The Global Language of Business

GS1 US Comment to the

United States Department Food & Drug Administration regarding:

Future Format of the National Drug Code

Docket No. FDA–2018–N–2610

Executive Summary

GS1 US® appreciates the opportunity to provide this comment to the United States Food and Drug Administration (FDA) regarding the *Future Format of the National Drug Code (NDC)*.

GS1® is the leading global standards organization in the healthcare industry, and GS1 US is the local member organization of GS1 responsible for supporting implementation of GS1 Standards in the United States. The GS1 System is widely used in healthcare, from pharmaceuticals to medical devices to many of the other products found in healthcare facilities and supplied by other business sectors. Preventing medical errors and combating counterfeiting are top-of-mind concerns facing the healthcare sector, and GS1 Standards are helping to solve these issues. In over 50 countries worldwide, GS1 Standards have been chosen to uniquely identify pharmaceutical products and medical devices. In addition, national and regional healthcare associations, organizations and regulators around the world have endorsed GS1 Standards. In fact, GS1 is an FDA-accredited Issuing Agency for medical device Unique Device Identifiers (UDI), and GS1 Standards are commonly used to implement the FDA UDI Rule and the Drug Supply Chain Security Act (DSCSA).

GS1 US would like to recognize the GS1 Healthcare US *New NDC Format Workgroup* for their participation in the development of these comments. Our dedicated workgroup members offer expert insight based on their years of experience working in the healthcare industry.

Note: GS1 Standards and solutions are voluntary, not mandatory. It should be noted that use of the words "must" and "require" throughout this document relate exclusively to technical requirements for the proper application of the standards to support the integrity of a user's implementation.

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About GS1

GS1® is a neutral, not-for-profit, global organization that develops and maintains the most widely-used supply chain standards system in the world. GS1 Standards improve the efficiency, safety, and visibility of supply chains across multiple sectors. With local Member Organizations in over 110 countries, GS1 engages with communities of trading partners, industry organizations, governments, and technology providers to understand and respond to their business needs through the adoption and implementation of global standards. GS1 is driven by over a million user companies, which execute more than six billion transactions daily in 150 countries using GS1 Standards.

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-based RFID, data synchronization, and electronic information exchange. GS1 US also manages the United Nations Standard Products and Services Code® (UNSPSC®).

About GS1 Healthcare

GS1 Healthcare is a global, voluntary healthcare user group developing global standards for the healthcare supply chain and advancing global harmonization. GS1 Healthcare consists of participants from all stakeholders of the healthcare supply chain: manufacturers, wholesalers, and distributors, as well as hospitals and pharmacy retailers. GS1 Healthcare also maintains close contacts with regulatory agencies and trade organizations worldwide. GS1 Healthcare drives the development of GS1 Standards and solutions to meet the needs of the global healthcare industry, and promotes the effective utilization and implementation of global standards in the healthcare industry through local support initiatives like GS1 Healthcare US® in the United States.

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 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.

WHO IS GS1 US?

GS1 US® is a not-for-profit member organization established over 45 years ago by the grocery industry to administer and manage Universal Product Codes, also known as U.P.C.'s. The U.P.C. remains one of the most successful standards in history – with billions of barcodes scanned daily worldwide. This method of identifying products and capturing product data has evolved into what is now known as the GS1 System, the world's most widely used supply chain standards, which include:

- globally-unique numbering formats (identification numbers) for **identifying** supply chain objects;
- barcodes and radio frequency identification (RFID) for **capturing** identification numbers; and
- data synchronization and electronic information exchange for **sharing** data.

GS1 US brings industry communities together to solve supply chain problems through the adoption and implementation of GS1 Standards. More than 330,000 businesses in 25 industries rely on GS1 US for trading partner collaboration and for maximizing the cost-effectiveness, speed, visibility, security and sustainability of their business processes using GS1 Standards. GS1 US also manages the United Nations Standard Products and Services Code® (UNSPSC®). Some of the world's largest corporations participate in our boards and work groups, motivated by the knowledge that GS1 Standards help their companies reduce costs and increase both the visibility and security of their supply chains.

GS1 US is not:

- a software provider
- a hardware provider
- a commercial solutions provider
- a technology company
- a government agency

GS1 US is a local member organization of GS1®, a global standards organization that has been recognized as a voluntary, consensus standards body pursuant to OMB Circular A-119. GS1 has been accredited by the FDA as an Issuing Agency for the assignment of UDIs in the context of the U.S. FDA Unique Device Identification System, and GS1 US serves as the first point of contact for the FDA. In addition, GS1 US works with and actively supports numerous federal government entities, including:

Department of Agriculture (USDA)
Department of Commerce (DOC)
Department of Defense (DOD)
Department of Homeland Security (DHS)
Department of Justice (DOJ)
Department of State
Department of the Treasury (DOT)
Department of Veteran Affairs (VA)
Centers for Disease Control & Prevention (CDC)
Commodity Futures Trading Commission (CFTC)
Consumer Product Safety Commission (CPSC)
Customs & Border Protection (CBP)
Environmental Protection Agency (EPA)
Federal Communications Commission (FCC)
Federal Deposit Insurance Corporation (FDIC)
Federal Trade Commission (FTC)
Food and Drug Administration (FDA)
National Aeronautics & Space Administration (NASA)
Securities & Exchange Commission (SEC)
United States Postal Service (USPS)
National Institute of Standards & Technology (NIST)
United States Congress
United States Trade Representative (USTR)

1 Foundational Standards & Technical Concepts

This section is intended to provide information and guidance about foundational standards and technical concepts to support the comments and recommendations provided throughout the remainder of this document.

1.1 Encoding NDCs

The Automatic Identification and Data Capture (AIDC) process involves encoding data, reading symbols, and decoding data. To support this, AIDC software incorporates standards (like GS1 Standards) so that it can recognize a symbol and encode/decode the data. The standards are not just about the appearance of the barcode symbol, but also the structure of the data encoded. Standards are essential to assure that a barcode created by one trading partner can be read and decoded by another. NDC is not a standardized identifier with the accompanying standards needed by AIDC systems to encode/decode it. Therefore, an NDC cannot be encoded in its native form.

The FDA linear barcode requirement in 21 CFR 201.25 states the following:

> (c) *What does the bar code look like? Where does the bar code go?* (1) Each drug product described in paragraph (b) of this section must have a bar code that contains, at a minimum, the appropriate National Drug Code (NDC) number **in a linear bar code that meets European Article Number/Uniform Code Council (EAN.UCC) [standards]** or Health Industry Business Communications Council (HIBCC) standards…[1] *(emphasis added)*

For clarity, GS1 US notes the following:

- **EAN/UCC is GS1.** In 2005, EAN and UCC merged. EAN is now known as GS1, and UCC is now known as GS1 US.
- **The UPC-A is a GS1 barcode.** The UPC-A is commonly used to implement the FDA linear barcode requirement.
- **The number encoded in a UPC-A barcode is a GS1 Global Trade Item Number® (GTIN®).** When used for the FDA linear barcode requirement, the number encoded in the UPC-A is a GTIN that embeds the NDC (as described *below*).

