March 21, 2018

The Honorable Michael Burgess  
Chairman  
Health Subcommittee  
House Committee on Energy and Commerce  
U.S. House of Representatives  
2125 Rayburn House Office Building  
Washington, DC 20515

The Honorable Gene Green  
Ranking Member  
House Subcommittee  
House Committee on Energy and Commerce  
U.S. House of Representatives  
2322A Rayburn House Office Building  
Washington, DC 20515

Re: 2018 Substance Use Disorder Treatment, Prevention, and Recovery Package

Dear Chairman Burgess and Ranking Member Green,

On behalf of the American Society of Addiction Medicine (ASAM), the nation’s oldest and largest medical specialty society representing more than 5,100 physicians and allied health professionals who specialize in the prevention and treatment of addiction, we are writing to offer legislative comments and recommendations as the House Energy and Commerce Subcommittee on Health works on a comprehensive, legislative response to our nation’s opioid overdose and addiction crisis.

As you know, the cost of substance misuse, and untreated and ineffectively treated addiction in the United States is staggering, both in economic terms and in terms of human lives lost. During the twelve-month period ending January 2017, the Centers for Disease Control and Prevention estimates there were approximately 64,000 drug overdose deaths.\(^i\) Recently, the White House Council of Economic Advisers announced that the cost of the opioid crisis, alone, approached $504 billion in 2015.\(^ii\) And while opioid-related overdose deaths may dominate national headlines, the associated costs are a fraction of the total societal cost of substance misuse and addiction. Each year alcohol misuse leads to approximately 88,000 deaths in America.\(^iii\) Cigarette smoking contributes to another 480,000.\(^iv\) These costs, however, could be dramatically reduced by utilizing effective substance misuse prevention practices and programs and by addressing untreated, and ineffectively treated, addiction in this country.

Given these alarming statistics, we appreciate your leadership regarding the possible passage of legislation aimed at addressing our country’s crisis of addiction involving opioid use. President Donald J. Trump’s direction to declare the opioid epidemic a nationwide public health
emergency on October 26, 2017 was a historic first step, but turning the tide on the current crisis and preventing future crises related to substance misuse and addiction require a new approach to the delivery of substance use prevention, addiction treatment, and recovery support services. Considering all the lives we have lost and all the lives we still risk losing, the time for transformational change is now. Thus, ASAM respectfully offers these comments for your consideration as you embark on the hard work that lies ahead.

**Advancing Cutting-Edge (ACE) Research Act (H.R. 5002/S. 2046)**

The ACE Research Act would facilitate additional research into treatments for public health epidemics such as the opioid addiction crisis by providing the National Institutes of Health (NIH) with new tools and flexibility to approve high-impact, cutting-edge research. Patients with addiction and patients with chronic pain, like all patients, should have available to them a robust and varied array of treatment options, as no one treatment modality is appropriate or therapeutic for everyone. We support research and the development of non-addictive pain treatment options and additional therapies to treat addiction. These new treatments could not only help save lives but help prevent addiction from taking hold in the first place. ASAM supports the ACE Research Act and recommends that Congress incorporate it into a future legislative package to address the opioid addiction epidemic.

**The Addiction Treatment Access Improvement Act (H.R. 3692/S. 2317) / Amendment in the Nature of a Substitute to H.R. 3692**

To make a meaningful and sustainable impact on the current opioid overdose epidemic, it is imperative that we build a robust treatment workforce. There are simply too few physicians and other clinicians with the requisite knowledge to meet the needs of the estimated 20.1 million Americans suffering from untreated substance use disorders. The Addiction Treatment Access Improvement Act makes great strides in doing so by codifying the Final Rule issued by the Department of Health and Human Services (HHS) in July 2016 that raised the DATA 2000 patient limit for certain physicians to 275 patients, eliminating the sunset date for nurse practitioners’ (NPs) and physician assistants’ (PAs) prescribing authority for buprenorphine, and expanding the definition of ‘qualifying practitioner’ to include nurse anesthetists, clinical nurse specialists, and nurse midwives.

