CARA, the 21st Century Cures Act: More Tools to Address the Opioid Epidemic

By: Hector Hernandez-Delgado

I. Background

Substance and opioid use disorders continue to be among the most pressing public health issues facing our country. The number of Americans reporting a substance use disorder (SUD) continues to increase, driven both by prescription opioid pain relievers (OPR) and illicit opioids like heroin. According to the Centers for Disease Control and Prevention (CDC), 33,091 Americans died due to an accidental or unintentional opioid-related overdose in 2015, more than any year on record and a significant increase from the 28,647 deaths reported in 2014.[1] Similarly, the number of non-fatal overdoses has increased dramatically in recent years. A recent report has shown that opioid-related emergency department visits and hospitalizations increased nationwide by 99% and 64%, respectively since 2005.[2] These data underscore both the severity and scope of the opioid epidemic, which has caused over half a million preventable deaths since 2000 and affects Americans from every state and all walks of life.

Luckily, Congress has recognized the importance of addressing the opioid epidemic with the recent passage of two important bills. In July 2016, President Obama signed into law the bipartisan Comprehensive Addiction and Recovery Act (CARA).[3] This legislation sought to advance evidence-based treatment and prevention measures intended to reduce the rate of OPR and heroin misuse and addiction. In December 2016, Congress enacted the 21st Century Cures Act (Cures Act), a sweeping bill that included, among other things, reforms to the FDA approval process and funding for cancer, Alzheimer's disease, and biomedical research.[4] In particular, the Cures Act also included several provisions intended to treat and prevent mental health problems and to reduce the impact of SUD and opioid use disorders (OUD).

[1] R.A. Rudd et al., *Increase in Drug and Opioid-Involved Overdose Deaths – United States, 2010-2015*, 64 MORBIDITY AND MORTALITY WEEKLY REP. 1378 (2016). Because of the way CDC calculates these data, this number is a lower bound; the actual number of Americans who died due to opioid-related causes is almost certainly higher. Personal communication with Peter Davidson, Ph.D., January 16, 2016.
[2] A.J. Weiss et al., *Opioid-Related Inpatient Stays and Emergency Department Visits by State, 2009 – 2014*, 219 AHRQ Statistical Brief 1 (2016). In 2014, there were 177.7 opioid-related ED visits and 224.6 opioid-related hospitalizations per 100,000 population. *Id*. at 2.
[3] Pub. L. No. 114-198 (2016).
[4] Pub. L. No. 114-255 (2016).

This issue brief explores how CARA and the Cures Act will impact the fight to curb the opioid epidemic by both preventing and treating mental health-related issues and SUD. It analyzes the way federal funding is allocated for state-level interventions to increase access to prevention and treatment for OUD and explores substantive policy changes introduced by the acts to reduce the impact of mental health illnesses and SUD. The brief also analyzes several criminal law reforms contained in CARA and the Cures Act that expand upon the federal government's recent shift in policy from an emphasis on criminal law to an acknowledgement of the importance of evidence-based interventions to reduce SUD and opioid-related overdoses.

II. Provisions Increasing Federal Funding to Treat OUD and Prevent Overdoses

CARA and the Cures Act address OUD by substantially increasing the federal funding available for state-level interventions to treat OUD, most notably by expanding access to evidence-based medication-assisted treatment (MAT).[5] The acts present funding opportunities for state governments, local governments, non-profit organizations, and treatment centers to be used to expand availability of MAT and to implement innovative strategies to prevent and treat OUD and related harms.

While CARA did not appropriate funding for opioid overdose prevention, the act authorizes a total of $181 million in new funding for programs designed to reduce the impact of OUD.[6] Specifically, CARA authorizes the Secretary of the Department of Health and Human Services (HHS) to award grants of up to $200,000 per year to federally qualified health centers (FQHCs), opioid treatment programs (OTPs), or health care practitioners given federal permission to provide treatment with buprenorphine to patients with OUD or to any other entity that the Secretary deems appropriate.[7] The act specifies that this funding should be used "to expand access to drugs or devices approved or cleared under the federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose."[8] This provision refers to naloxone, which is highly effective in reversing overdoses by binding to the opioid receptors in the brain more strongly than drugs like heroin and oxycodone, blocking those receptors.[9]

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[5] MAT consists of pharmacotherapy (often in conjunction with behavioral therapy) and is the evidence-based standard for opioid use disorder treatment. Treatment with the medications methadone and buprenorphine has repeatedly been proven effective in mitigating the outcomes of SUD and opioid dependence by improving treatment retention and reducing the risk of relapse (Catherine A. Fullerton et al., *Medication-assisted treatment with methadone: assessing the evidence*, 65 PSYCHIATRIC SERV. 146 (2014)); reducing drug-related criminal activity (Wayne Hall et al., *Effectiveness of MMT on Heroin Use and Crime*, Harwood Academic Publishers (1998)); by reducing bloodborne disease infections (Linda Gowing et al., *Oral Substitution Treatment of Injecting Opioid Users for Prevention of HIV Infection*, 8 COCHRANE DATABASE OF SYSTEMATIC REVIEWS CD004145 (2011)); and by reducing the risk of opioid related overdose death (Robert P. Schwartz et al., *Opioid agonist treatments and heroin overdose deaths in Baltimore, Maryland, 1995-2009*, 103 AM. J. PUBLIC HEALTH 917 (2013)).

[6] Through a Congressional Resolution passed in September 2016, Congress appropriated the following amounts to carry out the activities authorized by CARA:

- $17 million for grants available through the Department of Health and Human Services (HHS), and
- $20 million for grants available through the U.S. Attorney General.