Figure 1-1 UPC-A Barcode

1.2 What is a GTIN

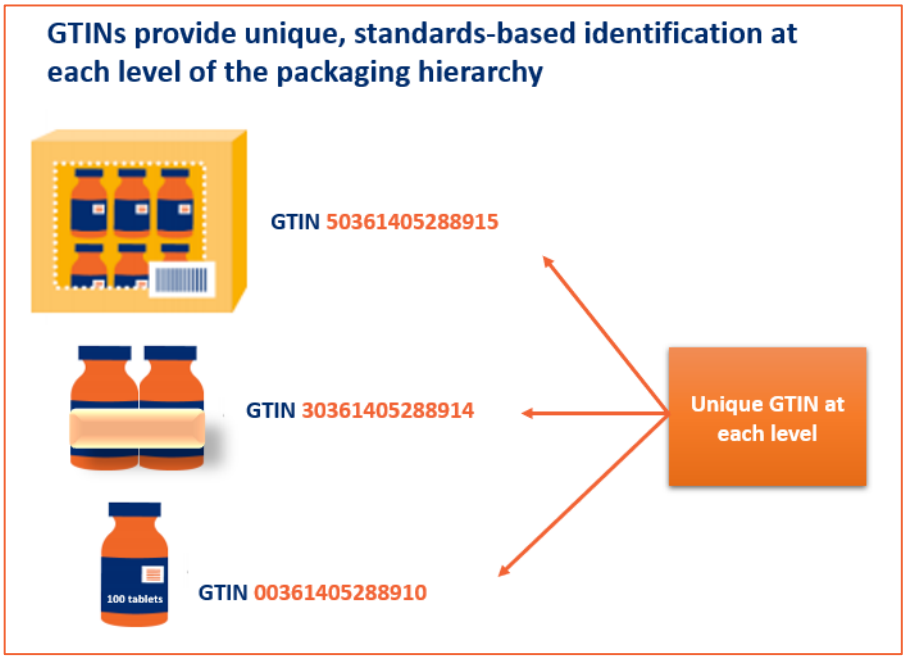
A GS1 Global Trade Item Number (GTIN) is the globally unique GS1 Identification Number used to identify "trade items" (i.e., products and services that may be priced, ordered or invoiced at any point in the supply chain). GTINs are used to identify individual trade item units (*like a bottle of 60 tablets of Drug A*), as well as all of their different packaging configurations (*e.g., 60-tablet bottle of Drug A; 2-pack of 60-tablet bottles of Drug A; case of 100 60-tablet bottles of Drug A; etc.*). GTINs are assigned

[1] FDA Linear Barcode Rule. 21 CFR 201.25(c). Retrieved November 5, 2018 from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=201.25

by the manufacturer of the product using GS1 Standards and allocation rules, which enable manufacturers to assure that their GTINs are globally unique and in a consistent format.

It is important to recognize that GTINs are not just the number in a barcode. GTINs are used anywhere that a product needs to be identified -- including IT systems, business transactions, the Internet, and the physical product itself. GS1 Standards define how to format and structure the GTIN across all those applications so that the same identifier can be used to uniquely identify a product across all systems and environments.

Figure 1-2 Unique GTIN at Every Packaging Level



1.3 Relationship between NDCs and GTINs

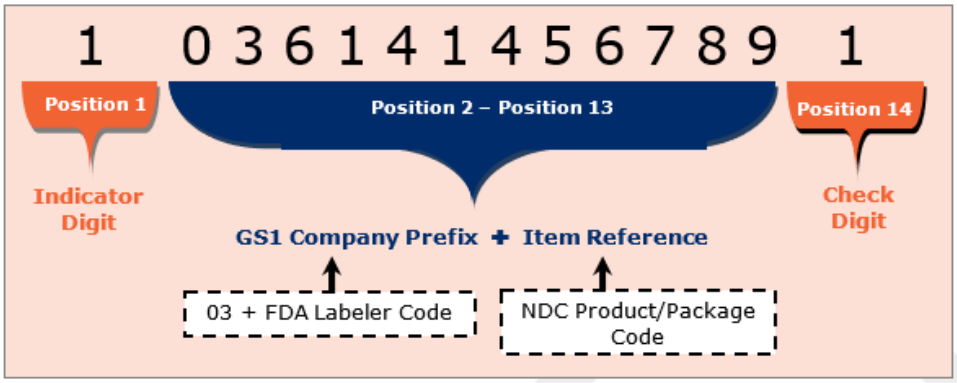
The NDC is a U.S. regulatory identifier used to identify pharmaceutical products for regulatory purposes. The GTIN is a global, standards-based identifier used to identify products for supply chain purposes. For over thirty-five years, GS1 has supported manufacturers of healthcare products in integrating their NDCs into their GTINs so that identification of pharmaceutical products for supply chain purposes is consistent with identification of pharmaceutical products for regulatory purposes.

To support integration of NDCs with GS1 Standards, GS1 US reserved a placeholder in its *Company Prefix* numbering system so that the GS1 *Company Prefixes* for pharmaceutical companies is simply their *Labeler Code* with a "03" appended in front. For example:

FDA-assigned *Labeler Code*	61414
Append GS1 US Placeholder	03
GS1 *Company Prefix*	0361414

This approach provides the basis for integrating NDCs into the GTIN structure. The figure below illustrates how the NDC segments (i.e., *Labeler Code, Product Code* and *Package Code*) are integrated into the segments of a GTIN. The NDC *Labeler Code* is integrated into the *GS1 Company Prefix*, and the NDC *Product Code and Package Code* are used to populate the *Item Reference* segment of the GTIN. The addition of the *Indicator Digit* and the *Check Digit* (standard segments in the GTIN structure) enable uniqueness at every packaging level and promote data integrity.

Figure 1-3 Embedding an NDC in a GTIN



2 FDA Context Questions

2.1 How would you describe your business or area of focus?

GS1 US is the local member organization of GS1 responsible for supporting implementation of GS1 Standards in the United States. GS1 Standards, which are the most widely-used supply chain information standards in the world, include:

- globally-unique numbering formats (identification numbers) for **identifying** supply chain objects;
- barcodes and radio frequency identification (RFID) for **capturing** identification numbers; and
- data synchronization and electronic information exchange for **sharing** data.

