House Committee on Energy and Commerce Hearing: Federal Efforts to Combat the Opioid Crisis

October 25, 2017

Questions for the Record – SAMHSA

The Honorable Michael C. Burgess

1**. CARA requires that resources be put in place to assist women and children affected by opioid addiction. What is SAMHSA doing to address opioid addiction in pregnancy and neonatal abstinence syndrome?**

Response:
Congress passed the Protecting Our Infants Act of 2015, the purpose of which is to address opioid use by pregnant women and resultant consequences to newborn infants. The Act tasked the Department of Health and Human Services to produce a three-part report to include: 1) a review of gaps, overlap, or duplication regarding prenatal opioid use and neonatal abstinence syndrome (NAS); 2) state of the science and clinical practice; 3) and a strategy and set of recommendations. On January 17, 2017, SAMHSA provided the report to Congress. HHS has convened a department-wide workgroup that is developing an implementation plan based on the strategy that will support decision-making by departmental leadership with regard to specific agency priorities.

In addition, SAMHSA is developing *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants*. This Guidance will outline the optimal management of pregnant and parenting women with an opioid use disorder (OUD) and their infants based on the recommendations of experts. This Guidance will help healthcare professionals determine the most clinically appropriate action for a particular circumstance, with the expectation that the healthcare professionals will make individualized treatment decisions. A cornerstone of the Guidance is that a healthy pregnancy results in a healthy infant and mother.

In Fiscal Year 2017, SAMHSA awarded 19 new grants for residential treatment centers for pregnant and parenting women. There are currently a total of 29 grantees receiving a total of $16 million. These programs provide comprehensive services to women with substance use disorders and their families. Treatment is required to include access to medications for women who are opioid dependent.

As a result of CARA, SAMHSA also awarded three new State Pilot Grants for Pregnant and Post-Partum Women (PPW). The goal of the PPW pilot is to expand outpatient services for pregnant and postpartum women and their families with substance use disorder, including OUD and/or co-occurring substance use and mental disorders at the community-level.

SAMHSA and the Administration for Children and Families (ACF) jointly fund the National Center on Substance Abuse and Child Welfare (NCSACW), a national resource center providing

information, expert consultation, training and technical assistance to child welfare, dependency court and substance abuse treatment professionals to improve the safety, permanency, wellbeing, and recovery outcomes for children, parents, and families. The NCSACW also makes available webinars, assessment instruments, training and program toolkits, resource lists, and other publications**.**

With SAMHSA and ACF support during 2017, NCSACW conducted 12 presentations and 11 web-based trainings/virtual meetings on opioids. During its September 2017 webinar, "Supporting Families Affected by Opioid and Other Substance Use Disorders, Child Abuse and Prevention Act, Plan of Safe Care," over 1,200 individuals attended. In addition, during the same period NCSACW received and responded to over 300 opioid-related technical assistance requests; produced and disseminated the Policy Academy brief, *Improving Outcomes for Pregnant and Postpartum Women with Opioid Use Disorders and Their Infants, Families, and Caregivers*; and developed a web-based directory of resources on best practices for the treatment of opioid use disorders and neonatal abstinence syndrome.

2. **Effective treatment options are key to helping solve the opioid crisis and many for-profit type entities have entered the treatment and recovery space. Are we doing enough to ensure quality among treatment and recovery centers? What more can we do to help those seeking help better find and compare the quality of treatment options?**

Response:
SAMHSA is committed to promoting effective practice across the behavioral health service system. Improving access to medication-assisted treatment remains a central part of SAMHSA's efforts to improve practice in the treatment of opioid use disorder. A number of SAMHSA's programs have this as a primary goal and a number of other related programs with a broader focus, such as drug courts, have also made use of medication assisted treatment a priority.

SAMHSA requires the use of evidence-based practices (EBPs) in its grant programs, including the recent State Targeted Response to the Opioid Crises Grant program authorized by the 21st Century Cures Act. Grant project officers ensure that EBPs are used by the grantees that they oversee and help programs address implementation issues by linking them to training or technical assistance.

To assist individuals seeking help for opioid use disorders, SAMHSA has supported a number of shared decision-making tools for consumers of treatment and recovery support services. Shared decision-making is an emerging best practice in behavioral and physical health that aims to help people in treatment and recovery have informed, meaningful, and collaborative discussions with providers about their health care services. It involves tools and resources that offer objective information. People in treatment and recovery can then weigh that information against their personal preferences and values. Shared decision-making tools empower people who are seeking treatment or in recovery to work together with their service providers and be active in their own treatment.

In 2016, SAMHSA released *Decisions in Recovery: Treatment for Opioid Use Disorder*, an innovative decision support tool for people in or seeking recovery from opioid use disorder, as well as for treatment providers. Consumers who use this tool learn about medication assisted treatment, how to be better positioned to compare treatment options and decide which is the best option for their recovery, and how to discuss preferences with a treatment provider.

SAMHSA continues to explore additional opportunities to share and disseminate these tools.

The Honorable Greg Walden

1**. The Comprehensive Addiction and Recovery Act of 2016 (CARA), which was signed into law over a year ago, empowered the Secretary of Health and Human Services to determine methods by which office-based opioid addiction treatment practitioners provide all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder. Similarly, CARA provides the Secretary with the authority to ensure that such practitioners are trained in evidence-based practices such as detoxification, relapse prevention and the use of all FDA-approved medications for the treatment of opioid use disorders.**

Please tell us what progress you have taken to implement these reforms to opioid addiction treatment. When do you expect SAMHSA to fulfill its requirement to ensure providers are educating on the full range of requirements in CARA? Finally, does SAMHSA have a timeline on when it will notify existing waivered providers on the requirements of CARA to offer all FDA-approved medications to patients seeking treatment?

Response:
SAMHSA held a meeting for all of the eligible training providers in September 2016. At that meeting, the group agreed to a revised curriculum with a new set of learning objectives that is in line with section 303 of CARA and includes information on the use of all FDA-approved medications. SAMHSA's training program, the Providers' Clinical Support System-Medication Assisted Treatment, completed its update of the online and live courses to be compliant with section 303 in November 2017. Now that TIP 63: *Medications for Opioid Use Disorders,* has been released, SAMHSA will ensure that currently waivered practitioners receive the TIP which includes information about the appropriate use of all FDA-approved medications for the treatment of opioid use disorders consistent with the requirements of CARA. At the same time, providers that do not work in SAMHSA regulated Opioid Treatment Programs are still not permitted by law to prescribe or dispense methadone for opioid use disorder treatment under the Controlled Substances Act.

2. **CARA and CURES provided significant funding for states to expand substance use disorder treatment, through grants administered by SAMHSA. In addition, CARA required grantees to submit data that will be posted online and easily searchable. Can you provide us with a status update on those requirements?**

Response:
All CARA program grants that were appropriated funding for Fiscal Year 2017 have been awarded. Funding opportunities for each of the programs required specific data elements to be collected.

Grantees for the First Responders - Comprehensive Addiction and Recovery Act Cooperative Agreement will respond to the following measures:

1. The number of first responders and members of other key community sectors equipped with a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose;
2. The number of opioid and heroin overdoses reversed by first responders and members of other key community sectors receiving training and supplies of a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose;
3. The number of responses to requests for services by the entity or sub-grantee, to opioid and heroin overdose; and
4. The extent to which overdose victims and families receive information about treatment services and available data describing treatment admissions.

The Improving Access to Overdose (OD) Treatment grantee will respond to the following measures.

1. Total amount of OD Treatment Access grant funds spent on purchase of FDA-approved overdose reversal drugs.
2. Number of health care providers and pharmacists trained on the prescribing of drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.
3. Total amount of OD Treatment Access grant funds spent on co-payments and other cost sharing associated with drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.
4. Number of patients who have experienced a drug overdose that are connected with appropriate treatment, including medication assisted treatment and appropriate counseling and behavioral therapies.

a. **What accountability measures is SAMHSA requiring of states to make sure that the grant monies are spent wisely?**

Response:
All SAMHSA grantees are required to report data to SAMHSA on a regular basis regarding their program's progress. Each program is required to report both output and outcome measures demonstrating project progress. These measures may include, but are not limited to:

1. Number of people served;
2. Abstinence from substance use;
3. Employment status;
4. Housing status;

5. Criminal justice involvement; and
6. Retention in treatment.

b. **How do we know if states are spending money on people who are most likely to respond to treatment?**

Response:
The State Targeted Response to the Opioid Crisis Grant provides states and jurisdictions with the flexibility to provide opioid use disorder treatment services in a variety of clinical settings. States were required to develop a strategic plan targeting geographic regions and populations that were most in need and to report the data that lead them to select those areas and populations in the application and in a strategic plan. The plans are monitored by grant project officers on regular monthly calls and by submission of progress reports by states twice per year.

States' and jurisdictions' administrative rules require substance use disorder treatment providers to utilize standardized assessment instruments to determine if a person meets the criteria for an opioid use disorder. The states and jurisdictions and their respective sub-recipients, i.e., community- and faith-based organizations, are required to implement or expand access to clinically appropriate evidence-based medications and services for persons with an opioid use disorder, including the use of FDA-approved medications designed for the treatment of an opioid use disorder. States and jurisdictions and their respective grant sub-recipients must also provide appropriate psychosocial intervention and recovery support services for persons in early recovery.

c. **Is there a formal risk assessment that states must use to make sure the monies are targeting the people who are most likely to benefit from such treatment programs?**

Response:
The State Targeted Response to the Opioid Crisis Grant requires states and jurisdictions to develop a needs assessment using statewide epidemiologic data. The needs assessments identify: (1) geographic areas within a state or jurisdiction where opioid misuse and related harms are most prevalent; (2) the number and location of opioid use disorder treatment providers in a state or jurisdiction; and (3) existing activities and services and their funding sources in a state or jurisdiction that address opioid use prevention, treatment and recovery activities and gaps in such activities and services.

