

EXECUTIVE SUMMARY OF AUTOMATIC IDENTIFICATION AND DATA CAPTURE (AIDC) ROLE IN IMPLEMENTATION OF THE DRUG SUPPLY CHAIN SECURITY ACT (DSCSA)

Automatic Identification and Data Capture (AIDC) technologies, also called **Automatic Identification Technologies (AIT)** are all around us. Our modern economy wouldn't and probably couldn't function without it. Retail stores everywhere rely on AIDC so that even children understand the ability to glean data from the barcode on toy packaging. In fact, UPC barcodes have been made into toys and games. Nearly everyone at one time or another has used AIDC while trying to speed their grocery store exit through the self-checkout line or stood and watched as a cashier has scanned item after item placed in front of them.

AIDC technologies include a wide range of solutions, each with different data capacities, form factors, capabilities, and "best practice" uses. While everyone is familiar with the UPC barcode, there are other forms of AIDC which are routinely used but the users may not fully appreciate the functionality of the technology. The common vehicle EZPass is a great example. EZPass is a form of AIDC, in this case radio frequency identification (RFID), that automatically collects and moves data. Barcodes, RFID, contact memory buttons and many other forms of AIDC all serve to address specific data collection and data use needs. AIDC technologies also include mobile computing devices that facilitate the collection, manipulation, or communication of data from barcodes and RFID tags as well as through operator entry of data via voice commands.

The public health issue crisis of opioid drug abuse has raised the importance of effective implementation and enforcement of section 582 of the Federal Food, Drug, and Cosmetic Act, the Drug Supply Chain Security Act (DSCSA) signed into law November 27, 2013. DSCSA's intent is to identify and trace prescription drugs sold in the U.S. in order to improve detection and removal of potentially dangerous products from the pharmaceutical distribution supply chain. Implementation of this Act using AIDC technologies improves the chain of custody of the supply chain from the producer to the patient. The World Health Organization estimates that as much as \$4.5B of counterfeit pharmaceuticals are sold annually in the U.S., jeopardizing patient safety as often counterfeit drugs are ineffective or even worse contain damaging materials. Counterfeit drugs can originate both in the U.S. or a foreign country, with the provisions of DSCSA helping stem illicit drugs from all locations.

A further threat to our public health system is drug recalls. Drug recalls impact in the range of 40 million doses of medicine per year in the U.S. alone, highlighting the need to have an effective method of quickly identifying the impacted drugs location and tracking to ensure that those drugs have been removed from the supply chain. The implementation and enforcement of the DSCSA using AIDC technologies is an important tool in helping secure our drug supply chain from the manufacturer to the pharmacy, hospital, and doctor's office.

One element that is critical to implementation of the DSCSA is use of barcodes on drug labels and packaging. The benefits of barcodes in quickly and accurately identifying crucial information of prescribed medication help those throughout the supply chain ensure that the drug is valid and its exact location can be tracked. In the event of a recall this information will help provide a thorough and fast removal of suspect drugs before they are administered to a patient.

AIDC technologies are low cost, with either existing barcode readers or nominal investment to upgrade readers, equipping the healthcare supply chain to enable use of serialized labels on pharmaceuticals. AIDC technologies are well understood in the pharmaceutical manufacturing and the logistics supply chain given their global use. AIM North America believes that our country cannot afford to delay further or weaken the provisions of the DSCSA.

STATE OF THE DSCSA

In June of 2017 the FDA announced guidance to industry that there would be a one-year delay, to November 26, 2018, in the enforcement of requirements for drug manufacturers to mark (serialize) drugs at the package level. The reasons for the delay cited by the FDA are manufacturers and others in the supply chain being adequately prepared to implement the systems needed for drug tracking despite the 4-year advanced notice between the law being signed and its effective date.

HOW AIM NORTH AMERICA CAN HELP

AIM North America is trade alliance comprised of Automatic Identification Technology (AIT) suppliers and manufacturers dedicated to raising awareness about AIT and encouraging the adoption of AIT policies within U.S. government agencies and the U.S. government contractor community. Our members may be competitors in the marketplace, but each of our members is a patriot and American taxpayer, dedicated to helping the U.S. government and public health stakeholders improve the way they do business by adopting AIT.

AIM North America serves as conduit to bring industry and government together to foster the exchange of information. This exchange provides clarity on the implementation of technology to achieve business process improvement goals.

We welcome the opportunity to provide independent advice on policy, technology, and implementation of standards through hands-on demonstrations, seminars, webinars, whitepapers, and case studies.

The AIM North America can be found at: www.aim-na.org

References:

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<https://www.interpol.int/Crime-areas/Pharmaceutical-crime/Pharmaceutical-crime>