The GS1 System is widely used in healthcare, from pharmaceuticals to medical devices to many of the other products found in healthcare facilities and supplied by other business sectors (e.g., office supplies, food, consumer packaged goods, etc.). GS1 US brings together members from all segments of the U.S. healthcare industry to address the supply chain issues that most impact healthcare in the United States, and to support their implementation and use of GS1 Standards.

For example, GS1 is an FDA-accredited Issuing Agency for medical device Unique Device Identifiers (UDI)[2], and GS1 Standards are commonly used to implement the U.S. FDA UDI Rule[3]. GS1 US supports industry use of GS1 Standards for UDI through implementation guidelines, training and education, webinars, and case studies. In addition, GS1 Standards are being used for industry implementation of the Drug Supply Chain Security Act (DSCSA). GS1 US launched a workgroup to provide leadership and drive decision-making the technical standards implementation, produced an implementation guideline, provides webinars and educational offerings aimed at supporting industry use of GS1 Standards in their DSCSA implementations. GS1 Standards are also recognized within and widely used to implement the FDA linear barcode rule[4] for pharmaceuticals, and GS1 US supports that effort with online tools, as well as educational materials and implementation support.

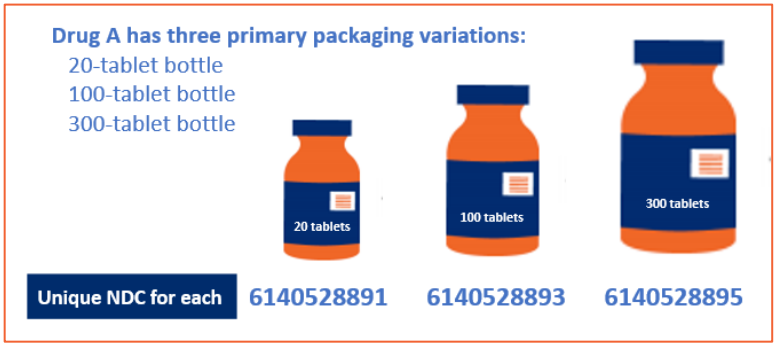
[2] United States Department of Health and Human Services. Food and Drug Administration. *UDI Issuing Agencies*. Accessed December 7, 2018 at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIIssuingAgencies/default.htm
[3] United States Department of Health and Human Services. Food and Drug Administration (September 2013). *Final Rule – Unique Device Identification System*. 78 FR 58785. Retrieved November 3, 2018 from: https://www.federalregister.gov/documents/2013/09/24/2013-23059/unique-device-identification-system
[4] 21 C.F.R. 201.25

2.2 What challenges does your organization or your members face with the current NDC and how do you overcome these challenges?

Unique identification at every level of the product hierarchy is essential for supply chain applications in general – and traceability in particular. However, NDC does not support unique identification at every level of the packaging hierarchy.

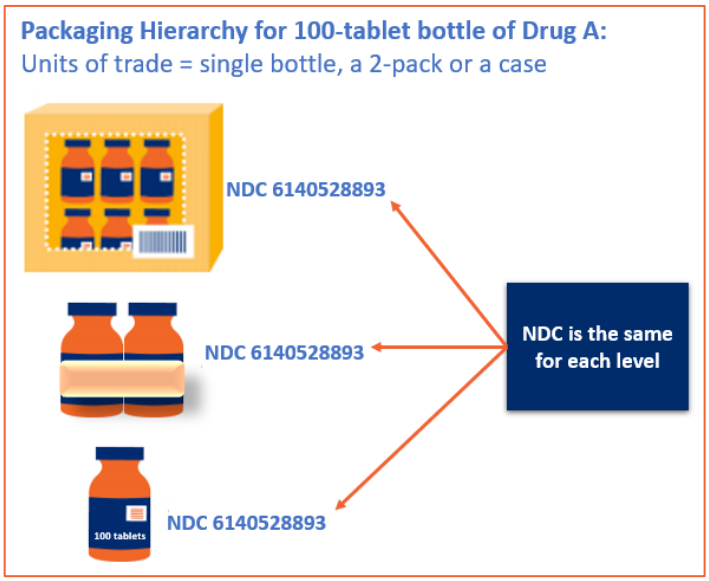
NDC *Package Codes* indicate package size and type. *Package Codes* only differentiate between different quantitative and qualitative attributes of the product packaging.[5] In other words, NDC *Package Codes* specify primary packaging variations (e.g., bottle, vial, blister pack – and quantity variations for each).

Figure 2-1 NDC Identification = Unique NDC at Each Primary Packaging Variation



In supply chain terms, this means that NDCs only identify a specific primary package configuration (e.g., unit of use and/or unit of sale). NDCs do not relate to, differentiate, or uniquely identify trade packaging levels (i.e., a 60-tablet bottle; 2-pack of 60-tablet bottles; a case of 100 60-tablet bottles, etc.). Instead, the NDC is the same across all trade packaging levels (also known as "product/packaging hierarchy"). In other words, a 60-tablet bottle of Drug A, a 2-pack of 60-tablet bottles of Drug A, and a case of 100 60-tablet bottles of Drug A will all have the same NDC because the NDC is only identifying the primary packaging variation: a 60-tablet bottle of Drug A.

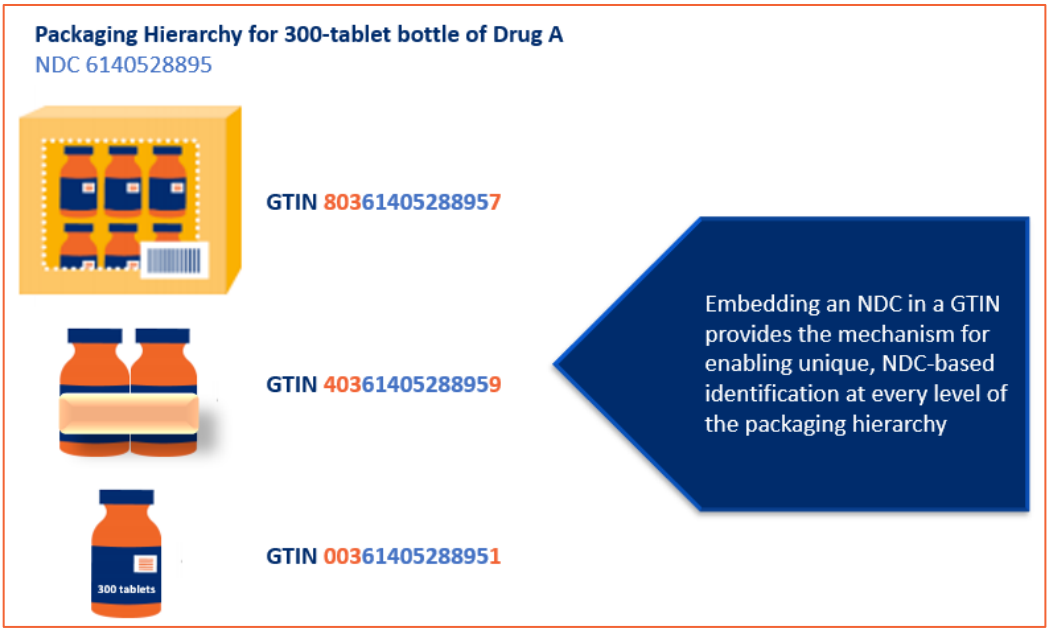
Figure 2-2 NDC and the Product Hierarchy