These changes would increase the number of the clinicians to meet the needs of patients who are seeking treatment for their addiction but are unable to find a practitioner who can treat them. It is essential that we increase the treatment workforce, and we urge Congress to include these provisions (or the provisions in the substitute amendment that would also shorten the timeframe to reach the 100-patient limit in certain circumstances) in any legislative package moving forward.

**Substance Use Disorder Workforce Loan Repayment Act (H.R. 5102/S. 2524)**

In addition to expanding and codifying the eligibility of existing treatment providers, it is imperative that our country make strategic investments to incentivize clinicians to work in programs and practices that specialize in the treatment of addiction. To accomplish this goal, the Substance Use Disorder Workforce Loan Repayment Act helps clinicians who pursue full-time substance use disorder treatment jobs in high-need geographic areas repay their student loans. Many parts of the United States, and particularly rural areas, suffer from a lack of treatment providers. ASAM supports the goals of this bill and its efforts to incentivize clinicians to work in...
substance use disorder treatment programs in these high-need areas and urges Congress to include it in any future legislative package to address the opioid epidemic.

The Reinforcing Evidence-Based Standards Under Law in Treating Substance Abuse (RESULTS) Act (H.R. 5272)

ASAM is pleased that the House Energy and Commerce Subcommittee on Health is holding a hearing that includes the RESULTS Act of 2018. The RESULTS Act would require grant, loan, and other recipients of funds from the Department of Health and Human Services for a mental health or substance use disorder prevention or treatment program to use evidence-based practices. We also support research and the development of new and innovative treatments for substance use disorders that will contribute to the body of knowledge that is needed for emergent or innovative programs and activities to become evidence-based.

There are many misconceptions about the disease of addiction, and we need a culture change in this country to drive patients to the treatment options that have been proven to be effective at reducing relapse and overdose deaths and supporting patients in remission and recovery. When it comes to opioid addiction, the most effective treatment options we have involve the use of medications in combination with specific psychosocial interventions to support remission and recovery. When we say, “Treatment works,” we’re not referring to every approach that claims to be treatment. We are physicians and other clinicians who specialize in the treatment of addiction. We're referring to those interventions that have scientific evidence to support their effectiveness.

The RESULTS Act would raise the clinical standard to a level that we demand from all other forms of medicine—to use clinical methods and practices based on evidence—and ASAM is proud to support that goal.

Preventing Overdoses While in Emergency Rooms Act (H.R. 5176)

With the rise in the use of potent synthetic opioids such as fentanyl and carfentanil, the rates of opioid overdoses and emergency department visits due to opioid overdose have increased significantly. Data from CDC’s Enhanced State Opioid Overdose Surveillance (ESOOS) program showed opioid overdose rates increased an average of 35% in the 16 states reporting from July 2016 through September 2017. Eight states reported substantial increases (25% or greater) in opioid overdose emergency department visits.

People who are admitted to a hospital for a drug overdose and discharged without treatment are at elevated risk to relapse and overdose again. H.R. 5176, the Preventing Overdoses While in Emergency Rooms Act, works to prevent that from happening by authorizing the Secretary of the Department of Health and Human Services to create grants for health care sites with emergency departments to develop protocols for discharging patients who have presented with a drug overdose and enhance the integration and coordination of care and treatment options for individuals with substance use disorders after discharge.

Addiction is a chronic brain disease and evidence shows that treatment is effective at achieving and sustaining remission and recovery. It is past due that we stop discharging patients from emergency rooms without treating their addiction. ASAM is proud to support the Preventing Overdoses While in Emergency Rooms Act and urges Congress to include it in any legislative package to address the needs of patients who have overdosed.
The Comprehensive Opioid Recovery Centers Act of 2018 (H.R. 5327)

Treatment of the disease of addiction, without also addressing associated social externalities such as homelessness, will result in poorer outcomes. The Comprehensive Opioid Recovery Center Act would help to fill this gap in wrap-around care and services, by creating competitive grants to entities to establish or operate comprehensive opioid recovery centers. This policy would accomplish the two-fold objective of increasing access to treatment and ensuring that the treatment is comprehensive - offering a full continuum of clinical, vocational, and educational services to meet the needs of patients. In addition, the grants would prioritize entities in a state or Indian country with high per capita drug overdose mortality rates, so the resources are focused in areas that need it most.

