THORN RUN PARTNERS
GOVERNMENT RELATIONS

Issue Brief – Opioid Policy Developments

May 3, 2016

I. EXECUTIVE SUMMARY

Opioid abuse has assumed a prominent role in federal policymaking, with Congress and the Administration seeking to advance solutions to a mounting epidemic. According to a recent Department of Health and Human Services (HHS) report, opioid overdose deaths quadrupled between 1999 and 2013, while only 1 million of an estimated 2.5 million people who may benefit from medication-assisted treatment (MAT) for opioid use disorder receive it.[1] Amid the increased public health toll of the epidemic and corresponding policy attention, this brief examines the landscape of opioid-related federal policy, including recent milestones, current status, and prospects for upcoming implementation.

II. ADMINISTRATION PRIORITIES

On March 26, 2015, the Obama Administration announced a three-part, targeted initiative aimed at reducing prescription opioid and heroin-related abuse and overdoses.[2] The three priority areas targeted by the initiative include:

- Providing training, resources, and guidelines to help providers make prescribing decisions;
- Increasing the uptake of naloxone, a drug that reverses overdoses; and
- Expanding the use of MAT, which combines use of Food and Drug Administration (FDA)-approved medicines with counseling and behavioral therapy to treat opioid use disorder.

In announcing its initiative, the Administration cited efforts underway to work with lawmakers for legislation requiring specific training for safe opioid prescribing and efforts to establish new opioid prescribing guidelines for chronic pain. Among other strategies, the Administration highlighted its intentions to promote states' use of Substance Abuse Block Grant funds to purchase naloxone, as well as states' use of federal funding to train first responders on its use.[3]

Ensuing steps in the Administration's efforts include:

September 2015 – HHS convenes a two-day conference with representatives of all 50 states and announces upcoming plans to revise regulations that currently cap the number of patients that physicians may treat with buprenorphine, one of three available FDA-approved MATs.[4] The agency also awards $1.8 million in grants promoting naloxone use in 13 rural states.[5]

October 2015 – The Administration announces additional efforts enhance prescriber training and to improve access to MAT.[6] For example, it requires federal agencies to

conduct a review to identify and address barriers to MAT for opioid use disorders. The Administration also announces partnerships with state and local agencies to assist in provider training and with the private sector to promote awareness of the opioid epidemic. The announcement highlights ongoing federal initiatives to prevent, treat, and reduce the supply of opioids through, for example, National Take-Back Days and through planned guidelines for prescribing opioids for chronic pain.

January 2016 – CMS' Center for Medicaid and CHIP Services releases guidance highlighting best practices for addressing prescription drug misuse and overdoses in Medicaid.[7]

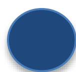
February 2016 – The President's fiscal year (FY) 2017 Budget Request includes $1.1 billion in new mandatory funding over two years to expand access to treatment for prescription drug abuse and heroin use, as well as $500 million to continue current federal efforts to expand state drug overdose prevention efforts, increase the availability of MAT programs, improve access to naloxone, and support law enforcement activities.[8] The vast majority – $920 million – would be directed toward states' efforts to expand access to MAT, with funding allocated based on the severity of the epidemic and on the strength of the state strategy to respond.

February 2016 – The FDA calls for a "sweeping review" of opioid policies, including those related to risk-benefit analysis and abuse deterrence, with subsequent announcements of class-wide labeling changes for immediate-release products highlighting addiction and misuse risks.[9]

March 2016 – The Centers for Disease Control and Prevention (CDC) releases highly anticipated final opioid prescribing guidelines for primary care physicians addressing opioids' use in treating adults with chronic pain in outpatient settings.[10] Across its 12 specific recommendations, the CDC emphasizes a preference for non-opioid therapy in cases other than active cancer, palliative, and end-of-life care and recommends that providers use the lowest possible effective dose to combat abuse and overdose risks.[11]

March 2016 – The Substance Abuse and Mental Health Services Administration (SAMHSA) releases a proposed rule that would change restrictions on the number of patients per practitioner that may be prescribed buprenorphine-containing products to treat opioid dependence.[12] The proposal would raise the existing limit of 100 patients per practitioner to 200 patients for a subset of practitioners, provided they fulfill several additional requirements. Among these requirements, providers must submit a Request for Patient Limit Increase form to SAMHSA, and must either possess a subspecialty board certification in addiction medicine or addiction psychiatry, or must practicing in a specified "qualified practice setting." Providers with the higher limit are subject under the proposal to greater responsibility for patient care-coordination as well as additional

data reporting and monitoring. The comment period for the proposed rule is open through **May 31, 2016**.



