



Via Electronic Submission

November 7, 2012

Mr. Jay Crowley
Center for Devices and Radiological Health
Food and Drug Administration
Division of Dockets Management (HFA- 305),
5630 Fishers Lane, Rm. 1061,
Rockville, MD 20852

Re: Comments on Unique Device Identification (UDI) Proposed Rule; Docket No: FDA-2011-N-0090 RIN No: 0910-AG31; Agency: Food and Drug Administration (FDA), HHS¹

Dear Mr. Crowley:

AAHomecare submits comments in response to the request for comments on the proposed rule cited above. Specifically, FDA has requested comments on the adoption and implementation of a unique device identifier (UDI) system. The system established by the rule, once finalized, will require the labeling of every medical device to bear a UDI, except where the rule provides for alternative placement of the UDI or provides an exception for a particular device or type of device. The UDI Database, which will be built and maintained by FDA, will contain identifying information about the device. One important goal in implementing the system is to enhance patient safety by facilitating access to specific device information for surveillance and product recalls.

AAHomecare members include providers and manufacturers of durable medical equipment (DME) and supplies which are used by patients in their homes. It is impossible to overstate the importance of the work that AAHomecare members perform. Numerous recent studies show that homecare technologies, supplies and services are effective for managing the health needs of the chronically ill while reducing the costs associated with inpatient care.² The innovative technologies, supplies and services furnished by AAHomecare members allow individuals to

¹ 77 Fed Reg. 40736 (Tuesday July 10, 2012).

² See for example, Landers, S. "Why Health Care Is Going Home," New England Journal of Medicine, October 20, 2010; Oba, Y. "Cost-Effectiveness of Long-Term Oxygen Therapy for Chronic Obstructive Pulmonary Disease," American Journal of Managed Care, February 2009; Lau, J., et al., Long-Term Oxygen Therapy for Severe COPD, June 11, 2004, Tufts-New England Medical Center Evidence Based Practice Center.

receive effective care in their homes quickly and safely without incurring expenses for inpatient stays. Given that AAHomecare represents both providers and manufacturers of DME devices, supplies and services, the association is uniquely qualified to comment on the proposed rule.

AAHomecare supports the goals underlying FDA's proposed rule. Our comments focus on the need for FDA to carefully balance the benefits of a UDI system and the potential financial and administrative burden on manufacturers that could translate into higher prices for providers who purchase these products. AAHomecare encourages FDA to implement the UDI requirement in a way that avoids duplication and administrative and financial burdens on providers and manufacturers. FDA also should ensure that UDI implementation is carried out in a way that is consistent with other standard-setting bodies, including those established under the administrative simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA), and which does not disrupt payment to providers. We also request that low risk Class 1 and Class 2 medical devices requiring a 510k or exempt from 510k approval be exempt from the requirements included in the proposed rule.

A. PROVIDER IMPLEMENTATION ISSUES

1. Implementation of the UDI system must not disrupt provider reimbursement.

The adoption and implementation of a UDI system must not disrupt payment to providers. AAHomecare recognizes that one benefit of the UDI would be to provide greater specificity about devices providers furnish to health plan enrollees. In order to accomplish this objective, however, the Department of Health and Human Services (HHS) must adopt the UDI as a new standard code set under the HIPAA administrative simplification regulations. This is a multi-step process beginning with recommendations by designated standard maintenance organizations (DSMOs) to adopt changes to the code sets and standard electronic transactions and culminating with the adoption by HHS of the new standard code sets and transactions through a formal regulatory process.

Currently, providers may use a national drug code (NDC) to report claims for devices and medical supplies on the NCPDP standard electronic transactions for pharmacy claims. Proposed 801.57³ would rescind the legacy NDC code assigned to a device on the date a device must bear a UDI. However, in order to preserve claims payment operations, providers and payers must retain the ability to use the NDC for devices and supplies on pharmacy claims upon adoption of the UDI until HHS modifies the pharmacy code sets and standard electronic transactions to accommodate the UDI. AAHomecare requests that the final rule include a grace period during which providers may continue to report pharmacy claims for medical devices and supplies using the applicable NDC.

³ 21 CFR § 801.57, proposed.

