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# Multiple Device Identifier Work Group Report

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# MULTIPLE DEVICE IDENTIFIER WORK GROUP REPORT

## VISION:

The concept that a specific type of medical device would have one consistent unique device identifier that would allow the device to be tracked from the point of creation through its journey across the supply chain and into a patient's health record was the vision that drove the creation of the Unique Device Identifier (UDI). A single UDI would be assigned for each packaging level. The intent was this identifier would improve patient and device safety by enhancing key patient safety systems like the product recall process and would improve device evaluation by supporting research to determine the clinical effectiveness of specific devices within different patient populations. A secondary goal was streamlining and improving the efficiency of the health care supply chain. The regulations that were developed to support the creation and adoption of the UDI were informed by a broad cross section of representatives from health care provider organizations, manufacturers, government agencies and standards organizations.

## CHALLENGE:

The steering committee for the Association for Health Care Resource & Materials Management (AHRMM) Learning Unique Device Identifier (UDI) Community approved the formation of a sub-group to investigate issues related to the allocation of multiple unique device identifiers (UDI-DI) to what health care providers and U.S. regulators considered the same medical device. The group was challenged to look at three specific issues and create a report back to the field. The issues included:

1. Understanding the circumstances that cause some manufacturers to assign multiple UDI-DIs to what health care providers and U.S. regulators consider the same medical device.
2. Understanding the implications on patient safety, clinical workflow, supply chain operations and outcomes research when manufacturers assign multiple UDI-DIs to what health care providers and U.S. regulators consider the same medical device.
3. Identifying efforts underway to mitigate the occurrence or the negative implications of multiple UDI-DIs and to share recommended practices.

## PROCESS:

A sub-group of approximately 75 representatives from various manufacturers, health care providers, U.S. FDA, GS1 US, GS1 Global Office, GS1 Australia, GS1 Canada, Health Industry Business Communication Council (HIBCC) and field consultants worked together to clarify and address the issues outlined above. The group worked to identify

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the primary allocation scenarios, implications of multiple UDI-DIs and mitigation efforts. This is not an all-inclusive list but a good representation of the state of the health care field. The sub-group focused primarily on the use of GS1 as the standards body for assigning the UDI-DI since it is the organization used by most manufacturers and providers. However, they also received input from HIBCC and ICCBBA. GS1's Global Trade Item Number (GTIN) and the HIBCC's Universal Product Number (UPN) and ICCBBA's Processor Product Identification Code (PPIC) are the equivalent to the FDA term UDI-DI.

## ALLOCATION OF UDI-DI:

- There is a lack of consistency between what manufacturers, health care providers and U.S. regulators define as the "same" device.
  - Some manufacturers take a more clinical or provider-centric view (focusing on the function of the device) and look for alternatives to minimize changes to the UDI-DI. Others believe by changing the UDI-DI, a new device is created, and therefore, there is no such thing as multiple UDI-DIs for the same device.
  - There is agreement between manufacturers that use GS1 standards that medical devices that are sold in single markets and not intended to be sold outside that market (e.g. catheter manufactured in China, labeled in Mandarin and restricted to sale in China) would have a different UDI-DI (GTIN) than the same catheter manufactured in the U.S. and labeled in English. These products are not intended to be interchangeable. It should be noted that according to providers, there have been circumstances where products intended for other countries have made their way into the U.S. market.
- There is no agreement among those using GS1 standards as to whether a product manufactured in multiple countries to basically the same specifications (what providers and U.S. regulators would consider the same medical device) and distributed to multiple markets should have different UDI-DIs.
  - Some manufacturers use multi-language labels, assign one UDI-DI (GTIN) and use lot numbers or other methods to track and communicate country of origin. This approach is also advised by HIBCC.
  - Some manufacturers assign different UDI-DIs (GTINs) as a means of managing global registration requirements and other internal manufacturing or distribution control changes.
- The HIBCC Supplier Labeling Standard (SLS) advises labelers to create a single global UDI-DI for a device. This UDI-DI should remain the same regardless of the

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market where it is sold, country of origin or package languages.