Later in 2016 – The U.S. Surgeon General is expected to release a sweeping report on substance abuse and addiction, which is likely to address opioid abuse and be accompanied by a national awareness campaign.[13]

III. CONGRESSIONAL ACTION

While the Administration has pursued its multi-faceted approach, Congress has held numerous hearings on opioid abuse and is poised for bicameral passage of separate measures that, despite some overlapping priorities, will ultimately have to be reconciled in conference. Spending is expected to be a particularly critical issue in conference because the House bills do not authorize any new spending and uses pay-go procedures that, among the targeted committee-advanced bills, would cut the CDC budget to offset some grant programs.[14] House Democrats have pressed for additional funding, including seeking an amendment during E&C Committee markup to add $1 billion in emergency funding that was defeated (24-22).[15]

On March 10, 2016, the Senate overwhelmingly passed (94-1) the Comprehensive Addiction and Recovery Act (CARA).[16] Only Sen. Ben Sasse (R-NE) opposed the measure in light of his concerns with the degree of federal involvement in combating addiction. Rather than take up the Senate-passed CARA, the House has advanced separate legislation in conjunction with numerous additional bills that are expected to comprise a still-emerging package for consideration on the House floor when the House reconvenes during the week of May 9.[17]

The emerging House package is likely to use the House Judiciary Committee-advanced Comprehensive Opioid Abuse Reduction Act of 2016 (H.R. 5046) as the "centerpiece" of the package, along with a subset of recent bills advanced by the House Energy and Commerce (E&C) and Judiciary Committees.[18] Following is a side-by-side of the Senate-passed CARA and the House's H.R. 5046. Appendix A of this issue brief provides a snapshot of additional House E&C and Judiciary-advanced bills that may be folded into a package for floor consideration.

Side-by-Side: Senate-Passed CARA; House Legislation

Issue	***Senate*** **Comprehensive Addiction and Recovery Act of 2015 (CARA)**[19]	***House*** **Comprehensive Opioid Abuse Reduction Act of 2016 (COARA)**[20]
Task Force	Directs HHS to establish a Pain Management Best Practices Inter-Agency Task Force to develop best practices for prescribing pain medication and a strategy for disseminating best practices.	N/A
Awareness	Provides for awareness campaigns.	N/A
IMD Exclusion	Directs the Comptroller General to report on the impact that the Medicaid Institutions for Mental Disease exclusion has on access to treatment for individuals with a substance use disorder.	N/A
Grant programs	Amends the Omnibus Crime Control and Safe Streets Act of 1968 to authorize the Attorney General to make grants to states, local governments, nonprofit organizations and tribal agencies.	Same
Education	Funds grants that expand prevention and educational efforts—particularly aimed at teens, parents, caretakers, and aging populations—to prevent the abuse of opioids and heroin and to promote treatment and recovery.	Funds grants aimed at developing, implementing, or expanding programs to prevent and address opioid abuse by juveniles in particular.
MAT	Funds grants that: • Expand the availability of naloxone to law enforcement agencies and other first responders to help in the reversal of overdoses to save lives; • Create a demonstration law enforcement program to prevent opioid and heroin overdose death.	Funds grants that: • Provide training and resources for first responders on carrying and administering a FDA-approved opioid overdose reversal drugs or devices. • Develop, implement, or expand a MAT program used or operated by a criminal justice agency.
Rx Drugs	Funds grants that: • Strengthen prescription drug monitoring programs to track prescription drug diversion; • Expand disposal sites for unwanted prescription medications to keep them out of the hands of children and adolescents.	Funds grants that: • Locate or investigate illicit activities related to the unlawful distribution of opioids; • Develop, implement, or expand a prescription drug monitoring program to collect and analyze data related to the prescribing of schedule II, III, and IV controlled substances through a centralized database administered by an authorized State agency, which includes tracking the dispensation of such substances, and providing for data sharing with other States.

