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June 16, 2017

The Honorable Chris Christie
Chair, President's Commission on Combating Drug Addiction and the Opioid Crisis
Eisenhower Executive Office Building
1650 Pennsylvania Ave NW
Washington, DC 20502

Dear Governor Christie,

On behalf of the American Society of Addiction Medicine (ASAM), a national medical specialty society representing more than 4,500 physicians and allied health professionals who specialize in the treatment of addiction, thank you for the opportunity to share our recommendations for reducing opioid overdose deaths and supporting recovery from opioid addiction to the President's Commission on Combating Drug Addiction and the Opioid Crisis.

Opioid overdoses and deaths are at an all-time high, and unfortunately, we expect the death rate to continue to increase. Despite the bipartisan and multi-stakeholder efforts to date, ASAM believes there remain opportunities to strengthen America's drug policies to enhance prevention and early intervention efforts as well as promote comprehensive treatment of addiction and recovery support services. Steps can and should be taken by the Administration in 2017 to prevent deaths and engage people in treatment, while laying the groundwork for more robust addiction treatment systems and workforce in the near future. Specifically, we believe the following key strategies to combat the opioid epidemic are critical and should be part of the Commission's recommendations:

Prevention

To date, federal prevention efforts have focused on community based initiatives such as those designed to be delivered through the workplace, schools, or faith-based or civic organizations. Programs like these that have been evaluated and shown to be effective should be continued, scaled, and replicated. However, we also need strategies to prevent

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prescription drug misuse through the health care system, which is where most people first encounter controlled substances and where many patients continue to access them even while presenting with risk factors or symptoms of a substance use disorder. Specifically, we know that the rate of opioid-related overdose deaths has risen dramatically over the past fifteen years, a trend that mirrors the significant increase in sales of prescription opioids.

ASAM is not alone in its belief that the amount of opioids being prescribed by our nation's doctors, dentists and nurses is excessive. While opioids offer relief to many patients with pain and should remain an available and acceptable option for pain management when medically indicated, it is clear from prescribing data and related addiction treatment admission and overdose death data that the medical community has over-relied on opioids to treat pain. The federal government has taken steps to inform more judicious opioid prescribing through the development of the Centers for Disease Control and Prevention's (CDC) Guideline for Prescribing Opioids for Chronic Pain (Guideline) and the dissemination of free and low-cost education programs through the National Institute on Drug Abuse (NIDA) and the Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategy (REMS) for extended-release, long-acting opioids.

Recommendations:

- ASAM recommends the Commission champion evidence-based prevention programs to reduce opioid misuse and prevent addiction. SAMHSA maintains a National Registry of Evidence-based Programs and Practices, and **funding should be made available to identify evidence-based prevention programs that can be efficiently scaled and replicated across the country.**
- ASAM also recommends the Commission include in its interim and final reports additional prevention principles related to prescriber education and coverage of non-pharmacological pain management options through federal, state and private health benefits. Specifically, the Commission should recommend that the Department of Health and Human Services (HHS) and White House Office of National Drug Control Policy (ONDCP):
    - Work with the CDC to promote the dissemination and implementation of its *Guideline for Prescribing Opioids for Chronic Pain*, and work with federal agencies who employ prescribing clinicians to ensure they are trained in safe prescribing practices and the recognition of a potential substance use disorder.
    - Facilitate coordination between the Food and Drug Administration (FDA) and Drug Enforcement Agency (DEA) to **implement a requirement that clinicians who apply for a registration to prescribe controlled substances demonstrate competency in safe prescribing, pain management, and substance use disorder identification.**
    - Work with the Centers for Medicare and Medicaid Services (CMS), the Departments of Defense and Veterans Affairs, and the Office of Personnel

Management to **ensure federally sponsored and supported health plans provide sufficient coverage of non-pharmacologic pain management options** such as physical therapy, weight management, and counseling services.

