HEALTHCARE SUPPLY CHAIN ASSOCIATION
Innovators In Evidence-Based Sourcing

January 19, 2021

U.S. Food and Drug Administration
Attention: Dockets Management Staff (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments of the Healthcare Supply Chain Association (HSCA) on FDA Request for Comments regarding FDA communications on medical device safety [Docket NO. FDA-2020-N-0096]

On behalf of the Healthcare Supply Chain Association (HSCA), we appreciate the opportunity to provide comments to the U.S. Food and Drug Administration (FDA) regarding the development of FDA's safety communications about medical devices to ensure stakeholders receive the information they need in a timely, clear, and consistent manner.

HSCA represents the nation's leading healthcare group purchasing organizations (GPOs), the sourcing and purchasing partners to virtually all of America's 7,000+ hospitals, as well as the vast majority of the 68,000+ long-term care facilities, surgery centers, clinics, and other healthcare providers. GPOs work with healthcare providers to negotiate competitive prices and support a safe and reliable supply of products. We play a critical role in helping to lower costs for patients, providers, payers, Medicare and Medicaid, and taxpayers. One report estimated that GPOs reduce supply-related purchasing costs by 13.1 percent annually and will reduce healthcare spending by up to $456.6 billion between 2017 and 2026. The value and services that GPOs provide allow healthcare providers and physicians to focus on their core mission: providing first-class patient care.

GPOs are fierce proponents of using data to help their provider partners and public authorities prepare for, and respond to, public health threats and emergencies. Timely information-sharing and leveraging data to gain insights are essential to facilitating an effective and efficient response effort. To further support data integration and critical information in the supply chain, HSCA and its GPO members are working with healthcare organizations to promote the use of data standards in the healthcare supply chain to enable solutions that increase traceability in the supply chain.

HSCA's Committee for Healthcare eStandards (CHES) is a leader in the healthcare industry's efforts to improve accuracy, efficiency, and safety through the application of electronic data standards in the healthcare supply chain. CHeS strives to provide an open and neutral forum for healthcare supply chain participants as part of an industry-wide collaborative approach to the application of standards in the healthcare supply chain. CHeS works to accelerate industry-wide deployment of standards and processes throughout the healthcare supply chain.

HSCA MEMBER COMPANIES

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HSCA and CHeS commend FDA for taking steps to review its current practices for medical device safety communications and seek input from stakeholders on areas of improvement. Given our unique line of sight over the healthcare supply chain, CHeS respectfully submits the following recommendations to help strengthen FDA communications regarding medical devices:

FDA Should Use the Unique Device Identifier as the Primary Device Identifier in All FDA Datasets and Require the Use of the UDI in All FDA Submissions and Communications

The medical device stakeholder community is broad and diverse with various needs regarding the type of information and level of detail required. The ability to quickly and confidently identify the medical device or device in question is a critical component of successful communication and will enable stakeholders to respond swiftly to ensure continued patient safety. CHeS encourages FDA to utilize the unique device identifier (UDI) as the primary device identifier in all FDA datasets and require the use of the UDI or device identifier (DI) in all FDA submissions and communications. Using UDI in this manner is consistent with the purpose of the 2013 Unique Device Identification System Final Rule, which is to:

> *"reduce existing obstacles to the adequate identification of medical devices used in the United States. By making it possible to rapidly and definitively identify a device and key attributes that affect its safe and effective use, the rule will reduce medical errors that result from misidentification of a device or confusion concerning its appropriate use. The identification system established under this rule will lead to more accurate reporting of adverse events by making it easier to identify the device prior to submitting a report. It will allow FDA, health care providers, and industry to more rapidly extract useful information from adverse event reports, pinpoint the particular device at issue and thereby gain a better understanding of the underlying problems, and take appropriate, better focused, corrective action."*

Using the UDI as a primary identifier when collecting adverse event, recall, and other manufacturer submissions would allow for the auto population of device data elements from the global unique device identification database (GUDID), enabling FDA to set up an online process for reporting adverse events, recalls and safety issues. An online reporting process would reduce administrative burden, eliminate redundancy, and enhance data quality. Key data elements could be populated with a simple scan of the device's automatic identification and data capture (AIDC) technology and quickly made available to providers and patients, streamlining recall and safety information communication processes.

We appreciate the opportunity to provide our perspective on this important issue. We support the FDA's efforts to improve its communications process on medical device safety, and we look forward to continuing to work with FDA to ensure patient access to safe and reliable healthcare. Please do not hesitate to contact us if we can be a resource on this issue moving forward.

Sincerely,

Curtis Miller
Executive Director, Committee for Healthcare eStandards
Healthcare Supply Chain Association