As you consider this legislation, ASAM offers these additional comments:

- Selected centers should be required to ensure that intake and ongoing evaluations meet the clinical needs of patients, including by offering assessments for services and level of care recommendations through independent, research-validated verification processes for reviewing patient placement in addiction treatment settings;
- Independent program evaluators should be required to evaluate program effectiveness; and
- Selected centers should be required to report on a set of pre-identified performance measures.

ASAM applauds this legislation which would make great strides in increasing access to comprehensive treatment and urges Congress to include it in any upcoming legislative package to address the opioid epidemic.

The Treatment, Education, and Community Help to Combat Addiction Act of 2018 (H.R. 5261)

This legislation would amend the Public Health Service Act to provide for regional centers of excellence to enhance and improve how health professionals are educated in pain management and substance use disorder through development, evaluation, and distribution of evidence-based curriculum for health care professional schools. ASAM has recommended for years that medical, nursing, dental, pharmacy and other clinical schools increase curriculum time devoted to addiction screening and treatment, safe prescribing and pain management. We would also encourage you to consider supporting future proposals which would establish an additional pathway for physicians who have had comprehensive training in medical school treating and managing opiate-dependent patients to apply for a DATA 2000 waiver.

We welcome this legislation and urge Congress to include it in any upcoming legislative package to address the opioid epidemic.

Confidentiality and 42 CFR Part 2

The federal regulations governing the confidentiality of drug and alcohol treatment and prevention records, 42 CFR Part 2 (Part 2), set requirements limiting the use and disclosure of
patients' substance use records from certain substance use treatment programs. Obtaining multiple consents from the patient is challenging and creates barriers to whole-person, integrated approaches to care, which are part of our current health care framework. Part 2 regulations may lead to a physician treating a patient and writing prescriptions for opioid pain medication for that individual without knowing the person has a substance use disorder. Separation of a patient's addiction record from the rest of that person's medical record creates several problems and hinders patients from receiving safe, effective, high-quality substance use treatment and coordinated care.

The advent of integrated health systems and electronic medical records has improved the safety, quality, and coordination of care for patients with any other health condition. Part 2 requirements prevent patients with addiction from sharing in these benefits, even though electronic exchanges of other health information are governed by strict privacy and security standards set by the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act.

ASAM holds patients' privacy rights in the highest regards but recognizes the barriers that Part 2 currently presents to coordinated, safe, and high-quality medical care cause significant harm, and that thoughtful changes to the law are necessary to mitigate this harm while protecting patients' privacy. Thus, we support changes that would align Part 2 with HIPAA's consent requirements for the purposes of treatment, payment, and healthcare operations. Such a change would allow for the sharing of patients' addiction treatment records within the healthcare system under HIPAA's well-established and modern privacy and security protections, while leaving in place Part 2's prohibition on disclosure of records outside the healthcare system. Moreover, we also welcome changes that would strengthen protections against the use of addiction treatment records in criminal proceedings, a further improvement to Part 2 that we see as essential to protect patients in treatment for substance use disorder.

CARA 2.0 Act of 2018 (H.R. 5311/S. 2456)

We appreciate the leadership of all the CARA 2.0 Act sponsors in filing this major legislative package aimed at addressing the opioid addiction crisis in our country. With that, we would like to respectfully provide comments and recommendations to you on provisions of the CARA 2.0 legislation for your consideration.

Section 3. Three Day Limit on Opioid for Acute Pain.

We appreciate the desire to help reverse the exponential increases in opioid misuse, addiction, and death by limiting initial prescriptions for opioids to three days or less while exempting certain conditions such as chronic pain care and pain being treated as part of palliative care. While this goal is important, a “hard” three-day limit in federal statute is inconsistent with evidence-based guidelines such as the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain (the “CDC Guideline”).

