Care?*, 14 HOUSTON J. HEALTH L. & POL'Y 132 (2014).

A. The Standard of Care

The ideal treatment of addiction is to "address the needs of the whole person," selecting from a menu of services.[76] Although detoxification and recovery models, such as 12-step programs, are used in the OUD space, the standard of care for severe OUD is MAT,[77] the use of FDA-approved medications in combination with counseling, and behavioral therapies.[78] Although more treatment modes are promised,[79] currently there are three: those using methadone, buprenorphine, or naltrexone.

While all three modes are generally safe, and reduce the risk of overdose, they differ in their chemical effects and, as a result, the conditions imposed on their delivery.[80] As to the former, methadone is an agonist, buprenorphine a partial agonist, and naltrexone is an antagonist.[81] These labels describe how closely their chemical effects resemble or mimic opioids; an agonist essentially tricks the brain into thinking there is an opioid present (by reducing cravings and delaying withdrawal), while an antagonist blocks an opioid from

76 *Drugs, Brains, and Behavior: The Science of Addiction*, NAT'L INST. ON DRUG ABUSE, https://www.drugabuse.gov/publications/drugs-brains-behavior-science-addiction/treatment-recovery (last updated July 2018).

77 Nora D. Volkow et al., *Medication-Assisted Therapies — Tackling the Opioid-Overdose Epidemic*, 370 NEW ENG. J. MED. 2063 (2014); *see also Drugs, Brains, and Behavior: The Science of Addiction*, *supra* note 76 ("Research shows that when treating addictions to opioids (prescription pain relievers or drugs like heroin or fentanyl), medication should be the first line of treatment, usually combined with some form of behavioral therapy or counseling.").

78 *Medication-Assisted Treatment (MAT)*, SUBSTANCE ABUSE AND MENTAL HEALTH SERV. ADMIN., https://www.samhsa.gov/medication-assisted-treatment (last updated Feb. 7, 2018); *see also CDER Conversation: Treatment for Opioid Use Disorder*, U.S. FOOD & DRUG ADMIN. (July 28, 2018), https://www.fda.gov/Drugs/NewsEvents/ucm611659.htm. *See generally* Kate Sheridan, *How Effective is Medication-Assisted Treatment for Addiction? Here's the Science*, STATNEWS (May 15, 2017), https://www.statnews.com/2017/05/15/medication-assisted-treatment-what-we-know/.

79 Press release, U.S. FDA, FDA Takes New Steps to Encourage the Development of Novel Medicines for the Treatment of Opioid Use Disorder (Aug. 6, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm615892.htm.

80 Sheridan, *supra* note 78.

81 CATHIE E. ALDERKS, SUBSTANCE ABUSE AND MENTAL HEALTH SERV. ADMIN., TRENDS IN THE USE OF METHADONE, BUPRENORPHONE, AND EXTENDED-RELEASE NALTREXONE AT SUBSTANCE ABUSE TREATMENT FACILITIES: 2003–2015 1 (Aug. 22, 2017), https://www.samhsa.gov/data/sites/default/files/report_3192/ShortReport-3192.pdf.

having any effect on the brain.[82] While the agonists, methadone and buprenorphine, are chemically related to opioids, the antagonist naltrexone is not opioid-based[83] (and so unlikely to be the subject of diversion).

SAMHSA requires that methadone only be dispensed through an opioid treatment program ("OTP") accredited by a "federally deemed accrediting body,"[84] while physicians who have obtained a Drug Enforcement Administration waiver, which requires buprenorphine-specific training, may prescribe buprenorphine,[85] and any licensed provider can prescribe naltrexone.[86] Patients should be evaluated to determine the most appropriate individual treatment, typically using the ASAM clinical guidelines.[87] Methadone is associated with robust long-term recovery but must be carefully calibrated and is prone to abuse or diversion,[88] while naltrexone should not be administered before full opioid withdrawal.[89] There is also some evidence that buprenorphine is superior to methadone for use by pregnant women, as fetal outcomes are slightly better.[90] Different clinical states of patients and their different contexts influence the choice of drug and emphasizes that the standard of

82 Sheridan, *supra* note 78; *see also Medication-Assisted Treatment: Naltrexone*, Substance Abuse and Mental Health Serv. Admin., https://www.samhsa.gov/medication-assisted-treatment/treatment/naltrexone (last visited Dec. 18, 2018).

83 *Medication-Assisted Treatment (MAT)*, *supra* note 78.

84 For background on the accreditation process see *Opioid Treatment Program (OTP) Accreditation*, Joint Comm'n (Nov. 14, 2018), https://www.jointcommission.org/facts_opioid_treatment_program_otp_accreditation/.

85 *See generally Medication-Assisted Treatment: Buprenorphine Waiver Management*, Substance Abuse and Mental Health Serv. Admin., https://www.samhsa.gov/programs-campaigns/medication-assisted-treatment/training-materials-resources/buprenorphine-waiver (last updated Jan. 18, 2018).

86 *Medication-Assisted Treatment: Naltrexone*, *supra* note 82.

87 Kyle Kampman & Margaret Jarvis, *American Society of Addiction Medicine National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use*, 9(5) J. of Addiction Med. 358 (2015).

88 *How effective are medications to treat opioid use disorder?*, Nat'l Inst. Drug Abuse (June 2018), https://www.drugabuse.gov/publications/research-reports/medications-to-treat-opioid-addiction/efficacy-medications-opioid-use-disorder. *See generally* Herbert D. Kleber, *Pharmacologic Treatments for Opioid Dependence: Detoxification and Maintenance Options*, 9 Dialogues Clinical Neuroscience 455 (2007).

89 *Medication-Assisted Treatment: Naltrexone*, *supra* note 82.

90 Barbara K. Zedler, et al., *Buprenorphine Compared with Methadone to Treat Pregnant Women with Opioid Use Disorder: A Systematic Review and Meta-Analysis of Safety in the Mother, Fetus and Child*, 111 Addiction 2115 (2016).

care requires the availability of all three forms of MAT.

Assessment of the recommended *levels* of care increasingly also is performed by reference to ASAM guidelines. In general, Level 1 refers to outpatient services; Level 2 intensive outpatient services; Level 3 residential inpatient services; and Level 4 intensive inpatient services.[91] ASAM also recognizes additional point levels. These include Level 0.5 (early intervention), 2.5 (partial hospitalization service), and 3.5 (clinically-managed, high-intensity residential services for adults and medium-intensity for adolescents).[92]

The standard of care notwithstanding, there are some very obvious examples of structural determinants (and not only in jails and prisons where the standard of care seldom is met). Across the nation, there are a limited number of OTPs certified by SAMHSA, with a few states having none,[93] while there are state variations in the number of providers who have applied for the buprenorphine waiver.[94]

B. *Stratification and Benefit Indeterminacy*

If educational, physical, and economic environments are social determinants of health, then limited access, high costs, and insufficient (limited or poor quality) services are structural determinants. Those with OUD are disproportionately represented in the cohorts without access or faced with social, financial, demonstrative, geographical, or other barriers to health.[95] These barriers are caused or exacerbated not only by the barriers intrinsic to each stratum (e.g., eligibility, cost-sharing, etc.) but also by the very fact of stratification. The root causes of this stratification are decisions that were made during the Second World War that linked healthcare

91 E. Chuang et al., *Factors Associated with Use of ASAM Criteria and Service Provision in a National Sample of Outpatient Substance Abuse Treatment Units*, 3 J. ADDICTION MED. 139 (2009).

92 *What are the ASAM Levels of Care?*, CONTINUUM: ASAM CRITERIA DECISION ENGINE (May 13, 2015), https://www.asamcontinuum.org/knowledgebase/what-are-the-asam-levels-of-care/.

93 *Opioid Treatment Program Directory*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVS. ADMIN., https://dpt2.samhsa.gov/treatment/directory.aspx (last visited Jan. 27, 2019).

94 *Number of DATA-Waived Practitioners Newly Certified Per Year*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., https://www.samhsa.gov/medication-assisted-treatment/treatment (last visited Jan. 27, 2019).

95 Kenneth A. Feder et al., *Trends in Insurance Coverage and Treatment Among Persons with Opioid Use Disorders Following the Affordable Care Act*, 179 DRUG & ALCOHOL DEPENDENCE 271 (2017).

to health insurance and health insurance to employment.[96] Writing before the ACA, Atul Gawande noted the path-dependence that has resulted.[97] Today, employer-provided private coverage remains our gold standard, with the constructs, such as managed care, designed to keep it afloat occasionally migrating to public insurance. Worse, health insurance provided outside of that idealized private scenario is viewed as suspect and increasingly as exceptional rather than a foundation on which to embrace and build universality. And, most sadly, the association of health insurance with employment has led to some embracing the perverse mission of curtailing Medicaid for those not working.[98] While many with OUD work, a large minority of them do not have access to the gold standard of employer group coverage,[99] the Medicaid that so many rely on is under political attack,[100] and their very eligibility for public health insurance may be at risk because of emerging administrative and work requirements.[101]

1. Differentially-Treated Cohorts

Stratification tends to be based on income (or the lack thereof) expressed in terms of relative variance from the Federal Poverty Level ("FPL").[102] As these vary, beneficiaries on the edge of the qualification tiers may experience churn between types of insurance, exacerbating indeterminacy of insurance and so healthcare.[103] There may also be a political cost. Persons on the margins of what are, after all, arbitrary eligibility dividing lines between coverages with different benefits

96 *See* Dan Gorenstein, *How Did We End Up with Health Insurance Being Tied to Our Jobs?*, MARKETPLACE (June 28, 2017, 4:00 PM), https://www.marketplace.org/2017/06/28/health-care/how-did-we-end-health-insurance-being-tied-our-jobs.

97 Atul Gawande, *Getting There from Here*, NEW YORKER: ANNALS PUB. POL'Y, (Jan. 26, 2009), https://www.newyorker.com/magazine/2009/01/26/getting-there-from-here.

98 *See infra* text accompanying note 172.

99 *The NSDUH Report*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVS. ADMIN. (Aug. 7. 2014), https://www.samhsa.gov/data/sites/default/files/NSDUH-SP132-FullTime-2014/NSDUH-SP132-FullTime-2014.pdf.

100 *See* discussion *infra* Section C.

101 Sara Rosenbaum, *Stewart v. Azar and the Future of Medicaid Work Requirements*, COMMONWEALTH FUND (July 3, 2018), https://www.commonwealthfund.org/future-of-Medicaid-work-requirements.

102 *See generally Federal Poverty Level*, HEALTHCARE.GOV, https://www.healthcare.gov/glossary/federal-poverty-level-fpl/ (last visited Dec. 16, 2018).

103 *See generally Health Insurance Churn: The Basics*, COMMUNITY CATALYST (Nov. 2016), https://www.communitycatalyst.org/resources/publications/document/Health-Insurance-Churn-November-2016_FINAL.pdf.

or premiums, may feel animosity to cohorts "treated better" on the other side of a cut-off (e.g., someone at 200 FPL comparing their premiums with those in the Medicaid expansion cohort).[104]

For decades, access to health insurance has been the key to access to healthcare in the U.S.[105] Those who cannot afford insurance are often denied access to healthcare.[106] Notwithstanding the reforms introduced by the ACA, 15.5% of those of working-age remain uninsured.[107] Those most at risk of being uninsured are those with low-income and people of color.[108] Although the majority of nonelderly adults with opioid addiction are employed, [109] they likely have low incomes and are therefore less likely than adults with higher incomes to have employer-provided health insurance. Approximately 10% are unemployed and 13% are disabled, and as a group they tend to suffer from comorbidities.[110]

When the Supreme Court in *NFIB v. Sebelius*[111] rendered Medicaid expansion voluntary for the states, it opened up another cleavage in access to healthcare, one based on the accident of state of residence. Over two million of the uninsured cohort lack health insurance because their states of residence (primarily in the south and, typically, correlating with poor social determinants) have decided to forego Medicaid expansion.[112]

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104 *See* Louise Norris, *The ACA's Cost-Sharing Subsidies*, HEALTHINSURANCE.ORG (Dec. 11, 2018), https://www.healthinsurance.org/obamacare/the-acas-cost-sharing-subsidies/.

105 *See generally* CHRISTY FORD CHAPIN, ENSURING AMERICA'S HEALTH: THE PUBLIC CREATION OF THE CORPORATE HEALTH CARE SYSTEM (2017).

106 *See generally* BEATRIX HOFFMAN, HEALTH CARE FOR SOME: RIGHTS AND RATIONING IN THE UNITED STATES SINCE 1930 (2012).

107 Sara R. Collins et al., *First Look at Health Insurance Coverage in 2018 Finds ACA Gains Beginning to Reverse*, COMMONWEALTH FUND: TO THE POINT (May 1, 2018), https://www.commonwealthfund.org/blog/2018/first-look-health-insurance-coverage-2018-finds-aca-gains-beginning-reverse.

108 JULIA FOUTZ ET AL., The Uninsured: A Primer 1 (2017), http://files.kff.org/attachment/Report-The-Uninsured-A-Primer-Key-Facts-about-Health-Insurance-and-the-Uninsured-Under-the-Affordable-Care-Act.

109 *NSDUH Report*, *supra* note 99.

110 Julia Zur & Jennifer Tolbert, *The Opioid Epidemic and Medicaid's Role in Facilitating Access to Treatment*, KFF (Apr. 11, 2018), https://www.kff.org/medicaid/issue-brief/the-opioid-epidemic-and-medicaids-role-in-facilitating-access-to-treatment/.

