

GS1 DataMatrix

Version 1.1

July 2021



This White Paper discusses the issues associated with the removal of the GS1 UPC-A and provides recommendations in supporting the requirements for manufacturers to affix or imprint the new product identifier to each package and homogenous case of a product.

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Published by:
National Council for Prescription Drug Programs, Inc.

Publication History:
Version 1.0 September 2017
Version 1.1 July 2021

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1. PURPOSE

Some manufacturers, decided to remove the traditional GS1 UPC-A and replace it with a GS1 DataBar due to space limitations on the lowest saleable unit packaging labels to meet the November 2017 requirements for the Drug Quality and Security Act (DQSA) as well as the *Bar Code Label Requirement for Human Drug Products and Biological Products* published February 24, 2004 Federal Register¹. As a result, issues arose downstream for stakeholders in the supply chain. Early removal of the GS1 UPC-A caused adverse effects on processing efficiency and patient care for the wholesaler and dispenser communities.

This white paper discusses the issues associated with removal of the GS1 UPC-A and provides recommendations in supporting the requirements for manufacturers to affix or imprint the new product identifier to each package and homogenous case of a product.

In anticipation of the DQSA's 2023 requirements NCPDP continues to be concerned with the GS1 2D DataMatrix barcode and the information contained within (Lot, Serial, Expiration, etc.). This white paper discusses additional issues/concerns as the industry continues to develop solutions to meet the final deadlines.

It is the intention of the NCPDP 2D Barcode Implementation Task Group for manufacturers to distribute this document to the appropriate staff, including those responsible for implementation of any changes to the product identifier as related to this legislation.

¹ [Federal Register 69 FR 9120](#)

2. OVERVIEW

The DQSA was signed into law on November 27, 2013. Title II of the DQSA is the Drug Supply Chain Security Act (DSCSA) which outlines the critical steps to build an electronic, interoperable system to identify and trace most prescription drugs as they are distributed in the United States from the point of manufacturer to the dispensing location.

This law requires the Food and Drug Administration (FDA) to develop standards, guidance documents and pilot programs, as well as conduct public meetings and other efforts necessary to support an efficient and effective implementation. Drug manufacturers, wholesale drug distributors, repackagers and many dispensers are currently working in cooperation with the FDA to develop a new system that meets these requirements.

The system will facilitate the retention, retrieval and exchange of information regarding where a drug is or has been in the supply chain at the individual package level. The new system will:

- Enable verification of the legitimacy of the drug product identifier down to the package level
- Enhance detection and notification of illegitimate products in the drug supply chain
- Be operational by November 27, 2023

By November 27, 2017, (enforcement discretion by the FDA² of November 26, 2018), each manufacturer and by November 27, 2018, each repackager was required to affix a 2-dimensional DataMatrix product identifier on all saleable packages and sealed homogenous cases at the lowest saleable unit packaging level. Supply chain trading partners agreed to use the GS1 2D DataMatrix barcode as the 2-dimensional DataMatrix product identifier. The GS1 2D DataMatrix barcode must be encoded with the product's National Drug Code (NDC)³, Expiration Date, Serial Number and Lot Number to comply with FDA guidance. The industry has decided to utilize the Global Trade Item Number (GTIN) to encode the NDC within the GS1 2D DataMatrix barcode.

Key Dates

- **Nov. 2017 (2018 discretion)**
Manufacturers product identifier compliance date
- **Nov. 2018**
Repackager compliance date
- **Nov. 2020 (2023 discretion)**
Pharmacy compliance date
- **Nov. 2023**
Supply chain compliance date to exchange information

As of November 27, 2020, the FDA requires dispensers to engage in transactions only if a product is encoded with the GS1 2D DataMatrix barcode that contains NDC, serial number, lot number and expiration date unless the product is considered “grandfathered” or exempt under the DSCSA. As a result, many dispensers have updated their older scanning technology throughout the dispensing process so it can interpret the traditional GS1 UPC-A as well as the GS1 2D DataMatrix barcodes. However, the industry has reported implementation issues regarding the quality of the GS1 2D DataMatrix barcode.

² <https://www.fda.gov/media/106198/download>

³ Product Identifiers Under the Drug Supply Chain Security Act Questions and Answers Guidance for Industry: <https://www.fda.gov/media/116304/download>

Dispensers must be able to verify the product identifier on suspect products (e.g., potentially counterfeit, diverted or otherwise unfit for distribution, etc.) for at least 3 packages or 10% of suspect products, whichever is greater by November 27, 2020, (enforcement discretion by the FDA⁴ of November 27, 2023).

