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Responses to Questions for the Record

House Energy and Commerce Subcommittee on
Oversight and Investigations

“What is the Federal Government Doing to Combat the Opioid Abuse Epidemic?”

May 1, 2015

I. Additional Questions for the Record

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 2013 report to Congress that they would explore a PDMP requirement in certification of EHRs. Can anyone speak to further discussion regarding including PDMPs as a requirement for certification of EHRs?**

Answer: In response to a Request for Comment Regarding the Stage 3 Definition of Meaningful Use of Electronic Health Records (EHRs) (comment deadline January 14, 2013), the Health IT Policy Committee recommended, as a criteria for certification, that EHR systems be capable of “streamlined access to prescription drug monitoring programs (PDMP) data.”¹ There was general support by the public for the recommended certification criteria; however, the Health IT Policy Committee’s Meaningful Use Workgroup, which was tasked with further exploring the inclusion of the PDMP criterion, ultimately determined that the technical standards to share information between an EHR system and PDMP were not mature enough at the time to include this as a criteria for certification as part of the Health IT Certification Program.

PDMPs and health information technology (IT) systems (*e.g.*, electronic health records, health information exchanges, and pharmacy systems) use different standards to communicate. In an effort to address this interoperability challenge, ONC and the

¹ Available at http://www.healthit.gov/sites/default/files/hitpc_stage3_rfc_final.pdf.

Substance Abuse and Mental Health Services Administration (SAMHSA) are leading work through the Standards & Interoperability (S&I) Framework's PDMP/Health IT Integration initiative to examine the technical standards necessary to enable more fluid data exchange between PDMPs and health IT systems. This work will harmonize and map the data elements of those standards to enable the information contained within the PDMP to be delivered directly to the hands of healthcare providers via their health IT systems, without the need for providers to login to different systems to obtain PDMP data, which interrupts the clinical workflow.

The S&I Framework is pilot-testing three standards (NCPDP 10.6, ASAP Web Services, HL7 V2 messaging) that the S&I community identified. Currently, there are five active pilot teams testing the NCPDP 10.6 standard with an anticipated deadline of late summer 2015. Upon completion of NCPDP pilot-testing, work will begin to pilot test the other standards. The FY 2016 President's Budget includes \$5.0 million to build on this work and further integrate health IT and PDMPs in support of the Department-wide effort to address opioid addiction.

2. HHS already held a 50-state summit on opioid abuse and will hold another summit this summer. Can you provide to my staff a copy of a report from the first summit?

Answer: A summary on the 2014 50 State Working Meeting to Prevent Opioid-Related Overdose is under development. HHS' Office of the Assistant Secretary for Planning and Evaluation (ASPE) will circulate the final report to the members of this Committee and make it available to the public on the ASPE webpage.

3. I have previously expressed my support for expanding access to naloxone. Potential solutions that have been raised include Good Samaritan laws and allowing for over the counter access to this treatment. Based off your experience, do you foresee any unintended consequences associated with increasing access to naloxone? What are the challenges?

Answer: Naloxone is a clinically-effective and cost-effective intervention that has been attributed to the prevention of over 10,000 overdose deaths since its introduction to the public through community-based programs in 1996. Increasing access to and use of naloxone, by both emergency personnel and at-risk individuals' associates, is critical to reducing overdose death. Studies to date have not shown any association between access to naloxone and increased drug use by naloxone recipients.² Lack of awareness about the effectiveness of this medication and policies that would limit the use of naloxone by first

² Bazazi A, Zaller N, Fu J, Rich J. Preventing opiate overdose deaths: examining objections to take-home naloxone. J Health Care Poor Underserved. 2010 Nov; 21(4): 1108-1113.

responders and overdose witnesses are barriers that we can overcome through improved research, education and implementation.

HHS is committed to identifying and disseminating best practice naloxone delivery models and strategies. On May 13, 2015 a notice was published in the Federal Register formally announcing a meeting on naloxone uptake and use, held by the Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), in collaboration with the National Institutes of Drug Abuse (NIDA), the Centers for Disease Control and Prevention (CDC), Substance Abuse and Mental Health Services Administration (SAMHSA), and the Health Resources and Services Administration (HRSA). This public meeting will be held July 1-2, 2015. The purpose of the public meeting is to explore issues surrounding the uptake of naloxone to treat opioid drug overdose. The meeting agenda will include topics on the clinical, regulatory, and legal implications of making naloxone more widely available. During the meeting, academic and government experts, industry representatives, and patient advocates will discuss which populations are at risk for opioid drug overdose and how the federal government can collaborate with these partners to encourage the use of naloxone to reduce the risk of overdose from opioid drugs.

a. There are also different naloxone products. Some require needles, while some are made into kits and can be used nasally. However there are potential downsides to each. Intravenous administration allows for potential exposure to blood borne pathogens to the administrator. Intranasal administration may decrease uptake of naloxone during an overdose, when every second counts. Can you talk about appropriate settings to incentivize each of these products?

Answer: The development of user-friendly naloxone delivery devices is essential to our strategy to expand utilization of naloxone. Currently, naloxone is typically administered intravenously or intranasally. Last year, the FDA approved Evzio, a new naloxone drug product that is administered with an auto-injector. The National Institute on Drug Abuse (NIDA) and FDA are working collaboratively with the pharmaceutical industry to rapidly develop additional user-friendly naloxone delivery models that could be appropriate for use in a variety of settings.

II. Member Requests for the Record

The Honorable Tim Murphy

1. **Please provide the committee with any federal legislative proposals that the Secretary has that would help combat this opioid epidemic and turn ideas into implementation.**

Answer: The FY 2016 President's Budget lays out critical proposed investments to help combat the growing problem of opioid addiction throughout the country. For the Department of Health and Human Services, the budget proposes an increase of \$99 million above FY 2015 for targeted efforts to reduce opioid-related morbidity and mortality and the prevalence and impact of opioid use disorders, which includes both prescription opioids and heroin. HHS looks forward to working with the Committee on further developing these ideas.

The Honorable David McKinley

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.

There are many contributors to the Secretary's initiative and effective efforts are already in play in communities across the nation.

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.