The Global Language of Business

Board Approved Statement of Direction

For the Adoption of Global Standards to enable a Clinically Integrated Supply Chain in Canada's Healthcare System

November 2021

The purpose of this Statement of Direction is to provide guidance, recommendations, and timelines for the adoption of global standards that enable a clinically integrated supply chain in Canada. The GS1 Canada Carenet Healthcare Board is calling for healthcare sector commitment to a clinically integrated supply chain, with an overarching vision that every patient record incorporates the common global supply chain language (standards) and accurate data that establish the foundation of: patient safety; best possible patient outcomes; robust analytics (clinical outcomes, value-based procurement); and safe, effective product recall management.

The adoption of GS1 Global standards and co-operating standards across the healthcare supply chain is foundational to achieving this vision. The common language of global standards creates a "thin layer" of consistency, so all healthcare supply chain stakeholders are able to identify, capture, and share data, enabling product traceability from point of sourcing, procurement, and inventory management through to patient care and the electronic medical record.

The movement to the adoption of global supply chain standards is gaining momentum. Globally, requirements for global standards are increasingly being driven by regulation, along with the digitization of healthcare delivery. Locally, GS1 Canada's community-led healthcare sector governance structure, comprised of healthcare provider organization leaders and their trading partners, is driving integration of GS1 Global Standards as a foundational component of the roadmap to a clinically integrated supply chain. Through GS1 Canada's community management process, members of the Healthcare Provider Deployment Committee are collaborating in a Community of Practice environment to support the adoption and implementation of GS1 Global Standards to achieve the vision of a clinically integrated supply chain.

Timelines for global standards adoption are as follows:

- Organizations currently in a state of digital readiness: by 2022.
- Organizations currently implementing or planning to implement digital capabilities: by 2025.
- Organizations not currently implementing or planning to implement digital capabilities: by 2025-2030.

Desired Future State: Full Global Standards Adoption

Identify

The Carenet Healthcare Sector Board's recommendations for a clinically integrated supply chain in Canada includes the adoption of the foundational global identification and data standards described below. The widespread utilization of global standards as the common language in the healthcare system is fundamental to process automation leading to visibility and traceability capabilities in a clinically integrated supply chain. Global standards adoption is at the foundational level of Healthcare Management and Systems Society (HIMSS) eight-stage Clinically Integrated Supply Outcomes Model (CISOM).

Positions and Assumptions:

Product Identification

- The manufacturers' barcode number (GTIN) and respective variable data (e.g., Lot Number, Expiry Date, Serial Number) to be adopted to enable automated process and traceability from sourcing and procurement, to patient care validation and electronic medical record traceability. Products should not be re-labelled with proprietary identifiers.
- Products are barcoded with a Global Trade Item Number (GTIN) at all packaging levels enabling device identification from unit of use to case.
- Barcodes should contain variable data (e.g., Lot Number, Expiry Date, Serial Number) enabling unique device identification (UDI).
- GS1 DataMatrix is the recommended carrier for barcoding Unit of Use, Primary and Secondary packaging levels.
- GS1-128 is used for logistics units (e.g., Case, Pallet) and contain GTIN, and variable data (e.g., Lot Number, Expiry Date, Serial Number). GS1 DataMatrix can be added provided that both barcode symbologies contain the same GTIN.
- Serial Shipping Container Code (SSCC) is recommended for identification of logistic units, which can be any combination of trade items packaged together for storage and transportation.

Product Classification and Nomenclature

- Standardized classification taxonomies are used to categorize and describe products (e.g., United Nations Standard Products and Services Code (UNSPSC), Global Product Classification (GPC)).
- Standardized nomenclature taxonomies are used to define and describe products (e.g., Global Medical Device Nomenclature [GMDN]).

Location Identification

- Global Location Number (GLN) is used to identify legal entities, ship to/from locations and locations within a facility (e.g., nursing stations, patient beds, medication carts).
- Standardized GLN and location attributes are used universally to identify locations across the clinically integrated supply chain.

Asset Identification

- Medical device equipment and hospital assets are identified and tracked using GS1 global standards (e.g., Unique Device Identification (UDI), Global Individual Asset Identifier (GIAI), and Global Returnable Asset Identifier (GRAI)).

Patient, Practitioner, Employee Identification

- Patients and healthcare staff are identified using a Global Service Relationship Number (GSRN).

Document Identification

- The Global Document Type Identifier (GDTI) is used by companies to identify documents, including the class or type of each document.

Transact

The Carenet Healthcare Board recommends that business transactions be based on global standards and integrate global identification standards.

The integration of standards within transaction sets is the foundation to enabling product visibility and traceability capabilities across the healthcare supply chain.

- Commercial transactions are exchanged electronically using ANSI.X12 EDI version 6020. GS1 global standards (e.g., GTIN, GLN) are used in commercial transactions. Recommended transactions include:
  - Invoice (810)
  - Price/Catalogue (832)
  - Purchase Order (PO) (850)
  - Purchase Order Consignment (850)
  - Purchase Order Acknowledgement (POA) (855)
  - Advance Ship Notice (ASN) (856)
  - Functional Acknowledgement (997)
  - Electronic Funds Transfer (EFT), Payment Order Remittance Advice (820)
  - Product Activity Data (852)
  - Product Transfer Resale Report (867)

The roadmap to GS1 standards adoption is a journey that must be taken in partnership with all stakeholders in Canada's healthcare system. Through the application of tools and resources such as the GS1 Canada digital readiness scorecard, all healthcare supply chain stakeholders will be supported to define realistic timelines that meet individual and collective requirements.