[5] United States Department of Health and Human Services. Food and Drug Administration. *National Drug Code Directory*. Accessed November 11, 2018 at: https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm

This limitation has been especially challenging because NDC has been incorporated as an identifier in various regulatory and statutory schemes aimed at supply chain applications where unique identification at every level of the product hierarchy is a technical necessity. For example, the FDA Standardized Numerical Identifier (SNI)[6] and DSCSA[7] both incorporate NDC even though NDC does not provide the level of unique identification needed to support their supply chain security and traceability goals. GS1 members have been able to overcome this challenge by embedding the NDC in a GTIN. This provides the mechanism for enabling unique, NDC-based identification at every level of the packaging hierarchy. This is another reason why the relationship between NDC and GTIN is so important. The *Indicator Digit* and the *Check Digit* (standard segments in the GTIN structure) are not simply a formatting addition. They are functional, enabling uniqueness at every packaging level and promoting data integrity.

Figure 2-3 Unique Identification for Supply Chain & DSCSA = GTIN Embedding NDC



2.3 What changes would you or your members need to make to your systems to accommodate the 6-digit labeler code or other larger NDC formats?

- Industry will not be able to use UPC barcodes for NDCs based on the 6-dgit *Labeler Code*
  - This is because NDCs based on the 6-digit *Labeler Code* are too long to be embedded into the GTIN structure for UPC the way that NDCs based on 5-digit and 4-digit *Labeler Codes* are today
- To continue to support industry in their NDC-based requirements, GS1 will create an Application Identifier (AI) for NDC. This approach is consistent with the approach taken for other countries that still require a country specific identifier (e.g., Germany, France, Spain, Brail and Portugal).
  - GS1 Application Identifiers (AIs) are a finite set of specialized identifiers encoded within barcodes to indicate the type of data represented in the various barcode segments. Each AI is a two, three, or four-digit numeric code. Each data element in a barcode is preceded by its AI.

[6] United States Department of Health and Human Services. Food and Drug Administration (March 2010). *Guidance for Industry Standards for Securing the Drug Supply Chain - Standardized Numerical Identification for Prescription Drug Packages.* Retrieved November 3, 2018 from: https://www.fda.gov/RegulatoryInformation/Guidances/ucm125505.htm

[7] Drug Supply Chain Security Act. Pub. Law No. 113-54, 127 Stat 587 (2013). Retrieved November 3, 2018 from: https://www.gpo.gov/fdsys/pkg/PLAW-113publ54/html/PLAW-113publ54.htm

There are approximately 100 AIs in the GS1 System. GS1 AI's commonly used in healthcare include AI (10) for lot/batch number, AI (17) for expiration date, and AI (21) for serial number.

- The transition of NDC out of the GTIN structure and into an AI impacts the barcodes available for products that need to encode their NDC.
  - The GS1 System supports six different barcode symbologies to enable users to select the barcode that best fits their application and environment. However, not all barcode symbologies can carry AIs. For example, UPC barcodes (currently used by the pharmaceuticals industry for the linear barcode rule) cannot carry AIs and therefore cannot be used to carry an NDC that is encoded as an AI.
  - There are three GS1 barcodes that could carry the NDC AI: GS1-128, GS1 DataMatrix, and GS1 DataBar®.
  - Barcode selection will need to consider symbol size and capacity (i.e., the number of characters that can be encoded) for very small healthcare products and/or DSCSA-marked products that must carry several data elements.

Table 2-1 GS1 Barcode Options for Encoding the NDC AI

GS1 Barcode	Type	# of Characters	Notes
GS1-128	linear	Up to 48 characters	▪ Can be read by traditional laser scanners ▪ Symbol size directly related to the number of characters (i.e., symbol can get quite large as more characters are encoded)
GS1 DataMatrix	2D	Up to 2,335 characters	▪ Requires camera-based scanners ▪ Small symbol with large data capacity
GS1 DataBar	linear	Up to 74 numeric or 41 alphabetic characters	▪ Scanned omnidirectionally by suitably programmed scanners

Examples of GS1 Barcodes for DSCSA:

DSCSA requires encoding of the SNI (i.e., NDC and serial number), lot/batch number, and expiration date in a data matrix for drug packages. The table below illustrates how that information can be encoded using GS1 Standards for NDCs based on 4 or 5-digit *Labeler Codes* and NDCs based on 6-digit *Labeler Codes*. (It should be noted that the size of the GS1 DataMatrix will increase with the addition of the new AI for NDC, which is an important consideration for packaging design and limitations with space availability for certain drug packages.

Table 2-2 GS1 Barcoding for DSCSA

NDC Structure	Encoded data elements	Sample barcode
NDCs based on 4-digit and 5-digit Labeler Codes	Encode four data elements: ▪ GTIN embedding NDC (01) ▪ expiration date (17) ▪ lot or batch number (10) ▪ serial number (21)	 GTIN (01) 00314141999995 EXP 2021-12-31 Batch/Lot (10) 987654321GFEDCBA Serial (21) 10000000234
NDCs based on 6-digit Labeler Codes	Encode five data elements: ▪ GTIN (01) ▪ expiration date (17) ▪ lot or batch number (10) ▪ serial number (21) ▪ NDC (7**)	 GTIN (01) 00314141999995 EXP 2021-12-31 Batch/Lot (10) 987654321GFEDCBA Serial (21) 100000000234 NDC (7**) 999999-1111-22 *Note: the AI for NDC has not yet been assigned. It is being represented as (7**) in the graphic above for illustration purposes only.*

3 FDA Impact Questions

3.1 Issues associated with the current lack of NDC uniformity

NDCs are currently assigned as 10-digit numbers in one of the following structures: 4–4–2, 5–3–2, 5–4–1 (including the hyphens). Although NDCs are assigned in this format, the hyphens are often removed when the 10-digit NDC is stored in stakeholder systems. In addition, the Department of Health and Human Services (HHS) adopted their own format for representing NDCs in all standard transactions under Health Insurance Portability and Accountability Act[8] (HIPAA).[9] The HIPAA NDC format is 11 digits in a 5-4-2 structure. Ten-digit NDCs are converted to the HIPAA format by adding a leading zero to the segment needed to achieve the 5-4-2 format. However, as FDA noted in the request for comment, some systems that utilize the HIPAA format for NDCs remove the hyphens as well.[10]

