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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Immediate Office of the Secretary

ReImagine HHS Accelerate Clinical Innovation Initiative; Public Hearing, June 20-21, 2019

AGENCY: Transformation Management Office, Immediate Office of the Secretary, HHS.

ACTION: Notice of meeting and request for comments.

SUMMARY: The Department of Health and Human Services (HHS) is announcing a public meeting to seek public input and comment on opportunities to leverage departmental resources, increase collaboration, and to partner with private stakeholders in the service of accelerating the process for clinical innovation in the United States. HHS is specifically interested in how to decrease the overall time for a new medical product (drug, medical device, biologic) to go from discovery to widespread patient access and use while maintaining the critical public health standards of the Department.

HHS is seeking participation in the meeting and written comments from all interested parties, including, but not limited to, patients, physicians, researchers, medical product developers, commercial health insurance plan sponsors and carriers, private investors, and the community at large. This meeting and the written comments are intended to assist HHS, in developing programs and procedures for assessing and accelerating the pace of the clinical innovation enterprise throughout the United States. HHS is seeking input on specific questions identified below but is interested in any other pertinent information participants in the public meeting would like to share. This meeting is open to the public.

DATES: Meeting Date: Thursday, June 20 8:30 a.m. to 4:00 p.m. eastern standard time (EST and Friday, June 21, 8:30 a.m. to 4:00 p.m. EST

Deadline for Meeting Registration, Presentations, Special Accommodations and Comments: Wednesday, June 12, 5:00 p.m., EST

ADDRESSES: Meeting Location: U.S. Department of Health & Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, S.W., Great Hall, Washington, DC 20201.

Presentations and Written Comments: Presentations and written comments should be submitted to: Benjamin Eloff, Associate Director for Innovation Policy and Processes, Accelerate Clinical Innovation, U.S. Department of Health & Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, S.W., Room 749D, Washington, DC 20201 or via e-mail at Benjamin.Eloff@fda.hhs.gov.

FOR FURTHER INFORMATION CONTACT: Benjamin Eloff, Associate Director for Innovation Policy and Processes, Accelerate Clinical Innovation, U.S. Department of Health & Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, S.W., Room 749D, Washington, DC 20201, phone: (240) 328-8717 e-mail: Benjamin.eloff@fda.hhs.gov. Press inquiries are handled through Carla Daniels, Public Affairs Specialist, Office of the Assistant Secretary for Public Affairs; phone: (202) 690-4595 e-mail: Carla.Daniels@hhs.gov.

SUPPLEMENTARY INFORMATION:

REGISTRATION: The meeting is open to the public, but attendance is limited to the space available. Persons wishing to attend this meeting must register at the website https://www.eventbrite.com/e/reimagine-hhs-accelerate-clinical-innovation-initiative-public-hearing-tickets-61875011826 or by contacting the individual(s) listed in the "FOR FURTHER INFORMATION CONTACT" section of this notice, by the date listed in the "DATES" section

of this notice. Individuals requiring sign language interpretation or other special accommodations should contact the individual(s) listed in the "FOR FURTHER INFORMATION CONTACT" section of this notice at the address listed in the "ADDRESSES" section of this notice by the date listed in the "DATES" section of this notice.

Registration to attend the public meeting will be accepted on a first-come, first-served basis. If seating capacity has been reached, you will be notified that the meeting has reached capacity.

Registration to present at the public meeting will be accepted on a first-come, first-served basis. To ensure a variety of viewpoints, HHS has specifically reserved portions of time to receive feedback from patients, medical product developers, investors, and private insurers. HHS has included questions for comment in section III of this document. Please identify by number each question you wish to address in your presentation and the approximate time requested. HHS will do its best to accommodate requests to speak. HHS will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. Once HHS notifies registered presenters of their scheduled times, presenters should submit a copy of each presentation, identified with docket number HHS-OS-2019-0006, to http://www.regulations.gov.

Individuals who need special accommodations should contact staff listed in the FOR FURTHER INFORMATION CONTACT section of this notice.

Submission of Comments for the Public Meeting

Submit electronic comments, identified with docket number HHS-OS-2019-0006, to http://www.regulations.gov.

Submit written comments to Comments for HHS Public Meeting, Transformation Management Office, U.S. Department of Health & Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, S.W., Room 749D, Washington, DC 20201.

I. Background

The HHS 2018-2022 strategic plan identifies ReImagine HHS as the approach to meet the strategic goals of the department. The Accelerate Clinical Innovation (ACI) initiative is one of ten initiatives under ReImagine HHS and is focused on identifying and facilitating ways to shorten the time needed for safe and effective medical products to go from discovery to patient use. ACI is seeking public comment regarding the entire medical innovation process at an enterprise level to ensure that patients have timely access to new medical products that meet the high public health standards expected and deserved by the American public and ensured by HHS.