111 NFIB v. Sebelius, 567 U.S. 519, 585 (2012).

112 Rachel Garfield et al., *The Coverage Gap: Uninsured Poor Adults in States that Do Not Expand Medicaid*, KFF (June 12, 2018), https://www.kff.org/medicaid/issue-brief/the-coverage-gap-uninsured-poor-adults-in-states-that-do-not-

In the stratified world of health insurance (and so of access to healthcare), the first stratum to recognize is the uninsured. Being uninsured does not preclude *all* access to healthcare. However, safety-net care such as emergency department access courtesy of Emergency Medical Treatment & Labor Act ("EMTALA")[113] only provides emergency care, not the preventative or chronic care necessary to identify or treat addictions.[114] As Julia Foutz and colleagues express the issue: "[h]ealth insurance makes a difference in whether and when people get necessary medical care, where they get their care, and ultimately, how healthy they are. Uninsured people are far more likely than those with insurance to postpone health care or forgo it altogether."[115]

Insured versus uninsured status is not a simple binary. The uninsured cohort *is* relatively cohesive; there may be some wealthy persons who forego insurance, but the overwhelming majority of the uninsured cohort are poor, likely suffering from one or more diseases of despair, and highly unlikely to have access to OUD treatment within the standard of care.[116]

In contrast, the insured are highly stratified. The largest stratum (approximately 50% of those with health insurance)[117] consists of those whose insurance is provided by their employer. In most cases their insurance will provide behavioral health coverage and therefore likely paths to treatment and recovery.[118] However, as the President's Commission recognized, "[t]here are commercial

expand-medicaid/; *see also* Fredric Blavin et al., *Medicaid Versus Marketplace Coverage For Near-Poor Adults: Effects On Out-Of-Pocket Spending And Coverage*, 37 HEALTH AFF. 299 (2018).

113 Social Security Act of 1935 § 1867, 42 U.S.C. § 1395 (2018).

114 *See* Sawyer, N. T., *Why the EMTALA Mandate for Emergency Care Does not Equal Healthcare "Coverage"*, 18 WESTERN J. EMERGENCY MED. 551, 551–52 (2017).

115 FOUTZ, *supra* note 108.

116 Feder, *supra* note 95. *See also* Li-Tzy Wu et al., *Treatment Utilization Among Persons with Opioid Use Disorder in the United States*, 169 DRUG & ALCOHOL DEPENDENCE 117 (2016); Praise O. Iyiewuare et al., *Demographic and Mental Health Characteristics of Individuals Who Present to Community Health Clinics with Substance Misuse*, 4 HEALTH SERV. RES. & MANAGERIAL EPIDEMIOLOGY 1 (2017).

117 HENRY J. KAISER FAMILY FOUNDATION, HEALTH INSURANCE COVERAGE OF THE TOTAL POPULATION (2017), https://www.kff.org/other/state-indicator/total-population/?.

118 Jessica M. Harwood et al., *The Mental Health Parity and Addiction Equity Act Evaluation Study*, 55 MED. CARE 164 (2017).

insurance barriers to MAT, such as dangerous fail-first protocols and onerous and frequent prior authorization requirements."[119] Additionally, this predominantly white, middle class group will find their treatment restricted in similar ways to the rest of their healthcare, with limits on types and days of care and massive cost shifting when using out-of-network care[120] (a real likelihood given the dearth of opioid treatment providers). Looking forward, the actuarial value of employer-provided coverage is in steep decline, creating a new stratum—the underinsured—who increasingly cannot afford to undertake their insured treatment or care because of high deductibles or other cost-shifting.[121]

Outside of employer-provided group coverage the insured generally fall into one of four health insurance cohorts: Medicare, Medicaid, Expanded Medicaid, or the Exchange Marketplaces.[122] Of these, Medicare has the greatest access to OUD care with the fewest barriers. Medicare enrollees, the elderly and near-elderly, do not immediately seem to fit the OUD demographic. However, they make up about 25% of long-term opioid users[123] and are among the fastest growing population with diagnosed OUD.[124]

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119 GOVERNOR CHRIS CHRISTIE ET AL., THE PRESIDENT'S COMMISSION ON COMBATING DRUG ADDICTION AND THE OPIOID CRISIS 70 (2017).

120 INST. OF MED. COMM. ON OPPORTUNITIES IN DRUG ABUSE RESEARCH, PATHWAYS OF ADDICTION: OPPORTUNITIES IN DRUG ABUSE RESEARCH (2018); *see also A Consumer's Guide to the Mental Health Parity and Addiction Equity Act*, NAT'L DISABILITY NAVIGATOR, http://www.nationaldisabilitynavigator.org/wp-content/uploads/resources-links/SAMHSA-Parity-guide.pdf.

121 *See* Thomas Beaton, *Health Plan Cost Sharing, Deductibles Outpace Members' Wage Growth*, HEALTHPAYERINTELLIGENCE (July 12, 2018), https://healthpayerintelligence.com/news/health-plan-cost-sharing-deductibles-outpace-members-wage-growth. *See generally* David Blumenthal, *The Decline of Employer-Sponsored Health Insurance*, THE COMMONWEALTH FUND: TO THE POINT (Dec. 5, 2017), https://www.commonwealthfund.org/blog/2017/decline-employer-sponsored-health-insurance.

122 This is an oversimplification because some persons will be insured by small group insurance, Short-Term, Limited-Duration Insurance, Association Health Plans, grandfathered Basic Health Plans in New York and Minnesota, and so on. However, for the purposes of this article these plans are statistically irrelevant.

123 *See* Ramin Mojtabai, *National Trends in Long-Term Use of Prescription Opioids*, 27 PHARMACOEPIDEMIOLOGY & DRUG SAFETY 526 (2017). *See also* Audrey J. Weiss et al., *Opioid-Related Inpatient Stays and Emergency Department Visits Among Patients Aged 65 Years and Older, 2010 and 2015*, HEALTHCARE COST AND UTILIZATION PROJECT (Sept. 2018), https://www.ahrq.gov/news/newsroom/press-releases/seniors-struggles-with-opioids.html.

124 CTRS. FOR MEDICARE & MEDICAID SERVS., OPIOID MISUSE STRATEGY

Medicare provides broad access to MAT, though there are some quirky omissions. In the words of one MAT provider, "[w]hile Medicare pays for the pain medications that are contributing to the OUD epidemic, it does not pay for the full range of treatment options necessary to treat beneficiaries' addiction."[125] Indeed, one of the greatest ironies is that Medicare covers methadone for the treatment of pain but not for the treatment of OUD. This is because Medicare Part D (covering prescription drugs) does not include methadone or buprenorphine when used for treatment of opioid dependence in an opioid treatment program (in large part this is because Part D only applies to retail pharmacy distribution).[126] MAT is less likely to be covered by traditional Medicare Part C but could be covered by Part C Medicare Advantage if they are part of a "bundled" service.[127]

2. *Acute Stratification on the Exchanges*

After Employer-Group and Medicare insurance, stratification increases apace. Health Insurance Marketplace plans, those established by the ACA,[128] are sold from online marketplaces or exchanges. The exchanges may be established and managed either by states or, if they are unwilling, by the federal government.[129] The policies offered on the exchanges are standardized; that is, they all offer the same benefits. However, their premium costs differ.[130] The plans often are referred to collectively as the "metallics" because

2016, 1 (2017), https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/ Downloads/CMS-Opioid-Misuse- Strategy-2016.pdf.

125 *The Opioid Crisis: Removing Barriers to Prevent and Treat Opioid Abuse and Dependence in Medicare, Hearing Before the H. Comm. on Ways & Means*, 115th Cong. 6 (2018) (statement of Jason Kletter, President, BayMark Health Services), https://waysandmeans.house.gov/wp-content/uploads/2018/02/20180206-HL-Testimony-Kletter.pdf [hereinafter Kletter, *Opioid Crisis*].

126 *See generally* CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 124, at 17.

127 Kletter, *Opioid Crisis*, *supra* note 125. *See generally* CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE COVERAGE OF SUBSTANCE ABUSE SERVICES (2016), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1604.pdf.

128 Patient Protection and Affordable Care Act § 1311(b), 42 U.S.C. § 18001 (2018).

129 *See generally* Patient Protection and Affordable Care Act, 42 U.S.C. §§ 18031–41 (2018).

130 *The 'Metal' Categories: Bronze, Silver, Gold & Platinum*, HEALTHCARE.GOV, https://www.healthcare.gov/choose-a-plan/plans-categories/ (last visited Dec. 23, 2018) [hereinafter *Metal Categories*].

of their gold, silver, bronze, etc., nomenclature.[131] The plans (and so their premiums) differ according to their actuarial value: that "percentage of total average costs for covered benefits that a plan will cover."[132]

At first sight, the choice between the metallics would be based on the level of out-of-pocket risk a person wishes to assume and, assuming a somewhat competitive state marketplace,[133] the plan cost. However, that "simple" model becomes more complicated and stratified because of how the ACA made premiums affordable (via tax credits)[134] and reduced the impact of cost-sharing (via insurance-company provided, but (originally) federal government financed, subsidies) for lower income persons.[135] In general terms, persons are eligible for financial assistance if their income is between 100% and 400% of the FPL.[136] In Medicaid expansion states, such assistance would apply to those between <138% and 400% FPL with expanded Medicaid picking up the cohort between 100% and 138% FPL. The premium tax credits are calculated on the basis of a family's modified adjusted gross income and size and apply to all of the metallics. Cost-sharing subsidies apply only to those enrolled in their state's

131 *Metal Levels for Health Insurance Plans*, eHEALTH (Oct. 9, 2014), https://www.ehealthinsurance.com/resources/affordable-care-act/metallic-health-plan-levels; *Understanding the Healthcare Exchange Plan Offering*, FORBES (Sept. 24, 2013 8:37AM), https://www.forbes.com/sites/thesba/2013/09/24/understanding-the-exchange-plan-offering/#7942c75f72bc; *see Metal Categories*, *supra* note 130.

132 *Glossary Definition of Actuarial Value*, HEALTHCARE.GOV, https://www.healthcare.gov/glossary/actuarial-value/ (last visited Dec 23, 2018); *see, e.g.*, *What's the Difference Between Bronze, Silver and Gold Plans?*, BLUE CROSS BLUE SHIELD BLUE CARE NETWORK OF MICH., https://www.bcbsm.com/index/health-insurance-help/faqs/topics/buying-insurance/metal-tiers.html (last visited Dec. 23, 2018).

133 *See generally* Cynthia Cox et al., *Sizing Up Exchange Market Competition*, HENRY J. KAISER FAM. FOUND. (Mar. 17, 2014), https://www.kff.org/health-reform/issue-brief/sizing-up-exchange-market-competition/.

134 *See generally* King v. Burwell, 135 S. Ct. 2480 (2015) (holding that the ACA authorized tax credits for health insurance purchased either from state or federally established exchanges).

135 *See generally* BERNADETTE FERNANDEZ, CONG. RESEARCH SERV., HEALTH INSURANCE PREMIUM TAX CREDITS AND COST-SHARING SUBSIDIES (2018), https://fas.org/sgp/crs/misc/R44425.pdf.

136 "Federal poverty levels are used to determine your eligibility for certain programs and benefits, including savings on Marketplace health insurance, and Medicaid and CHIP coverage." *Glossary Definition of Federal Poverty Level* (FPL), HEALTHCARE.GOV, https://www.healthcare.gov/glossary/federal-poverty-level-fpl/ (last visited Dec. 23, 2018).

"silver" plan and apply only to those between 100% (or <138% in an expansion state) and 250% FPL.[137]

Another wrinkle and potentially destabilizing occurrence was the 2017 decision by the Trump Administration to stop making the payments (known as Cost-Sharing Reduction Payments) to insurance companies that compensated them for providing the cost-sharing subsidies to their very low-income customers.[138] However, under the ACA, insurance companies were still responsible for subsidizing the silver plan cost-sharing by increasing the actuarial value of policies purchased by those eligible for cost-sharing subsidies.[139] Absorbing those costs would cause costs, and hence premiums, to rise. Insurers' rather clever retort was to disproportionally increase the cost of silver plans.[140] This strategy keeps non-sliver plans relatively affordable while essentially passing on to the federal government the increased cost of silvers plans.[141] Notwithstanding, this strategy may increase insurance costs for the cohort that has income <400% FPL and so lacks tax credits to offset the large premium increases.[142]

Moreover, as the cost of exchange-based insurance for the unsubsidized cohort rises, they are going to be far less likely to purchase insurance, thereby reverting to uninsured status. Cost increases and concomitant declines in the number of insured likely will

137 *See Questions and Answers on the Premium Tax Credit*, IRS, https://www.irs.gov/affordable-care-act/individuals-and-families/questions-and-answers-on-the-premium-tax-credit (last updated Mar. 16, 2018); Louise Norris, *The ACA's Cost-Sharing Subsidies*, HEALTHINSURANCE.ORG (Dec. 27, 2018), https://www.healthinsurance.org/obamacare/the-acas-cost-sharing-subsidies/.

138 Much of the (somewhat arcane) history is to be found in the now settled litigation referred to as U.S. House of Representatives v. Price, No. 16 –5202, 2017 WL 3271445 (D.C. Cir. Aug. 1, 2017). *See also* Sarah Lueck, *Trump Move Would Boost Premiums, Raise Federal Costs, Destabilize Insurance Market*, CTR. ON BUDGET & POL'Y PRIORITIES (July 31, 2017, 4:30 PM), https://www.cbpp.org/blog/trump-move-would-boost-premiums-raise-federal-costs-destabilize-insurance-market.

139 Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 (2018).