- Other factors that cause some manufacturers to assign multiple UDI-DIs (GTINs) to what providers and U.S. regulators would consider the same medical device include:
  - Timing factors related to when the license and registration are introduced to a market.
  - Having a decentralized corporate structure where individual locations are separate legal entities each requiring a UDI-DI prefix.
  - Mix of languages on the package.
  - Internal business processes and configuration of the manufacturers' enterprise resource planning (ERP) and related inventory control systems. Note: Configuration issues are the most frequent cause of manufacturers assigning multiple UDI-DIs to what providers and U.S. regulators would consider the same medical device.
- The relationships between regulatory agencies, manufacturers, GS1 Global (and Member Organizations (MOs)) is complex and can lead to confusion regarding what is a requirement, a standard, a guideline or a best practice.
  - Each jurisdiction has regulatory agencies that establish labeling requirements and other rules, which manufacturers must meet to sell devices within that country.
  - GS1 standards are intended for global use. In the event of a conflict, local regulatory and legal requirements take precedent.
  - Note: Representatives from GS1 were not aware of any situations where local regulations created a requirement that would result in multiple UDI-DIs being assigned to what providers and U.S. regulators consider the same medical device.
  - In the GS1 GSMP (Global Standards Management Process) a "GS1 guideline" is created under the same process as a "standard." Within any standard, there will be some finite rules ("shalls"), some recommendations ("shoulds") and some things that will be up to the discretion of those who control the allocation process (e.g. manufacturers). This applies to the HIBCC Supply Labeling Standards (SLS) process as well.
  - GS1 is a member-based, "federated" organization, made up of the GS1 Global Office (based in Brussels BE and Lawrenceville NJ, USA) and 112 autonomous, (country-based) MOs, such as GS1 US.
  - GS1 Global Office's is responsible for providing standards development, technical and educational support to the MOs so they can adopt it and provide it locally to their members and drive global harmonization.

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- Historically MOs have used the GS1 standards to develop recommendations and “best practices” based on their member needs.
- GS1 Global Office facilitates discussion and information sharing between their MO’s in the Healthcare Interest Groups (HIGs) to discuss needs and issues on a more global basis.
- When the GS1 Global Healthcare initiative originally started the focus was on development of standards in the health care sector and then implementation of the GS1 system. Manufacturers and wholesalers were the first to engage and implement GS1 standards broadly in their supply chains, often driven by regulatory requirements. Over the past few years, the needs and use cases of the care providers have been integrated into the focus of the work with the project “Imagine.” In parallel, the awareness of software application providers to the needs in the sector has been raised and specific work is ongoing to drive interoperability in the provider environment.
- GS1 standards and guidelines are member-driven, consensus-based and developed through the GSMP (noted above) based upon the input of its members.
- HIBCC standards are also intended for global use and in the event of a conflict, local regulatory and legal requirements take precedent. The HIBCC U.S. Office is the owner and maintainer of the HIBCC SLS. Any changes to the standard would need to be made by the HIBCC U.S. Office and would apply globally.
- ICCBBA standards are intended for global use for labeling medical products of human origin (MPHO). In the event of a conflict, local regulatory and legal requirements take precedent. Their use in UDI is limited to those situations where MPHO products are regulated as medical devices. (Reference the [AHRMM guidance on labeling HCT/P regulated as medical devices](#) and the [HCT/P Presentation materials](#))
  - The ICCBBA UDI-DI carries an identifier of the labeler, an internationally standardized product description code (PDC) and a facility-defined product code (FPC) element.
  - ICCBBA internationally standardized PDC are based on a publicly available standard terminology for MPHO (<https://www.iccbba.org/docs/tech-library/technical/standardterminology.pdf>). Terminology and PDC are managed by ICCBBA international technical advisory committees of volunteer subject matter experts
  - The ICCBBA PDC are allocated to distinguish between products that have clinically significant differences in composition but do not distinguish to the level of physical characteristics such as dimensions or quantities. This further level of distinction is identified by the FPC. This approach supports

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biovigilance activities as clinically similar products from different processors (labelers) carry the same PDC.

- There are challenges harmonizing data requirements for various government regulatory agencies such as the GUDID for the U.S. and EUDAMED for the European Commission.
  - One of the factors, which causes differences in the data sets, is the intended purpose of the data itself. Regulators may be intending to use the data for different purposes (e.g. traceability versus outcomes research),
  - A second factor contributing to the challenge is data definitions and their role in determining if two attributes with the same or similar names mean the same thing.
  - Thirdly, local requirements can differ between countries.
  - The International Medical Device Regulators Forum UDI Guidance<sup>1</sup> and UDI Application Guide<sup>2</sup> are intended to promote global harmonization on labeling and other requirements but will not eliminate all differences due to differences in requirements by jurisdiction. The IMDRF UDI Application Guide draft addressed the multiple DI issue from a harmonization perspective.
  - There are regulations around UDI expected in the next few years in other countries in the world. (e.g. China, Korea, Taiwan, Australia, Saudi Arabia).

