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Written testimony on behalf of the following witness from the Department of Health and Human Services (HHS):

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Good morning Chairman Jordan, Chairman Palmer, Ranking Member Krishnamoorthi and Ranking Member Demings and Members of the SubCommittees. Thank you for the opportunity today to discuss the Department of Health and Human Services' efforts regarding regulatory reform.

HHS is committed to improving the regulatory process as laid out by the President's Executive Orders, and our Department is always willing to engage with both the Members of this Committee and your staff to help us improve our work.

On January 30, 2017, the President signed Executive Order 13771. The purpose of this Executive Order was to announce the policy of the Executive Branch to be "prudent and financially responsible" when burdening private entities with federal regulations. To that end the Executive Order asked that for "every one new regulation issued, at least two prior regulations be identified for elimination."

On February 24, 2017, the President signed Executive Order 13777. This Executive Order established the structure that would help implement the previous Order. It required the head of each agency to designate a Regulatory Reform Officer. This Officer would oversee the implementation of regulatory reform initiatives and polices. The Order also requires agencies to establish a Regulatory Reform Task Force. This Task Force was instructed to evaluate existing regulations and make recommendations regarding the repeal, replacement, or modification of those regulations.

The President's February Executive Order instructed each Task Force to identify regulations that eliminate jobs, or inhibit job creation; and to find regulations that are outdated, unnecessary, or ineffective. The Task Forces must also review regulations that impose costs that exceed benefits and evaluate regulations that create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies.

Importantly, this Executive Order also instructed agencies that the Task Force should seek input and other assistance from those entities significantly affected by federal regulations. In particular, agencies should seek input from state and local governments, small businesses, and consumers.

HHS established its Regulatory Reform Task Force on April 13, 2017. Its leadership is comprised of the following:

- The Regulatory Reform Officer is the Deputy Secretary; The Deputy Secretary cannot currently serve as the RRO because he is the Acting Secretary. Therefore, he has designated Charles Keckler from his senior staff to serve as the Acting RRO;
- The Regulatory Policy Officer is the Acting General Counsel; and
- The representative to the Task Force from the "central policy office" is the Executive Secretary.

Among others the remaining members of the Regulatory Reform Task Force are:

- The Secretary's Senior Counselors and Counselors

- The Assistant Secretary for Financial Resources;
- The Assistant Secretary for Planning and Evaluation;
- A senior official from Food and Drug Administration (FDA); and
- A senior official from Centers for Medicare and Medicaid Services (CMS).

The Task Force meets once per week to evaluate deregulatory proposals from Operating and Staff Divisions across HHS using instructions and criteria outlined in Executive Orders 13771 and 13777 and OMB Guidance documents M-17-21 and M-17-23. The deregulatory proposals are presented to the Task Force for consideration only after they have been evaluated by the Regulatory Reform Working Groups.

The Working Groups are designed to offer a forum for the Department's subject matter experts to carefully assess deregulatory proposals using criteria that complement the goals of the executive orders. Each Working Group meets regularly and consists of 15-23 career staff experts from across HHS.

There are six Working Groups:

- **The FDA Working Group** assesses proposed deregulatory actions by FDA twice a month;
- **The CMS Working Group** assesses proposed deregulatory actions by CMS, Office of the National Coordinator, Departmental Appeals Board, Office of the Inspector General, and Office of Medicare Hearings and Appeals twice a month;

- **The Services Working Group** assesses proposed deregulatory actions by Administration for Children and Families, Health Resources and Services Administration, Indian Health Service, Office of Civil Rights, Office of the General Counsel, and Substance Abuse and Mental Health Services Administration once a month;
- **The Science and Public Health Working Group** assesses proposed deregulatory action by Centers for Disease Control and Prevention, National Institutes of Health, and Office of the Assistant Secretary for Health once a month;
- **The Performance Measures Working Group** meets once a month and develops measures to report on HHS regulatory reform performance; and
- **The Analytics Team** meets regularly and develops internal guidance to Operating and Staff Divisions on how to measure regulatory costs, cost-savings, and benefits.

Each Operating and Staff Division has a Regulatory Reform Officer (RRO) who is responsible for submitting deregulatory proposals once a month to relevant Working Groups. The deregulatory proposals are then assessed by the Working Groups, and ultimately the Task Force. The RRO is also charged with communicating important information on regulatory reform to their respective division. Once a month, a call is held with the RROs to answer questions and share best practices.

The regulatory review process at the Department of Health and Human Services encompasses all agency rule making, including the Centers for Medicare & Medicaid Services. CMS is committed to putting patients first, and easing the regulatory burden that is harming the relationship between a patient and his or her doctor or other type of healthcare provider.

Regulations have their place and are important to ensuring quality, integrity, and safety in our health care system. But, if rules are misguided, outdated, or are too complex, they can have a suffocating effect on health care delivery by shifting the focus of providers away from the patient and toward unnecessary paperwork, and ultimately increase the cost of care.

CMS is working hard to evaluate and streamline regulations with a goal to reduce unnecessary burden, increase efficiencies, and improve the beneficiary experience by allowing their providers to spend more time with them. In October 2017, CMS announced a new Patients Over Paperwork initiative, which is an effort to review all of the agency's regulations to reduce regulatory burden on providers. CMS Administrator Verma hosted stakeholders from across the healthcare spectrum at CMS for a Listening Session on Regulation Reform – an opportunity for clinicians, hospitals, specialties, family physicians, nurses, nursing homes, skilled nursing facilities, and long-term care facilities to provide feedback on their work and on how they think CMS can decrease burden, ultimately allowing them to better serve patients. CMS wants to know the impact of current regulations, so it is taking a close look at its rules to determine if they are necessary, and whether they impact patient care or improve outcomes. Through this important initiative, CMS will move the needle and begin to remove regulatory obstacles that get in the way of providers spending time with patients. CMS has already made great strides internally by setting up an enterprise-level process to evaluate and streamline regulations and operations.