Issue	***Senate*** **Comprehensive Addiction and Recovery Act of 2015 (CARA)[19]**	***House*** **Comprehensive Opioid Abuse Reduction Act of 2016 (COARA)[20]**
Treating people in the Justice System	Funds grants that: • Create a treatment alternative to incarceration programs for individuals in contact with the juvenile or criminal justice system, who have a substance use disorder, mental illness, or both; • Expand resources to identify and treat incarcerated individuals suffering from addiction disorders by collaborating with criminal justice stakeholders and providing evidence-based treatment; • Address the use of opioids and heroin among pregnant and parenting female offenders.	Funds grants that: • Train criminal justice agency personnel on substance use disorders and co-occurring mental illness and substance use dis-orders; • Create a mental health or drug court.
Veterans	Funds grants that: • Establish or expand veterans treatment court programs, peer to peer services or programs that provide treatment, rehabilitation, legal, and transitional services to incarcerated veterans, and training programs to teach criminal justice, mental health, and substance abuse personnel how to identify and appropriately respond to incidents involving veterans.	• Same
Medicare	Enables Medicare Part D plans to limit beneficiaries to certain prescriber(s) for frequently abused drugs	N/A

CQ notes that the House's array of legislation (see Appendix A), which is soon expected to crystallize into a package for floor consideration, includes some provisions absent from CARA, such as provisions within a bill (H.R. 4599) addressing partial medication fills.[21] "But the House package is also missing some prominent components of the Senate-passed legislation, including the creation of [HHS] grant programs to develop community-based recovery services and new consumer education and awareness programs," *CQ* adds. The Senate bill also includes, as highlighted above, authority for Medicare Part D plans to limit beneficiaries to certain prescribers for frequently abused medications, a provision that is not included in the House Judiciary-advanced Comprehensive Opioid Abuse Reduction Act of 2016.

IV. Conclusion

TRP Health Policy will continue to track developments in the House's floor action and keep you posted as consideration moves forward. We hope this is a helpful overview and are happy to discuss at your convenience.

Appendix A: House Committee-Advanced Opioid Bills

Following is a topline inventory of additional House E&C and Judiciary-advanced bills that could emerge as part of an opioid package on the House floor in early May. Summary details derive from Committee-level releases.

Bill	Committee Action	Details
Lali's Law (H.R. 4586)	E&C passage; April 28	Authorizes grants to states for developing standing orders for naloxone prescriptions and educating health care professionals regarding the dispensing of opioid overdose reversal medication without person-specific prescriptions.[22]
Co-Prescibing to Reduce Overdoses Act (H.R. 3680)	E&C passage; April 28	Creates a grant program for co-prescribing opioid reversal drugs for patients who are at a high risk of overdose.[23]
Improving Treatment for Pregnant and Postpartum Women Act of 2015 (H.R. 3691)	E&C passage; April 28	Reauthorizes a residential treatment program that currently provides numerous services to aide pregnant women or postpartum women engaged in substance abuse.[24]
H.R. 4641	E&C passage; April 27	Establishes an inter-agency task force to review, modify, and update best practices for pain management and how pain medication is prescribed.[25]
Nurturing and Supporting Healthy Babies Act (H.R. 4978)	E&C passage; April 27	Requires the Comptroller General of the United States to issue a report one year after enactment on Neonatal Abstinence Syndrome (NAS). Note that this bill was amended to exempt abuse-deterrent formulations from the definition of line extensions under the Medicaid drug rebate program.[26]
Veteran Emergency Medical Technician Support Act (H.R. 1818)	E&C passage; April 27	Creates a demonstration program to streamline emergency medical technician state requirements and procedures for veterans who have already completed military emergency medical technician training.[27]
Opioid Use Disorder Treatment Expansion and Modernization Act (H.R. 4981)	E&C passage; April 27	Amend the Controlled Substances Act to expand access to medication-assisted treatment, while ensuring that patients receive the full array of quality evidence-based services and minimizing the potential for drug diversion.[28]
John Thomas Decker Act (H.R. 4969)	E&C passage; April 27	Directs HHS to study what information and resources are available to youth athletes and their families regarding the dangers of opioid use and abuse, non-opioid treatment options, and how to seek addiction treatment. HHS would then be required to report its findings and work with

