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"Examining Legislative Proposals to Combat our Nation's Drug Abuse Crisis"
Committee on Energy and Commerce, Subcommittee on Health
U.S. House of Representatives
October 8, 2015

Attachment — Additional Questions for the Record

The Honorable Representative Joseph R. Pitts

1. **Dr. Frank, a number of questions at the hearing focused on the Department's announcement related to the current DATA 2000 patient caps.**

    a. **Can you please explain the factors that will be considered in determining how to raise these caps while limiting the potential for diversion?**

Response: Rulemaking related to DATA 2000 is one piece of the Department's strategy to expand access to medication-assisted treatment (MAT) for the treatment of opioid use disorder, and we are considering several options to help achieve this goal. Medicines containing buprenorphine that can be administered in office based settings as part of MAT have the potential to reach more patients than methadone, which can only be delivered by a certified, accredited opioid treatment program (OTP). We are therefore looking at factors related to the delivery of high-quality MAT and those that are consistent with the lowest risk of diversion.

    b. **How will differences in various settings at which buprenorphine can be prescribed and/or administered be considered? Are you considering expanding the type of settings at which buprenorphine can be prescribed and/or administered? If so, how?**

Response: Buprenorphine can currently be prescribed in primary care and other office based settings once a physician receives a DATA 2000 waiver. In the first year, physicians can treat up to 30 patients. After the first year, physicians can request approval to prescribe to up to 100 patients. All considerations, including different treatment settings, are being examined according to their impacts on access to treatment, quality of care, and the risks of diversion. This includes all elements of evidence-based MAT.

    c. **How will differences in certain types of patients or products be considered when determining whether and how to change the current limitations?**

Response: All considerations, including certain patient types or products, are being examined according to their impacts on access to treatment, quality of care, and the risks of diversion. We are committed to ensuring that the medication is delivered in accordance with the best clinical science, which includes supportive services such as counseling and toxicology screening. We recognize that innovative products may reduce risks of diversion and will consider these within

the context of our activities. HHS continues to support research to improve MAT technologies. For example, the National Institute on Drug Abuse (NIDA) has partnered with pharmaceutical companies to develop an implantable version of buprenorphine that provides continuous medication delivery (up to six months) and has the potential to address concerns about treatment adherence and drug diversion.

2. **Given the public health crisis and the acknowledgement by professional societies that practice guidelines should include opioid alternatives, should CMS should develop quality standards or metrics to encourage providers to consider a pain management strategy for patients that is more comprehensive than just opioids? How could CMS most efficiently develop and advance such quality metrics? How might CMS expedite an effort to help providers consider alternatives to opioids in circumstances where that could be the appropriate standard of care?**

3. **CMS is in a position to impact the prescription drug abuse crisis more significantly, using a variety of levers at its disposal. In addition to curbing the risk of abuse in Part D, CMS could also take steps to reduce the overuse of opioids by Medicare providers in the surgical setting. There is a growing number of alternatives to opioids, often referred to as multimodal analgesia, that manage pain in the acute care setting without using more addictive opioids. According to the American Society of Anesthesiologists Task Force on Acute Pain Management, there is strong support for the use of such alternatives to minimize the unnecessary use of opioids (Anesthesiology, 2012).**

    a. **Given the public health crisis and the acknowledgement by professional societies that practice guidelines should include opioid alternatives; wouldn't you agree that CMS should develop quality standards or metrics to encourage providers to consider a pain management strategy for patients that is more comprehensive than just opioids?**
    b. **How could CMS most efficiently develop and advance such quality metrics?**
    c. **Do you agree that this is a reasonable goal and if so, how might CMS expedite an effort to help providers consider alternatives to opioids in circumstances where that could be the appropriate standard of care?**

Response to #s 2 and 3: CMS currently is exploring the potential development of quality measures related to the use of opioids. Such measures could be used under the Medicare Hospital Inpatient Quality Reporting program or the new Merit-based Incentive Payment System for physicians and other professionals. An expert working group is being convened to provide input on development of measures evaluating opioid overuse. Before measures are added to the programs referenced above, input from other stakeholder groups will be sought.

