PREMIER TRANSFORMING HEALTHCARE TOGETHER®

January 22, 2019

The Honorable Scott Gottlieb, M.D.
Commissioner
Food and Drug Administration
Attention: Dockets Management Staff (HFA-305), FDA-2018-N-3017
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Submitted electronically to: http://www.regulations.gov

Re: FDA-2018-N-3017, Prescription Drug-Use-Related Software; Establishment of a Public Docket; Request for Comments

Dear Commissioner Gottlieb,

The Premier healthcare alliance appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) on the request for comments titled *"Prescription Drug-Use-Related Software"* which was published in the November 20, 2018 *Federal Register*. In the request for comments, the FDA seeks input on a proposed framework for regulating software applications disseminated by or on behalf of drug sponsors for use with one or more of their prescription drug products. Under the proposed framework, prescription drug-use-related software output would be regulated as labeling because it "accompanies" a specific drug.

Premier is a leading healthcare improvement company, uniting an alliance of more than 4,000 U.S. hospitals and health systems and approximately 165,000 other providers and organizations to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. A 2006 Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. A key component of our alliance is our Integrated Pharmacy Program, which combines essential clinical data with purchasing power to deliver reduced costs, improved quality and safety, and increased knowledge-sharing with other healthcare professionals.

Premier strongly supports a competitive drug marketplace that strikes the appropriate balance between innovation, access, and competition to lower drug prices. As the FDA develops the framework for prescription drug-use-related software output, ***Premier cautions FDA to ensure that regulating software output as labeling does not inadvertently thwart competition***. For example, the FDA should ensure that manufacturers do not utilize the proprietary nature of their software to extend patent protections and market exclusivity by preventing generic or biosimilar competitors from entering the marketplace. Prescription drug-use-related software output should not be an additional hurdle that generic and biosimilar manufacturers must overcome to enter the marketplace and help lower drug prices.

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In closing, the Premier healthcare alliance appreciates the opportunity to submit comments on FDA-2018-N-3017. Premier looks forward to working with the FDA to ensure advances in technology do not inadvertently thwart the creation of a competitive drug marketplace.

If you have any questions regarding our comments or need more information, please contact Soumi Saha, Senior Director of Advocacy, at soumi_saha@premierinc.com or 202-879-8005.

Sincerely,

Blair Childs
Senior Vice President, Public Affairs
Premier Inc.