## IMPLICATIONS OF MULTIPLE UDI-DI:

In October 2015, the Office of the National Coordinator (ONC) finalized a rule requiring that certified health information technology products have the functionality to record, access, parse and exchange Unique Device Identifiers (UDIs) for implantable devices in a standardized way by January 2018. The Center for Medicare and Medicaid Services (CMS) also incorporated UDI into the Common Clinical Data Set (CCDS) and has continued to support UDI as the CCDS has transitioned from a Meaningful Use Stage 3 requirement to a US COR data requirement of the Promoting Interoperability Program. Complying with these regulations involves health care providers integrating data between their business ERP systems and their certified Electronic Health Record (EHR) systems.

Prior to the introduction of the above regulations, some manufacturers chose to use the UDI-DI as the means to manage distribution control. They used it to differentiate

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<sup>1</sup> The IMDRF UDI Guidance ([IMDRF/UDI WG/N7Final:2013](#))

<sup>2</sup> The Unique Device Identification system (UDI system) Application Guide ([IMDRF/UDI WG/Proposed Working Draft: 2019](#))

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country of origin, manufacturing location and other internal information. This practice resulted in multiple UDI-DIs being assigned to medical devices that health care providers and U.S. regulatory authorities consider to be the same medical device. Given the expansion of stakeholders using the UDI-DI, the existence of multiple UDI-DIs is causing confusion, inefficiencies and increasing patient risk.

To fully appreciate the implications of this practice, it's important to understand the fundamental structure of health care information systems. From there, the primary implications to the other aspects of patient care and operations management can be explored.

## **Information Systems:**

Health care systems in the U.S. utilize ERP systems to manage purchasing, inventory management and payment functions. The ERP system is considered the "source of truth" for data related to medical devices (e.g. UDI-DI, descriptions, price, etc.). Health care providers utilize EHRs for clinical documentation, including documentation of medical device utilization and to support patient care. These systems are natively designed to link data elements in a one-to-one relationship. In addition, ERP systems automatically assign an internal number to every record created. In the provider's system they are generally called item numbers. Therefore, the UDI-DI must be linked to these internal numbers and since the systems link information in a one-to-one relationship, only one UDI-DI per unit of measure can be associated with one internal number.

These systems work together with the ERP system sending descriptive information about the medical device, including the UDI-DI, into the EHR where the details of a clinical intervention are documented. The combined data is then used for supply chain operations and analytical purposes. Although some health care providers have developed work arounds to accommodate multiple UDI-DIs in either their ERP or EHR systems, these solutions require system customization and/or purchase of third-party software applications. Additionally, they do not address the full spectrum of problems caused by the multiple UDI-DIs. The lack of a one-to-one data element relationship has far-reaching consequences. The following highlights are not all inclusive but address the primary implications.

## **Clinical Workflow:**

When a medical device is scanned into the EHR, the UDI-DI is compared to the information that was interfaced from the ERP system. If the scanned UDI-DI does not match the UDI-DI from the ERP system, the item will not successfully scan and the nurse will receive an error message. The nurse must then determine if the device is considered an implant or a supply, go to the correct screen within the EHR and manually enter the UDI-DI, manufacturer number, lot or serial number, unit of measure and potentially other information that would have been populated automatically if the UDI-DI had matched. Manual documentation takes the nurse's attention away from the



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patient and creates a frustrating work environment. Additionally, more post-procedure follow-up is required to manually add the cost of the product and the applicable revenue code so the patient can be accurately billed for the device. Correcting errors created by the inability to scan can involve people from four different departments and can take multiple days to complete.