Pub. L. No. 114-223, § 116(a)–(b)

[7] 42 U.S.C. § 290dd–3 (2016), as added by Pub. L. No. 114-198, § 107(a).

[8] 42 U.S.C. § 290dd–3(a)(1).

[9] *See* James M. Chamberlain & Bruce L. Klein, *A Comprehensive Review of Naloxone for the Emergency Physician*, 12 AM. J. EMERGENCY MED. 650 (1994) (providing an exhaustive explanation of the mechanism and effect of naloxone).

CARA lists the specific ways in which organizations can use this funding for the purpose of expanding access to naloxone for people at risk of an overdose.[10] First, the act authorizes the organizations eligible to receive funding to establish a program for prescribing naloxone to patients with SUD. Second, eligible organizations can use the funding for the training of health care providers and pharmacists on the prescribing of naloxone. Third, the act authorizes recipients to use the funding for the purchase of naloxone for treatment or to be prescribed to their patients. Fourth, eligible organizations can use the funding to offset the co-payments and other cost sharing associated with naloxone. Finally, CARA authorizes the use of the funding to establish protocols to connect patients who have experienced a drug overdose with outside entities providing MAT and counseling and behavioral therapies.

CARA also authorizes the HHS Secretary to award grants to state substance abuse agencies, local governments, or nonprofit organizations in geographical areas with high rates of heroin or other opioid use.[11] This funding is available for activities related to expanding MAT. To be eligible, entities must submit a plan for the periodic evaluation of the project to measure its success in providing more access to evidence-based treatment for people with OUD.[12] The provision authorizes HHS to allocate a total of $25 million per year between 2017 and 2021 for expansion of MAT and presents an opportunity for states and local governments to provide evidence-based treatment to individuals with SUD in areas with high prevalence of SUD and OUD.

Finally, CARA provides the HHS Secretary with the authority to award additional grants for states, or combination of states, to "implement an integrated opioid abuse response initiative."[13] Under this provision, the Secretary may award up to a total of $5 million per year between 2017 and 2021.[14] Funding from these grants must be used by states for establishment of a comprehensive response plan to the opioid epidemic, including the following components:

- Educational activities aimed at health care providers;
- Establishment, maintenance, or improvement of a prescription drug monitoring program (PDMP) to track the dispensing of controlled substances;
- Development, implementation, or expansion of prescription drug and opioid addiction treatment programs, including expanding the availability of MAT and behavioral therapy, implementing screening for individuals with OUD for hepatitis C and HIV, and developing recovery support programs at institutions of higher educations; and
- Enhancement of education programs targeting the public, providers, patients, consumers, and appropriate entities to raise awareness regarding the dangers of opioid abuse, safe disposal of prescription medications, and detection of early warning signs of OUD.[15]

The Cures Act also increases federal funding for states to develop and implement initiatives to reduce the opioid epidemic. The act authorizes a total of $1 billion in grants to states for 2017

[10] 42 U.S.C. § 290dd-3(c).
[11] 42 U.S.C. § 290bb–10 (2016), as added by Pub. L. No. 114-198, § 301.
[12] 42 U.S.C. § 290bb–10(c).
[13] 42 U.S.C. § 290ee-3 (2016), as added by Pub. L. No. 114-198, § 601.
[14] 42 U.S.C. § 290ee–3(c).
[15] 42 U.S.C. § 290ee–3(b)(2).

and 2018 and, as opposed to CARA, the statute authorizes appropriations of the funding for the first of the two fiscal years of the program.[16] The $500 million per year will be distributed across the 50 states for "the purpose of addressing the opioid abuse crisis within such states."[17] In awarding these grants, the HHS Secretary may give preference to states with a higher incidence or prevalence of OUD and may provide increased funding to such states.[18] States can use the awarded funding to improve their state PDMP; to implement prevention activities and evaluation of such activities to identify strategies to prevent opioid abuse; for training of health care practitioners, including best practices for prescribing OPRs, pain management, and recognition of potential cases of substance abuse; to support access to health care services and MAT for people with SUD and OUD; and for other public health activities related to addressing the opioid epidemic.[19]

Moreover, the Cures Act authorizes the HHS Secretary to award grants and cooperative agreements to states or state agencies collaborating with community health centers to support the integration of primary care and behavioral health care.[20] The act authorizes appropriation of $51.878 million per year from 2018 to 2022 for this purpose; each recipient may receive up to $2 million.[21] This funding is available for activities related to promotion of full integration and collaboration in clinical practices between primary and behavioral health care; support of integrated care models for primary care and behavioral health care; and promotion of integrated care services related to screening, diagnosis, prevention, and treatment of mental disorders and SUD, and co-occurring physical health conditions.[22]

Finally, the Cures Act authorizes and reauthorizes funding for new and current programs to address mental health and SUD (see Table 1 for a list of some of the programs authorized or reauthorized by the act).

Table 1. Mental Health and SUD Programs Authorized or Reauthorized by the 21st Century Cures Act

Program Name	Funding Appropriated[23]	Period	Purpose
Priority Mental Health Needs of Regional and National Significance Program[24]	$394.550 million	2018-2022	Support of prevention, treatment, and rehabilitation of mental health services

[16] Pub. L. No. 114-255, § 103.
[17] Pub. L. No. 114-255, § 103(c)(1).
[18] *Id*.
[19] Pub. L. No. 114-255, § 103(c)(2).
[20] 42 U.S.C. § 290bb–42 (2010), as amended by Pub. L. No. 114-255, § 9003.
[21] 42 U.S.C. § 290bb–42(h).
[22] 42 U.S.C. § 290bb–42(b)(2).
[23] Funding encompasses the full period of the program, unless otherwise indicated.
[24] 42 U.S.C. § 290bb–32 (2000), as amended by Pub. L. No. 114-255, § 7003.