According to Recommendation 6 of the CDC Guideline, “[w]hen opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed.” Further, the applicable CDC Guideline narrative reads as follows:
Experts thought, based on clinical experience regarding anticipated duration of pain severe enough to require an opioid, that in most cases of acute pain not related to surgery or trauma, a ≤3 days’ supply of opioids will be sufficient. Some experts thought that because some types of acute pain might require more than 3 days of opioid treatment, it would be appropriate to recommend a range of ≤3–5 days or ≤3–7 days when opioids are needed. Some experts thought that a range including 7 days was too long given the expected course of severe acute pain for most acute pain syndromes seen in primary care.

Considering the foregoing, we highlight three observations for your consideration. First, unlike the CDC Guideline, Section 3 of CARA 2.0 is not limited to primary care prescribers. Second, patients with acute pain related to surgery or trauma and for whom three days or less can be insufficient, may have to incur financial costs and bear logistical burdens to obtain additional medically-appropriate opioid medication. Further, such a 3-day limitation would inevitably and disproportionately impact patients with lower incomes and patients living in rural areas located many miles from their prescribers. Third, violating a federal statute can carry significant legal ramifications for prescribers trying to treat acute pain appropriately as compared to deviating from a voluntary guideline, such as the CDC Guideline. Therefore, ASAM strongly recommends that any statutory acute pain limitation passed by Congress incorporate more flexibility for prescribers to meet the medical needs of all their patients and should more closely align with the recommendations of the CDC Guideline.

Section 4. First Responder Training.

This section would provide funds primarily to make naloxone available to first responders to train and provide resources for carrying and administering naloxone. While we know state and local governments would certainly welcome federal assistance for naloxone training and distribution given the increasing cost of naloxone in this country, we urge you to consider enacting policy interventions which would allow the federal government to bulk purchase naloxone at discounted prices to increase access to this life-saving medication. Our nation’s Vaccines for Children Program may be an existing model Congress could rapidly replicate to increase naloxone access for first responders, public health departments, and community organizations. Such a program, coupled with investments aimed at enhancing the Centers of Disease Control and Prevention’s surveillance capabilities for identifying overdose clusters and infectious disease outbreaks, could go a long way in preventing the spread of infectious diseases and death.

Section 6. Building Communities of Recovery.

ASAM supports additional investments in recovery support services for people trying to achieve long-term remission and recovery from the disease of addiction. However, we strongly caution against any statutory language which states that addiction recovery support services can be “in lieu of addiction treatment.” Nearly 90% of Americans with addiction do not receive treatment and 80% of individuals with opioid addiction are not treated. As many families know all too well, remission and recovery from addiction involving opioid use is often only preceded by evidence-based medical treatment. To put it simply, there is no remission or recovery if you are dead.

Therefore, our nation must come to terms with the difficult reality in which we find ourselves: the current addiction treatment gap will never be closed with the current addiction treatment
workforce. While we want you to support additional investments in recovery support services, we urge you also to prioritize federal funding for Accreditation Council for Graduate Medical Education (ACGME)-accredited addiction medicine and addiction psychiatry fellowship positions and a loan repayment program for students who enter the substance use disorder treatment workforce. Additionally, please consider revising the Public Health Service (PHS) Act to include addiction medicine specialists in the definition of "behavioral and mental health professionals" within the National Health Service Corps.

Section 7. Medication-Assisted Treatment for Recovery from Addiction.

ASAM applauds the efforts in Section 7 of CARA 2.0 that would expand access to medication-assisted treatment for remission and recovery from addiction. As previously noted, it is imperative that we build a robust treatment workforce, and this section would make great strides in doing so by eliminating the sunset date for nurse practitioners’ (NPs) and physician assistants’ (PAs) prescribing authority under DATA 2000 and expanding the definition of ‘qualifying practitioner’ to include nurse anesthetists, clinical nurse specialists, and nurse midwives. This section would also give individual states the option to waive the limit on the number of patients a physician can treat so long as the state directs its applicable state regulatory body to adopt evidence-based prescribing guidelines for the use of medication to treat addiction involving opioid use, such as ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. This policy change would help accomplish the two-fold objective of increasing access to and the quality of the prescribing medications for the treatment of addiction involving opioid use.

