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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Effective and Innovative Approaches/Best Practices in Health Care in Response to the COVID-19 Pandemic; Request for Information (RFI)

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Request for information (RFI).

SUMMARY: The U.S. Department of Health and Human Services (HHS) seeks to gain a comprehensive understanding of the impact of changes adopted by health care systems and health care providers in response to the COVID-19 pandemic. Many healthcare systems and clinicians have rapidly reengineered their policies and programs to improve access, safety, quality, outcomes including mortality and morbidity, cost, and value for both COVID-19 and non-COVID-19 related medical conditions. HHS plans to identify and learn from effective innovative approaches and best practices implemented by non-HHS organizations in order to inform HHS priorities and programs.

DATES: We recommend that you submit your comments through the Innovation RFI Response Portal (https://rfi.grants.nih.gov/?s=5f89e1e8400f00001a0036f2) to ensure consideration. Comments must be received through this portal no later than midnight Eastern Time (ET) on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submissions received after the deadline will not be reviewed. Comments may also be submitted in regulations.gov.

ADDRESSES:

Comments, including mass comment submissions, must be submitted electronically using the Innovation RFI Response Portal (https://rfi.grants.nih.gov/?s=5f89e1e8400f00001a0036f2). Please respond concisely, in plain language, and in a narrative format in the field provided for each question, to ensure accurate interpretation and analysis. You may respond to some or all of

the topic areas covered in the RFI, and/or you can also provide relevant information that may not have been referenced. You can also include links to online material or interactive presentations. Please do not include any personally identifiable patient information or confidential business information in your comment.

FOR FURTHER INFORMATION CONTACT: CAPT Meena Vythilingam, Director, Center for Health Innovation, Office of the Assistant Secretary for Health, Meena. Vythilingam@HHS.gov or 202 260 7382.

SUPPLEMENTARY INFORMATION:

I. Background

In response to the 2019 novel coronavirus or COVID–19 pandemic, the Secretary of Health and Human Services (HHS) declared a public health emergency effective January 27, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d¹) and renewed it continually since its issuance. The impact of the COVID-19 pandemic on the nation's healthcare system has been complex, widespread, and potentially enduring. This unprecedented pandemic has impacted the safety, quality, continuity, outcomes, value, and access to timely health care in numerous healthcare settings. Anecdotal reports as well as data from varied public sources confirmed that in addition to COVID-19-related increases in mortality and morbidity, the mortality and morbidity for numerous non-COVID-19-related medical conditions has also increased.² The COVID-19 public health emergency is disproportionately affecting vulnerable populations, particularly the elderly, and racial and ethnic minorities.³ Local health systems with a significant burden of COVID–19 cases have faced multiple challenges including surge capacity, staffing, and supply chain issues, that directly impact access, quality, and experience of care for all medical conditions.⁴ Decreases in help-seeking behaviors in the context of the COVID-19

¹ https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx

² Weinstein E, Ragazzoni L, Burkle F, Allen M, Hogan D, Della Corte F. Delayed Primary and Specialty Care: The Coronavirus Disease-2019 Pandemic Second Wave [published online ahead of print, 2020 May 7]. Disaster Med Public Health Prep. 2020; 1-3. doi:10.1017/dmp.2020.148

³ https://www.cms.gov/newsroom/press-releases/cms-updates-data-covid-19-impacts-medicare-beneficiaries

⁴ Francis JR. COVID-19: Implications for Supply Chain Management. *Front Health Serv Manage*. Fall 2020, 37(1):33-38. doi: 10.1097/HAP.0000000000000002.

pandemic may have also contributed to delays in accessing timely care, resulting in poor outcomes.⁵ In addition to the disruption in healthcare, the delivery of long-term services and supports (LTSS) to many seniors and people with disabilities has also been disrupted during the pandemic.

In response to the COVID–19 pandemic, medical providers, medical facilities, academic centers, and health systems rapidly reengineered healthcare policies and programs to ensure preservation of health care access, safety, quality, continuity, value, and outcomes. As a result, there has been a proliferation of innovative programs, policies, and best practices to prevent and mitigate the consequences of COVID–19, while simultaneously preserving access to routine and emergency healthcare services for non-COVID-19 medical conditions.⁶ An example of the paradigmatic shift in the delivery of health care is the rapid adoption and scaling of telehealth services.⁷ Although the pandemic disrupted the entire health care ecosystem in the U.S., it also provided an opportunity and impetus to innovate across the continuum of individual and population health, including screening, surveillance, prevention, treatment, supply chain management, and public health interventions. These changes may persist for the duration of the public health emergency, and potentially beyond it.