Priority Substance Use Disorder Treatment Needs of Regional and National Significance Program[25]	$333.806 million	2018-2022	Improvement of quality and availability of treatment and rehabilitation services for SUD services in targeted areas
Community Mental Health Services Block Grant[26]	$532.571 million	2018-2022	Provision of community mental health services for individuals with serious mental illness and emotional disorders
Substance Abuse Prevention and Treatment Block Grant[27]	$1.858079 billion	2018-2022	Training for SUD prevention and treatment professionals on trends in drug abuse and evidence-based practices
Grants for Jail Diversion Programs[28]	$4.269 million for each fiscal year	2018-2022	Development and implementation of jail diversion programs to divert individuals with mental illness from the criminal justice system to community-based services
Projects for Assistance in Transition from Homelessness[29]	$64.635 million for each fiscal year	2018-2022	Provision of services to homeless individuals with serious mental illness and SUD
Assisted Outpatient Treatment Grant Program[30]	Increases gradually for each fiscal year	2018-2022	Implementation and evaluation of new assisted outpatient treatment programs to reduce incidence of psychiatric hospitalizations while improving health and social outcomes for people with mental illness.
Youth Suicide Early Intervention and Prevention Strategies Grant[31]	$30 million for each fiscal year	2018-2022	Initiation of youth suicide prevention activities and provision of resources to reduce the burden of suicidal behaviors among youth

III. Provisions Increasing Access to Mental Health and SUD Prevention and Treatment

Funding opportunities for opioid overdose prevention initiatives afforded by CARA and the Cures Act are complemented by other provisions in the statutes aimed at increasing access to treatment and rehabilitation services for people with mental health disorders and SUD.

A. Inpatient Opioid Addiction Treatment

[25] 42 U.S.C. § 290bb–2 (2000), as amended by Pub. L. No. 114-255, § 7004.
[26] 42 U.S.C. § 300x(b) (1992), as amended by Pub. L. No. 114-255, § 8001.
[27] 42 U.S.C. § 300x–21(b) (1992), as amended by Pub. L. No. 114-255, § 8002(a).
[28] 42 U.S.C. 290bb–38 (2000), as amended by Pub. L. No. 114-255, § 9002.
[29] 42 U.S.C. § 290cc et seq. (1992), as amended by Pub. L. No. 114-255, § 9004.
[30] 42 U.S.C. § 290aa (2010), as amended by Pub. L. No. 1114-255, § 9014.
[31] 42 U.S.C. § 290bb–36 (2016), as amended by Pub. L. No. 114-255, § 9008(b).

CARA expands access to MAT for individuals with SUD and OUD by expanding health care practitioners' authority to prescribe and administer the medication buprenorphine. Buprenorphine is highly effective in treating SUD and in preventing relapse and overdoses.[32] Despite its demonstrated effectiveness and safety, pursuant to federal law, practitioners are required to obtain a waiver from HHS before being able to provide treatment with buprenorphine to an individual with SUD.[33] The law specifies that this waiver authorizes health care practitioners to treat up to 30 patients with SUD during the first year following approval of the waiver request and up to 100 patients thereafter.[34] Prior to enactment of CARA, however, only physicians authorized to prescribe controlled substances were eligible to apply for the buprenorphine waiver.

Under federal law, the Substance Abuse and Mental Health Services Administration (SAMHSA) has the authority to expand, through regulation, the maximum number of patients that a physician can treat with buprenorphine.[35] Pursuant to this authority, SAMHSA recently promulgated a rule allowing physicians who already hold a waiver to treat 100 patients with buprenorphine to treat up to 275 patients with SUD at any given time.[36] The rule specifies that a physician is eligible to obtain the new waiver if he or she has additional credentialing in addiction medicine from a specialty medical board or professional society or practices medicine in a "qualified setting,"; provides access to case-management services for patients; uses health information technology if required to use it; is registered to use the state PDMP; and accepts third party payments for costs in providing health services.[37]

CARA expanded eligibility to obtain a buprenorphine waiver to include non-physician health care practitioners. Pursuant to the act, nurse practitioners (NPs) and physician assistants (PAs) can now obtain a waiver to prescribe buprenorphine for up to 30 patients with SUD at a time.[38] Before applying for the waiver, NPs and PAs must be licensed under state law to prescribe Schedule III, IV, or V medications for the treatment of pain; must have completed at least 24 hours of training for the treatment of opioid dependency or have any other training deemed by the HHS Secretary as demonstrating ability to treat and manage opioid dependency; and, if required by state law, must work in collaboration with or under supervision of a qualifying physicians during the treatment of opioid dependency.[39]

In November 2016, SAMHSA announced the development of the training on opioid dependency that NPs and PAs will be required to complete before being approved for a waiver to prescribe

[32] *See* Bennett W. Fletcher & Robert J. Battjes, *Introduction to the Special Issue: Treatment Process in DATOS*, 57 DRUG AND ALCOHOL DEPENDENCE 81 (1999); Linda Gowing et al., *supra* note 5.
[33] 21 U.S.C. § 823(g)(2)(A) (2016).
[34] 21 U.S.C. § 823(g)(2)(B)(iii)(I)–(II).
[35] 21 U.S.C. § 823(g)(2)(B)(iii)(III).
[36] 42 C.F.R. §§ 8.610 – 8.655 (2016).
[37] 42 C.F.R. § 8.610. The regulations define the term "qualified setting" as a practice setting that provides professional coverage for patient medical emergencies during hours when the practitioner's practice is closed
[38] 21 U.S.C. § 823(g)(2)(G)(iv), as added by Pub. L. No. 114-198, § 303(a)(1)(C)(v). *See also* 42 C.F.R. § 8.615.
[39] *Id*.