There are three core issues with NDC as it exists in the marketplace today:

- **Use of hyphens:** The use of hyphens is generally not an IT best practice and not always supportable within technical tools and systems. As a result, the hyphens are removed in some IT systems. The use of hyphens in some NDC formats and the deletion of hyphens in other NDC formats creates data quality and integrity issues that are exacerbated with the zero and padding approaches discussed below.
- **Use of zero as a valid value for digits and as a pad (i.e., leading zero):** Without rules about the use of zero in leading and trailing positions in each NDC segment, there is no way to determine if a zero in those positions is a value or a pad digit when NDCs are stored in the HIPAA format (with or without the hyphens).
- **Padding individual segments:** Although segments are a useful tool when allocating identifiers, those segments should not be treated independently once the identifier is created. Instead, the identifier should only be treated as a whole. When zeros are added to pad individual NDC segments (as is done in the HIPAA format), a different number is created. Although industry has worked hard to create workarounds and techniques to help them recognize and connect these different numbers as the same NDC, this is a high-maintenance, error-prone effort that undermines data integrity.

Because of these issues, there are actually four different formats for representing NDC in IT systems today. Specifically, NDC can be stored as assigned with the hyphens, as assigned without the hyphens, in HIPAA format with the leading zeros and hyphens, and in HIPAA format with leading zeros without the hyphens. This means the same NDC is being represented in four different ways in electronic systems. Although a trained human eye may recognize these four formats as the same NDC, computer systems do not. Computer systems recognize them as four different numbers.

Table 3-1 Four different formats for representing NDC 99999-123-45 in IT systems

NDC Format	Example	Description
As assigned (5-3-2)	**99999-123-45**	▪ 10 digits with hyphens between segments
As assigned without the hyphens	**9999912345**	▪ 10 digits with hyphens omitted
HIPAA format (5-4-2)	**99999-0123-45**	▪ 11 digits with leading zeros and hyphens between segments
HIPAA format without the hyphens	**99999012345**	▪ 11 digits with leading zeros and no hyphens

[8] Pub. L. 104–191, 110 Stat. 1936 (1996).
[9] United States Department of Health and Human Services. Food and Drug Administration (August 2000). *Final Rule - Health Insurance Reform: Standards for Electronic Transactions*. 65 FR 50312. Retrieved November 3, 2018 from: *https://aspe.hhs.gov/report/health-insurance-reform-standards-electronic-transactions*
[10] Department of Health and Human Services. Food and Drug Administration (August 7, 2018). *Future Format of the National Drug Code; Public Hearing; Request for Comments*. 83 FR 38666, 38668. Retrieved November 10, 2018 from: *https://www.federalregister.gov/documents/2018/08/07/2018-16807/future-format-of-the-national-drug-code-public-hearing-request-for-comments*

The multiple NDC formats create fundamental problems that inhibit and undermine the value of NDC as an identification number for drugs outside of the NDC registry:

- **Breaks the connection between systems:** Computer systems recognize the different NDC formats as four different numbers. This breaks the connection between those systems, inhibiting the collective use of those systems to enhance the quality and amount of data available to support operational, regulatory, and clinical processes. It also inhibits automated connections between and among systems to push/pull/view more data, automate business process, support analytics and reporting, etc. Moreover, it creates a high-maintenance, error-prone environment that adds complexity, inaccuracy and cost.
- **Undermines NDC integrity:** Different stakeholders using different formats for different systems creates an environment where downstream users are "translating" NDCs from one format to another using visual, manual, or some automated approach. Moreover, there can be multiple translations – backward (i.e., extracting an NDC from one format) **and** forward (i.e., putting the extracted NDC into another format). These downstream translations create data quality issues that undermine the integrity of the NDC in IT systems.

  Example 1: the HIPAA 11-digit NDC uses the number zero as both a value and a pad

  - A dispenser has an NDC in the HIPAA 11-digit format (5-4-2). They need the NDC in its original 10-digit format. However, the number zero is used as both a value and a pad in the HIPAA 11-digit format. Therefore, there is no reliable way to ascertain the original 10-digit NDC structure if there is more than one leading zero in the different segments. For example, NDC 09999-0123-01 could be:
    - 9999-0123-01
    - 09999-123-01 or
    - 09999-0123-1

  Example 2: once the hyphens are removed, there is no reliable way to know where the hyphens were in the original NDC structure

  - When an NDC is encoded in a UPC, the hyphens are removed. When a dispenser scans the barcode, the 12-digit GTIN embedding the NDC (without hyphens) is captured in their system.
  - Dispensers often strip away the first digit (i.e., the "3" prefix for the *Labeler Code*) and the last digit (i.e., the check digit) to isolate the 10-digit NDC embedded within. However, there is no way to know where the dashes were in the original NDC. The retrieved NDC 9999912345 could have been assigned as:
    - 9999-9123-45
    - 99999-123-45 or
    - 99999-1234-5
  - Dispensers select the structure they believe was used in the original NDC using visual, manual, or some automated approach, combined with their experience and ingenuity.
  - Then, they translate that to the HIPAA 11-digit format.

  This type of bi-directional translation of NDCs is error-prone and undermines the integrity of NDCs in the systems and applications that use them. Moreover, these efforts demonstrate the burden that has been put on dispensers and industry in general to develop their own approaches to navigate this non-standardized environment and make the systems built on NDC work.

3.2 Impact of transitioning from a 5-digit labeler code to a 6-digit labeler code

The NDC was created to support the Drug Listing Act of 1972[11], which requires each registered drug establishment to provide FDA with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by the establishment for commercial distribution.[12] Drug products are identified and reported using the NDC. If NDC was used only by these two parties (i.e., drug establishments and FDA) and only for this purpose (i.e., providing a list of drugs to FDA), there would be very little impact from the transition from a 5-digit *Labeler Code* to a 6-digit *Labeler Code*.

However, over the years, NDC has been adopted, incorporated, and used in many other government applications, including:

- federal statutory and regulatory requirements (e.g., DSCSA, HIPAA, barcode rule, SNI, CMS, DEA, CDC, etc.) and
- state statutory and regulatory requirements (e.g., Medicaid; State Boards of Pharmacy; etc.).

These requirements infused NDC into numerous supply chain functions (e.g., pharmaceutical labeling and packaging, prescribing, dispensing, reimbursement, safety, clinical management, supply chain management, etc.) across all stakeholders in the healthcare supply chain (e.g., manufacturers, distributors, pharmacies, providers, payers, etc.). In addition, standards organizations that operate in the healthcare space have also incorporated accommodations for NDC within their standards in order to support these requirements for their users (e.g., GS1, HL7, X12, etc.).