2. FDA must address provider implementation issues in establishing compliance effective dates in the final rule.

FDA proposes to phase-in compliance with UDI requirements over a seven-year period beginning with riskier Class III devices, which must be in compliance with the labeling and data submission requirements within twelve (12) months of the FDA's adoption of a final rule. As a practical matter, we question whether a 12-month period is adequate for manufacturer compliance with UDI requirements and recommend that this time frame be expanded by an additional twelve months. However, regardless of the timeframe FDA designates for a manufacturer's UDI implementation, FDA must consider the operational needs of providers and ensure that they have the necessary resources to incorporate the UDI effectively in their systems and give them sufficient time to do so. Additionally, we recommend that FDA engage in outreach to providers to educate them about its implementation of the UDI system and its impact on their operations.

3. FDA should clarify the responsibilities of providers down the chain of distribution in the event a manufacturer fails to comply with the UDI requirements within the compliance deadline for that type of device.

We understand the proposed rule to require the labeler of a device to comply with the UDI and reporting requirement. Similarly, we understand that the "labeler" is typically the manufacturer but may include other entities identified in the regulations. However, in the event a labeler fails to comply with requirements of the proposed rule, the obligations of the down-stream supplier or distributor are unclear. In this scenario, would a distributor be precluded from distributing the product?

B. OTHER IMPLEMENTATION ISSUES

1. The UDI expiration date format must be consistent with the formats required by other global standard-setting bodies.

The proposed rules would require manufacturers to conform dates to a specified format that may be inconsistent with that of other international regulating bodies. This inconsistency would impose an administrative and financial burden on manufacturers that distribute their products globally. These manufacturers must meet the requirements of any given locality and the introduction of a lesser-used date format will require international companies to accommodate multiple date formats in their labels which also may not be feasible depending on the type of product and the size of the label. If improving surveillance and patient safety through enhanced device traceability and identification is truly a goal of UDI, increasing the prospect of user and caregiver confusion as a result of having multiple date formats on a label is counterintuitive and should be avoided by harmonizing the date format standard with those of other standards issuing bodies.

Additionally, one of the association's predominant concerns with the adoption and implementation of the UDI regulations is that the administrative and financial costs of implementing the new rules will ultimately be reflected in the amount manufacturers will charge for their products. Our members will be adversely affected by any price increases that follow the implementation of the UDI system since medical equipment is paid on a set fee schedule.

Consequently, FDA should streamline the requirements it imposes on manufacturers under a final rule and avoid duplication or inconsistencies with existing requirements administered by other standard-setting bodies. In this case, we recommend that the final rule adopt a data format standard that is consistent with the recommendations of the International Medical Device Regulatory Forum (IMDRF) UDI subgroup.

2. FDA should clarify the exception for devices sold at retail.

Under proposed 801.30,⁴ devices sold at retail, other than "prescription devices," would be exempt from the requirement to bear a UDI. FDA should clarify what it intends in carving out "prescription devices" from the retail exception. Specifically, under FDA regulations, the label of a prescription device must bear a legend stating: "Caution: Federal law restricts this device to sale by or on the order of a [physician]."⁵ However, some devices furnished to patients on the basis of a prescription are not legend devices within the meaning of 801.109. These devices may require a prescription to satisfy payer requirements for medical necessity documentation, not because of the device's "potentiality for harmful effect" or because "the method of its use or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use for such device"⁶

For example, health care reimbursement accounts established under certain health plans will not reimburse over-the-counter drugs and devices unless plan enrollees furnish a physician's order for the drug or device. This is purely an administrative requirement for reimbursement imposed by the health plan that is unrelated to the device's "potentiality for harmful effect." As currently written, proposed §801.30 would render this provision of the retail exception meaningless because payers require a prescription for the reimbursement of many non-legend devices sold at retail. Moreover, whether or not a device is furnished under a prescription would not be a useful criterion for determining whether a device is exempt from the UDI labeling requirement because a prescription may or may not be necessary depending on a payer's policies and not because of any inherent attributes of the device.

⁴ 21 CFR §801.30 (a) (1)

⁵ 21 CFR § 801.109 (b) (1).

⁶ 21 CFR 801.109.

Consequently, FDA should distinguish between prescription devices that are legend devices within the meaning of 801.109 and devices that merely require a prescription as a condition for coverage under an applicable public or commercial health plan. Moreover, these devices already bear a UPC which can be used in the event of a recall. AAHomecare believes that it is more appropriate and less administratively burdensome to apply the retail exception to non-legend devices than it is to determine whether the retail exception applies based on the presence or absence of a prescription, which in turn, depends on a payer's specific reimbursement policy.