buprenorphine.[40] Once training is completed, NPs and PAs will be able to apply for and obtain a waiver to prescribe buprenorphine beginning in early 2017. The agency also announced that it will soon seek to initiate rulemaking to allow NPs and PAs who have a had a waiver to treat up to 30 patients with buprenorphine for a year to apply for a new waiver that permits them to treat a maximum of 100 patients at any given time, further increasing the opportunities for individuals with OUD to access evidence-based MAT.[41]

CARA also introduced an important change in the way the number of patients with SUD that a health care practitioner treats with buprenorphine is calculated. Before the passage of CARA, patients to whom buprenorphine was directly administered by a practitioner in a medical office setting (outside of a substance treatment center) were included in this calculation. Because of buprenorphine's demonstrated safety and effectiveness, in-office administration of the medication is effective as an early intervention strategy for individuals with short SUD histories or with less physical dependence.[42] Pursuant to CARA, the HHS Secretary now has the authority to exclude patients to whom buprenorphine is directly administered in an office setting from the maximum number of patients that a practitioner can treat with buprenorphine at any given time.[43] This provision is expected to significantly increase the number of patients with SUD being treated with MAT and the number of patients to whom buprenorphine is directly administered by a provider in a medical office setting.[44]

B. Changes in Medicaid Policy

The Cures Act introduced significant changes to Medicaid policy with regards to mental health and SUD benefits. Because Medicaid is the single largest source of health care coverage for people with mental health disorders and SUD, these changes are likely to have a substantial impact on mental health treatment in the U.S.[45] In particular, two provisions in the law are expected to dramatically expand access to treatment for beneficiaries with SUD by enhancing reimbursement for services related to mental health and SUD.

First, the Cures Act clarifies that separate payment for the provision of mental health and primary services provided to an individual on the same day is not prohibited.[46] Prior to the

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[40] Dept. of Health and Human Services, HHS takes additional steps to expand access to opioid treatment, November 16, 2016, https://www.hhs.gov/about/news/2016/11/16/additional-steps-expand-opioid-treatment.html (last visited Jan. 27, 2017).
[41] *Id*.
[42] Richard K. Ries et al., *Principles of Addiction Medicine* (4th ed. 2009).
[43] 21 U.S.C. § 823(g)(2)(B)(iii)(IV), as added by Pub. L. No. 114-198, § 303(a)(1)(A).
[44] Moreover, while CARA affords states the flexibility to reduce the limit of patients that a practitioner can treat with buprenorphine, the act prohibits states from imposing a limit lower than 30 patients. 21 U.S.C. § 823(g)(2)(I)(i), as added by Pub. L. No. 114-198, § 303(b).
[45] Deborah Bachrach et al., *Medicaid: States' Most Powerful Tool to Combat the Opioid Crisis*, July 2016, http://statenetwork.org/wp-content/uploads/2016/07/State-Network-Manatt-Medicaid-States-Most-Powerful-Tool-to-Combat-the-Opioid-Crisis-July-2016.pdf (last visited Feb. 10, 2017).
[46] Pub. L. No. 114-255, § 12001. This provision provides: "Nothing in title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) shall be construed as prohibiting separate payment under the State plan under such title (or under a waiver of the plan) for the provision of a mental health service or primary care service under such plan, with respect to an individual, because such service is—

passage of the act, mental health providers were not able to bill Medicaid for services provided to a beneficiary who also received services from a primary care provider on the same day. The result of this policy was that beneficiaries had to schedule primary care and mental health services on different days regardless of the proximity of the providers' place of business. This problem also made it difficult for Medicaid to integrate mental health with primary care and other services. Under the Cures Act, both mental health and primary care providers are now able to bill Medicaid for services provided to a beneficiary on the same day, a fix that is expected to help patients with SUD by encouraging the integration of mental health care with physical care. Second, pursuant to the Cures Act, children receiving Medicaid-covered inpatient psychiatric hospital services will now also be eligible for the full range of Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) services provided in an institution for mental diseases (IMD). Under Medicaid law and regulations, federal financial participation (FFP) is not available for services provided to an individual who is under age 65 and who is a patient in an IMD.[47] This limitation is known as the IMD exclusion, and, prior to the Cures Act, it excluded coverage preventive services provided to Medicaid enrollees under 21 provided in these institutions.[48] The Cures Act lifts this prohibition so that Medicaid beneficiaries under 21 who are being treated in an IMD can receive the full range of preventive services in Medicaid's EPSDT benefit, expanding access to preventive services for children with mental disorders and substance and opioid dependency.[49]

C. Mental Health Parity

The Mental Health Parity and Addiction Equity Act (MHPAEA) and the Affordable Care Act (ACA) generally require most health insurance plans to treat mental health and SUD benefits on equal footing with medical and surgical benefits.[50] This means that plans cannot impose limitations on mental health and SUD benefits that are more restrictive than limitations imposed on coverage of other services. The parity requirement applies to group health plans, individual plans offered through the ACA marketplace, Medicaid Alternative Benefit Plans (ABPs), and Medicaid managed care plans.[51] Because of the complexity of the parity law and enforcement difficulties, however, ensuring compliance with the requirement has been proven challenging and many insurance plans continue to impose onerous restrictions on mental health and SUD

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(1) a primary care service furnished to the individual by a provider at a facility on the same day a mental health service is furnished to such individual by such provider (or another provider) at the facility; or
(2) a mental health service furnished to the individual by a provider at a facility on the same day a primary care service is furnished to such individual by such provider (or another provider) at the facility."

[47] 42 U.S.C. § 1396d(a)(B) (providing that medical assistance payment is not available for services provided to individuals aged 21 to 65 in IMDs).

