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OFFICE OF
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Use Of Universal Product Numbers For Medical Equipment And Supplies

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E X E C U T I V E   S U M M A R Y

PURPOSE

To provide a descriptive summary of the healthcare industry's use of Universal Product Numbers (UPNs) and their potential use by the Medicare program.

BACKGROUND

A Universal Product Number (UPN) is a product identifier which is encapsulated in the bar code media. A bar code is a medium which allows a number or other information to be read automatically by a bar code reader and entered into a computer without having to manually type in the data. UPNs can be encapsulated within a number of data structures and can be used with or without a bar code.

All UPNs are variable length alphanumeric strings of either 14 or 20 characters that can be used universally as the key identifier on each inventory unit for durable medical equipment and supplies. They can also be used as the key identifier to communicate product information among all trading partners in the supply chain. A number can be assigned to each packaging level (or inventory unit) of each product.

We based our study on information gathered from manufacturers and suppliers of durable medical equipment and supplies who have been using UPNs and bar codes as well as software producers and representatives from industry groups.

FINDINGS

Universal Product Numbers Are Currently Used By Some Hospitals, Distributors, and Manufacturers

Primary Use -- Supply chain management

Bar codes are currently being used within the healthcare industry primarily as a mechanism to control the supply chain. However, we found UPNs are not used in every situation in which an item is bar coded because not all manufacturers assign UPNs to their products. In these circumstances, users of bar codes must assign their own proprietary numbers to effectively utilize their bar coding systems.

Hospitals -- Experimenting with bar coding systems

We identified three hospitals currently using UPNs. They began utilizing UPNs to more effectively eliminate waste and overutilization of costly supplies and equipment, assist in modifying physician practice patterns, and streamline the patient billing process.

Some distributors and manufacturers are currently using bar coding systems

We identified a number of distributors and manufacturers currently using UPNs to simplify ordering systems for customers. At least one large manufacturer also allows customers to find products by UPN on their web site.

UPNs May Be Valuable To Medicare If Impediments Can Be Overcome

Product Identification

Most industry members agree that UPNs would allow for a number of advantages to both Medicare and the industry as a whole by allowing Medicare to specifically identify the product being claimed and provide more efficient edits. They would also aid in fraud and abuse detection.

Impediments to effective use of UPNs

There are a number of impediments that must be overcome if UPNs are to be utilized effectively by the Medicare program. For example, a standard national data repository does not exist. In those databases that do exist, there is insufficient detail for full identification of product equivalencies, and UPNs are not assigned to all medical equipment and supplies. Some manufacturers also have concerns about their responsibility to assign these numbers. Furthermore, HCFA currently lacks authority to appropriately control the system.

CONCLUSION

UPNs, While Promising, Are Not Ready To Be Adopted By The Medicare Program

In order for UPNs to be used by Medicare, it will be necessary to:

S   address the specific impediments discussed above;

S   methodically implement important steps in utilizing UPNs, and conduct periodic assessment of their viability;

S   involve all major players fully in the process, including manufacturers, suppliers, distributors, the coding industry and HCFA; and

S   provide adequate funding for planning and implementing this program.

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PURPOSE

To provide a descriptive summary of the healthcare industry's use of Universal Product Numbers (UPNs) and their potential use by the Medicare program.

BACKGROUND

Universal Product Numbers (UPNs) have been in existence for more than 10 years, being used for supply-chain management[1], pricing, and billing. While most people recognize the bar code used on many products, the UPN is not as familiar. It is a product identifier which is encapsulated in the bar code media. A UPN can be used with or without a bar code. A bar code is a medium which allows a number or other information to be read automatically by a bar code reader and entered into a computer without having to manually type in the data.

To be useful, product identifiers must be unique. This allows systems to distinguish one product at a given packaging level from another. Data processing systems are unaffected by whether product identifiers are numeric or alphanumeric, descriptive or encoded, or of fixed or variable length. This requirement of uniqueness led to the creation of the UPN, a unique identifier combining a manufacturer number, item number, and packaging level information. UPNs can be encapsulated within a number of data structures or bar codes.