3. FDA should permit manufacturers the flexibility to choose the AIDC technologies used in providing UDIs.

AAHomecare believes that FDA should give the health care industry and the issuing bodies the flexibility to choose the AIDC technologies that are used in issuing AIDC. The FDA's involvement in this decision or in the approval of new technologies will stifle innovation and ultimately increase the financial and administrative burdens of complying with the UDI regulations. These costs will eventually be reflected in the price manufacturers charge for the products and will be borne by their health care provider customers.

4. Data submission requirements should be balanced against the cost and administrative burdens of submission.

FDA specifically requests comments on whether it should solicit other data elements in addition to those proposed for submission to the GUDID under the proposed rule. The following data elements are among the additional elements FDA is considering for submission to the GUDID:

- a. Prescription and/or over-the-counter;
- b. Magnetic Resonance Imaging (MRI) Compatibility Type (safe, unsafe, conditional); if conditional, the description of the conditions;
- c. Storage and handling conditions (e.g., maximum storage temperature, needs to be refrigerated, keep out of light);
- d. Country of origin, manufacturer, and/or intended sale
- e. Short and/or long descriptions
- f. Marketed for home use
- g. Labeled as hazardous
- h. Contains radioactive isotopes (radioactive element and atomic number)
- i. Has Material Safety Data Sheet (MSDS)

AAHomecare believes that FDA should consider the operational burdens and costs that manufacturers will bear in implementing the UDI regulations. Consequently, the Association discourages the Agency from adopting additional data elements for submission by manufacturers to the GUDID. In particular, AAHomecare is cognizant that implementation costs

will inevitably be passed down the distribution chain and reflected in the amount providers pay for devices. AAHomecare recommends that FDA refrain from adopting additional data elements for submission to the GUDID in the final rule. Moreover, FDA should solicit comments and give stakeholders adequate notice of any changes to the data elements it intends to make in the future.

5. FDA should clarify the obligation of manufacturers of constituent or component parts that are incorporated into other products.

AAHomecare understands that “combination products” are products that consist of a device and a drug or biological. The proposed rule would not require that a device bear a UDI if it is combined with another product physically or chemically such that it may be used solely as part of the combination product. However, it is unclear to us how the UDI requirements would apply to constituent or component devices that are incorporated into other devices either manufacturer’s own products or those of another manufacturer. The examples below may be useful in understanding the scope of our question:

Example 1: A manufacturer of mobility aids manufactures its own walkers. Walkers require rubber tips at the end of the legs which the manufacturer also makes. Do the rubber tips in this example require their own UDI?

Alternatively, the manufacturer makes the walker frames, but sources the rubber tips from manufacturer B? Is manufacturer B required to comply with the UDI requirements with respect to the rubber tips?

In each of these scenarios, AAHomecare questions the value of applying UDI requirements to the rubber tips given that the rubber tips are incorporated into the base product such that they cannot be used independently of the base product, the walker. While this is a simplistic example, we believe that the rationale for excluding these types of constituent or component parts extends to all medical devices that contain these types of parts and request that FDA clarify that they would be exempted from the UDI requirements.

Example 2: Manufacturer “A” makes motors that are used in repairs of other manufacturer’s products such as power wheelchairs or electric beds. Generally, these are “repair components” that cannot be used independently of the base device. Does manufacturer “A” have to comply with the UDI requirement for these repair components?

As in Example 1 above, devices that serve as repair components used in other devices and which cannot be used independently of the base device should be exempted from UDI requirements.

C. CONCLUSION

AAHomecare appreciates the opportunity to submit these comments. As we have emphasized above, our main concerns with the adoption and implementation of a UDI system are that FDA carefully balance the benefits of a UDI system against the potential financial and administrative burden on manufacturers that could translate into higher prices for providers who purchase these products. AAHomecare encourages FDA to implement the UDI requirement in a way that avoids duplication and administrative and financial burdens on providers and manufacturers. It is important that UDI implementation is carried out in a way that is consistent with other standard-setting bodies, including international standards setting organizations standards that apply to global manufacturers. It is also very important that UDI implementation not disrupt payments to providers and that the FDA balance the costs and burdens a final rule will impose on manufacturers against the benefits of requiring product labels to bear a UDI. Ultimately, health care providers will bear the costs of compliance in the form of higher prices for the devices they purchase. Finally, we request that low risk Class 1 and Class 2 medical devices requiring a 510k or exempt from 510k approval be exempt from the requirements included in the proposed rule.

Sincerely,



Walter J. Gorski,
Vice President for Government Affairs