Further, the State Targeted Response to the Opioid Crisis Grant requires states and jurisdictions to develop comprehensive strategic plans to address the gaps in prevention, treatment and recovery services identified in their respective needs assessments. The states and jurisdictions prepared and submitted their respective needs assessments on or before July 31, 2017, and their respective strategic plans on or before August 30, 2017.

The plans are monitored by grant project officers on regular monthly calls and by submission of progress reports by states twice per year. Reports on the first six month progress were due December 15, 2017.

The Honorable Markwayne Mullin

1. Preliminary estimates from the CDC show that 64,000 Americans died from opioid overdoses last year. Another 50,000 or 60,000 of our fellow citizens will die from medical conditions closely related to opioid abuse like HIV/AIDS, Hepatitis C and cirrhosis. Yesterday, I became the lead sponsor of Rep. Tim Murphy's bill, the Overdose Prevention and Patient Safety Act, which would make it easier to share addiction medical records in care coordination settings. Do you believe 42 CFR Part 2 is an impediment to addressing our nation's opioid crisis?

Response:
The federal regulations at 42 C.F.R. Part 2 (Part 2) allow substance use disorder (SUD) patient information to be shared among providers in certain circumstances. For example, a patient can give written consent to authorize the sharing of his or her SUD treatment record with any treating provider. Also, Part 2 typically does not apply to entire hospitals, emergency rooms (ER)/departments, or trauma centers, which would usually be considered general medical facilities. Accordingly, Part 2 is not an impediment to the sharing of SUD treatment records among providers in these settings, where the HIPAA Privacy Rule would continue to apply. With regard to general medical facilities or staff within such facilities, Part 2 applies only to an identified unit in the facility to the extent that the unit holds itself out as providing and provides SUD services, or to staff within the facility whose primary function is the provision of SUD services and who are identified as providers of such services. When Part 2 applies, it allows sharing without a patient's consent in medical emergencies, such as opioid overdoses. The Part 2 medical emergency exception allows a patient's SUD information to be shared with other medical personnel when there is a bona fide medical emergency in which the patient's consent cannot be obtained. The determination of whether a medical emergency exists is made by the treating/disclosing provider. Information disclosed by a Part 2 program during a medical emergency can be further shared with medical providers as needed (i.e., re-disclosed) in order to diagnose or treat the patient during the emergency.

At the same time, there are statutory limitations related to sharing protected SUD patient information absent written consent, and the exceptions to the consent requirements are limited. The statute has been an impediment to sharing addiction records in care coordination settings. Within the constraints of the statute, SAMHSA has been working diligently to issue clarifications and education providers about what information sharing is permissible under both the statute and the regulation.

As required by the 21st Century Cures Act (section 11002), SAMHSA held a public meeting on January 31, 2018, to obtain input about the impact of Part 2 on "patient care, health outcomes, and patient privacy." The information gathered during this Part 2 public meeting can help policymakers better assess what changes can and should be made under current regulations or whether statutory changes are required to accomplish such objectives.

i. If yes – Are you supportive of a legislative fix like my bill (HR 3545) that would align Part 2 with HIPAA?

Response:
While the Administration has not taken a position on this bill HHS remains happy to provide technical assistance on any legislation if desired. SAMHSA supports further consideration of the benefits of aligning Part 2 with HIPAA.

ii. If no – why do you support a separate privacy rule for patients with addictions?

Response:
N/A

b. The President's Opioid Commission and the Former CDC Administrator Tom Frieden have highlighted a need to fix Part 2. What have your agencies heard in the numerous round table discussions held across the country? Can any of you address this problem internally?

Response:
SAMHSA acknowledges concerns expressed by stakeholders. SAMHSA regularly responds to inquiries and participates in calls with stakeholders who both generally favor and are critical of Part 2. While SAMHSA does not provide legal advice, the Agency strives to understand stakeholder concerns about Part 2 implementation and regulatory requirements. SAMHSA staff often discuss the rule with stakeholders and potential approaches to such issues as data sharing by all-payer claims databases, use of electronic health records, responding to medical emergencies, research and many other topics.

In addition to such discussions with stakeholders, SAMSHA also received numerous public comments on Part 2 as part of the notice-and-comment rulemaking process including:

- During a June 2014 listening session (May 12, 2014, 79 FR 26929; https://www.samhsa.gov/about-us/who-we-are/laws-regulations/public-comments-confidentiality-regulations);
- Following publication of a notice of proposed rulemaking in February, 2016 (Feb. 9, 2016; 81 FR 6987); and
- Following publication of a supplemental notice of proposed rulemaking (82 FR 5485) in January 2017.

In compliance with the 21st Century Cures Act, SAMHSA hosted a listening session on January 31, 2018.

c. Part 2 is cited as the reason why most states are not sharing data or not tracking outcomes in regards to treatment. What guidance can be given to states to measure outcomes but protect patient information?

Response:
Part 2 does not preclude sharing of Part 2 data for purposes of research, audit, or evaluation. The final 2017 Part 2 rule allows a Part 2 program or other lawful holder of patient identifying information to disclose Part 2 data to qualified personnel for purposes of conducting scientific research if the researcher provides documentation of meeting certain requirements for existing protections for human research (HIPAA and/or HHS Common Rule, 45 CFR Part 46). In the final rule, SAMHSA expanded permissible data linkages to enable researchers holding Part 2 data to link to data sets from federal and non-federal data repositories. Similarly, Part 2 permits a Part 2 program or other lawful holder to disclose patient identifying information to certain persons for audit or evaluation purposes, if certain requirements are met. Thus, states can measure outcomes while protecting patient information by conducting research based on client outcome measures as well as evaluating outcomes of patients utilizing the current Part 2 provisions related to these areas.

d. Does anyone have a sense of the potential savings for Medicare and Medicaid if we are able to amend Part 2?

Response:
To SAMHSA's knowledge, there is no independent, peer-reviewed research concerning the costs of Part 2 to Medicare and Medicaid. As noted in the final 2017 rule, SAMHSA has used HIPAA costs as a proxy for estimating the regulatory impact of Part 2. SAMHSA therefore cannot specifically quantify the estimated savings or costs to these programs, were Part 2 to be amended.

e. If we are able to save money via care coordination, shouldn't we be able to adequately fund treatment programs back in the states?

Response:
Care coordination is an effective way to identify patients with high service utilization or clinical risks and to address these needs and risks through increased support from specialized doctors or a care manager/coach that collaboratively assist in the management of disease. Care coordination provides benefits for the individual's health status, as well as in managing foreseeable and expensive costs related to crisis and emergency needs, while supporting the individual with the provision of lower-cost alternative care. Care coordination is promising, but there is insufficient data to know if the savings generated would provide significant reinvestment opportunities. Better health at a lower cost has been a long-standing goal of health care systems. Coordinated care may provide some system savings that could be reintroduced into state and community systems to meet emerging funding needs. Currently, disclosing information related to treatment-related activities such as care coordination requires written consent under Part 2. SAMHSA supports further consideration of the benefits of aligning Part 2 with HIPAA.

2. According to the CDC, Native Americans have the highest rates of both opioid overdose deaths as well as HCV-related deaths. Does your department engage with these populations around risk factors associated with opioid abuse, including the spread of infectious diseases such as HIV and HCV?

Response:
SAMHSA is committed to addressing the behavioral health needs of the nation, including American Indians and Alaska Natives (AI/AN). In response to behavioral health and related issues faced by AI/ANs, SAMHSA established the Office of Tribal Affairs and Policy to improve the Agency's response and coordination of resources for these populations. SAMHSA has improved access to prevention resources for AI/ANs that address behavioral health-related risks for tribal communities. These resources include behavioral health information specifically for tribal communities, as well as funding opportunities that allow tribes to address targeted substances of abuse.

For example, the Tribal Behavioral Health Grant program (also called TBHG or Native Connections) focuses on preventing and reducing suicidal behavior and substance abuse and promoting mental health among Native young people. Among other actions, each TBHG grantee assesses their substance abuse, suicide, and other mental health needs and develops a targeted plan for addressing them. Based on the tribal grantee's assessment, the targeted substance(s) of abuse may include opioids, alcohol, methamphetamines, and/or other drugs. There are similar opportunities to address opioids through other substance abuse prevention grants for which tribal entities are eligible. In addition, SAMHSA-supported resources such as the "Risk and Protective Factors for Substance Abuse and/or Mental Health Problems Among Alaska Native and Native American Populations" publication identify specific risk and protective factors based on published studies that assist in developing targeted tribal programming for Alaska Natives.

Mental and substance use disorders can contribute to the risk for HIV/AIDS and viral hepatitis. As a result, SAMHSA supports efforts such as the HIV Capacity Building Initiative, Minority AIDS Initiative Continuum of Care, and Targeted Capacity Expansion-HIV Program. Tribal communities have been supported through some of these efforts which allow for HIV testing (and pre- and post-test counseling), referrals for treatment, integration of medical HIV/AIDS and behavioral health care, and testing for other infectious diseases such as hepatitis C. SAMHSA also developed an information resource called "Hepatitis C/HIV in Native American Populations" and distributed it widely to elevate the awareness of tribal communities on these risks, actions they can take, and funds available through the agency.

