

Baxa Corporation

Healthcare Bar Codes: Setting a Universal Standard

Technical Paper

An overview of the key barcode standards, including trends and issues, and the impact on industry for establishing a universal standard.



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Overview: Barcode Issues and Definitions

The adoption of barcode standards within the US marketplace reflects changes in the technology landscape, as well as the presence of extremely large players (e.g., Wal-Mart), whose economies of scale have created *de facto* market standards that drive market acceptance. Original standards reflected the immaturity of the barcode marketplace; their linear format and encoded data were exclusively numeric and lacked the density necessary to encode large amounts of information in small spaces.

Over the intervening decades, the barcode industry has matured to produce symbologies that encompass the Unicode data set (more than 64,000 characters) as well as the ability to use two-dimensional formats that can encompass large amounts of text.

Economies of scale in the retail environment hastened the mass adoption of industry standards. The healthcare marketplace has suffered, however, from the lack of a single, large player able to set a *de facto* commercial standard. The result is two not-for-profit standards-making bodies that command approximately equal market share, each of whom offers approximately the same value and service. These are GS1 (formerly the Uniform Code Council) and HIBCC (Health Industry Business Communications Council). Both offer:

- Standardized, easily parsed data
- Support for a large number of symbologies
- Global database of encoded values
- Training and support materials for users of the standard
- Membership organization for participation in standards-setting

Both organizations focus primarily on the needs of the e-commerce marketplace, offering little or nothing in support of clinical practice. Therefore, the practical impact of adopting either standard lies in the ability of that standard to support ordering, fulfillment, delivery and inventory of medical goods and supplies. Each offers little, if anything, in support of clinical, patient-safety applications such as barcode medication administration (BCMA).

Although both adopt the “.org” nomenclature of a not-for-profit organization, both groups aggressively seek to become the dominant player in the barcode arena. Both also see significant commercial benefit from that dominance.

The generally even distribution of these two players in the healthcare marketplace creates a situation in which the designation of a single standard within that marketplace will result in significant conversion costs for any of the vendors who chose the “losing” side. So the question must be raised whether the benefits of moving to one standard versus the other outweigh the costs of that conversion in comparison to the cost of supporting both standards in practical use.

Recent marketing activities by GS1 in concert with certain group purchasing organizations (GPOs) have resulted in attempts to enforce standardization to one barcode standards vendor – GS1. In considering the potential value and impact of such a move it is important to consider what value, if any, arises from this “single source of truth” and whether or not that value is worth its cost.

A review of this issue therefore requires that one consider the relative merits of the offerings of these two competing standards, as well as the relative ease of interconversion by the industry versus the relative ease of recognizing and using both standards. This paper presents an overview of these barcode standards, the key trends and issues relative to their adoption, and the impact on industry for establishing and maintaining a universal standard.

Definitions

Group Purchasing Organization (GPO) – Entity designed to help healthcare providers realize savings and efficiencies by aggregating purchasing volume and using that leverage to negotiate discounts with manufacturers, distributors, and other vendors.

Health Industry Bar Code (HIBC) – Created by HIBCC (see below) and composed of two parts: Part One, the HIBC Supplier Labeling Standard, covering the formats used by suppliers of products; and Part Two, the HIBC Provider Standard, covering the formats used for internal labeling by health care providers themselves.

Health Industry Business Communications Council (HIBCC) - An industry-sponsored and supported not-for-profit organization whose primary function is to facilitate electronic communications by developing appropriate standards for information exchange among all healthcare trading partners.

GS1 –A not-for-profit standards organization that administers the Universal Product Code (UPC) and provides a full range of integrated standards and business solutions for more than 251,000 member companies doing business in 23 major industries, one of which is the healthcare industry.

Value of Bar Coding

Without a doubt, the medical industry has experienced the benefits of integrating barcode technology throughout its supply chain. Even in the presence of two barcoding standards, healthcare has been able to leverage the experience of other industries to streamline the ordering and fulfillment of both pharmaceuticals and medical goods.