Many of the technologies and standards impacted by NDC are either hard-coded (i.e., fixed, 10-digit field lengths) and/or directly impacted by a change to the length of the NDC. Databases, IT systems, electronic transactions, scanning hardware, labeling, packaging lines, and many other areas will require change.

GS1 US and its members believe that regardless of which option or approach is taken for the future format of NDC, the transition will have significant, widespread impact.

Considering the number of the parties, systems, and processes impacted, our industry members believe it will be comparable to an industry-specific Y2K.

4 Recommendations

GS1 US launched the *New NDC Format Workgroup* to support the development of these comments. Through this workgroup, GS1 US worked directly with industry members to assess the impact of the transition to a new NDC format, analyze issues and options, and develop recommendations for the path forward.

The workgroup included participants from across the supply chain, including manufacturers, distributors, providers, pharmacies, associations, educational institutions, and solution providers. This dedicated group of seasoned professionals brought deep subject matter expertise to the numerous, complex topics involved. GS1 US appreciates their invaluable insight, and the lively discussion of the important questions at hand.

[11] 21 U.S.C. 360
[12] United States Department of Health and Human Services. Food and Drug Administration. *ANNEX B - The Drug Listing Act of 1972 Information Bulletin*. Accessed November 11, 2018 at: https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm079592.htm

4.1 Comment on Options A, B and C

FDA proposed four options for the future format of NDC. In its analysis, FDA noted risk of collision (i.e., the same NDC could be assigned to more than one product) is present with Option A, B and C.[13]

Because unique identification of pharmaceuticals is crucial for patient safety, the workgroup considered risk of collision to be a fatal flaw for any option. Therefore, the workgroup does not believe that Options A, B, or C are viable options for the future format of NDC.

4.2 Recommended Approach

Based on the discussions in the GS1 US *New NDC Format* workgroup, industry's ultimate vision and goal is for NDC to have a standards-based format similar to FDA Unique Device Identifiers for medical devices[14]. For example, an NDC based on GS1 Standards would be a GTIN. This would promote interoperability and data integrity across stakeholders and systems, and resolve issues related to NDC's current non-standardized format (e.g., barcoding; unique identification at every packaging level; data quality; etc.). Moreover, use of standardized NDC format would enable collective use of systems to enhance the quality and amount of data available to support supply chain, regulatory, and clinical processes.

However, the workgroup recognizes how engrained the 3-segment NDC is across the dispenser community today. For example:

- Manual data entry is widely recognized as error-prone and inefficient as compared to automated data capture (e.g., barcodes). In addition, the prevalence of smart-phones and intelligent personal assistants have advanced a culture where people are more accustomed to and reliant of technology for many things that used to be done manually. Nonetheless, there is a historical, embedded sense of security gleaned by dispensers in having a three-segment NDC in human-readable format presented on the label.
- Today, best practice for master data management of supply chain information is to create an authoritative database where product identifiers are stored with all associated master data. Users scan a barcode to capture the product identifier, and then their system uses that identifier to pull the needed product data from the authoritative database and display it to the user (e.g., the labeler, product type and packaging type). But, decades of working with NDCs with segments to represent that information has created a cultural dependency on a segmented format in the dispenser community, even though the segment only offers a number representing data (e.g., labeler code, product code, packaging code) not the actual data (i.e., labeler name, product description, packaging type).

Change is difficult, and our workgroup recognized the need to support the dispenser community in the transition. Therefore, the workgroup recommends a two-step approach for the future format of NDC:

- **Step 1: Implement FDA Option D**
- **Step 2: Implement a standards-based format for NDC**

[13] United States Department of Health and Human Services. Food and Drug Administration. *Public Hearing: Future Format of the National Drug Code*. Accessed October 20, 2018 at: https://www.fda.gov/drugs/newsevents/ucm574488.htm

[14] United States Department of Health and Human Services. Food and Drug Administration (September 2013). *Final Rule – Unique Device Identification System*. 78 FR 58785. Retrieved November 3, 2018 from: https://www.federalregister.gov/documents/2013/09/24/2013-23059/unique-device-identification-system

4.3 Step 1 – Implement FDA Option D

4.3.1 Description

Step 1 is FDA adoption of Option D as the format for NDC.

FDA description of Option D:

- Harmonize NDC assignment at FDA with other stakeholders by moving toward a uniform NDC in a 6-4-2 sequenced format at a future date.
- Once FDA starts assigning 6-digit *Labeler Codes*, all NDCs (new and existing) would be required to be presented in a 6-4-2 sequenced format.
- Existing NDCs would be converted from their existing format by adding leading zeros to the short segments.
- This would create one standard configuration for all NDCs and provide the industry with more product or package codes.

4.3.2 Pro's of Option D

- Supports dispensers in the transition to a standardized format by maintaining the three-segment structure based on *Labeler Code*, *Product Code*, and *Package Code* for additional time
- Provides a uniform NDC length and structure
  - Although it still would not be a standard, this would be a step forward for industry because it could help eliminate some of the variability that is undermining the integrity of the identifier throughout the channel.
- Stakeholders can begin transitioning existing NDCs to the new format (6-4-2) in internal systems immediately
- Streamlines and simplifies GS1 Company Prefix management for manufacturers
  - Manufacturers have noted that needing to use a specific Company Prefix (i.e., based on the *Labeler Code*) for all products intended for the U.S. complicates Company Prefix management across global manufacturing operations. Therefore, separating NDC from the GTIN enables them to use whatever Company Prefix they want to generate the GTIN, which will streamline and simplify GS1 Company Prefix management across global operations.
- Provides a bridge to help industry transition to the standards-based format for NDC in Step 2
  - Under Option D, GS1 barcodes will carry NDC and GTIN separately (see *above*), and both will be captured during scanning
    - Existing GTINS with NDC embedded can still be used for the GTIN (and the NDC in the required FDA format will be carried in the new AI)
  - Introduction of standalone GTIN and NDC in Option D supports dispensers in getting used to GTINs and allows for a glide path to GTIN as a standardized format for NDC (see *Step 2* below)

4.3.3 Con's of Option D

- UPC can no longer be used to encode NDCs. The new 6-4-2 format for all NDCs eliminates the ability to use UPC barcodes for any NDCs (i.e., neither existing NDCs based on the 4 or 5-digit *Labeler Code* nor new NDCs will be able to use UPC)
  - A GS1-128 barcode may be used instead of a UPC, however that may require changes to dispensing systems and scanners, and may drive product packaging changes due to space limitations

