**Recommendations to President’s Commission**

1. Provider Education. Increase Provider Education as only seven percent of medical school’s mandate courses in substance use disorders. This leaves those who will ultimately prescribe opioids and who will encounter the health effects of opioid and other substance use disorders in their practices utterly unprepared to provide safe and effective care. Meanwhile, the federal government provides literally every medical and nursing school in our country with billions of dollars in low-cost loans for student tuition. We recommend that medical, nursing physician assistant students who access these federal loans, can only do so if they attend a school that has at least one approved course in each of addiction and the CDC Guideline. The immediate effect would be that all medical, nursing, dental and likely other related professional schools would adopt existing courses that have been to this date ignored. There are approved, online courses for second year medical and nursing students, and there are well structured residency training programs available through ASAM – these simply have not been used by the schools.
2. Develop the Infrastructure to Ensure All Treatment is Evidenced Based. Per the Surgeon General Report, well-supported scientific evidence shows that substance use disorders can be effectivelytreated, with recurrence rates no higher than those for other chronic illnesses such as diabetes, asthma and hypertension. However, treatment for OUD is most often delivered without the use of evidence-based quality measures.

In 2006, the Institute of Medicine published a report, *Improving the Quality of Health Care for Mental and Substance-Use Conditions*. Recommendation 4.3 in this report urged DHHS, in partnership with the private sector, to direct and financially support an entity to convene government regulators, accrediting organizations, consumer representatives, providers and purchasers, with the purpose of reaching consensus and implementing a common, continuously improving set of M/SU health care quality measures for providers, organizations and systems of care to follow. Participants in this consortium should commit to:

* Requiring the reporting and submission of the quality measures to a repository of performance measures.
* Requiring validation of the measures for accuracy and adherence to specifications.
* Ensuring the analysis and display of measurement results in formats understandable by multiple audiences, including consumers, those reporting the measures, purchasers, and quality oversight organizations.
* Establishing models for benchmarking and quality improvement purposes at sites of care delivery.
* Performing continuing review of the measures’ effectiveness in improving care.

These recommendations have not been implemented, and in this regard, Shatterproof recently began an initiative, [The Substance Use Disorder Treatment Task Force](https://www.shatterproof.org/substance-use-disorder-treatment-task-force), to do so. Pursuant to the IOM recommendation 4.3, we recommend that DHHS become involved in this initiative to accelerate its implementation.

We also recommend that reimbursement rates are at a level appropriate with the care being provided.

1. Drive accountability for quick and broad adoption of the CDC Guideline for Prescribing Opioids for Chronic Pain (“CDC Guideline).

There is consensus among all the experts that this epidemic was caused, and continues to be driven by the over-prescribing and mis-prescribing of opioids. We believe the greatest opportunity to stem the opioid epidemic is for prescribing behaviors to be consistent with the latest science. On March 15, 2017, the Centers for Disease Control and Prevention issued the *CDC Guideline for Prescribing Opioids for Chronic Pain* (CDC Guideline). The CDC Guideline must be adopted in emergency timeline.

To do so, we recommend the CDC develop a robust reporting process to drive prescriber and state accountability. This would include:

* An analysis of new patient prescribing that is outside the CDC Guideline (i.e. new opioid prescriptions for more than 3 days) to set a benchmark goal for our nation in the aggregate, and for each state individually;
* Quarterly public publishing of results, actual to goal, within 30 days of the end of each quarter to drive accountability.

This will have enormous impact. I discussed w Dr. Frieden, and he liked it a lot. I then discussed with Deb Houry, and she liked it a lot as well. In this regard, she now has the CDC working on a national goal. However, based on limited resources at the CDC, progress is slower than it could be with additional resources. Based on the number of deaths this could save, the federal government should ensure this gets done asap. The cost in relation to the lives saved would be the best dollars our government could ever spend. There is not a business in America that has spent dollars to create a guideline, and has not set goal to measure against and a system in place to track performance / accountability, in real time.

1. Access to MAT for Every American with an Opioid Use Disorder.

* Close the gap in health care professionals prescribing buprenorphine must be eliminated. Action items:
  + Immediate analysis of supply of prescribers to demand in each country in the US.
  + To close supply gap, federally paid for free training for the 8-hour course, and possibly incentive payments.
  + To increase the number of providers certified to prescribe buprenorphine, increase reimbursement substantially until certain benchmarks in public health are achieved.
* Close the gap of needed specialists to deliver evidence-based behavioral therapies by mobilizing an Emergency Training Program. The program can be developed by the federal government within 60 days of this letter, and fully implemented by December 31, 2018.
* Close the gap in financing by having the federal government paying for MAT for a period of (x) years for those who do not have insurance to do so. In addition, eliminate all prior authorizations in all insurance plans in the United States for any, and all aspects of MAT.