We also welcome the opportunity to work with you and the CARA 2.0 sponsors to improve the innovative “Offer 2 Types of Medication-Assisted Treatment” minimum requirement in Section 7(d) of CARA 2.0. For example, we would recommend that such minimum, two-medication requirement for medications to treat opioid use disorder only apply to residential treatment providers, prisons, and jails that receive federal funds for a program or activity offering addiction treatment to people with opioid use disorder, especially if a residential provider is receiving Medicaid funding due to a waiver or repeal of the Institutes for Mental Diseases (IMD) Exclusion within the Medicaid program. We would want to avoid any policy intervention which could result in an unintended consequence of decreasing access to life-saving medications prescribed by individual prescribers treating patients whose health care is federally-subsidized.

Section 13. Require the Use of Prescription Drug Monitoring Programs (PDMP).

ASAM believes that prescription drug monitoring programs (PDMPs) are an important tool to inform safe prescribing. From 2014 to 2016, there was a 121 percent increase in the number of queries by health professionals to state PDMP databases. As a result, we applaud the creative policy innovations outlined in this section - namely that prescribers or their designees be required to query the PDMP upon initial prescription of a controlled medication and quarterly thereafter if treatment continues. Further, requiring proactive reports, increased timeliness of data entry, and de-identified data sets for research and evaluation are also welcomed policy changes. However, requiring state agencies to provide reports to law enforcement agencies and licensing boards “describing any prescribing practitioner that repeatedly fall [sic] outside of expected norms or standard practices for the prescribing practitioner’s field” is troubling as it could have an unintended chilling effect on appropriate prescribing, particularly with respect to disclosures to law enforcement outside of a court-supervised process. PDMP information should be considered what it is: personal health information, and, therefore, should be protected from release like other personal health information.
In addition, we would be remiss not to urge you to fund research and evaluation programs that study best practices for integrating PDMPs into EHRs and clinician workflow in a meaningful, user-friendly manner. While PDMPs now exist in almost every state and practitioners are increasing their use of them, the lack of integration with electronic health records continues to inhibit the effective use of these clinical support tools. Further, in addition to improving and integrating these programs, ASAM recommends that Congress urge the Department of Health and Human Services to support the development of training for primary care providers to know how to engage a patient whose PDMP report indicates he or she may be inappropriately accessing controlled substances. Without such training, many clinicians might simply dismiss patients from their practice without an assessment for substance use disorder or referral to treatment, if indicated. These clinicians are missing an important opportunity to engage patients in treatment and should be equipped to use the PDMP report as a conversation-starter with patients at risk of addiction or overdose death.

**Telemedicine**

As stated in a [testimony](#) on behalf of ASAM before the House Energy and Commerce Subcommittee on Health, telemedicine provides significant opportunities to reach more patients in urban and rural communities. However, the current restrictions on internet prescribing under the Ryan Haight Act and the seven, specific “practice of telemedicine” exceptions it provides for are of limited utility for expanding access to treatment with buprenorphine for addiction involving opioid use via telemedicine. As you know, the Ryan Haight Act generally requires an “in-person medical evaluation” in the physical presence of the prescribing clinician for the prescription to be considered valid.

The “practice of telemedicine” exceptions to this requirement provide for circumstances in which the patient is being treated by, and physically located in, a DEA-registered hospital or clinic, or in which the patient is being treated by and in the physical presence of another DEA-registered practitioner. It generally does not allow for circumstances in which a patient may have received a medical evaluation by another qualified practitioner but is not physically present in a DEA-registered hospital or clinic or with another DEA-registered practitioner. While The ASAM’s [Standards of Care](#) and [The ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use](#) make it clear that patients presenting for treatment of addiction involving opioid use should receive a physical examination by a qualified and appropriately licensed healthcare professional as part of a comprehensive assessment process, they specifically allow for this examination to be conducted by a healthcare professional other than the prescriber, as long as the prescriber “ensure[s] that a current physical examination is contained within the patient medical record before a patient is started on a new medication for the treatment of his/her addiction.”

