AMA
AMERICAN MEDICAL ASSOCIATION

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Mr. Russell Vought
Acting Director
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Re: Memorandum Providing Guidance for Regulation of Artificial Intelligence Applications

Dear Acting Director Vought:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comment on the Office of Management and Budget's (OMB) memorandum providing guidance to federal departments and agencies on regulation of artificial intelligence (AI) applications. The AMA applauds the Administration's commitment to advancing innovation in this emerging space, as well as its focus on appropriate oversight of these important new applications. The AMA strongly supports federal and state policies that promote AI applications in health care when those applications advance the health care quadruple aim and equity. However, it is important to note that AI applications utilized in health care delivery pose unique risks and raise potentially different questions about the appropriate level of oversight relative to non-health care uses of such technology. **We therefore urge the Administration to carefully consider how this guidance may apply to health care AI and work closely with stakeholders, including physicians and patients, to ensure appropriate oversight is in place before these tools are deployed in clinical settings.**

In June 2018, the AMA's House of Delegates adopted policy on health care augmented intelligence.[1] This policy provides that the AMA will leverage its ongoing engagement in digital health and other priority areas for improving patient outcomes and physicians' professional satisfaction by helping set priorities for health care AI. First and foremost, that policy supports the use of AI systems where those systems advance the quadruple aim of health care. Specifically, AI systems should: 1) enhance the patient experience of care and outcomes; 2) improve population health; 3) reduce overall costs for the health care system; and 4) support the professional satisfaction of physicians and the health care team. The policy further provides that the AMA will promote the development of thoughtfully designed, high-quality, clinically validated health care AI that:

[1] The term artificial intelligence and augmented intelligence are utilized interchangeably by AMA. However, the term augmented intelligence is utilized as it reflects that machines should be designed to complement humans and scale their ability. Assistive and autonomous AI are considered part of augmented intelligence.

- is designed and evaluated in keeping with best practices in user-centered design, particularly for physicians and other members of the health care team;
- is transparent;
- conforms to leading standards for reproducibility;
- identifies and takes steps to address bias and avoids introducing or exacerbating health care disparities, including when testing or deploying new AI tools on vulnerable populations; and
- safeguards patients' and other individuals' privacy interests and preserves the security and integrity of personal information.

Furthermore, **it is necessary for appropriate professional and governmental oversight to ensure safe, effective, and equitable use of and access to health care AI applications and systems.** The use of AI applications in clinical settings raises a number of new and novel questions and concerns for patients and physicians, and introduces a level of risk to the health and wellbeing of our patients in ways that may not apply to AI deployed in non-health care settings. We understand and agree that current oversight systems for medical devices are not necessarily a good fit for emerging and rapidly changing technologies such as software that functions as a medical device and AI-based medical software systems. We support and encourage the work of medical device regulators at the U.S. Food and Drug Administration (FDA) to advance new oversight systems for these innovative technologies. However, **in developing new regulatory structures, patient safety must be the first and foremost consideration and an appropriate balance between encouraging innovation and protecting the health and wellbeing of our patients must be found.**

We appreciate the thoughtful approach to federal regulation proposed in the Administration's memorandum on regulation of AI applications. However, we believe that the development and regulation of health care AI may require different considerations than the approach recommended in some of the included principles. For example, the guidance suggests that federal regulation of AI applications should not incorporate standards so high as to discourage innovation and growth. While appropriate for some AI applications, the development and adoption of AI in the health care, particularly those tools intended for clinical use, will depend upon physician and patient trust in those tools. With traditional drugs and medical devices, confidence in the safety and performance of those products has been assured through a rigorous system of pre-market regulatory review ensuring products have been clinically validated and robust post-market surveillance and enforcement activities. For widespread clinical AI adoption to occur, physicians must be confident in the safety and performance of AI applications, especially those providing diagnostic and clinical decision making-type functions. We agree that new considerations must be made for appropriate regulation and oversight of AI-based and other medical software tools. Yet, **lowering the bar for regulatory review of these products may result in lowering the level of confidence physicians can expect to have in these new technologies and potentially introduces new risks to the health and safety of our patients.**

We understand that software-based medical devices present a host of new challenges to the traditional regulatory system. Keeping these challenges in mind, we agree with the Administration that some level of risk-benefit analysis and regulatory flexibility may be appropriate, even within health care settings. For example, we agree with the FDA that under several of its proposals for regulation of items, such as clinical decision support (CDS) tools and Software as a Medical Device (SaMD), software-based medical devices that present a low risk to patients' health and safety may be appropriate for some form of abbreviated pre-market review. **However, where software-based medical devices pose moderate or**

high risks to patients, we urge regulators to ensure rigorous levels of regulatory review. Where heightened risks to patients exist, we simply cannot afford to compromise patient safety in the name of innovation.