HHS as a department is involved in all stages of the clinical innovation enterprise, including performing and funding basic laboratory research, clinical trials, small business grants, protecting patient rights and welfare, evaluating scientific data, approving products for use, establishing criteria and payment rates for their inclusion in the Medicare program, and monitoring products in the marketplace. These different functions of HHS are performed across separate divisions. When an innovation completes development and becomes available to patients, it is uncommon for the Department to perform a retrospective review of lessons learned about the processes involving coordination between multiple divisions that could promote future reforms to improve the service delivery model and make the process more efficient or effective. HHS is seeking public comment from key stakeholders involved in the biomedical innovation process. Specifically, HHS would like to receive public comment regarding:

1. The appropriate federal role, if any, in connecting medical product developers with payers, commercial plan carriers, and/or Medicaid managed care plans for purposes of making the coverage decision process more efficient;

2. Enhanced knowledge sharing to assist in the innovation enterprise stakeholder's decision-making processes;

3. Metrics for the overall innovation system to assess the viability of the system and measure the impact of procedural and policy changes; and,

4. Procedures, methods, and data for the identification and prioritization of diseases or conditions that would benefit from enhanced focus.

Coverage Decision Process Facilitation

HHS is seeking more information about an appropriate federal role, if any, in connecting medical product developers with payers, commercial plan carriers and/or Medicaid managed care plans for purposes of making the coverage decision process more efficient. We have heard from certain stakeholders, especially medical product developers from smaller companies, that they have experienced inefficiency and expense associated with educating payers, carriers, and plans on new medical products after they have been cleared or approved for use by the Food and Drug Administration. Similarly, we have heard from representatives of payers, carriers, and plans that they find the process of learning about new medical products to be inefficient.

HHS is seeking comments from members of the public regarding the coverage decision process in the commercial market. We are particularly interested in hearing from plan sponsors/administrators, carriers, and medical product developers about whether there may be an appropriate role for the federal government in helping to more efficiently promote information sharing between product developers and payers, carriers and plans; the kind of information

needed to make a coverage determination; and what mechanisms could be used to promote information sharing to make the process more efficient for all stakeholders.

Knowledge Sharing

HHS is interested in knowledge sharing in several domains. First, HHS collectively holds massive data resources from clinical trials, epidemiological data, grants, and many other sources that can inform a host of decisions beyond the specific purpose of any individual data set. HHS is interested to receive comments regarding how the biomedical innovation stakeholder community can use data in making decisions, and what data would be useful to investors and non-CMS payers to build business cases and to make coverage and reimbursement decisions. HHS is also interested in knowledge sharing related to experiences bringing an innovation through the development process, and what opportunities exist for enhanced communication and collaboration among HHS components or with other federal and non-federal stakeholders to reduce inefficiency and increase predictability, without altering scientific standards and while appropriately protecting research participant privacy and security. The data from these resources are a mix of publicly-available and confidential information, therefore, any use or sharing of data would require the appropriate consent and procedures to remove identifying characteristics.

Enterprise-level Biomedical Innovation Metrics

Each individual working unit within HHS measures performance based on metrics necessary to achieve the specific functions of that unit. Likewise, private businesses (developers, payers, providers, investors) have fiduciary responsibilities to measure progress, increase efficiency, and deliver results. However, there are no universally agreed-upon metrics for the performance of the clinical innovation enterprise as a whole, and therefore, no objective way to assess the effects of process or procedural changes within HHS intended to accelerate innovation. ACI is working to

identify metrics and is seeking specific public comment regarding measures that would accurately reflect the pace of clinical innovation in the United States.

Identification and Prioritization of Areas of Focus

The ACI initiative has identified some strengths and opportunities for HHS to leverage that will move the department to a more proactive stance for clinical innovation. HHS has a strong workforce with a broad array of expertise, unparalleled by any other organization in the world this is motivated by — and believe strongly in — the public health mission of the Department. HHS also holds vast amounts of scientific and clinical data that can provide insights into opportunities for innovation. When focused on specific issues, HHS has a strong track record of achieving meaningful results by working together in the Department, across the Federal government, with private partners, and with patients. These assets are the foundation upon which an innovation accelerator can be built. However, HHS resources are limited, necessitating prioritization of diseases or conditions that would benefit from enhanced department-wide focus to accelerate biomedical innovation and present the greatest possible impact on public health. HHS is seeking specific input regarding the factors, types of data and analysis methods, and other aspects of the process for focus area identification and prioritization. It is not the intent of this public hearing to identify or address specific diseases or conditions at this time, but rather to develop an objective process for doing so.

II. Public meeting

A. Purpose and Scope of the Meeting

The public meeting is intended to provide an opportunity for broad public participation and comment concerning the process for biomedical innovation in the United States and how HHS can act by itself or in partnership to accelerate the pace of bringing new safe, effective medical

products to patients who need them. HHS specifically is requesting input regarding opportunities to assess and improve the overall innovation process across HHS through information sharing and collaboration among federal agencies and through public-private partnership. This meeting and the written comments are intended to assist HHS in developing programs and processes at the HHS enterprise level to accelerate the pace of clinical innovation while maintaining critical public health standards for safety and effectiveness.