- Encourage funding for the newly-announced National Institutes of Health private-public partnership on opioids, similar to collaborations to address other diseases such as diabetes, cancer and Parkinson's. The partnership should strategically focus on:
  - Medication Assisted Treatment options
  - Overdose treatment options
  - Alternatives to opioids

Early Intervention

As prescription drug monitoring programs (PDMPs) are enhanced and prescribers are encouraged to access them before prescribing, it's important to ensure that health care providers know what to do when the report suggests prescription drug misuse. Too often, we hear that patients are simply denied a medication and turned away. This response does nothing to address the patient's potential substance use disorder. Instead, prescribers should be trained in engagement strategies that result in linking patients to treatment when indicated.

Recommendation:

- The Commission's report should promote early intervention by supporting 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.
- The Commission should also identify and recommend funding to replicate or scale promising practices to connect patients who have experienced an overdose to treatment. Too often, patients who have experienced an overdose are discharged from an emergency department with little more than a phone number to call for ongoing treatment. Handoffs from emergency departments to evidence-based treatment services should be seamless and coordinated so that patients are engaged in treatment quickly.

Treatment

It has been well-noted that America has a large addiction treatment gap. Specifically, the Substance Abuse and Mental Health Services Administration (SAMHSA) reports that in 2015, an estimated 21.7 million people aged 12 or older (8.1% of that population) needed substance use treatment, but only an estimated 2.3 million people aged 12 or older who needed substance use

treatment received treatment at a specialty facility. Stated another way, only 10.8 percent of adolescents and adults who needed treatment received it.[1]

One driver of the treatment gap is a lack of understanding among the public of what addiction is and what evidence-based treatment options are available. There are many misconceptions about the disease, and even more misconceptions about the way experts agree it should be treated. 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 recovery.

Additionally, while some administrative progress has been made in recent years to expand access to evidence-based treatment, such as increasing the office-based opioid treatment patient limit for physicians and other providers, too often patients who seek addiction treatment face barriers that they would not face for any other chronic disease. One of the most critical issues is limited or lacking insurance coverage of evidence-based therapies such as medications for opioid addiction and needed psychosocial supports.

Recommendations:

- The Commission should recommend that **the Centers for Disease Control and Prevention (CDC) launch a public awareness campaign to educate the public and health care providers about addiction as a chronic brain disease that can be effectively treated with evidence-based interventions.** Public education should include information about the types of treatment options that have been shown to be effective, such as medications for opioid addiction, so that patients and families know how to identify quality treatment services. Only the federal government has the capacity and reach to raise public awareness effectively. We saw this in the 1980's with the CDC's America Responds to AIDS public information campaign (1987), and the distribution of Understanding AIDS (1988), a brochure that was delivered to every residential mailing address in the United States. Opioid overdose deaths have surpassed deaths at the height of the AIDS crisis, yet we have not seen similar efforts to educate the public about the disease of addiction or the treatment they should seek.
- The Commission should also recommend near-term policy changes to expand access to evidence-based treatment, including:
    - o Recommending that HHS direct and incentivize states to use the FY 2018 installment of the State Targeted Response Grants (21st Century Cures funding) to fund treatment at programs that meet level-of-care standards defined by the ASAM Criteria and meet evidence-base standards as outlined by the ASAM *National Practice Guideline for the Use of Medications in the*

[1] Lipari RN, Park-Lee E, and Van Horn S. America's need for and receipt of substance use treatment in 2015. The CBHSQ Report: September 29, 2016. Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Rockville, MD.

  - *Treatment of Addiction Involving Opioid Use*. The ASAM Criteria is a validated tool to match patients to the right level of care based on their disease severity, and will ensure this funding is used in the most clinically sound, effective, and efficient way. The National Practice Guideline summarizes the evidence available on the proper use of medications to treat opioid addiction, and offers clinical guidance to health care provider to support evidence-based decision making.
  - Recommending that Congress permanently authorize buprenorphine prescribing authority for nurse practitioners and physician assistants under DATA 2000.
- If a patient needs treatment and is ready to seek it, restrictive payer policies should not prohibit access to the kind of care we know works, but far too often that is the case. Recommendations to address this inequity include:
  - ***Equitable Coverage and Reimbursement Policies***. The Commission's report should strongly recommend the Administration use the full strength of its influence and every policy lever available to it to ensure public and private payers cover evidence-based addiction treatment just as they would cover treatment for other chronic medical conditions. This may include directing HHS and ONDCP to work with CMS on Medicare policies (as Medicare does not cover methadone treatment for opioid use disorder) and to influence state Medicaid programs, many of which do not cover all FDA-approved medications for opioid addiction treatment, and working with the Department of Labors, HHS and Treasury to enhance enforcement of the Mental Health Parity and Addiction Equity Act (MHPAEA).