All UPNs are variable length alphanumeric strings of either 14 or 20 characters that could be used universally as the key identifier on each inventory unit for durable medical equipment and supplies. The UPN can change if the product's characteristics, such as labeling or packaging changes (i.e., product color, use of a product trade name, or use of a generic name). It can also be used as the key identifier to communicate product information among all trading partners in the supply chain (i.e., manufacturer, distributor, supplier, provider, and end user). Such a number can be assigned to each packaging level (or inventory unit) of each product. Modern data systems accommodate all data types efficiently and, provided one adheres to basic design conventions for product identifiers, alphanumeric identifiers do not impact data processing procedures. Moreover, information such as manufacturer, item number, and level of packaging cannot be extracted from this number to identify individual components.

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[1]The term "supply-chain management" refers to the management of the process of manufacturing, ordering, distribution, and reordering equipment and supplies utilized by any given company. Because many organizations are decreasing or no longer maintaining inventories due to the advent of just-in-time inventory control, management of the supply-chain became more important and an increasingly popular way to lower costs.

The process begins with the manufacturer. First, manufacturers must join one of the two Code Councils, the Health Industry Business Communications Council (HIBCC) or the Uniform Code Council (UCC). When they do so, they are granted a manufacture number and the right to assign a UPN. When manufacturers create new products, or modify existing products, they submit a data form to the Code Council of which they are a member. This form contains basic information such as the UPN assigned by the manufacturer, the color, name, and unit of measure of the product. There is also a field for a description of the product. This field is currently 75 characters, but there is discussion to lengthen it to 120 characters. Once this form is submitted, the UPN is assigned. HIBCC maintains a database of those UPNs assigned by its members. A third party such as a distributor may assign a new UPN to a product if the distributor repackages the product with their name on the package. In this case, they become a labeler and therefore may be able to assign a new UPN to a product.

Once a UPN is assigned, the manufacturer generally bar codes the related products. This bar code is then scanned by distributors when they receive the package and entered into their computer system. They forward the product to the provider which also scans the bar code thereby entering it into its computer system. When the product is used by the provider, it scans the bar code at the time it is furnished to the beneficiary. This enters the UPN into the computer system and tells the computer that one product of this type has been used. In the case of just-in-time inventory management, the item is also entered into the reordering system, which takes the UPN and returns it in the form of an electronic purchase order to the distributor. It forwards the item to the manufacturer which in turn ships out a new product. In cases where the provider maintains an inventory, a count of all products is kept on the computer system and when the UPN is scanned, it removes one unit of the product from that inventory count. When the computer system hits a reorder point, the electronic form is produced and submitted to the distributor for filling which then submits the order to the manufacturer for shipment of the products. Most organizations use a combination of just-in-time inventory control and maintaining a small amount of inventory. Unique identifiers such as Universal Product Codes (UPCs) have facilitated the move to just-in-time inventory control in retail stores and chains.

Both code councils use a product "look-up" because it is faster, error-free, and provides a reliable source for validating the product identifier after it has been put into the system. This means that the system utilizes tables keyed to the complete identifier to look-up either component or supplementary information about the product represented by it. To do this "look-up," a repository for all UPNs is needed. This repository is meant to be a master catalog of all medical surgical products containing basic data elements such as UPN, manufacturer name, description, item number, color, unit of measure, and quantity associated with the unit of measure. It is a single place to collect and redistribute the information necessary for the healthcare industry to cross-reference manufacturers' part numbers to UPNs.

Problems Identified by The General Accounting Office

The General Accounting Office (GAO) issued a report on UPNs in 1998.[2] According to the report, "[the Health Care Financing Administration] does not know specifically what Medicare is paying for when its contractors process claims for... [durable medical equipment and supplies]" and, it noted that Medicare reimburses large suppliers and individual beneficiaries at the same rates without regard to discounts many manufacturers give suppliers. Furthermore, it noted that Medicare pays approximately $4.6 billion a year for medical equipment, but the problem with the current system according to the UPN supporters is the manner in which it is paid. Medicare's payment rates are based on broad product categories called billing codes. These codes can contain medical items with more than one price. Within each billing code, Medicare pays an average cost based on a complicated formula that essentially averages the price so that some products are overpaid and some are underpaid. For example, the GAO report stated that there are more than 200 types of catheters. These range in price from $.42 to $34.95. Medicare paid a little more than $11.00 for each due to the limitation with their current coding system. The GAO raised as a possible problem the fact that there is an incentive for a hospital to use a $1.00 catheter, submit a claim, and be reimbursed over $11.00.

