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.
GS1 DataMatrix

Version 1.0
Copyright (©) 2017, National Council for Prescription Drug Programs, Inc.

This work is owned by National Council for Prescription Drug Programs, Inc., 9240 E. Raintree Drive, Scottsdale, AZ 85260, (480) 477-1000, ncpdp@ncpdp.org, and protected by the copyright laws of the United States. 17 U.S.C. §101, et. seq. Permission is given to Council members to copy and use the work or any part thereof in connection with the business purposes of the Council members.

The work may not be changed or altered. The work may not be sold, used or exploited for commercial purposes. This permission may be revoked by National Council for Prescription Drug Programs, Inc., at any time. The National Council for Prescription Drugs Programs, Inc. is not responsible for any errors or damage as a result of the use of the work.

NCPDP® recognizes the confidentiality of certain information exchanged electronically through the use of its standards. Users should be familiar with the federal, state, and local laws, regulations and codes requiring confidentiality of this information and should utilize the standards accordingly.

NOTICE: In addition, this NCPDP® Standard contains certain data fields and elements that may be completed by users with the proprietary information of third parties. The use and distribution of third parties' proprietary information without such third parties’ consent, or the execution of a license or other agreement with such third party, could subject the user to numerous legal claims. All users are encouraged to contact such third parties to determine whether such information is proprietary and if necessary, to consult with legal counsel to make arrangements for the use and distribution of such proprietary information.

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

Publication History:
Version 1.0 September 2017
# Table of Contents

1. **Purpose** ................................................................. 4

2. **Overview** .............................................................. 5

   2.1 Use of the GS1 UPC-A ........................................... 6

   2.2 Impact to the Industry ........................................... 6

   2.3 FDA Compliance Guidance ................................... 7

3. **Recommendations** ................................................. 8

4. **Conclusion** ........................................................... 9

5. **Appendix** ............................................................. 10

   5.1 Definitions .......................................................... 10

   5.2 FAQs from GS1 ................................................ 12

   5.3 Barcode Examples Provided by GS1 ....................... 15

   5.4 Timeline ............................................................. 16
1. PURPOSE

Some manufacturers, in anticipation of the November 27, 2017 requirements of the Drug Quality and Security Act (DQSA) have 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. As a result, issues are arising downstream for stakeholders in the supply chain. Early removal of the GS1 UPC-A is causing 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.

It is the intention of the NCPDP 2D Barcode Implementation Task Group that manufacturers distribute this document to the appropriate staff, including those responsible for implementation of any changes to the product identifier as related to this legislation.
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 (now November 26, 2018 according to FDA granted exception), each manufacturer must affix a 2-dimensional data matrix product identifier on all saleable packages and sealed homogenous cases at the lowest saleable unit packaging level. Supply chain trading partners have agreed to use a GS1 DataMatrix as the 2-dimensional data matrix product identifier. The GS1 DataMatrix will be encoded with the product’s Global Trade Item Number (GTIN), Expiration Date, Serial Number, and Lot Number to comply with FDA guidance.

The FDA has recently adopted a policy of enforcement discretion, allowing additional time for manufacturers to comply with this law. Under this discretion, the FDA does not intend to take action against manufacturers who do not affix or imprint a product identifier to their packages and homogenous cases of product between November 27, 2017 and November 26, 2018.

Dispensers have until November 27, 2020 to accept and verify serialized products using the specified product identifier. Many dispensers are currently utilizing scanner technology throughout the dispensing process that can only interpret the traditional GS1 UPC-A and are unable to read and interpret data encoded in the GS1 DataMatrix.

In anticipation of the required product identifier implementation date, some manufacturers have decided to remove the traditional GS1 UPC-A that uses the GTIN-12 (containing the National Drug Code (NDC)), and replaced it with a GS1 DataBar to remedy space limitations on the lowest saleable unit packaging labels.

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

Version 1.0
©National Council for Prescription Drug Programs, Inc.
- 5 -
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 National Drug Code (NDC) number. The GS1 UPC-A uses the GTIN-12, which contains the NDC. The NDC number is a unique 10-digit number used to identify and describe the individual product and is subsequently used in payment determination for pharmaceutical services throughout the US healthcare industry. The NDC number is the key to product identification throughout the supply chain.

