March 13, 2020

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

Re: Guidance for Regulation of Artificial Intelligence Applications

Dear Acting Director Vought:

On behalf of the membership of the Pharmacy Health Information Technology Collaborative (Collaborative), we are pleased to submit comments regarding the Office of Management and Budget’s Guidance for Regulation of Artificial Intelligence Applications.

The Collaborative has been involved with the federal agencies, including the Office of the National Coordinator (ONC) and the Centers for Medicare & Medicaid Services (CMS), developing the national health information technology (HIT) framework since 2010.

Pharmacists are users of health IT, and in particular, e-prescription and EMR (EHR) systems. The Collaborative supports the use of these systems, including artificial intelligence (AI), which are important to pharmacists in working with other health care providers to provide needed medications and transmit patient information related to overall patient care, transitions of care, immunization (historical and administered), immunization registry reporting, medication lists, medication allergies, allergy reactions, patient problem lists, smoking status, reporting to public health agencies, clinical decision support services/knowledge artifacts, drug formulary checking, and electronic prescribing.

The following are our comments regarding the Guidance for Regulation of Artificial Intelligence Applications.

Generally, the Collaborative is supportive of the overall direction of the outline presented for policy considerations regarding AI applications and oversight. What appears to be missing, though, is guidance for AI standards. Standards are mentioned briefly in the “Voluntary Consensus Standards” section on page 7. The Collaborative strongly recommends that agencies considering regulatory and non-regulatory approaches for AI applications for use
in health care require AI be designed using United States evidence-based guidelines and data and that guidance should be provided. For pharmacists, this is particularly critical for clinical decision support (CDS) systems. AI applications should also be certified. Using United States evidence-based guidelines and data would help reduce some concerns about introducing bias that could produce discriminatory outcomes or decisions that undermine the public trust in AI, as discussed in “Fairness and Non-Discrimination” on page 5, as well as aid in ensuring safety and security (discussed on page 9). Patient safety should be among the top factors related to the AI tools that may be considered.

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The Pharmacy HIT Collaborative comprises the major national pharmacy associations, representing 250,000 members, including those in pharmacy education and accreditation. The Collaborative’s membership is composed of the key national pharmacy associations involved in health information technology (HIT), the National Council of Prescription Drug Programs, and 14 associate members encompassing e-prescribing, health information networks, transaction processing networks, pharmacy companies, system vendors, pharmaceutical manufacturers, and other organizations that support pharmacists’ services.

As the leading authority in pharmacy health information technology, the Pharmacy HIT Collaborative’s vision and mission are to ensure the U.S. health IT infrastructure better enables pharmacists to optimize person-center care. Supporting and advancing the use, usability, and interoperability of health IT by pharmacists for person-centered care, the Collaborative identifies and voices the health IT needs of pharmacists; promotes awareness of functionality and pharmacists’ use of health IT; provides resources, guidance, and support for the adoption and implementation of standards driven health IT; and guides health IT standards development to address pharmacists’ needs. For additional information, visit www.pharmacyhit.org.

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On behalf of the Pharmacy HIT Collaborative, thank you again for the opportunity to comment on the Memorandum on Guidance for Regulation of Artificial Intelligence Applications.

For more information, contact Shelly Spiro, executive director, Pharmacy HIT Collaborative, at shelly@pharmacyhit.org.

Respectfully submitted,

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