Legislative Action on UPNs

Following the issuance of the GAO report, legislation was introduced in both the Senate and the House (S. 256 and H.R. 418) which would require the use of UPNs on all Medicare DME claims submitted for payment. The legislation would require that the UPN be accommodated on Medicare claim forms by February 1, 2001. It further requires the Secretary to review the UPN covered items billed under the HCFA "Common Procedure Coding System and adjust such coding system to ensure that functionally equivalent UPN covered items are billed and reimbursed under the same codes." No payment would be made for "any claim for reimbursement for any UPN covered item unless the claim contains the universal product number of the UPN covered item."

The system proposed by the legislation would conceivably initiate a new process of reimbursement whereby technology currently being used in most stores would be implemented to capture the specific item claimed and then pay the price of the medical equipment or supply. HCFA, in its comments to the GAO report, stated that there is insufficient information to make the UPN useful to claims processing decisions. It also indicated that "if HCFA required the submission of UPNs, it would not have the authority to require manufacturers to reveal what each UPN represents [such as product features, manufacturers' price, purpose and uses of a product, HCPCS code with which the UPN would be associated, and the number of items per

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[2] Medicare, Need to Overhaul Costly Payment System for Medical Equipment and Supplies, GAO/HEHS-98-102.

package.]" They also stated that it is possible manufacturers would consider such product information proprietary and resist any voluntary requests for information.

Healthcare Electronic Data Infrastructure Coalition

The Healthcare Electronic Data Infrastructure Coalition (HEDIC) is an organization whose stated mission is to "improve the efficiency of business interaction through the collaborative development and optimization of the Electronic Data Infrastructure (EDI) in the healthcare industry. This 'infrastructure' includes the use of Bar-Codes, Automatic Identification and Data Capture, Electronic Data Interchange, Electronic Commerce, and Central Industry Data Repositories based on the adoption of universal identification, codification, communication and data standards..."[sic]. HEDIC is composed of healthcare providers and their trading partners such as healthcare plans, suppliers, data communications services, software developers, consulting services, employers and government agencies.

Uniform Code Council

The Uniform Code Council, Inc.'s (UCC) purpose is "to take a global leadership role in establishing and promoting multi-industry standards for product identification and related electronic communication. The goal is to enhance supply chain management thus contributing added value to the customer." The European Article Numbering Association International (EAN) and the Uniform Code Council, Inc. are voluntary standards organizations that manage the EAN/UCC system. EAN International has a decentralized structure with a membership composed of Numbering Organizations that manage the EAN system in a particular country or economic region. The UCC manages the numbering system for the U.S. and Canada. The EAN International's head office is responsible for coordinating and facilitating activities that deal with the development, management and promotion of the EAN/UCC system amongst the Numbering Organizations.

Health Industry Business Communications Council

The Health Industry Business Communications Council (HIBCC)was founded in 1984 by the provider community and its trading partners for the specific purpose of creating a bar code labeling standard to meet the needs of hospitals. There were two barriers that inhibited use of the technology: (1) there was no standard which accommodated unique product numbering schemes prevalent in healthcare; and (2) the high cost, bulk, and inflexibility of bar code equipment.

The HIBCC labeling standard provided flexibility to accommodate various data structures, thereby solving the first impediment. Low cost code scanners capable of reading multiple types of symbologies and inexpensive high-speed computers capable of storing and retrieving huge volumes of information contained in databases have solved the second. The HIBCC and the

Uniform Code Council (UCC) have together provided labeling standards that address the needs of almost all manufacturers.

Department of Defense

About 5 years ago the Department of Defense (DOD) abandoned depot facilities and commercial distribution centers. During this process they looked to commercial sector distributors to obtain information on products that did not vary much between distributors and product with similar qualities from different distributors. DOD's process of ordering by part number was not satisfactory because each manufacturer uses their own numbering system. The DOD needed to use one number for distribution, ordering, and processing shipments electronically and it needed to be globally recognizable and unique to the product and its packaging. It tapped into use of the UPN which it found successful in inventory control and purchasing.