CMS Administrator Verma also launched a review of all quality measures to ensure they are the most meaningful. Too often, health care quality measures focus on process, and not on whether that process improved the quality or safety of health care. Clinicians and hospitals have to report

an array of measures to different payers. The measures are often different, and there are many steps involved in submitting them, taking time away from patients. For example, across the CMS hospital quality reporting programs, inpatient hospitals report up to 61 quality measures. According to the American Academy of Family Physicians, some family practitioners have to report nearly 30 measures to 7 different payers, which can lead to less time focused on patients and contributes to clinician burnout. Through CMS's review, we will focus measurement on assessing those core issues that are most vital to providing high-quality care and improving patient outcomes, with a focus on achieving results, as opposed to trying to micromanage and measure processes.

CMS knows that clinicians, patients and other stakeholders are best positioned to tell us about the relief they need from regulatory burden. To gather this feedback, CMS has included Requests for Information (RFIs) as part of its annual Medicare payment rulemaking process to obtain feedback on positive solutions to better achieve transparency, flexibility, program simplification, and innovation. This feedback will inform the discussion of ways to reduce burden in program requirements. Through these RFIs, CMS is starting a national conversation about improving the healthcare delivery system, how Medicare can contribute to making the delivery system less bureaucratic and complex, and how CMS can reduce burden for clinicians, providers, and patients in a way that increases quality of care and decreases costs – thereby making the healthcare system more effective, simple, and accessible while maintaining program integrity. CMS is reviewing the robust feedback received through these RFIs to determine the next steps in reducing burden in the health care system. Our goal is to address the burden areas CMS hears most about with innovative approaches that improve patient care and lessen regulatory burden.

Similarly, the Food and Drug Administration also seeks public engagement in how to strengthen and modernize the FDA's regulatory framework. As part of the FDA's commitment to protecting and promoting the public health, the agency is undertaking a comprehensive review of their regulations.

The FDA has announced a number of broad policy efforts to address public health opportunities in areas such as regenerative medicine, tobacco products, and increased drug competition to improve patient access to affordable medicines. As with everything the FDA does, this work is rooted in the mission to protect and promote the public health, foster safe and effective innovation that can benefit patients, adopt regulatory approaches that enable the efficient development of new innovations, and provide for a safe, healthy and nutritious food supply.

In line with that framework, in May 2017, FDA extended the compliance date for the final rule requiring disclosure of certain nutrition information for standard menu items in certain restaurants and retail food establishments. This extension allows for further consideration of what opportunities there may be to reduce costs and enhance the flexibility of these requirements beyond those reflected in the final rule. FDA is also reviewing how rules concerning new drugs are being used in ways that may create obstacles to the timely entry of generic competition. We want to make sure FDA's policies aren't being misused in ways that thwart the competition that Congress intended when it created the modern generic drug framework. We know that vigorous generic competition can help benefit patients by lowering drug costs, which improves access to

medicines. It's one example of where a closer analysis of FDA's existing policies can help make sure FDA's regulations are having their intended purpose.

This comprehensive review is a large undertaking given the breadth of FDA's public health mission and the fact that FDA-regulated products account for about 20 cents of every dollar consumers spend each year.

Today, FDA's regulations comprise more than 4,000 pages in the Code of Federal Regulations. Some regulations may not adequately reflect advances in science, technology or changes in industry practice. For example, FDA will be seeking to withdraw a regulation that accords new drug status to any drug that has been sterilized by irradiation, thus subjecting the drug to new drug approval requirements. While this regulation made sense decades ago, we now better understand the science of irradiation, and appropriate and effective sterilization is encompassed within other FDA requirements.

Other regulations may be geared toward products and practices that have largely ceased to exist. For example, FDA is working to finalize removing requirements to submit multiple paper copies of medical device regulatory pre-submissions and submissions, and replace them with a requirement to submit one copy in an electronic format. These revisions would facilitate an electronic submission program and increase efficiency. In a world of increasing challenges and opportunities, we need to ensure that FDA is risk-based in everything that it does in order to make sure FDA is using its resources efficiently. Our goal is to have regulations that reflect modern risks and opportunities and use the full scope of FDA's authorities to achieve its consumer protection mission.

In addition to the ongoing internal review and changes that have already been made, in just the past few months, the FDA has released seven requests for information. These requests seek comments and information from interested parties to help the FDA identify existing regulations and related paperwork requirements that could be modified, repealed, or replaced, consistent with the law, to achieve meaningful burden reduction while allowing the FDA to achieve their public health mission and fulfill statutory obligations. These requests for information covered many subjects: general regulatory issues, the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, the Center for Tobacco Products, the Center for Food Safety and Applied Nutrition, and the Center for Veterinary Medicine.

CONCLUSION

Thank you for the opportunity to testify today. I am glad that the Committee is taking the time to review the complex and often overbearing regulatory system that exists in the United States. Stakeholder feedback is a critical part of the work we are undertaking at HHS to reduce regulatory burden.

As we reach out and listen to providers, patients, experts, and consumers, I also wish to note that Congress remains our most valued stakeholder. Please know that our Department is always ready to discuss any regulations that you believe are problematic, or even those that need to be strengthened. In preparing for this hearing, we have had several productive conversations with both the Majority and Minority Committee staff. I want to thank them for the thoughtful effort

they have put into this matter, and we look forward to working with them even more in the future.

I am happy to answer any questions you may have.