140 Rabah Kamal et al., *How the Loss of Cost-Sharing Subsidy Payments is Affecting 2018 Premiums*, HENRY J. KAISER FAM. FOUND. (Oct. 27, 2017), https://www.kff.org/health-reform/issue-brief/how-the-loss-of-cost-sharing-subsidy-payments-is-affecting-2018-premiums/.

141 *See* Margot Sanger-Katz, *Trump's Attack on Insurer 'Gravy Train' Could Actually Help a Lot of Consumers*, N.Y. TIMES (Oct. 18, 2017), https://www.nytimes.com/2017/10/18/upshot/trumps-attack-on-insurer-gravy-train-could-actually-help-a-lot-of-consumers.html?.

142 *See id.*

be accelerated in 2019 with the demise of the individual mandate,[143] and the likely further destabilization of the marketplace risk pools as the Trump Administration's favored Short-Term, Limited-Duration Insurance[144] and Association Health Plans ("AHPs") come online.[145]

Stratification and persistent questions about affordability aside, marketplace plans do provide coverage for behavioral healthcare as an EHB.[146] Unfortunately, this is one point at which the conventional wisdom that health insurance equals access to healthcare breaks down. The problem is that insurance provides reimbursement, not care, and so is dependent on the insurer having adequate treatment relationships with behavioral healthcare providers. In 2017, Stephen Melek and colleagues published a major study examining relative access to behavioral healthcare, finding both major disparities in the use of out-of-network providers (and so higher-priced or non-reimbursed services) and in reimbursement rates for behavioral healthcare providers. Specifically, the researchers found that for the period from 2013–2015 "the proportion of inpatient facility services for behavioral healthcare that were provided out-of-network was 2.8 to 4.2 times higher than for medical/surgical services, and the proportion of outpatient facility services for behavioral healthcare that were provided out-of-network was 3.0 to 5.8 times higher than for medical/surgical services."[147]

143 *See* Tax Cuts and Jobs Act, Pub. L. No. 115-97, 131 Stat. 424 (2017) (codified at I.R.C. 48 § 5000A) (reducing penalty for not having insurance to $0); *see also* Christine Eibner & Sarah Nowak, *The Effect of Eliminating the Individual Mandate Penalty and the Role of Behavioral Factors*, THE COMMONWEALTH FUND (July 11, 2018), https://www.commonwealthfund.org/publications/fund-reports/2018/jul/eliminating-individual-mandate-penalty-behavioral-factors.

144 *See generally* Karen Pollitz et al., *Understanding Short-Term Limited Duration Health Insurance*, HENRY J. KAISER FAM. FOUND. (Apr. 23, 2018), https://www.kff.org/health-reform/issue-brief/understanding-short-term-limited-duration-health-insurance/.

145 *See* John Arensmeyer, *Association Health Plans Will Destabilize Small Group Market*, SMALL BUS. MAJORITY (June 19, 2018), http://www.smallbusinessmajority.org/press-release/association-health-plans-will-destabilize-small-group-market.

146 *See What Marketplace Health Insurance Plans Cover*, HEALTHCARE.GOV, https://www.healthcare.gov/coverage/what-marketplace-plans-cover/ (last visited Feb. 6, 2019).

147 STEPHEN P. MELEK ET AL., MENTAL HEALTH TREATMENT & RESEARCH INST., ADDICTION AND MENTAL HEALTH VS. PHYSICAL HEALTH: ANALYZING DISPARITIES IN NETWORK USE AND PROVIDER REIMBURSEMENT RATES 1 (2017), http://www.milliman.com/uploadedFiles/insight/2017/NQTLDisparityAnalysis.pdf.

Regarding reimbursement, "primary care providers were paid 20.7% to 22.0% higher rates for office visits than behavioral providers, and medical/surgical specialty care providers were paid 17.1% to 19.1% higher rates for office visits than behavioral providers."[148] Research by Jane Zhu and colleagues that focused on exchange-marketplace plans found "structural barriers" to behavioral healthcare because approximately half of all plans featured behavioral health "narrow networks:" networks where fewer than 25% of providers are "in-network."[149]

The ACA's EHB requirement may not be an absolute guarantee of affordable mental health services. Nevertheless, it does require *some* services and may deliver better than that in competitive marketplaces. Unfortunately, the Trump Administration has taken issue with EHBs, increasing state discretion in their benchmarking.[150] Further, the Administration's Short-Term, Limited-Duration Insurance and AHPs online will feature deprecated EHBs.[151] Thus, at a time when persons suffering from OUD desperately need coverage for behavioral health services, the Administration is actively promoting "skimpy" policies that frequently will not include coverage for mental health, substance use, or OUD-appropriate prescriptions drugs.

The stratification of health insurance may (for good reason) seem arcane, and its connection to OUD treatment somewhat remote. However, comprehending stratification helps us understand why there is no *one* solution to improving opioids treatment interventions. Rather, each stratum requires separately tailored improvements in the applicable insurance model because those in different strata face different barriers.[152] For a start, there are those who remain uninsured. These include undocumented persons, those

148 *Id.* at 2.

149 Jane M. Zhu et al., *Networks in ACA Marketplaces are Narrower for Mental Health Care Than for Primary Care*, 36 HEALTH AFFAIRS 1624, 1626 (2017).

150 Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2019, 83 Fed. Reg. 16930 (Apr. 17, 2018).

151 John Arensmeyer, *Association Health Plans Will Destabilize Small Group Market*, SMALL BUS. MAJORITY (June 19, 2018), http://smallbusinessmajority.org/press-release/association-health-plans-will-destabilize-small-group-market. *See generally* Karen Pollitz et al., *Understanding Short-Term Limited Duration Health Insurance*, KAISER FAM. FOUND. (Apr. 23, 2018), https://www.kff.org/health-reform/issue-brief/understanding-short-term-limited-duration-health-insurance/.

152 *See generally* Kathleen Rowan et al., *Access and Cost Barriers to Mental Health Care, by Insurance Status, 1999-2010*, 32 HEALTH AFF. 1723 (2013).

who fall within the Medicaid expansion gap (100% FPL to 138% FPL) in non-expansion states, and those with income <400% FPL who, without tax credits, cannot afford a marketplace plan or could not use one absent cost-sharing subsidies. Then, and more fully described in the next section, are those who should benefit from Medicaid or expanded Medicaid but who either are unaware of the coverage, cannot meet the program's administrative requirements, or (increasingly) fall afoul of new eligibility hurdles such as paperwork or premium requirements.[153]

Stratification based on income was intended to mitigate the impact of poverty on access to healthcare. In actuality, it perpetuates classism and health disparities by shuffling persons into different healthcare systems with different coverages, expectations, and realities. As stressors like the opioids epidemic vividly demonstrate, a stratified system is a poor alternative to a single payer, universal care model.

C. *Medicaid's Devolution from Solution to Potential Problem*

It is difficult to overestimate Medicaid's potential for alleviating the opioid crisis. Approximately 12% of the adult Medicaid population suffers from a SUD,[154] Medicaid covers nearly 40% of nonelderly adults with OUD,[155] and overall, the program funds more than 20% of all addiction treatment.[156] Additionally, Medicaid offers opportunities for innovation and states have considerable leeway to adopt the kinds of treatments and services urgently needed by those suffering from OUD.[157] States can open up such opportunities

153 *See* discussion *infra* Section C.1.

154 *Medicaid Works for People with Substance Use Disorders*, CTR. ON BUDGET & POLICY PRIORITIES (Jan. 19, 2018), https://www.cbpp.org/research/health/medicaid-works-for-people-with-substance-use-disorders.

155 *Nonelderly Adults with Opioid Addiction Covered by Medicaid Were Twice as Likely as Those with Private Insurance or the Uninsured to Have Received Treatment in 2016*, KAISER FAM. FOUND. (Apr. 12, 2018), https://www.kff.org/medicaid/press-release/nonelderly-adults-with-opioid-addiction-covered-by-medicaid-were-twice-as-likely-as-those-with-private-insurance-or-the-uninsured-to-have-received-treatment-in-2016/.

156 Julia Zur & Jennifer Tolbert, *The Opioid Epidemic and Medicaid's Role in Facilitating Access to Treatment*, KAISER FAM. FOUND. (Apr. 11, 2018), http://files.kff.org/attachment/Issue-Brief-The-Opioid-Epidemic-and-Medicaids-Role-in-Facilitating-Access-to-Treatment.

157 U.S. DEP'T OF HEALTH & HUMAN SERVS., FACING ADDICTION IN AMERICA: THE SURGEON GENERAL'S REPORT ON ALCOHOL, DRUGS, AND HEALTH 6-35 to 6-38 (2016), https://addiction.surgeongeneral.gov/

by applying to the Secretary for a Section 1115 Medicaid waiver to use federal funds for additional services.[158] Indeed, states that have not expanded Medicaid have generally seen their percentage of uninsured persons *increase*.[159]

Persistent insurance coverage such as that provided by Medicaid expansion has proven very positive in improving the management of other chronic diseases.[160] As noted in the Surgeon General's report, "Medicaid expansion is a key lever for expanding access to substance use treatment because many of the most vulnerable individuals with substance use disorders have incomes below 138% of the federal poverty level."[161] Indeed, after Kentucky expanded Medicaid, it experienced a 700% increase in the utilization of substance use services.[162]

Medicaid was recognized as a key vehicle to increase the health of near-poor adults even before the expansion of behavioral health services by the MHPAEA and, subsequently, the ACA. From 2001, the Bush Administration's Health Insurance Flexibility and Accountability initiative encouraged states to request Section 1115 waivers in an attempt to provide coverage (albeit constrained by budget neutrality) to persons <200% FPL.[163]

Originally, even before the ACA, Section 1115 demonstration projects often were used to *reduce* stratification.[164] The ACA itself

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sites/default/files/surgeon-generals-report.pdf.

158 42 U.S.C. § 1315 (2018) (originally enacted by the Social Security Act of 1962, the waiver provision even predated Medicaid).

159 Jennifer Haley et al., *Adults' Uninsurance Rates Increased by 2018, Especially in States That Did Not Expand Medicaid*, HEALTH AFF. BLOG (Sept. 26, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180924.928969/full/.

160 *See, e.g.*, Rebecca Myerson et al., *Medicaid Eligibility Expansions May Address Gaps in Access to Diabetes Medications*, 37 HEALTH AFF. 1200 (2018).

161 U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 68, at 6–7.

162 *Substance Use and the ACA in Kentucky*, FOUND. FOR A HEALTHY KY. 7, 7 (2016), https://www.healthy-ky.org/res/images/resources/Full-Substance-Use-Brief-Final_12_16-002-.pdf.

163 *See generally* Hefei Wen et al., *Effect of Medicaid Expansions on Health Insurance Coverage and Access to Care among Low Income Adults with Behavioral Health Conditions*, 50 HEALTH SERVS. RES. 1787 (2015).

164 NAT'L CONFERENCE OF STATE LEGISLATURES, UNDERSTANDING MEDICAID SECTION 1115 WAIVERS: A PRIMER FOR STATE LEGISLATORS 4 (2017), http://www.ncsl.org/Portals/1/Documents/Health/Medicaid_Waivers_State_31797.pdf; THE KAISER COMM'N ON MEDICAID AND THE UNINSURED, A LOOK AT SECTION 1115 MEDICAID DEMONSTRATION WAIVERS UNDER THE ACA: A FOCUS ON CHILDLESS ADULTS 4 (2013), https://kaiserfamilyfoundation.files.wordpress.com/2013/10/8499-a-look-

signaled considerable interest in that model by permitting more ambitious projects under an additional waiver process.[165] Overall, Section 1115 waivers could help in implementing state innovations in behavioral health such as suspending the Institutions for Mental Diseases exclusion,[166] reimbursing care coordination, or paying for services that address health-related social needs such as supportive housing, transportation, and food.[167]

1. Regressive Trends in Section 1115 Waivers

During the Obama Administration, the waiver process continued much as before until Medicaid expansion stalled because states with conservative administrations declined to opt-in to expansion.[168] The Administration then took a detour from traditionally approved waivers and began approving requests that appealed to generally-held conservative views on health policy. In particular, the Administration allowed waivers that required enrollees to have some "skin in the game;"[169] for example, by paying small premiums, contributing to health savings accounts, or requiring healthy/wellness behaviors.

At least two objections can be levelled at these Obama-era waivers. First, there are serious doubts about the effectiveness

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at-section-1115-medicaid-demonstration-waivers.pdf; *see, e.g.*, *Background on Oregon's 1115 Medicaid Demonstration Waiver*, OR. HEALTH AUTH., https://www.oregon.gov/oha/HSD/Medicaid-Policy/Pages/Background.aspx (last visited Dec. 18, 2018).

165 *See* Patient Protection and Affordable Care Act § 1332, 42 U.S.C. § 18052 (2018).

166 Social Security Act § 1905(a)(B), 42 U.S.C. § 1396(d) (2018) (prohibiting Medicaid financing for behavioral care provided in residential treatment facilities with more than 16 beds); *see* discussion *infra* notes 215–18.

167 *See* NAT'L ASS'N OF MEDICAID DIR., MEDICAID SECTION 1115 WAIVER TRENDS IN AN ERA OF STATE FLEXIBILITY (2018), http://medicaiddirectors.org/wp-content/uploads/2018/03/Section-1115-Waiver-Trends-NAMD-Whitepaper-1.pdf.

