AMERICAN ACADEMY OF NURSING
transforming health policy and practice through nursing knowledge

March 13, 2020

Russell T. Vought
Acting Director
Office of Management and Budget
Eisenhower Executive Office Building, Room 252
17th Street and Pennsylvania Avenue, NW
Washington, DC 20504

RE: Request for Comments on a Draft Memorandum to the Heads of Executive Departments and agencies, "Guidance for Regulation of Artificial Intelligence Applications"

Dear Director Vought:

The American Academy of Nursing (Academy) is pleased to offer the following recommendations in response to the January 13, 2020, request for comments on guidance for regulation of artificial intelligence (AI) applications for executive departments and agencies. The Academy serves the public by advancing health policy through the generation, synthesis, and dissemination of nursing knowledge. Academy Fellows are inducted into the organization for their extraordinary contributions to improve health locally and globally. With more than 2,800 Fellows, the Academy represents nursing's most accomplished leaders in policy, research, administration, practice, and academia.

The Academy acknowledges that AI has the potential to positively impact the healthcare industry supporting the statement, "AI is expected to have a positive impact across sectors of social and economic life, including employment, transportation, education, finance, healthcare, personal security, and manufacturing."[1] We suggest the Office of Management and Budget (OMB) modify and supplement its principles with the following critical components:

- Broaden the concept around use of AI related to social goals;
- Include attention to ethical issues in all regulatory initiatives related to AI;
- Include an emphasis and investment in research;
- Include data accuracy, validity, and reliability in the evaluation of the risks, benefits, and cost of AI; and
- Clarify guidance related to the use of personal health information.

Broaden the Concept Around the Use of AI Related to Social Goals

Federal agencies should broaden the concept around use of AI related social goals when considering fairness and non-discrimination in healthcare. The Academy believes that to truly improve health and well-being, policies must expand access to quality care through innovative approaches, such as AI, in order to eliminate health disparities. We strongly recommend federal agencies consider the impact of AI on health equity and vulnerable populations. A Pew Research Center report found that a growing number of Americans are using their smartphone as their primary device to access the internet, with the

largest groups being non-white with lower education and income levels.[2] The Pew report also noted that more than half of all smartphone owners used their devices to access health information. Should health apps be AI enabled, there may be inequitable differences among these demographic groups in the means, education levels, or physical capabilities needed to purchase, understand or use the tools.[3]

In addition, the OMB draft guidance recommends public participation and as such we further recommend methods and strategies for public participation from a multitude of stakeholders, especially stakeholders from vulnerable populations, be developed as part of the guidance. "Citizen science is a form of collaboration where members of the public participate in scientific research, a paradigm where the activities of an engaged public are intertwined with professional scientific research."[4] The JASON report on AI in health and health care led to the recommendations based on discovery-based challenges that build on crowdsourcing and citizen science lessons. Specifically, it recommends the support of competitions created to advance understanding of the nature of health and health care data as well as share data in public forums to engage scientists in helping to find new discoveries that will benefit health.[5]

Attention to Ethical Issues in All Regulatory Initiatives Related to AI

We also suggest federal agencies include attention to ethical issues in all regulatory initiatives related to the development, dissemination, and evaluation of AI. The Academy has long advocated for all patients to have access to information, education, and privacy related to their health care.[6] As AI plays an increasingly important role in the provision of patient care, research, and education, it is imperative that patients and consumers are aware of the opportunities and limitations of AI in their own health care.

Emphasize and Invest in AI Research

The Academy recommends that federal agencies invest in research and post-market surveillance to monitor the impact of deployed AI. Innovation in the health care industry, as well as emerging practices around AI, must be tested and advanced for heightened impact and outcomes. Furthermore, we encourage further investments in the research being conducted at the National Institute for Biomedical Imaging and Bioengineering at the National Institutes of Health (NIH) to support the use of AI in healthcare.

