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Responses to Questions for the Record

House Committee on Energy and Commerce Subcommittee on Oversight and Investigations

"What is the Federal Government Doing to Combat the Opioid Abuse Epidemic?"
May 1, 2015

The Honorable Michael C. Burgess

1. **While technology has the potential to solve many problems in healthcare, we are hearing similar complaints about PDMPs as we do with EHRs. Some doctors suggest that PDMPs interrupt clinical workflow. The Health IT Policy Committee sought public comment on whether EHR certification could enable and support streamlined access to PDMPs. Because PDMPs are a critical tool for patient care and clinical decision making, ONC suggested in their September 20 13 report to Congress that they would explore a POMP requirement in certification of EHRs. Can anyone speak to further discussion regarding including PDMPs as a requirement for certification of EHRs?**

   Answer: I refer you to the response provided on behalf of the Department by Assistant Secretary Frank.

The Honorable Jan Schakowsky

1. **There are currently significant barriers to accessing treatment for pregnant and postpartum women with opioid dependence. For pregnant women, in-patient treatment is not always appropriate, as these women may have full-time jobs or be the primary caregiver for their other children -- situations that don't allow them to put their lives on hold to enter an inpatient facility. In addition, many facilities don't allow or can't accommodate women with young children. For postpartum women, Medicaid coverage for pregnancy expires 6 weeks postpartum. That means that young mothers may lose access to buprenorphine or methadone soon after giving birth, when stability is needed most.**

   How can we ensure that pregnant and postpartum women have better access to treatment options that work for them -- like outpatient treatment -- and ensure that they do not lose access to their maintenance medications shortly after giving birth?

   Answer: SAMHSA agrees that residential treatment is not a one-size-fits-all approach and that pregnant women with substance use disorders should have access to a range of evidence-based treatment models across the spectrum of care.

In order to bolster the availability of family-based residential treatment options when they are needed, SAMHSA administers the Pregnant and Postpartum Women Program (PPW), which is a grant program that provides residential treatment services for pregnant and postpartum women with substance use and/or co-occurring substance use and mental disorders and their minor children. The program was last reauthorized in the Children's Health Act of 2000 and the statute specifies that the program is for residential treatment. SAMHSA agrees that pregnant and postpartum women need better access to treatment options that work for them, such as outpatient treatment.

From FY 2003 to FY 2014, SAMHSA funded 101 three-year PPW grants. In FY 2015, SAMHSA anticipates funding up to six additional, three-year PPW grants.

SAMHSA added new reporting requirements to the 2016-2017 Behavioral Health Assessment and Plan for pregnant women and women with dependent children, which will help track and improve the care for women with opioid use disorder after discharge from residential treatment. The new reporting requirements include information on strategies to ensure treatment availability; details on how states ensure that pregnant women are admitted to treatment within 48 hours or provided interim treatment services if no treatment facility is readily available; and specific program data, including geographic areas that cannot provide adequate care (including medication-assisted treatment (MAT)). SAMHSA expects that states will use this information to improve the planning of care for opioid dependent pregnant women, across all levels of care, from hospital-based, to residential, intensive outpatient, and outpatient treatment.

SAMHSA also manages the Substance Abuse Prevention and Treatment Block Grant (SABG), which includes a requirement that states expend a percentage of their annual SABG allotment on services specifically for pregnant women and women with dependent children. The women's set-aside is a performance requirement that allows states the flexibility to expend a combination of federal and non-federal funds to support residential or outpatient treatment services for pregnant women and women with dependent children. In 2014, more than 28,000 pregnant women received services through the set-aside.

The Centers for Medicare & Medicaid Services (CMS) remains committed to making sure women have access to needed medications. A life change such as having a baby qualifies a woman for a special enrollment period for coverage in the Health Insurance Marketplaces. The special enrollment period enables an eligible woman who recently gave birth to enroll in health insurance and receive tax subsidies outside of the annual open enrollment period if she qualifies.

In states that have expanded Medicaid coverage as outlined in the Affordable Care Act, many individuals, including new mothers, have increased access to coverage. Expanding Medicaid is a good deal for states financially. The Federal Government will cover 100 percent of the cost of covering people made newly eligible for Medicaid for the first three years (2014-2016). The Federal Government will cover no less than 90 percent on a

permanent basis. This is the most generous matching rate applied to any coverage group in the history of the program.

Member Requests for the Record

During the hearing, Members asked you to provide additional information for the record, and you indicated that you would provide that information. For your convenience, descriptions of the requested information are provided below.

The Honorable Tim Murphy

1. **During the hearing I asked you about your response to our March 18 letter, specifically regarding NREPP and evidence-based programs. Please provide the committee with a list of what you consider to be some of the models of evidence-based programs within the Federal registry.**

   Answer: The National Registry of Evidence-based Programs and Practices (NREPP) includes several well-established and well-known programs. It is worth noting that NREPP has been built exclusively through voluntary submissions by program developers. Given this approach, not every well-known and established evidence-based practice has been reviewed or captured by NREPP. As detailed in our response to your March 18 letter, in the future, developers will still have the option of submitting their programs for review, but SAMHSA will also conduct independent literature searches in an effort to identify a broad swath of evidence-based programs and practices that otherwise might not be submitted to NREPP.