In addition, dispensers utilize scanning of the individual product’s barcode throughout the prescription dispensing process. Supply chain system computers, third party prescription claims processing, and reporting also use the NDC number which is encoded in the GS1 UPC-A. Due to supply chain entities’ inability to scan the new GS1 Datamatrix and subsequent removal of the GS1 UPC-A, supply chain entities are therefore unable to determine the product’s NDC number.

2.2 **Impact to the Industry**

As manufacturers prepare to meet the DSCSA serialization requirements, some have interpreted the requirements as a need to remove the GS1 UPC-A from the products, which was not an anticipated change by the rest of the pharmaceutical supply chain. This has resulted in products at the individual saleable unit being distributed in the marketplace with the new GS1 DataMatrix and without a GS1 UPC-A. The GS1 DataBar is being used in place of the GS1 UPC-A. Pharmaceutical supply chains are not prepared to read the GS1 DataMatrix with the GS1 UPC-A missing from these products.

Removal of the GS1 UPC-A impacts current workflow and patient safety by replacing automation in place today with manual processes due to the supply chain entities’ inability to interpret the GS1 DataBars. Numerous supply chain entities have reported that existing hardware and/or software configurations cannot be upgraded and are therefore unable to process the GS1 DataMatrix and/or GS1 DataBars at this time. Patient access to life saving pharmaceuticals is negatively impacted by these changes and the industry needs additional time to acquire new technology and develop processes to be able to utilize these Product Identifiers.

As of July 2017, wholesalers have reported that a small group of less than 20 branded and generic manufacturers have implemented GS1 DataBars in place of the GS1 UPC-A on individual saleable unit packages. At present, less than 20% of all manufacturers have serialized products circulating in the US supply chain. The GS1 DataBar appears to be used on a product-by-product basis versus being applied to the manufacturer’s entire product line. NCPDP foresees a larger impact coming soon as the next DSCSA milestone requires manufacturers to apply a serialized product identifier to each homogenous case and unit package that enters the supply chain for commercial trade. As a larger percentage of the 500+ manufacturers begin to implement serialization, the downstream operational disruptions caused by the GS1 DataBar will continue to grow in scope for dispensers.
2.3 **FDA COMPLIANCE GUIDANCE**

The FDA has recognized that some manufacturers are facing challenges meeting the product identifier requirements milestone of November 27, 2017. In order to avoid supply chain disruption and ensure patient access to life saving medications, the FDA has adopted a modified enforcement policy and does not intend to take action against non-compliant manufacturers between November 27, 2017 and November 26, 2018. This policy, also known as “enforcement discretion”, provides manufacturers an additional 12 months to collaborate with trading partners to address labeling obstacles and produce uniform serialized labels that are aligned with GS1 General Specifications and Healthcare Distribution Alliance (HDA) Guidance.
3. RECOMMENDATIONS

In order to minimize the impact to patient safety and supply chain workflow, NCPDP recommends manufacturers maintain the GS1 UPC-A on their packaging until FDA enforces the dispenser’s traceability deadline of 2020. This will require manufacturers to rework their package artwork if they have already eliminated the GS1 UPC-A. Although challenging, NCPDP recommends manufacturers make every attempt to revert to the use of the GS1 UPC-A to avoid patient safety and workflow issues.

In instances where the product unit label is too small to support the continued use of GS1 UPC-A in addition to the GS1 DataMatrix, a potential alternative solution is to reduce the size of the UPC-A barcode, also known as X-Dimension. Other GS1 DataBars are less preferred based on current hardware and configuration changes necessary within existing systems throughout the supply chain.
4. CONCLUSION

Several obstacles surrounding barcode symbology within the pharmaceutical supply chain have arisen from DSCSA requirements. As manufacturers race to serialize products and modify packaging labels ahead of the 2017 DSCSA milestone (now 2018 per the FDA’s enforcement discretion), downstream partners are noticing disruptions in 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.

Many dispensers do not have the necessary technology in place to scan and utilize the data encoded in a GS1 DataBar since dispensers were not anticipating updating their scanning technology until closer to the 2020 compliance date. A dispenser uses scanning technology throughout the prescription dispensing process and it is essential for patient safety checks. Additional time and capital is required to implement new scanning technology, train associates, and update software systems in order to integrate solutions into current operational processes to avoid negative impacts to workflow and patient care.

