



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Facilitation of Public-Private Dialogue to Increase Innovation and Investment in the Healthcare Sector

AGENCY: Immediate Office of the Secretary, HHS.

ACTION: Request for information.

SUMMARY: This request for information solicits public comment on a planned initiative of the Office of the Deputy Secretary of HHS to develop a workgroup to facilitate constructive, high-level dialogue between HHS leadership and those focused on innovating and investing in the healthcare industry. HHS seeks comment on how to structure a workgroup, or other form of interaction between the Department and such participants in the healthcare industry, in order to best support communication and understanding between these parties that will spur investment, increase competition, accelerate innovation, and allow capital investment in the healthcare sector to have a more significant impact on the health and wellbeing of Americans. HHS also seeks comment more broadly on opportunities for increased engagement and dialogue between HHS and those focused on innovating and investing in the healthcare industry.

DATES: Comments must be submitted within 30 days after the date of publication in the Federal Register.].

ADDRESSES: You may submit comments in one of three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments through <http://www.regulations.gov>.
2. *By regular mail.* You may mail written comments to the following address ONLY:

Immediate Office of the Secretary

Office of the Deputy Secretary

U.S. Department of Health and Human Services

Attention: RFI Regarding Healthcare Sector Innovation and Investment Workgroup

200 Independence Avenue SW

Washington, DC 20201

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may mail written comments to the following address

ONLY:

Immediate Office of the Secretary

Office of the Deputy Secretary

U.S. Department of Health and Human Services

Attention: RFI Regarding Healthcare Sector Innovation and Investment Workgroup

200 Independence Avenue SW

Washington, DC 20201

FOR FURTHER INFORMATION CONTACT:

William Brady, (202) 690-6133.

SUPPLEMENTARY INFORMATION:

I. Background

The healthcare industry is a complex and highly regulated industry, and although significant investment occurs within the industry, innovation and investment in the healthcare industry must increase to produce more significant impact on the health and wellbeing of the

American people. Through this effort, the Department intends to provide a forum for HHS leadership to engage in a dialogue with those focused on innovating and investing in the healthcare industry, such as healthcare innovation-focused companies, healthcare startup incubators and accelerators, healthcare investment professionals, healthcare-focused private equity firms, healthcare-focused venture capital firms, and lenders to healthcare investors and innovators. While HHS seeks comment on the structure and focus of the workgroup, as well as other opportunities for engagement, the Department envisions the workgroup as a forum to hear the individual perspectives of attendees and foster new and innovative approaches to tackle the complicated challenges facing the healthcare industry. The Department intends for non-HHS attendees to be diverse across the subsectors of the healthcare industry and the investment and innovation lifecycles, and for HHS attendees to be diverse across the Department in senior leadership positions. Workgroup members will not be asked to provide any reports or collaborative work product. No travel expenses, per diem, or compensation of any type will be provided to attendees.

II. Solicitation of Comments

HHS seeks comment on how to structure the workgroup in order to best support communication and understanding between these parties that will spur investment in the healthcare industry, increase competition, improve innovation, and allow capital investment in the healthcare sector to have a more significant impact on the health and wellbeing of Americans. HHS also seeks comment more broadly on opportunities for increased engagement and dialogue between HHS and those focused on innovating and investing in the healthcare industry. Specifically, HHS seeks comments addressing the following topics:

1. Specific areas of inquiry or focus for the workgroup. Should the workgroup review

recent developments in health innovation and investing? Should the workgroup examine perceived barriers to innovation and competition in the healthcare industry? Should the workgroup encourage outside parties to provide HHS with information about how they are affected by HHS programs or regulatory requirements? Should the workgroup provide a forum for attendees to share their perspectives as to how the Department may improve relevant regulations, guidance, or other documents? Should the workgroup examine ways to encourage private sector investment to help combat health crises? What other areas of focus would best help the Department engage with diverse subsectors of the healthcare industry and investment industry in order to increase innovation and investment in the healthcare sector?

2. How the workgroup should be convened and structured, including what subsectors of the healthcare economy should be invited to participate, and the most effective size. How should the agency structure meetings or other engagements in order to best facilitate the exchange of information and the presentation of attendees' individual perspectives? The Department seeks comment on how suitable attendees should be identified and selected to attend and engage in an exchange of ideas about the Department's goals of increasing innovation and investment in the healthcare sector.

3. HHS also seeks comment more broadly on opportunities for increased engagement and dialogue between HHS and those focused on innovating and investing in the healthcare industry, including alternatives to the workgroup structure discussed in this request for information. The Department is interested in comments that propose alternatives for developing a durable and consistent approach to increase innovation and investment in the healthcare sector to improve the public health and wellbeing of Americans.

This is a request for information only. Respondents are encouraged to provide complete

but concise responses to any or all of the questions outlined above. This request for information is issued solely for information and planning purposes; it does not constitute a notice of proposed rulemaking or request for proposals, applications, proposal abstracts, or quotations, nor does it suggest that the Department will undertake any particular action in response to comments. This request for information does not commit the United States Government (“Government”) to contract for any supplies or services or make a grant award. Further, HHS is not seeking proposals through this request for information and will not accept unsolicited proposals. Respondents are advised that the Government will not pay for any information or administrative costs incurred in response to this request for information; all costs associated with responding to this request for information will be solely at the interested party’s expense. Not responding to this request for information does not preclude participation in any future rulemaking or procurement, if conducted. It is the responsibility of the potential responders to monitor this request for information announcement for additional information pertaining to this request. We also note that HHS will not respond to questions about the policy issues raised in this request for information. HHS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review the responses submitted under this request for information. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained in response to this request for information may be used by the Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This request for information should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All

submissions become Government property and will not be returned. HHS may publicly post the comments received, or a summary thereof. While responses to this request for information do not bind HHS to any further actions related to the response, all comments may be posted online on <http://www.regulations.gov>.

III. Collection of Information

This document does not impose information collection requirements; that is, reporting, recordkeeping or third-party disclosure requirements. This request for information constitutes a general solicitation of comments. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA) at 5 CFR 1320.3(h)(4), information subject to the PRA does not generally include “facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency’s full consideration of the comment.” Consequently, this document need not be reviewed by the Office of Management and Budget under the authority of the PRA (44 U.S.C. 3501 et seq.).

Authority: 42 U.S.C. 3501.

Dated: June 1, 2018.

Eric D. Hargan,

Deputy Secretary,

Department of Health and Human Services.

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