3**. Do you currently have the ability to help tribal and public health systems develop programs to alert providers of care for opioid abuse to also test for concomitant infectious diseases and provide a pathway to treatment? Are you engaging in these activities currently, if so, can you please elaborate on these efforts and provide any findings on the results?**

Response:

Yes, SAMHSA has the ability to help tribal and public health systems develop programs. Specifically, SAMHSA addresses the risks for HIV/AIDS and viral hepatitis by supporting grants that improve coordination of mental and substance use disorder treatment, including HIV testing with pre- and post-test counseling and referrals for treatment; integrated medical, HIV/AIDS, and behavioral health care; and testing for other infectious diseases. Examples of funded tribal projects include the following grants:

- Native American Health Center's Ekwahness ("To Hold Tightly")
- Salish Kootenai College Integrative Community Empowerment
- College of the Muscogee Nation's Guarding the Future

Currently, SAMHSA administers the "Minority AIDS Initiative Continuum of Care Pilot - Integration of HIV Prevention and Medical Care into Mental Health and Substance Abuse Treatment" program. This program supports projects that coordinate and integrate services through the co-location of behavioral health treatment and HIV medical care including American Indians and Alaska Natives. The focus is on substance abuse treatment programs and community mental health programs that can co-locate and fully integrate HIV prevention and medical care services within them.

In Fiscal Year 2017, SAMHSA announced the "First Responders - Comprehensive Addiction and Recovery Act Cooperative Agreement" program. SAMHSA awarded over $11 million over four years to 21 grantees to train and provide resources for first responders and members of other key community sectors on carrying and administering an FDA-approved product for emergency treatment of known or suspected opioid overdose. States and tribal entities (American Indian and Alaska Native tribes, tribal organizations, and consortia of tribes or tribal organizations) were eligible to apply. The tribal entities receiving a grant were the Choctaw Nation of Oklahoma, White Earth Band of Chippewa Indians, Lac Du Flambeau Band of Lake Superior Chippewa Indians, and the Cherokee Nation.

4. How could we strengthen our public health system infrastructure to better respond to the opioid epidemic and its long term health consequences?

Response:
The opioid epidemic has had a significant impact on the nation and tribal communities. According to SAMHSA's 2016 National Survey on Drug Use and Health report, which provides national and state-level data on the use of tobacco, alcohol, illicit drugs (including non-medical use of prescription drugs) and mental health in the United States, 11.8 million people in the U.S. aged 12 or older misused opioids in the past year and 948,000 reported using heroin. Within this number, 63,000 American Indians and Alaska Natives aged 12 and older reported misusing opioids and 5,000 aged 12 and older reported using heroin. In 2015 and 2016, illicit drug use was higher among American Indians and Alaska Natives as compared to the total U.S. population.

In FY 2017, the Department of Health and Human Services announced that $485 million would be awarded to states and territories to combat opioid addiction through the State Targeted Response (STR) to the Opioid Crisis Grant program. The STR program is administered by

SAMHSA and aims to: increase access to treatment; reduce unmet treatment needs; and reduce opioid overdose related deaths through the provision of prevention, treatment, and recovery activities for opioid use disorder, including prescription opioids, as well as illicit drugs such as heroin. By statute, tribes were not directly eligible for an STR grant, and SAMHSA can encourage but not compel states to include tribes in their STR plans. .

<u>The Honorable Gus Bilirakis</u>

1. As more treatments for diseases transition from more expensive care settings like inpatient to out-patient facilities and even to the home, what is the importance of being able to treat addiction in a home setting versus a traditional methadone clinic?

Response:
Treatment of addiction is increasingly accessible and affordable for individuals in an outpatient or intensive outpatient setting versus a more expensive and confining inpatient or residential setting. Outpatient treatment services include the availability of safe and effective medication-assisted treatment programs for patients with opioid use disorders, using methadone, buprenorphine, or naltrexone, in combination with evidence-based addiction counseling and related services and supports. For some people who are stable or for whom the risk of complications is low, treatment that does not require regular attendance at a facility may be the most appropriate because convenience of treatment often improves adherence. Having more options that can address the variety of patient needs improves outcomes. The Drug Addiction Treatment Act of 2000 (DATA 2000) enabled buprenorphine to be prescribed or administered to a patient on an outpatient basis by a physician, nurse practitioner, or physician assistant with a certain type of waiver. Patients who are treated by providers with waivers are not required to attend a program daily, as is generally the practice when a patient begins methadone treatment in an Opioid Treatment Program. Another treatment option that is becoming increasingly popular is the use of extended-release injectable naltrexone, which is administered as a once a month injection by a physician for individuals to prevent relapse to opioid dependence, after the patient has completed opioid detoxification. This medication also has the advantage of not requiring that a patient be able to attend a daily or weekly treatment program. In addition, in May, 2016, the Food and Drug Administration approved the first buprenorphine implant for the maintenance treatment of opioid dependence. This medication is designed to provide a constant, low-level dose of buprenorphine for six months in a patient who is already stable on low-to-moderate doses of other forms of buprenorphine, as part of a complete treatment program. In November, 2017 the Food and Drug Administration also approved the first once-monthly injectable buprenorphine product for the treatment of moderate-to-severe opioid use disorder in adult patients who have initiated treatment with a transmucosal (absorbed through mucus membrane) buprenorphine-containing product. This product provides a new treatment option for patients in recovery for whom the once-monthly injection may be more appropriate than other forms of buprenorphine, as it may reduce the burden of taking medication daily as prescribed (medical adherence).

2. **Currently there isn't a clear standard for medication assisted treatment (or MAT) prescribing, and we've heard reports of an increasing number of rogue actors offering MAT. In many cases these "pop up clinics" actively recruit vulnerable client populations and provide substandard services with minimal oversight. While we support consumer choice and market competition, we also want to balance this with consumer safeguards to ensure that this problem improves, not worsens, and that bad actors are not rewarded via federal dollars. Additionally, questions have been raised as to whether states are requiring evidence-based practices be used in the STR grant program. What is SAMHSA doing to ensure rogue actors are not the recipient of federal dollars and evidence-based practices are being used so that funds expended go to providing the best possible treatment and recovery services?**

Response:
SAMHSA regulates Opioid Treatment Programs through an initial certification process and ongoing accreditation oversight. SAMHSA also manages the DATA 2000 waiver program for physicians, physician assistants, and nurse practitioners that provide office-based prescribing of certain FDA-approved medications for opioid use disorder. In addition to management and oversight of STR Grantees (as described above), SAMHSA is providing ongoing technical assistance (TA) to all grantees using conferences, webinars, learning collaboratives, and the $12 million Opioid State Targeted Response TA program. Evidence-based MAT prescribing, supported by a variety of SAMHSA tools and resources, is an essential aspect of this TA.

SAMHSA required states to identify the evidence-based practice that they intended to use in their initial application for STR funds and in their strategic plans submitted in August of 2017. Grant project officers have monthly calls with each state to discuss progress on implementation of their plans and any concerns that either the state or SAMHSA has with progress. Grant project officers are also making site visits to states to meet with state staff and providers and patients to understand the implementation process on the ground. States are required to report twice a year on a set of questions including the numbers of people that received specific services. Additionally, the program is being evaluated by an external evaluator. The evaluation includes an assessment of use of evidence-based practices.

SAMHSA also recently released a fact sheet, "Finding Quality Treatment for Substance Use Disorders." This fact sheet provides individuals and families with some of the right questions to ask when looking for quality treatment, including whether the treatment program is licensed or certified by the state, whether the program offers FDA approved medications, whether the program includes family members in the treatment process, and whether the program provides other supports in addition to treatment. The fact sheet is on SAMHSA's website: https://store.samhsa.gov/shin/content//PEP18-TREATMENT-LOC/PEP18-TREATMENT-LOC.pdf.

<u>The Honorable Chris Collins</u>

1. Despite the staggering overdose reports from my district's coroners and the CDC, opioids are still primarily used for the treatment of pain. It is estimated that around 250

million Schedule II prescriptions are filled across the country each year. However, there are other effective options for pain management. For example, several academic peer-reviewed journals have found that states that have legalized the use of marijuana for medical purposes had significantly lower state-level opioid overdose mortality rates…and found that it was an effective form of pain management. Alternatively, anesthesia is utilized in various surgical and non-surgical procedures to improve perioperative *[preoperative, intraoperative, and postoperative]* pain control while minimizing systemic opioid consumption.

a. **Under the Opioid State Targeted Response (STR) grants, are states using funds to educate physicians and providers on utilizing non-opiate treatment for pain?**

Response:
The State Targeted Response to the Opioid Crisis Grant program provides states and jurisdictions with the flexibility to obligate and expend funds to train substance use and mental health care practitioners on topics such as best practices for prescribing opioids, pain management, recognizing potential cases of substance use disorder, referral of patients to treatment programs, and overdose prevention, including the Centers for Disease Control and Prevention's (CDC) Guidelines for Prescribing Opioids (https://www.cdc.gov/drugoverdose/prescribing/guideline.html) to train practitioners. The Opioid STR Mid- and End-Year Reports do not capture any information regarding the use of non-opioids for the treatment of chronic pain or training focused on the use of non-opioids for the treatment of pain. The states and jurisdictions also have the flexibility to train opioid use disorder prevention and treatment providers, such as physicians, nurses, nurse practitioners, physicians assistants, counselors, social workers, care coordinators, and cases managers. SAMHSA's Opioid Overdose Prevention Toolkit (https://store.samhsa.gov/shin/content/SMA13-4742/Overdose_Toolkit_2014_Jan.pdf) must be used when developing training to address opioid overdose, as well as CDC's Guidelines for Prescribing Opioids.**.**

2. CARA established the Pain Management Best Practices Inter-Agency Task Force to provide advice and recommendations for development of best practices for pain management and prescribing pain medication. The Task Force is also expected to develop a strategy for disseminating such best practices to relevant federal agencies [the Department of Veterans Affairs, Department of Defense, and Department of Health and Human Services] and the general public.

a. What is the current status of the nominations process? As this is an advisory committee, to what degree do you expect providers to adopt these practices? Please explain.

Response:
The deadline for nominations to serve on the Task Force closed on September 27, 2017; HHS is currently in the process of reviewing all applications, and it is anticipated that decisions will be made soon. Once selections have been made and agreements to serve have been secured, the Task Force membership roster will be announced on the HHS webpage, https://www.hhs.gov/ash/advisory-committees/pain/index.html.