Providing clinicians with the education and tools they need to make informed prescribing decisions for opioids is a primary focus of HHS's Opioid Initiative. This includes efforts to improve opioid analgesic prescribing across practice settings, including the surgical setting. CMS, in both the Medicare and Medicaid programs, is undertaking a number of activities to help support HHS's goal of improving opioid prescribing. Under the Medicaid program, a number of Informational Bulletins have been released to provide guidance to state Medicaid plans about evidence-based strategies they can use to improve the appropriate use of medications based on

the best available science. In 2014, CMS released the Information Bulletin on Medication Assisted Treatment for Substance Use Disorders which provided the most recent scientific data on MAT, including MAT for opioid use disorders. The Information Bulletin also provided information of innovative ways states are working to expand access to MAT. CMS is now developing an Informational Bulletin that will provide best practices Medicaid programs are employing to ensure the appropriate use of opioid analgesics for pain management within the context of the full complement of pain treatment modalities.

Under the Medicaid program, a number of Informational Bulletins have been released to provide guidance to state Medicaid plans about evidence-based strategies they can use to improve the appropriate use of medications based on the best available science. In 2014, CMS released the Information Bulletin on MAT for Substance Use Disorders which provided the most recent scientific data on MAT, including MAT for opioid use disorders. The Information Bulletin also provided information of innovative ways states are working to expand access to MAT. CMS is now developing an Informational Bulletin that will provide the best practices Medicaid programs are employing to ensure the appropriate use of opioid analgesics for pain management within the context of the full complement of pain treatment modalities.

In Medicare Part D, CMS launched the Overutilization Monitoring System (OMS) in 2013. The OMS reviews opioid utilization patterns among Part D patients to identify potential opioid overutilizers ("outliers") based on pre-specified criteria. Once outliers are identified, Part D plan sponsors take steps both to identify the appropriateness of utilization among these patients and then to curb utilization that is determined to be outside of good clinical practice. During the most recent review cycle, from January 2015 to July 2015, the number of opioid outliers reported by the OMS decreased by 3,364, or 19 percent, from 19,632 to 15,998.

In addition to efforts at CMS, other HHS agencies are engaged in work that will guide quality pain management across clinical practice settings. For example, the Centers for Disease Control and Prevention (CDC) is developing guidelines for opioid prescribing for chronic pain outside the setting of active cancer treatment, palliative care, or end-of-life care. To ensure effective implementation of these guidelines, the Office of the National Coordinator for Health Information Technology (ONC) will build upon this work by exploring opportunities to convert guidelines into standardized, sharable, health IT-enabled clinical decision support interventions. In addition, the National Institutes of Health is leading the development of a National Pain Strategy which is expected to be released early in 2016. This Strategy will examine a number of issues related to the current state-of-the-science of pain treatment and opportunities that exist to expand the use of multimodal, multidisciplinary pain care.

4. Should patients addicted to opioids receive treatment based on their individual clinical needs? How does HHS intend to incorporate this principal into its recently proposed rule?

Response: Studies have shown that the most effective treatments for opioid use disorders are those that include a medication approved by the Food and Drug Administration (FDA) for the treatment of opioid use disorders in combination with comprehensive medical, social, psychological and rehabilitation services that address all the needs of the individual. There are three medications approved by the FDA for MAT: buprenorphine, methadone, and extended

release injectable naltrexone, and each has different characteristics and indications with advantages and disadvantages for different types of patients. Our goal is to ensure that patients have the opportunity to receive high-quality, patient-centered evidence-based treatment that meets their needs.

Our undertaking of rule-making related to buprenorphine is only one component of our comprehensive strategy which targets the expanded use of all medications approved to treat opioid use disorders. Expanding access to all forms of MAT will help us meet our goal of helping patients access the evidence-based treatment that is most appropriate for their clinical situation. Taking these steps will help to ensure that clinicians and patients can work together to decide the best treatment that will meet their needs.

5. Dr. Frank, should patients be able to choose from among all FDA-approved medications for opioid use disorder in any given treatment setting? Is that currently possible – why or why not?