2.1 USE OF THE GS1 UPC-A

The GS1 UPC-A is the linear barcode currently utilized by many stakeholders throughout the supply chain to identify the product's NDC number using barcode scanning technology. The GS1 UPC-A uses the GTIN-12, which contains the NDC for prescription drug products. The FDA NDC is a unique 10-digit number used to identify and describe the individual product and is subsequently used throughout pharmacy workflow. The NDC number is the key to product identification throughout the supply chain.

Since the *Bar Code Label Requirement for Human Drug Products and Biological Products* did not specify the type of linear barcode that must be printed on product labels some manufactures are utilizing linear barcodes that many pharmacies cannot read with current barcode scanning technologies such as the GS1 DataBar. Dispensers historically relied on the scanning of the GS1 UPC-A at various points in the prescription dispensing process including, but not limited to, the following:

1. Data entry
2. Saleable and non-saleable returns
3. Inventory management
4. Filling prescriptions/quality check
5. Point of sale (OTCs)
6. Billing and invoicing
7. Pill counting devices, quality checks (when medicine is removed from the manufacturer's stock bottle)
8. Quality check prior to direct patient administration

As the industry transitions to new technology that is able to read the GS12D DataMatrix barcode and/or GS1 DataBar to perform the functions listed above, it is imperative the GS1 UPC-A continue to exist on product packaging to enable stakeholders to determine the product's NDC number through automation.

2.2 USE OF HUMAN-READABLE PRODUCT IDENTIFIER

To aid healthcare practitioners that require product information, such as checking the expiration date or recording the NDC and lot number into a patient record, the FDA provided subsequent guidance in September 2018 regarding the human-readable portion of the product identifier⁵. In the guidance, the FDA recommends the human-readable product identifier appear in the following format:

⁴ <https://www.fda.gov/media/131005/download>

⁵ <https://www.fda.gov/media/116304/download> (See section IX Questions and Answers - #4)

NDC: [insert product's NDC] – typically located on the front panel

SERIAL: [insert product's serial number]

LOT: [insert product's lot number]

EXP: [insert product's expiration date]

The NDC and serial number are the two components of the Standardized Numerical Identifier (SNI) as defined in section 581(20) of the DSCSA/DQSA Title II/Federal Food, Drug, and Cosmetic Act (FD&C) Act. The drug package label must include the product identifier (the NDC, serial number, lot number and expiration date) in both the human-readable form and machine-readable, GS1 2D DataMatrix barcode form. While the NDC is encoded within the GTIN, the NDC must be listed separately in human-readable format on the package for identification purposes. As long as the NDC is on the label in its FDA-assigned 3-segment format, the associated GTIN may also be imprinted on the label.⁶

FDA recommends the human-readable expiration date on the drug package label include a year, month and non-zero day in YYYY-MM-DD format if using only numerical characters or in YYYY-*MMM*-DD if using alphabetical characters to represent the month. If there are space limitations on the drug package, the human-readable text may include only a year and month, expressed as YYYY-MM if using only numerical characters or YYYY-*MMM* if using alphabetical characters to represent the month. FDA recommends using a hyphen or a space to separate the portions of the expiration date.

Variations may exist in how to abbreviate the human-readable portion of the label for the NDC, serial number, lot number and expiration date. Unfortunately, inconsistencies regarding how this human-readable information is displayed continues to cause operational challenges and more importantly put patients at risk.

Issues encountered:

- Inconsistent placement of information
 - Human-readable information is not located in a consistent location on a label, causing pharmacy personnel valuable time to locate on the package to manually check NDC, lot or expiration date.
- Inability to read information
 - Selection of ink coloration other than black, poor ink quality that maybe smeared and reflective surfaces all affect the ability to read the human-readable information on the label.
- Inaccurate information
 - NDC is not always formatted with dashes to ensure proper interpretation.
 - Expiration date may differ from the date presented in the GS1 2D DataMatrix barcode (e.g., barcode may indicate product expiration of 1/15/2022 while human-readable presents 1/2022).
- Lack of serialization on all packaging components

⁶ <https://www.fda.gov/media/116304/download> (See section IX Questions and Answers - #5)

- Any saleable units with an outer package (which may be discarded prior to dispensing) containing the product identifier (e.g., birth control pills). Thus, making it impossible to perform verification requests prior to dispensing if outer package is discarded.

