



Via Electronic Submission to: www.regulations.gov

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.

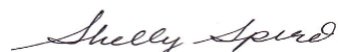
The Pharmacy HIT Collaborative comprises the major national pharmacy associations, representing 250,000 members, including those in pharmacy education and accreditation. The Collaborative’s membership is composed of the key national pharmacy associations involved in health information technology (HIT), 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.

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,



Shelly Spiro, RPh, FASCP
Executive Director, Pharmacy HIT Collaborative
shelly@pharmacyhit.org

Susan A. Cantrell, RPh, CAE
Chief Executive Officer
Academy of Managed Care Pharmacy
scantrell@amcp.org

Janet P. Engle, PharmD, Ph.D. (Hon), FAPhA,
FCCP, FNAP
Executive Director
Accreditation Council for Pharmacy
Education (ACPE)
jengle@acpe-accredit.org

Lynette R. Bradley-Baker, Ph.D., CAE, R.Ph.
Senior Vice President of Public Affairs and
Engagement
American Association of Colleges of
Pharmacy
lbbaker@aacp.org

Thomas E. Menighan, BS Pharm, MBA, ScD
(Hon), FAPhA
Executive Vice President and CEO
American Pharmacists Association (APhA)
tmenighan@aphanet.org

Arnold E. Clayman, PD, FASCP
Vice President of Pharmacy Practice &
Government Affairs
American Society of Consultant Pharmacists
aclayman@ascp.com

Amey C. Hugg, B.S.Pharm., CPHIMS, FKSHP
Director, Section of Pharmacy Informatics
and Technology Member Relations Office
American Society of Health-System
Pharmacists
ahugg@ashp.org

Brad Tice, PharmD, MBA, FAPhA
Senior Vice President Pharmacy Practice
Aspen RxHealth
bradt@aspenrxhealth.com

Paul Wilder
Executive Director
CommonWell Health Alliance
paul@commonwellalliance.org

Samm Anderegg, Pharm.D., MS, BCPS
Chief Executive Officer
DocStation
samm@docstation.com

Stacy Sochacki
Interim Executive Director
Hematology/Oncology Pharmacy
Association
ssochacki@hoparx.org

Rebecca Snead
Executive Vice President and CEO
National Alliance of State Pharmacy
Associations
rsnead@naspa.us

Sara E. Roszak, DrPH, MPH
Vice President, Pharmacy Care & Health
Strategy
National Association of Chain Drug Stores
sroszak@nacds.org

Ronna B. Hauser, PharmD
Vice President, Pharmacy Policy &
Government Affairs Operations
National Community Pharmacists
Association (NCPA)
ronna.hauser@ncpanet.org

Stephen Mullenix, RPh
Senior Vice President, Communications &
Industry Relations
National Council for Prescription Drug
Programs (NCPDP)
smullenix@ncpdp.org

Rebecca Chater, RPh, MPH, FAPhA
Director, Clinical Health Strategy
Omniceil, Inc.
rebecca.chater@omnicell.com

Reid Kiser
Senior Vice President Performance
Measurement & Research
Pharmacy Quality Alliance (PQA)
rkiser@pqaalliance.org

Parmjit Agarwal, PharmD, MBA
Director, Pharmacy Development
Pfizer
Parmjit.Agarwal@pfizer.com

Jeff Newell
Chief Executive Officer
Pharmacy Quality Solutions, Inc.
jnewell@pharmacyquality.com

Michelle M. Wong, PharmD
Chief Executive Officer
Pharmetika
mwong@pharmetika.com

Josh Howland, PharmD. MBA
VP Clinical Strategy
PioneerRx
Josh.Howland@PioneerRx.com

Mindy Smith, BSPHarm, RPh
Vice President Pharmacy Practice
Innovation
PrescribeWellness
msmith@prescribewellness.com

Ed Vess, RPh
Director Pharmacy Professional Affairs
Smith Technologies
ed.vess@smithtech.com

Ken Whittemore, Jr., RPh, MBA Vice
President, Professional
& Regulatory Affairs
Surescripts
ken.whittemore@surescripts.com

Steve Gilbert, R.Ph., MBA
Vice-President, Performance Improvement
Tabula Rasa HealthCare
sgilbert@trhc.com