The FDA mandate for inclusion of the national drug code (NDC) on each and every pharmaceutical container has further enabled the use of bar coding to ensure that the correct medication actually reaches the patient. Known variously as barcode medication verification (BMV), barcode medication administration (BCMA) and barcode point-of-care (BPOC), this technology now reaches a significant number of hospital beds, with more being adopted every year.

Interestingly, the only standardization around this mandate is that the bar code must encode at least the 10-digit unformatted NDC. The result is that there are a large number of variations present in the actual data structure encoded within the barcode on pharmaceutical containers to which the BCMA industry seems to have adapted handily. This would seem to belie the notion that standardization of the data structure is necessary to enable barcode usage. While a large number of pharmaceutical companies use some form of the GS1 standard, such adoption is hardly unique or ubiquitous, and there are a wide variety of other options, including one vendor whose barcode literally contains “NDC: *nnnnnnnnnn*” where *nnnnnnnnnn* is the 10-digit unformatted NDC. Complicating this “universal” coding is that NDCs are established only for pharmaceuticals (drugs). Medical device manufacturers each create their own unique product numbering schemes, as there is no device NDC.

Throughout the supply chain, bar coding enables tracking and traceability of pharmaceuticals and equipment. It saves time with inventory control, ordering, shipping and billing. Currently, processes function equally well regardless of standard, although the number of HIBCC users continues to increase, with 2007 spurring the largest growth ever in worldwide HIBCC labeling.ⁱ

Review of Current Healthcare Barcode Standards

Use of automated data capture via bar coding in the medical channel lagged acceptance compared with other industries, most notably retail and grocery. When it became evident that proprietary formats might begin to dominate the medical supply chain, which would inhibit competition between manufacturers and distributors, an intra-industry task force formed.

This group approached the leading grocery channel standards development organizations, then known as the Uniform Code Council (UCC) – today’s GS1. The principal issue under discussion was the medical group’s insistence on an alphanumeric standard to fit the most common labeling practice extant in the industry. Current studies at that time indicated that alphanumeric identifiers provided more reliable scanning, which could potentially affect patient safety.ⁱⁱ

At the time, UCC/GS1 primarily serviced the interests of the grocer industry and saw no need to deviate from its all-numeric UPC. Hence the founding members chose to form their own, industry-specific standards development organization, which became HIBCC. The American National Standards Institute accredited HIBCC soon after.ⁱⁱⁱ To this date, the GS1 standard continues to mandate an entirely numeric data encoding structure.

Additionally, the GS1 standard limits the implementation of bar codes to symbologies whose intellectual property is owned by GS1. As a result, the Aztec symbology, which is currently achieving wide industry use, is not permitted within the GS1 standard set.

By comparison, HIBCC encoding permits the use of both alphabetic and numeric characters and offers no limitation on symbology use. While the numbers are similar, it appears that HIBCC enjoys slightly broader current use than does GS1, primarily on the packaging of medical devices and supplies.^{iv}

The alphanumeric flexibility of the HIBCC's barcode system fits nicely with the medical industry's long-time use of alphanumeric characters in their labeling practices. In addition, studies at the time that HIBCC was created demonstrated that alphanumeric identifiers were more reliably scanned.^v

Both systems provide extensions for reporting so-called "secondary" data (such as lot and expiration dates or serial numbers) that are expected to provide additional benefits in clinical applications such as BCMA. Finally, a cost comparison for the two systems indicates that participation in GS1 is substantially more costly than participation in HIBCC.^{vi} In fact, Dennis Harrison, president of GS1, has "conceded that the GS1 standards are "no better or worse" than those supported by HIBCC."^{vii}

Impact of a Single Standard

Despite widespread claims, no concrete evidence exists to support the theory that a single standardized system will deliver a better quality of patient care. One might consider that the adoption of such a standard would accelerate adoption of bar coding by reducing the complexity of programming barcode applications. ***However, to a large extent those applications are already written and already support the use of both GS1 and HIBCC as well as a variety of non-standard encoding.***

Even in those cases where coding support would be required, current software tools make such work trivial in comparison to the effort of changing databases, both within the supplier community and the corresponding changes within the customer databases, many of which involve legacy systems not amenable to automated changes.

