July 5, 2018

Immediate Office of the Secretary
Office of the Deputy Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Attention: RFI Regarding Healthcare Sector Innovation and Investment Workgroup

Dear Secretary Azar,

The College of Healthcare Information Management Executives (CHIME) welcomes the opportunity to submit comments in response to the recent Request for Information (RFI) regarding the *Facilitation of Public-Private Dialogue to Increase Innovation and Investment in the Healthcare Sector*, published on Thursday, June 7, 2018.

CHIME is an executive organization dedicated to serving chief information officers (CIOs), chief medical information officers (CMIOs), chief nursing information officers (CNIOs) and other senior healthcare IT leaders. With more than 2,600 members, CHIME provides a highly interactive, trusted environment enabling senior professional and industry leaders to collaborate, exchange best practices, address professional development needs and advocate for the effective use of information management to improve the health and healthcare in the communities they serve.

CHIME appreciates that the Department of Health and Human Services (HHS) has decided to take such an active stance on promoting innovation and investment within the healthcare sector to drastically increase the quality of care for the nation's patients. For the healthcare industry to thrive, we agree that promoting competition, accelerating innovation and fostering investment is pivotal. CHIME agrees that engaging industry could help increase innovation and investment in the healthcare industry to improve the health and well-being of the American people.

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I. Responses to RFI Questions

Q1: 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?

A1: Recommendation: One of the biggest challenges that the workgroup will face is identifying an effective way to incentivize or otherwise promote ongoing, responsible innovation. We recommend that this new workgroup: 1) Offer the Secretary its recommendations for a set of standards – based on the factors outlined below – that innovators should consider in developing technology to help treat patients and help caregivers; and 2) HHS use the recommendations to develop a voluntary framework for use by innovators.

- **Prioritize ethical considerations:** We believe that technology has great potential to help achieve better care and greater efficiencies. Yet it is critical to balance the drive for innovation and use of technology with the need to ensure that innovators understand the downstream ethical considerations that will determine the extent of adoption by the end-users – clinicians and patients. Such considerations may not be immediately apparent to innovators. However, they are significant for both clinicians and patients and will help determine the overall success of the innovation. We recognize that this balance is often a delicate one such that innovation is not stifled, yet ethical considerations must continuously be at the forefront as technology is being developed and rolled out. For example, with many research projects involving Institutional Review Boards (IRBs), researchers will work to understand the ethical impact of their findings, moving forward. Yet, when it comes to technology, innovators often move forward with discoveries without adequately considering the ethical consequences of their inventions.

- **Involve clinicians and patients early**: New technology can present implementation challenges that can be addressed by engaging end users early in the design phases as well as the rollout phases. As an example, we have a member who is using a smart speaker, which is already in widespread use in homes, in their facility. One of the biggest challenges they are encountering is how to manage patient consent with this technology.

- **Address cybersecurity threats:** The cybersecurity threats in healthcare are mounting, increasing costs to the industry and creating patient safety concerns. Cybercrime in healthcare settings is now a lucrative industry for bad actors. The growing nature of our interconnected healthcare world is also raising the stakes for the likelihood of negative patient outcomes attributed to a cyber event. Innovations in technology must consider these growing threats.

- **Streamline vetting processes:** We believe it is important to be thorough in the vetting of products used to treat patients, however it is often very time consuming. For example, we have a member who was working with a manufacturer on an exoskeleton for approval by the Food and Drug Administration (FDA) and it took two years to achieve this. Frustration developed because the invention had already been approved on the manufacturer's end but it was not approved for use by clinicians. These types of scenarios bog down innovation and hold back our sector and should be avoided when possible.

- **Focus on closing the digital divide**: It's important to consider the existing gap between well-resourced providers and those with fewer resources. Less resourced providers who may be serving underserved and hard-to-reach patients may lack the capital to purchase cutting-edge technologies. Policies must seek to narrow the digital divide, rather than place these often small and rural providers at a further disadvantage. For instance, many hospitals failed to meet the rigorous standards put forward by the program formerly known as Meaningful Use. There are certainly many hospitals that will be able to purchase new innovations that include technologies such as artificial/augmented intelligence but others will not.