168 *See generally Where the States Stand on Medicaid Expansion*, ADVISORY BD. (June 8, 2018), https://www.advisory.com/daily-briefing/resources/primers/medicaidmap; Sara Rosenbaum, *The Trump Administration Re-Imagines Section 1115 Medicaid Demonstrations – and Medicaid*, HEALTH AFF. BLOG, (Nov. 9, 2017), https://www.healthaffairs.org/do/10.1377/hblog20171109.297738/full/.

169 *See* Seema Verma & Brian Neale, *Health Indiana 2.0 is Challenging Medicaid Norms*, HEALTH AFF. BLOG (Aug. 29, 2016), https://www.healthaffairs.org/do/10.1377/hblog20160829.056228/full/.

of "skin-in-the-game" and wellness initiatives.[170] Second, some of the approved provisions were likely to *decrease* enrollment or service utilization. Because this was a likely result, the Obama Administration likely considered these to be worthy trade-offs in order to make headway in states reticent to expand Medicaid. Equally, conservative-led states could expand Medicaid with a modicum of political cover; what Abbe Gluck and Nicole Huberfeld call the "secret boyfriend model" of federalism.[171]

An example of a "skin-in-the-game" waiver is found in Indiana's "Healthy Indiana Plan 2.0."[172] Under this waiver, Medicaid benefits were tiered; the higher tier included vision and dental coverage and did not impose a co-pay for most services.[173] To qualify for this higher tier, otherwise-eligible persons had to contribute to a health savings account. Failure to make contributions (or never signing up) had a differential impact depending whether the otherwise-eligible person was in the traditional Medicaid or expanded cohort. In broad terms, failure to contribute would move those at 100% FPL or below to the lower benefits tier, while those in the expanded >138% FPL cohort would not receive those additional benefits, or if they stopped paying would be locked out of benefits for a period of time.[174] Analysis of HIP 2.0 has shown that 55% of those eligible to pay premiums failed to do so, either dropping down to the lower benefits tier (< 101% FPL) or never being enrolled or losing coverage (>100% FPL).[175] "The top two reasons cited by people who never enrolled in or lost HIP 2.0 coverage were affordability

170 *See generally* Jane B. Wishner et al., The Urban Inst., Medicaid Expansion, the Private Option, and Personal Responsibility Requirements (2015), https://www.urban.org/sites/default/files/publication/53236/2000235-Medicaid-Expansion-The-Private-Option-and-Personal-Responsibility-Requirements.pdf.

171 Abbe R. Gluck & Nicole Huberfeld, *What is Federalism in Healthcare for?*, 70 Stan. L. Rev. 1689, 1767 (2018).

172 Letter from Marilyn Tavenner, Dep't of Health & Human Serv., to Joseph Moser, Medicaid Dir. for Ind. Family and Soc. Serv. Admin. (Jan. 27, 2015), https://www.in.gov/fssa/hip/files/IN_HIP_2.0_CMS_Approval_Ltr_1_27_15.pdf.

173 Robin Rudowitz et al., Kaiser Fam. Found., Digging Into the Data: What Can We Learn from the State Evaluation of Healthy Indiana (HIP 2.0) Premiums 3 (2018), http://files.kff.org/attachment/Issue-Brief-Digging-Into-the-Data-What-Can-We-Learn-from-the-State-Evaluation-of-Healthy-Indiana-HIP-20-Premiums.

174 *Id.* at 2.

175 *Id.* at 3.

and confusion about the payment process."[176]

Overall, the results from these Obama-era waiver approvals undoubtedly show net gains in the number of covered persons.[177] However, the picture seems cloudier with regard to the behavioral health cohort. The Indiana Medicaid population is approximately 1.3 million.[178] Approximately 100,000 (or 7%) suffer from SUD, although under-reporting makes it likely that the number is roughly twice that (or 14%).[179] It seems arguable that programs that lead with paperwork and not treatment will have a disproportionately negative impact on those needing behavioral health services. Either Medicaid eligibility paperwork will not be completed or the staff in emergency rooms or other treatment situations will find themselves pausing from their clinical responsibilities to help fill in forms.

Clearly, the Trump Administration is doubling down on the approach to Section 1115 waivers taken by the Obama Administration. First, it is approving draconian provisions, such as work requirements, that the prior administration rejected.[180] Second, while the Obama Administration used Section 1115 waivers as a carrot offered to states vacillating over expansion, the Trump Administration is using the waiver process to *reform* traditional Medicaid.[181] There is, therefore, more going on here than simply

176 *Id.* at 4.

177 *See, e.g.*, Seth Freedman et al., *Learning from Waiver States: Coverage Effects Under Indiana's HIP Medicaid Expansion*, 37 HEALTH AFF. 936, 939–40 (2018).

178 *See Medicaid in Indiana*, KAISER FAMILY FOUND. (Nov. 2018), http://files.kff.org/attachment/fact-sheet-medicaid-state-IN (providing the statistic that 20% of Indiana's population is on Medicaid, which is approximately 1.3 million).

179 NICOLAS P. TERRY ET AL., LEGAL AND POLICY BEST PRACTICES IN RESPONSE TO THE SUBSTANCE ABUSE CRISIS 32 (2018), https://grandchallenges.iu.edu/doc/iu-grand-challenges-legal-and-policy-best-practices.pdf.

180 *See, e.g.*, Michael Ollove, *Should Medicaid Recipients Have to Work?*, PEW (Sept. 30, 2015), https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2015/09/30/should-medicaid-recipients-have-to-work; Mattie Quinn, *On Medicaid, States Won't Take Feds' No for an Answer*, GOVERNING (Oct. 11, 2016), http://www.governing.com/topics/health-human-services/gov-medicaid-waivers-arizona-ohio-cms.html; Sara Rosenbaum, *The Trump Administration Re-Imagines Section 1115 Medicaid Demonstrations – and Medicaid*, HEALTH AFF. BLOG (Nov. 9, 2017), https://www.healthaffairs.org/do/10.1377/hblog20171109.297738/full/.

181 MARYBETH MUSUMECI ET AL., SECTION 1115 MEDICAID DEMONSTRATION WAIVERS 3–5 (2018), http://files.kff.org/attachment/Issue-Brief-Section-1115-Medicaid-Demonstration-Waivers-The-Current-Landscape-of-

approving more conservative waivers or providing political cover for the most conservative states to expand Medicaid. Rather, it indicates a major shift in philosophy regarding Medicaid.

In 2017, this was laid bare in just the third paragraph of a letter to the country's governors from then-HHS Secretary Tom Price and CMS Administrator Seema Verma (hereinafter the "Price-Verma letter"). Whether conscious or not of their historical revisionism, they wrote, "[t]he expansion of Medicaid through the [ACA] to non-disabled, working-age adults without dependent children was a clear departure from the core, historical mission of the program."[182] It was in this letter that the new Administration also announced its belief that "[t]he best way to improve the long-term health of low-income Americans is to empower them with skills and employment."[183] In January 2018, then-CMS Director Brian Neale provided more details in a letter to state Medicaid directors (hereinafter the "Neale letter").[184]

Predictably, states with conservative leadership applied for new waivers or added work requirements to requests for renewal of existing waivers—that cohort exemplified by Indiana, Kentucky, and Ohio, states that have been hit particularly hard by the opioid epidemic.[185] Both the Price-Verma and the Neale letters reflected on

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Approved-and-Pending-Waivers.

182 Letter from Thomas E. Price, Sec'y, U.S. Dep't of Health & Human Servs., and Seema Verma, Adm'r, Ctrs. for Medicare & Medicaid Servs., to U.S. State Governors 1 (March 14, 2017), https://www.hhs.gov/sites/default/files/sec-price-admin-verma-ltr.pdf [hereinafter Price-Verma Letter].

183 *Id.*

184 Letter from Brian Neale, Medicaid Deputy Adm'r & Dir., Ctrs. for Medicare & Medicaid Servs., to State Medicaid Dirs. (Jan. 11, 2018), https://www.medicaid.gov/federal-policy-guidance/downloads/smd18002.pdf; *see also* Marian Jarlenski et al., *Shaping Health Policy for Low-Income Populations: An Assessment of Public Comments in a New Medicaid Waiver Process*, 42 J. HEALTH POL., POL'Y, & L. 1039, 1047 (2017) (examining whether the comment letters used the rhetoric of "personal responsibility," "consumer choice," or "consumer-driven care" rather than "vulnerable populations").

185 *Indiana Opioid Summary*, NAT'L INST. ON DRUG ABUSE (Feb. 2018), https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/indiana-opioid-summary; Billy Wynne & Taylor Cowey, *State Waivers as a National Policy Lever*, HEALTH AFF. BLOG (Feb. 6, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180202.543483/full/; *see, e.g.*, Kyle Fee, *The Opioid Epidemic and Its Effects*, FED. RES. BANK CLEVELAND (May 31, 2018), https://www.clevelandfed.org/newsroom-and-events/publications/community-development-briefs/db-20180531-the-opioid-epidemic.aspx; *see Where the States Stand on Medicaid Expansion*, ADVISORY BOARD (Nov. 5, 2018,

the opioid epidemic. While the former included language pledging CMS's cooperation with the states to provide a "full continuum of care,"[186] the Neale letter included a promise of carve-outs from the work requirements for those with SUD. These included required respect for civil rights protections and "counting time spent in medical treatment towards an individual's work/community engagement requirements."[187] However, whether compliance with the Americans with Disabilities Act ("ADA"),[188] and some requirement that states use some kind of "medical frailty" safe harbor, [189] will be sufficient protections for those with OUD remains an open question.

Again, to use Indiana's Medicaid as an example, the state's 2018 waiver extension includes additional potential barriers to Medicaid enrollment. For example, the extension approves a tobacco surcharge, a work requirement (beginning in 2019), and more process requirements.[190] Persons with OUD likely will have difficulty meeting the accompanying administrative requirements. Many may be transients whose qualifying paperwork fails to reach them,[191] and others cycle in and out of relapse,[192] making regular

12:51 PM), https://www.advisory.com/daily-briefing/resources/primers/medicaidmap.

186 Price-Verma Letter, *supra* note 182, at 3.

187 Letter from Brian Neale, *supra* note 184, at 6.

188 Title II of the ADA protects qualified individuals with disabilities from discrimination on the basis of disability from services, programs, or activities provided by state and local government entities. A person with OUD may be a "qualified individual with a disability." 28 C.F.R. § 35.130 (2018).

189 MARYBETH MUSUMECI ET AL., APPROVED CHANGES IN INDIANA'S SECTION 1115 MEDICAID WAIVER EXTENSION 5 (2018), http://files.kff.org/attachment/Issue-Brief-Approved-Changes-in-Indianas-Section-1115-Medicaid-Waiver-Extension.

190 Letter from Demetrios Kouzoukas, Principal Deputy Adm'r, Ctrs. for Medicare & Medicaid Servs., to Allison Taylor, Medicaid Dir., Indiana Family & Soc. Servs. Admin. (Feb. 1, 2018), https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/in/Healthy-Indiana-Plan-2/in-healthy-indiana-plan-support-20-ca.pdf. *See generally* MUSUMECI ET AL., *supra* note 189, at 1.

191 SUZANNE WIKLE, MEDICAID WORKS: NO WORK REQUIREMENT NECESSARY 6 (2018), https://www.clasp.org/sites/default/files/Medicaid%20Works-No%20Work%20Requirement%20Necessary%20updated%20December%202018%20final.pdf; *see also* Lydia Coutré, *Ohio Hospitals Battle Proposed Medicaid Work Requirements*, MODERN HEALTHCARE (Apr. 30, 2018), https://www.modernhealthcare.com/article/20180430/NEWS/180439992.

192 NIH NIDA actually defines drug abuse and addiction as a "relapsing brain disease." *See The Science of Drug Use and Addiction*, NAT'L INST. ON DRUG

employment problematic. The new program will be subject to the ADA, containing a SUD-exception from the work requirement, and a medical frailty care exception to lockout.[193] However, it is unclear how these will operate and precisely how substantiation burdens will fall on those with SUD. It is at least arguable that these additional requirements will increase the barriers to healthcare among the poor and near-poor in Indiana, and disproportionately impact persons with OUD.[194] While the proportion of those with SUD or OUD is not broken out, new figures from Arkansas, which has imposed an 80-hour-per-month work requirement, suggest that thousands of persons are at risk of being dropped from the state's Medicaid program.[195]

If the worst-case scenario plays out with those needing behavioral health services excluded because of a politically-motivated work requirement, the irony will be cruel. Expanding Medicaid should be one of the most effective interventions in the OUD epidemic, extending healthcare to a particularly hard-hit demographic. However, the price for that intervention, a Medicaid expansion "tax," may create new barriers to eligibility for large numbers in the very cohort that needs help. These waivers or waiver extensions are adding increased premiums, work requirements, documentation burdens, and requirements that recipients log onto state computer systems to report employment details; failure to comply with even the minutest requirements leads to lockouts.[196]

ABUSE (July 2018), https://www.drugabuse.gov/publications/media-guide/science-drug-use-addiction-basics.

193 MUSUMECI ET AL., *supra* note 189, at 4, 8.

194 HANNAH KATCH ET AL., TAKING MEDICAID COVERAGE AWAY FROM PEOPLE NOT MEETING WORK REQUIREMENTS WILL REDUCE LOW-INCOME FAMILIES' ACCESS TO CARE AND WORSEN HEALTH OUTCOMES (2018), https://www.cbpp.org/sites/default/files/atoms/files/2-8-18health2.pdf.