- Barcode symbol size and capacity considerations may complicate and/or limit the GS1 barcode options
  - Could necessitate 2D barcodes, which would require dispensers to upgrade scanning hardware and software to read data matrix barcodes (which they may not have done even by this compliance date)
  - When considering, it is important to differentiate retail pharmacies from provider pharmacies in terms of their drivers and resources for transitioning to 2D scanning systems to support data matrix
- Potential risk of collision: 6-digit *Labeler Code* cannot start with zero to avoid duplication with "padded" 5-digit
- Maintains independent segments which are a source of data integrity issues downstream
- Continues the use of hyphens which are a challenge to IT systems and a source of data integrity issues downstream
- Promotes two identifiers for the same item: NDC and GTIN

4.3.4 Additional Comments

- The new Option D format has significant *impact on GS1 barcoding of NDC*, most notably that UPC barcodes will no longer be an option for any NDC (current or future). Although adjustments to the FDA linear barcode rule may take place prior to implementation of Option D, FDA should be aware that they will likely need to revisit that rule in advance of and as preparation for Option D implementation.
- The SNI Guidance will need modification in advance of and as preparation for Option D implementation. The SNI guidance defined SNI as NDC + serial number. However, as described *above*, this does not support unique identification at every level of the packaging hierarchy, and therefore is not sufficient to support traceability. GS1 members had been able to overcome this challenge by embedding the NDC in a GTIN. However, with Option D, members will no longer have this technical mechanism.
- Once NDC is independent of the GTIN and in its own AI, DSCSA verification, tracing, notification, etc. cannot be based on SNI alone anymore without risk of collision between package and case SNIs. Therefore, additional guidance may be needed for DSCSA stakeholders.
- FDA should consider providing guidance that the hyphens should only be used for printing the human-readable NDC on packages and should not be included systems and databases.
- FDA should consider providing guidance that NDCs should be stored in IT systems and databases in an alpha-numeric field (not text) to avoid stripping away any leading zeros.
- FDA should conduct a mathematical and/or algorithmic analysis of the Option D format in the context of (i) existing NDC formats, (ii) the new 6-digit labeler code, and (iii) the practice of removing hyphens. Such an evaluation should be able to identify any potential *collision or translation issues* with the new NDC format.
  - This will enable FDA to identify any issues in advance of implementation and put rules in place to help avoid them (e.g., what value to begin assigning 6-digit *Labeler Codes*; use of zero in leading and trailing positions of each segment; etc.). For example, our workgroup noted that 6-digit *Labeler Codes* should not start with zero in order to avoid collision with padded 5-digit *Labeler Codes*.
  - Any such rules could reduce NDC capacity within the 6-digit Labeler Code scheme (e.g., the number of 6-digit *Labeler Codes* available; the number of *Product Codes* possible for a *Labeler Code*; the number of *Packaging Codes* available; etc.). Therefore, the mathematical/algorithmic analysis should include estimated NDC capacity within the 6-digit *Labeler Code* scheme in light

of any necessary rules to enable FDA to update the projected lifespan and timelines for the future NDC format accordingly.

- Although the compendia and industry have worked very hard with the existing NDC formats to avoid collision and manage allocation issues on their own, the best approach is for FDA to identify any potential issues in advance and provide guidance to avoid them. This will help to minimize the data integrity issues, especially when translations occur downstream.

4.4 Step 2: Implement a standards-based format for NDC

4.4.1 Description

Step 2 is FDA adoption of a standards-based format for NDC.

Based on the discussion in the GS1 US *New NDC Format* workgroup, industry's ultimate vision and goal is for NDC to have a standards-based format similar to FDA Unique Device Identifiers for medical devices. For example, an NDC based on GS1 Standards would be a GTIN. This would promote interoperability and data integrity across stakeholders and systems, and resolve issues related to NDC's non-standardized formats (e.g., barcoding; unique identification at every packaging level; data quality; etc.). Moreover, use of standardized NDC format would enable collective use of systems to enhance the quality and amount of data available to support supply chain, regulatory, and clinical processes. These capabilities and the associated benefits are why initiatives to adopt standards and implement them across healthcare are so important for advancing delivery of care, patient safety and cost reduction in U.S. healthcare.

4.4.2 Pro's

- UPC is a viable GS1 barcode option for existing and future NDCs
- Provides reliable, uniform, standards-based structures
- Single format across IT systems (e.g., GTIN is stored in a 14-digit, right justified, text field with leading zero's as needed)
- Supports unique identification at every level of the packaging hierarchy to support DSCSA traceability and other supply chain processes
- Automated translations with backward and forward compatibility based on standards incorporated into systems
- Aligns identification of drugs with identification of medical devices for providers and payer systems
- Significant amount of standardized sharing mechanisms already in place (e.g., barcodes; radio frequency identification (RFID); EDI and XML transactions/messages; Electronic Product Code Information Services (EPCIS); Global Data Synchronization Network™ (GDSN®); etc.)
- Available in many systems today (e.g., where NDC is represented by a GTIN)
- Compatible with IT best practices
  - Eliminates independent segments
  - Eliminates hyphens
- Promotes a single identifier for each item
- Leverages systems that have been put in place for devices and DSCSA
- Global approach
  - U.S. leadership for global harmonization efforts

- More consistent with direction other countries are taking: other countries adopting GTIN format for regulatory pharmaceutical identification include:
  - Belgium
  - Bulgaria
  - Croatia
  - Cyprus
  - Czech Republic
  - Denmark
  - Estonia
  - Finland
  - Hungary
  - Iceland
  - Ireland
  - Latvia
  - Liechtenstein
  - Lithuania
  - Luxembourg
  - Malta
  - Netherlands
  - Norway
  - Poland
  - Romania
  - Slovakia
  - Spain
  - Sweden
  - Switzerland
  - United Kingdom
- More collaborative regulator forum

- Streamlines and simplifies GS1 Company Prefix management across global operations for manufacturers
- Lowers administrative burden to FDA (because it outsources NDC assignment to standards bodies)

4.4.3 Con's

- Eliminates the three-segment structure for visually interpreting labeler, product and package (although the actual data for manufacturer, product, and packaging and many other master data elements will be available in their systems – see above *discussion*)
  - Culture change
  - Need for industry education
  - May be mitigated with other human-readable and understandable components on labels

4.4.4 Additional Comments

- Adopting standardized format for NDC will resolve the issues in the SNI Guidance due to NDC not being unique at each packaging level. The standardized NDC format will mean that each packaging level will have a unique NDC, and thus NDC + serial number will then be able to provide unique, NDC-based identification to support traceability.
- The standardized format will also resolve the issue of DSCSA incorrectly codifying the application of SNI to packages and cases.