  - ***Full Federal and State Implementation and Enforcement of the Mental Health Parity and Addiction Equity Act***. The Commission should recommend the full implementation and enforcement of MHPAEA, including full parity compliance analyses and the results of the plan's compliance assessment. One of the most common barriers reported by the patients ASAM members serve is the lack of disclosure by health plans on the development and application of Non-Quantitative Treatment Limits (NQTLs). Parity compliance testing cannot be performed on coverage limitations such as prescription drug formulary design, medical and administrative management techniques, including restrictions based on facility type or provider specialty, without this information. For example, in order to determine whether a plan is in compliance with the law, consumers and their providers, who often serve as authorized representatives for patients, may request medical management criteria and protocols, information on how these criteria and protocols are developed and applied (both as written and in operation), for both MH/SUD and medical/surgical benefits.

To ensure documents and information are fully disclosed, consistent with MHPAEA's statute and implementing regulations, we recommend regulators develop template forms showing the plan's NQTL parity compliance analysis require the documents and information outlined in Attachment A to be supplied for review upon request by regulators, patients and authorized patient representatives.

- Parity regulatory guidance required under the *21st Century Cures Act* on non-quantitative treatment limitations and other issues should be issued as soon as possible, but no later than the statutory deadline of December 2017.

- ***Addiction and Mental Health Benefits Must Continue to be Covered***. The Commission's report should recommend that addiction and mental health treatment benefits continue to be available to Americans enrolled in the individual, small and large group markets as well as Medicaid plans, and that these benefits are compliant with MHPAEA.

  Medicaid expansion has been associated with an 18.3 percent reduction in unmet need for addiction treatment services among low-income adults. Any reduction to the Medicaid expansion or fundamental change to Medicaid's financing structure to cap spending on health care services will certainly reduce access to evidence-based treatments and reverse much or all progress made on the opioid crisis last year. Moreover, the loss of Medicaid-covered mental health and substance use disorder services for adults would result in more family disruption and out-of-home placements for children, significant trauma which has its own long-term health effects and a further burden on a child welfare system that is struggling to meet the current demand for foster home capacity.

- ***Medicaid Coverage for Addiction and Mental Health for Justice-Involved Individuals***. In addition, Medicaid offers the only opportunity to access medical care for most citizens re-entering the community from criminal justice settings, a population deeply in need of mental health and substance use disorder treatment.

- ***Quality of Care***. The Commission's report should include action items related to quality of care. ASAM is committed to promoting evidence-based addiction treatment, and has heard often from policymakers and payers about the challenges they face in identifying and rewarding high-quality care. 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. ASAM recommends HHS and ONDCP expand efforts to promote quality of care to include: (1) support for the 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*, (2) support for the development and validation of quality measures for addiction treatment, and (3) support for treatment center and/or clinician certification programs that could provide patients, families and payers with a reliable indicator that providers are delivering a certain quality or 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.

Workforce

The current addiction treatment gap will never be closed with the current addiction treatment workforce. There are simply too few physicians and other clinicians with the requisite training to meet the treatment needs of the estimated 19.4 million Americans suffering from untreated substance use disorders. To make a meaningful and sustainable impact on the current opioid overdose epidemic, and to stave off future epidemics related to other addictive substances such as cocaine, benzodiazepines or methamphetamine, it is imperative that our nation invest in training opportunities for clinicians seeking to specialize in addiction treatment.

