Healthcare Executive Overview: The Role of Standards in the Post-Pandemic Healthcare Supply Chain

SITUATION:

While the upheaval and crisis created by the COVID-19 pandemic continues, healthcare organizations throughout the entire supply chain are also turning their attention to the future to look for answers to the questions, "What could we have done differently?" and "How should we prepare for future pandemics and other crises?". Federal, State and Local government agencies are reacting similarly with a number of supply chain related proposals. Much of this activity could have possibly been avoided if unique identification standards, many already in play, had been more broadly adopted across the healthcare supply chain.

Where should industry focus its attention to generate the most impact when there are seemingly so many issues that need to be addressed? The exchange and synchronization of reliable, trusted quality data seems to be paramount to every aspect of opportunities for improvement. The Association for Health Care Resource & Materials Management (AHRMM), Healthcare Supply Chain Association (HSCA), Strategic Marketplace Initiative (SMI) and GS1 US, through dialogue with our respective industry members, believe that one place to start is with broad and swift adoption and use of standards and in particular those standards already in play as a result of specific regulations such as unique device identification, or UDI, and the Drug Supply Chain Security Act (DSCSA). Full adoption of the global standards supporting these regulations could help address 2 critical themes that have been shown to adversely impact patient care as well as patient and clinician safety.

- Product Transparency
- Data Driven Demand Planning and Forecasting

These challenges, we feel, could have been greatly reduced by the adoption and use of global standards for both medical devices and pharmaceutical products. The challenge seems to be getting industry to more broadly and quickly adopt and use them. The following sections provide an overview of how global standards might support improvement in these areas.

CRITICAL THEMES:

1. Product Transparency - Patient care, as well as patient and clinician safety, are at risk due to a lack of standardized information about products

Products used in patient care are typically well vetted by healthcare professionals before they are ever brought in for use in the treatment environment. During the pandemic, there was an influx of new products from non-traditional suppliers. This surge of new products and suppliers created a significant backlog that providers needed to vet before products could be properly added to the system and purchased. Supply chain professionals lacked insight into all of the necessary product attributes for these to be efficiently and accurately added to item master files. For example, without basic information like classification schemas such as United Nations Standard Products and Services Code (UNSPSC), they were not able to categorize or link "like" products in order to support their ability to quickly and confidently shift from one product to another equivalent. Clinicians sometimes struggled to balance patient safety and new product use because they lacked full understanding of the quality of the product or how it compared to a previously used device or drug. Without efficient supplier and product onboarding, a hospital's ability to maintain the flow of inventory for even the most basic types of devices and pharmaceuticals was hindered. The lack of product transparency that contributed to slower uptake of these devices and drugs into the patient care arena creating short supply situations and risks for patient care and staff safety can be addressed with the use of standardized, reliable data

that can be efficiently shared across trading partners to improve confidence and flexibility for healthcare stakeholders.

2. **Data Driven Demand Planning and Forecasting – the inability to measure product use across the supply chain and understand outcomes negatively impacts patient care and, in the specific case of PPE shortages, patient and clinician safety.**

Poor visibility into products used at the point of care (i.e., what was used and where it was used) proved to be a significant blind spot during the pandemic. This lack of visibility, impacting both medical devices and pharmaceuticals, in some cases delayed product from being available or positioned where it was most needed. The resulting lack of existing inventory level accuracy, coupled with limited demand planning and forecasting, contributed to significant product shortages. Furthermore, understanding changes in product utilization to drive specific patient outcomes requires quickly and accurately identifying products as they are being used. This was especially true during the height of the COVID pandemic as unique uses of both devices and drugs depleted the availability of certain products. Tying product usage to patient driven outcomes allows for expedited recognition of what products are in play for the treatment of pandemic related patient care situations.

The use of standards for the globally unique identification of both products and locations would provide consistent identification by all supply chain stakeholders of products used at the point of care and improve the ability to anticipate demand. Armed with these product and demand specifics, both manufacturers and providers would be better positioned to anticipate and forecast demand and position available product to align with pandemic requirements and immediate needs.

RECOMMENDATIONS:

AHRMM, HSCA, SMI and GS1 US believe that accelerating the adoption and use of data standards across the industry and public sector will serve as a foundation for improving supply chain transparency, planning and resiliency of medical devices and pharmaceuticals while reducing administrative burden.

For each of the challenges identified above the expanded use of existing unique device identifiers (UDIs) and other currently available data standards across the US healthcare supply chain is a critical facilitator to resolving the problems.

Product Transparency and Administration - The use of UDI's to quickly and positively identify products improves product transparency by supporting automated systems that can 1) confirm the product being used is that which the clinician requested 2) link the UDI to additional attributes about the product such as latex content, expiration date and other clinically relevant information and 3) allow for like products to be categorized together thus improving flexibility and usage at the clinical level.

Supply chain professionals in healthcare routinely engage in manual efforts to clean, manage, and analyze data in order to complete tasks and processes that most consumer goods industries have automated utilizing data standards as a foundation. As a result, reactions to changes in utilization or sourcing and obtaining clinically acceptable substitute products from new sources can take longer and delay critical supplies in reaching the patient care setting. The broader use of identification standards within healthcare would support the automation of these processes, relieving the current administrative burden, streamlining the process, and expediting the delivery of these products to front line healthcare workers thereby reducing shortages and errors.

