July 6, 2018

Eric D. Hargan
Deputy Secretary
Immediate Office of the Secretary,
Office of the Deputy Secretary,
U.S. Department of Health and Human Services,
200 Independence Avenue SW
Washington, DC 20201

Re: RFI Regarding Healthcare Sector Innovation and Investment Workgroup

Deputy Secretary Hargan:

The American Medical Informatics Association (AMIA) appreciates the opportunity to provide input regarding plans to develop a "Healthcare Sector Innovation and Investment Workgroup."

Health informatics is the 50-years-plus field of study concerned with data collection, analysis, and application within broad domains of health, including healthcare delivery, public health, consumer health, clinical research, and translational research. AMIA is the professional home for more than 5,500 health informatics professionals, representing front-line clinicians, researchers, educators and public health experts who bring meaning to data, manage information and generate new knowledge across the health and health care enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA members advance health and wellness by moving basic research findings from bench to bedside, and evaluating information and communication technology interventions, innovations, and public policy across care, research and community settings.

AMIA would like to convey two primary recommendations to HHS as it considers the contours and content of an Innovation and Investment Workgroup. First, **we strongly recommend that the Workgroup include representation from the health informatics community**, as this viewpoint and subject matter expertise will bring both clinical and technical knowhow to Workgroup deliberations. Second, **HHS should determine areas for Workgroup focus**, rather than assume convergence based on open-ended questions. These focus areas should be informed through broad public input from specific groups of stakeholders and an assessment of HHS goals.

The need to have input from clinicians and clinical researchers on Workgroup priorities should be obvious. Less obvious, but no less important, is the need to have clinical and clinical research informatics representation and input. The informatics community brings deep and rich clinical knowledge, spanning from genomics to social determinants, and combines this with a technical pedigree that invented natural language processing, created clinical decision support, advanced the use of machine learning in health and developed IT standards for computation. To be successful in

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identifying areas for innovation and investment, the Workgroup must have representation from the informatics community, and AMIA stands ready to help fulfill this need.

In addition to having the right experts, the Workgroup needs broad input combined with clear guidance from HHS. We recommend HHS focus the Workgroup on innovating and investing in areas that are (1) strategically important to HHS goals, (2) currently under-resourced and/or under-developed, and (3) have a strong potential for return on investment.

Consistent with recommendations delivered to the Networking and Information Technology Research and Development (NITRD) Draft Health Information Technology Research and Development Strategic Framework, we recommend this Workgroup look for ways to:

1. **Use data to improve the safety, reliability, and quality of healthcare.** Funding efforts meant to make sense of the oncoming deluge of data[1] in the service of care delivery and wellness represents one of the largest opportunities faced by the federal government. Of particular importance is sustained and increased support for new and novel kinds of clinical decision support. AMIA foresees a near-term need to transition smaller CDS demonstrations to larger scale projects. Leadership in this capacity will be essential.

2. **Support basic, applied, and advanced informatics training[2] so that we have a modern healthcare workforce that demonstrates:**
    - A basic "informatics literacy" for all health professionals that is part of medical education, biomedical research, and public health training to give clinicians the skills needed to collect and analyze information and apply it in their practice;
    - Intensive applied informatics training to improve leadership and expertise in applying informatics principles to healthcare problems; and
    - Support for education professionals who will advance the science and train the next generation of informatics professionals in this developing and dynamic field of study.

3. **Develop public policy to help foster a responsible ecosystem of innovation and investment.** Data generated by a host of other systems, including laboratory, imaging, consumer mHealth, and medical devices have the potential to transform health. These systems are either governed by different programs/policies or are not regulated at all, in the case of mHealth. AMIA recommends policy development at the intersection of consumer health and traditional health technology to help spur responsible innovation.

We further underscore the need for R&D in three distinct areas: development of granular data specifications; true interoperability testing, and a "digital, computable print all" functionality for improved data portability.

First, a focus on development of granular data specifications will enable a "periodic table of elements," approach to biomedical data standards. We lack a formalized approach to combine

[1] Such as EHRs, the IoT, new kinds of medical devices (including SaaMD), environmental, and genomic data

[2] Perlin, J., Baker D., et al. "Information Technology Interoperability and Use for Better Care and Evidence: A Vital Direction for Health and Health Care," National Academy of Medicine. September 19, 2016

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discrete data elements for specific use cases – e.g. quality measurement. To facilitate data re-use and interoperability, federal agencies should work with stakeholders to develop granular data specifications, including metadata, and standards to support research for use in the federal health IT certification program.

Second, we reiterate our call for true interoperability testing, not just conformance testing, for health IT modules certified to federal requirements. Interoperability testing ensures that systems can not only send data using a specified standard, but that a system can receive numerous variations on a standard. We refer you to Postel's Robustness Principle, which is to construct a system capable of being conservative in what it sends, but liberal in what it accepts from other systems.

