

66th Meeting of the
Substance Abuse and Mental Health Administration (SAMHSA)
National Advisory Council (NAC)
September 26, 2019
DRAFT Meeting Summary

NAC Members:

Jeffrey Geller, M.D., M.P.H.
Ellen Gerstein, M.A.
Dave Gustafson, Ph.D.
Sally Satel, M.D.
Gail Stuart, Ph.D.
Terri White, M.S.W.

SAMHSA Staff:

Elinore F. McCance-Katz, M.D., Ph.D.
CAPT Carlos Castillo, USPHS
Deepa Avula, M.P.H.
Thomas Clarke, Ph.D.
Roberto Coquis, M.A.
Johnnetta Davis-Joyce, M.A.
Paolo del Vecchio, M.S.W.
Neeraj Gandotra, M.D.
Anne Herron, M.S.
Daryl Kade, M.A.

Elizabeth Lopez, Ph.D.
Louis Trevisan, M.D.

Ex-Officio Representation:

Wilson Compton, M.D., National Institute on Drug Abuse (NIDA), on behalf of Nora Volkow, M.D.
Robert Heinszen, Ph.D, National Institute of Mental Illness, on behalf of Joshua A. Gordon, M.D., Ph.D.
Marsden H. McGuire, M.D., M.B.A., Department of Veterans Affairs
Aaron White, Ph.D., National Institute on Alcohol Abuse and Alcoholism, on behalf of George F. Koob, Ph.D.
Rick Mooney, M.D., M.P.H., Department of Defense, on behalf of Terry Adirim, M.D., M.P.H., M.B.A.

Call to Order

CAPT Carlos Castillo, Designated Federal Official and Committee Management Officer, called the meeting of SAMHSA's NAC to order on September 26, 2019, at 9:06 a.m. The SAMHSA NAC meeting was conducted in a combined virtually/in person fashion, and the members in attendance constituted a quorum.

Welcome, Introductions, Opening Remarks

Dr. Elinore McCance-Katz, the Assistant Secretary for Mental Health and Substance Use, welcomed NAC members. In her opening remarks, she shared the following:

- **Next Meeting** – This will be an in-person meeting either in January or February 2020. SAMHSA staff will be sending NAC members potential dates for consideration later this week.
- **Approval of July 2019 Minutes** – There were no edits to the July 23, 2019, NAC summary. It was motioned for approval and seconded.

- **New Center for Integrated Health Solutions** – SAMHSA has awarded a grant to provide technical assistance to support the integration of physical and behavioral health care. NAC members had emphasized that integration efforts target health administrators so SAMHSA has prioritized this target population as a primary focus for the new center. The grant starts on October 1, 2019.
- **Prac-Ed Grants** – SAMHSA also has launched a new grantee program (Prac-Ed) which will embed substance use disorder (SUD) screening and treatment approaches into undergraduate curricula. The program will begin with training students about opioid and co-occurring disorders but will eventually expand to include other SUD issues. Dr. McCance-Katz noted that SAMHSA is making awards to ten schools and has also been working to encourage credentialing boards to include SUD-related questions into their placement examinations. She noted that it is important to start at the general education level to normalize treatment for SUD, reduce stigma, and increase access to care.
- **Mental Disorder Prevalence Study** – The Epidemiological Catchment Area Study which assessed the prevalence of mental disorders in specific sites and access to services is more than 40 years old. SAMHSA has awarded a single three-year grant to initiate an updated prevalence survey. While the survey will not be done in every county, it is being designed to allow for national estimates. Jails/prisons, nursing homes, homeless facilities, and colleges/universities, will be surveyed in the study. The study will also ensure that there is enough representation to allow for analysis across rural and urban settings. The survey will only focus on adult populations. Dr. McGuire wanted to know if SAMHSA can share who the awardee is. Dr. McCance-Katz said that she needed to find out from her administrator staff whether she would be able to share this information.
- **Contingency Management for Stimulant Use Disorders** – SAMHSA recently convened a meeting of State Opioid Response Program Grantees from all 50 States. A full-day was dedicated to discussions about contingency management (CM). In addition, SAMHSA is allowing States to use grant funding for CM activities. SAMHSA will be able to track the use of CM with grant funds. Dr. Compton said that NIDA would be receptive to amplifying SAMHSA’s work related to the uptake of CM.
- **Factsheets (FAS and Methamphetamines)** – SAMHSA is in the process of developing new factsheets focused on methamphetamines, as well as fetal alcohol syndrome (FAS). Dr. Aaron White offered NIAAA’s assistance in the development of the FAS factsheet.
- **Expert Panel on Marijuana** – SAMHSA convened an expert panel to review research and prevalence trends for marijuana. In addition to providing a landscape of marijuana use, the panel also provided concrete recommendations. The meeting report will be available in the next few weeks and shared with NAC members.
- **Psychiatric Advanced Directive App** – SAMHSA has developed a process for making an award in the development of a psychiatric advanced directive app.