195 Erin Brantley & Leighton Ku, *Arkansas's Early Experience with Work Requirements Signals Larger Losses to Come*, THE COMMONWEALTH FUND: TO THE POINT (Oct. 31, 2018), https://www.commonwealthfund.org/blog/2018/arkansas-early-experience-work-requirements; Jessie Hellmann, *Arkansas Medicaid Work Requirements Could Cost Thousands Coverage, Data Show*, THE HILL (Aug. 15, 2018), https://thehill.com/policy/healthcare/401975-new-data-shows-arkansass-medicaid-work-requirements-could-cost-thousands; *see also* Jessica Greene, *Medicaid Recipients' Early Experience with the Arkansas Medicaid Work Requirement*, HEALTH AFF. BLOG (Sept. 5, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180904.979085/full/.

196 *See generally* MUSUMECI ET AL., *supra* note 189.

There is particular potential for additional "churn" as those with OUD drop in and out of these programs with complex administrative or work requirements.[197] It is at least arguable that those types of conditions for eligibility would disproportionally harm those with OUD. Many with OUD will likely be unable to handle the administrative burdens and simply walk away.

Re-architecting the Medicaid program around employment is flawed on a number of fronts. First, the policy shift likely is not worth the administrative costs; only a very small number of Medicaid eligible persons who could work choose not to.[198] Sixty percent work and most of those who don't are disabled, caregivers, or in school.[199] Only seven percent would qualify as not-working and there are many reasons, including lack of jobs in a particular locale, which could explain some of that number.[200] Second, the CMS explanation for a work requirement is based on some twisted logic. While it is true that those who are employed generally have better health, it is false to conclude that making people work will increase their health. As Douglas Jacobs observes, "it could just as easily be that poor health causes unemployment" while research suggests "that having Medicaid made it easier to look for a job."[201]

At present, the impact of imposing work requirements is uncertain. Some programs do not begin until 2019 and the legality of the waivers is under attack. For example, in *Stewart v. Azar*, Medicaid enrollees challenged the section 1115 waiver CMS granted to Kentucky HEALTH which included a work requirement, premiums, additional cost-sharing, and a coverage lockout for failure

197 RACHEL GARFIELD ET AL., IMPLICATIONS OF WORK REQUIREMENTS IN MEDICAID 5 (2018), http://files.kff.org/attachment/Issue-Brief-Implications-of-Work-Requirements-in-Medicaid-What-Does-the-Data-Say; *see also* Letter from Demetrios Kouzoukas, *supra* note 190. *See generally* MUSUMECI ET AL., *supra* note 189.

198 MARYBETH MUSUMECI ET AL., MEDICAID AND WORK REQUIREMENTS (2018), http://files.kff.org/attachment/Issue-Brief-Medicaid-and-Work-Requirements-New-Guidance-State-Waiver-Details-and-Key-Issues.

199 *Id.*

200 *Id.*

201 Douglas Jacobs, *The Social Determinants Speak: Medicaid Work Requirements Will Worsen Health*, HEALTH AFF. BLOG (Aug. 6, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180730.371424/full/; *see also* LARISA ANTONISSE & RACHEL GARFIELD, THE RELATIONSHIP BETWEEN WORK AND HEALTH (2018), http://files.kff.org/attachment/Issue-Brief-The-Relationship-Between-Work-and-Health-Findings-from-a-Literature%20Review.

to promptly renew.[202] Kentucky itself admitted that almost 100,000 Kentuckians would lose coverage.[203] In June 2018, the federal district court decided that the Secretary's waiver decision was arbitrary and capricious because he failed to consider the impact of the waiver policies on insuring people (Medicaid's primary purpose) given the estimate of how many would lose coverage.[204] Undoubtedly, neither the litigation nor the question of obstructive Medicaid restrictions are over, and reports suggest that CMS is not inclined to change its new embrace of work requirements.[205] On a brighter note, there are indications that an increasing number of non-expansion states are now leaning toward expansion[206] and, as a result, a net increase in the number of insureds. However, it is unclear how many of these recent converts to expansion will have to adopt draconian conditions to cement the transition.[207] Nor, as already discussed, is it clear whether those "skin-in-the-game" policies and work requirements will disproportionally impact those needing behavioral health services.

2. Medicaid Reimbursement for Behavioral Health Services

For those needing behavioral health services the stakes are high. Those covered by Medicaid are twice as likely as those who are uninsured or have private insurance to receive treatment for OUD and almost three times more likely to have received outpatient treatment.[208] Overall, Medicaid provides access to more

202 Stewart v. Azar, 313 F. Supp. 3d 237, 248 (D.D.C. 2018).

203 *Id.* at 263.

204 *Id.* at 259–62; *see* MARYBETH MUSUMECI, EXPLAINING *Stewart v. Azar* (2018), http://files.kff.org/attachment/Issue-Brief-Explaining-Stewart-v-Azar-Implications-of-the-Courts-Decision-on-Kentuckys-Medicaid-Waiver.

205 *See* Dan Diamond & Rachana Pradhan, *CMS Plots Path Forward for Kentucky Work Requirements After Court Setback*, POLITICO (July 18, 2018), https://www.politico.com/story/2018/07/18/kentucky-medicaid-work-requirements-cms-court-setback-694575.

206 Donald Moulds et al., *A New Group of States Looks to Expand Medicaid*, THE COMMONWEALTH FUND: TO THE POINT (Aug. 27, 2018), https://www.commonwealthfund.org/blog/2018/states-look-expand-medicaid.

207 *See generally id.*

208 Julia Zur & Jennifer Tolbert, *The Opioid Epidemic and Medicaid's Role in Facilitating Access to Treatment*, THE HENRY J. KAISER FAM. FOUND. (Apr. 11, 2018), https://www.kff.org/medicaid/issue-brief/the-opioid-epidemic-and-medicaids-role-in-facilitating-access-to-treatment/.

comprehensive behavioral health services than marketplace plans.[209] However, while states generally are obliged to provide such services writ large, not all states provide robust services.[210] Three variables are at work here: first, the extent to which a state provides different modes of treatment; second, the levels of care that are available; and third, the extent to which an individual state has taken advantage of additional coverages (for example, Health Homes) or requested waivers under Section 1115 to address issues that go beyond mainstream clinical care (for example, wraparound services).

While Medicaid (courtesy of the MHPAEA and ACA) requires states to include reimbursement for substance use treatment, it did not require all three forms of MAT until the 2018 opioid legislation.[211] While a majority of states do require such reimbursements, many still do not, the omission frequently being methadone-based treatment, which is absent from numerous state plans.[212]

Medicaid has approved the ASAM guidelines providing the appropriate levels of care.[213] However, yet again, there are considerable state-by-state disparities in the availability of these levels of care under Medicaid. Particular deficiencies are identified in levels 3 (residential inpatient services) and 4 (intensive inpatient

209 *Medicaid Works for People with Substance Use Disorders*, CTR. ON BUDGET & POL'Y PRIORITIES (Jan. 19, 2018), https://www.cbpp.org/research/health/medicaid-works-for-people-with-substance-use-disorders.

210 *See id.*

211 *See* MEDICAID INNOVATION ACCELERATOR PROGRAM, OVERVIEW OF SUBSTANCE USE DISORDER (SUD) CARE CLINICAL GUIDELINES: A RESOURCE FOR STATES DEVELOPING SUD DELIVERY SYSTEM REFORMS 1 (2017), https://www.medicaid.gov/state-resource-center/innovation-accelerator-program/iap-downloads/reducing-substance-use-disorders/asam-resource-guide.pdf; *see also Insurance and Payments*, SUBSTANCE ABUSE & MENTAL HEALTH SERV. ADMIN., https://www.samhsa.gov/medication-assisted-treatment/treatment/insurance-payments (last updated Sept. 28, 2015); SUPPORT for Patients and Communities Act, Pub. L. No. 115-271, § 2001 (2018).

212 Colleen M. Grogan et al., *Survey Highlights Differences in Medicaid Coverage for Substance Use Treatment and Opioid Use Disorder Medications*, 25 HEALTH AFF. 2289, 2292 (2016); *States Reporting Medicaid Coverage of Medication Assisted Treatment (MAT) Drugs*, THE HENRY J. KAISER FAM. FOUND., https://www.kff.org/medicaid/state-indicator/states-reporting-medicaid-coverage-of-medication-assisted-treatment-mat-drugs/ (last visited Dec. 14, 2018).

213 *See* Letter from Vikki Wachino, Dir., Ctrs. for Medicare & Medicaid Servs., to State Medicaid Dirs. 7 (July 27, 2015), https://www.medicaid.gov/federal-policy-guidance/downloads/SMD15003.pdf; *see also* MEDICAID INNOVATION ACCELERATOR PROGRAM, *supra* note 211, at 2–3.

services), along with other state-by-state variations such as pre-authorization requirements and coverage limitations.[214]

The relative lack of level 3 residential inpatient care is to a large extent because of what is known as the Institutions for Mental Disease ("IMD") exclusion that applies to reimbursement for adults aged 21–64.[215] As should be obvious from its name, the IMD exclusion is a relic from the past, prior to the integration of behavioral health services with general medical care. IMDs are hospitals or treatment facilities that have more than 16 beds and that primarily provide mental health or substance use care.[216] Increasingly, CMS seems willing to approve Section 1115 waivers to the IMD prohibition and allow Medicaid reimbursement[217] while recent federal opioid legislation brought about the exclusion's suspension but not its ultimate demise.[218]

Section 1115 waivers are the one part of the third aspect of Medicaid treatment; the potential to reimburse for and so unlock expanded behavioral health services. The other key route for states is to adopt "state plan amendments." One of these, included in the ACA,[219] is the Medicaid "health home" that provides time-limited federal funding for creating "homes" for beneficiaries that provide case management, care coordination, and other services that would be of particular utility when dealing with those requiring behavioral health services. Approximately 15 states have adopted some form of this model.[220]

In contrast, Section 1115 waiver applications are being adopted broadly to increase reimbursable behavioral health

214 Grogan et al., *supra* note 212, at 2292.

215 42 U.S.C. § 1396d(a)(29)(B) (2018).

216 *See generally* MaryBeth Musumeci, *Key Questions about Medicaid Payment for Services in "Institutions for Mental Disease,"* The Henry J. Kaiser Fam. Found. (June 18, 2018), https://www.kff.org/medicaid/issue-brief/key-questions-about-medicaid-payment-for-services-in-institutions-for-mental-disease/.

217 *See* Letter from Brian Neale, Dir., Ctrs. for Medicare & Medicaid Servs., to State Medicaid Dirs. 2 (Nov. 1, 2017), https://www.thenationalcouncil.org/wp-content/uploads/2017/11/smd-17-003.pdf.

218 SUPPORT for Patients and Communities Act, Pub. L. No. 115-271, §§ 1012-13, 5052, 132 Stat. 3894, 69-70 (2018).

219 *See* 42 U.S.C. § 256a-1 *et seq.* (2018).

220 Kathy Moses & Brianna Ensslin, Ctr. for Health Care Strategies, Seizing the Opportunity: Early Medicaid Health Home Lessons 1 (2014).

services.[221] This route has been encouraged by both the Obama[222] and Trump Administrations.[223] In addition to IMD waivers (the most popular), a large number of states have applied for waivers to expand community-based services (such as supportive housing or peer coaching), increase the eligible cohort, or finance delivery system reforms (such as integrating services).[224] However, these demonstration projects must be budget neutral,[225] which likely creates difficult decisions for states as they increase their behavioral health services (for example, calibrating the appropriate balance of spending on institutional versus community-based care).

As Jonathan Oberlander has commented, "[t]he ACA is stuck in purgatory, beyond comprehensive repeal but subject to a war of attrition that jeopardizes its gains."[226] Medicaid expansion, a major component in improving behavioral health services, continues to be under threat, potentially leading to the loss of some or all insurance for hundreds of thousands of persons with behavioral health issues.[227] The worst case scenario is that even traditional Medicaid may be cut back if reformers succeed in moving "welfare" programs to a block grant model.[228]

221 MaryBeth Musumeci et al., *Section 1115 Medicaid Demonstration Waivers: The Current Landscape of Approved and Pending Waivers*, THE HENRY J. KAISER FAM. FOUND. (Sept. 20, 2018), https://www.kff.org/medicaid/issue-brief/key-questions-about-medicaid-payment-for-services-in-institutions-for-mental-disease/.

222 *See* Letter from Vikki Wachino to State Medicaid Dirs., *supra* note 213, at 4 (replaced by Nov. 1, 2017 letter below).

223 *See* Letter from Brian Neale to State Medicaid Dirs., *supra* note 217, at 1.

224 MARYBETH MUSUMECI, THE HENRY J. KAISER FAMILY FOUND., KEY THEMES IN MEDICAID SECTION 1115 BEHAVIORAL HEALTH WAIVERS 2 (2017).

225 Letter from Timothy B. Hill, Acting Dir., Ctrs. for Medicare & Medicaid Servs., to State Medicaid Dirs. 1–2 (Aug. 22, 2018), https://www.medicaid.gov/federal-policy-guidance/downloads/smd18009.pdf.

226 Jonathan Oberlander, *The Republican War on Obamacare — What Has It Achieved?*, 379 NEW ENG. J. MED. 703, 705 (2018).

227 Peggy Bailey, *ACA Repeal Would Jeopardize Treatment for Millions with Substance Use Disorders, Including Opioid Addiction*, CTR. ON BUDGET & POL'Y PRIORITIES (Feb. 9, 2017), https://www.cbpp.org/research/health/aca-repeal-would-jeopardize-treatment-for-millions-with-substance-use-disorders; Richard G. Frank & Sherry A. Glied, *Keep Obamacare to Keep Progress on Treating Opioid Disorders and Mental Illnesses*, THE HILL (Jan. 11, 2017), http://thehill.com/blogs/pundits-blog/healthcare/313672-keep-obamacare-to-keep-progress-on-treating-opioid-disorders.