The Task Force is required to propose updates to best practices and recommendations on addressing gaps or inconsistencies between best practices for pain management (including chronic and acute pain) developed or adopted by Federal agencies. The proposed updates and recommendations will be submitted to relevant Federal agencies and the general public to consider.

3. Under CARA's Opioid State Targeted Response grants, states would distribute funds using a strategic planning process and upon which states were required to submit a needs and capacity assessment to SAMHSA. The use would go to nine allowable activities.

Is this information and distribution of funds collected in a database? If so, can you please describe how you can utilize this data in further identifying gaps in prevention, treatment, and recovery?

Response:
States were required to submit both a needs assessment and strategic plan describing how needs would best be addressed in each state. Once the funds were released to the states, the states determined how to further allocate the funding. States identify who is funded in their bi-annual reports, and the data is compiled in SAMHSA's online block grant application system (WebBGAS) available for further review.

4. Under Section 303 of the Comprehensive Addiction and Recovery Act, eligible physician assistants and nurse practitioners can receive a waiver to prescribe drugs for maintenance or detoxification treatment (i.e. buprenorphine) for 30 or less patients that the total number applicable to the qualifying practitioner. The cap can be raised to 100 after the prescriber has been waivered for one year. As this program has gotten off the ground, we are starting to hear from some practitioners working in addiction clinics that may quickly reach the 30 patient limit, and clinics in areas that have a challenging time finding waivered practitioners may have to turn away patients who are seeking treatment for opioid addiction.

Is raising the cap beyond Section 303 something Congress or HHS should consider raising? Why or why not?

Response:
SAMHSA began processing waiver applications for mid-level practitioners in February 2017, and it is preparing a report, as required by CARA, that addresses, among other issues, whether there is a need for the Secretary to increase or decrease the number of patients a practitioner with a waiver may treat. That report is due in July 2019. SAMHSA will continue to implement the provisions of CARA and looks forward to receiving input from stakeholders regarding this matter, which will inform the July 2019 report.

__**The Honorable Tim Walberg**__

1. Section 102 of CARA provides for a National Awareness Campaign to educate both parents and youth. We need to ensure that we are doing all we can to protect the next generation with robust prevention programming messages to serve as a counterweight to the proliferation of pro-drug messaging in the media today. However, the Awareness Campaign has yet to be funded – or even really acknowledged. An awareness campaign is desperately needed.

What is the status of implementing Section 102 of CARA?

Response:
The office of the Assistant Secretary of Public Affairs (ASPA) is coordinating the National Awareness Campaign. There are three components of this Campaign. The Campaign will help to educate Americans across the lifespan to:

- Understand their roles in the opioid crisis;
- Adopt behaviors to prevent opioid medication-sharing; and
- Engage in safe storage and disposal practices.

2. What is SAMHA's plan for implementing the National Awareness Campaign?

Response:
SAMHSA's component is still under development.

__**The Honorable David McKinley**__

1. Police, fire fighters, and other emergency personnel are the first to arrive on an opioids related scene. These professionals are there to protect us, but they are at risk of being exposed to potent opioids and their synthetic analogues, such as fentanyl and carfentanyl. What's being done to protect these first responders, what more can be done, and what do you need from Congress?

Response:
SAMHSA acknowledges the importance of protecting our first responders who are out in the field saving lives, but may be at risk of exposure to opioids and/or its analogues. SAMHSA administers the Grants to Prevent Prescription Drug/Opioid Overdose-Related Deaths (PDO) and the First Responders – Comprehensive Addiction and Recovery Act Cooperative Agreement (FR-CARA) grant programs. Through technical assistance and training, SAMHSA encourages our grantees to use the following two resources in addition to SAMHSA's Opioid Overdose Prevention Toolkit:

1. Fentanyl: A Briefing Guide for First Responders (June 2017)

    - https://www.dea.gov/druginfo/Fentanyl_BriefingGuideforFirstResponders_June2017.pdf
2. Fentanyl: Preventing Occupational Exposure to Emergency Responders, Protecting Workers at Risk (August 30, 2017)
    - https://www.cdc.gov/niosh/topics/fentanyl/risk.html

It is also important that all first responders have easy access to naloxone not just for preventing the death of the individuals they serve in the community, but for preventing the death of their first responder colleagues as well. This goes hand-in-hand with training of first responders on information such as the nature of the opioids involved, the safe handling of these drugs and how to protect oneself (e.g. having access and utilizing personal protective equipment), the signs and symptoms of an overdose, how to administer naloxone, and the possibility of administering more than one or two doses.

2. The 21st Century Cures Act passed last year provided nearly $1 billion in funding designated predominantly to expand treatment for opioid use disorders through the State Targeted Response grant program. We appreciate HHS releasing the first round of $485 million in funding this year, but were surprised that West Virginia was not awarded funding in the first round of $144.1 million additional funding. Specifically, SAMHSA awarded $9.8 million over three years for a new State Pilot Pregnant and Postpartum Women's (PPW) program. We received notice from the West Virginia Department of Health and Human Resources (DHHR) that they applied for this funding and were denied.

a. What determinants are taken into consideration when allocating certain dollar amounts?

Response:
Each grant has its own set of evaluation criteria, which are used to review applications. These evaluation criteria are listed in each funding opportunity announcement and includes Statement of Need; Proposed Approach; Staff, Management, and Relevant Experience; and Data Collection and Performance Measurement. The STR formula consisted of two elements: treatment gap and number of drug poisoning deaths. The treatment gap is weighed at 70 percent; the mortality figure is given at 30 percent weight.

b. Does a state with a higher level of deaths receive more funding or preference than a state with a lower level of deaths?

Response:
Whether an applicant is successful for any of the non-formula based grants under the programs authorized by CARA is based on the particular need for funding as articulated in the responses by the applicant to the Funding Opportunity Announcement and that application then is scored by a peer review panel. SAMHSA provides non-formula based grants to the applicants with the highest scores with the funding available to SAMSA by Congress. The STR formula consisted of two elements: treatment gap and number of drug poisoning deaths. The treatment gap is weighted at 70 percent; the mortality figure is given a 30 percent weight. Each state receives a

proportional share of the funding based on the state's proportional share of the national numbers for the measures listed above.

c. If so, then why was West Virginia's application declined?

Response:
Applications submitted by entities from West Virginia for additional discretionary funding did not score high enough in the peer review process to receive a competitive award.

d. What can they and similar entities in their situation do in the future to strengthen their application?

Summary statements will be sent to each applicant detailing the peer reviewer response to the application. The summary statements for each applicant will include a narrative describing the strengths and weaknesses for each evaluation criteria section of the application. This will help inform the applicant on ways to improve their submissions. The summary statements for the First Responders and State Pilot Grant for Treatment of Pregnant and Post-Partum Women have been completed and released to organizations. The summary statements for Building Communities of Recovery and Services Grant Program for Residential Treatment for Pregnant and Post-Partum Women are in the process of being written.

3. In addition, I have heard that some states have not fully released STR funding which has created obstacles for rural communities to combat the opioid crisis directly. What barriers are preventing the use of this grant money and what is HHS doing to address these barriers? What can be done to expedite getting these dollars into the communities that need them most?

Response:
SAMHSA released the FY 2017 State Targeted Response (STR) to the Opioid Crisis Grant Notices of Award on April 27, 2017, and the funds were available for distribution on May 1, 2017. Most states' administrative rules required the Opioid STR recipients to follow their respective procurement rules applicable to federal funds. As a result, some states experienced delays in making Opioid STR funds available to sub-recipients, i.e., community-and faith-based organizations approved by the states to provide opioid use disorder prevention, treatment and recovery services. All states have subsequently fulfilled their respective procurement processes and opioid funds are being made available to sub-recipients.

4. What is being done to address difficulties that individuals have accessing treatment for opioid use disorder, especially in rural and underserved communities? How should we address the lack of treatment providers with addiction treatment skills?

Response:
One way SAMHSA addresses the lack of treatment providers is by is working with the Health Resources and Services Administration and other operating divisions within HHS and across the federal government to expand access via telehealth. We are in the process of developing a use case that explains how telehealth can be used to provide MAT in rural areas.

SAMHSA is also developing an Extension for Community Healthcare Outcomes (ECHO) pilot to examine how additional training and mentoring impact physician practice change (e.g. treating more patients with opioid use disorders). Project ECHO is a model developed by the University of New Mexico to expand medical knowledge and get best practice care to those who need it. Multipoint videoconferencing is used to provide didactic and case-based learning to health professionals more effectively developing capacity to safely and effectively treat individuals with a substance use disorder (SUD). Many waivered providers do not prescribe because they do not feel competent to treat a complex condition like opioid use disorder. This method has been shown to help providers in rural areas provide care that is comparable to specialty care for other complex conditions. More than half of the states are using their Opioid STR funding to create ECHO programs to support rural providers. States are also setting up hub and spoke systems modeled on the state of Vermont program. In this model, patients are stabilized in a specialty care setting (hub) and once on a stable dose of medication they are referred to a primary care provider (spoke) who can manage the medication. If the primary care provider has questions or concerns, s/he can reach out to the hub provider for guidance and support.

In addition, SAMHSA's Addiction Technology Transfer Center (ATTC) Program develops and strengthens the specialized behavioral healthcare and primary healthcare workforce that provides SUD treatment and recovery support services. The ATTCs deploy a variety of methods to accelerate the adoption and implementation of evidence-based and promising SUD treatment and recovery-oriented practices and services by heightening the awareness, knowledge, and skills of the workforce addressing the needs of people with substance use or other co-occurring health disorders; and fostering regional and national alliances among culturally diverse practitioners, researchers, policy makers, funders, and the recovery community.