HHS strongly supports innovation to preserve a resilient healthcare system in the face of the COVID–19 pandemic and recognizes the importance of learning from effective and innovative approaches and best practices implemented by non-HHS healthcare systems, academic centers, and healthcare providers. HHS will determine if these innovative approaches and best practices can help inform and/or improve HHS priorities and programs.

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⁵ https://www.cdc.gov/mmwr/volumes/69/wr/mm6925e2.htm?s_cid=mm6925e2_e&deliveryName=USCDC_921-DM31231#F1_down

⁶ Short JB, Mammen. A Pandemic Application of Creative Destruction in Healthcare. Fall 2020, Front Health Serv Manage.;37(1):4-9. doi: 10.1097/HAP.000000000000003

Wosik J, Fudim M, Cameron B, et al. Telehealth transformation: COVID-19 and the rise of virtual care. J Am Med Inform Assoc. 2020; 27(6):957-962. doi:10.1093/jamia/ocaa067

II. Scope and Assumptions

- The main purpose of this Request for Information (RFI) is for HHS to gather information on *effective* innovative approaches and best practices in health care in response to the COVID-19 pandemic by non-HHS health care systems and providers. The information provided will help inform and guide the HHS response to build a healthy and resilient nation.
- This RFI includes innovations and best practices in health care for both COVID-19 and non-COVID-19 health conditions.
- The definition of "health" system or services and/or "healthcare" system or services, for the purposes of this RFI, is broad. We seek an understanding of effective best practices and innovations in the provision of services across the health and public health continuum by a variety of organizations. Responses can focus on select aspects or on the entire continuum of care, to include surveillance, screening, prevention, treatment, and/or public health interventions.
- We are specifically interested in novel approaches and best practices that are associated with data confirming efficacy and/or effectiveness with demonstrated improvements in one or more of the following measures: patient outcomes, access to health care, safety, quality, and/or value.
- Responses should include the following:
 - A description of the innovation/best practice.
 - The rationale for the implementation of the innovation/best practice.
 - Data and/or results confirming efficacy and/or effectiveness of the innovation/best practice, including demographic data; control conditions; outcomes measures (e.g., mortality, morbidity, health care access, safety, quality, cost, value, etc.); analytic strategy; and results. If the evaluation is currently underway, please describe the study design and expected timeline for completion of the study.
 - Costs associated with implementing the the innovation/best practice.

- Have these innovations/best practices been incorporated as permanent organizational changes? If not, why not?
- Can the innovation/best practice be scaled to larger, diverse groups and/or locations for a longer period? If yes, please describe the potential impacts on outcomes.
- Did or could specific HHS policies or programs facilitate the design and implementation of an innovation/best practice? (If yes, please provide details of how the policy or program affects or could affect the innovation/best practice positively).
- By contrast, did or could specific HHS policies or programs hinder the design and implementation of an innovation/best practice? (If yes, please provide details of how the policy or program affects or could affect the innovation/best practice negatively).

III. Information Requested / Key Questions

Please respond to specific topics in which you have the most amount of evidence and expertise.

Respondents are requested to share the objective results of an evaluation for each topic when possible. Response to every item is not required.

A. Health Promotion and Prevention of COVID-19 and Non- COVID-19 medical conditions

- A description of the innovation/best practice.
- The rationale for the implementation of the innovation/best practice.
- Data and/or results confirming efficacy and/or effectiveness of the innovation/best practice, including demographic data; control conditions; outcomes measures (e.g., mortality, morbidity, health care access, safety, quality, cost, value, etc.); analytic strategy; and results. If the evaluation is currently underway, please describe the study design and expected timeline for completion of the study.
- Costs associated with implementing the the innovation/best practice.