228 *See* Aaron E. Carroll, *How Would Republican Plans for Medicaid Block Grants Actually Work?*, N.Y. TIMES (Feb. 6, 2017), https://www.nytimes.com/2017/02/06/

Assuming the survival of Medicaid and expanded Medicaid, the practical challenge will be to minimize the impact of "skin-in-the-game" work requirements and increased administrative burdens that will disproportionally have a negative impact on those needing behavioral health services. Philosophically and politically, the greater challenge will be to reverse the current Administration's "welfare" labelling of these important programs. As Sara Rosenbaum noted regarding the Price-Verma letter's rollout of work requirements and the Administration's new objectives, "[i]n all of this there is absolutely no mention of Medicaid as insurance."[229]

D. Differential Architectures, Fragmentation, and a Paucity of Wraparound Services

From the early days of addiction science, those with SUD were viewed as "morally flawed and lacking in willpower . . . which led to an emphasis on punishment rather than prevention and treatment."[230] Not surprisingly, behavioral and non-behavioral health services developed with differential architectures implicating, inter alia, treatment models, places for care, and data sharing. Deinstitutionalization began decades ago while, more recently, the MHPAEA and the ACA strengthened the integration or mainstreaming of treatments for substance use disorder and mental illness. However, in yet another example of path dependency, the practices and structures of the past haunt the present. The stigma surrounding SUD and mental illness remains as an intermediary determinant of health for those with OUD, while access and treatment differentials play out as structural determinants because patients and providers struggle with fragmentation and lack of care coordination. These flaws in the provision of behavioral healthcare services are amplified by fragmentation problems in healthcare generally and the lack of investment in case management, care coordination, and wraparound services by both healthcare and social welfare services.

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upshot/how-would-republican-plans-for-medicaid-block-grants-actually-work.html.

229 Sara Rosenbaum, *The Trump Administration Re-Imagines Section 1115 Medicaid Demonstrations – And Medicaid*, HEALTH AFFAIRS (Nov. 9, 2017), https://www.healthaffairs.org/do/10.1377/hblog20171109.297738/full/.

230 NAT'L INST. ON DRUG ABUSE, DRUGS, BRAINS, AND BEHAVIOR: THE SCIENCE OF ADDICTION 2 (2018), https://www.drugabuse.gov/publications/drugs-brains-behavior-science-addiction/preface.

To a large extent, lack of care coordination or fragmentation of care are defining features of the U.S. healthcare system.[231] The need for improved coordination frequently has been cited by organizations such as the National Academies of Science,[232] the Agency for Healthcare Research and Quality,[233] and the National Quality Forum.[234]

Successful care coordination has several key pillars, including "access to a range of health care services and providers," effective communications and care plan transitions (hand-offs) between providers, a focus on the patient's needs, the communication of "clear and simple information that patients can understand,"[235] and the effective use of health information technologies.[236] Demonstration projects have identified cost-savings in the Medicaid program from the use of care coordination interventions for those with chronic conditions.[237]

1. Fragmentation and the Continuum of Care for Those with OUD

It is broadly recognized that many of the care coordination issues that present in the OUD context follow from the historic segregation of substance use diagnosis and treatment from mainstream healthcare delivery, with the former frequently thought of as social or criminal justice issues that should be dealt with by psychiatric hospitals or prisons.[238] As we now recognize, persons

231 *See, e.g.*, FAMILIES USA, THE PROMISE OF CARE COORDINATION: TRANSFORMING HEALTH CARE DELIVERY 3 (2013).

232 *See, e.g.*, THE NAT'L ACADS. OF SCIS., IMPROVING DIAGNOSIS IN HEALTH CARE 6–9 (2015).

233 *Care Coordination*, AGENCY FOR HEALTHCARE RES. & QUALITY, https://www.ahrq.gov/professionals/prevention-chronic-care/improve/coordination/index.html (last visited Dec. 14, 2018).

234 *Care Coordination Measures*, NAT'L QUALITY FORUM, http://www.qualityforum.org/ProjectDescription.aspx?projectID=73700 (last visited Dec. 14, 2018).

235 *What Is Care Coordination?*, NEJM CATALYST (Jan. 1, 2017), https://catalyst.nejm.org/what-is-care-coordination/.

236 *Improved Care Coordination: The Need for Better Improved Care Coordination*, HEALTHIT.GOV, https://www.healthit.gov/providers-professionals/improved-care-coordination (last visited Dec. 14, 2018).

237 *See, e.g.*, Jingping Xing et al. *Care Coordination Program for Washington State Medicaid Enrollees Reduced Inpatient Hospital Costs*, 34 HEALTH AFF. 653 (2015).

238 U.S. DEP'T OF HEALTH & HUMAN SERVS., FACING ADDICTION IN AMERICA: THE SURGEON GENERAL'S REPORT ON ALCOHOL, DRUGS, AND HEALTH 1–19, 6–5 (2016).

suffering from OUD are particularly vulnerable populations that in practice require high levels of care coordination. These cohorts also need a well-thought-out continuum of care such that harm reduction or emergency department interventions can lead to treatment or, later, that treatment can lead to recovery services.[239]

The insurance policy stratification discussed above relates primarily to access to care, including the near-zero access experienced by the uninsured and the differential levels of care available to cohorts insured within different strata. Fragmentation is less about access and more about the quality of care that is delivered. Of course, those flaws overlap. For example, facilities being detox-only or not offering a full range of evidence-based medication assisted treatments[240] exhibit aspects relating both to access and quality. Similarly, the absence of a progressive continuum of care not only frustrates clinical interventions but also other innovative programs. For example, researchers found that, while an innovative police-led referral program[241] proved effective in referring persons to short-term services, it could not "overcome a fragmented treatment system focused on acute episodic care which remains a barrier to long-term recovery."[242]

Behavioral healthcare frustrates clinical interventions by placing limitations on the number of treatment options at a time when the opposite is required. As already discussed, Medicaid previously maintained an IMD exclusion, prohibiting Medicaid payments for some residential programs.[243] There are also limitations on the number of OTPs that are the requisite location for most MAT treatments.[244] By law, OTPs must be accredited

239 *See* P. Todd Korthius et al., *Primary Care-Based Models for the Treatment of Opioid Use Disorder*, 166 Annals Internal Med. 268, 276 (2017).

240 Hannah K. Knudsen et al., *Barriers to the Implementation of Medication-Assisted Treatment for Substance Use Disorders: The Importance of Funding Policies and Medical Infrastructure*, 34 Evaluation & Program Plan. 375, 375–76, 379 (2011), https://doi.org/10.1016/j.evalprogplan.2011.02.004. *See also* Brendan Saloner & Colleen L. Barry, *Ending the Opioid Epidemic Requires a Historic Investment in Medication-Assisted Treatment*, 37 J. Pol. Analysis & Mgmt. 431 (2018).

241 *Police Assisted Addiction & Recovery Initiative*, https://paariusa.org/ (last visited Sept. 28, 2018).

242 Davida M. Schiff et al., *A Police-Led Addiction Treatment Referral Program in Gloucester, MA: Implementation and Participants' Experiences*, 82 J. Substance Abuse Treatment 41, 41 (2017).

243 *See supra* text accompanying notes 215–18.

244 *Medication and Counseling Treatment*, Substance Abuse & Mental Health Servs. Admin., U.S. Dep't. of Health & Human Servs., https://www.

by an approved accrediting body and certified by SAMHSA.[245] The regulatory model is designed to ensure that medications are accompanied by appropriate "counseling and behavioral therapies, to provide a 'whole-patient' approach to the treatment of substance use disorders."[246] Additionally, and with specific applicability to agonists, the regulatory model is intended to prevent diversion.[247] An exception applies to the partial agonist buprenorphine, through the waiver structure introduced by the Drug Addiction Treatment Act of 2000.[248] Although that waiver program increased the number of physicians permitted to prescribe buprenorphine, it also placed somewhat arbitrary limits on the numbers of patients that physicians with waivers are permitted to treat.[249]

Those suffering from OUD face a sadly limited view of the continuum of care. For example, there is strong evidence syringe exchange programs open a path to treatment, do not increase rates of addiction,[250] and reduce the risk of needle stick injuries among law enforcement officers in the community.[251] Syringe exchange

samhsa.gov/medication-assisted-treatment/treatment (last updated Sept. 28, 2015); *see also* SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., U.S. DEP'T. OF HEALTH & HUMAN SERVS., FEDERAL GUIDELINES FOR OPIOID TREATMENT PROGRAMS 4 (2015), http://mpcmh.org/wpcontent/uploads/ 2017/12/SAMHSA_Guidelines_Opiod-Treatment-Programs.pdf.

245 Opioid Treatment Program Certification, 42 C.F.R. § 8.11 (2018).

246 *Medication-Assisted Treatment (MAT)*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., U.S. DEP'T. OF HEALTH & HUM. SERVS., https://www.samhsa.gov/medication-assisted-treatment (last updated Sept. 28, 2015).

247 FEDERAL GUIDELINES FOR OPIOID TREATMENT PROGRAMS, *supra* note 244.

248 *DEA Requirements for DATA Waived Physicians (DWPs)*, D.E.A. DIVERSION CONTROL DIV., U.S. DEP'T. OF JUSTICE, https://www.deadiversion.usdoj.gov/pubs/docs/dwp_buprenorphine.htm (last visited Dec. 16, 2018).

249 *See generally* Andrea G. Barthwell et al., *What's in a Number? Recommending Practicality in the Data 2000 Patient Limits*, 12 J. OPIOID MGMT. 243 (2016). A situation that was somewhat improved by the 2018 opioid legislation. *See* SUPPORT for Patients and Communities Act, Pub. L. No. 115-271, § 3201(a) (2018).

250 Steffanie A. Strathdee et al., *Needle-Exchange Attendance and Health Care Utilization Promote Entry into Detoxification*, 76 J. URB. HEALTH 448 (1999), https://www.ncbi.nlm.nih.gov/pubmed/10609594; *see also* INST. OF MED., NAT'L ACAD. OF SCI., PREVENTING HIV INFECTION AMONG INJECTING DRUG USERS IN HIGH-RISK COUNTRIES: AN ASSESSMENT OF THE EVIDENCE 141 (2006), https://www.nap.edu/read/11731/chapter/6#140.

251 Samuel L. Groseclose et al., *Impact of Increased Legal Access to Needles and Syringes on Practices of Injecting-Drug Users and Police Officers – Connecticut, 1992-1993*, 10 J. ACQUIRED IMMUNE DEFICIENCY SYNDROMES & HUM. RETROVIROL 82,

programs are safe places and a place of re-entry from the streets for those with OUD. They offer persons with OUD a route to a safer life, the minimization of comorbidities such as HIV/AIDS or Hepatitis-C, treatment, and even recovery,[252] suggesting they should be more formally recognized as part of the continuum of care.[253] Similarly, emergency department treatment should be recognized as a step toward treatment or at least chronic disease management.[254] As noted by Mark Olfson and colleagues, "[t]he high and broadly distributed mortality risks after nonfatal opioid overdose underscore the importance of coordinating medical, substance use, and mental health management after opioid overdose."[255]

2. *Non-Aligned Data Protection Models*

Healthcare data enjoy exceptional protection under federal law when compared to data in other domains.[256] Some data in healthcare subdomains experience even greater degrees of protection; these include the exceptional protection for process notes taken by psychotherapists[257] and the Genetic Information Nondiscrimination Act of 2008's prohibitions on the acquisition of genetic information.[258] Arguably, the strongest protection given to any healthcare data is that applied to behavioral health information by the Confidentiality of Substance Use Disorder Patient Records

86–88 (1995).

252 ELIZABETH TAYLOR, AIDS FOUND., AIDS WATCH: SYRINGE EXCHANGE PROGRAMS (2015), https://www.aidsunited.org/data/ files/Site_18/ AW2015Syringe Exchange_Web.pdf.

253 *See* Michael Kidorf et al., *Benefits of Concurrent Syringe Exchange and Substance Abuse Treatment Participation*, 40 J. SUBSTANCE ABUSE TREATMENT 265 (2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3056913/ (users of syringe exchange programs also participating in any type of substance abuse treatment reported less drug use).

254 *See* Andrew Herring, *Addiction Treatment Comes to the Emergency Department*, CAL. HEALTH CARE FOUND. (May 17, 2018), https://www.chcf.org/blog/ addiction-treatment-comes-to-the-emergency-department/. *See generally* Gail D'Onofrio et al., *Emergency Department–Initiated Buprenorphine/Naloxone Treatment for Opioid Dependence: A Randomized Clinical Trial*, 313 JAMA 1636 (2015).

255 Mark Olfson et al., *Causes of Death After Nonfatal Opioid Overdose*, 75 JAMA PSYCHIATRY 821, 821 (2018).

256 *See generally* Nicolas Terry, *Regulatory Disruption and Arbitrage in Healthcare Data Protection*, 17 YALE J. HEALTH POL'Y L. & ETHICS 143, 162–71 (2017).

257 45 C.F.R. §§ 164.501, 164.508(a)(2) (2018).

258 45 C.F.R. § 164.502(a)(5)(i) (2018).

rule, often referred to as 42 C.F.R. Part 2 (or just "Part 2").[259]

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") Privacy Rule applies to patient data in most traditional healthcare environments.[260] As a result, HIPAA privacy applies to patients being treated for substance use or other mental health issues.[261] HIPAA permits broad data-sharing between providers without requiring any patient consent.[262] The Privacy Rule does not contain any provisions specific to substance use patients.