2.3 USE OF GS1 2D DATAMATRIX BARCODE

Section 582(a)(9) of the FD&C Act requires the product identifier to be in a “2-dimensional DataMatrix barcode” for packages and in a “linear or 2-dimensional DataMatrix barcode” for homogenous cases, which can be verified using “human-readable or machine-readable methods.” The industry has decided to adopt the GS1 2D DataMatrix barcode as the 2-dimensional DataMatrix barcode.

If space permits, the GS1 2D DataMatrix barcode should be affixed or imprinted near or next to the human-readable portion of the product identifier on a package. FDA believes this placement will help downstream trading partners (repackagers, wholesale distributors and dispensers) associate the information encoded in the GS1 2D DataMatrix barcode with the human-readable information.

Some trading partners may utilize the GS1 2D DataMatrix barcode to electronically read or retrieve the encoded information for reasons such as data entry for inventory purposes, patient medical records or product verification. Positioning the GS1 2D DataMatrix barcode near the human-readable portion of the product identifier may help reduce the confusion when a product has multiple types of barcodes on the label because they are either required by law or are included voluntarily for other purposes (e.g., QR codes).

The GS1 2D DataMatrix barcode formatted specifically for compliance for DSCSA includes:

- GTIN
- Serial Number
- Lot Number
- Expiration Date

It should be noted the GS1 2D DataMatrix barcode includes a GTIN, not the product NDC. While the industry’s practice is to use a GTIN that may incorporate the digits of the NDC, the GTIN typically contains additional digits and is not in the 3-segment format by which the NDC is defined in FDA regulations. Moreover, FDA has expressed concern⁷ that use of the GTIN alone in the human-readable portion of the product identifier could lead to improper identification of the NDC and drug product. If the NDC is on the label in its FDA-assigned 3-segment format, a company may also voluntarily affix or imprint the associated GTIN on the label.

⁷ <https://www.fda.gov/media/116304/download> Product Identifiers Under the Drug Supply Chain Security Act Questions and Answers Guidance for Industry (September 2018)

Unfortunately, inconsistencies regarding where and how this barcode is displayed continue to cause operational challenges similar to those listed in section 2.2 above:

- Inability to scan GS1 2D DataMatrix barcode⁸
 - Selection of ink coloration other than black, poor ink quality that maybe smeared and reflective surfaces⁹.
- Inaccurate information
 - Expiration date may differ from the date presented in the human-readable information (e.g., barcode may indicate product expiration of 1/15/2022 while human-readable presents 1/2022).
- Barcode Traffic
 - Numerous barcodes located too closely together causes operational issues when trying to scan the intended barcode.
 - Numerous 2D barcodes (DataMatrix and QR codes) causes confusion to users due to not knowing what barcode is intended for DSCSA compliance which will add more time to receiving and inventory management.
- Lack of serialization on all packaging components
 - Any saleable units with an outer package (which may be discarded prior to dispensing) containing the product identifier (e.g., birth control pills). Thus, making it impossible to perform verification requests prior to dispensing if outer package is discarded.

⁸ https://www.gs1.org/docs/barcodes/GS1_General_Specifications.pdf

⁹

https://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=2314&language=en-US&PortalId=0&TabId=134

3. IMPACT TO THE INDUSTRY

An important requirement of the product tracing schema outlined in the DSCSA is the product identifier. Section 582 requires each package and homogenous case of product in the pharmaceutical distribution supply chain bear a product identifier in a human-readable form and the 2-dimensional DataMatrix barcode. The product identifier includes the product's standardized numerical identifier, lot number and expiration date. Additionally, the FDA's point of sale rule¹⁰ requires a linear barcode. Industry expectations are that all three data elements must be present on the package and are considered essential to ensure compliance with existing regulations.

It is critical that all three elements (GS1 UPC-A, Human-Readable and GS1 2D DataMatrix barcode) be present, readable on the product label and consistent with each other. The inability to read any of these elements or inconsistencies among these elements may result in a negative impact on patient safety. The human-readable identifier is used by dispensers as a "safety-check" and must be easily read and located to be utilized as such in pharmacy day-to-day operations (e.g., checking expiration dates, verification of NDC, etc.).