As a result, one can readily demonstrate that conversion to a single standard will generate considerable cost to convert both product labeling and legacy systems to support only the "winning" standard.^{viii} It should be clear that selecting GS1 as a single standard would affect the vendor, regulator, and provider communities:

- Vendors will be required to change internal databases and label formats and to obtain FDA approval for all new label designs for regulated products.
- The FDA would be literally flooded with label design changes requiring approval.
- The provider community would likewise be required to convert their current item masters to support the new encoding. They would also need to support both old and new encoding during the transition between the systems, leading to confusion and increased possible error.
- Customers, vendors, wholesalers, and distributors alike would need to update product listings, catalogs, online sales channels, and all other materials to accommodate the new order numbers for products, since the two current standards are not compatible.

By comparison, any cost needed to support both standards (a cost that has already been paid) pales in comparison. Because the standards are so different (starting with the ability of one, and not the other, to support alphabetic characters), code can be (and has been) written that readily distinguishes between HIBCC and GS1 encoding.

Standardization allows for easy and consistent identification of products, trading partners, and locations within the medical supply chain. Vendors in the medical industry have used these standards for many years, but these standards have largely been ignored by the provider community.^{ix} Presentations at various ASHP (American Society of Health-System Pharmacists) meetings on the perils of BCMA include diatribes on the varieties of different bar codes they encounter on pharmaceuticals, many of which are simply permitted variants of the GS1 standard. The clinical community neither acknowledges nor uses these standards and BCMA systems have been forced to handle a multiplicity of presentations whose only common denominator is that they have a 10-digit, unformatted NDC buried somewhere within them. Since the industry has already solved this problem in an extensible manner, standardization to one format offers no apparent benefits.

It must, therefore, be emphasized that a conversion to a single encoding standard cannot, and does not, offer improved patient safety. The only barcode programs that do so are programs that use bar codes to verify the selection of the appropriate pharmaceuticals. There are no such programs for medical devices, nor is there any apparent work flow through which bar coding of medical devices would result in a reduction in patient harm. Pharmaceuticals are already bar coded in the United States, as mandated by the FDA, and the programs that use those bar codes to prevent inappropriate drug administration already handle a multiplicity of encoding with apparent grace. ***Therefore, the conversion to a single encoding standard offers no benefit to patient safety.***

The conversion from HIBCC to GS1 would prove difficult and costly, expenses that would be ultimately borne by hospitals and patients.^x Outside of healthcare affordability lie other hidden pitfalls. The U.S. Supreme Court decreed that manufacturers are held accountable to the information on their labels.^{xi} Mistakes can easily be made on product labels during this time of cross-referencing add/or reconstruction. Thus, the conversion to the GS1 standards will push manufacturers toward risky cross-referencing or label reconstruction that will increase identification errors and put them at great and unnecessary liability.^{xii}

Issues for Manufacturers

Converting to a single standard would create a pronounced financial penalty to manufacturers, as they would be required to register with GS1 to create the UPCs for their products. The beneficiary would be GS1 – not hospitals or their patients –which would collect substantial required fees from manufacturers registering their products, as well as group purchasing organizations (GPOs).

A mandated migration to GS1 would require many manufacturers to abandon directly encoded alphanumeric product identifiers and replace them with numeric-only versions, thereby reverting to the days when computer scanners could only recognize one level of identifier. Cross-referencing or replacing existing identifiers is a risky practice that will impose huge costs, which ultimately would be borne by hospitals and patients.^{xiii}

Issues for Health Systems

To many longtime industry observers, the question of whether to abandon a generation of work by HIBCC to convert to a standard over which we have limited control seems arbitrary and more than a bit political. If we were to move forward with a single standardized system, it should be because there is substantial evidence that the new system will be safer and more efficient than the one being replaced.^{xiv} To date, no one has been able to provide anything more than broad generalizations about why a single standard should be in place. The debate fails miserably in proving that GS1 would be worth the monumental investment by all parties involved.