Response: HHS's goal is for patients to have access to all types of MAT, but given current law, it is not possible to do this in all treatment settings. We want to expand access to MAT in a way that allows patients the maximum opportunity to choose the right treatment for their clinical circumstances within the regulatory framework that currently exists for each type of medication assisted treatment. Each type has different characteristics with advantages and disadvantages for different types of patients. Currently, the only setting in which all three types of MAT approved for the treatment of opioid use disorder can be provided is in a certified, accredited opioid treatment program (OTP), because it is the only setting in which methadone can be dispensed for the treatment of opioid use disorder. OTPs can also dispense buprenorphine and extended release naltrexone if they choose. Buprenorphine can be administered in an office based setting after a physician takes the required steps to become DATA 2000 waived for prescribing. These same physicians could prescribe extended release naltrexone to appropriately selected patients.

Since naltrexone is a non-narcotic opioid antagonist with no potential for non-medical use, it can be prescribed for the treatment of opioid use disorder by any health care provider who is licensed to prescribe medications. However, naltrexone must still be administered in an evidence-based fashion much like methadone and buprenorphine, in conjunction with services such as toxicology screenings and counseling. Additionally, naltrexone requires 7-10 days of complete opioid withdrawal before treatment can begin and may not suitable for all patients.

6. How can Prescription Drug Monitoring Programs, including their rates of use by practitioners across the country, be improved?

Response: Prescription Drug Monitoring Programs (PDMPs) are among the most promising tools to curb non-medical use of prescription opioids and inappropriate prescribing practices. . PDMPs can provide a prescriber or pharmacist with important information regarding a patient's prescription history, allowing prescribers to identify patients who are potentially misusing medications. Additionally, PDMPs provide a mechanism for identifying potentially problematic prescribing practices. PDMPs are managed by each individual state and are subject to individual states' laws and regulations.

Building off the infrastructure of the Prevention Boost and Core Violence and Injury Prevention programs, CDC received an increase of $20 million in Fiscal Year (FY) 2015 to launch the Prescription Drug Overdose Prevention for States program, which will expand state-level interventions in states with high burdens of prescription drug overdose morbidity and mortality, including enhancements to PDMPs (i.e., improving access, expanding proactive reporting of inappropriate prescribing patterns, shortening the PDMP reporting interval). The President's FY 2016 Budget proposes an additional $45 million to expand that program to all 50 states and Washington, DC.

In addition to the CDC funding for states, the Substance Abuse and Mental Health Services Administration (SAMHSA) and ONC have funded work in states to advance integration of PDMP data with electronic health records, to develop standards for data sharing, and to expand interstate data sharing of PDMP information. Increasing reporting regularity, widening delegate access, and improving interoperability across state borders are all ways in which states have made and continue to make progress and improve upon their PDMPs and increase their use.

7. IOM recommended creation of a national strategy to transform how pain is assessed, understood and treated. Dr. Frank, has HHS made any progress on this front?

Response: Yes, in response to the IOM recommendation, HHS created the Interagency Pain Research Coordinating Committee (IPRCC). The IPRCC has engaged with a broad range of experts and stakeholders to develop the National Pain Strategy. While an exact publication date has not yet been determined, we anticipate that it will be released in 2016.

8. Improving professional education about opioid prescribing and appropriate pain management is critical. What is the government doing to improve provider education across the spectrum of disciplines and throughout the continuum of undergraduate, graduate and continuing health profession training?

Response: Providing health care providers with the education and tools they need to prescribe opioids appropriately is a central component of the HHS Opioid Initiative. We are taking actions across the spectrum of health professional education and practice in this area. For example, the National Institutes of Health has funded 11 health professional schools as designated Centers of Excellence in Pain Education (CoEPEs). The CoEPEs will act as hubs for the development, evaluation, and distribution of pain management curriculum resources for medical, dental, nursing, pharmacy and other schools to enhance and improve how health care professionals are taught about pain and its treatment.