However, Part 2 provides an *additional* layer of confidentiality for the records of SUD (and therefore OUD) patients.[263] Part 2 applies to federally-assisted programs that provide SUD programs to diagnosis, treat, or refer. Part 2 can apply to personnel or a unit contained within a general medical facility.[264] Most importantly, Part 2 has required an additional, highly specific consent from the patient before SUD records may be shared.[265]

In 2017, SAMHSA updated Part 2 including some changes to the consent process.[266] The updated consent provisions allow for a limited "general" consent contained in the "To Whom" section of the consent, under which a SUD patient may designate certain providers to receive certain, specified SUD information.[267] Technically, the

259 42 C.F.R. pt. 2 (2018). *See generally* LAURA ASHPOLE ET AL., 42 C.F.R. PART 2 IN RETROSPECTIVE: THE 30-YEAR JOURNEY OF THE ALCOHOL AND DRUG ABUSE TREATMENT CONFIDENTIALITY REGULATIONS (2017), https://www.healthlawyers.org/Members/PracticeGroups/TaskForces/BH/briefings/Documents/42_CFR_Part2_MB.pdf.

260 45 C.F.R. §§ 160, 162, 164 (2018). In general, the HIPAA rules apply to "covered entities," including most doctors, hospitals, and treatment facilities. *Covered Entities and Business Associates*, U.S. DEP'T OF HEALTH & HUMAN SERVS., https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html (last visited June 16, 2017).

261 45 C.F.R. § 164.501 (2018).

262 45 C.F.R. § 164.506 (2018).

263 Susan Awad, *Confused by Confidentiality? A Primer on 42 CFR Part 2*, AM. SOC. OF ADDICTION MED. (Aug. 15, 2013), https://www.asam.org/resources/publications/magazine/read/article/2013/08/15/confused-by-confidentiality-a-primer-on-42-cfr-part-2.

264 42 C.F.R. § 2.11 (2018).

265 42 C.F.R. § 2.31 (2018). *See generally Substance Abuse Confidentiality Regulations*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., U.S. DEP'T. OF HEALTH & HUMAN SERVS., https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulations-faqs (last updated May 1, 2018).

266 Confidentiality of Substance Use Disorder Patient Records, 82 Fed. Reg. 6052 (Jan. 18, 2017).

267 42 C.F.R. §§ 2.31, 2.33 (2018).

new consent rules operate quite differently from HIPAA and bring with them distinct accountability, research, and other provisions. Although the updated disclosure rule does include a new "medical emergency" exception,[268] even that is not as permissive as the equivalent HIPAA approach. In 2018, SAMHSA revisited some of these issues but again declined to further align HIPAA and Part 2 provisions.[269]

There has been a consistent drumbeat to better align these two sets of privacy regulations. For example, The President's Commission on Combating Drug Addiction and The Opioid Crisis recommended action to "[b]etter align, through regulation, patient privacy laws specific to addiction with the Health Insurance Portability and Accountability Act (HIPAA) to ensure that information about SUDs be made available to medical professionals treating and prescribing medication to a patient."[270]

The differential approach to protecting SUD records is blamed for inadequate integration of full SUD patient data in electronic health records, the exclusion of SUD records from statewide sharing through Health Information Exchanges, the perpetuation of stigma by treating SUD patients differently, and the exclusion of SUD patients from potentially beneficial research based on electronic health records data.[271]

Continued data segregation has been justified on the grounds that such data are particularly sensitive and that there has been a history of discrimination against SUD patients.[272] For example, The

268 42 C.F.R. § 2.51 (2018).

269 Confidentiality of Substance Use Disorder Patient Records, 83 Fed. Reg. 239, 241 (Jan. 3, 2018).

270 Office of Nat'l Drug Control Policy, The President's Commission on Combating Drug Addiction and The Opioid Crisis Final Report 210 (2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-15-2017.pdf; *see also* Letter from Rebecca Murow Klein, Chair, P'ship to Amend 42 CFR Part 2, to Orrin Hatch, Chairman, U.S. Senate Comm. on Fin., and Ron Wyden, Ranking Member, U.S. Senate Comm. on Fin. (Feb. 16, 2018), http://www.helpendopioidcrisis.org/wp-content/uploads/2018/02/Partnership-to-Amend-42-CFR-Part-2-Recommendations.pdf.

271 *See* Austin B. Frakt & Nicholas Bagley, *Protection or Harm? Suppressing Substance-Use Data*, 372 New Eng. J. of Med. 1879 (2015).

272 U.S. Dep't of Health & Human Servs., Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health 6-1, 6-33 to 6-34 (2016), https://addiction.surgeongeneral.gov/sites/default/files/surgeon-generals-report.pdf.

Surgeon General's Report noted, "[c]urrently, persons with substance use disorders involving illicit drugs are not protected under anti-discrimination laws, such as the ADA."[273] This is partially correct; although SUD *is* recognized by the ADA as a disability, protection is lost if the person is "currently engaging in the illegal use of drugs."[274] As noted by SAMHSA, disclosure of SUD information can lead to a host of negative consequences, "including: [l]oss of employment, loss of housing, loss of child custody . . . discrimination by medical professionals and even arrest, prosecution, and incarceration."[275] It is arguable that those seeking behavioral health services are less concerned about data sharing between providers but particularly fearful of information about their illness being shared with law enforcement and corrections.

An overarching policy imperative is to normalize or mainstream the treatment of SUD. However, if our healthcare delivery is to move to a position where SUD is treated as a mainstream disease, then segregation of data between SUD populations and other populations must be better managed. There is a very real safety angle here; for example, there is some evidence that patients with a substance use history unknown to treating physicians have been put at risk by opioid prescribing.[276]

This is not a newly identified problem and there have been unsuccessful attempts to pass legislation to provide regulatory authority to better align the rules.[277] As HHS rolls out regulations and policies authorized under the 21st Century Cures Act to

273 *Id.* at 6-34.

274 42 U.S.C. § 12114(a) (2018); *see also* 42 U.S.C. § 12111(6) (2018).

275 Confidentiality of Substance Use Disorder Patient Records, 82 Fed. Reg. 6052, 6053 (Jan. 18, 2017); *see* Paul N. Samuels & Patty McCarthy Metcalf, *Relaxing Patient Privacy Rules Would Worsen the Opioid Epidemic*, STAT NEWS (Nov. 24, 2017), https://www.statnews.com/2017/11/24/opioid-epidemic-patient-privacy/ (presenting strong defenses of Part 2); *see also* Karla Lopez & Deborah Reid, *Discrimination Against Patients with Substance Use Disorders Remains Prevalent and Harmful: The Case for 42 CFR Part 2*, HEALTH AFF. BLOG (Apr. 13, 2017), https://www.healthaffairs.org/do/10.1377/hblog20170413.059618/full/.

276 *See* Constance M. Weisner et al., *Trends in Prescribed Opioid Therapy for Non-Cancer Pain for Individuals with Prior Substance Use Disorders*, 145 PAIN 287 (2009).

277 *See, e.g.*, Overdose Prevention and Patient Safety Act of 2017, H.R. 3545, 115th Cong. (2017); Helping Families in Mental Health Crisis Act of 2016, H.R. 2646, 114th Cong. (2016).

promote interoperability,[278] discourage "information blocking,"[279] and establish a Trusted Exchange Framework,[280] more and improved clinical sharing inevitably will result and may, in the future, lead to some consensus on how to proceed with the differential laws.

HHS's Office of Civil Rights has published FAQs encouraging sharing[281] and, more recently, issued a "clarifying" Opioid Crisis Guidance that notes the flexibility in the HIPAA rule that permits providers to disclose information to families in dangerous or emergency situations and the fact that a patient's personal representative (recognized as such by state law) has the same rights as the patient.[282] However, the Guidance does not address the relationship between HIPAA and the more stringent Part 2.[283] Equally, SAMHSA has issued a FAQ on the interrelationship of Part 2 and the Health Information Exchange.[284] This dichotomous approach is clearly insufficient.

Although the House of Representatives' version of the 2018 opioid legislation would have amended Part 2's enabling legislation[285] to permit the sharing of SUD records with other treatment providers, as permitted under the HIPAA Privacy Rule,[286]

278 42 U.S.C. § 300jj (2018). *See generally* Don Rucker, *Achieving the Interoperability Promise of 21st Century Cures*, HEALTH AFF. BLOG (June 19, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180618.138568/full/.

279 42 U.S.C. § 300jj-52(a)-(b) (2018).

280 THE OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., DRAFT TRUSTED EXCHANGE FRAMEWORK (2018), https://www.healthit.gov/sites/default/files/draft-trusted-exchange-framework.pdf.

281 *FAQ: Disclosures to Family and Friends*, HHS.GOV, https://www.hhs.gov/hipaa/for-professionals/faq/disclosures-to-family-and-friends/index.html (last visited Dec. 15, 2018).

282 *HHS Office for Civil Rights Issues Guidance on How HIPAA Allows Information Sharing to Address the Opioid Crisis*, HHS.GOV (Oct. 27, 2017), https://www.hhs.gov/about/news/2017/10/27/hhs-office-civil-rights-issues-guidance-how-hipaa-allows-info-sharing-address-opioid-crisis.html.

283 *Id.*

284 LEGAL ACTION CTR. FOR THE SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., FREQUENTLY ASKED QUESTIONS: APPLYING THE SUBSTANCE ABUSE CONFIDENTIALITY REGULATIONS TO HEALTH INFORMATION EXCHANGE (HIE) (2010), https://www.samhsa.gov/sites/default/files/faqs-applying-confidentiality-regulations-to-hie.pdf.

285 42 U.S.C. § 290dd-2 (2018).

286 Overdose Prevention and Patient Safety Act, H.R. 6082, 115th Cong. (2018). *See generally* Mary Butler, *House of Representatives Passes Privacy Law Updates Governing Opioid Abuse Treatment*, J. OF AHIMA (June 20, 2018), http://journal.ahima.org/2018/06/20/house-of-representatives-passes-privacy-law-

that provision did not survive reconciliation and was omitted from the final legislation.[287] Separately, however, on July 26, 2018, HHS Deputy Secretary Hargan tweeted that the agency would soon be issuing Requests for Information on HIPAA and Part 2 and would be "taking regulatory action,"[288] a position confirmed by Secretary Azar.[289]

From harm reduction through treatment and recovery services, together with the accompanying patient data, there needs to be a more global sense of how to improve and coordinate behavioral health services. States need to improve case management, increase the availability of peer coaches, and invest in wraparound services, either through direct service improvements or by incenting stakeholders such as Medicaid managed care providers to step up. The ASAM levels of care discussed above[290] should be seen as an important baseline but one to which harm reduction and long-term recovery should be added.

V. The Healthcare Wasteland: Jails and Prisons

I think we are in rats' alley
Where the dead men lost their bones.[291]

More than half of state prisoners and two-thirds of sentenced jail inmates meet the diagnostic criteria for SUD.[292] A quarter of inmates suffer from both SUD and a co-occurring mental health

updates-governing-opioid-abuse-treatment/.

287 SUPPORT for Patients and Communities Act, H.R. 6, 115th Cong. (2018).

288 Eric D. Hargan (@DepSecHargan), TWITTER (Jul. 26, 2018, 1:05 PM), https://twitter.com/DepSecHargan/status/1022573758475849728.

289 Alex M. Azar II, Sec'y, U.S. Dep't of Health & Human Servs., Remarks to the Heritage Foundation (July 26, 2018), https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-to-the-heritage-foundation.html.

290 *See supra* text accompanying note 52.

291 T.S. ELIOT, THE WASTE LAND (1922).

292 JENNIFER BRONSON ET AL., U.S. DEP'T OF JUSTICE, DRUG USE, DEPENDENCE, AND ABUSE AMONG STATE PRISONERS AND JAIL INMATES, 2007-2009 1 (2017), https://www.bjs.gov/content/pub/pdf/dudaspji0709.pdf; THE NAT'L CTR. ON ADDICTION & SUBSTANCE ABUSE AT COLUMBIA UNIV., BEHIND BARS II: SUBSTANCE ABUSE AND AMERICA'S PRISON POPULATION 3 (2010), https://www.centeronaddiction.org/addiction-research/reports/behind-bars-ii-substance-abuse-and-america%E2%80%99s-prison-population.

problem.[293] It has been estimated that between a quarter and a third of those who suffer from heroin addiction pass through the corrections system each year.[294] Ironically, however, the criminal justice system is the place where the medicalization of substance use is least likely to be endorsed.[295] Worse, the criminal justice system frequently embraces the very opposite of the policy needed to address the opioid epidemic by criminalizing those who need behavioral healthcare services. Just as the Penrose hypothesis played out,[296] transforming our corrections facilities into a makeshift mental health system,[297] so now the cycle has repeated as prisons and jails now also house a significant population of those with SUD.

A. The State of Jails and Prisons

Fewer than 30 of the nation's 5,100 jails and prisons offer methadone or buprenorphine-based MAT.[298] This is despite the evidence that those treatments result in significant reduction in

293 THE NAT'L CTR. ON ADDICTION & SUBSTANCE ABUSE AT COLUMBIA UNIV., *supra* note 292, at 3. *See generally* Roger H. Peters et al., *Co-Occurring Substance Use and Mental Disorders in The Criminal Justice System: A New Frontier of Clinical Practice and Research*, 38 PSYCHIATRIC REHABILITATION J. 1 (2015) (discussing the prevalence of substance use disorders among prison inmates with mental disorders than those without a mental disorder).