[48] While the IMD exclusion was subsequently amended to permit IMDs to bill Medicaid for mental health treatment provided to enrollees under 21, these institutions were still prohibited from billing Medicaid for provision of EPSDT benefits.

[49] 42 U.S.C. § 1396d(a)(16) (2013), as amended by Pub. L. No. 114-255, § 12005. This provision will go into effect in January 2019.

[50] 42 U.S.C.A. § 300gg–26 (2010).

[51] *See* 29 U.S.C. § 1185(a) (2009) (applying the MHPAEA's parity requirements to employer-sponsored health insurance plans); 42 U.S.C. § 18031(j) (2015) (applying the MHPAEA's parity requirements to qualified health plans); 42 U.S.C. § 1396u-7(b)(6)(A) (applying the MHPAEA's parity requirements to Medicaid ABPS, previously known as benchmark and benchmark-equivalent Medicaid plans); and 42 U.S.C. § 1396u-2(b)(8) (2015) (applying the MHPAEA's parity requirements to Medicaid managed care organizations).

coverage that do not conform with the requirement.[52] The Cures Act seeks to strengthen and facilitate enforcement of the mental health parity requirement by requiring federal agencies to provide guidance on the rules and by expanding the agencies' role in assessing compliance.

The Cures Act first requires the HHS, the Department of Labor, and the Department of Treasury to release compliance guidance on the parity requirement no later than June 2017.[53] The statute specifies that this guidance should include illustrative examples of past findings of compliance and noncompliance and descriptions of the violations that were uncovered during past investigations into health plans compliance with the parity requirement.[54] Examples may include disclosure requirements and quantitative and non-quantitative treatment limitations. The act also requires the departments to include in the guidance recommendations to advance compliance and to encourage plans to adopt internal controls to monitor adherence to the parity requirement.[55] The federal government, furthermore, must update the guidance every two years and add new examples of compliance and noncompliance every time the guidance is updated.[56]

The Cures Act also provides the Secretaries of HHS, Labor, and Treasury with the authority to audit health plans to assess their compliance with mental health plans.[57] The statute specifies that this authority will be triggered when a group health plan or health insurance issuer offering group or individual health insurance has violated the parity requirement at least five times. Pursuant to the statute, the Secretaries will audit the health plan documents in the plan year following the fifth determination of noncompliance in order to help improve compliance with the parity requirement in the subsequent years.

Finally, the Cures Act strengthens enforcement of metal health parity requirements by enhancing and encouraging coordination of efforts between the federal government and states. To advance this goal, the act requires HHS to produce an action plan for improved coordination of enforcement efforts no later than June 2017.[58] The action plan must take into consideration the White House Mental Health and Substance Use Disorder Parity Task Force's recommendations, and must reflect input from various stakeholders, including the Department of Justice, the Department of the Treasury, state health insurance commissioners, health insurance issuers, and providers of mental health and SUD treatment.[59] Specifically, the action plan should identify strategic objectives for collaboration between federal and state agencies and provide a timeline for implementation of these objectives. The Cures Act also provides examples of how the strategic objectives could be met, including:

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[52] *See* Michael Ollove, *Despite Laws, Mental Health Still Getting Short Shrift*, Stateline, May 7, 2015, http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2015/5/07/despite-laws-mental-health-still-getting-short-shrift (last visited Feb. 7, 2017). *See also* A Long Road Ahead, National Alliance on Mental Illness (2015), http://www.nami.org/About-NAMI/Publications-Reports/Public-Policy-Reports/A-Long-Road-Ahead/2015-ALongRoadAhead.pdf (last visited February 7, 2017); Elizabeth Edwards. *Mental Health Parity and Addiction Equity Act of 2008 Final Regulations and Federal Guidance*, National Health Law Program, January 2014;
[53] 42 U.S.C. § 300gg-26(a) (2010), as amended by Pub. L. NO. 114-255, § 13001(a).
[54] 42 U.S.C. § 300gg-26(a)(6)(B).
[55] 42 U.S.C. § 300gg-26(a)(6)(C).
[56] 42 U.S.C. § 300gg-26(a)(6)(D).
[57] Pub. L. NO. 114-255, § 13001(d).
[58] Pub. L. NO. 114-255, § 13002.
[59] Pub. L. NO. 114-255, § 13002(c).

- Providing common educational information and documents to patients about their rights under the mental health parity requirements;
- Facilitating the collection of patient complaints and inquiries relating to the parity requirement;
- Developing memoranda of understanding between federal and state law enforcement agencies to better coordinate enforcement responsibilities and sharing of information; and
- Recommending Congress to provide additional legal authority for improvement of enforcement of the parity requirement.

D. Mental Health Treatment and Patient Privacy under HIPAA

The Cures Act seeks to improve the quality of treatment for patients with serious mental illnesses by facilitating supported decision making in areas where the patient's mental illness may impact his or her capacity to determine a course of treatment.[60] Regulations promulgated pursuant to the Health Insurance Portability and Accountability Act (HIPAA) generally prohibit mental health providers from sharing personal information related to a patient's SUD diagnosis and treatment, unless the patient consents to the sharing of information.[61] Through the Cures Act, Congress sought to clarify situations in which a health care provider may disclose protected personal information for the purpose of securing the best course of treatment for a patient with a serious mental illness. As such, the Cures Act requires the HHS Secretary to issue guidance clarifying the extent of HIPAA when treating patients with serious mental illnesses.