Recommendations:

- The Commission should include in its report a recommendation that the federal government fund ACGME-accredited addiction medicine and addiction psychiatry fellowship positions and create a loan repayment program for physicians who complete these fellowships and enter into the practice of addiction medicine or addiction psychiatry. One immediate opportunity to accomplish this goal is for Congress to **fully appropriate $10 million in funding for Section 9022 of the 21st Century Cures Act**, which authorizes the Secretary to establish a training demonstration program within the Health Resources and Services Administration (HRSA) to award grants for medical residents and fellows to practice psychiatry and addiction medicine in underserved, community-based settings. Beyond this funding, we strongly urge the Administration to **identify robust and ongoing funding opportunities that can be used to support addiction specialist training programs,** to build an adequate workforce to have a substantial and sustained impact on this epidemic**.**

  In 2016, addiction medicine was recognized as an American Board of Medical Specialties (ABMS) subspecialty under the American Board of Preventive Medicine

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(ABPM). The first ABMS addiction medicine board exam will be 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 period, 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. Additionally, in the years leading up to 2022, ASAM urges that the report recommend that HHS and ONDCP should coordinate efforts among federal agencies to raise awareness among qualified physicians of the opportunity to take the board exam without completing a fellowship program.

- The Commission should make recommendations to increase education related to addiction treatment, safe opioid prescribing, and pain management in clinical school curricula. Health care professionals-in-training currently receive very little formal instruction on these topics and feel unprepared to manage pain or identify and treat patients with addiction upon graduation. Our nation's clinical schools should be obligated to equip the next generation of health care professionals with the knowledge and skills needed to address the opioid epidemic.

Research

In the midst of the ongoing opioid epidemic, there is urgent need for research into non-opioid forms of effective pain relief, new and better medications to treat opioid use disorder and reverse overdose, and better psychosocial interventions to help people enter and stay in recovery. There is also a need for basic research to understand better the genetic and environmental underpinnings of addiction, and what factors increase someone's risk of developing addiction or protect them from doing so.

Recommendation:

- We urge the Commission to make its report truly comprehensive by including priorities to increase research into effective ways to prevent substance misuse, treat addiction, reverse overdose, and support individuals in recovery. The National Institute of Drug Abuse (NIDA) and National Institute on Alcoholism and Alcohol Abuse (NIAAA) should be key players in the development of the Commission's report and should be targets for additional funding to support needed research.

Thank you for the opportunity to comment as the Commission develops its report. We stand ready to serve as a resource to you.

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Sincerely,

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

Attachment A

NQTL Compliance: 5-Step Process

We believe that additional guidance is needed to clarify for those obligated to disclose what is meant by "documentation" as used in sub-regulatory guidance relating to each of the components of the NQTL test. Based on our experience and the experiences of other providers with assisting patients, **we recommend utilization of a 5-step parity compliant analysis and state and federal regulators issue template forms that require the disclosure of key plan documents.** The 5-step process explained and illustrated below provides clear guidance on the type of information and documentation that is required to be disclosed.

These 5 steps are based on the MHPAEA Final Rules, related federal regulations, as well as previously issued sub-regulatory guidance. We emphasize once again how no consumer, authorized representative or regulator can possibly know whether a plan is compliant with or in violation of the NQTL rule of the federal parity law based on the information that, to our knowledge, has not been submitted by any plan to date.

5-Step Parity Compliance NQTL Analysis (template forms developed by state and federal regulators should ensure all of this information is disclosed to both plan members and their authorized representatives).

Step 1. Describe the NQTL and both the MH/SUD services and medical/surgical services to which it applies. (Any separate NQTL that applies only to MH/SUD benefits within any particular classification is in violation of MHPAEA).

Step 2. Identify the factor(s) used in the development of the specific NQTL.

A description of each of the factors that were in fact used to develop the specific NQTL, including the rationale for the relevancy of such factor(s) and the sources for ascertaining each of these factors: e.g., external research studies, internal claims analyses, internal quality standard studies, etc.

Illustrative examples of factors that could be used include:

- Excessive utilization
- Recent medical cost escalation
- Lack of adherence to quality standards
- High levels of variation in length of stay
- High variability in cost per episode of care
- Lack of clinical efficacy of treatment

Step 3. Identify the evidentiary standard(s) used to define such factor(s).