¹⁰ <https://www.federalregister.gov/documents/2004/04/07/04-7815/bar-code-label-requirement-for-human-drug-products-and-biological-products-correction>

4. FDA COMPLIANCE GUIDANCE

Due to several factors, most notably the current public health emergency due to COVID-19, the FDA announced in October 2020 the following “enforcement discretions.”

1. Delaying until 11/27/2023 the requirement regarding the wholesaler verification of prescription drug returns prior to resale
2. Delaying until 11/27/2023 the requirement for dispensers to verify product identifiers in suspect and illegitimate product investigations

Trading partners should continue to monitor both the FDA’s enforcement discretion changes and the industry’s progress¹¹ and continue to develop solutions to meet the DSCSA requirements.

¹¹ <https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa>

5. RECOMMENDATIONS

In order to minimize the impact to patient safety and supply chain workflow, NCPDP recommends manufacturers continue to imprint both the GS1 UPC-A and the GS1 2D DataMatrix barcode on product packaging of the DSCSA regulated products until November 27, 2023.

Human-readable information should be placed in a consistent location that can be easily located on the product package, barcodes should be printed using black, high quality ink on a white background to ensure scannability and NDCs should be formatted with dashes to ensure proper identification.

In instances where the product unit label is too small to support the continued use of both the GS1 UPC-A and the GS1 2D DataMatrix barcode, a potential alternative solution is to reduce the size of the UPC-A linear barcode, using X-Dimension formatting. However, manufacturers should keep in mind that the UPC-A barcode may become too small and potentially unreadable. NCPDP recommends manufacturers work with downstream partners to ensure readability of barcodes. Although other GS1 DataBars exist, they are less preferred based on current hardware and configuration changes necessary within existing systems throughout the supply chain.

Additionally, it is imperative that manufacturers provide consistent information between the GS1 UPC-A, the GS1 2D DataMatrix barcode and the human-readable formats. Failure to provide this consistency has potential detrimental impact on patient safety issues and can adversely affect a dispenser's operation.

While progress has been made, a recent report from GS1¹² indicates 13% of packages still lack readable barcodes with all four DSCSA elements.

¹²

https://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=2314&language=en-US&PortalId=0&TabId=134

6. CONCLUSION

Several obstacles surrounding barcode symbology within the pharmaceutical supply chain have arisen as a result of 2017 DSCSA requirements. As manufacturers modify packaging labels to meet these DSCSA requirements, downstream partners are noticing some disruptions in their automated processes that traditionally rely on scanning the product's GS1 UPC-A. The DSCSA product identifier requirements consume the limited space that remains on unit packaging labels, challenging manufacturers to implement space saving design solutions. Multiple manufacturers have decided to remove the GS1 UPC-A from the unit package and replace it with one of the various GS1 DataBar symbol types as a space saving solution.

While most dispensers have been able to obtain the necessary systems and technology to scan and utilize the data encoded in the GS1 DataMatrix 2D barcode, barriers to full implementation still remain including, but not limited to:

- Inconsistent placement of barcode information on labels
- Numerous barcodes grouped too closely together causes operational issues when trying to scan the intended barcode
- Ink coloration, poor quality or reflective surfaces making barcode information unreadable
- Lack of serialization on all packaging components

Additionally, the integrity of human-readable information on the package is critical to ensure that dispensers can implement final safety checks on medication prior to dispensing. NDCs must be formatted with dashes to ensure proper interpretation.

Therefore, NCPDP recommends all three elements (GS1 UPC-A, Human-Readable and GS1 2D DataMatrix barcode) be present, readable on the product label and consistent with each other. Specifically, NCPDP recommends the GS1 UPC-A remain on products until after the DSCSA final compliance date of 2023 to ensure that systems are fully capable of integrating the GS1 2D DataMatrix barcode throughout the supply chain.

7. APPENDIX A

7.1 DEFINITIONS

The terminology used throughout this document is consistent with the definitions below which come directly from the Public Law 113–54, 113th Congress, also known as the Drug Quality and Security Act (DQSA).

DISPENSER –

(A) is a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and

(B) does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5).

DISTRIBUTE OR DISTRIBUTION –

The sale, purchase, trade, delivery, handling, storage, or receipt of a product, and does not include the dispensing of a product pursuant to a prescription executed in accordance with section 503(b)(1) or the dispensing of a product approved under section 512(b).