- Have these innovations/best practices been incorporated as permanent organizational changes? If not, why not?
- Can the innovation/best practice be scaled to larger, diverse groups and/or locations for a longer period? If yes, please describe the potential impacts on outcomes.
- Did or could specific HHS policies or programs facilitate the design and implementation of an innovation/best practice? (If yes, please provide details of how the policy or program affects or could affect the innovation/best practice positively).
- By contrast, did or could specific HHS policies or programs hinder the design and implementation of an innovation/best practice? (If yes, please provide details of how the policy or program affects or could affect the innovation/best practice negatively).
- Describe effective innovations/best practices that prevented the transmission of SARS-CoV-2 infections in staff, patients and/or beneficiaries.
- 2. Describe effective innovations/best practices to prevent SARS-CoV-2 outbreaks among residents and staff in long-term care facilities including assisted living facilities, nursing homes, rehabilitation facilities, intermediate care facilities for individuals with intellectual disabilities (ICF/ID), and palliative care settings.
- 3. Describe innovative programs/policies and best practices to ensure timely access to health care and continuity of care for patients with chronic illnesses that increase vulnerability to COVID-19.
- 4. Provide details on innovations or best practices that prevented increases in morbidity and mortality due to deferred care for acute medical conditions (e.g., cardiac arrests, strokes, etc.).
- 5. Describe effective programs or practices that helped ensure timely administration of immunizations to pediatric patients and other vulnerable populations including the elderly and individuals with disabilities.
- 6. Elaborate on effective educational and messaging campaigns targeting prevention.

7. Describe effective health promotion and prevention policies and programs implemented in response to COVID-19, that will continue beyond this pandemic.

B. Screening/Surveillance/Case Identification of COVID-19 and Non- COVID-19 medical conditions

- A description of the innovation/best practice.
- The rationale for the implementation of the innovation/best practice.
- Data and/or results confirming efficacy and/or effectiveness of the innovation/best practice, including demographic data; control conditions; outcomes measures (e.g., mortality, morbidity, health care access, safety, quality, cost, value, etc.); analytic strategy, and results. If the evaluation is currently underway, please describe the study design and expected timeline for completion of the study.
- o Costs associated with implementing the the innovation/best practice.
- Have these innovations/best practices been incorporated as permanent organizational changes? If not, why not?
- Can the innovation/best practice be scaled to larger, diverse groups and/or locations for a longer period? If yes, please describe the potential impacts on outcomes.
- Did or could specific HHS policies or programs facilitate the design and implementation of an innovation/best practice? (If yes, please provide details of how the policy or program affects or could affect the innovation/best practice positively).
- By contrast, did or could specific HHS policies or programs hinder the design and implementation of an innovation/best practice? (If yes, please provide details of how the policy or program affects or could affect the innovation/best practice negatively).
- Describe effective approaches to screening, surveillance and case identification of COVID-19.

- 2. Describe efforts to ensure that patients continue to receive United States Preventive Services Task Force-recommended screening procedures on time during the COVID-19 pandemic. Please include data on the program's ability to prevent negative outcomes due to timely screening and early detection, if available.
- 3. Outline innovative programs to continue screening for HIV, hepatitis and sexually transmitted diseases during the pandemic, (e.g. in syringe services programs (SSPs).

C. Treatment for COVID-19 and Non- COVID-19 medical conditions

- A description of the innovation/best practice.
- The rationale for the implementation of the innovation/best practice.
- O Data and/or results confirming efficacy and/or effectiveness of the innovation/best practice, including demographic data; control conditions; outcomes measures (e.g., mortality, morbidity, health care access, safety, quality, cost, value, etc.); analytic strategy, and results. If the evaluation is currently underway, please describe the study design and expected timeline for completion of the study.
- Costs associated with implementing the the innovation/best practice.
- Have these innovations/best practices been incorporated as permanent organizational changes? If not, why not?
- Can the innovation/best practice be scaled to larger, diverse groups and/or locations for a longer period? If yes, please describe the potential impacts on outcomes.
- Did or could specific HHS policies or programs facilitate the design and implementation of an innovation/best practice? (If yes, please provide details of how the policy or program affects or could affect the innovation/best practice positively).
- By contrast, did or could specific HHS policies or programs hinder the design and implementation of an innovation/best practice? (If yes, please provide details of how the policy or program affects or could affect the innovation/best practice negatively).