Currently, there are different levels of compliance by DOD vendors. At the shipper level (i.e., where the main distributor purchases from the manufacturer directly) there is 75 percent compliance, but over 95 percent compliance for high volume items. There is less compliance as the packaging is reduced to the box level and then to the unit of use level. This is what supporters of UPN legislation hope to fix by requiring the coding of smaller packages or even the individual items. This could mean more expense for manufacturers.
The DOD has tested for vendor compliance with its ordering system and has found that distributors can accept UPNs. It purchases items by the case lots from manufacturers directly then break it down to the box level for customers. However, it believes that legislation should require UPNs at every level of packaging. Since 1995, the DOD has been asking manufacturers to do this. However, it has limited power to require it because its purchases represent only 4 percent of the market.

METHODOLOGY

As part of our development, we carried out extensive research into UPN literature, including various articles and product information. We also conducted interviews with a number of manufacturers and suppliers of durable medical equipment and supplies who have been using UPNs and bar codes, as well as software producers and representatives from industry groups, to obtain perceptions of the use of these designations for various programs, particularly claims processing and adjudication. Sources of referral for interviews came from industry contacts, Federal and State agency discussions, UPN-related conference attendance, and user references. We conducted this inspection in accordance with the ***Quality Standards for Inspections*** issued by the President's Council on Integrity and Efficiency.

F I N D I N G S

Universal Product Numbers Are Currently Used by Some Hospitals, Distributors, and Manufacturers

Health care entities are primarily using UPNs for supply-chain management

Currently bar codes are being used within the healthcare industry primarily as a mechanism to control the supply-chain. However, we found UPNs are not used in every situation in which an item is bar coded because not all manufacturers assign UPNs to their products. In these circumstances, users of bar codes must assign their own proprietary numbers to effectively utilize their bar coding systems.

< **Manufacturers are assigning UPNs to some products.**
According to HEDIC, healthcare manufacturers of medical/surgical supplies are already bar coding a UPN on about 70 percent of shipping cases. The percentage decreases as packaging levels decrease to box and unit of use. A few of the larger manufacturers, however, are bar coding up to 95 percent of their products at all packaging levels. The remaining 5 percent are not bar coded due to transitions in the companies such as recent acquisitions or mergers.

< **Distributors and providers encourage manufacturers to bar code products.**
Two providers told us that the efficiencies gained in their system paid for their bar coding system within 5 months of implementation. Distributors and providers are the most frequent users of bar codes. They use bar codes (with and without UPNs) to track orders, increase/decrease inventory, and submit orders. One organization representing the distributor industry told us that many distributors would be willing to bar code items if HCFA requires their inclusion on Medicare claims.

A few hospitals are currently using bar coding systems in supply-chain management and patient care

We identified three hospitals currently using UPNs. They began utilizing them for the following reasons:

< **To more effectively provide services to beneficiaries, while operating with fewer resources.**

Due to competition and other factors, hospitals are attempting to eliminate unnecessary costs which has led to streamlining the supply-chain.

< **To eliminate waste and overutilization of costly equipment and supplies.** One hospital uses their bar coding system to determine what supplies a particular disease code uses 95 percent of the time. These supplies are then packaged together and delivered to the unit where needed. This has eliminated multiple trips to unclean areas (e.g., hallways, store rooms), resulting in improved patient care. Supplies are still maintained for atypical cases allowing the hospital to adjust products as practice patterns or patient needs require.

< **To assist in modifying physician practice patterns.** Another hospital provides physicians with information about the supplies they utilize during particular procedures. When a physician is found to be utilizing equipment or supplies that are not cost-effective, staff and physicians meet to discuss whether those items are the most appropriate. This often results in changes in physician practice patterns.

< **To streamline the billing process.** A third hospital wanted a more automated system which would require fewer employees, fewer mistakes in data entry, and greater accuracy. This hospital is using bar codes to enter charge codes into an electronic form which is then submitted for payment and printed and sent to the patient. The proprietary number used by the hospital is linked to a plain language description of the service which assists patients' understanding of the bills they receive. This hospital is not, however, using UPNs, nor is it planning to do so at this time. Instead they are focused on patient billing.