294 Amy E. Boutwell et al., *Arrested on Heroin: A National Opportunity*, 3 J. OF OPIOID MGMT. 328, 328 (2007).

295 *See How People with Opioid Addictions are Treated in Prison*, NPR (Aug. 30, 2018), https://www.npr.org/2018/08/30/643445817/how-people-with-opioid-addictions-are-treated-in-prison; *see also* Erin Schumaker, *Inadequate Prison Policies Put Former Inmates at Greater Risk of Opioid Death*, HUFFINGTON POST (July 31, 2018) https://www.huffingtonpost.com/entry/inadequate-prison-policies-put-former-inmates-at-greater-risk-of-opioid-death_us_5b58e0c9e4b0b15aba94c3b6.

296 L.S. Penrose, *Mental Disease and Crime: Outline of a Comparative Study of European Statistics*, 18 BRITISH J. MED. PSYCHOL. 1 (1939). The hypothesis is that there is an inverse relationship between a country's available psychiatric beds and its prison population. *See, e.g.*, Mark Toynbee, *The Penrose Hypothesis in the 21st Century: Revisiting the Asylum*, 18 EVIDENCE-BASED MENTAL HEALTH 76 (2015).

297 Samantha Raphelson, *How the Loss of U.S. Psychiatric Hospitals Led to a Mental Health Crisis*, NPR (Nov. 30, 2017, 1:15 PM), https://www.npr.org/2017/11/30/567477160/how-the-loss-of-u-s-psychiatric-hospitals-led-to-a-mental-health-crisis.

298 Timothy Williams, *Opioid Users Are Filling Jails, Why Don't Jails Treat Them?*, N.Y. TIMES (Aug. 4, 2017), https://www.nytimes.com/2017/08/04/us/heroin-addiction-jails-methadone-suboxone-treatment.html.

post-release overdoses or deaths[299] and decreased recidivism.[300] According to Redonna Chandler and colleagues, "the criminal justice system provides a unique opportunity to intervene and disrupt the cycle of drug use and crime in a cost-effective manner," however they also recognize that "[t]he challenge of delivering treatment in a criminal setting requires the cooperation and coordination of 2 disparate cultures: the criminal justice system organized to punish the offender and protect society and the drug abuse treatment systems organized to help the addicted individual."[301]

That last reason aside, there are several explanations for the low rate of utilization of MAT in the criminal justice system. In jails the stays are, or should be, brief—rendering effective treatment questionable. However, jails do offer an opportunity for screening and referral to treatment. The situation in prisons is more complicated, with cost issues,[302] multiple levels of stigma,[303] and an institutional culture that is oppositional to the use and potential diversion of agonist or partial agonist drugs.[304]

Nevertheless, methadone treatment has been successfully employed at Rikers Island in New York City for 30 years, resulting in "overall health care cost savings, reduced crime and recidivism, reduced HIV and hepatitis C transmission, and better than average rates of recovery from drug use."[305] A similar success story has

299 John Marsden et al., *Does Exposure to Opioid Substitution Treatment in Prison Reduce the Risk of Death After Release? A National Prospective Observational Study in England*, 112 ADDICTION 1408, 1415 (2017).

300 Vincent Tomasino et al., *The Key Extended Entry Program (KEEP): A Methadone Treatment Program for Opiate-Dependent Inmates*, 68 MOUNT SINAI J. MED. 14, 19–20 (2001).

301 Redonna K. Chandler, et al., *Treating Drug Abuse and Addiction in the Criminal Justice System: Improving Public Health and Safety*, 301 JAMA 183, 189–90 (2009) (citation omitted).

302 An issue not limited to SUD. *See, e.g.*, Adam Beckman et al., *Follow California's Lead: Treat Inmates with Hepatitis C*, HEALTHAFFAIRS (July 24, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180724.396136/full/?.

303 German Lopez, *How America's Prisons are Fueling the Opioid Epidemic*, VOX (Mar. 26, 2018, 9:20 AM), https://www.vox.com/policy-and-politics/2018/3/13/17020002/prison-opioid-epidemic-medications-addiction.

304 Leah Pope et al., *A New Normal: Addressing Opioid Use Through the Criminal Justice System*, VERA INST. JUST., https://www.vera.org/publication_downloads/new-normal-opioid-use-criminal-justice-system/new-normal-opioid-use-criminal-justice-system.pdf (last visited Sept. 28, 2018).

305 Christine Vestal, *At Rikers Island, a Legacy of Medication-Assisted Opioid Treatment*, PEW (May 23, 2016), http://www.pewtrusts.org/en/research-and-analysis/

been reported from the Rhode Island Department of Corrections;[306] a unified prison/jail system that uses all three forms of MAT that extends the continuum of care such that individuals who are on MAT at intake are not tapered and, upon reentry, connect treated individuals to community-based resources.[307]

Notwithstanding these successes, at least "28 [states] don't fully offer *any* medication to prisoners with opioid use disorders."[308] It is hardly surprising, therefore, that there are examples of persons suffering from a diagnosable and diagnosed disease, but who have been denied the accepted standard of care, who have then sought legal redress.[309] The courts have adopted a high bar for Eighth Amendment inadequate treatment claims, "medical indifference," that requires the showing of not only medical malpractice but also animus.[310]

Therefore, as jurisprudence stands today, Title II of the ADA[311] may be a better vehicle for bringing actions against jails and prisons for inadequate OUD treatment. For example, the U.S. Attorney's office in Massachusetts has initiated an investigation of the Massachusetts Department of Corrections for discontinuing MAT upon incarceration.[312] A lawsuit filed by the American Civil Liberties Union of Washington State against Whatcom County Jail in Bellingham, Washington goes further, arguing that prisoners

blogs/stateline/2016/05/23/at-rikers-island-a-legacy-of-medication-assisted-opioid-treatment.

306 Andrew Joseph, *One State Takes a Novel Approach to Opioid Addiction: Access to Treatment for All Inmates*, STAT (Aug. 3, 2017), https://www.statnews.com/2017/08/03/opioid-treatment-prisons/.

307 Traci C. Green et al., *Postincarceration Fatal Overdoses After Implementing Medications for Addiction Treatment in a Statewide Correctional System*, 75 JAMA PSYCHIATRY 405, 405–407 (2018).

308 Lopez, *supra* note 303.

309 *See, e.g.*, Gallegos v. Bernarlillo Cty. Bd. of Comm'rs, No. CIV 16-0127 JB/WPL, 2017 WL 3575883, *1–2 (D. N.M. Aug. 17, 2017); Niemic v. UMass Corr. Health, 89 F. Supp. 3d 193, 198-99 (D. Mass. 2015).

310 *See, e.g.*, Helling v. McKinney, 509 U.S. 25, 30–35 (1993); Estelle v. Gamble, 429 U.S. 97, 103–107 (1976); *cf.* Brown v. Plata, 563 U.S. 493, 510 (2011) (allowing prisoner release after showing of overcrowding and systemic failures related to medical treatment).

311 42 U.S.C. § 12131; 28 C.F.R pt. 35 (2018) (protecting individuals with disabilities from discrimination on the basis of disability regarding services, programs, and activities provided by State and local government entities).

312 Letter from U.S. Att'y Gen., Dist. of Mass., to Mass. Exec. Office of Pub. Safety & Sec., Gen. Counsel, and Mass. Exec. Office of Health & Human Servs., Gen. Counsel (Mar. 16, 2018).

should be treated with opiate-withdrawal medication rather than being required to go "cold turkey."[313]

B. Reentry and Avoiding Recidivism

According to the National Center on Addiction and Substance Abuse, "[r]eleased inmates are more than three times likelier than the general population to meet clinical criteria for substance abuse,"[314] while "[o]ver half (52.2 percent) of substance-involved inmates have one or more previous incarcerations compared with 31.2 percent of inmates who are not substance involved."[315] More specifically, with regard to OUD, and according to German Lopez, "[s]ince so few state prisons offer adequate access to treatment, the days and weeks after a person's release from prison are perhaps the single deadliest time period in the US's opioid epidemic."[316] Huge numbers of our fellow citizens are therefore trapped in a cycle of imprisonment, untreated OUD, and reincarceration. Many die shortly after release, with one study finding, "[d]uring the first 2 weeks after release, the risk of death among former inmates was 12.7 times that among other state residents."[317]

This does not have to be the case even in corrections facilities that are opposed to agonists. For example, a pilot study found that treating prisoners with extended-release naltrexone just prior to reentry from jail was associated with significantly lower rates of opioid relapse.[318] The negative structural determinants go beyond the availability of treatment. The social determinants are equally negative, with released inmates highlighting "the significance of

313 Gene Johnson, *Lawsuit: Washington Jail Must Provide Addiction Treatment*, U.S. NEWS & WORLD REP. (June 7, 2018, 7:53 PM), https://www.usnews.com/news/best-states/washington/articles/2018-06-07/lawsuit-washington-jail-must-provide-addiction-treatment.

314 NAT'L CTR. ON ADDICTION AND SUBSTANCE ABUSE AT COLUM. UNIV., *supra* note 292, at 59.

315 *Id.* at 5.

316 Lopez, *supra* note 303.

317 Ingrid A. Binswanger et al., *Release from Prison – A High Risk of Death for Former Inmates*, 356 NEW ENG. J. MED. 157, 161 (2007).

318 Joshua D. Lee et al., *Opioid Treatment at Release from Jail Using Extended-Release Naltrexone: A Pilot Proof-of-Concept Randomized Effectiveness Trial*, 110 ADDICTION 1008, 1012 (2015); *cf.* Aaron D. Fox et al., *Release from Incarceration, Relapse to Opioid Use and the Potential for Buprenorphine Maintenance Treatment: A Qualitative Study of the Perceptions of Former Inmates with Opioid Use Disorder*, 10 ADDICTION SCI. & CLINICAL PRAC. 2 (Jan. 2015) (reporting multiple factors behind prisoners refusing buprenorphine upon release).

poor social support, medical problems, and inadequate financial resources to support" re-integration while they simultaneously faced "ubiquitous exposure to drugs in the neighborhoods to which they were released."[319] There are very few wraparound services that aid prisoner reentry by, for example, assisting with serious issues such as employment and housing,[320] while failure to acquire post-release employment is associated with poverty and recidivism.[321]

VI. Conclusion

"Between 2001 and 2016, the number of opioid-related deaths in the United States increased by 345% . . . 33.3 to 130.7 deaths per million population;" a public health crisis particularly responsible for the premature deaths of young and middle-aged adults.[322] Estimates suggest that opioids could be responsible for another half million drug-related deaths during the next decade,[323] becoming this generation's AIDS epidemic, [324] and likely even exceeding its death toll.[325]

Both our current healthcare system and the opioid epidemic deserve to be labelled as wicked problems. In both scenarios we are appropriately warned that wicked problems resist unitary diagnosis or single solutions.[326] Although the epidemic is national in its scope, in the end, the greatest toll of the opioid epidemic likely will fall

319 Ingrid A Binswanger et al., *Return to Drug Use and Overdose After Release from Prison: A Qualitative Study of Risk and Protective Factors*, 7 ADDICTION SCI. & CLINICAL PRAC. 3 (2012) (small qualitative study using semi-structured interviews).

320 *See generally* Faith E. Lutze et al., *Homelessness and Reentry: A Multisite Outcome Evaluation of Washington State's Reentry Housing Program for High Risk Offenders*, 41 CRIM. JUST. & BEHAV. 471 (2014).

321 Adam Looney & Nicholas Turner, *Work and Opportunity Before and After Incarceration*, BROOKINGS INST. (Mar. 2018), https://www.brookings.edu/wp-content/uploads/2018/03/es_20180314_looneyincarceration_final.pdf.

322 Tara Gomes et al., *The Burden of Opioid-Related Mortality in the United States*, 1 JAMA NETWORK OPEN, June 2018, at 1.

323 Max Blau, *STAT Forecast: Opioids Could Kill Nearly 500,000 Americans in the Next Decade*, STAT (June 27, 2017), https://www.statnews.com/2017/06/27/opioid-deaths-forecast/.

324 Andrew Sullivan, *The Opioid Epidemic is This Generation's AIDS Crisis*, N.Y. MAG. (Mar. 16, 2017), http://nymag.com/daily/intelligencer/2017/03/the-opioid-epidemic-is-this-generations-aids-crisis.html.

325 Carol Levine, *The Statistics Don't Capture the Opioid Epidemic's Impact on Children*, STAT (Jan. 2, 2018), https://www.statnews.com/2018/01/02/opioid-epidemic-impact-children/.

326 Lee, *supra* note 36, at 51.

disproportionately on the Midwestern and Southern states that exhibit poverty, marginalized populations, poor social determinants of health, underfunded public health, and limited access to healthcare.[327]

Starting from the hypothesis that many of the barriers to effective interventions in the opioid crisis are properties of our deficient health access and delivery processes, it is not difficult to suggest some relevant flaws that rise to the level of structural determinants: access and benefit stratification, the changing role of Medicaid, problems associated with fragmentation of care (the lack of behavioral health services integrated into our primary care systems cannot be overemphasized), and the lack of wraparound services. It is not necessary that we all end up agreeing that healthcare is a major cause; that "It's the Healthcare, Stupid!" However, what we should all be able to agree on is that we will have to re-engineer our healthcare system if we wish to make any headway against this or future addictions crises.

327 *Tobacco Nation: The Deadly State of Smoking Disparity in the U.S.*, TRUTH INITIATIVE, https://truthinitiative.org/sites/default/files/Tobacco-Nation-FINAL.pdf (last visited Dec. 17, 2018).