The ATTC grantees work directly with SAMHSA on activities aimed at improving the quality and effectiveness of treatment and recovery, and work directly with providers of clinical and recovery services, and others that influence the delivery of services, to improve the quality of workforce training and service delivery across the nation and in rural and underserved communities. The ATTC program supports Opioid Treatment Programs to develop their workforce capacity. Project ECHO (mentioned above) is an example of a technology that the ATTC's use to improve the skills of treatment providers and increase access to SUD care.

SAMHSA supports a number of training initiatives to increase the number of qualified healthcare providers who can provide treatment for opioid addiction. In the last four years, more than 62,000 medical professionals have participated in online or in-person trainings on MAT for opioid addiction through SAMHSA's Providers' Clinical Support System (PCSS)-MAT. This program is a national training and clinical mentoring project that provides mentoring of newly trained physicians by experienced specialists, maintains a library of evidence-based practice materials, and offers at no cost to the trainee the required DATA 2000 waiver training to enable

providers to prescribe buprenorphine for opioid addiction treatment. SAMHSA recently awarded a grant to provide technical assistance and training related to prevention, treatment and recovery from opioid use disorder to states and communities on individual needs within these jurisdictions as a means to better assure the use of evidence based practices and to expand the healthcare workforce providing treatment for opioid addiction.

The Honorable Pete Olson

1. Of the grant funding provided for in CARA, how much funding has been allocated to state prescription drug monitoring programs (PDMPs)?

Response:
The FY 2017 appropriations act did not provide funds to SAMHSA to carry out the PDMP provisions of CARA.

2. Do you think states need additional federal grant funding to improve their PDMP or to fund clinical workflow integrations?

Response:
States have multiple potential sources of funds to improve their PDMPs. Many specialty addiction care providers still do not participate in electronic data transfer as they do not have electronic health records. This may impact workflows and information sharing and impede the integration of care.

The Honorable Bill Johnson

1. Community-based organizations like Field of Hope are on the front lines of the opioid epidemic. CARA included numerous grant programs and funding sources to address addiction treatment, but it does not seem to have trickled down to the front-line providers. What is SAMHSA doing to ensure that grant funding aimed at substance abuse benefits on-the- ground providers, and are there ways we could improve in that area?

Response:
SAMHSA carries out its role through a variety of mechanisms, including administering grant programs (e.g. drug court grants, pregnant and postpartum women treatment grants, youth and family treatment grants); convening policy academies and expert meetings; providing training and technical assistance to the field; and developing and disseminating information resources.

SAMHSA's criminal justice programs recognized that drug court professionals needed enhanced awareness and skills in understanding and connecting clients with medication assisted treatment (MAT). SAMHSA responded by increasing the amount of grant dollars grantees can allocate towards MAT and provided a grantee training on how to implement MAT. As a result of these and other efforts, 57 percent of SAMHSA's criminal justice programs have integrated MAT into their programming.

Also, the Building Communities of Recovery grants were awarded to eight organizations in Fiscal Year 2017. The purpose of this new CARA-funded program is to mobilize resources within and outside of the recovery community to increase the prevalence and quality of long-term recovery support from substance abuse and addiction. These grants support the development, enhancement, expansion and delivery of recovery support services.

Additionally, in Fiscal Year 2017, SAMHSA funded:

- Nineteen new residential treatment programs for pregnant and postpartum women and their families with substance use disorder (SUD) and/or co-occurring substance use and mental disorders at the community-level.
- Three new state programs to primarily expand outpatient services for pregnant and postpartum women and their families with SUD and/or co-occurring substance use and mental disorders at the community-level.
- Twelve new state youth treatment grants with a requirement to expand the number of treatment providers to serve youth with SUD and/or co-occurring substance use and mental disorders.
- Seventy five criminal justice grants to organizations to provide treatment to individuals involved in the criminal justice system.

The Honorable Susan Brooks

1. I have heard you say that preventing drug use before it begins is this the most cost-effective way to reduce drug use and its consequences. In your opinion, what are the characteristics of successful prevention intervention programs? Besides lack of resources, what are the barriers to implementing intervention programs?

Response:
Characteristics of successful prevention intervention programs are represented in the National Institute on Drug Abuse's Preventing Drug Use among Children and Adolescents: A Research-Based Guide for Parents, Educators, and Community Leaders (2nd ed.). Sixteen prevention principles are presented to assist parents, educators, and community leaders to think about, plan for, and deliver research-based drug abuse prevention programs at the community level. The areas addressed include, but are not limited to: risk factors and protective factors, prevention planning, and prevention program delivery. The core elements of effective research-based programs include: Structure – how each program is organized and constructed; Content – how the information, skills, and strategies are presented; and Delivery – how the program is selected or adapted and implemented, as well as how it is evaluated in a specific community. When adapting programs to match community needs, it is important to retain these core elements to ensure the most effective parts of the program stay intact. SAMHSA promotes the use of its Strategic Prevention Framework, a planning process, as a comprehensive guide to plan, implement, and evaluate prevention programs.

Successful implementation strategies take time and resources. The essential challenge is to ensure that the incentives, structures, and operations at the systems, organizational, and

practitioner level are consistent with each other and aligned in a way that supports the desired practitioner behavior. In "Implementation Research: A Synthesis of the Literature," researchers found that well planned and carefully executed implementation strategies can be used to improve services at the practitioner level, organizational level, and national level. In the programs that were examined, the core implementation components involved: careful selection; staff training, coaching, and performance evaluation; program evaluation and facilitative administration; and methods for systems interventions.

With regard to barriers to program implementation, one of the biggest challenges to the field is the ability to take effective programs and replicate them with fidelity across the country. In the Institute of Medicine's "Strategies for Scaling Effective Family-Focused Preventive Interventions to Promote Children's Cognitive, Affective, and Behavioral Health (workshop summary)," barriers identified to scaling up research-based programs include: lack of demand for the programs, insufficient organizational capacity, lack of sustainable funding, and factors other than evidence from research that influence decision making around whether or not to implement a particular program. The potential for many evidence-based interventions is not fully realized when interventions are not implemented with quality, or that quality is not sustained over time. Scaling up a program can also be hampered by an over-reliance on program developers who do not have the expertise or time to scale-up and disseminate their programs, and rigid adherence to the programs which may need to be adapted to specific populations or organizations.

2. Substance use disorder confidentiality regulations limit the use and disclosure of patients' addiction records from certain treatment programs. I've heard from health providers that separating a patient's addiction record from the rest of his or her medical record may hinder the delivery of receiving safe, effective, and coordinated treatment.

a. In the context of the opioid crisis, do you believe it is important that a patient's provider has access to his or her substance use disorder record?

Response:
Yes, it is important that a patient's provider have access to the patient's substance use disorder treatment record as the health and safety of the patient should be the first priority of all providers. While SAMHSA has undertaken efforts to facilitate information exchange by revising its regulations related to confidentiality of substance use disorder treatment records (42 CFR Part 2), the current statute can be an obstacle to a providers' ability to access their patients' records and Part 2 is not completely aligned with HIPAA.

b. Do you think a patient whose doctor doesn't know that he or she is in recovery from an opioid addiction is getting the best evidence-based care?

Response:
SAMHSA believes strongly that patients who have received or are receiving treatment for a substance use disorder benefit from receiving integrated, coordinated care. Accordingly,

SAMHSA's 2017 and 2018 final Part 2 rules reflect the agency's efforts to balance the need for integrated care with the need to ensure patients receiving diagnosis, treatment and referral for treatment for substance use disorders also understand how and by whom their part 2 patient identifying information is used. Part 2 permits patients to consent in writing to sharing information with their treating providers. Indeed, the final 2017 rule makes this process easier than previously was the case by permitting the use of a general designation (i.e., the patient can choose to share their Part 2 information with "all of my current treating providers"). SAMHSA encourages Part 2 programs and patients to discuss the benefits patients may obtain from coordinated care which, in turn, is best facilitated by permitting their health care providers to receive part 2 information. Moreover, during a medical emergency when prior patient consent cannot be obtained, a Part 2 program also may disclose information needed to respond to that emergency (42 CFR 2.51 - Medical emergencies.)

c. There is a lot of talk about mental health and addiction parity. Do you think it's parity for a substance use record to be treated differently from a mental health or HIV record? Can the same quality care be given when a provider does not know that their patient is being treated for an addiction?

Response:
SAMHSA supports further consideration of the benefits of aligning the statute governing Part 2 with HIPAA to ensure parity.

<u>The Honorable Richard Hudson</u>

1. Many people coming out of the correctional system have had problems with opioids and represent some of those at highest risk for overdose and death. What is SAMHSA doing to address this?

Response:
SAMHSA's role in the criminal justice system is to bring about strategic linkages between community-based behavioral health providers, the criminal justice system, and community correctional health programs; promote effective diversion and reentry programs; and foster policy development at the intersection of behavioral health and justice issues. Recognizing that individuals leaving the correctional system have a high risk for overdose and death, SAMHSA encourages drug courts and offender reentry program grantees to spend up to 20 percent of their annual grant award to pay for Food and Drug Administration-approved medications for treatment or substance use disorders.

Offender reentry program grants are also required to develop and implement an overdose prevention program as part of their service delivery for soon-to-be released offenders and those recently released from a correctional setting. These grantees collaborate with community corrections programs, law enforcement, and judges on the program. The opioid overdose prevention programs must include an educational component, which includes SAMHSA's

Opioid Overdose Prevention Toolkit (https://www.samhsa.gov/capt/tools-learning-resources/opioid-overdose-prevention-toolkit).

SAMHSA also provides training on how to implement opioid overdose prevention programs and medication assisted treatment programs for its criminal justice grants through webinars, on-site technical assistance, trainings, grantee meetings and conferences.