Some distributors and manufacturers are currently using bar coding systems

We identified some distributors and manufacturers currently using UPNs. At least one large manufacturer allows customers to find products by UPN on their web site.

< **Distributors use UPNs to simplify their order systems for customers.** HIDA told us that many distributors are beginning to use UPNs to aid customers in purchasing medical equipment and supplies. UPNs also help them track orders in their own inventory systems. The organization is encouraging the use of UPNs because they see the industry as moving toward their use. One industry group reported distributors are currently bar coding 70 percent of shipping and inner packs, but only 25 percent at the unit of use level. Many are already making changes to their ordering systems to accommodate bar codes and they point out that the American National Standards Institute already has a space for UPNs on their insurance claims forms.

< **Some manufacturers are assigning UPNs to their products.**
Some larger manufacturers are assigning UPNs to their products and at least one uses UPNs as a look-up number on their web site.

Users Cite a Number of Concerns about UPNS

Some users, mainly larger hospital systems, have concerns about bar coding systems and UPNs. Some manufacturers also have concerns centering on their responsibility to assign these numbers.

< **Hospitals cannot require their suppliers to bar code products.**
As a consequence, hospitals and other providers using bar codes for inventory control, utilization, and reordering purposes assign their own codes and affix bar codes to these products. This results in additional costs to the hospitals and other providers. However, costs associated with product coding should be less for a manufacturer capable of working it into their packaging system. Two hospitals said they were willing to absorb added cost from manufacturers for UPN and bar coding of products and supplies.

< **Implementation of UPNs requires a substantial investment.**
This concern was raised by a number of large hospital systems. These providers must change multiple computer systems at different facilities to accept the UPN and maintain these systems.

< **Providers' systems in general are not able to use bar codes.**
Some hospitals told us that their computer systems were still using operating systems as old as DOS and that there would need to be large system upgrades to utilize bar codes and UPNs. We were unable to find any physician's practice that would be capable of using bar codes or UPNs.

< **Skepticism of the system**.
The accounting department of one facility is skeptical of the system and the charges resulting from the system, so the facility hired an auditor to double-check all billings as they are produced.

< **Manufacturers are concerned about providing too much information about their products.**
At least one manufacturer told us that they were concerned that competitors may attempt to submit false information about their products to existing databases. The same manufacturer also told us that they did not want to provide information that could be used by their competitors against them. They also think they should not be required to provide information sufficient to make

functional equivalency determinations when the organization making those determinations could simply look in a company catalog.

Sheer Number of Possible UPNs.

Universal Product Numbers are extremely sensitive. Although the UCC recommends not assigning new UPNs for insignificant changes in products, there is no prohibition against doing so. As such, the smallest change in the product, including color, could result in the issuance of a new UPN. Therefore it is possible that as products are updated, redesigned, and modified in other ways, a new UPN could be assigned. One manufacturer and HCFA staff are concerned that this could result in slight changes for nothing more than marketing purposes or to game the system. Attempting to pay based on the UPN itself would require a process to consider equivalencies and pricing for massive numbers of items either on the repository or coming onto the repository at any one time.

UPNs May Be Valuable To Medicare If Impediments Can Be Overcome

Product Identification

Most industry members agree that UPNs would allow for a number of advantages to both Medicare and the industry as a whole.

< **UPNs would allow Medicare to specifically identify the product being billed.**
This would be useful for determining Medicare coverage and appropriate payment.

< **UPNs will assure that providers are looking at the same product for both payment and medical review of items.**
One hospital system noted they are experiencing problems analyzing the same products among each of their 17 facilities.

< **UPNs could provide more efficient edits.**
The ability to specifically identify the product could enable carrier edits to work more efficiently.

< **UPNs could aid in fraud and abuse detection.**
Individuals from HCFA and industry told us that UPNs would help detect fraud and abuse if the system would provide for the independent and objective indexing of the salient characteristics for products. UPNs could also reduce

claims fraud. If listed on the claim, the UPN will specifically identify the manufacturer and the type of product claimed, as compared to the current system which relies on HCPCS codes which are not always product specific.