A description of the evidentiary standard(s) used to define each of these factors identified in Step 2.

Illustrative evidentiary standards that may define the factors listed above include:

- Two standard deviations above average utilization per episode of care (may define excessive utilization)
- Medical costs for certain services increased 10% or more per year for 2 years (may define recent medical cost escalation)
- Deviation from national generally accepted quality standards for a specific disease category more than 30% of time based on clinical chart reviews (may define lack of adherence to quality standards)
- 25% of patients stayed longer than the median length of stay for acute hospital episodes of care (may define high level of variation in length of stay)
- Episodes of outpatient care are 2 standard deviations higher in total costs than the average cost per episode 20% of the time in a 12 month period (may define high variability in cost per episode)
- More than 50% of outpatient episodes of care for specific disease entities are not based on evidence-based interventions (as defined by nationally accepted best practices) in a 12 month sample (may define lack of clinical efficacy)

Please note: The term "evidentiary standards" may also include any evidence a plan considers in developing its medical management techniques, such as recognized medical literature and professional standards and protocols (including comparative effectiveness studies and clinical trials).

Step 4. Methods and Analyses used to establish comparability in the development of the NQTL.

A description of the methods and analyses used to determine that any factors used, evidentiary standards relied upon, and processes employed in developing the NQTL for MH/SUD services and medical/surgical services are comparable. The results of these analyses are to be included. *Illustrative methods and analyses to determine if factors, evidentiary standards, and processes are comparable include*:

- Internal claims database analyses that showed key factors (which are each defined by specific evidentiary standards) were present in a comparable manner in both MH/SUD and medical/surgical class of benefits.
- Review of the published literature on rapidly increasing cost for services for both MH/SUD and medical/surgical conditions and determination that a key factor(s) was present with similar frequency in specific categories of both MH/SUD and medical/surgical services.
- Methodology and results for analyzing that all medical/surgical service categories that had a "high cost variability" (defined in the same manner for both medical and MH/SUD services) were subject to pre-authorization, as were all types of MH/SUD services that fit this definition
- Analyses that the processes for setting usual and customary provider rates for both MH/SUD and medical/surgical were the same, both as developed and applied, along with the results from these analyses.

<u>Step 5</u>. Testing and Reviews conducted to establish comparability and no more stringency in the application of this NQTL "in operation".

Documentation of any testing, audits or reviews and the results thereof that demonstrate that the processes employed "in operation" for MH/SUD benefits in each relevant classification of benefits are comparable to and applied no more stringently than the same processes employed "in operation" for medical/surgical benefits in the corresponding classification of benefits.
Illustrative documentation of methods and analyses to determine the comparability and equivalent stringency of processes used in NQTL application, in operation, include:

- Documentation that specific audits were performed with respect to the frequency of medical/surgical vs. MH/SUD reviews within the same classifications of benefits to assure that the NQTL is applied comparably and no more stringently.
- Audit results that physician to physician utilization reviews were similar in frequency and length of time for medical/surgical vs. MH/SUD within the same classifications of benefits to assure that the reviews were comparable and no more stringently applied in these respects.
- Audit results that demonstrate that frequency of reviews for the extension of initial determinations for MH/SUD benefits were comparable to the frequency of reviews for the extension of initial determinations for MH/SUD benefits.
- Data from analyses to determine whether the out-of-pocket spending by members for inpatient SUD and MH services are similar to those for out-of-pocket spending for medical/surgical members in similar types of facilities.
- Results of compliance testing of network access standards that wait times for primary care office visits were the same as the wait times for psychiatric office visits.

<u>Please note</u>: There are many other processes that may be used in operation for any given NQTL, particularly those that involve medical management techniques, such as consultations with expert reviewers, clinical rationale used in approving or denying benefits, and the selection of information deemed reasonably necessary to make a medical necessity determination, etc. Plans must analyze every process employed in operation for comparability and equivalent stringency in application.