March 13, 2020

Russell T. Vought
Acting Director
Whitehouse Office of Management and Budget (OMB)

Submitted electronically via: http://www.regulations.gov

Dear Mr. Vought:

Re: Guidance for Regulation of Artificial Intelligence Applications

Thank you for the opportunity to provide comments on the proposed guidance to all Federal agencies to inform the development of regulatory and non-regulatory approaches regarding technologies and industrial sectors that are empowered or enabled by artificial intelligence (AI) including consideration of ways to reduce barriers to the development and adoption of these technologies.

The Alliance for Nursing Informatics (ANI), co-sponsored by AMIA & HIMSS advances nursing informatics leadership, practice, education, policy and research through a unified voice of nursing informatics organizations. We transform health and healthcare through nursing informatics and innovation. ANI is a collaboration of organizations that represent more than 20,000 nurse informaticists and brings together 25 distinct nursing informatics groups globally. ANI crosses academia, practice, industry, and nursing specialty boundaries and works in collaboration with the more than 4 million nurses in the U. S. in practice today.

As nursing informatics stakeholders, we have reviewed the proposed guidance of artificial intelligence and offer the following comments and proposed supplement to the outlined OMB principles:

- Artificial intelligence (AI) applications in healthcare offer a significant opportunity to leverage patient data and health data from the patient's experience to enable the following:
    - Improved patient safety, higher quality of care and augmented clinical decision making and shared decision making, in addition to prevention of adverse and unintended consequences[1],[2],[3],[4],[5],[6],[7],[8].

[1] Robert James Lucero et al., "A Data-Driven and Practice-Based Approach to Identify Risk Factors Associated with Hospital-Acquired Falls: Applying Manual and Semi- and Fully-Automated Methods," *International Journal of Medical Informatics* 122 (February 2019): 63–69, https://doi.org/10.1016/j.ijmedinf.2018.11.006.

[2] Sarah Collins, "How Extra Nursing Notes Point to Deterioration," *Nursing Times* 110, no. 22 (June 28, 2014): 19–20.

[3] Dawn Dowding, "Using Computerised Decision-Support Systems," *Nursing Times* 109, no. 36 (September 11, 2013): 23–25.

[4] Karen A. Monsen, Arindam Banerjee, and Puja Das, "Discovering Client and Intervention Patterns in Home Visiting Data," *Western Journal of Nursing Research* 32, no. 8 (December 2010): 1031–54, https://doi.org/10.1177/0193945910370970 .

[5] Kenrick D. Cato, Walter Bockting, and Elaine Larson, "Did I Tell You That? Ethical Issues Related to Using Computational Methods to Discover Non-Disclosed Patient Characteristics," *Journal of Empirical Research on Human Research Ethics: JERHRE* 11, no. 3 (2016): 214–19, https://doi.org/10.1177/1556264616661611.

[6] Kenrick D. Cato et al., "Electronic Surveillance of Surgical Site Infections," *Surgical Infections* 18, no. 4 (June 2017): 498–502, https://doi.org/10.1089/sur.2016.262.

[7] Maxim Topaz et al., "Mining Fall-Related Information in Clinical Notes: Comparison of Rule-Based and Novel Word Embedding-Based Machine Learning Approaches," *Journal of Biomedical Informatics* 90 (2019): 103103, https://doi.org/10.1016/j.jbi.2019.103103.

[8] Susan McBride et al., "Statewide Study to Assess Nurses' Experiences With Meaningful Use-Based Electronic Health Records," *Computers, Informatics, Nursing: CIN* 35, no. 1 (January 2017): 18–28, https://doi.org/10.1097/CIN.0000000000000290.