Transformation Requirements and Critical Success Factors

Commitment on the part of all trading partners to establishing the conditions that enable a clinically integrated supply chain is a critical success factor. Healthcare Providers, Shared Service Organizations (SSOs), Group Purchasing Organizations (GPOs), Solution Providers, Distributors and Manufacturers must engage in the collective movement to embed use of global supply chain standards, as listed below, into their clinical and non-clinical workflows.

- Global Trade Identification Number (GTIN)
- Serial Shipping Container Code (SSCC)
- Global Location Number (GLN)
- Electronic Data Interchange (EDI) v4010 (minimum) or v6020 (ideal)
- Global Product Classification (GPC), United Nations Standard Products and Services Code (UNSPSC)
- Global Medical Device Nomenclature (GMDN)
- Global Service Relationship Number (GSRN)
- Global Individual Asset Identifier (GIAI); Global Returnable Asset Identifier (GRAI)
- Global Document Type Identifier (GDTI)

What Do Healthcare Providers, Shared Service Organizations Need to Do?

- implement capabilities to capture, store and process global standards
- request manufacturers to barcode all product packaging hierarchies using GS1 barcodes that are compliant with the GS1 General Specifications
- replace use of proprietary barcoding solutions and identifiers with global standards
- implement camera ready barcode scanners to scan 1D/2D barcodes across the organization
- implement solutions to scan/ingest and store GTIN and variable product data (e.g., Lot Number, Expiry Date, Serial Number) across hospital systems

- ensure systems are enabled to identify and ingest GTINs for multiple packaging hierarchies and to manage global data attributes for each level
- exchange Global Location Numbers (GLNs) (e.g., legal entity, bill to, ship to) with trading partners
- implement capabilities to manage EDI standards
- exchange commercial transactions using ANSI.X12 version 6020 or 4010 and include GTIN and GLN identifiers
- create a supply best practice guideline that details requirements for global standards

What Do Group Purchasing Organizations (GPO) Need to Do?

- implement capabilities to capture, store and process global standards
- request manufacturers to barcode all product packaging hierarchies using GS1 barcodes that are compliant with the GS1 General Specifications
- exchange Global Trade Item Numbers (GTINs) for all product packaging hierarchies with GPO members
- exchange Global Location Numbers (GLNs) (e.g., legal entity) with trading partners
- create a supply best practice guideline that details requirements for global standards

What Do Technology Solution Providers Need to Do?

- develop capabilities within solutions that enable the use of global standards that support a clinically integrated supply chain
- implement capabilities to capture, store and process the Global Trade Item Number (GTIN) and variable data (e.g., Lot Number, Expiry Date) from GS1 barcodes
- ensure EDI readiness with most updated version of standards in their e-commerce solutions
- enable commercial transaction exchange using ANSI.X12 version 6020 or 4010 and include Global Trade Item Number (GTIN) and Global Location Number (GLN) identifiers
- ensure IT infrastructure capabilities to:
  - capture, store and report GSRN in the Electronic Medical Record (EMR) and Electronic Health Record (EHR)
  - capture, store and report GSRN to trigger events (e.g., controlled access to secured areas within the hospital such as pharmacy or medication dispensing cabinets)

What Do Manufacturers Need to Do?

- implement capabilities to capture, store and process global standards
- barcode all product packaging hierarchies using GS1 barcodes that are compliant with the GS1 General Specifications
- apply the GS1 DataMatrix barcode to Unit of Use, Primary and Secondary packaging levels for all products
- exchange Global Location Numbers (GLNs) (e.g., legal entity, order from, remit to) with trading partners
- apply standardized classification and nomenclature to all medical device products and include in product data synchronization with trading partners
- implement capabilities to manage EDI standards
- exchange commercial transactions using ANSI.X12 version 6020 or 4010 and include GTIN and GLN identifiers
- establish Electronic Funds Transfer (EFT) through a financial institution
- communicate product recalls using an integrated national platform based on global standards.

What Do Distributors Need to Do?

- implement capabilities to capture, store and process global standards
- exchange Global Location Numbers (GLNs) (e.g., legal entity, order from, remit to) with trading partners
- implement capabilities to manage EDI standards
- exchange commercial transactions using ANSI.X12 version 6020 or 4010 and include GTIN and GLN identifiers

- establish Electronic Funds Transfer (EFT) through a financial institution
- communicate product recalls using an integrated national platform based on global standards.

How can you join the movement to adopt Global Standards to enable a Clinically Integrated Supply Chain in Canada's healthcare system?

- Become a Subscriber of GS1 Canada.
- Join the GS1 Canada Community Groups and provide input around standards implementation requirements.
- Contact GS1 Canada to support your organization's implementation efforts.

Background

In 2020, The Carenet Healthcare Board approved the National Roadmap to a Clinically Integrated Supply Chain, comprised of three foundational components:

- Global standards as the common language that enable a clinically integrated and interoperable supply chain within Canada;
- A centralized primary source of truth in the form of national healthcare product and location registries based on global standards and community commitment to data integrity; and
- A common platform to communicate and receive product recall and withdrawal notifications.

In support of the first foundational component, GS1 Canada's Healthcare Provider Deployment Committee participated in a series of workshops with a view to conducting a gap analysis between the current state and desired future state of global standards adoption in Canada's healthcare system.

Transformational requirements and critical success factors for mass adoption of global standards were identified. Concurrently, a digital readiness scorecard was developed for use by stakeholders across the healthcare supply chain as a self-evaluation tool and indicator of transformation needed at the organizational level to adopt global standards that enable clinical and non-clinical workflows.

Global standards adoption is at the foundation of the 8-level HIMSS Clinically Integrated Supply Outcomes Model (CISOM), the building blocks required to achieve a full clinically integrated supply chain from point of manufacture to patient outcome analytics.