We also understand that a certain amount of flexibility to consider new regulatory paradigms for new technologies that pose novel challenges is necessary in the current environment. Traditional medical device oversight structure is not well-suited to address the rapid rate of innovation in this space nor is it flexible enough to address the rapid rate of modifications in software-based devices. However, physicians and patients have come to rely on our current regulatory system as one that ensures product safety and efficacy. Changes to the types of review performed by the FDA, as well as the requirements for garnering FDA clearance or approval can cause confusion for physician and patients alike. Physicians must have regulatory consistency in order to have confidence in the output of health care AI applications, which means flexibility should be limited to that which is reasonably necessary.

Similar considerations exist for transparency, risk assessment, and management. As discussed above, clinical integration of these promising new technologies will be unlikely to succeed if physicians do not feel that they understand and trust these new products. **AMA believes that transparency surrounding AI-based applications and systems is critical to engendering this trust.** With regards to risk assessment and management, we do not agree with the Administration that "It is not necessary to mitigate every foreseeable risk" as it concerns health care AI applications. If a foreseeable risk exists with respect to an AI application deployed in a clinical setting, the AMA believes it is imperative that this risk be mitigated before that product enters the market. Any regulatory system for health care AI applications must strengthen physician and public trust and guard against patient harm and should not tolerate any type of foreseeable risk.

Federal regulation of AI applications in the health care space must also ensure that appropriate considerations are given to the use of patient data and personal health information. **The Administration's guidance should promote equity for all individuals, not only those with the skills and resources needed to protect themselves from discrimination based on digital phenotyping.** Health care information is one of the most personal types of information an individual can possess and generate—regardless of whether it is legally defined as "sensitive" or protected health information under HIPAA. Accordingly, patients should also have the right to know whether their health data will be used to develop and/or train machines or algorithms, particularly if such machines or algorithms will be commercialized. The opportunity to participate in data collection for such purposes should be on an opt-in basis—regardless of the potential good that can come from the AI tool. Lack of patient awareness and informed consent to use an individual's data could foster patient mistrust, particularly in populations that have been harmed by past medical studies and interventions.

We additionally emphasize that ethical use of AI tools (including the data sets on which they are built) must include mechanisms to address bias in product systems-design; failure to do so will contribute to inequitable health outcomes. Patients must be protected from discrimination, stigma, discriminatory profiling, and exploitation occurring during collection and processing of data, and resulting from use and sharing of data, with attention paid to vulnerable communities. **The AMA recommends the Administration include in its AI guidance a strategy to protect patients from discrimination, stigma, and exploitation and promote transparency and equity in data collection and use.**

While considering appropriate regulation of AI applications, it is important to note that these technologies may exist in numerous forms and settings across the health care marketplace. The above considerations are taken to apply to health care AI applications deployed in clinical settings, such as CDS software, AI-based diagnostic tools, etc. However, we appreciate that AI applications may also be deployed elsewhere within the health care market, such as in direct-to-consumer applications, wearable devices, and for use in administrative functions by physician practices, hospitals, health systems and payers. While not all of these may pose significant risks to the health and safety of our patients, it is important to note that, on occasion, these tools can impact the level and type of clinical care that patients receive, especially where administrative uses of AI are concerned. For instance, a recent study demonstrated that an administrative AI tool aimed at improving clinic efficiencies around appointments and wait times negatively impacted black patients' care experience.[2] Despite the fact that patient care may be impacted by the outputs of these types of AI applications, it is likely that, under current systems, they will not be subject to regulatory oversight. Given that there is no current structure to provide oversight of these types of tools, **we encourage the Administration to consider that there may be instances in which some type of oversight or mandatory standards need apply to non-device AI applications in order to limit potential harm to patients.**

Lastly, we encourage the Administration to consider how government-wide collaboration may be useful in determining appropriate regulatory oversight of AI applications. The AMA believes that all stakeholders in this space would benefit from greater collaboration and standardization of certain elements of AI oversight. For example, there is currently no standard terminology in place to describe AI, for developers and manufacturers, physicians, regulators, or the general public. As regulatory bodies, such as the FDA, move towards implementation of new regulatory structures, it is critical that all stakeholders are speaking off the same page, using the same, well-defined terms to describe these technologies. **We urge the Administration to consider how best to provide consistency and harmonization, limit confusion, and provide collaborative direction to stakeholder where possible.**

The AMA looks forward to working with the Administration as we pursue clinical integration of these new and exciting technologies and advance effective human-AI collaborations. While new AI applications hold tremendous promise for advancing the quadruple aim of health care, it is essential that the appropriate oversight is in place to ensure the safety and security of these AI systems in order to foster trust, mitigate risks to patients, protect privacy, and avoid bias or disparities in health care. We further encourage the Administration to expand dialogue and collaboration with physician and patient stakeholders to ensure these important perspectives are captured in this work.

Should you have any questions or wish to discuss this matter in further detail, please do not hesitate to contact Shannon Curtis, Assistant Director of Federal Affairs, at (Shannon.Curtis@ama-assn.org) or 202-789-8510.

Sincerely,

James L. Madara, MD

[2] Michele Samorani et al., *Overbooked and Overlooked: Machine Learning and Racial Bias in Medical Appointment Scheduling*, October 9, 2019, available at https://ssrn.com/abstract=3467047.