In short, barcode alterations have created unforeseen issues that will take additional time and resources for the industry to address. The recently issued FDA guidance on enforcement discretion provides additional time for manufacturers to revert to the GS1 UPC-A barcode and may allow dispensers time to acquire and implement new scanning technology. However, NCPDP still recommends the GS1 UPC-A remain on products until the FDA enforces the dispenser’s traceability deadline of 2020.
5. **APPENDIX**

5.1 **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](http://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.

**5.2 FAQs FROM GS1**

GS1 US recently published a new document for the Pharma Industry preparing for DSCSA FAQ’s. The entire document is located at:
https://www.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*

3.1.1 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.”

3.1.9 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 3-1 GS1 Application Identifiers Applicable to DSCSA Requirements

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

(*) 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.

3.1.16 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 repacker. 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
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.”

3.1.6 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.”

3.1.7 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.”
## 5.3 Barcode Examples Provided by GS1

### GS1 Barcode Chart

<table>
<thead>
<tr>
<th>Barcode</th>
<th>Display</th>
<th>Numeric Digits</th>
<th>Data Structure</th>
<th>Usage</th>
<th>Usage Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>EAN-8</td>
<td></td>
<td>8</td>
<td>GTIN-8</td>
<td>The EAN-8 is used on small packages where the Global Trade Item Number (GTIN-8) is also used by retailers to identify privately owned brand products sold only in their stores.</td>
<td>Used on small retail items such as cosmetics, that cross point of sale applications.</td>
</tr>
<tr>
<td>UPC-A</td>
<td></td>
<td>12</td>
<td>GTIN-12</td>
<td>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.</td>
<td>Used on retail items that cross point of sale applications.</td>
</tr>
<tr>
<td>UPC-E</td>
<td></td>
<td>12</td>
<td>GTIN-12</td>
<td>The UPC-E allows the use of UPC 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.</td>
<td>Used on small retail items such as cosmetics, packs of chewing gum, and cigarettes.</td>
</tr>
<tr>
<td>EAN-13</td>
<td></td>
<td>13</td>
<td>GTIN-13</td>
<td>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 worldwide. Also used by retailers to identify privately owned brand products sold only in their stores.</td>
<td>Used on small retail items that cross point of sale applications such as periodicals, magazines, and books. Also used on coupons outside of North America.</td>
</tr>
<tr>
<td>ITF-14</td>
<td></td>
<td>14</td>
<td>GTIN-12, GTIN-13, GTIN-14</td>
<td>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.</td>
<td>Used on standard product groupings such as a case of dish washing detergent (24 bottle count).</td>
</tr>
<tr>
<td>GS1 DATABASE™ TRUNCATED</td>
<td></td>
<td>16</td>
<td>GTIN-12, GTIN-13, GTIN-14</td>
<td>The GS1 Database 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.</td>
<td>Used on unit dose pharmaceuticals.</td>
</tr>
<tr>
<td>GS1 DATABASE STACKED OMNIDIRECTIONAL</td>
<td></td>
<td>14</td>
<td>GTIN-12, GTIN-13</td>
<td>The GS1 Database 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.</td>
<td>Used on very small consumable items. GTIN Only (i.e., loose products).</td>
</tr>
<tr>
<td>GS1 DATABASE LIMITED</td>
<td></td>
<td>14</td>
<td>GTIN-12, GTIN-13, GTIN-14</td>
<td>The GS1 Database 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.</td>
<td>Used on very small healthcare items such as ampoules.</td>
</tr>
</tbody>
</table>

