AMERICAN ASSOCIATION FOR HOMECARE

Supporting Quality Health Care Services at Home

Via Courier, Facsimile and Electronic Mail

November 9, 2006

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane,
Room 1061
Rockville, MD 20852

Re: **Docket No. 2006N–0292: Unique Device Identification; Request for Comments**

Dear Sir or Madam:

The American Association for Homecare (AAHomecare) offers the following comments per the Food and Drug Administration's (FDA) request on the Unique Device Identification (UDI) system discussed in the Federal Register on August 11, 2006, at page 46233.

AAHomecare represents approximately 700 health care providers with 4000 locations nationwide, including manufacturers and suppliers who furnish home health services, rehab and assistive technologies, and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) to millions of Medicare and other government and private payers' beneficiaries. AAHomecare will limit its comments to those issues related to the UDI system applicable to providing medical devices to patients at their residences.

First, we would like to contrast the unique home healthcare environment with the acute care setting. In a hospital environment, medical devices are distributed from a central location to patients within the same facility; however, in a homecare setting, there are a great many points of distribution (e.g., movement from a central warehouse to branch warehouses via multiple trucks, then to individual patients in their homes or elsewhere via multiple delivery vehicles). To require bar-coding equipment in each vehicle and at each distribution point would be cost prohibitive and unduly burdensome, and we believe would provide little additional assurance of patient safety, if any. The complexity of a UDI system may also have a significant impact on usability in the home healthcare environment.

Regarding the questions related to Developing a System of Unique Device Identifiers:

2006N-0292

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On page 46234 of the Federal Register notice, the FDA describes some of the elements it envisions a UDI might include. Our comments relate to these elements.

1. How should a unique device identification system be developed? What attributes or elements of a device should be used to create the UDI?

   We leave it to the device manufacturers to answer the question "How should the UDI system be developed?" In answer to what elements should be used to create the UDI, we fully agree with the commentary in the FDLI report of the October 27, 2005, meeting with regard to the level of identification (bullet 7 under III (c) 4). Specifically, for disposable equipment items, it would be sufficient to identify them just down to the lot number and unduly burdensome to identify them down to the individual item.

2. What should be the role, if any, of FDA in the development and implementation of a system for the use of UDIs for medical devices? Should a system be voluntary or mandatory?

   If UDI is approved, we suggest that it be implemented in close coordination with the industry over a long enough period of time to be affordable. We believe the system should be voluntary.

3. What are the incentives for establishing a uniform, standardized system of unique device identifiers?

   For the home medical equipment industry, incentives for establishing a UDI system, and the infrastructure to support it, are minimal at best. If the agency implements UDI, then uniformity of unique device identifiers may minimize the impact on users.

4. What are the barriers for establishing unique device identifiers? What suggestions would you have for overcoming these barriers?

   We leave it to the device manufacturers to offer an answer to this question.

5. Have you implemented some form of UDI in your product line? Please describe the extent of implementation, type of technology used, and the data currently provided.

   We leave it to the device manufacturers to offer an answer to this question.

6. Should unique device identifiers be considered for all devices? If yes, why? If not, what devices should be considered for labeling with a UDI and why?

   In an acute care setting it may be appropriate to have UDIs for Class II and III medical devices and, as stated previously, it would be sufficient to identify them

down to the lot number or serial number. See our response to Question #1 for additional comments on this question.

7. At what level of packaging [that is unit of use] should UDIs be considered? Should UDIs be considered for different levels of packaging? If yes, should the level of packaging be based on the type of device? Why or why not?

   The appropriate level to be addressed by the UDI should be based on the type of device. One cannot say that "one size fits all."

8. What solutions have you developed or could be developed for addressing the technological, equipment, and other problems that might arise in developing and implementing a UDI system (e.g., solutions for packaging issues)?

   We leave it to the device manufacturers to offer an answer to this question.

Regarding the questions related to Implementing Unique Device Identifiers:

9. What is the minimum data set that should be associated with a unique device identifier? Would this minimum data set differ for different devices? If so, how? How would the data in the minimum data set improve patient safety? What other data would improve patient safety?

   We leave this question to the manufacturers and the users who intend to use the data.

10. How should the UDI and its associated minimum data set be obtained and maintained? How and by whom should the UDI with its associated minimum data set be made publicly available?

    The data set should be input by equipment manufacturers and be controlled by the FDA on its website.