The Honorable Ben Ray Lujan

1. While the funding provided by the 21st Century Cures Act was extremely welcome in my state, we still need to do more to expand treatment capacity. For many of my constituents it often feels like we are trying to hold back the ocean armed with a tablespoon. Listen to a few lines from a letter I received just a few days ago from a distraught father in my district:

"As a responsible parent, I must inform my daughter about the dangers of pills and opioids because, statistically speaking, she's more likely to die from an overdose than anything else. So how do I begin to explain how we got here? How do I explain that Congress, the President, and even the DEA are ignoring the issue, and things are getting worse? This isn't hyperbole: overdoses are killing far more Americans than gun homicides and opioids in particular are killing more people than cocaine, meth, or any other illegal narcotic. And I am now in the impossible position of having to explain all of this to my daughter."

So while the funding provided in Cures was a first step, we must do more. What the advocates and planners in our states and cities need is certainty. They can't hope to hire new staff or spend money on infrastructure if they don't think funding is going to last for more than 2 years. As a result, I've heard from my community that money has gone toward short-term and stopgap measures. Measures that do little to reassure parents in Santa Fe or in other parts of my state that Congress understands their concerns and that we are providing real help for a very real problem.

We all know that short-term solutions aren't enough to seriously address this epidemic. We need to seriously invest time and money into combatting this crisis in our communities, and we need to do so in a way that builds in stability and allows our communities to do long term planning.

a. Assistant Secretary McCance-Katz are you aware of which, if any, states have used the funding passed in 21st Century Cures to expand physical infrastructure or undertake strategic planning that goes beyond the 2 year funding window passed in 21st Century Cures?

Response:
The State Targeted Response to the Opioid Crisis Grant (STR) requires states to prepare and submit needs assessments and strategic plans. The assessments were submitted on or before July

31, 2017, and the strategic plans were submitted on or before August 3, 2017. States recognize that the 2-year funding authorized by section 1003 of the 21st Century Cures Act will assist states in addressing some of their emergent needs regarding prevention, treatment and recovery support services for persons with opioid use disorders. The STR grants allow a very small portion of grant funds to be used to renovate or alter existing facilities, building new facilities is not an allowable expense.

2. I think we need to do more to build long-term capacity to address this epidemic. That is why I have introduced the Opioid and Heroin Abuse Crisis Investment Act to extend the 21st Century Cures funding for an additional five-years – a timeframe that allows for long-term planning and more than stopgap measures. I'd welcome my colleagues support on this effort and hope that we can work together in a bipartisan fashion to find creative ways to get more support to those in need.

The Comprehensive Addiction and Recovery Act (CARA) made critical strides in the fight against the opioid epidemic. This committee worked to help expand access to vital addiction treatment options including medication assisted treatment (MAT). CARA allowed Nurse
Practitioners (NPs) and Physician Assistants (PAs) to prescribe MAT in accordance with state law. I supported that effort and I think we can build on that work.

Congressman Tonko and I recently introduced legislation to do just that. Current law sunsets the authority for NPs and PAs – our bill makes it permanent. The legislation also recognized the integral role played by Advanced Practice Registered Nurses (APRNs) in health care teams all across the country, but especially in rural states like New Mexico where thousands of families depend on APRNs for so much of their routine health care. We especially need to make it easier for pregnant and postpartum women struggling with addiction to get help.

Allowing all APRNs, including Certified Nurse Midwives, to prescribe and refer to MAT will expand access for addicted New Mexicans and Americans across the country.

a. What is SAMHSA doing to ensure medication assisted treatment is easily accessible to all who need the help?

Response:
SAMHSA develops and publishes documents to educate providers and patients regarding FDA approved medications for the treatment of substance use disorders. SAMHSA further provides education including DATA waiver training and mentoring to providers through its Providers' Clinical Support System on the use of medication-assisted treatment in providing care to populations affected by substance use disorders. SAMHSA has a treatment locator to help patients locate Opioid Treatment Programs and Drug Addiction Treatment Act waivered providers on its website. SAMHSA works in partnership with DEA and State Opioid Treatment Authorities to administer technical assistance to providers establishing new treatment programs. SAMHSA offers the State Targeted Response Grants, Medication Assisted Treatment-Prescription Drug Opioid Addiction grants, and Block grants which are all sources of funding for

medication assisted treatment. Finally, SAMHSA processes all applications for new providers regulated by the Agency as expediently as possible.

b. How would expanding who can prescribe medication assisted treatment impact access in rural areas like parts of New Mexico?

Response:
Expanding prescribing authority to qualified providers may have a positive impact on access to care in all geographic settings, but could be especially helpful in rural areas that do not have as many physicians as NPs, PAs and other non-physician providers.

3. Assistant Secretary McCance-Katz: We appreciate all of the work your agency has been doing to provide block grants to our communities back home. I recently had the opportunity to visit with a recovery center in Española, New Mexico. During this visit I was surprised to learn that rural treatment centers are not always considered eligible for grant funding because of certain grantee requirements – even as rural regions in the US are getting hit harder!

I'd like to share a specific example from Hoy Recovery. Recently, a Center for Substance Abuse Treatment Targeted Capacity Expansion grant became available. The grant would have been ideal for this center except New Mexico was disqualified because the grant required a substantial increase in admissions to Medication Assisted Treatment.

New Mexico was not able to demonstrate increased use MAT because we didn't have the workforce capacity and needed assistance to expand – the exact thing the grant would have provided.

Another example: There was a recent Office of Minority Health grant that Hoy also applied for. However, the evaluation requirements called for a greater number of patients served than they, as a small, rural community, could produce.

While I understand the importance of targeting funding to the largest number of people possible, many of the communities that need help the most are much smaller than 100,000 people.

a. How does SAMHSA justify requiring proof of capacity expansion for grants intended to help organizations expand capacity?

Response:
SAMHSA did not receive an application for a Targeted Capacity Expansion Medication Assisted Treatment Prescription Drug and Opioid Addiction grant from New Mexico. SAMHSA does allow applicants for this program to spend funds on infrastructure development to begin developing capability not just to expand capacity.

SAMHSA did not define eligibility for this program. Eligibility was articulated in the FY 2017 Omnibus, which required that eligibility for MAT-PDOA be limited to the states with the highest

rates of admissions, including those that had demonstrated a dramatic increase in admissions for the treatment of opioid use disorder. As identified by SAMHSA's Treatment Episode Data Set (TEDS): 2007 – 2014, 17 states were eligible to apply. New Mexico was not one of the 17 states with the highest rates of primary treatment admissions for heroin and opioids per capita, and therefore was not eligible to apply for a MAT-PDOA grant in FY 2017.

b. What can we tell our constituents who live in small, rural communities that are ineligible for more funding simply because they are small?

Response
SAMHSA does not restrict eligibility on its community-based grants based on size. All applications are accepted from all communities. SAMHSA has funded and continues to fund small, rural communities.

c. Has SAMHSA produced any materials that explore barriers and restrictions for funding of rural communities?

Response:
While smaller, rural communities are not restricted from applying for funding opportunities, SAMHSA recognizes they may face challenges in developing and submitting all required application materials, especially the first time. For this reason, SAMHSA hosts applicant webinars to walk potential applicants through the entire process, including application and registration processes, requirements and validations, and the post-submission process. Recordings of the webinars are generally posted on the SAMHSA website as well for those unable to join at the scheduled times. Certain grant programs have also included program specific webinars and FAQs for potential applicants. As well, each funding opportunity announcement includes staff contacts at SAMHSA whom applicants can reach out to with programmatic or financial questions.

4. In 2015, 33,000 Americans died from opioids. According to the CDC, almost half of those deaths were from prescription opioids. The New York Times reports that in 2016, overdoses from all drugs was the leading cause of death of people under the age of 50. Drug overdoses now kill more Americans each year than at the height of the HIV epidemic and the worst year for auto accident deaths. The Times and drug use experts attribute the sharp rise in all drug overdose deaths to the rise of opioids. What we need to fight this epidemic is continued and reliable long-term investments in prevention, treatment, recovery, and monitoring.

The President's budget proposal for fiscal year 2018, coupled with other administration initiatives, takes several steps back in the fight against opioid addiction, including a cut in funds for SAMHSA. Overall, the President's proposed budget cuts HHS by 16.2 percent, the CDC by 17 percent and NIH by 19 percent. It cuts funding for addiction research, treatment and prevention. Even the White House Office on National Drug Control Policy would take a
95 percent hit.

a. Assistant Secretary McCance-Katz, do you have all of the tools you need to stop the opioid epidemic?

Response:
HHS is currently reviewing the need for additional resources and authorities to address the opioid epidemic in order to ensure a coordinated response by the Department in partnership with other areas of the Federal Government.

b. Given the 10 percent cuts to SAMHSA in the President's budget proposal, what programs relating to the opioid epidemic will be cut? Which programs would have been expanded that will now not be?

Response:
The Substance Abuse Treatment appropriation was preserved in its entirety. Additionally, all programs in the Substance Abuse Prevention appropriation specifically related to opioids were also preserved in their entireties in the Fiscal Year 2018 President's Budget.

<u>The Honorable Paul Tonko</u>

1. With the passage of CARA, PAs and NPs can receive a waiver to prescribe buprenorphine after completing 24 hours of education. This 24 hour requirement is viewed by many healthcare providers as a barrier to care, given that many qualified PAs or NPs will have difficulty completing this requirement, and especially given the fact that physicians are only required to complete eight hours. Do you have any data that justifies the differences in requirement for this waiver, and are changes to this requirement something that you think the Department should consider?

Response:
The 24-hour training requirement is a congressional mandate under CARA. SAMHSA does not have any data to justify the difference in the requirement or evidence that the additional hours of training are a significant burden to mid-level providers.

2. In order to receive a waiver to prescribe buprenorphine, PAs and NPs are currently required to have their supervising or collaborating physician be "waiver eligible." This requirement has the potential to restrict access to treatment for those suffering from opioid addiction. The Secretary HHS has the ability to allow PAs and NPs that work in collaboration with a physician to obtain waivers, even if that collaborating physician is not a waiver-qualified provider. Are changes to this requirement something that you think the Department should consider?