### GS1 Barcodes

<table>
<thead>
<tr>
<th>Barcode</th>
<th>Display</th>
<th>Alpha/Numeric</th>
<th>Data Structure</th>
<th>Usage</th>
<th>Usage Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>GS1-128</td>
<td></td>
<td>Up to 46 characters</td>
<td>GS1 Application Identifiers (AIs)</td>
<td>Used on large bulk items such as pallets or logistic units.</td>
<td></td>
</tr>
<tr>
<td>GS1 DATABASE EXPANDED</td>
<td></td>
<td>Up to 74 numeric or 41 alphanumeric characters</td>
<td>GS1 Application Identifiers</td>
<td>Used for additional information such as expiration date on fresh foods, and also used on coupons in North America.</td>
<td></td>
</tr>
<tr>
<td>GS1 DATABASE EXPANDED STACKED</td>
<td></td>
<td>Up to 74 numeric or 41 alphanumeric characters</td>
<td>GS1 Application Identifiers</td>
<td>Used for additional information such as expiration date on fresh foods, and also used on coupons in North America.</td>
<td></td>
</tr>
<tr>
<td>GS1 DATAMATRIX</td>
<td></td>
<td>Up to 2335 characters</td>
<td>GS1 Application Identifiers</td>
<td>Used for direct part marking of surgical instruments.</td>
<td></td>
</tr>
<tr>
<td>GS1 QR CODE</td>
<td></td>
<td>Up to 4,296 characters</td>
<td>GS1 Application Identifiers A1 (01) and A1 (0200)</td>
<td>Used for marketing information retrieved by a consumer from a point of sale product.</td>
<td></td>
</tr>
</tbody>
</table>

5.4 **Timeline**

**Federal Implementation Timeline**

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>NOVEMBER 27, 2013 Congress enacts the Drug Supply Chain Security Act</td>
</tr>
<tr>
<td>2014</td>
<td>JANUARY 1, 2015 Manufacturers receive TI/TH/TS and begin direct purchase statement</td>
</tr>
<tr>
<td></td>
<td>Suspect and Illegitimate Product Requirements Effective</td>
</tr>
<tr>
<td>2015</td>
<td>NOVEMBER 27, 2015 Manufacturers serialize product</td>
</tr>
<tr>
<td>2016</td>
<td>NOVEMBER 27, 2016 Repackagers serialize product</td>
</tr>
<tr>
<td>2017</td>
<td>NOVEMBER 27, 2017 Urn-level traceability</td>
</tr>
<tr>
<td>2018</td>
<td>NOVEMBER 27, 2018 Distributor traceability</td>
</tr>
<tr>
<td>2019</td>
<td>NOVEMBER 27, 2019 Distributor traceability</td>
</tr>
<tr>
<td>2020</td>
<td>NOVEMBER 27, 2020 Dispenser traceability</td>
</tr>
<tr>
<td>2021</td>
<td>NOVEMBER 27, 2021</td>
</tr>
<tr>
<td>2022</td>
<td>NOVEMBER 27, 2022</td>
</tr>
<tr>
<td>2023</td>
<td>NOVEMBER 27, 2023</td>
</tr>
<tr>
<td>2024</td>
<td>NOVEMBER 27, 2024</td>
</tr>
</tbody>
</table>

**FDA Milestones**

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>NOVEMBER 27, 2014 National standards for wholesaler distribution license anticipated</td>
</tr>
<tr>
<td></td>
<td>National standards issued for 3PLs</td>
</tr>
<tr>
<td>2015</td>
<td>NOVEMBER 27, 2015 Waiver guidance issued for exchange of TI/TH/TS</td>
</tr>
<tr>
<td></td>
<td>Standards issued for exceptions to product identifier requirements</td>
</tr>
<tr>
<td></td>
<td>Standards issued for grandfathering product</td>
</tr>
<tr>
<td>2016</td>
<td>MAY 1, 2016</td>
</tr>
<tr>
<td></td>
<td>TI/TH/TS enforcement discretion ends</td>
</tr>
</tbody>
</table>

**Supply Chain Milestones**

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>JANUARY 1, 2015 Wholesale distribution license reporting begins</td>
</tr>
<tr>
<td></td>
<td>Publicly available database of wholesale distributors established by FDA</td>
</tr>
<tr>
<td>2016</td>
<td>NOVEMBER 27, 2016 Standards published for TI/TH/TS</td>
</tr>
<tr>
<td></td>
<td>3PL license reporting begins</td>
</tr>
<tr>
<td>2017</td>
<td>MAY 24, 2017</td>
</tr>
<tr>
<td></td>
<td>Draft guidance on suspect product and terminating notification</td>
</tr>
</tbody>
</table>

**KEY**

- TI – Transaction Information
- TH – Transaction History
- TS – Transaction Statement

**Note:**

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