The UPN could be a valuable piece of additional evidence when trying to prosecute a fraudulent provider. For instance, if the HCPCS for which the provider has submitted a claim for payment is not accurate, it could be due to the use of a mistaken code. However, when a provider also submits a UPN on that claim form, it is more difficult to claim a mistake when the UPN is readily identifiable.

Impediments to effective use of UPNs

There are a number of impediments that must be overcome if UPNs are to be used by the Medicare program.

> **A standard national data repository does not exist.**
> Currently there is no nationally recognized database usable by all members of the industry. There are a number of smaller databases, but none of them are used industry wide. The HIBCC and UCC databases contain fewer than 500,000 UPNs. Others, such a those developed by Mitch Cooper & Associates and St. Alexius Medical Center, are smaller and are not now used by the industry as a whole.

> **There is insufficient information contained in the repositories.**
> In the HIBCC database, most commonly referred to as an industry standard repository, there are only 80 character spaces for descriptive information. The industry believes that this amount is sufficient, but those familiar with the current databases indicated that it could be increased to 120 characters. Still, some HCFA staff believe the available space is insufficient to provide the information needed to identify the appropriate HCPCS code or to make determinations concerning functional product equivalencies. A separate contractor would be needed over and above the carrier to collect UPN data and to build a data repository for these codes and their HCPCS equivalents. This would increase the integrity of the information available to HCFA as well as assure access to it by all providers. HCFA may need to be able to control the information required on the database. Because space is limited, some information may be of lesser value in determining product equivalencies than other information. Further, industry may be reluctant to provide certain data if it is not specifically mandated. However, information that HCFA finds of lesser value may be needed by other industry members utilizing such a repository and, therefore, determination of what information should be required would need to be a cooperative effort.

< **HCFA would need control of the system.**
It may also be necessary for HCFA to be able to control various aspects of the implementation of UPNs. Such concerns might include what type of information is submitted to the database and the methodology used to assign UPNs. Because suppliers vary in size and technology, HCFA may also need to control the phasing in of such a system to allow less technical suppliers to meet their systems needs. HCFA would also need to be able to determine who may assign UPNs to products. This is necessary to ensure that all manufacturers are treated fairly and that onerous membership costs and fees are not incurred as a requisite to assign a UPN.

< **Many computer systems are inadequate.**
Manufacturers, hospitals, and suppliers all cited inadequate systems as a problem. Many hospitals are on older computer systems that would need upgrading to accommodate UPNs and bar code technology. Manufacturers also would need time to not only change their computer systems, but also their packaging processes to accommodate changes in labels and boxes.

< **Bar codes are not applied to all medical equipment and supplies.**
As indicated, UPNs are assigned and bar codes are applied to about 70 percent of medical/surgical supplies. If Medicare requires the inclusion of UPNs on all claims forms, the most troublesome issue is who is required to bar code. Manufacturers do not have a direct link to the Medicare program unless they are also suppliers. Therefore, if manufacturers decide not to bar code their products, suppliers must decide whether to purchase from another manufacturer (provided the product is produced by another manufacturer) or whether to bar code themselves. As the proposed legislation would require manufacturers of medical equipment and supplies to assign UPNs to all their products, this would also affect those manufacturers who do not sell products to Medicare suppliers.

< **At this time, no payer requires UPNs for claims processing.**
The largest government agency currently utilizing UPNs is the Department of Defense. They advised us that the DOD has utilized UPNs for a number of years, but only uses them for supply-chain management. We could not identify any insurance or government payer currently requiring the inclusion of UPNs on claims for payment. The State of California is considering, but has not implemented, the use of UPNs in their claims forms.

CONCLUSION

UPNs, While Promising, Are Not Ready To Be Adopted By The Medicare Program

In order for UPNs to be used by Medicare, it will be necessary to:

S   address the specific impediments discussed above;

S   methodically implement important steps in utilizing UPNs, and conduct periodic assessment of their viability;

S   involve all major players fully in the process, including manufacturers, suppliers, distributors, the coding industry and HCFA; and

S   provide adequate funding for planning and implementing this program.