EXCLUSIVE DISTRIBUTOR –

The wholesale distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer’s product to a subsequent repackager, wholesale distributor, or dispenser.

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. Additional information is available at www.gs1.org

GS1 US –

GS1 US®, a member of GS1® global, is a not-for-profit information standards organization that facilitates industry collaboration to 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®). Additional information is available at www.gs1us.org

MANUFACTURER – With respect to a product –

(A) a person that holds an application approved under section 505 or a license issued under section 351 of the Public Health Service Act for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product;

(B) a co-licensed partner of the person described in subparagraph (A) that obtains the product directly from a person described in this subparagraph or subparagraph (A) or (C); or

(C) an affiliate of a person described in subparagraph (A) or (B) that receives the product directly from a person described in this subparagraph or subparagraph (A) or (B).

PACKAGE –

(A) IN GENERAL – The smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product.

(B) INDIVIDUAL SALEABLE UNIT – For purposes of this paragraph, an ‘individual saleable unit’ is the smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser.

PRESCRIPTION DRUG –

A drug for human use subject to section 503(b)(1).

PRODUCT –

A prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution). For purposes of section 582, does not include blood or blood components intended for transfusion, radioactive drugs or radioactive biological products (as defined in section 600.3(ee) of title 21, Code of Federal Regulations) that are regulated by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021), imaging drugs, an intravenous product described in clause (xiv), (xv), or (xvi) of paragraph (24)(B), any medical gas (as defined in section 575), homeopathic drugs marketed in accordance with applicable guidance under this Act, or a drug compounded in compliance with section 503A or 503B.

PRODUCT IDENTIFIER –

A standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.

REPACKAGER – A person who owns or operates an establishment that repacks and relabels a product or package for –

- (A) further sale; or
- (B) distribution without a further transaction.

7.2 FAQs FROM GS1

GS1 US published a document for the pharmacy industry preparing for DSCSA FAQ's. The entire document is located at:

gs1us.org/industries/healthcare/standards-in-use/dscsa/frequently-asked-questions

Extracts from the GS1 FAQ document that may prove useful are included below.

Note: Entities should check the above referenced document for updated FAQs

7.2.1 WHAT IS A GS1 DATAMATRIX?

“GS1 DataMatrix is a two-dimensional (2D) barcode which may be printed as a square or rectangular symbol made up of individual squares. This representation is an ordered grid of dark and light squares bordered by a finder pattern. The finder pattern is partly used to specify the orientation and structure of the symbol. The data is encoded using a series of dark or light squares based upon a pre-determined size. The size of these squares is known as the X-dimension.

FDA regulations require pharmaceutical products to be marked with a linear barcode that carries their NDC. However, DSCSA requires pharmaceutical products to be marked with a barcode that carries their NDC, serial number, lot number, and expiration date. To satisfy these requirements, pharmaceutical manufacturers are marking products with a GS1 DataMatrix to satisfy DSCSA serialization/traceability requirements.”

7.2.2 HOW ARE APPLICATION IDENTIFIERS (AIs) USED IN A DATA CARRIER?

“There is an AI for each GS1 Identification Number (GTIN, SSCC, etc.). In addition, there are AIs for various types of secondary information to enable supply chain partners to communicate item-specific information wherever the barcode is scanned (e.g., expiration date; lot number; batch number; etc.). The following table lists the AIs that are relevant for DSCSA.”

Table 7-1 GS1 Application Identifiers Applicable to DSCSA Requirements

Use Case	Typical Barcode Type	Data Element	AI	Characters following the AI
Serialized drug (trade item)	GS1 DataMatrix	GTIN	01	14 digits
		Expiration Date	17	6 digits
		Batch/Lot Number	10	1-20 alphanumeric characters (*)
		Serial Number	21	1-20 alphanumeric characters (*)
Logistic unit (mixed case, pallet, etc.)	GS1-128	SSCC	00	16 digits
Location tag in a warehouse	GS1-128 GS1 DataMatrix	GLN	414	13 digits
		GLN Extension	254	1-20 alphanumeric characters (*)

(*) As this data element is of variable length, it must be followed by an <FNC1> terminator character unless it is the last data element in the barcode.