- Describe innovations/best practices in COVID-19 treatment that resulted in decreased mortality and morbidity.
- 2. Describe if and how a health care system was effectively reengineered to ensure timely access and quality of care in the Emergency Department, Outpatient or Inpatient settings.
- 3. Describe how appropriate utilization of emergency medical services was facilitated during the pandemic.
- 4. Detail effective changes in intensive care unit (ICU) care and post-hospital care/follow-up.
- 5. Detail best practices to ensure continuity of treatment for HIV, hepatitis and sexually transmitted diseases during the pandemic.
- 6. Describe effective programs/policies to prevent/manage dental emergencies during the pandemic.
- 7. Outline novel and effective approaches to ensure compliance with medications, including refills, during the pandemic.
- 8. Please list effective treatment-related policies or programs that will continue beyond the COVID-19 pandemic.

D. Telehealth

- A description of the innovation/best practice.
- The rationale for the implementation of the innovation/best practice.
- Data and/or results confirming efficacy and/or effectiveness of the innovation/best practice, including demographic data; control conditions; outcomes measures (e.g., mortality, morbidity, health care access, safety, quality, cost, value, etc.); analytic strategy, and results. If the evaluation is currently underway, please describe the study design and expected timeline for completion of the study.

- Costs associated with implementing the the innovation/best practice.
- Have these innovations/best practices been incorporated as permanent organizational changes? If not, why not?
- Can the innovation/best practice be scaled to larger, diverse groups and/or locations for a longer period? If yes, please describe the potential impacts on outcomes.
- Did or could specific HHS policies or programs facilitate the design and implementation of an innovation/best practice? (If yes, please provide details of how the policy or program affects or could affect the innovation/best practice positively).
- By contrast, did or could specific HHS policies or programs hinder the design
 and implementation of an innovation/best practice? (If yes, please provide details
 of how the policy or program affects or could affect the innovation/best practice
 negatively).
- 1. Describe effective best practices to deliver clinical and nonclinical services using telehealth (e.g. surveillance, prevention and treatment services etc).
- 2. Describe best practices and innovations to improve access to care for rural/remote populations using telehealth, during the pandemic.
- 3. Detail effective use of remote monitoring/telemonitoring of chronic medical conditions including diabetes and hypertension and for delivering home health services.
- 4. List criticial barriers to implement telehealth in healthcare systems.
- 5. What are some of the key facilitators of telehealth?
- 6. Outline innovative approaches to inegrate telehealth into the clinical work flow.
- 7. List effective telehealth programs that will continue beyond this pandemic.
- 8. Describe technological systems that facilitate telehealth, including use of audio or video telehealth, telehealth programs or apps, or other approaches.

9. Describe technological systems that might or might not facilitate telehealth, including uses of audio or video telehealth, telehealth programs or apps, or other approaches.

E. Mental Health/Behavioral Health and Substance Use Disorder Innovations/Best Practices

- A description of the innovation/best practice.
- The rationale for the implementation of the innovation/best practice.
- Data and/or results confirming efficacy and/or effectiveness of the innovation/best practice, including demographic data; control conditions; outcomes measures (e.g., mortality, morbidity, health care access, safety, quality, cost, value, etc.); analytic strategy, and results. If the evaluation is currently underway, please describe the study design and expected timeline for completion of the study.
- Costs associated with implementing the the innovation/best practice.
- Have these innovations/best practices been incorporated as permanent organizational changes? If not, why not?
- Can the innovation/best practice be scaled to larger, diverse groups and/or locations for a longer period? If yes, please describe the potential impacts on outcomes.
- Did or could specific HHS policies or programs facilitate the design and implementation of an innovation/best practice? (If yes, please provide details of how the policy or program affects or could affect the innovation/best practice positively).
- By contrast, did or could specific HHS policies or programs hinder the design and implementation of an innovation/best practice? (If yes, please provide details of how the policy or program affects or could affect the innovation/best practice negatively).