Consideration of Patient, Provider, and System Burden in AI Evaluation

Also, we recommend federal agencies consider patient, provider, and system burden in the evaluation of AI benefits and costs. The American Academy of Nursing supports efforts to reduce regulatory burden on daily practice while balancing patient privacy protections. In order to achieve the goal of placing the patient at the center of care delivery, policies must equally support providers and systems. We encourage federal agencies to seek public input from health care providers and systems on how to reduce burden.

Include Data Accuracy, Validity, and Reliability in the Evaluation of the Risks, Benefits, and Cost of AI

The quality of the data used for AI has a direct correlation on the magnitude and nature of the consequences should an AI tool fail. Individual data points need to be captured seamlessly, completely, accurately, consistently, and in a standardized format to improve the use of electronic health data for AI and AI algorithms. To this extent, the Academy supports continued efforts to federally support further work on data and health information technology standards. In order to capitalize on AI in the healthcare industry, it will be critical to continue development of these standards. Furthermore, use of comprehensive data sources, including social determinants of health (SDOH), inter-professional clinical data, and patient

reported outcomes (PROs) is essential to the development of AI solutions. If AI is going to be used to build a deeper understanding of disease, one needs to ensure that the training data incorporates all of the relevant data streams including environmental exposures.[7] Environmental exposures are broadly defined as exposure to chemicals, pathogens, noise, and energy sources (microwave, UV, ionizing radiation). For many diseases, environmental exposures play a bigger role in health outcomes than genetics[8] and this is especially true when analyzing the health of our most vulnerable populations. The Academy recommends the OMB guidance to agencies on methods for evaluation of the integration of AI within the broader health information technology infrastructure include not only data on genetics, but environmental data as well.

Clarify Guidance Related to the use of Personal Health Information (PHI)

Protection of PHI as described in the section on consistency with the memorandum needs further clarification as it could be subject to various interpretations. It is imperative that any consistency related to PHI continues to protect the healthcare consumer and personal health information of all individuals. Re-evaluation of the Health Insurance Portability and Accountability Act (HIPAA) and PHI may be necessary in light of AI efforts to de-identify data as elimination of key data points (such as zip code) may result in the loss of context which is so important for AI solutions. The JASON report on AI recommends a requirement that development of AI applications include approaches to insure privacy and transparency of data use.[9] The Academy encourages federal agencies to seriously consider clarifying guidance in this area.

Thank you for the opportunity to provide our comments and recommendations, and I hope you will contact us for assistance in any efforts to address these issues or policies. If you have any questions or need additional information, please feel free to contact the Academy's Senior Director of Policy, Christine Murphy, at cmurphy@aannet.org or 202-777-1170.

Sincerely,

Eileen Sullivan-Marx, PhD, RN, FAAN
President

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[1] *Draft Memorandum: Guidance for Regulation of Artificial Intelligence Applications*. (2019). Office of Management and Budget.
[2] *The Smartphone Difference*. (2015). Pew Research Center. https://www.pewresearch.org/internet/2015/04/01/us-smartphone-use-in-2015/.
[3] *Artificial Intelligence for Health and Health Care*. (2017). JASON.
[4] JASON, 2017.
[5] JASON, 2017.
[6] Starkweather, A. R., Coleman, B., Barcelona de Mendoza, V., Fu, M. R., Menzies, V., O'Keefe, M., & Williams, J. K. (2018). Strengthen federal regulation of laboratory-developed and direct-to-consumer genetic testing. *Nursing Outlook*, *66*(1), 101–104. https://doi.org/10.1016/j.outlook.2017.11.004.
[7] Kaput, J., & Rodriguez, R. L. (2004). Nutritional genomics: the next frontier in the postgenomic era. *Physiological Genomics*, *16*(2), 166–177. https://doi.org/10.1152/physiolgenomics.00107.2003.
[8] JASON, 2017.
[9] JASON, 2017.