11. Should the UDI be both human readable and encoded in an automatic technology? Should the UDI be on the device itself (e.g., laser-etched) for certain devices?

    Yes, if UDI is implemented, both human readable and encoded information should be included at some levels; however, UDI number length and/or barcode technology would make the additional tracking highly burdensome for the home medical equipment industry, given that serial and lot numbers are already tracked for certain devices, and given the greater number of distribution points for home medical equipment providers, as discussed earlier. The device manufacturers should determine whether the UDI should be on the device itself, rather than mandating it by regulation.

12. Should a UDI be based on the use of a specific technology (e.g., linear bar code) or be nonspecific? Please explain your response. If a bar code is recommended, is a

specific type of symbology preferred, and if so, what type and why? Should the bar code be "compatible" with those used for the drug bar code rule? If yes, why? If not, why not.

We suggest settling on a specific technology that is consistent with the bar code rule for drug tracking.

Regarding the questions related to UDI Benefits and Costs:

On page 46234 and 46235 of the Federal Register notice, the FDA describes first in broad terms and then specifically the perceived benefits of a UDI system to report adverse events and institute recalls, and also "to promote safe device use" and interface with a national database. The FDA also describes what it perceives to be ancillary benefits. Our comments relate to these perceived benefits.

13. From your perspective, what public health and patient safety benefits could be gained from having a standardized unique device identifier system? How would such a system contribute to meeting device recall and adverse event reporting requirements, and to reducing medical error?

    The current non-UDI systems in use have adequately protected the public health. We are not aware of any substantiated evidence indicating an enhancement in public health and patient safety will be derived from a standardized UDI system in a home healthcare environment.

14. From your perspective, what are the setup costs measured in time and other resources associated with the development, implementation and use of a UDI system?

    This is difficult to answer without an understanding of what will be required of the UDI system and the associated tracking requirements. We believe implementing the highly technical Information Systems necessary to support a UDI system would be cost prohibitive in the current home healthcare reimbursement environment.

15. If you have already implemented a form of unique identification on your medical device labeling, what investments in equipment, training, and other human and physical resources were necessary to implement the use of UDIs? What factors influence your decision to implement such a system? What changes in patient safety or economic benefits and costs have you observed since the institution of UDIs?

    We have not implemented the use of UDIs.

16. From your perspective what is the expected rate of technology acceptance in implementing or using a UDI system?

    We anticipate a very low rate of bar code technology capability within the home healthcare environment.

17. From your perspective, what are the obstacles to implementing or using a UDI system in your location?

    Unlike IT systems in a hospital, home healthcare IT systems are not self-contained in one facility and may not be available at the branch (patient service facility) level and in the field (delivery vehicles at patients' homes). Current reimbursement levels (unlike acute care settings) represent a significant obstacle to implementing or using a UDI system in the multiple locations operated by home healthcare firms.

18. For hospitals and other device user facilities considering technology investments, what would be the relative priority of developing UDI capabilities compared to other possible advancements, such as Electronic Health Records, bedside bar-coding for pharmaceuticals dispensing, data sharing capabilities across hospitals and other device user facilities and other possible advances?

    In the home healthcare industry, developing UDI capabilities has been, and is anticipated to remain, a low priority.

19. What infrastructure or technological advancements are needed for hospitals and other device user facilities to be able to capture and use UDI for basic inventory control and recall completion purposes? How costly are these advancements?

    Since it has been a low priority, it is impossible to say at this time the costs associated with the use of a UDI system, which would require additional study. As a very interested stake holder, AAHomecare respectfully requests to have the opportunity to work with the FDA on this critical issue, and have input going forward.

20. Referring specifically to completing medical device recalls in your hospital or other device user facility, for what share of the most serious (Class I) or next most serious (Class II) recalls would having access to and an ability to capture UDI information help you to respond?

    An electronic system may be beneficial but it is unclear to what extent in comparison to our current manual system utilized by the industry to track medical devices.

We appreciate the Food and Drug Administration giving us the opportunity to comment on the Unique Device Identifier system, and look forward to working with the FDA on this important issue. Should you have any questions, please contact Ann Howard, Director, Federal Policy, at (703) 535-1891. Again, thank you for your consideration of AAHomecare's comments.

Sincerely,

Tyler J. Wilson
President and CEO
American Association for Homecare