SUPPORT Act Language on Waivered Providers

Dr. Elinore McCance-Katz explained that the October 2018 [SUPPORT for Patients and Communities Act](#) has broadened the type of profession that are now qualified to prescribe medication-assisted treatment (MAT). The legislation also increases the cap on the number patients a prescriber is authorized to treat. For example, providers who were originally capped at 100 patients per year would now be able to treat 275 patients.

The Assistant Secretary wanted to get feedback from NAC members about the implications of this legislative change. NAC members shared the following:

- **Supervision** – Several NAC members wanted information about the level of supervision for these new prescribers. The Assistant Secretary said that it is State-specific, so it will vary.
- **Increase Access to MAT** – Dr. Stuart supports efforts to improve access to MAT. She noted that nurse practitioners are highly regulated with few malpractice concerns compared to other professions. She felt that this expansion wouldn't jeopardize patient safety. Ms. White also felt that for rural locations, such as Oklahoma, increasing the patient cap will expand access.
- **Diversification of MAT** – Dr. Geller said that buprenorphine abuse has increased and it needs to be monitored. Dr. Compton said that there should be research studies to look at how this change could impact diversion rates. Currently, there is minimal research available on this question.
- **Case Management** – Dr. McCance-Katz noted that MAT is required to incorporate behavioral health therapies as part of the treatment approach. SAMHSA is committed to ensuring that qualified practice settings comply with this requirement.
- **Focus on Financial Benefits** – Ms. Gerstein noted that an increase in the cap might change incentives from patient care to financial benefit. She noted that in Georgia there are “pop-up methadone clinics” who are aggressively marketing their services.

42 CFR Notice of Proposed Rulemaking

The 42 CFR provides enhanced confidentiality assurances (e.g., beyond HIPAA) for SUD programs and provider organizations. SAMHSA has received feedback from stakeholders over the years about how the regulation has created barriers to patient treatment and makes coordination of services difficult. SAMHSA [has proposed the following nine updates](#) to the current regulation in order to be responsive to some of these patient care concerns:

1. **Rediscovery** – Currently, if a non-Part 2 provider has SUD information, it is protected under 42 CFR. However, the new regulation would instead protect these records under the auspices of HIPAA. However, if the same entity gets information shared from a Part-2 provider, that information would still be segregated and protected by 42 CFR.
2. **Consent** – Currently, 42 CFR requires that a patient can only consent for release of their information to a specific person rather than an organization. This has been problematic, for example, in applying for social security benefits. So, the proposed rulemaking will allow a patient to consent release of their records to an entity.
3. **Clarification of Disclosures** – Additional text has been added that should help clarify what type of information is allowed be shared with patient consent. Specifically, it would be information to reduce duplication across treatment providers and/or to get information about a patient's medication list.
4. **Reporting to the Prescription Drug Monitoring Program (PDMP) Registry** – Opioid-Treatment Providers will be permitted to report to the PDMP registry, if required by states.
5. **National Emergencies** – During National emergencies, providers will be able to share information so that patient treatment services aren't disrupted (e.g. having to transfer

services to another provider because the original provider is unable to operate due to disruption by a natural disaster).