Third, we anticipate that data portability, which receives no mention in this document, is of cross-cutting concern. Were EHRs, for example, able to provide full digital exports that maintained computability for all patients who ask for them, then we expect a dramatic proliferation of tools and applications would arise to help patients utilize their data. This has not occurred because patients do not have a "digital, computable print all button" they can push to get structured and unstructured data from their record. Likewise, clinicians complain about the usability of their systems, but they are unable to export their patient data from one system and import it into another without tremendous cost – indeed, they will likely never get all the data from one system to another, but only summary records. This may be a narrow area of focus, but the state of data portability is surely a concern across the health ecosystem.

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Thank you for considering our comments. Should you have questions about these comments or require additional information, please contact Jeffery Smith, Vice President of Public Policy at jsmith@amia.org or (301) 657-1291. We look forward to continued partnership and dialogue.

Sincerely,

Douglas B. Fridsma, MD, PhD, FACP, FACMI
President and CEO
AMIA

(Enclosed: AMIA comments to specific HHS Innovation RFI questions)

HHS seeks comment on how to structure a 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?

AMIA Comment: Yes, requiring the workgroup to be cognizant of the latest developments in health innovation and investing would better ensure that their advice is meaningful and relevant.

Should the workgroup examine perceived barriers to innovation and competition in the healthcare industry?

AMIA Comment: Yes, and HHS should identify broad areas where input is to be focused, such as pricing, patient-centered care, etc.

Should the workgroup encourage outside parties to provide HHS with information about how they are affected by HHS programs or regulatory requirements?

AMIA Comment: Yes, as long as such inquiries are targeted. Open-ended questions about generic HHS programs and regulatory requirements will not yield useful feedback for this group.

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?

AMIA Comment: Yes, uniformity in how regulations, guidance and other documents are communicated would be helpful. This group may have specific data points or formats of interest that HHS could provide when publishing such documents.

Should the workgroup examine ways to encourage private sector investment to help combat health crises?

AMIA Comment: Yes, this is already done through Challenge Grants. Generally, these grants have a good return on investment and attract entrepreneurs beyond the traditional stakeholders. See ONC's challenge grant portfolio for examples.

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?
AMIA Comment: Primary areas of focus should sit at the intersection of where high-growth technology and HHS strategic priorities overlap. For instance, HHS has placed renewed interest on

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enabling patients to be first-order participants in their care by ensuring that they have access to their data in a computable format. When this HHS priority is aligned with trends in consumer technology, we have synergistic developments, such as the announcement of Apple Health Record.

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.

AMIA Comment: We strongly encourage HHS to include participants who sit at the intersection of care delivery and technology, such as a Board Certified Clinical Informatician. These individuals are educated and trained to:

- Assess and develop effective solutions to meet the information and knowledge needs of health care and public health professionals, patients, and citizens in general.
- Implement and evaluate effective systems to support health and health care decision-making and manage personal health.
- Characterize, develop, evaluate, and refine health and health care processes that support effective, efficient, safe, timely, equitable, and patient-centered care.
- Develop effective practice improvements, process and workflow redesign, or automation.
- Utilize informatics approaches to improve system design, implementation, evaluation, and evolution/optimization.
- Ensure the legal, ethical, and effective use of health and health care data and information.
- Lead procurement, customization, development, integration, implementation, management, evaluation, and continuous improvement of health and health care informatics systems.
- Align system priorities with clinical/health care and health needs.
- Utilize the rapidly expanding amounts of data becoming available in various health and health care organizations (eg, payers, providers, pharmaceuticals) to derive insights for improving care delivery and population health.

Further, AMIA recommends HHS also consider informaticians who are steeped in clinical or translational research, as well as informaticians who understand population and consumer health. These individuals focus on applying the same knowledge and skills described above to the research enterprise, public / population health, and consumer health domains, respectively. The future of care delivery, research, population and consumer health is digital, and HHS would be remiss to omit experts from the field of informatics.

Finally, AMIA recommends that HHS strive to establish a workgroup that includes 30-40 members and HHS should strive for diversity along several dimensions, including: gender, ethnicity, background (e.g. private sector/for-profit, public sector, academia, small business entrepreneur, non-profit), and stakeholder type (e.g. clinician, investor, technology developer, patient/consumer, and other stakeholders specific to the foci of interest).

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?

AMIA Comment: HHS should follow FACA guidelines in structuring its meetings in the following ways:

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1. Provide notice and comment opportunities through the *Federal Register*.
    a. This enables and promotes broad public input by allowing non-Workgroup members to deliver recommendations and voice opinions through a well-established mechanism in the *Federal Register*.
    b. If the *Federal Register* requires too cumbersome a set of processes, we recommend HHS establish a dedicated website for the Workgroup and provide notice and comment opportunities via this website
2. These meetings should be open to the public via both in-person and virtual attendance options.
    a. Discussion regarding intellectual property and / or trade secrets should be discouraged. If such discussion is absolutely necessary, HHS should make explicit this or any other reason for a meeting to be closed to the public.

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.

AMIA Comment: HHS should issue a call for volunteers, outlining specific categories of stakeholders who are of interest to HHS's priority areas of focus. HHS agency staff and advisors should be