Data Driven Demand Planning and Forecasting - The ability to quickly and confidently identify a product anywhere in the supply chain is a necessary precondition to implementing systems that will provide understanding of what is used and where it is located or consumed. Data standards like the GS1 Global Trade Item Number (GTIN) or the Global Location Number (GLN) provide this capability. The systems most Americans are familiar with in consumer goods that track packages for delivery or

report on inventory availability at specific stores are dependent on data standards to identify products and places. Unfortunately, while these standards are available, the use of these standards is not yet ubiquitous in the healthcare supply chain.

In summary, U.S. regulations exist for both medical devices and pharmaceutical products that require these products to be uniquely identified and marked in both human and machine readable (i.e., scannable barcode) formats. These regulations are intended to provide a standardized way to confidently and uniquely identify medical devices and pharmaceuticals across all information sources and systems, including electronic health records, enterprise resource planning systems and devices registries. Unfortunately, these unique identifiers are not in use by all players in the healthcare supply chain, so many of the benefits to patient care and staff safety are not being realized.

Much emphasis has been placed on these regulations and their overarching objective of improving patient safety. Using the unique identifier for both devices and drugs all the way to patient care will allow for a safer and more cost-effective patient experience by:

- facilitating the efficient identification of legitimate products and sources
- allowing products used in patient care to become part of a patient's clinical care health record
- supporting the study of device and drug effectiveness and efficacy
- facilitating the efficient identification and removal of expired and recalled devices and drugs

Beyond these regulatory based goals, unique identification of products has been foundational to supply chain and operational opportunities or efficiencies for over 40 years. In addition to carrying a globally unique product and location identifier adoption across all healthcare stakeholders (manufacturers, distributors/wholesalers, providers/dispensers) and integration of these identifiers along with other product and location specific information into all sources and systems including procurement, warehouse, inventory management and point of use systems would allow alignment and interoperability across the product and patient continuum.

The level of visibility possible by the use of data standards has obvious advantages from a supply availability perspective. Adopting these data standards can also serve as a foundation for enhanced analytics. Product efficacy, patient outcomes, spend analytics, utilization or "burn rate", recall management, device registries – all of these become more powerful when standards are used as the link to identify a product or location across various systems or databases.

The pandemic has demonstrated that rapid adoption and use of data standards is more important now than ever before in contributing to safe and effective patient care. Regulations such as UDI and DSCSA have laid a foundation on which we can look to build a safer, more visible, efficient, and resilient supply chain leading to our shared goal of patient safety. The industry has begun this work, and we have other industries to learn from to help us realize this shared vision.

INDUSTRY CALL TO ACTION:

AHRMM, HSCA, SMI and GS1 US are aligned on a common desire to expedite industry's adoption and use of data standards for supply chain and UDI. We encourage all healthcare stakeholders to engage with any of these organizations as we collaborate together to provide aligned forums intended to accelerate the adoption of global standards in these critical theme areas. By working together we can be better prepared the next time we are faced with a pandemic or other crisis. Please reach out to any of these organizations to express your interest in engaging in their associated activities.

About GS1 US

GS1 US®, a member of GS1 global, is a not-for-profit information standards organization that facilitates industry collaboration to help improve supply chain visibility and efficiency through the use of GS1 Standards, the most widely used supply chain standards system in the world. Nearly 300,000 businesses in 25 industries rely on GS1 US for trading partner collaboration that optimizes their supply chains, drives cost performance and revenue growth, while also enabling regulatory compliance. They achieve these benefits through solutions based on GS1 global unique numbering and identification systems, barcodes, Electronic Product Code (EPC®)-based RFID, data synchronization, and electronic information exchange. GS1 US also manages the United Nations Standard Products and Services Code® (UNSPSC®).

About GS1 Healthcare US

GS1 Healthcare US® is an industry group that focuses on driving the adoption and implementation of GS1 Standards in the healthcare industry in the United States to help improve patient safety and supply chain efficiency. GS1 Healthcare US brings together members from all segments of the healthcare industry to address the supply chain issues that most impact healthcare in the United States. Facilitated by GS1 US, GS1 Healthcare US is one of over 30 local GS1 Healthcare user groups around the world that supports the adoption and implementation of global standards developed by GS1.

About AHRMM

The Association for Health Care Resource & Materials Management (AHRMM) of the American Hospital Association is the leading professional membership group for the health care supply chain. AHRMM provides its 3,600 members worldwide, and the greater health care supply chain, with the education, resources, leadership opportunities and advocacy needed to remain at the top of their field. AHRMM is proudly advancing health care through supply chain excellence. For more information about AHRMM, please visit http://www.ahrmm.org/

About the Healthcare Supply Chain Association (HSCA)

The Healthcare Supply Chain Association (HSCA) represents the nation's leading healthcare group purchasing organizations (GPOs), which are critical cost-savings partners to America's hospitals, homes, nursing home pharmacies, clinics, home healthcare providers and surgery centers. GPOs deliver billions in savings annually to healthcare providers, Medicare and Medicaid, and taxpayers. HSCA and its member GPOs are committed to delivering the best products at the best value to healthcare providers.

About SMI

SMI provides a nexus for healthcare providers, suppliers, and distributors to network and collaborate on innovations that drive meaningful improvements in supply chain agility, efficiency, and resilience. We provide a unique, non-commercial community where members forge long-term relationships as they work together to improve patient care. For more information about SMI, including a complete list of members, visit: http://www.smisupplychain.com/.