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RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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November 17, 2017

The Honorable Elinore McCance-Katz
Assistant Secretary for Mental Health and Substance Use
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. McCance-Katz:

Thank you for appearing before the Committee on Energy and Commerce on October 25, 2017, to testify at the hearing entitled "Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on December 5, 2017. Your responses should be mailed to Zack Dareshori, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to zack.dareshori@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Committee.

Sincerely,

Greg Walden
Chairman

cc: The Honorable Frank Pallone, Jr., Ranking Member

Attachment

Attachment — Additional Questions for the Record

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?

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?

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.

2. 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.

3. 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?

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

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

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

    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?

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?

    a. Follow up:
        i. If yes – Are you supportive of a legislative fix like my bill (HR 3545) that would align Part 2 with HIPPAA?
        ii. If no – why do you support a separate privacy rule for patients with addictions?

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

    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?

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

    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?

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

The Honorable Gus Bilirakis

1. As more treatments for diseases transition from more expensive care settings like in-patient 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?

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?

The Honorable Chris Collins

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?

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.

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.

    a. 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?

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.

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

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.

2. What is the status of implementing Section 102 of CARA?

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

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?

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?

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

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

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

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?

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?

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

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?

The Honorable Susan Brooks

1. I have heard you say that preventing drug use before it begins is the is 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?

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?

    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?

    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?

The Honorable Richard Hudson

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?

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?

   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.

2. 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?

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

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?

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

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

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?

   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?

The Honorable Paul Tonko

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?

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?

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?

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?

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?

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?

   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?

   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?

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?

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?

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. 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?

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?

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

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?

b. How has this change affected our response?

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