7.2.3 WHEN INCLUDING AIS IN BARCODES (SUCH AS GS1-128 OR GS1 DATAMATRIX), IS THERE A PREFERENCE AS TO WHAT AIS ARE INCLUDED (AS IT RELATES TO DSCSA)? ARE THERE ANY RESTRICTIONS?

“For an item-level package or homogeneous case, DSCSA requires a linear barcode or 2-dimensional GS1 DataMatrix with a product identifier affixed to, or imprinted upon, the package or homogeneous case corresponding to the standardized numerical identifier, lot number, and expiration date assigned to the product by the manufacturer or the repackager. The GS1 AIs corresponding to these DSCSA requirements are:

- GTIN AI (01)***
- Expiration Date AI (17)***
- Serial Number AI (21)***
- Batch/Lot Number AI (10)***

Note the sequence of the fixed length AIs first, followed by variable length as defined in 3.1.10.

The Healthcare Distribution Alliance (HDA) also recommends the use of these four AIs (01), (21), (17), and (10).

Case Quantity AI (30) is an additional identifier which may have been included in the past. The GS1 General Specifications and GS1 Standards no longer permit inclusion of case quantity represented by AI (30) in the GS1 DataMatrix. However, during a transition period where the historical GS1-128 primary and secondary linear barcode symbols are still in use, case quantity using AI (30) in the secondary symbol will continue to be used.

Applications reading barcodes must be prepared to process the barcode no matter the sequence of the AIs. Applications should not rely on the AIs appearing in any particular sequence. Applications reading barcodes must also be prepared to process the barcode even if it contains additional AIs beyond the above four.

While barcode reading applications should work correctly even if additional AIs are present, the use of additional AIs is discouraged to avoid possible problems if downstream barcode reading applications are not implemented correctly.”

7.2.4 WHICH OF THE BARCODES DO I NEED TO BE COMPLIANT WITH DSCSA IN NOVEMBER 2017?

“DSCSA requires pharmaceutical products to be marked with a barcode that carries its NDC (typically embedded within a GTIN), serial number, lot number, and expiration date. Prior FDA regulations require individual sale units to be marked with a linear barcode containing the NDC. To satisfy both of these requirements, many pharmaceutical manufacturers are marking products that move through a Point-of-Sale (POS) with both a GS1 UPC-A (to satisfy the FDA linear barcode requirement) FAQs by the Pharmaceutical Industry in Preparing for the US DSCSA R1.0 MAY 23 2017 © 2017 GS1 US ALL RIGHTS RESERVED Page 26 of 42 and a GS1 DataMatrix (to satisfy DSCSA serialization/traceability requirements). Higher-level groupings that do not cross point-of-sale such as homogeneous cases are marked with just the GS1 DataMatrix.”

7.2.5 CAN I HAVE MULTIPLE BARCODES ON MY PRODUCTS?

“Yes. You may have both a linear barcode as well as the required GS1 DataMatrix on your products. It is not recommended, however, to have more than one linear barcode or more than one GS1 DataMatrix since it may cause disruption to the distribution chain.”