		stakeholders to disseminate resources to students, parents, and those involved in treating a sports related injury.[29]
Reducing Unused Medications Act of 2016 (H.R. 4599)	E&C passage; April 27	Amends the Controlled Substances Act (CSA) to clarify when a prescription for a drug listed on Schedule II of the CSA may be partially filled.[30]
Opioid Review Modernization Act (H.R. 4976)	E&C passage; April 27	Requires the FDA to work closely with expert advisory committees before making critical product approval and labeling decisions, and to make recommendations regarding education programs for prescribers of extended-release and long-acting opioids.[31]
Examining Opioid Treatment Infrastructure Act of 2016 (H.R. 4982)	E&C passage; April 27	Requires the Comptroller General of the United States to issue a report to Congress on substance abuse treatment availability and infrastructure needs throughout the United States. This report would include an evaluation of various substance abuse treatment settings including inpatient, outpatient, and detoxification programs. Also passing with the bill were two amendments, one offered by Rep. David McKinley (R-WV) and one offered by Rep. Markwayne Mullin (R-OK). Rep. McKinley's amendment examines barriers to accessing real-time data on overdoses, and Rep. Mullin's amendment studies access to treatment in the Indian health program. [32]
DXM Abuse Prevention Act (H.R. 3250)	E&C passage; April 27	Prohibits the sale of a drug containing dextromethorphan (DXM) to an individual under 18, unless the individual has a prescription or is actively enrolled in the military and place restrictions on distribution of bulk DXM. DXM is commonly found in cough syrup.[33]
Opioid Program Evaluation Act (H.R. 5052)	House Judiciary passage, April 27	Direct the Attorney General and HHS Secretary to evaluate the effectiveness of grant programs whose primary purpose is providing assistance in addressing problems pertaining to opioid abuse.[34]
Good Samaritan Assessment Act of 2016 (H.R. 5048)	House Judiciary passage, April 27	Requires the Government Accountability Office to study state and local Good Samaritan laws that protect caregivers, law enforcement personnel, and first responders who administer opioid overdose reversal drugs or devices from criminal liability, as well as those who contact emergency service providers in response to an overdose.[35]

[1] HHS Assistant Secretary for Planning and Evaluation report, March 26, 2015, available here.
[2] HHS release, March 26, 2015, available here.
[3] *Ibid*.
[4] HHS release, Sept. 17, 2015, available here.
[5] *Ibid*.
[6] White House fact sheet, Oct. 21, 2015, available here.
[7] Wachino, CMCS Informational Bulletin, Jan. 28, 2016, available here.
[8] FY 2017 Budget Request, February 2016, available here.
[9] FDA release, Feb. 4, 2016; FDA release; March 22, 2016.
[10] CDC Opioid Prescribing Guidelines, *Morbidity and Mortality Weekly*, March 15, 2016, available here.
[11] CDC press release, March 15, 2016, available here.
[12] 81 *Federal Register* 17639, available here.

[13] Surgeon General remarks, Oct. 4, 2015, available here.
[14] Siddons, *CQ*, April 28, 2016.
[15] Siddons, *CQ*, April 27, 2016.
[16] *The Hill*, March 10, 2016, available here.
[17] Siddons, *CQ*, April 27, 2016, available here.
[18] *Ibid*.
[19] S. 524, available here.
[20] H.R. 5046, available here.
[21] Siddons, *CQ*, April 27, 2016, available here.
[22] E&C release, April 28, 2016, available here.
[23] *Ibid*.
[24] *Ibid*.
[25] E&C release, April 27, 2016, available here.
[26] *Ibid*.
[27] *Ibid*.
[28] *Ibid*.
[29] *Ibid*.
[30] *Ibid*.
[31] *Ibid*.
[32] *Ibid*.
[33] *Ibid*.
[34] House Judiciary release, April 27, 2016, available here.
[35] *Ibid*.