## **Patient Safety:**

Manual data entry significantly increases the risk that incorrect information will be entered into the patient's medical record. Correct device identification is critical in the case of a recall as well as to determine the safety of future procedures and interventions, such as the ability to perform MRIs or have the correct tools for an implant revision. Additionally, clinician's frustration with tedious data entry process can result in failure to document medical supplies. An audit completed by one health care provider who had put in place extensive procedures to capture and correct errors, found ten instances where the wrong implant was documented in the medical record. Another health care system's audit of one month of manually entered information revealed 30 instances with missing expiration dates, seven instances of expired product being used, 11 missing manufacturers and nine records missing other UDI production identifier (UDI-PI) details.

The issues of device recall tracking and documentation were highlighted in a recent audit completed by the Office of Inspector General (OIG) on health care provider's compliance with the Warranty Credit Program. The program requires hospitals to report the replacement of a beneficiary's implanted device if the hospital receives full or partial credit from the manufacturer for a device that is covered under warranty or replaced due to a recall. The OIG report examined 296 claims in 2017 that covered \$7.7 million in payments to hospitals for 153 inpatient and 143 outpatient claims for replaced cardiac medical devices. All 296 claims contained errors in coding, missing or incorrect modifiers and demonstrated significant gaps in tracking the warranties and credits for the explanted, replaced devices. The OIG cited the lack of a unique device identifier as a key contributor to the problem. As a result, the OIG has recommended that CMS work with the X12 committee to require the placement of UDI-DIs in the next version of payment claims forms.<sup>3</sup>

## **Supply Chain Operations:**

Multiple UDI-DIs negatively impact a health system's ability to efficiently order products, manage its inventory and pay invoices. Examples include a health care system whose purchase order was cancelled because the device with that specific UDI-DI was on backorder but the exact same device with another UDI-DI was available. The canceled order resulted in product being rushed in from another location and a surgery that was almost postponed.

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<sup>3</sup> Jarmon, Gloria L., Deputy Inspector General for Audit Services, "Hospitals Did Not Comply With Medicare Requirements for Reporting Certain Cardiac Device Credits", A-05-16-00059, March 2018.



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Additionally, supply utilization data is key in determining inventory levels, monitoring contract compliance and identifying clinical variation. Systems can't automatically aggregate utilization of medical devices with multiple DIs. This can result in product stock outs and time spent creating manual work-arounds such as the creation and reconciliation of alias tables. One provider indicated they have multiple people assigned full-time to managing alias tables and correcting data errors in their various systems. According to health care providers, multiple UDI-DIs are the primary cause of those data errors.

## **Outcomes Research:**

One of the most compelling arguments for the implementation of the UDI was the ability to associate specific devices with patient outcomes providing information to manufacturers that could result in improved device design, increased likelihood of better patient outcomes and the potential to reduce overall health care costs. Projects such as Building UDI into Longitudinal Data for Medical Device Evaluation (BUILD) and others are looking at using the UDI-DI within registries and other medical research projects. One obstacle to successfully achieving this goal are medical devices with multiple UDI-DIs assigned to them. The lack of a one-to-one relationship necessitates the creation and maintenance of cross-reference tables that add such cost and complexity as to significantly impede or stop the progress of this type of research. Other obstacles such as the need to systematically categorize devices from multiple manufacturers are being addressed by other Learning UDI Communities.

## **CURRENT EFFORTS:**

### **Health Care Providers:**

There are no software solutions that resolve all the issues caused by multiple UDI-DIs. There are systems that can help providers cope with the multiple UDI-DI situation. Some health care providers have purchased third-party (middleware) systems to assist with inventory management and a variety of operational issues. Most middleware systems focus on the procedural areas (e.g. OR and Cath Lab) and allow the RN to effectively scan bar codes on items whose UDI-DI is not contained in the organization's ERP system. The middleware maintains and has an automated process to update tables that associate multiple UDI-DIs and connect them to the correct UDI-PI information. This significantly improves the clinical workflow and the accuracy of the data elements captured in the EHR, which in turn, improves patient safety.

Other health care systems have customized their systems and employ individuals to create and maintain alias tables that link devices with multiple UDI-DIs. These solutions and customizations help improve efficiency and accuracy in a segment of the supply chain and can be of assistance in managing UDI-DI changes.

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Neither solution address end-to-end issues that would provide solutions related to outcomes research nor replace efforts to eliminate the assignment of multiple UDI-DIs to what health care providers and U.S. regulators consider the same medical device.