1. Patient Education. Recommendations #2 and #3 in the CDC Guideline are critical to patient health. One possible way to ensure this happens is an amendment to the Controlled Substance Act whereby every time a prescription is written for greater than three days, the prescriber must have the patient sign a consent form explaining the risks and benefits. Alternatively, this may be able to be accomplished by Presidential Executive Order.

In addition, CMS Part D plans put in a prior authorization requirement which would state that prior to the prescribing of any opioid for longer than three days, an Informed Consent Form must be signed by the patient.

1. Maximize Effective Use of State Prescription Drug Monitoring Programs**.** Consistent with the CDC Guideline, doctors must be required to check their state PDMP before making the decision to prescribe Schedule II, III or IV Controlled Substances.

The CDC Guideline has 12 recommendations. Recommendation #9 states: “Clinicians should review the patient’s history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.”

Recommendation #11 states: “Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.”

Well established exceptions for checking the PDMP are i) for terminally ill patients under the supervised care of a hospice program, ii) prescriptions of three days or less supply with no refills, iii) rare instances when it is impossible to query the PDMP in a timely manner due to an emergency situation or if the program is not operational due to technological or electrical failure or natural disaster, iv) patient is in a long-term care facility where medication orders are filled by its own pharmacy or hospital pharmacy, and v)patients being administered methadone or buprenorphine for treatment of opioid addiction.

According to a [recent study by John Hopkins University](C://Users/Gary%20Mendell/Box%20Sync/Advocacy/2016_2018%20Advocacy/Hopkins/2015-prescription-opioid-epidemic-report.pdf), data are accessed in fewer than a quarter of the instances when these physicians prescribe an opioid. As a result, prescribers are solely reliant on information shared by patients to inform clinical decision-making. This practice is fraught with risk because a patient who is misusing opioid medications or has an opioid use disorder may be motivated to conceal prescription history, or alternatively, a patient’s memory or understanding of their own drug intake may be inaccurate or incomplete.

In addition, for prescribers to have the best information possible, pharmacies must be required report all dispensed controlled substances within 24 hours. Approximately half the states require this, and approximately half the states are 7 days, providing doctors old information.

In addition, consistent with both the NGA Report: *Finding Solutions to the Prescription Opioid and Heroin Crisis: A Road Map for States* (National Governors Association Center for Best Practices Health Division and Homeland Security and Public Safety Division’s work on prescription opioid misuse and heroin since 2012), and the Shatterproof Report: *Prescription Drug Monitoring Programs: Effective Elements of State Legislation*:

* States to provide PDMP data to provide proactive analyses and reporting to professional licensing boards and law enforcement
* Make PDMPs easier to use by integrating PDMP data into electronic health records and health information systems and by allowing prescribers to establish delegate accounts
* Ensure PDMP interoperability with other states.
* Ensure access to deidentified PDMP data to identify geographical hot spots and alert law enforcement, public health entities, community coalitions, substance abuse prevention and treatment agencies and the public.
* Authorize medical examiners to obtain PDMP data for death investigations.
* Use de-identified PDMP data to pin-point communities with elevated levels of high-risk opioid and benzodiazepine prescribing as areas at potential high risk for heroin use.

There are two levers to effect broad implementation of these recommendations:

1. President Trump requires prescribers and states to do these actions pursuant to his authority in declaring a Federal Emergency,
2. President Trump, pursuant to the authority vested in him pursuant to declaring a Federal Emergency, that each state signing into law these requirements by April 1, 2018, to be effective no later than September 1, 2018, and if not, a state will not be eligible for its allocation of i) 2018 SAMHSA Prevention and Treatment Block Grants (~$1.8 billion), 21st Century Opioid Funding ($500 million) and CARA Funding (~$180 million).
3. FDA Labeling. FDA can promote more cautious prescribing through improved labeling. Review of opioid labeling as opioids are one of the only medication classes that lack a suggested maximum dose on its FDA-approved label. Even over-the-counter medications include a suggested upper dose. Another problem with opioid labels is that they are too broad, allowing opioid makers to promote use for conditions where risks outweigh benefits.