The HIPAA provisions of the Cures Act require the Office for Civil Rights of HHS to "ensure that health care providers, professionals, patients, and their families, and others involved in mental or [SUD] treatment have adequate, accessible, and easily comprehensible resources relating to appropriate uses and disclosures of protected health information […]."[62] Moreover, the act instructs the HHS Secretary to issue guidance clarifying the circumstances under which a provider may use or disclose protected health information of adults or minor patients with serious mental health illnesses to family members, caregivers, other individuals involved in the care of the patient, and law enforcement.[63] This guidance should facilitate treatment decisions in situations where serious mental health illness may affect the capacity of an individual to determine a course of treatment without assistance.

At the same time, however, the Cures Act preserves the privacy protections afforded by HIPAA. While a previous version of the legislation would have significantly altered the language of the HIPAA privacy rule, the adopted measure did not include actual changes to the rule. Instead, the Cures Act only requires HHS to clarify situations in which disclosure of protected information is warranted pursuant to HHS's current privacy rule.[64] In other words, HHS's guidance should

[60] Pub. L. No. 114-255, § 11001(b).
[61] 42 U.S.C. § 1320d (2010) (defining protected health information as "past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual"); *See also* 42 C.F.R. §§ 2.13, 2.33 (2017) (extending HIPAA protections to patients' records related to alcohol and drug abuse).
[62] Pub. L. No. 114-255, § 11003(a).
[63] Pub. L. No. 114-255, § 11003(b).
[64] Pub. L. No. 114-255, § 11003(b)(2)–(3).

provide examples of exceptions to the general rule prohibiting disclosure without patient consent without altering the current requirements of the privacy rule.

Relatedly, HHS recently promulgated a rule increasing providers' flexibility to use substance abuse and treatment records.[65] This rule eases the restrictions on sharing of SUD records between providers in a way that seeks to increase treatment coordination for patients with mental and substance use disorders. While providers were previously required to get approval from patients each time substance abuse-related information was shared, the new rule only requires providers to ask patients to sign a single consent form that establishes which information they are disclosing and acknowledging that the patient is aware that the information is being disclosed. The Cures Act requires the HHS Secretary to convene "relevant stakeholders to determine the effect of such regulations on patient care, health outcomes, and patient privacy."[66] The legislation requires HHS to take this action no later than a year after the rule is finalized.

E. Increased Access to Care for Veterans at Risk of Overdose

CARA expands access to prevention and treatment services for veterans at risk of an opioid-related overdose in several ways. First, the act makes grants available for states, local governments, or nonprofit organizations for establishment or expansion of one of the following programs to provide SUD and OUD-related services for qualified veterans:[67]

- Veterans treatment court programs;[68]
- Peer-to-peer services;[69]
- Practices that identify and provide treatment, rehabilitation, legal, transitional, and other appropriate services to qualified veterans who have been incarcerated; or

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[65] Alicia Ault, *Feds Issue Final Rule on Sharing of Substance Abuse Records*, Medscape Medical News, January 13, 2017, http://www.medscape.com/viewarticle/874445 (last visited Feb. 10, 2017). As of February 10, 2017, this rule has been put on hold by the Trump administration. Andrea Restuccia & Nick Juliano, *White House orders 'immediate regulatory freeze'*, January 20, 2017, http://www.politico.com/story/2017/01/white-house-orders-immediate-regulatory-freeze-233951 (last visited Feb. 16, 2017).

[66] Pub. L. No. 114-255, § 11002.

[67] CARA defines "qualified veterans" as "a preliminary qualified offender who (i) served on active duty in any branch of the Armed Forces, including the National Guard or Reserves; and (ii) was discharged or released from such service under conditions other than dishonorable, unless the reason for the dishonorable discharge was attributable to a [SUD]." 42 U.S.C. § 3797aa(i)(1)(B) (2016), as added by Pub. L. No. 114-198, § 502(2).

[68] The law defines "veterans treatment court programs" as "a court program involving collaboration among criminal justice, veterans, and mental health and substance abuse agencies that provides qualified veterans with--

> (i) intensive judicial supervision and case management, which may include random and frequent drug testing where appropriate;
> (ii) a full continuum of treatment services, including mental health services, substance abuse services, medical services, and services to address trauma;
> (iii) alternatives to incarceration; or
> (iv) other appropriate services, including housing, transportation, mentoring, employment, job training, education, or assistance in applying for and obtaining available benefits."

42 U.S.C. § 3797aa(i)(1)(C), as added by Pub. L. No. 114-198, § 502(2).

[69] The law defines "peer-to-peer services" as "services or programs that connect […] veterans with other veterans for the purpose of providing support and mentorship to assist qualified veterans in obtaining treatment, recovery, stabilization, or rehabilitation."42 U.S.C. § 3797aa(i)(1)(A), as added by Pub. L. No. 114-198, § 502(2).

- Training programs to teach criminal justice, law enforcement, corrections, mental health, and substance abuse personnel how to identify and appropriately respond to incidents involving qualified veterans.[70]

CARA also requires the Department of Veterans Affairs (VA) to expand its Opioid Safety Initiative (OSI) to include all VA medical facilities.[71] Because opioid overdose is higher among veterans than among non-veterans, the VA implemented OSI as an educational aid for VA physicians treating pain with opioids.[72] The initiative generally follows the Centers for Disease Control and Prevention's (CDC) prescribing guidelines and establishes a process for pain management at VA facilities that does not rely solely on opioid prescribing. Prior to the enactment of CARA, the OSI program was launched as a pilot program in selected sites across the country. Because of the program's demonstrated success in reducing the use of opioids among veterans being treated for pain, CARA now instructs the VA to expand the initiative to all VA medical facilities.[73]

In expanding OSI, CARA also requires the VA to ensure that physicians treating veterans for pain have access to state PDMPs in order to determine whether the patient has been prescribed opioids outside of the VA facility.[74] Furthermore, the legislation instructs the VA Secretary to enter into memoranda of understanding with state governments to facilitate the VA's access to each state's PDMP data.[75]

