American Hospital Association

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September 12, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave., S.W.
Washington, DC 20201

Robert M. Califf, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Dear Mr. Slavitt and Dr. Califf:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) is writing to clarify our position regarding the business requirements for capturing a unique device identifier (UDI) on health care claims, as addressed in the letter you sent to the Accredited Standards Committee (ASC) X12 on July 13. For more than two years, stakeholders including the AHA, have worked in good faith through the X12 process to find a solution for sharing the UDI through the claims process. We look forward to continuing to work together on these issues with the goal of finding a solution that meets your needs and is workable for providers.

The AHA has long supported the UDI as important for patient safety reasons, such as managing recalls. The AHA also supports the monitoring of high-risk implantable devices and the adoption of UDI labeling on medical devices. Under Food and Drug Administration (FDA) regulations, hospitals are currently required to include the UDI on adverse event reports. In addition, many hospitals participate in registries that seek to better understand how devices perform. We understand, however, that FDA would like to expand its post-market surveillance of high-risk implantable devices through its Sentinel Initiative. Under the Sentinel Initiative, health plans can voluntarily choose to contribute claims data to the FDA, and the FDA would like those claims to include UDI data.

The AHA is committed to working collaboratively with other stakeholders to find a solution for gathering the DI portion of the UDI directly on the claim, rather than on the claims attachment, the solution we previously supported. The AHA greatly appreciates your recognition that "collecting the DI (device identifier) is complex and involves providers changing their workflow and billing systems." However, **there are several considerations that we believe will be essential to ensure that the solution ultimately adopted through the X12 process is workable and does not create inefficiencies in claims generation and processing.** The health

care sector saves $2.3 billion per year by adhering to a streamlined and standardized claims processing system. As we develop solutions to include the UDI on claims, we also must be mindful to maintain efficiency by maximizing the ability to automate processes.

X12 has begun a new stream of work to determine how best to include the DI directly on the claim form, as opposed to including it as part of the claims attachment. In asking X12 to initiate this work (through Change Request 1652), FDA and CMS said that the agencies "support willing trading partners collecting only the DI portion of the UDI for high-risk implantable devices on the claims form." The AHA is committed to working through the X12 process on this new approach. However, the AHA believes that all of the following items must be in place to ensure a positive outcome:

1. **Ensure reporting of the UDI is limited to only the DI portion, as you recommended.** As noted in your letter, the DI is only a fraction of the full UDI, which is 75 characters in length. The shorter version will be easier to operationalize and presents fewer technical challenges.

2. **Accommodate reporting of the UDI at the claim level (as opposed to the service line level) for hospital and other institutional claims.** This step is absolutely key to minimizing burden for hospitals, as it will limit the extent of required operational and information system changes.

3. **Provide clarity on the "high-risk implantable devices" that FDA intends to track**. To make reporting feasible, FDA must provide a list of the high-risk implantable devices it seeks to track. There are millions of different medical devices, and hundreds of thousands of implantable devices. However, neither the FDA classification system nor the UDI itself provides a specific marker of what is a "high-risk implantable device." Having a list of the specific DIs that FDA considers to be "high-risk implantable devices" would maintain efficiency and ensure that data on devices of interest are captured. The FDA should limit the list to those devices that it will actively surveil so that providers can be assured that their reporting is, in fact, supporting post-market surveillance. We recommend that the list be updated no more often than annually so that both plans and providers can update their systems in an orderly fashion and at the same time to ensure they match.

4. **Provide information on the payers that are participating in the FDA's Sentinel Initiative.** Today, the FDA receives claims data through the payers that voluntarily participate in the Sentinel Initiative and provide the agency with de-identified claims data. Knowing which plans are actively participating in the Sentinel Initiative, or any other mechanisms the FDA sets up to receive claims data on medical devices, is essential.

5. **Maintain language regarding "willing trading partners."** As noted above, all X12 discussions about including the UDI on claims have been premised on the notion that reporting will happen between willing trading partners. This approach is consistent with

the long-standing principle that only the minimum necessary information should be included on claims.

Many of these considerations can be addressed in the X12 process; however, the list of high-risk implantable devices and information on payers' participation in the Sentinel Initiative require separate action from the FDA. Therefore, we ask for your support in crafting a solid solution, and would welcome the opportunity to discuss these items in more detail.

If these considerations are not addressed, we fear that the solution will create inefficiencies in the billing process and fail to achieve the post-market surveillance objectives the Department of Health and Human Services seeks to achieve.

Thank you for your willingness to work with us on this important issue. If your team has any questions or would like to discuss further, Chantal Worzala, vice president of policy, is our point of contact. You can reach her at cworzala@aha.org or (202) 626-2313.

Sincerely,

/s/

Richard J. Pollack
President and Chief Executive Officer