   NREPP contains programs that seek to improve a person's adherence to their medication regimen while addressing other critical issues, such as coordinated care with physical health co-morbidities. These include, but are not limited to:

   - Interim Methadone Maintenance[1]
   - Motivation Enhancement Therapy[2]
   - Dialectical Behavioral Therapy[3]

   On the current registry, there is also a family of programs that use cognitive behavioral therapy, including but not limited to:

   - Cognitive Behavioral Intervention for Trauma in Schools;
   - Cognitive Behavioral Therapy for Adolescent Depression;
   - Cognitive Behavioral Therapy for Late-life Depression; and,
   - Cognitive Processing Therapy for Posttraumatic Stress Disorder.

   Cognitive behavioral therapy is often used in conjunction with other modalities, including medication, to address issues related to psychoses and other serious mental illnesses and has a significant evidence base to support its use with multiple target populations and a range of behavioral health issues.

[1] Available at http://www.nrepp.samhsa.gov/ViewIntervention.aspx?id=19.
[2] Available at http://www.nrepp.samhsa.gov/ViewIntervention.aspx?id=347.
[3] Available at http://www.nrepp.samhsa.gov/ViewIntervention.aspx?id=36.

2. **During the hearing I was following up on a question I asked you in a previous hearing regarding the Building Blocks website. You indicated that the website had been taken down and you were in the process of updating it. Please provide the committee with process reports.**

   Answer: On March 19, 2015, the Building Blocks website was taken down and a message posted that the site is temporarily unavailable.

   SAMHSA's Center for Substance Abuse Prevention (CSAP) worked with the National Institute on Drug Abuse (NIDA) regarding ways to strengthen the evidence base for substance use disorder prevention content on the website.

   SAMHSA is scheduled to re-launch the Building Blocks website with revised content this summer.

3. **You mentioned at the hearing that SAMHSA has been rethinking the 42 CFR part 2 rules, and that last year you held a listening session for stakeholders and took those pieces of input, and are trying to balance privacy concerns with the need for access to data. Can you please let the committee know as soon as you have something available for public input addressing these issues?**

   Answer: SAMHSA held a public listening session in June 2014 to solicit input from the public on potential updates to the 42 CFR Part 2 regulation. SAMHSA invited general comments, as well as comments on six key provisions of 42 CFR Part 2: Applicability, Consent Requirements, Re-disclosure, Medical Emergency, Qualified Service Organization, and Research. In addition, SAMHSA solicited input on electronic prescribing and Prescription Drug Monitoring Programs, areas that could potentially impact Part 2 programs. About 1,800 individuals participated in the listening session, either in person or by phone, and over 700 comments were submitted.

   In addition to considering the wealth of public input received, SAMHSA is collaborating with its Federal partners in drafting a Notice of Proposed Rulemaking (NPRM). SAMHSA would be pleased to brief the committee on NPRM as soon as it is published.

<u>The Honorable David McKinley</u>

1. **What one thing would you recommend that we could do to try to start reversing this epidemic and this problem?**

   Answer: We are pleased that this Subcommittee is interested in finding ways that the Congress can have a positive impact on tackling this important issue.

   The causes of the current opioid use disorder epidemic and related overdose deaths in the United States are complex and include an amalgam of medical, social, and economic

factors. The consequences are also far reaching, affecting the health, social, and economic welfare of individuals with opioid addiction, as well as their families and the larger community.

Unfortunately, the consensus among experts is that there is no single approach or initiative that will solve this complicated problem. Furthermore, no single organization or entity can address this problem alone; a coordinated, multifaceted response involving the Federal Government, state governments, public health officials, medical and other health partners, and community organizations is required.

Addressing this crisis is a top priority for HHS and to do so, the Department has developed an aggressive, multi-pronged initiative that focuses on three priority areas, grounded in the best research and clinical science available, to combat opioid abuse. By leveraging the distinct strengths of the HHS agencies, HHS's three-part plan aims to:

- Improve opioid prescribing practices to address the over-prescribing of opioids;
- Expand the use of naloxone, used to treat opioid overdoses, to help reduce the number of deaths associated with opioid overdose; and
- Expand the use of Medication-assisted Treatment (MAT), a comprehensive treatment model that combines the use of medication with counseling and behavioral therapies to treat substance use disorders.

These priorities represent activities and interventions where evidence suggests that HHS has the greatest opportunity for measureable impact.

SAMHSA supports the Secretary's initiative to address opioid related overdose, death, and dependence through our programs and initiatives that address the three key areas of the Department's initiative: opioid prescribing practices, increasing use of naloxone, and expanding use of MAT.

As the rates of prescription drug misuse and abuse, heroin use, overdoses, and opioid-related overdose deaths increase, communities are searching for ways to reduce the mortality rate of opioid-related overdoses. The FY 2016 Budget for SAMHSA includes $12 million for a new program which would provide grants to 10 states to purchase naloxone, equip and train first responders in high-risk communities on its use, support education on the use of naloxone and other overdose death prevention strategies, and support dissemination efforts.

These grantees would be required to develop an Opioid Overdose Prevention Toolkit dissemination plan and a training course tailored to meet the needs of their community. The course would use SAMHSA's Opioid Overdose Prevention Toolkit as a guide, and include a comprehensive prevention program which will focus on prevention, treatment and recovery services to decrease the likelihood of drug overdose recurrence. The Centers for Disease Control and Prevention (CDC) would evaluate this grant program for its efficacy in reducing overdose deaths from opioids.

By supporting this new program, the Congress can take an important step to advance SAMHSA's efforts to address the public health crisis related to opioid misuse and abuse.

The opioid abuse epidemic is a critical issue for HHS, the Administration, and the Nation as a whole, and we know we cannot solve it alone. We look forward to continuing to partner with the Congress, the states, and other stakeholders to continue to make progress on this vital issue and prevent further morbidity and mortality from opioid related overdoses.