- Learn from a broader base of patients leading to the ability to provide patient-specific and personalized care recommendations to emphasize and support shared decision making
- Facilitation of healthcare research by addressing elements of research questions through the use of real-world data

- Regulatory initiatives must include attention to the ethical issues related to the development, dissemination, and evaluation of AI. AI plays an increasingly important role in the provision of patient care, research and education, it is imperative that patients and consumers are supported with knowledge of the opportunities and limitations of AI[9],[10],[11],[12].
- Commercial vendor applications such as Siri, Alexa, Google Home, etc. offer significant promise as tools to deliver healthcare across diverse care settings, including the home, however these should be regulated to capture data with individuals active and dynamic consent processes and should not engage in open. Use should not imply consent. Some vendors may have larger market share and may develop AI that is only as good as the data that is fed into it and may not reflect the needs of the population[13].
- We encourage the review and redefinition of HIPAA regulations to support the reduction of barriers for appropriate data use, re-use and exchange, while continuing to protect health information. Working with completely de-identified data removes valuable context of social determinants (including zip code) and negatively impacts the use of datasets.
- Continued protection of protected health information (PHI) is essential. It is critical that any consistency related to PHI continues to protect the healthcare consumer and personal health information of all individuals. Patients are choosing to share their data in applications where "patients like me" is an option. Having an opt-in option for patients to share their data in healthcare IT technology that is normally covered by HIPAA could advance the learning possible with artificial intelligence[14].
- Creating safe and reliable patient care experiences for individuals, families and communities, is a primary domain in the nursing scope of practice. AI applications used by nurses, and between nurses, patients, and family caregivers offer the greatest opportunities for improved care coordination, emphasizing prevention and proactive interventions with an emphasis to reduce the overall cost of care while improving patient experience and outcomes. While CMS data may be available, this data is billing-related and does not capture nursing and allied health data as it relates to their contribution to care interventions that address the social determinants of health and patient outcomes. Contributing data that will document the experience of the patient beyond the billable care is paramount to realizing the potential of AI in healthcare[15].
- Nurses and nurse informaticists must be present in drafting and enacting future regulations and plans to implement EO 13859[16].

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[9] Kun-Hsing Yu, Andrew L. Beam, and Isaac S. Kohane, "Artificial Intelligence in Healthcare," *Nature Biomedical Engineering* 2, no. 10 (October 2018): 719–31, https://doi.org/10.1038/s41551-018-0305-z.

[10] Fei Jiang et al., "Artificial Intelligence in Healthcare: Past, Present and Future," *Stroke and Vascular Neurology* 2, no. 4 (December 1, 2017): 230–43, https://doi.org/10.1136/svn-2017-000101.

[11] Weber, G. M., Mandl, K. D., & Kohane, I. S. (2014). Finding the Missing Link for Big Biomedical Data. JAMA, 311(24), 2479-2480. doi:10.1001/jama.2014.422.

[12] Molly K McCarthy, "Artificial Intelligence in Health: Ethical Considerations for Research and Practice," HIMSS, June 17, 2019, https://www.himss.org/artificial-intelligence-health-ethical-considerations-research-and-practice.

[13] The Risks of Bias and Errors in Artificial Intelligence. Santa Monica, CA: RAND Corporation, 2017. https://www.rand.org/pubs/research_reports/RR1744.html.

[14]Forcier, M. B., Gallois, H., Mullan, S., & Joly, Y. (2019). Integrating artificial intelligence into health care through data access: can the GDPR act as a beacon for policymakers? Journal of Law and the Biosciences, 6(1), 317-335. doi:10.1093/jlb/lsz013.

[15] Moon, L. A., Clancy, G., Welton, J., & Harper, E. (2019). Nursing Value User Stories: A Value Measurement Method for Linking Nurse Contribution to Patient Outcomes. CIN: Computers, Informatics, *Nursing, 37*(3), 161-170. doi:10.1097/cin.0000000000000520.

[16] Glauser, W. (2017). Artificial Intelligence, Automation and the Future of Nursing: Technological change is already shaking up the profession. What is your relationship with technology going to be? *Canadian Nurse, 113*(3), 24-26.

ANI appreciates the opportunity to offer our comments to advance the use of artificial intelligence in healthcare. We are available and interested in supporting and collaborating on further development of this response, as well as future public responses on these important healthcare issues.

Sincerely,

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