To improve clinical decision-making to reduce inappropriate opioid prescribing, CDC is developing guidelines for opioid prescribing for chronic pain among patients who are not in active cancer treatment, palliative care, or end-of-life care. To ensure effective implementation of these guidelines, ONC will build upon this work by exploring opportunities to convert guidelines into standardized, sharable, health IT-enabled clinical decision support interventions. The guidelines are scheduled to be released in 2016.

In addition, multiple HHS agencies provide continuing education programs on appropriate opioid prescribing to practicing clinicians. FDA's Risk Evaluation and Mitigation Strategy for

Extended-Release/Long-Acting Opioid Analgesics requires manufacturers of these products to make available continuing education programs, based on an educational blueprint developed by FDA, available at no or nominal cost to providers. Both the National Institute on Drug Abuse through its NIDAMED program SAMHSA through its Providers' Clinical Support System for Opioids offer educational programs for health professionals on opioid prescribing.

The Honorable Representative Tim Murphy

1. **On September 17, Secretary Burwell announced that HHS would be revising the regulations related to buprenorphine dispensing in the physician office setting to "safely and effectively increase access."**

    a. **What is the timeframe you anticipate for this action and how, if at all, are you engaging with stakeholders to inform this process?**

Response: HHS is working as expeditiously as possible to publish a Notice of Proposed Rule Making (NPRM) for public comment. Prior to and since the Secretary's announcement in September, we regularly have met with a diverse group of stakeholders on this issue to exchange facts and information. While we are unable to discuss specific provisions at this time because the rulemaking is ongoing, we are thoughtfully weighing all stakeholder opinions and input. Additionally, there will be a formal public comment period once the NPRM is released. This will allow stakeholders to review and provide input on the proposed regulation before it is finalized.

    b. **Throughout this process, what attention is being given to the threat of drug diversion associated with the higher levels of supply envisioned?**

Response: HHS is keenly aware of the potential for buprenorphine diversion. As we consider various options during the rulemaking process, we are carefully weighing the risks of diversion and the need to ensure that buprenorphine is delivered in a high-quality manner in accordance with the best clinical practices, which includes supportive services such as counseling and toxicology screening.

    c. **How can an effective drug diversion control plan assist in reducing the incidence of diversion? What are its limitations?**

Response: Monitoring for diversion is an essential responsibility of physicians engaged in prescribing buprenorphine for opioid use disorder. The National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use recently released by the American Society of Addiction Medicine states:

> "Clinicians should take steps to reduce the chance of diversion…Strategies to reduce the potential of diversion include: frequent office visits, urine drug testing including testing for buprenorphine and metabolites, observed dosing, and recall visits for pill counts. Patients receiving treatment with buprenorphine should be counseled to have adequate means to secure their medications to prevent theft. Unused medication should be disposed of safely."

    d. **How does the Secretary's initiative account for extended engagement and monitoring of patents by medical and addiction professionals?**

Response: The goals of the Secretary's Initiative are to reduce prescription opioid and heroin dependence, overdose and death. With respect to patients receiving treatment for opioid use disorders, our goal is to ensure that patients receive high-quality evidence-based care. Studies

have shown that the most effective way to manage opioid use disorders is through use of a set of comprehensive medical, social, psychological and rehabilitation services that address all the needs of the individual. Implicit in this treatment is an ongoing partnership and engagement between patients and their treating health care providers. Substance use disorders are chronic relapsing conditions that require continuous engagement of providers and patients.

2. **How do federal privacy rules surrounding the sharing of patient alcohol and substance abuse data – such as 42 CFR Part 2 – frequently obstruct communication between healthcare providers or even among state agencies? What, if anything, can be done about this?**

Response: Privacy protections found at 42 CFR Part 2 limit the sharing of data that might identify a person as a substance use disorder treatment patient in certain settings. These protections prohibit the disclosure of patient identifying information without consent, unless an exception applies. These protections limit the sharing of data among members of the care team in some cases, and do not permit exchange of data among various state agencies. SAMHSA is currently working on an NPRM to revise 42 CFR Part 2 regulations. The revisions under consideration would continue to uphold privacy protections, while allowing for the exchange of data within certain entities such as like accountable care organizations for treatment purposes.