## **Manufacturers:**

For those manufacturers that use GS1 standards, there are alternatives to using the UDI-DI (GTIN) to manage product<sup>4</sup> distribution control and comply with global regulatory requirements. Many manufacturers only change the GTIN when there is a significant change to form, fit or function that would impact the clinical user or the patient. They use lot numbers or other Application Identifiers (AI) to denote other changes. For example, lot number, AI (10), is also part of the UDI-PI information. It is an effective way to identify manufacturing location and track other manufacturing changes without negatively impacting health care providers. In addition, there are a variety of other Application Identifiers (AIs) that can be added to the end of the UDI following the UDI-PI information<sup>5</sup>. Some of these, like AI (422), which identifies country of origin, can be used throughout the supply chain. Others can only be used by the manufacturers for internal tracking purposes. These AIs are intended for use by the brand owner and any third party working on their behalf. Examples include, AI (20), which adds a 2-digit product variant for tracking manufacturing changes, and AI (91-99) can be used to document additional manufacturer specific data.

In contrast to AI (10), lot number, that is part of the UDI-PI, data elements associated with AIs that track internal manufacturing information are not meant to be transmitted into health care provider systems. The recommended practice is for providers to configure the ERP and EHR software to read the entire barcode and apply the associated logic so only UDI-DI and UDI-PI information is processed and other AIs are ignored. In some cases, this configuration must be done at the scanner level. Scanner level configuration is more difficult to manage and recommended only in cases where the application software (e.g. EHR or ERP) does not provide this functionality. Appropriate configuration will prevent supplier AI information from creating a scanning error. Utilization of AIs allows for minor variation in product information without assigning a new UDI-DI. The above strategies provide an alternative to meeting the needs of the expanding universe of UDI stakeholders.

Manufacturers who utilize GS1 standards have access to the Global Data Synchronization Network (GDSN), which can be used to help manage the multiple UDI-DI situation. The GDSN has attributes called “reference trade item type codes” and “reference trade item type GTIN” that can be used to identify clinically equivalent devices that have been assigned different GTINs. It also allows manufacturers that move from HIBCC to GS1 to store prior HIBCC codes. The GDSN is not a comprehensive

<sup>4</sup> GS1 term “product” is synonymous with UDI term “medical device.”

<sup>5</sup> The Draft FDA Form and Content Guidance document provides additional information and can be accessed at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM512648.pdf>. Note that this draft is under review and may change when it becomes final.

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solution as it does not include HIBCC or ICCBBA information. In addition, providers must subscribe to a certified GDSN data pool to access the information and, in most cases, there is a subscription fee.

For those manufacturers using HIBCC standards, HIBCC encourages manufacturers to assign the UPN in a one-to-one relationship and provides a limited number of AIs for internal documentation.

## Software Application Providers

Most software application providers (e.g. EHR, ERP, inventory management systems, etc.) can capture, parse, read and share the data elements related to the UDI-DI and the UDI-PI. Many however are not able to read, parse and apply logic to other Application Identifiers contained within the barcode. In addition, frequently the parsing program in application software is not looking for a delimiter (GS1 FNC1 Group Separator (GS)) after a variable length data segment. Parsing issues are compounded in some instances where software applications have limits on field capacity related to the UDI-DI and UDI-PI. These issues result in failed barcode scans and often necessitate configuration at the scanner level. All of which increases the burden on the health care provider and the clinical staff.

Several providers have indicated that the major software application providers for EHRs don't have a detailed understanding of UDI requirements or how their software integrates with other application providers software (e.g. relationship with ERP and scanners). Some providers indicated they have been told by their software application provider that the GUDID was limited to GS1 standards and did not include HIBCC. Others were given misleading information related to the efforts required to add new products and synchronize data between systems.

## RECOMMENDED PRACTICES TO IMPROVE UDI ADOPTION:

The potential promise that effective UDI adoption offers related to improved patient and device safety and enhanced patient outcomes, as well as improved supply chain efficiencies, compels all stakeholders to seek ways to support achieving the vision of the UDI and not view this as a regulatory compliance issue. Specific recommended practices include:

### Health Care Providers:

- Educate manufacturers and others within the field that the health care supply chain extends into the patient record and outcomes research data bases and impacts billing and compliance requirements.
- Identify and meet with manufacturers that assign multiple UDI-DIs to what providers and U.S. regulators consider the same medical device. Invite them to come on-

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site and follow their product through the entire supply chain and clinical workflow process. Challenge them to work with providers to develop mutually beneficial solutions.