7.3 BARCODE EXAMPLES PROVIDED BY GS1



GS1 BARCODE CHART

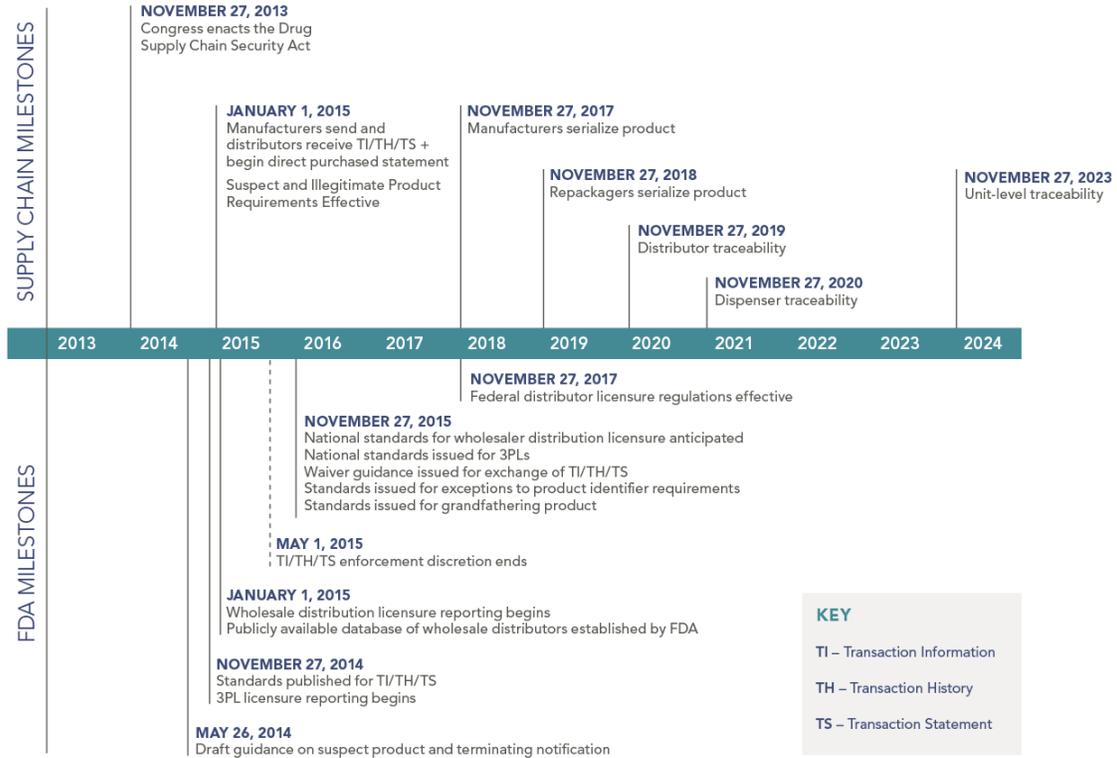
THIS LIST IS A SUBSET, NOT ALL INCLUSIVE

BARCODE	DISPLAY	NUMERIC DIGITS	DATA STRUCTURE	USAGE	USAGE EXAMPLES
EAN-8	 20123451	8	GTIN-8	The EAN-8 is used on small packages where the EAN-13 barcode would be too large. It encodes the Global Trade Item Number™ (GTIN-8) and is also used by retailers to identify privately owned brand products sold only in their stores.	Used on small retail items such as cosmetics, that cross point of sale applications.
UPC-A	 1414100754	12	GTIN-12	The UPC-A uniquely identifies a product for retail checkout. It encodes the Global Trade Item Number (GTIN-12) and is also used by retailers to identify privately owned brand products sold only in their stores.	Used on retail items that cross point of sale applications.
UPC-E	 01254598	12	GTIN-12	The UPC-E allows the use of U.P.C. barcodes on smaller packages where the UPC-A may not fit. It utilizes a zero-suppression method to compress the Global Trade Item Number (GTIN-12) into an 8-digit format.	Used on small retail items such as cosmetics, packs of chewing gum, and cigarettes.
EAN-13	 9876543210128 >	13	GTIN-13	The EAN-13 is used for marking products often sold at retail point of sale and general distribution. It encodes the Global Trade Item Number (GTIN-13). Used on retail product marking world wide. Also used by retailers to identify privately owned brand products sold only in their stores.	Used on retail items that cross point of sale applications such as periodicals, magazines, and books, and also used on coupons outside of North America.
ITF-14	 2 00 14141 98765 2	14	GTIN-12 GTIN-13 GTIN-14	The ITF-14 is generally used on higher packaging levels of a product, such as a case or carton. It lends itself well to be directly printed on corrugate material. It encodes three specific instances of the Global Trade Item Number (GTIN), (e.g., GTIN-12, GTIN-13, GTIN-14).	Used on standard product groupings such as a case of dish washing detergent (24 bottle count).
GS1 DATABAR™ TRUNCATED	 (01) 0 0614141 98765 8	14	GTIN-12 GTIN-13 GTIN-14	The GS1 Databar Truncated is designed for very small item identification and is mainly used within the healthcare industry. It cannot be scanned with Flatbed POS scanners. It encodes three specific instances of the Global Trade Item Number (GTIN), (e.g. GTIN-12, GTIN-13, GTIN-14).	Used on unit dose pharmaceuticals.
GS1 DATABAR STACKED OMNIDIRECTIONAL	 (01) 0 0614141 98765 8	14	GTIN-12 GTIN-13	The GS1 Databar Stacked Omnidirectional is used to condense the GTIN information into a more compact and square barcode suitable for use on small packages and loose fresh produce. It has the capability for omnidirectional scanning. Retail point-of-sale accepts GTIN-12 and GTIN-13 structures.	Used on very small consumer items GTIN Only (i.e., loose produce).
GS1 DATABAR LIMITED	 (01) 0 0614141 98765 8	14	GTIN-12 GTIN-13 GTIN-14	The GS1 Databar Limited is designed for very small item identification and are mainly used within the healthcare industry. It cannot be scanned with Flatbed POS scanners. It is "limited" to the use of zero '0' or one '1' in the first data position.	Used on very small healthcare items such as ampoules.
BARCODE	DISPLAY	ALPHA/NUMERIC	DATA STRUCTURE	USAGE	USAGE EXAMPLES
GS1-128	 (00) 0 0614141 000098765 8	UP to 48 characters	Concatenated strings using GS1 Application Identifiers	The GS1-128 uses a series of GS1 Application Identifiers (AIs) to include additional data such as Best Before Date, Batch/Lot Number, Quantity, Weight, and many other attributes. It also encodes the SSCC (Serial Shipping Container Code).	Used on large bulk items such as pallets or logistic units.
GS1 DATABAR EXPANDED	 (01) 0 0614141 00734 9	Up to 74 numeric or 41 alphabetic characters	Concatenated strings using GS1 Application Identifiers	The GS1 Databar Expanded is used for marking products that cross point of sale applications. It encodes any of the GS1 Identification Numbers plus supplementary AI Element Strings, such as Weight and Best Before Date, in a linear symbol that can be scanned omnidirectionally by suitably programmed scanners.	Used for additional information such as expiration date on fresh foods, and also used on coupons in North America.
GS1 DATABAR EXPANDED STACKED	 (01) 0 0614141 00734 9 (17) 111231 (10) A1B2C3D4	Up to 74 numeric or 41 alphabetic characters	Concatenated strings using GS1 Application Identifiers	The GS1 Databar Expanded Stacked is used for marking products that cross point of sale applications. It encodes any of the GS1 Identification Numbers plus supplementary AI Element Strings, such as Weight and Best Before Date, in a stacked linear symbol that can be scanned omnidirectionally by suitably programmed scanners.	Used for additional information such as expiration date on fresh foods, and also used on coupons in North America.
GS1 DATAMATRIX		Up to 2,335 characters	Concatenated strings using GS1 Application Identifiers	The GS1 DataMatrix is a two-dimensional matrix symbol with specific healthcare applications in the GS1 System. It requires image based scanners and it is currently specified for healthcare items.	Used for direct part marking of surgical instruments.
GS1 QR CODE		Up to 4,296 characters	GS1 Application Identifiers AI (01) and AI (8200)	The GS1 QR Code is a two-dimensional symbol with specific marketing applications in the GS1 System. It requires image based scanners and it is currently specified to capture marketing information.	Used for marketing information retrieved by a consumer from a point of sale product.