6. **Audit and Evaluation** – This was already referenced in the preamble of 42 CFR. However, it is being reiterated in the body of the rule for easier reference.
7. **Communications by Personal Devices** – If a patient shares information through a provider’s personal device system and there is a turnover in provider, these communications are no longer bound to the sanitized requirement. Instead, the provider can merely delete the communication.
8. **Disclosures for Research Purposes** – HIPAA-covered entities will be allowed to disclose Part-2 specific information to research entities, even if those entities are not themselves covered by HIPAA or the Common Rule. This will allow entities, such as the Centers for Medicare and Medicaid Treatment, to have access to program data for analytical purposes.
9. **Expansion of Court Ordered Undercover Placement** – Court ordered placement of an undercover agent or informant is currently permissible for up to six months. The proposed rulemaking would allow the placement to be expanded to 12 months. The placement can be further extended by a follow-up court order.

Dr. McCance-Katz noted that the regulations will continue to prohibit law enforcement access to SUD patient records in criminal prosecution and restricts the disclosure of SUD treatment records without patient consent, other than as statutorily authorized. The comment period for the Notice of Proposed Rulemaking (NPRM) ends on October 26, 2019.

Following are comments about the 42 CFR discussion by NAC members:

- **Bifurcated Treatment System** – Dr. Geller asked if SAMHSA would consider removing 42 CFR as it artificially segregates the treatment system. Dr. McCance-Katz said SAMHSA is required to adhere to regulations but her office has done what they can to more closely align 42 CFR to HIPAA. She agreed that the different regulations go against the need for and spirit of integrated services. A patient with the same needs can walk into two separate doors (e.g., their primary care provider or specialized provider) and their records would be treated differently, even though the services would be the same.
- **Appreciation of the Explanations** – Dr. Compton was grateful for the detail provided on the nine changes because he wanted to be sure that clients would not be resistant to seeking out treatment because of concerns that their records would be shared with law enforcement. He also didn’t understand the research disclosure as NIDA is HIPAA covered. The Assistant Secretary’s explanations helped to allay and address these concerns. He also said that he hoped that the national emergencies update would also encompass events like 9-11 which also can disrupt treatment services.
- **“Allegedly Committed by the Patient” Phrase** – Dr. Compton asked for clarification on this phrase which was mentioned in the current NPRM. Dr. McCance-Katz noted that this phrase was already in the rule but had never been through the public comment process. SAMHSA’s Legal Counsel pointed this out. After discussions with the Department of Justice, SAMHSA chose to go back to the original 2017 text. But it is still required to be included for public comment.
- **Additional Restrictions to Research** – Dr. Gustafson asked if there were any changes in the rule that would restrict research. The Assistant Secretary said that the proposed

rulemaking expanded access in some instances, but there were no changes that would restrict the current opportunities for research.

Update on Marijuana Restriction/Language in Notice of Grant Awards

The Assistant Secretary shared that States and other grantees have received notification that SAMHSA funding will not be allowed to directly or indirectly support the use of marijuana for any treatment services related to SUD or mental health. This is in response to the marijuana industry's aggressive efforts to promote marijuana as a health benefit along with concerns related to the THC content of products. She noted that eight states currently have statutes which allow the use of marijuana for OUD treatment, despite the fact that there is no medical evidence to support this. She said that this notification does not restrict funding for research purposes.

Following are questions and comments from NAC members:

- **Non-grant Activities of the Organization** – Dr. McGuire wanted to know if there was another part of the organization that was using marijuana outside of the grant program, would that be prohibited. Dr. McCance-Katz said it would be.
- **NAC Letter to the Editor** – Dr. Gustafson asked if NAC members were allowed to write letters to the editor and other supportive efforts about this. And, if so, could they reference their NAC appointment? Dr. McCance-Katz said that NAC members are appointed as advisors to SAMHSA so they are free to reference that designation. However, SAMHSA cannot provide guidance to the NAC members on their efforts.
- **Research** – It was noted that the exemption on research was important, particularly since universities were concerned about the implication of this restriction on their activities.

Surgeon General's Advisory on Marijuana Use and the Developing Brain

Practitioners have expressed concern about current legislations related to the use of marijuana for OUD. For example, would OUD providers be compelled to provide this approach if a patient specifically asks for this “treatment” In response to these and other concerns, the Surgeon General has issued [an Advisory](#) focused particularly on the impact of marijuana to adolescents and pregnant and parenting women. The Advisory also references concerns related to vaping.