While HHS is considering opportunities for accelerating clinical innovation in the United States, including data sharing, outreach, collaborations, and partnerships, this meeting is not intended to specifically address changes to policies, procedures, scientific or regulatory standards, review processes or similar programmatic details enacted and overseen by the constituent operating and staff divisions of HHS.

B. Format of the Meeting

The meeting will be conducted by a panel of HHS officials. The majority of the meeting will be reserved for presentations of comments, recommendations, and data from registered presenters. The time for each presenter's comments will be determined by HHS and will be based on the number of registered presenters. Presentations will be grouped by the sector the presenters represent, with time reserved for patients and their representatives, payers including plan sponsors, carries, and managed care plans, and investors. Within the groups, presenters will be scheduled to speak in the order in which they register. Only the HHS panel members may question any presenter during or at the conclusion of each presentation. The meeting will be recorded and transcribed.

In addition, written comments will also be accepted and presented at the meeting, time permitting, if they are received by the date specified in the DATES section of this notice.

C. Live Streaming Information

For participants who cannot attend the public meeting in person there will be an option to view the public meeting via live streaming technology. Information on the option to view the meeting via live streaming technology will be posted at a later time www.regulation.gov.

III. Issues for Discussion

HHS invites comment at the public meeting about how the Department can act to accelerate the pace of clinical innovation while maintaining critical public health standards. When providing comment, please include a discussion of which phase of development (e.g. discovery, preclinical, first-in-man, feasibility, pivotal clinical trial, registration, marketing, benefit categorization, coding, coverage, reimbursement, inclusion in standards of practice, etc.) and which stakeholder sector(s)' (e.g. patients, physicians, researchers, medical product developers, commercial health insurance plan sponsors and carriers, private investors, and the community at large) experiences you are providing. HHS is specifically interested in public input on the following questions:

1. What existing resources can HHS leverage to provide the biomedical innovation community with timely, meaningful information to promote product development, while promoting competition and maintaining commercial confidential information?
2. Which aspects of the regulatory framework for biomedical product development marketing are the most unclear to your stakeholder community, and how could HHS act to clarify processes?
3. What additional information or data would be helpful to your stakeholder sector (e.g. patients, physicians, private insurance, product developers, private investors, etc.) to improve decision-making and efficiency of product development?

4. Are there specific metrics for the overall biomedical innovation enterprise across public and non-public sectors that HHS could use to track and measure results of process changes?

5. What metrics, data sources, procedures or other factors should be considered in the identification and prioritization of diseases or conditions that would receive the most impact from enhanced HHS-wide focus?

IV. Security, Building, and Parking Guidelines

The meeting is open to the public, but attendance is limited to the space available. Persons wishing to attend this meeting must register by contacting the individual(s) at the address listed in the "ADDRESSES" section of this notice or by telephone at the number listed in the "FOR FURTHER INFORMATION CONTACT" section of this notice by the date specified in the "DATES" section of this notice. This meeting will be held in a federal government building, the Hubert H. Humphrey (HHH) Building; therefore, federal security measures are applicable.

The REAL ID Act of 2005 (Pub. L. 109–13) establishes minimum standards for the issuance of state-issued driver's licenses and identification (ID) cards. It prohibits federal agencies from accepting an official driver's license or ID card from a state for any official purpose unless the Secretary of the Department of Homeland Security determines that the state meets these standards. Beginning October 2015, photo IDs (such as a valid driver's license) issued by a state or territory not in compliance with the Real ID Act will not be accepted as identification to enter federal buildings. Visitors from these states/territories will need to provide alternative proof of identification (such as a valid passport) to gain entrance into federal buildings. The current list of states from which a federal agency may accept driver's licenses for an official purpose is found at http://www.dhs.gov/real-id-enforcement-brief.

We recommend that confirmed registrants arrive reasonably early, but no earlier than 45 minutes prior to the start of the meeting, to allow additional time to clear security. Security measures include the following:

- Presentation of a government issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Inspection, via metal detector or other applicable means, of all persons entering the building. We note that all items brought into HHH Building, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set up, safety, or timely arrival of any personal belongings or items used for presentation or to support a presentation.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting.

V. Transcripts

As soon as a transcript of the public meeting is available, it will be accessible on www.regulations.gov. A transcript also will be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the PHS FOIA Office, 7700 Wisconsin Avenue, Suite #920, Bethesda, MD 20857; phone: (301) 492-4800; fax: (301) 492-4848; email: FOIARequest@psc.hhs.gov.

VI. Collection of Information

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. All information will be received subsequent to a general solicitation of comments in the Federal Register or solicited at or in connection with a public hearing or meeting, thereby making the information collection requests

in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(h)(4) and 5 CFR 1320.3(h)(8), respectively. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq).

Dated: May 20, 2019.

Charles N.W. Keckler,

Associate Deputy Secretary,

Immediate Office of the Secretary.

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