3. **How can Prescription Drug Monitoring Programs, including their rates of use by practitioners across the country, be improved?**

Response: Prescription Drug Monitoring Programs (PDMPs) are among the most promising clinical tools to curb non-medical use of prescription opioid and inappropriate prescribing practices. PDMPs can provide a prescriber or pharmacist with important information regarding a patient's prescription history, allowing prescribers to identify patients who are potentially misusing medications. Additionally, PDMPs provide a mechanism for identifying potentially problematic prescribing practices. PDMP evaluations have detected positive changes in prescribing patterns, decreased use of multiple providers and pharmacies, and decreased substance use disorder treatment admissions. PDMPs are managed by each individual state and are subject to individual states' laws and regulations.

In FY 2015, CDC received an increase of $20 million to launch the Prescription Drug Overdose Prevention for States Program, which expanded state-level interventions focusing on improving prescribing to prevent overdose, including enhancements to PDMPs. The President's FY 2016 Budget proposes an additional $45 million to expand that program to all 50 states and Washington, DC.

In addition to the CDC funding for states, SAMHSA and ONC have funded work in states to advance integration of PDMP data with electronic health records, to develop standards for data sharing, and to expand interstate data sharing of PDMP information. Increasing reporting regularity, widening delegate access, and improving interoperability across state borders are all ways in which states have made and continue to make progress and improve upon their PDMPs and increase their use.

The Honorable Representative Gus Bilirakis

1. **Dr. Frank, how will HHS ensure that patients receive comprehensive, effective treatment if the patient caps are raised without requiring physicians at DATA 2000 clinics to have the capacity to provide other services, such as counseling and patient monitoring?**

Response: Our goal is to ensure that patients receiving buprenorphine-based medication assisted treatment receive highest quality care. Studies have shown that the most effective way to manage opioid use disorders is through use of a set of comprehensive medical, social, psychological and rehabilitation services that address all the needs of the individual. As the rulemaking process is currently underway, I cannot provide details on specific provisions, but all considerations are being carefully weighed with the risks of diversion and ensuring that the medication is delivered in accordance with the best clinical science, which includes supportive services such as counseling and toxicology screening.

2. **Are there regulations in place to ensure that buprenorphine provided at these clinics is not diverted?**

Response: Buprenorphine is a schedule III controlled substance under the Controlled Substances Act (CSA). The same requirements in the CSA intended to reduce diversion that apply to other schedule III drugs, also apply to buprenorphine. In addition, buprenorphine-based MAT is governed by the Drug Addiction Treatment Act of 2000(DATA), an amendment to the Controlled Substances Act (CSA). Under this law, physicians may treat up to 30 patients at a time in the first year and then file a request to treat up to 100 patients at a time. The patient prescribing limits were established, in part, to prevent diversion of the medication.

In addition, monitoring for diversion is an essential responsibility of physicians engaged in prescribing buprenorphine for opioid use disorder. The National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use recently released by the American Society of Addiction Medicine states:

> "Clinicians should take steps to reduce the chance of diversion…Strategies to reduce the potential of diversion include: frequent office visits, urine drug testing including testing for buprenorphine and metabolites, observed dosing, and recall visits for pill counts. Patients receiving treatment with buprenorphine should be counseled to have adequate means to secure their medications to prevent theft. Unused medication should be disposed of safely."

3. **Patients suffering from opioid addiction not only need treatment using prescription drugs, but also need comprehensive support services like counseling and patient monitoring. It is my understanding that under the DATA 2000 law, clinics are not required to offer any of these services. Since you spoke of the importance of medication-assisted treatment, which includes other therapy services, why shouldn't DATA 2000 clinics be required to adopt these patient-centered practices if they wish to raise patient caps?**

Response: Waivers under DATA 2000 are issued to individual physicians as opposed to practices. The best clinical science on MAT indicates that it must be delivered in conjunction with a comprehensive set of supportive psychosocial services. All considerations — including the ability to provide other therapy services such as counseling and toxicology screening — are being carefully weighed during the proposed rulemaking process to ensure that the medication is delivered in accordance with the best clinical science while minimizing the risks of diversion.