

**Via Electronic Submission to:** <https://www.regulations.gov>

January 31, 2018

Mr. Adam Kroetsch  
Mr. Aaron Sherman  
Center for Drug Evaluation and Research  
Food and Drug Administration  
10903 New Hampshire Ave., Bldg. 51  
Silver Spring, MD 20992-0002

**Re: REMS Platform Standards Initiative: Needs Assessment**

Dear Mr. Kroetsch, Mr. Sherman:

On behalf of the membership of the Pharmacy Health Information Technology Collaborative (Collaborative), we are pleased to submit comments for the *REMS Platform Standards Initiative: Needs Assessment*.

Pharmacists are users of health IT and are supportive of interoperability standards, especially those utilizing certified EHR technology (CEHRT). The Collaborative supports use of these particular standards which are important to pharmacists for working with other health care providers, transitions of care, allergy reactions, immunizations (historical and administered), immunization registry reporting, medications, medication allergies, patient problems, smoking status, reporting to public health agencies, clinical decision support services/knowledge artifacts, drug formulary checking, and electronic prescribing (including new versions).

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

The following are our comments regarding changes the *REMs Platform Standards Initiative: Needs Assessment*.

**Information Exchange (Interoperability, Bidirectional Communication)**

The Collaborative believes exchanging electronic health information is essential to improving health outcomes and strongly supports the goal of interoperability established by the

Office of the National Coordinator (ONC). In order for this goal to be successful, we believe the FDA needs to coordinate its REMS activities with the ONC. Upon review of the REMS platform outline, it is not clear whether such coordination is occurring. We note there is no reference or mention in the outline of interoperability or how such will be achieved. FDA only states its desire to work with “established standards development organizations,” such as the National Council for Prescription Drug Programs (NCPDP), Health Level 7 International, and Integrating the Healthcare Enterprise. Interoperability, as well as bidirectional communication within REMS, is essential and of critical importance to pharmacists using electronic health information (EHI) systems and who will be REMS users.

The bidirectional exchange of information is presently not at a level that can readily improve patient outcomes. Bidirectional communication is still lacking for pharmacists. Although the pathways for it exist, full functionality has not been made possible. Pharmacists need such functionality in order to fully participate and communicate electronically with prescribers and other health care providers.

REMS appears to be designed for communication between the REMS administrators and providers or dispensers. As the graphic on page 7 shows, REMS does not allow for communication directly between prescribers and dispensers, which is critical, as detailed in the example on page 5, pertaining to predisensing authorization. As that example states, when there is an issue, multiple exchanges of information between the prescriber and pharmacist take place to resolve it. What the example doesn't discuss is how the exchanges currently occur. Most are done via telephone or fax.

The Collaborative advocates for and recommends leveraging current health IT initiatives for interoperability and the bidirectional exchange of pharmacist-provided patient care health information and dispensing data. The Collaborative strongly encourages the FDA to ensure that REMS has the full functionality for bidirectional communication.

### **Net Neutrality Repeal**

The Collaborative strongly encourages and recommends that the FDA examine the potential impact of the net neutrality repeal on REMS, if it has not already begun to explore this area. The ending of net neutrality could go well beyond the average Internet user's day-to-day experience. It is our concern that repealing net neutrality may have a substantially negative impact on the health care arena, health IT that is reliant on the Internet, and the sharing of health care data via the Internet. Health care programs and providers could find their abilities to provide and share health care data with others slowed if they are not in a position to pay for prioritized access (aka, fast lanes). ISPs could become information blockers, as they would be controlling the flow of information and data, which would impede achieving the interoperability goals established the Office of the National Coordinator for the use of health IT nationwide. Information blocking is an issue that Congress has examined and included a prohibition of such in the 21<sup>st</sup> Century Cures Act.

## Responses to Feedback Questions

- *Does the needs assessment cover all of the REMS activities for which standards development would be beneficial?*

As indicated in our comments, the needs assessment does not cover interoperability and bidirectional communication between participants.

- *What standards already exist that could be used to address the needs and facilitate the REMS activities in the needs assessment?*

Several standards exist that are currently used in the health care arena by the CMS for its programs and by the ONC for moving forward on its nationwide interoperability roadmap and HIT framework. Such standards include: HL7, FHIR, SNOMED CT, LOINC, and the National Council for Prescription Drug Programs (NCPDP) standards (e.g., SCRIPT).

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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 nine associate member 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](http://www.pharmacyhit.org).

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On behalf of the Pharmacy HIT Collaborative, thank you again for the opportunity to comment on *REMS Platform Standards Initiative: Needs Assessment*.

For more information, contact Shelly Spiro, Executive Director, Pharmacy HIT Collaborative, at [shelly@pharmacyhit.org](mailto:shelly@pharmacyhit.org).

Respectfully submitted,



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