

Via Electronic Submission to: www.regulations.gov

December 30, 2023

Dr. Micky Tripathi
National Coordinator for Health Information Technology
Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Mary E. Switzer Building
330 C Street, SW
Washington, DC 20201

RIN: 0955-AA05; 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking

Dear Dr. Tripathi:

On behalf of its membership, the Pharmacy Health Information Technology Collaborative (PHIT) is pleased to submit comments on the 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking proposed rule.

PHIT has been involved with the federal agencies, including the Department of Health and Human Services (HHS) Office of the National Coordinator (ONC) and the Centers for Medicare & Medicaid Services (CMS), in developing the national health information technology (HIT) framework for implementing secure access of electronic health information to improve health outcomes since 2010.

Pharmacists provide essential, patient-centered care services to their patients, including Medicare and Medicaid beneficiaries. Pharmacists use health IT, provider directories, telehealth, e-prescribing (eRx), electronic medical record (EMR)/electronic health record (EHR) systems, and certified EHR technology (CEHRT) to help manage patients' health needs. PHIT supports the use of these systems, which are important to pharmacists in working with other health care providers to provide longitudinal person-centered care planning, needed medications, and transmit patient information related to overall patient care, transitions of care, immunization, medication lists, medication allergies, allergy reactions, patient problem lists, smoking status, and social determinants of health (SDOH). Pharmacists also use health IT for reporting to public health agencies (e.g., immunization reporting), clinical decision support services/knowledge artifacts, drug formulary checking, and comprehensive medication management (CMM).

Comments

Although a pharmacist and a pharmacy are defined in the health care provider term (42 U.S.C. 300-jj) used in this proposed rule, the disincentives for information blocking outlined in the proposal cannot be applied to them, as they are not participants in the EHR Incentive Program for which the proposed rule applies. Pharmacists and pharmacies are not defined as meaningful users of CEHRT (certified electronic health record technology) in the Merit-Based Incentive Payment System (MIPS) program, as they are not defined as eligible professionals nor as meaningful EHR users in the EHR Incentive Program by the Centers for Medicare & Medicaid Services (CMS) since the 2009 creation of the program. Since 2009, PHIT has been requesting the Secretary to correct this omission.

A pharmacist's or pharmacy's certification and use of certified EHR in the MIPS Promoting Interoperability Program is voluntary because they do not receive incentives from the EHR Incentive Program for demonstrating use of CEHRT. Until EHR requirements and criteria for interoperability are identified for a pharmacist or a pharmacy, disincentives cannot be applied; only the reporting of possible information blocking by a pharmacist or pharmacy is allowed. Interestingly, the Department of Health and Human Services (HHS) states in the Request for Information section of this proposed rule that it plans to establish and apply "appropriate disincentives" to pharmacies (and other health care providers) in future rulemaking, even though EHR requirements and criteria for interoperability that need to be identified for pharmacies are not in place.

IV. Request for Information (page 74966-67)

HHS states it is important to establish appropriate disincentives that would apply to all health care providers to ensure that any health care provider that has engaged in information blocking would be subject to appropriate disincentives by an appropriate agency. In requesting information on additional appropriate disincentives that should be considered and applied to health care providers in future rulemaking, HHS specifically mentions pharmacies in its examples of possible health care providers that were not implicated by the disincentives proposed in this rule and should be considered in future rulemaking.

As noted previously, until EHR requirements and criteria for interoperability are identified for a pharmacy, disincentives cannot be applied. PHIT recommends HHS not proceed with establishing or applying disincentives for pharmacies until such EHR requirements and criteria for interoperability are in place for pharmacies. One key to achieving the latter is the Trusted Exchange Framework and Common Agreement (TEFCA). Future disincentives should be related to TEFCA. TEFCA is establishing universal governance, standardization, and the technical floor interoperability, as well baseline legal technical requirements through the Common Agreement, which covers information blocking. In all likelihood, pharmacies will be part of TEFCA through their participation in Qualified Health Information Networks (QHINs) once QHINs are approved and operational.

The Pharmacy HIT Collaborative comprises the major national pharmacy associations, representing 250,000 members, including those in pharmacy education and accreditation. PHIT's membership is composed of the key national pharmacy associations involved in health IT, the National Council for Prescription Drug Programs, and 12 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, PHIT's vision and mission are to ensure the U.S. health IT infrastructure better enables pharmacists to optimize person-centered care. Supporting and advancing the use, usability, and interoperability of health IT by pharmacists for person-centered care, PHIT 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 PHIT, thank you again for the opportunity to comment on the 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking proposed rule.

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

Respectfully submitted,

Shelly Spire

Shelly Spiro, RPh, FASCP

Executive Director, Pharmacy HIT Collaborative

shelly@pharmacyhit.org

Janet P. Engle, PharmD, Ph.D. (Hon), FAPhA, FCCP, FNAP
Executive Director
Accreditation Council for Pharmacy
Education (ACPE)

jengle@acpe-accredit.org

Ilisa BG Bernstein, PharmD, JD, FAPhA
Senior Vice President, Pharmacy Practice &
Government Affairs
American Pharmacists Association (APhA)
IBernstein@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, Member Relations
Section of Pharmacy Informatics and
Technology
Section of Digital and Telehealth Practitioners
American Society of Health-System Pharmacists
ahugg@ashp.org

Randy Craven
Project Manager, Medication Therapy
Management (MTMP)
Centene Evolve Pharmacy Solutions Wellcare
randy.craven@wellcare.com

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

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

Youn J. Chu, PharmD, RPh Clinical Consultant, Population Health Management EnlivenHealth an Omnicell Innovation youn.chu@omnicell.com

Anne Krolikowski, CAE
Executive Director
Hematology/Oncology Pharmacy Association
akrolikowski@hoparx.org

Kevin N. Nicholson, R.Ph., J.D.
Vice President, Public Policy, Regulatory, and
Legal Affairs
National Association of Chain Drug Stores
(NACDS)
knicholson@nacds.org

Joni Cover Vice President of Strategic Initiatives National Alliance of State Pharmacy Associations jcover@naspa.us

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

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

Lisa Hines, PharmD, CPHQ Chief Quality & Innovation Officer Pharmacy Quality Alliance (PQA) LHines@Pgaalliance.org

Josh Howland, PharmD. MBA SVP Clinical Strategy & Development PioneerRx, RedSail Technologies Josh.Howland@PioneerRx.com

Ross E. Pope CEO Prescribery ross@prescribery.com

Paige Clark, RPh.
VP of Pharmacy Programs and Policy
Prescryptive
Paige.Clark@prescryptive.com

Ken Whittemore Jr.
VP, Pharmacy & Regulatory Affairs
Surescripts
Ken.Whittemore@surescripts.com

Mindy Smith, BSPharm, RPh, MHA Senior Vice President Professional Affairs Tabula Rasa HealthCare MSmith@trhc.com

Jeffery Shick, R.Ph.
Director, Translational Informatics
Digital & Innovation
US Pharmacopeia (USP)
Jeff.shick@USP.org