Response:

The Secretary has regulatory authority over the requirements that must be satisfied to qualify as a “qualifying other practitioner,” and this authority includes the authority over the "collaborating or supervising physician requirement" under 21 USC 823(g)(2)(G)(iv)(III).

In addition, some states have laws that require nurse practitioners or physician’s assistants to prescribe medications for the treatment of opioid use disorder in collaboration with or under the supervision of a physician. Twenty-eight states require some degree of collaboration or supervision of nurse practitioners by physicians.[1] The regulations regarding what physician assistants (PAs) can prescribe vary by state; in 44 states and the District of Columbia PAs can prescribe all FDA-approved medication-assisted medications, while 5 states allow them to prescribe only buprenorphine and naltrexone, and Kentucky allows them to prescribe only naltrexone.[2] PAs generally practice under physician supervision. SAMHSA began processing waiver applications for mid-level practitioners in February 2017 and it is preparing a report, as required by CARA, informed by input from stakeholders.

3. Can you briefly discuss your experience with expanding MAT in jails and prisons in Rhode Island, and how SAMHSA and this Administration could help support and expand these innovative approaches?

Rhode Island has implemented a program in which individuals incarcerated are screened for opioid use disorder and evaluated to determine medical needs related to this condition. If a person is already receiving medication assisted treatment for an opioid use disorder, this is continued. If a person is opioid-addicted and at risk for withdrawal they are offered medical treatment including initiation of medication assisted treatment (for those with short sentences). For those who are near release and have a history of opioid use disorder and are not on medication assisted treatment; they are offered the opportunity to begin treatment prior to leaving the Dept. of Corrections. All of those with opioid use disorder are connected to ongoing outpatient treatment prior to leaving and naloxone is also offered on release. This program has been well accepted by inmates and staff alike and Rhode Island is seeing success in assuring ongoing care for this population which is at high risk for overdose death on leaving jail or prison without medication assisted treatment and clinical follow up.

Response:
SAMHSA’s criminal justice programs focus on developing systemic and strategic linkages between community-based behavioral health providers, the criminal justice system, and community correctional health programs to promote effective diversion and reentry programs; and foster policy development at the intersection of behavioral health and justice issues.

Recognizing that individuals leaving the correctional system have a high risk for overdose and death, SAMHSA encourages drug courts and reentry grants to spend up to 20 percent of their

[1] https://www.aanp.org/legislation-regulation/state-legislation/state-practice-environment
[2] https://www.aapa.org/wp-content/uploads/2017/03/f-833-4-8256527_dk6DMjRR_Prescribing_IB_2017_FINAL.pdf

annual grant award to pay for Food and Drug Administration-approved medications for medication assisted treatment. Reentry grants have been required to provide a plan and implement an overdose prevention program as part of their service delivery for soon-to-be released offenders and those recently released from a correctional setting. These grantees collaborate with community corrections programs, law enforcement, and judges to develop and implement an opioid overdose prevention program. The opioid overdose prevention programs must include an educational component, which includes SAMHSA's Opioid Overdose Prevention Toolkit (https://www.samhsa.gov/capt/tools-learning-resources/opioid-overdose-prevention-toolkit).

SAMHSA provides training on how to implement opioid overdose prevention programs and medication assisted treatment programs for its criminal justice grantees through webinars, on-site technical assistance, trainings, grantee meetings and conferences.
SAMHSA is aware of several department of corrections programs (Rhode Island, Pennsylvania, Massachusetts, Kentucky) who have developed MAT programming, including all three FDA approved medications, with the purpose of improving outcomes and success rates after the individual is released to the community. SAMHSA grantees, regional administrators, and community partners are key links in working with the Department of Corrections to ensure there is a continuum of care, accountability, and support as individuals' transition from incarceration to the community.

The Honorable Frank Pallone, Jr.

1. With 90 percent of addictions beginning in the teenage years, we know there is a critical need for effective drug prevention programming, especially during this current opioid crisis. In the past decade, our national prevention infrastructure has been decimated (including the elimination of funding for the National Youth Anti-Drug Media Campaign) and our ability to educate young people and prevent more teens from becoming addicted is hobbled. We need prevention messages to serve as a counterweight to the proliferation of pro-drug messaging in the media today.

In order to convey the risk of opioid and other drug abuse and reverse the stark addiction and overdose trends that are creating heartbreak in families across the country, investment in prevention messaging is crucial. Regarding Section 102 in CARA- the National Awareness Campaigns provision, can you please tell us what the status of implementation and investment is? What do the various agencies plan to do to move forward with this provision and how can we help?

Response:
The Office of the Assistant Secretary of Public Affairs (ASPA) is coordinating the National Awareness Campaign. There are three components of this Campaign. The Campaign will help to educate Americans across the lifespan to:

- Understand their roles in the opioid crisis;
- Adopt behaviors to prevent opioid medication-sharing; and

- Engage in safe storage and disposal practices.

In addition, the Centers for Disease Control and Prevention (CDC) released the Rx Awareness communications campaign publicly in September. The campaign features real-life accounts of individuals living in recovery from opioid use disorder, and those who have lost someone to a prescription drug overdose. The campaign will increase awareness and knowledge among Americans about the risks of prescription opioids and deter inappropriate use.

2. Press coverage of the response to the epidemic often focuses on expanding access to treatment and increasing the availability of naloxone. However, those are two elements that must fit into a larger, more comprehensive response.

Dr. McCance-Katz – Could you briefly discuss the importance of deploying a comprehensive response to this epidemic spanning the entire spectrum from primary prevention to recovery?

Response:
To fully address the opioid crisis, our nation must prevent people from developing a problem by reducing use of opioids and stopping misuse before it develops into a disease state. If an individual does develop an opioid use disorder (OUD), service systems must make sure the individual has access to evidence-based treatment and recovery support services. HHS' five point opioid strategy is designed to cover the entire spectrum and includes:

1) Strengthen public health data reporting and collection to improve the timeliness and specificity of data and to inform a real-time public health response;
2) Advance the practice of pain management to enable access to high-quality, evidence-based pain care that reduces the burden of pain while also reducing inappropriate use of opioids and related harms;
3) Improve access to addiction prevention, treatment, and recovery support services;
4) Target the availability and distribution of overdose-reversing drugs to ensure broad availability of these medications to people likely to experience or respond to an overdose; and
5) Support cutting-edge research to advance understanding of pain and addiction, lead to the development of new prevention interventions and treatments, and identify effective public health interventions to reduce opioid-related harms.

3. Dr. Volkow and Dr. McCance-Katz I would like to ask you a few questions related to treatment approaches for opioid use disorder. I have been particularly struck by stories of individuals with opioid use disorder and families who have been targeted and referred to low quality and non-evidence-based treatment services. As I'm sure you're aware, in many cases, this has led to tragic consequences upon leaving such programs.

a. Dr. Volkow and Dr. McCance-Katz – I understand that the evidence is clear that medication assisted treatment is the gold standard of opioid use disorder treatment. What are some of the barriers of widespread uptake for this treatment approach?

Response:
The biggest barrier is access to providers who can prescribe or administer the medications. There are not enough providers who are willing and able to treat patients with opioid use disorder. As of April 13, 2018, there are 1,585 Opioid Treatment Programs and over 49,000 waivered prescribers many of whom never prescribe MAT or do not prescribe to their patient limit[3] there is an inadequate supply of providers who can treat individuals with OUD. While any licensed prescriber can administer Vivitrol, the requirement to be medically withdrawn from opioids prior to its administration means that it can be difficult to initiate in an outpatient setting.

The second barrier is knowledge and attitudes. Many parents of young adults report multiple admissions into short term residential treatment settings for their children without ever having been told about medication. Patients and families may not know about medication as an option and medication free treatment programs often do not raise it as a possibility because of misperceptions about utilizing medication to treat certain substance use disorders.

Patients receiving MAT may face discrimination in many systems including in the work place, in criminal justice settings, in child protective settings and others that discourage or mandate that patients not take medication for their OUD.

Finally, difficulty accessing medication by reason of insurer requirements such as prior authorizations and cost can be a barrier for some people.

b. What is the difference between this and other chronic conditions as far as uptake of evidence-based medical care? And could you dispel some of the stigma that exists about the use of medications to treat this chronic condition that doesn't exist for the use of medications to treat like diabetes or heart disease?

Response:
Approximately 20 percent of individuals with opioid use disorder receive treatment for this condition. Fewer than half of private-sector treatment programs offer medications for opioid use disorders. Thus, uptake of treatment and evidence based care is much less than it is for other conditions. SAMHSA continues to work to dispel the stigma regarding use of medications to treat opioid use disorder, but in many communities stigma is ingrained at levels from family members to providers and government officials. More work needs to be done to ensure that patients can access evidence-based care.

c. What are you doing to increase awareness among the general public and the medical community about these evidence-based approaches to opioid use disorder?

Response:
SAMHSA produces a number of publications and tools, and delivers technical assistance for providers and laypersons to increase awareness of medication-assisted treatment (MATx App, PCSS-MAT, toolkits, continuing medical education).

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[3] Drug Alcohol Depend. 2017 Dec 1;181:213-218. doi: 10.1016/j.drugalcdep.2017.10.002. Epub 2017 Oct 18.

As required by CARA, SAMHSA is developing a Toolkit for Improving Practice (TIP) replacing two TIPs on medications to treat opioid use disorder (TIP 40, "Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction"; and TIP 43, "Medication Assisted Treatment for Opioid Addiction in Opioid Treatment Programs") with a single TIP that covers all approved medications.

SAMHSA also works with professional associations and consumer groups to inform members and the general public about the evidence for medication assisted treatment.