Following are questions and comments from NAC members:

- **Post-Traumatic Stress Disorder (PTSD)** – Ms. Gerstein mentioned that in Georgia, CBD has been added as a treatment for PTSD.
- **Hemp** – New legislation has allowed for the growing of hemp which has lower THC contents. However, it was noted that the way products are manufactured can provide for highly concentrated final products regardless of the original source. The products are also unregulated so there may be other substances mixed in.
- **Workforce Concerns** – The public doesn't realize that use of CBD products will result in positive urine tests and can put their employment in jeopardy.
- **Vaping** – The Food and Drug Administration has authority over nicotine products, but SAMHSA does have a role in providing education about vaping either with nicotine or marijuana products. SAMHSA also manages the Synar Initiative which requires States to enforce efforts that prohibit tobacco access to youth.

- **The Veterans Administration** – VA providers can't advocate for the legitimacy of marijuana use nor can veterans bring marijuana on Federal property. However, marijuana use are discussions that VA providers are allowed to have with their clients.

NAC Comments about Emerging Issues of Concern

Dr. McCance-Katz asked NAC members to share any other concerns that they have related to mental health and substance use concerns. NAC members shared the following:

- **Gun Violence** – Dr. Stuart felt that gun violence is one of the largest public health issues today.
- **Alcohol Use in Teens** – Dr. White shared that if you look at the overall alcohol use rates among teens, the percentages have plummeted. However, a more in-depth look reveals that non-college bound youth are more likely to continue use and that females are more likely to binge drink. He described it a “hardening of use” for some resistant subpopulations.
- **Vaping** – Ms. Gerstein expressed concern with the increase in vaping and the impact that vaping has had on adolescent's age of onset for smoking. Dr. Compton noted that the Monitoring the Future survey has shown dramatic increases in vaping. In addition, other members shared concern about the lung injuries and also that often kids don't know what products they are actually vaping.
- **Methamphetamine** – Dr. Compton stated that methamphetamine overdoses have been on the rise and also is increasingly being seen as a secondary drug among OUD clients. He was glad to see SAMHSA sharing information about CM approaches.
- **SAMHSA-NIDA Partnerships** – Dr. Compton referenced several positive joint initiatives including the Rural Initiative which is looking into models for addiction treatment to address HIV, HPA and the opioid crisis specific to rural parts of the Nation. Another example is the HEALing Communities randomized trial to test whether a systemized integrated community approach has a greater synergistic impact on reducing overdoses.
- **The HEAL Initiative** – NIH has announced \$945 million for the HEAL initiative which funds research to enhance pain management and improve treatment for opioid misuse and addiction. The funding will be appropriated across a two-year period.
- **Labelling Marijuana** – In combatting marijuana, Dr. Geller suggested modelling after similar efforts to challenge advertising that tobacco was a health product. Warning labels were one outcome of that advocacy.
- **Co-Occurring Disorders** – Dr. Geller noted that individuals with dual diagnosis are often shuffled to different agencies as no entity seems to take responsibility for these cases. Dr. McCance-Katz agreed and shared that this has been an important concern of hers. She shared that the recent reorganization of SAMHSA's Technical Assistance Centers is to improve both technical assistance and the implementation of evidence-based practice on a variety of issues, including specialized areas. Co-occurring disorders has been identified as a cross-cutting concern for all the centers to focus on.

Public Comments

There were no public comments.

Closing Remarks/Adjourn

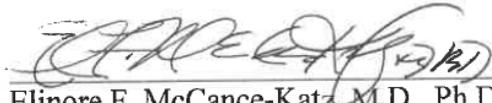
CAPT Carlos Castillo thanked everyone for their participation. He adjourned the meeting at 1:35 p.m.

Certification

I hereby certify that, to the best of my knowledge, the foregoing minutes and the attachments are accurate and complete.

NOV 13 2019

Date


Elinore F. McCance-Katz, M.D., Ph.D.
Assistant Secretary for Mental Health and
Substance Abuse

Minutes will be formally considered by SAMHSA NAC at its next meeting, and any corrections or notations will be incorporated into the minutes of that meeting.