- **Accurately identify patients:** New technologies should support a uniform way to uniquely and accurately identify patients and connect them to their medical records – something that is a barrier to maximizing the benefits of existing and emerging technologies. Consistently identifying patients across health systems and different electronic health record (EHR) platforms is a significant challenge. As patients seek care at different providers and seek the most cost-effective treatment, this situation will only grow more complicated.

- **Preserving the patient/clinician relationship:** Our members are enormous proponents of technology, yet, they also understand the importance of the human touch. Technical innovation must flourish but it is also important to keep in mind the importance of fostering the connection between patients and their clinicians. We therefore believe HHS must be mindful of keeping patients and caregivers connected to their provider so technology can be used to deliver better care, not detract from patient care. For instance, the Promoting Interoperability program has unwittingly incentivized clinicians to spend less time with their patients and more time in front of their computer screens. If innovations cause the distance between clinicians and their patients to grow, technology may be perceived as a barrier rather than a solution.

Q2: 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.

Q2: Recommendation: As noted above, we believe a workgroup could add value by offering a set of standards to guide industry leaders in vetting their potential innovations and design and rolling out their technologies. The composition of workgroup should consist of broad consensus of stakeholders. We recommend that HHS include the below representatives in the new workgroup, given their respective roles in shaping adoption, use and long-term value assessments of new technologies:

1) **CIOs:** Chief Information Officers (CIOs) and other healthcare IT executives are key decision makers for purchasing and deploying new technologies for most health systems. They will offer critical insights on gaps and the challenges that we must overcome to move toward value-based, outcomes-driven healthcare models as well as the factors that inform adoption of new technologies and system transformation;
2) **CISOs:** The privacy and security of patient data – as well as the federal and state regulations governing such information – must be considered as new innovations and technologies are incorporated into healthcare delivery systems. CISOs offer unique perspective and considerations for ensuring innovations address growing cybersecurity threats to patient data;
3) **Providers:** The work group should include on-the-ground providers, clinicians and other practitioners who can provide feedback on the potential impact on service delivery and health outcomes as well as the usability of the innovation;
4) **Patients and caregivers:** A strong representation of patients and caregivers for which the technologies are being developed should be included;
5) **EHR vendor perspective needed:** Not only do consumers need to be heard, but the work group will benefit by having EHR vendor representation. The nexus between the EHR vendors and existing technologies must also be represented. For instance, telehealth and remote patient monitoring (RPM) are innovations, that while in existence for some time, are only now beginning to gain traction and their use can benefit patients greatly. Congress and the administration are just beginning to approve payment for some of these technologies and these new reimbursement streams could pave the way for more innovation to take root.
6) **Include innovators of all sizes and types:** Although the group is sure to include well-known tech giants that are on the forefront of radical innovations in the consumer technology and healthcare spaces, it is important to include other health innovation experts. Some areas where expertise will be necessary is in genomics, machine learning, voice recognition and cybersecurity so that responsible innovation can take place. As stated previously, in consumer technology, the same standards of ethics and safety are not in place in comparison to healthcare and sensitive patient health information.

Q3: 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.

A3: Recommendations: We recommend HHS: 1) Support innovation that targets ways to uniquely and accurately identify patients; and 2) utilize the Centers for Medicare and Medicaid Services' (CMS) Center for Medicare and Medicaid Innovation (CMMI) to promote private sector-led solutions in patient identification.

As identified above, solving the patient identification issue is essential. Given the Congressional ban in place since 1998 that prohibits HHS from spending any funds to establish or deploy a unique patient identifier, innovation in the private sector is needed to overcome this hurdle to improved patient care. CHIME has long been a supporter of developing a national patient identifier to accurately and efficiently match patients with the correct record. This is integral to CMS' goal to achieve the free-flowing exchange of patient records and true interoperability. From the perspective of CHIME, accurately matching patients to their data should be one of the principal goals of the innovation work group.

II. Conclusion

CHIME appreciates the opportunity to comment and we welcome the chance to continue to help shape important policies that impact patients, providers and others in the healthcare system. Should you have any questions about our letter, please contact Mari Savickis, Vice President, Federal Affairs, at Mari.Savickis@chimecentral.org.

Sincerely,

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