- 1. Describe effective, novel mental health prevention and/or treatment programs in response to the COVID-19 pandemic.
- 2. Describe effective and innovative substance use disorder programs during the COVID-19 pandemic.
- 3. Describe innovative efforts to provide medication-assisted treatment, including access to counseling and support groups, during the pandemic.
- 4. Provide information on effective suicide prevention programs implemented during the pandemic.
- 5. Provide information on effective programs designed to identify childhood abuse, elder abuse and/or domestic violence during the pandemic.
- 6. Detail effective approaches to prevent COVID transmission in psychiatric and substance use disorder residential and group treatment facilities.

F. Population-Level Interventions

- A description of the innovation/best practice.
- The rationale for the implementation of the innovation/best practice.
- Data and/or results confirming efficacy and/or effectiveness of the innovation/best practice, including demographic data; control conditions; outcomes measures (e.g., mortality, morbidity, health care access, safety, quality, cost, value, etc.); analytic strategy, and results. If the evaluation is currently underway, please describe the study design and expected timeline for completion of the study.
- Costs associated with implementing the the innovation/best practice.
- Have these innovations/best practices been incorporated as permanent organizational changes? If not, why not?
- Can the innovation/best practice be scaled to larger, diverse groups and/or locations for a longer period? If yes, please describe the potential impacts on outcomes.

- Did or could specific HHS policies or programs facilitate the design and implementation of an innovation/best practice? (If yes, please provide details of how the policy or program affects or could affect the innovation/best practice positively).
- o By contrast, did or could specific HHS policies or programs hinder the design and implementation of an innovation/best practice? (If yes, please provide details of how the policy or program affects or could affect the innovation/best practice negatively).
- Describe innovations/best practices in preventing and/or treating COVID-19 in high risk
 and vulnerable populations including but not limited to, African-Americans, Asian
 Americans, Hispanics/Latinos, American Indians/Alaska Natives, persons with
 disabilities, persons with limited English proficiency and others who might have been
 disproportionately impacted by COVID-19, directly or because treatment for other
 medical conditions has been disrupted.
- 2. Provide details on effective, community-based, innovative programs to improve population health during the COVID-19 pandemic (e.g., programs to address social determinants of health).
- 3. Outline effective and innovative approaches to address health disparities across the continuum of care during the COVID-19 pandemic.
- 4. Detail effective approaches to address social isolation in vulnerable populations including older-adults and people with disabilities in both institutional and community settings.

-G. Other Topics

 Please describe effective strategies to address other critical barriers, including work force concerns, provider well-being, supply chain, etc., to ensure continuity of operations in a healthcare system.

- Outline best practices to ensure seamless delivery of long-term services and supports
 (LTSS) to residents of group homes for individuals with disabilities, and other recipients
 of home-and-community-based services during the pandemic.
- Detail new programs/policies and efforts that were implemented during the pandemic, but found to be ineffective in improving healthcare access, safety, quality, continuity, value and outcomes.
- 4. Please describe other input not already covered by the previous topics.

HHS encourages all potentially interested parties including individuals, healthcare providers, networks and/or associations, academic researchers and institutions, non-HHS federal healthcare systems, non-governmental organizations, and private sector entities to respond.

IV. How to Submit Your Response

Please upload your responses to each question in this Innovation RFI response tool which has clearly marked sections for individual questions. Please respond concisely, in plain language, and in narrative format. You may respond to some or all of the questions listed in the RFI. Please ensure it is clear which question you are responding to. You may also include links to online material or interactive presentations.

Please note that this is a request for information (RFI) only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h) (4), this general solicitation is exempt from the PRA. 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, are not generally considered information collections and therefore not subject to the PRA.

This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the

U.S. Government to contract for any supplies or services or make a grant award. Further, we are

not seeking proposals through this RFI and will not accept unsolicited proposals. We note that

not responding to this RFI does not preclude participation in any future procurement, if

conducted. It is the responsibility of the potential responders to monitor this RFI announcement

for additional information pertaining to this request.

HHS may or may not choose to contact individual responders. Such communications would be

for the sole purpose of clarifying statements in written responses. Contractor support personnel

may be used to review responses to this RFI. 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

as a result of this RFI may be used by the Government for program planning on a non-attribution

basis. This RFI should not be construed as a commitment or authorization to incur cost for which

reimbursement would be required or sought. All submissions become U.S. Government property;

and will not be returned.

Dated: November 5, 2020.

Eric D. Hargan,

Deputy Secretary,

Department of Health and Human Services (HHS).

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