CARA also introduced various policies to increase veteran's access to naloxone. First, the act requires the Department of Veterans Affairs to make sure that each pharmacy of the Department is equipped with naloxone to be dispensed to patients as needed.[76] Second, CARA expands the VA's Overdose Education and Naloxone Distribution program, which ensures that veterans who are at risk of opioid overdose have access to life-saving medications by training patients on proper naloxone administration techniques and how to prevent, recognize, and respond to an opioid overdose.[77] Finally, CARA eliminates copayment requirements for coverage of naloxone when it is dispensed to a veteran who is at high risk of opioid overdose and for veterans receiving education regarding the use of naloxone to reverse an overdose.[78]

IV. Criminal Law Reform Provisions in CARA and the Cures Act

CARA and the Cures Act continue the federal government's recent shift in efforts to combat the opioid epidemic from an emphasis on law enforcement to an increasing acknowledgement of the

[70] 42 U.S.C. § 3797aa(i)(2)(A), as added by Pub. L. No. 114-198, § 502(2).
[71] 38 U.S.C. § 1701 (2008), as added by Pub. L. No. 114-198, § 911(a).
[72] Dept. of Veterans' Affairs, VA Initiative Shows Early Promise in Reducing Use of Opioids for Chronic Pain, February 25, 2014, https://www.va.gov/opa/pressrel/pressrelease.cfm?id=2529 (last visited Feb. 10, 2017).
[73] Lewei A. Lin et al., *Impact of the Opioid Safety Initiative on Opioid-Related Prescribing in Veterans*, 10.1097 PAIN (2017).
[74] 38 U.S.C. § 1701 (2008), as added by Pub. L. No. 114-198, § 911(d)(1).
[75] 38 U.S.C. § 1701, as amended by Pub. L. No. 114-198, § 911(d)(1)(A).
[76] 38 U.S.C. § 1701, as amended by Pub. L. No. 114-198, § 911(e)(1)(B)(i).
[77] 38 U.S.C. § 1701, as amended by Pub. L. No. 114-198, § 911(e)(1)(B)(ii).
[78] 38 U.S.C. § 1722A(a)(4) (2016), as amended by Pub. L. No. 114-198, § 914(a); 38 U.S.C. § 1710(g)(3)(B) (2016), as amended by Pub. L. No. 114-198, § 914(b).

importance of evidence-based initiatives to prevent and treat mental health disorders and SUD. Both statutes include poignant language highlighting the importance of diversion programs that direct people detained for low-level drug law violations away from the criminal justice system and into evidence-based treatment and substance abuse services. The statutes also provide support for training of law enforcement officials on how to manage situations with persons with mental illnesses and SUD and for the establishment of drug and mental health courts.

CARA provides for the expansion of programs that reduce the role of criminalization in state and local drug control efforts in several ways. First, the law authorizes the HHS Secretary to make grants available to states, local governments, Indian tribes, and nonprofit organizations to develop, implement, or expand treatment alternatives to incarceration, including training for law enforcement personnel on SUD and co-occurring mental illness, establishment of a mental health court, and establishment of a community-based substance use diversion program sponsored by a law enforcement agency.[79] Grants are also available for states to improve coordination between law enforcement agencies and substance abuse agencies in order to "more efficiently and effectively carry out activities or services […] that address problems related to opioid abuse."[80] Similarly, CARA makes grants available for training first responders and other criminal justice personnel on the use of MAT, including buprenorphine and methadone, and naloxone.[81]

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[79] 42 USC § 3797ff(a)(1) (2016), as added by Pub. L. No. 114-198, § 201(a)(1), provides: "the Attorney General may make grants to States, units of local government, and Indian tribes, for use by the State, unit of local government, or Indian tribe to provide services primarily relating to opioid abuse, including for […] [d]eveloping, implementing, or expanding a treatment alternative to incarceration program, which may include—[…]

> (B) training for criminal justice agency personnel on substance use disorders and co-occurring mental illness and substance use disorders;
> (C) a mental health court […];
> (D) a drug court […];
> (E) a veterans treatment court program […];
> (F) a focus on parents whose incarceration could result in their children entering the child welfare system; and
> (G) a community-based substance use diversion program sponsored by a law enforcement agency."

[80] 42 USC § 3797ff(a)(2), as added by Pub. L. No. 114-198, § 201(a)(1).

[81] 42 USC § 3797ff(a)(3)–(5), as added by Pub. L. No. 114-198, § 201(a)(1), provides: "the Attorney General may make grants to States, units of local government, and Indian tribes, for use by the State, unit of local government, or Indian tribe to provide services primarily relating to opioid abuse, including for […]:

> (3) Providing training and resources for first responders on carrying and administering an opioid overdose reversal drug or device approved or cleared by the Food and Drug Administration, and purchasing such a drug or device for first responders who have received such training to so carry and administer.
> (5) Developing, implementing, or expanding a medication-assisted treatment program used or operated by a criminal justice agency, which may include training criminal justice agency personnel on medication-assisted treatment […]"

See also 42 USC 290ee-1 (2016), as added by Pub. L. No. 114-198, § 202, which provides, in relevant part: "An entity shall use a grant received under this section to--

> (1) make a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose available to be carried and administered by first responders and members of other key community sectors;
> (2) train and provide resources for first responders and members of other key community sectors on carrying and administering a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose; and
> (3) establish processes, protocols, and mechanisms for referral to appropriate treatment, which may include an outreach coordinator or team to connect individuals receiving opioid overdose reversal drugs to followup services."