ASAM recommends that Congress pass legislation to revise the Ryan Haight Act to include an additional exception to the requirement for an in-person physical exam by the prescribing clinician to allow for a current physical exam to be conducted by another appropriately licensed healthcare professional and documented in the patient’s medical record. Additionally, ASAM recommends limiting this exception to the in-person physical exam requirement for patients who will be treated with buprenorphine for opioid addiction only to those physicians who hold “additional certification” or who practice in a “qualified practice setting” per the definitions in the 2016 SAMSHA rule that raised the DATA-2000 prescribing limit.
Additional Recommendations

On March 8, 2018, the Senate HELP Committee held a hearing titled “The Opioid Crisis: Leadership and Innovation in the States.” Hearing participants discussed recommendations from Governors across the U.S. expressed at the National Governors Association annual winter meeting. Toward the conclusion of that hearing, Chairman Alexander highlighted the problem of an “unevenness” in addiction treatment program quality across the country. We would be honored to have the opportunity to meet with Congressional leaders to discuss, in greater detail, possible federal action that could start incentivizing states to continue building out an addiction treatment infrastructure that can consistently deliver quality care for people suffering with addiction.

We know well that as the field of addiction treatment works to integrate more fully with traditional medical care, it is imperative that it “catch up” with other medical specialties in terms of clinical guideline development and quality measurement. Federal efforts to promote high-quality addiction treatment could include support for the following:

- Development and dissemination of clinical practice guidelines for addiction treatment, such as the ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use and of science-based patient guides, such as the Opioid Addiction Treatment: A Guide for Patients, Families and Friends, that include information on assessment, treatment overview (including treatment plans, patient participation, and counseling), and all the medications available to treatment opioid use and overdose;

- Establishment and maintenance of addiction treatment programs that ensure intake and ongoing evaluations meet the clinical needs of patients by offering assessments for all substance use disorder services and level of care recommendations through an independent, research-validated verification process for reviewing patient placement in addiction treatment settings; and

- Implementation of, and related technical assistance for, nationally-recognized and research-validated treatment center certification programs that can provide patients, families, and payers with a reliable indicator that providers are delivering a certain level of care.

Efforts such as these are critically needed to help improve the overall quality of addiction treatment provided in our nation and assure those who are seeking and paying for treatment that they are receiving medically appropriate and high-quality care.
Thank you for the opportunity to make recommendations and offer additional tools that may be helpful to combat this public health emergency. We look forward to working with you to build upon the progress already made and help lay the foundation for a future in which long-term remission and recovery from addiction is not only possible, but probable. If you have any questions or concerns, please contact Kelly Corredor, ASAM’s Director of Advocacy and Government Relations, at kcorredor@asam.org or at 301-547-4111.

Sincerely,

Kelly J. Clark, MD, MBA, DFASAM
President, American Society of Addiction Medicine

cc: The Honorable Greg Walden
The Honorable Frank Pallone

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7 Id.

By way of further background, in 2016, addiction medicine was recognized as an American Board of Medical Specialties (ABMS) subspecialty under the American Board of Preventive Medicine (ABPM). The first ABMS addiction medicine board exam was offered in October 2017. While the board exam will be open to any American physician with a primary ABMS board certification until 2022, after that time, physicians will need to complete a year-long fellowship program to be qualified to sit for the exam. In five short years, the number of accredited and funded addiction medicine fellowship programs and slots will be the limiting factor in determining how many addiction medicine specialists can receive board certification.
It is critical that all stakeholders work to maximize funded addiction medicine fellowship opportunities before their number begins to limit qualified examinees.