4. According to SAMHSA's annual survey on drug use and health, in 2016, there were approximately 21 million Americans aged 12 years or older that need substance abuse treatment, however, only around 11 percent or 2.2 million of these individuals received treatment.

a. What are some of the barriers that exists for individuals receiving treatment for their opioid use disorder?

Response:
There were about 2.1 million people with active opioid use disorder in 2016 and about 20 percent of them received some type of treatment. Most people do not seek out care. For those that do, the primary barrier is access to care. In many locations there is no provider, or there are waiting lists to receive treatment. For some people, barriers are resources to pay for treatment or transportation to treatment programs, or other obligations like family and work that make it hard to find time to go through the process of becoming eligible for treatment.

SAMHSA is encouraged by the efforts in some states to reach out to people with opioid use disorder in emergency departments and in community settings to try to engage them in seeking care. Some state programs are guaranteeing immediate access to treatment for people with opioid use disorder who ask community outreach workers, first responders or others for care.

b. I understand that approximately 96% of those who need substance abuse treatment do not believe they need treatment. How can we further increase the likelihood that those with substance abuse disorders understand the need for and their ability to acquire substance abuse treatment?

Response:
Training providers to recognize, screen for, and treat substance use disorders, particularly in primary and general medical settings will assist in identifying more patients with substance use disorder and getting them into appropriate treatment programs.

However, many people with substance use disorders do not access healthcare services of any kind. Many communities are using people in recovery to conduct outreach and engagement activities to encourage more people to enter treatment. These efforts are taking place in emergency departments, in community settings like homeless shelters or areas where people who use drugs may congregate, and in other settings like fire and police stations. In addition,

SAMHSA's Screening, Brief Intervention, and Referral to Treatment (SBIRT) grants encourage the participation of Employee Assistance Programs (EAPs) to provide early identification and support of those with substance use disorders. Currently, an SBIRT grantee is has a targeted initiative to utilize SBIRT in EAPs.

In order to get individuals with substance use disorders to understand that they need help and that help is available, their perceptions about the need for and the benefit of receiving treatment must change. SAMHSA works to increase availability of gender-specific and culturally-appropriate education, prevention, and early interventions, which includes strategies for outreach and engagement. SAMHSA recognizes the importance of providing outreach and other engagement strategies to increase participation in and access to treatment for diverse populations; thus, there is standard language regarding this in SAMHSA's funding opportunity announcements.

5. Dr. McCance-Katz, I am interested in learning more about efforts to expand the substance abuse treatment workforce. I am pleased that Congress and the Obama Administration were able to take steps to expand the workforce and efforts to expand access to buprenorphine by better utilization of the existing health care workforce.

However, we continue to hear that workforce shortages are limiting access to substance abuse treatment.

a. Could you briefly describe the current supply of the substance abuse treatment workforce and how that matches up with the demand for substance use disorder treatment services?

Response:
Many reports have documented the supply and distribution of professionals who oversee the care of persons with substance use and mental disorders. Each report had unique methodologies and occupations that were included. Data exists for psychiatrists, psychologists, advance practice nurses, social workers, licensed professional counselors (substance use disorder and mental health) and other counselors, marriage and family therapists, school psychologists, and to some limited extent on prevention specialists, peer recovery specialists, and psychiatric aides. Information on Drug Addiction Treatment Act 2000 waivered prescribers is also available.

Methodologies used to measure future demand vary, leading to mixed conclusions. However, most studies anticipate worker shortages. With a few exceptions, southern states and several mid-west states have the greatest deficits in psychologists, counselors and social workers. (2013, Health Resources and Services Administration "The U.S. Health Workforce Chart book. Part IV: Behavioral and Allied Health).

The Rural Health Research Center Data Brief (Supply and Distribution of the Behavioral Health Workforce in Rural America, 2016) describes non-metropolitan counties without behavioral health providers, and the large percentage of counties without any of these professionals (psychiatrists - 65 percent; psychologists - 47 percent; psychiatric nurse practitioners - 81 percent).

A report by the SAMHSA Addiction Technology Transfer Centers, “Vital Signs: Taking the Pulse of the Addiction Treatment Workforce, A National Report” (2012, Ryan, Murphy, Krom) reported that annual turnover of direct care staff newly hired in the previous 12 months was 52 percent, and the previous 12-month turnover for all staff (new and more than 12 months) was 18.5 percent. The report concluded that high turnover rates add to provider training and recruitment costs and could threaten the quality of care received by clients entering treatment. Retention of staff is an important consideration impacting supply and distribution of staff.

SAMHSA and the Health Resources and Services Administration implement congressionally mandated programs to address workforce shortages. All of the programs aim to provide training fellowships/scholarships and loan repayment programs to students pursuing health professions, some that are specific to behavioral health and others that are for primary health care providers who could provide care in an integrated health care setting. These programs are all primarily aimed at addressing the supply and distribution issues. The Minority Fellowship Program managed by SAMHSA also addresses the supply issue for Fellows working with underserved populations.

As we learn to more effectively engage people in treatment and begin to better address barriers to care, such as stigma and misunderstanding, fragmentation of services, and insurance limitations, the need for a qualified and stable workforce will grow.

b. Could you talk about some of the barriers that prevent students and health care providers from pursuing careers in the treatment of substance use disorder specifically and behavioral health more generally?

Response:
There are several barriers that, combined, make it difficult to encourage students and health care professionals to become behavioral health (substance use and mental health treatment) providers.

1. Stigma – There remains a great deal of stigma toward individuals with substance use and mental disorders. There is still the idea that individuals with behavioral health conditions can “pull themselves up by their bootstraps” and not a very good understanding that these are neurobiological disorders.
2. As with other chronic disorders, it can be frustrating to see the struggles and not the success in treatment in many instances.
3. Reimbursement – In comparison to many other fields in health care – professionals who treat behavioral health conditions do not make as much money as their counterparts who treat physical health conditions and are not reimbursed at the same rates for comparable work, a factor that likely drives much of the field’s challenges around workforce turnover.

c. What can we do to encourage more health professional students and health care providers to pursue these type of careers?

Response:

1. Encourage opportunities to meet with observe and interact with persons in successful sustained recovery.
2. Encourage opportunities to have rotations in behavioral health treatment settings.
3. Loan repayment programs for persons that work in behavioral health.
4. Consider the incorporation education about treatment of behavioral health conditions in undergraduate and graduate medical education curriculum as well as in the curricula of other healthcare professions (nurses, nurse practitioners, physician assistants, pharmacists, psychologists, social workers, medical assistants, etc.).
5. Encourage the modernization of behavioral health treatment facilities through technology, telemedicine follow up and use of interactive applications that engage persons over time.
6. Education to "normalize" these brain disorders. These are physical disorders of the brain not "mental disorders."
7. Examine issues regarding professional re-imbursement.
8. Foster greater integration and coordination with broader health systems so that behavioral health generally and substance use disorder in particular, begin to be viewed as standard components of health care systems.

6. Much of the discussion last year in the lead up to the passage of CARA focused on the overprescribing of prescription drugs. As the epidemic has continued to evolve, we understand that heroin and synthetic opioids like carfentinil are playing an increasing role in overdose deaths across the country. I'm interested in learning more about how this evolution in the epidemic is changing our response.

a. How is the increased use of heroin and increase in synthetics, such as carfentinil affecting our response?

Response:
SAMHSA is updating its publications on addressing opioid overdose awareness and response to ensure first responders and laypersons are aware of the nuances between traditional opioids and synthetics such as carfentanil.

SAMHSA's grantees are providing additional patient education on the potential for synthetics infiltrating other opioids.

Further, treatment programs are beginning to administer greater patient education and dissemination of naloxone products within treatment programs. In addition, NIDA is funding research to address the issue that multiple doses of naloxone are sometimes needed to revive individuals who have taken high-potency, synthetic opioids like fentanyl and carfentanil. In the future, stronger formulations of naloxone would help to ensure that overdoses from powerful synthetic opioids can be effectively reversed when administered in time.

The great risks associated with fentanyl and its analogues create greater urgency to ensure people are able to access medication assisted treatment in a timely manner, leading to more efforts to engage patients in emergency departments, community settings where people use, and needle exchange programs. SAMHSA is working with states to ensure programs are able to triage patients and provide immediate access to care for people with opioid use disorder, particularly those that use illicit opioids.

b. How has this change affected our response?

Response:
We know that many people will need multiple doses of naloxone in order to be revived, so we are training first responders about the changes that are occurring. We also know that fentanyl analogues can and are being combined with drugs other than opioids, so we are warning first responders that people known to use other drugs may still have overdosed on fentanyl. This is important for first responders both in terms of how they approach the patient but also in terms of their own safety.

Finally, because the risk of death is so high, we are working with states to increase their outreach and engagement activities to get active users into treatment quickly and ensure that treatment is available to people at high risk on demand. We are providing training and technical assistance to states on implementing outreach models and changing treatment practices to permit triage and rapid admission instead of lengthy admissions processes that create bottlenecks in access to care.

c. Are there specific approaches that we should be considering to combat this change in the epidemic?

Response:
Yes, those approaches include**:**

1. Ensuring adequate availability of naloxone;
2. Beginning treatment when people are in emergency departments or other parts of a hospital for opioid use related causes (infections, overdose, etc.) or are otherwise identified as having an OUD;
3. Access to treatment on demand through active community outreach by peer counselors or via drop in centers at fire (e.g., Safe Stations) and police stations (e.g. Angel Initiative/PAARI); and
4. Ensuring access to medication assisted treatment rather than relying on detoxification and/or residential treatment which are less effective and associated with an elevated risk of overdose if medication is not provided post-detoxification (extended-release naloxone may be used following completion of detoxification) or as part of residential treatment, including as part of continuing outpatient treatment: Opioid use disorder is a chronic disease that requires ongoing disease/recovery management and is not appropriately treated through short episodes of detoxification episodes or inpatient/residential treatment.