Several provisions of the Cures Act provide support for criminal justice reforms and for diverting individuals with mental health and substance use disorders away from jails and into evidence-based SUD treatment. For example, the legislation authorizes the U.S. Attorney General to establish a pilot program to determine the effectiveness of diverting drug law offenders away from prosecution and placing them in drug or mental health courts.[82] The pilot program will involve judicial supervision of participants with SUD or mental illness; mandatory periodic testing for the use of controlled substances; substance abuse treatment for each participant who requires such services; diversion or supervised release based on compliance with the program requirements; case management (including education, vocational training, and job and housing placement); and outpatient or inpatient mental health treatment.[83]

The Cures Act also makes grants available to states, local governments, Indian Tribes, and nonprofit agencies for development of "behavioral health screening and assessment program framework[s] for state or local criminal justice systems."[84] The grant funding must be used for the following purposes:

- Promoting use of assessment tools to assess substance abuse needs and mental health needs of individuals;
- Establishing initiatives to match the risk factors and needs of individuals to programs and practices associated with research-based outcomes;
- Implementing methods for identifying and treating individuals who are most likely to benefit from coordinated supervision and treatment; and
- Establishing collaborative decision-making strategies among the heads of criminal justice agencies, mental health systems, judicial systems, substance abuse systems, and others.

Moreover, the Cures Act provides grant opportunities for states and local governments to develop and implement specialized SUD treatment programs for inmates with SUD and other mental illnesses and for development, implementation, or expansion of treatment alternative to incarceration programs.[85] Finally, the act provides numerous opportunities for training of law enforcement and criminal justice personnel to respond to situations involving a person with a mental health or substance use disorder. For example, the Act authorizes the U.S. Attorney General to make grants available for law enforcement officer orientation programs and education training that teach state and federal law enforcement personnel how to identify and respond to incidents involving persons with mental health and substance use disorders.[86] The act also requires the Attorney General to, no later than December 2018, issue guidance on training programs that offer specialized and comprehensive training for first responders on how to respond to situations involving an individual with a mental health disorder or a SUD.[87]

[82] Pub. L. No. 114-255, § 14003(b).
[83] Pub. L. No. 114-255, § 14003(c).
[84] 42 U.S.C. § 3796ii et seq. (2000), as amended by Pub. L. No. 114-255, § 14004.
[85] 42 U.S.C. § 3711 et seq. (1984), as amended by Pub. L. No. 114-255, § 14013.
[86] 42 U.S.C. § 3797aa(h), as amended by Pub. L. No. 114-255, § 14024(1).
[87] Pub. L. No. 114-255, § 14008(a)(1).

V. Strengthening Leadership and Accountability for Mental Health and SUD Services

The Cures Act introduced several provisions to strengthen federal oversight of mental health and SUD services. The most important of these measures is the establishment of the position of Assistant Secretary for Mental Health and Substance Use as the new head of SAMHSA.[88] The Assistant Secretary will be vested with all duties and authorities that were previously vested in the Administrator of SAMHSA. The act also requires the Assistant Secretary to appoint a Chief Medical Officer in charge of evaluating, organizing, integrating, and coordinating programs between HHS and SAMHSA.[89] The Chief Medical Officer will also promote evidence-based practices regarding prevention and treatment of mental health disorders and SUD and will assess the use of performance metrics to evaluate prevention and treatment programs and activities.[90]

The legislation also creates the Interdepartmental Serious Mental Illness Coordinating Committee.[91] This committee is charged with evaluating federal programs related to serious mental illness and with providing recommendations on how to better coordinate mental health services for people with SUD.[92] In addition, the Cures Act requires SAMHSA, in collaboration with state and local governments, to develop a strategic plan no later than September 2018 for the planning and operation of activities carried out by the agency, including development of programs to increase access to quality services for individuals with mental health disorders and SUD.[93] The strategic plan must include strategies to encourage individuals to pursue careers in mental health and for strengthening of the mental health workforce.[94]

VI. Conclusion

The passage, with overwhelmingly bipartisan support, of CARA and the Cures Act represents a step in the right direction in the fight against the opioid epidemic. These new laws provide much needed increases in funding for programs improving access to MAT and naloxone for individuals with SUD and OUD who are at risk of opioid-related overdose. These medications have been consistently proven effective in reducing the effects of substance and opioid use disorders and, in the case of naloxone, help reverse ongoing overdoses. The acts also provide funding for training of first responders and other criminal justice personnel, which will help officials deescalate crises involving individuals with mental illness and SUD. Moreover, by funding jail diversion and rehabilitation programs, the acts emphasize the importance of public health-based, scientifically-sound interventions in reducing the impact of the opioid epidemic. CARA and the Cures Act will expand upon the resources to combat the opioid epidemic and the strides already achieved through the ACA's Medicaid expansion and individual marketplaces.[95]

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[88] 42 U.S.C. § 290aa(c) (2010), as amended by Pub. L. No. 114-255, § 6001(a).
[89] 42 U.S.C. § 290aa(g)(1), as amended by Pub. L. No. 114-255, § 6003(4).
[90] 42 U.S.C. § 290aa(g)(3).
[91] Pub. L. No. 114-255, § 6031.
[92] Pub. L. No. 114-255, § 6031(c).
[93] 42 U.S.C. § 290aa, as amended by Pub. L. No. 114-255, § 6005.
[94] 42 U.S.C. § 290aa(l)(4)(D).
[95] For a discussion on how CARA's and the Cures Act's funding ties to achievements made by the ACA, *see* Corey Davis & Hector Hernandez-Delgado, *Medicaid and the Affordable Care Act: Vital Tools in Addressing the Opioid Epidemic*, National Health Law Program (February 7, 2017).