- If inaccurate or incomplete data is found in the Global UDI Data base (GUDID) report it to the manufacturer using the Customer Contact information populated in the GUDID. Inaccurate information can also be reported to the [FDA help desk](#).
- Work with other providers and manufacturers to create a form to communicate errors and track associated outcomes. Appendix A contains an example of a form for communicating errors to the manufacturer.
- Include the UDI-DI in the contracting process and capture it in the item master. Consider using barcode scan quality as a metric when selecting manufacturer partners.
- Work with your software application providers to ensure their software is configured to read all information (including hidden characters) contained within a barcode. Be able to parse and apply logic to all AIs, including the logic to ignore those AIs used exclusively for internal manufacturing processes.
- Challenge software application providers to improve interoperability between systems and develop mechanisms to effectively manage UDI-DI changes.
- Develop internal process maps and make sure supply chain and those responsible for the ERP systems are working closely with the clinical staff and those responsible for the EHR and any other associated systems.

## **Manufacturers:**

- Review internal processes to identify opportunities to minimize proliferation of multiple UDI-DIs.
- For those using GS1 standards, review guidelines and the recommended practices contained in this report to identify opportunities to minimize proliferation of multiple UDI-DIs.
- Utilize AIs as an alternative to multiple UDI-DIs where viable.
- Change the UDI-DI only when there is a major change to form, fit or function that would impact the clinical user or the patient.
- Consider the downstream impact and associated cost to other stakeholders when making changes that require an UDI-DI change. For example, changing the quantity of product in a box mandates a new UDI-DI so carefully consider the cost and impact to providers before deciding to make that change.
- Populate the “Customer Contact” field in the GUDID with contacts that are qualified to fix errors and respond to customer issues.

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- When errors are identified, update the GUDID with the correct information.
- Conduct site visits and gain a clear understanding of the impact of UDI-DI changes across the entire supply chain.
- Work with health care providers to develop a clear and effective process for communicating and managing UDI-DI changes.
- Print only the UDI for that specific unit of measure on the package. (e.g. don't put both the UDI-DI for the box and the UDI-DI for the single package on a single package).
- Select either HIBCC or GS1 as your UDI provider. Do not use both standards and do not label products with two different UDI codes.

## **Software Application Providers:**

- Configure software to read all information (including hidden characters) contained within a barcode. Be able to parse and apply logic to all AIs, including the logic to ignore those AIs that are for internal manufacturing use only. Make sure the parsing program identifies delimiters (GS1 FNC1 Group Separator (GS)) after variable length fields.
- Software application provider systems must accommodate UDI-DIs for every level of packaging not just unit of purchase or unit of use. They also should provide functionality for providers to manage UDI-DI changes.



## **External Scanner Vendors:**

- Scanners function as the input device and read all characters contained in the barcode including hidden characters.
- Logic is applied at the software application level.
- Configuration at the scanner level is not required unless application provider software does not contain this functionality at a global level.
- Be sure to include the appropriate configuration barcode images for the various keyboards used in the hospital field.

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## EXHIBIT A

### Sample Letter

 Send	To...	maria
	CC...	
	Bcc...	
Subject	Case 3: Incorrect label format - invalid Expiration Date S50000 - Peel Pack	
Attached	 Case Details.pdf 238 KB	

Maria. Thank you for taking the time to help resolve a barcode issue that was identified.

The interior peel pack(s) for the Perforated tissue have incorrect coding; containing 0000 expiration date. The UDI referenced above indicates an incorrect format. The concern is an invalid date could be scanned as part of the patients record. Please advise when issue has been resolved so that product can be replaced.

Please note that there are 7 separate label areas for RNs to navigate. Multiple labels have led to patient safety concerns. The Alloderm Select packaging UDI HIBCC labels have slightly different information on each component: peel pack, label sheet, interior and exterior box labels. We also request for Allergan to consider standardization of the interior labels. Does the interior box, peel pack and label sheets need to contain different information? For the RN in the OR, it would be beneficial if labels were consistent. RNs are trained to look for symbols as well. The manufacturer symbol only appears on the peel pack. Having the incorrect expiration date on the only component that contains the MFG leads to added time and patient safety issues.

Thank you for your consideration. We request quick resolution and look forward to your response.

Please respond by October 6, 2018.

Thank you for your time.

Joan

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