4.5 Transition

To support the transition, the workgroup provides the following recommendations:

- The final guidance on the new NDC format should be published no later than 2020.
- Do not implement any changes to new NDC Format until after DSCSA interoperability is fully implemented. The period between 2019 – 2023 should remain status quo to not interfere with or complicate implementation of DSCSA.
- Option D should not be implemented until 2028 at the earliest to provide for stabilization after full DSCSA interoperability implementation. (This will include the new GS1 AI for the 12-digit NDC.)
- The strategic vision for a standardized format for NDC (e.g., GTIN) is recommended for the 2030's.

4.6 Timeline

The GS1 US workgroup proposes the following timeline for implementation activities for Option D and the standardized NDC format:

	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034
Milestones	Written Comments to FDA		FDA final Guidance			DSCSA Interoperability	Industry DSCSA Stabilization				New NDC format: Option D (6-4-2 with 6-digit Labeler Code and GS1 AI)			New standards-based NDC format (e.g., GTIN)			
GS1				GS1 to add NDC as an AI													
Rx MFG's								Packaging line change for NDC AI and 12 digits - should be a single set date									
All Parties								IT System Changes for new NDC Format				IT System Changes for GTIN as the Primary Identifier					
US FDA			Provide final guidance on new NDC Format		Modify Linear Barcode Rule to accommodate the NDC AI		System and Rule Making changes		Look at SNI for uniqueness of Labeler Code								
All Trading Partners & Regulators								Convert to GS1 DataMatrix with new NDC Format				Update software systems to recognized the GTIN					
Dispensers & HC Providers								Update Scanner and associated software to read 2D barcodes				Update software systems to recognized the GTIN					
Other Federal Agencies							Update/align regulations: HIPAA, CMS, DEA (ARCOS) etc.					Update/align regulations for using the GTIN: HIPAA, CMS, DEA (ARCOS) etc.					
State Board of Pharmacies								Update operating systems to recognize the 6-digit NDC				Update operating systems to recognize the GTIN					
Other State Agencies								Update operating systems to recognize the 6-digit NDC				Update operating systems to recognize the GTIN					

5 Appendix A: GS1 Healthcare US New NDC Format Workgroup

GS1 US would like to recognize the GS1 Healthcare US New NDC Format Workgroup for their participation in the development of these comments.

- 1WorldSync
- 3M
- Abbott Laboratories
- AbbVie
- Adents
- Adept Group LLC
- Albertsons Companies
- AmerisourceBergen Corporation
- Amgen, Inc.
- Apotex Corp
- AstraZeneca Pharmaceuticals
- Atlantic Health
- AXWAY
- Baxter International Inc.
- Bayer HealthCare LLC
- BD (Becton Dickinson & Co.)
- BrandSure, LLC
- Bristol-Myers Squibb
- Cardinal Health
- Center for Supply Chain Studies
- ConsortiEX, Inc.
- Covectra
- CVS Health
- Department of Veteran Affairs
- EMD Serono
- Excellis Health Solutions
- Franciscan Missionaries of Our Lady Health
- Fresenius Kabi Deutschland GmbH
- Geisinger Health System
- Genentech
- GS1
- GS1 Canada
- GS1 Healthcare
- GS1 US
- Healthcare Distribution Alliance (HDA)
- Healthcare Supply Chain Association (HSCA - formerly HIGPA)
- Immunization Services Division, NCIRD, CDC
- Johnson & Johnson Services, Inc. / Johnson & Johnson Consumer Inc.
- Kaiser Permanente
- McKesson Corporation
- Movilitas Consulting LLC
- Nestle Health Science/ Nestle Professional
- Optel Vision
- Pfizer, Inc.
- Reed Tech
- Systech International
- TraceLink, Inc
- University Hospital Schleswig-Holstein
- USDM Life Sciences
- ValueCentric LLC
- Vizient
- Walgreens Company

6 Appendix B: About GS1 Standards

The GS1 System is an integrated suite of global standards that provides for accurate identification and communication of information regarding products, assets, services and locations. Using GS1 Identification Numbers, companies and organizations around the world are able to globally and uniquely identify *physical things* like trade items, assets, logistic units and physical locations, as well as *logical things* like corporations or a service relationship between provider and recipient. When this powerful identification system is combined with the GS1 Global Data Synchronization Network™ (GDSN®), the connection is made between these physical or logical things and the information the supply chain needs about them.

Global Location Number (GLN)

The Global Location Number (GLN) is the globally unique GS1 Identification Number for locations and supply chain partners. The GLN can be used to identify a *functional entity* (like a hospital pharmacy or accounting department), a *physical entity* (like a warehouse or hospital wing or even a nursing station), or a *legal entity* (like a health system corporation). The attributes defined for each GLN [e.g., name, address, location type (e.g., ship to, bill to, deliver to, etc.)] so that each GLN is specific to one unique location within the world.

Global Trade Item Number (GTIN)

The Global Trade Item Number® (GTIN®) is the globally unique GS1 Identification Number used to identify "trade items" (i.e., products and services that may be priced, ordered or invoiced at any point in the supply chain). GTINs are assigned by the brand owner of the product and are used to identify products as they move through the global supply chain to the hospital or ultimate end user. The GTIN uniquely identifies a product at each packaging level (e.g., a blister of two aspirin tablets; a bottle of 100 aspirin tablets; etc.).

Global Data Synchronization Network (GDSN)

Each user not only defines and maintains its own GLNs and GTINs with their associated attributes, but is also responsible for sharing this information with its supply chain partners. To support those efforts, the Global Data Synchronization Network™ (GDSN®) provides an efficient and effective approach to (1) storing GS1 Identifiers with their associated attributes, (2) checking to make sure that the identifiers and attributes are properly formatted pursuant to GS1 Standards, and (3) sharing that information with supply chain partners. The GDSN offers a continuous, automated approach to data management so that supply chain information is aligned among trading partners, increasing data accuracy and driving costs out of the supply chain.

EPC Information Services (EPCIS)

The EPC Information Services (EPCIS) standard defines a data-sharing interface that enables supply chain partners to capture and communicate data about the movement and status of objects in the supply chain. The EPCIS specification provides technical standards, as well as a standardized set of service operations and associated data elements. In addition, the EPCIS standard also incorporates data standards for how to populate EPCIS data elements. (See Core Business Vocabulary below.)

Core Business Vocabulary (CBV)

The Core Business Vocabulary (CBV) provides data standards for populating EPCIS data elements. The CBV provides lists of acceptable values for how to express what business process was operating on an object and the status of the object upon exiting the process. It includes syntaxes, vocabularies, and element values (with definitions).

IAPMO

In this publication, the letters "U.P.C." are used solely as an abbreviation for the "Universal Product Code" which is a product identification system. They do not refer to the UPC, which is a federally registered certification mark of the International Association of Plumbing and Mechanical Officials (IAPMO) to certify compliance with a Uniform Plumbing Code as authorized by IAPMO.

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