https://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=160&language=en-US&PortalId=0&TabId=134

7.4 TIMELINE

FEDERAL IMPLEMENTATION TIMELINE



Note:

1. The Federal Implementation timeline may not reflect actual milestones achieved.

8. APPENDIX B: DOCUMENT REVISIONS

Version 1.0

- Original Publication

Version 1.1

- Section 1: Purpose
 - Updates to the first paragraph. And addition of footnote.
 - Added third paragraph.
- Section 2: Overview
 - Major modifications to paragraph 4 and 5.
 - Updated Key Dates image.
 - Added footnotes 2 and 3.
 - Added paragraph 6.
 - Section 2.1
 - Major modifications and rewrites throughout this section.
 - Added Sections 2.2 and 2.3.
 - Added footnotes.
- Section 3: Impact to the industry
 - Previously section 2.2.
 - Complete rewrite of the entire section.
 - Added footnote.
- Section 4: FDA Compliance Guidance
 - Previously section 2.3.
 - Complete rewrite of the entire section.
 - Added footnote.
- Section 5: Recommendations
 - Paragraph 1 major rewrite/clarifications.
 - Paragraph 2 is new.
 - Paragraph 3 major rewrite/clarifications.
 - Paragraphs 4 and 5 are new.
 - Added footnote.
- Section 6: Conclusion
 - Minor updates to paragraph 1.
 - Replaced the remaining paragraphs with paragraphs 2 through 4.
- Section 7: Appendix A
 - Added “A” after Appendix.
 - Section 7.2 fixed sub-bullets numbering.
- Section 8: Addition of Appendix B: Document Revisions

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