Bilanx Consulting LLC

Balanced Quality Systems and Regulatory Compliance

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061,
Rockville, MD, 20852.

Re: Docket 2006N-0292

Dear Sir/Madam

Introduction

Thank you for the opportunity to comment on this important docket on the Use of Identifier Systems for Medical Devices. Several years ago, I served on the AdvaMed committee on Bar Code Systems several years ago when this topic first arose. The AdvaMed committee submitted comments following the July 2002 Bar Code Labeling for Medical Products meeting the FDA held. The comments submitted at that time might be reviewed for any relevance to the current effort by the agency.

The company for which I was employed at the time, used bar coding to identify products during the production and later servicing of the product in the field while improving the company's processes. While researching the implementation of this effort in the middle 1990's we found no customers that had any interest in implementing such a system. Our devices were hospital beds, long term capital products, and we chose to implement such a system for our own advantage, in spite of the disinterested customers.

While on the AdvaMed committee we discussed the wide variety of devices that might benefit from such a identification scheme, and found that it would be difficult if not impossible to implement a single scheme for products that ranged from tongue depressors to artificial hearts. We also could not find a benefit for all devices that would prevent medical errors. The use of a bed or a tongue depressor did not seem to create the possibility for an error, such as the possibility the FDA was discussing at the time in drugs.

Currently, I am active as a risk management and quality systems consultant to the medical devices industry. In my nearly 20 years in the industry I have worked in a number of device areas in Class I, Class II and Class III devices. Among the devices I have worked with are software systems for connecting obstetric monitors in hospitals, hospital beds, air-fluidized beds, external defibrillators, wound treatment devices, operating tables, and accessories and stents. Presently, I serve on AAMI standards committees on Quality

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Systems, Risk Management and Hospital Beds. I have served on the SC-62A Committee that developed the new IEC 60601-1 medical electrical equipment safety standard and the IEC/ISO international risk management standards committee. Also, I served as a member of the FDA's Hospital Bed Safety Workgroup from its inception to the present. All of these group efforts have shown that a cross-functional group can develop a better solution to a problem than the development by a single group in a vacuum.

Discussion

As you are well aware, the wide-range of the thousands of different types of medical devices would make the use of RFI or bar-coding or any other single scheme difficult for the manufacturer to implement. It would require the medical facility to implement a system to read such identification on medical devices. With the implementation of nano-technology the depth of the problem seems to only escalate.

Currently, the FDA has minimal requirements in place for labeling of medical devices in 21 CFR 801, which require the manufacturer to be identified. Manufacturers usually exceed this minimum requirement by including the device model and any lot or serial number for ease in servicing devices or for identifying the device when Medical Device Reports may need to be filed.

The FDA should analyze the Medical Device Reports that have been filed to determine the usefulness of any identification scheme. It is possible that the agency would find that in many cases no identification is included with these reports, as found in researching the MAUDE database. However, the motivation or the reasoning behind the incomplete reports is not evident in such research. Since the reason behind the lack of complete reports cannot be found in a simple database research, if is highly unlikely that the agency can identify a method for improving the reporting of device errors when the reason the present system is not working is not evident. Until the reasons for incomplete Medical Device Reports can be identified, it is unlikely that a solution for improving the reporting can be accurately be developed and improved reporting can occur.

As stated earlier, there is a wide range of medical devices including things such as software in medical systems, MRIs, beds, bandages, surgical instruments, surgical robots, hospital beds, and thousands of other devices. Some of the devices are quite small, limiting the amount of "real estate" available for identification causing the manufacturer to place such labels on the packaging. If the packaging is separated from the device during use, the information useful in investigating the medical error, recall, etc. is no longer available.

The agency must also consider that the medical device manufacturing community consists primarily of small manufacturers, most with no more than 100 employees. A mandatory identification scheme will cause a large expense for these small companies, including the HIBCC fee based on sales just to obtain an identification number for the devices sold by the company.

There is also a concern for the use of technology such as RFI as to how it will play in the real world. If an implanted device contains an RFI identifier, how will if affect the scanner at the exit at WalMart or Lowes? There is a privacy concern here as well. The use of such an identifier may be "read" by unauthorized devices allowing access to medical information about a patient.

If the agency chooses a single mandatory scheme to identify devices, and it mandates a private identification database, such as HIBCC, the agency creates a costly requirement for manufacturers, which must be passed on to users. Just to get a manufacturer identification number is a large expense especially for the smaller manufacturer. If, however, the agency decides to internally manage such a scheme, it will require resources that the already short-staffed agency does not have available.

Next to consider, is the method of identification. Should the agency mandate barcodes or RFI? Should the agency mandate the coding scheme? Should the healthcare community have any input to the scheme

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chosen? Or will the agency make an arbitrary decision and force a "one size fits all" decision on the medical device community?

It is possible that there is no single solution that will provide the desired outcome by the FDA. The only outcome from the agency inquiry may be that the healthcare community may use some automatic identification scheme in conjunction with medical devices at the discretion of the healthcare community.

With the identified beneficial outcome "A unique device identifier system could have broad applications in reducing medical errors, facilitating device recalls, improving medical device adverse event reporting and encouraging cost effectiveness by improving delivery and supply chain efficiency", the agency seems to be trying to find a hammer that will drive a nail, a screw, or a bolt into a square hole or a round one of various sizes. The agency, in saying "could have" also does not apparently have any confidence that the identification scheme will have any benefit based on the uncertainty in the outcome statement. Such an ambiguous problem statement as announced in the docket, will lead to a incomplete and inaccurate solution.

Additionally, the area of "delivery and supply chain efficiency" is one that the FDA does not have authority to regulate and must therefore not be a part of the FDA thinking. It is important that the healthcare community make its own decisions in this arena, especially as technology is making rapid advances. The agency might settle on a solution that is obsolete before it can be implemented, and the healthcare community would be stuck with a system of reduced efficiency. In this area, the marketplace should be the driver for the problem identification and the solution to be developed.

Recommendation

In short, the proposal by the agency is fraught with implementation difficulty. The agency must become more specific in requesting comments to have any impact on determining the problem to be solved and a solution or solutions. If the agency chooses to implement such a scheme on the medical device community, it must have the input of all stakeholders to determine what is the problem being solved, and then what solutions are available to solve the problem, and finally what is the solution that provides the benefit being sought.

The effort required to come up with such a solution demands a stakeholder effort such as the one the agency developed in the Hospital Bed Safety Workgroup. This group identified the problem, determined solutions available and chose those solutions that would provide such a benefit. Such a group may find there is no single approach that will work or is appropriate for all medical devices.

The problem research and solution determination is a long-term effort by a large number of interested parties. The agency should announce the formation of a workgroup and invite participation by interested parties.

It is imperative that the agency take an informed, research-based approach to better identify the problem to be solved. The medical device community must participate in the entire process if the agency is to be successful. If, however, the agency only wants to look like it is doing something, then make a decision and implement a regulation with no outside input.

Sincerely,

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