The president of Premier Healthcare Alliance has stepped forward in support of converting to the GS1 standard, noting that these standards will be required through Premier contracts with medical device manufacturers with full adoption in contract and operations over the next five years.^{xv}

Interestingly, Premier's Chief Information Officer also sits on the board of governors for GS1. A link of this nature brings into question Premier's – and other GPO's – motives for the requirement (i.e., increased patient safety).^{xvi} The bottom line is that mandates such as Premier's will force many manufacturers to choose between sales and safety when confronted with winning contracts.^{xvii} Therefore, it is vital to distinguish between adopting standards that provide genuine benefit to the parties who use them and using the standards to establish a monopoly that creates no more net benefits.

Conclusion

Bar coding of pharmaceuticals, medical supplies, and medical devices offers potential benefits throughout the supply chain. Current practice within the American healthcare supply chain supports the use of at least two clearly distinct encoding standards: GS1 and HIBC. Neither of these standards appears to dominate the marketplace, and neither appears to offer benefits over the other. Software within the supply chain has long existed that permits the user community to accept and handle both standards, which has resulted in the expected benefits – streamlining the logistics of procurement and handling.

The application of bar coding to patient safety is relatively recent and has proceeded in the absence of any clear standards. Many BCMA systems already exist in the marketplace, each of which distinguishes and appropriately handles a multiplicity of barcode formats, among which are HIBC and GS1. Since the pharmaceutical marketplace has no uniform standards, and the BCMA industry has already

accommodated that lack of standards in its product offerings, there is no opportunity for further standardization to improve patient safety.

The lack of argument for patient safety, and the clear ability of current systems to handle multiple standards, removes any compelling argument for adopting a single standard for health care. The cost to the industry, the regulatory sector, and the provider community for adopting a single standard (as has been proposed by the GS1 organization) is appallingly high. The funds necessary to support such adoption would be far better spent on technologies believed to ameliorate medical error, such as computerized prescriber order entry, or barcode medication administration.

References

ⁱ Almon T. *Standards Movement Shifts Toward GS1 Version: More Standardization, but is it Worth the Conversion Costs?* Hospital Materials Management. March 2009; 4-6. Pg 4-5.

ⁱⁱ Ibid. Pg 5.

ⁱⁱⁱ Ibid. Pg 6.

^{iv} Hankin R. *Do Labeling Requirements Address Patient Safety?* MD&DI. November 2008. Pg. 24.

^v Almon T. *Standards Movement Shifts Toward GS1 Version: More Standardization, but is it Worth the Conversion Costs?* Hospital Materials Management. March 2009; 4-6. Pg 5.

^{vi} Hankin R. *Do Labeling Requirements Address Patient Safety?* MD&DI. November 2008. Pg. 24.

^{vii} Almon T. *Standards Movement Shifts Toward GS1 Version: More Standardization, but is it Worth the Conversion Costs?* Hospital Materials Management. March 2009; 4-6. Pg 5.

^{viii} Ibid. Pg 4.

^{ix} Ibid. Pg 5.

^x Hankin R. *Do Labeling Requirements Address Patient Safety?* MD&DI. November 2008. Pg 24.

⁹ Stout D. *Drug Approval Is Not a Shield from Lawsuits, Justices Rule.* The New York Times. March 5, 2009. Accessed at http://www.nytimes.com/2009/03/05/washington/05scotus.html?_r=1. Last accessed 6/5/2009.

^{xii} Hankin R. *Do Labeling Requirements Address Patient Safety?* MD&DI. November 2008. Pg. 24.

^{xiii} Ibid.

^{xiv} *Positioning Your Organization with a Barcode Technology.* ISMP Teleconference. April 8, 2003. Slide 18.

^{xv} <http://www.premierinc.com/connect/general-news/Dec-10-GS1.jsp>

^{xvi} Hankin R. *Do Labeling Requirements Address Patient Safety?* MD&DI. November 2008. Pg. 24.

^{xvii} Ibid.