NUBC™

National Uniform Billing Committee

March 21, 2014

To: Margaret Weiker- ANSI ASC X12N - Chair
Walter G. Suarez MD. - NCVHS – Subcommittee on Standards – Co-Chair
W. Ob Soonthornsima – NCVHS – Subcommittee on Standards – Co-Chair
Devon Jopp – Workgroup for Electronic Data Interchange (WEDI) - President
Robert Tagalicod - CMS OESS - Director

I am writing on behalf of the members of the National Uniform Billing Committee (NUBC). The NUBC is one of four organizations recognized in the Health Insurance Portability and Accountability Act (HIPAA) for a special consultative role in the development of HIPAA transaction standards. Recently there has been much discussion at our meetings about the merits of reporting the Unique Device Identifier (UDI) on the claim. Over the course of the past 8 months, starting with the August 2013 meeting, the NUBC held numerous discussions on the pros and cons of adding UDI to the UB-04 data set (institutional claim). Based on our discussions, and an overwhelming majority opinion from the NUBC, the UDI should not be included in the claim standard. We believe that it will impose enormous costs associated with managing the UDI for billing purposes. In addition, to date no health plan has indicated how the UDI will affect their processing and payment of the claim.

Our committee has always sought to balance the benefit of collecting data needed to adjudicate the claim against the burden of collecting and reporting this information. As a committee, we generally interpret that to mean that the claim should ask only for that information needed to adjudicate the claim. We do not believe that the UDI falls into that category, and note that the current ICD-9-CM diagnosis and procedure codes already include categories of care and treatment associated with medical devices. The upcoming ICD-10-CM and ICD-10-PCS codes provide even more specific information concerning implants and in particular the specific nature of implants subject to revision.

We understand the importance of tracking medical devices, especially those that are recalled, fail prematurely, or simply need to be replaced earlier than anticipated and support the public health goals of the introduction of the UDI as a means to better track adverse outcomes of devices and facilitate recalls of faulty devices, as outlined below. We would also note that the UB-04 data set already has a data field to support the health plan's review of a claim when a medical device is being replaced within the product lifecycle and/or the replacement of the product is due to a manufacturer or FDA recall. In these instances the providers also inform the manufacturer. The inclusion of the UDI on the claim will require the introduction of new billing processes that do not currently exist. Developing a new process entails considerable cost and effort by the provider, and will also include work from payers to accommodate receipt of the UDI. Currently, there are no other purchased items indicated on the claim that require this level of identification and enumeration (device identifier and production identifier

(serial and lot numbers)). In fact, this request represents a significant departure from existing routines, and will require a new billing system look-up and interface that currently does not exist. Typically, requests of this magnitude are subject to the Administrative Procedures Act (APA), and must go through a notice and comment rulemaking process. The rule-making process requires identification of the benefits and costs of a proposal, consideration of alternative approaches to achieving the goal of the proposal, and an opportunity for all affected parties to respond to the proposal in a systematic fashion. The healthcare community needs to have access to a complete assessment of the costs associated with this proposal as well as the benefits, including who incurs the cost and who benefits from its adoption, as well as consideration of alternative approaches. Accordingly, the NUBC strongly believes that ANSI ASC X12 should not take any steps for the inclusion of the UDI in the standard until this analysis occurs.

The final rule on UDI was issued in December 2013, and requires manufacturers to phase in the inclusion of the UDI on packaging materials and some actual devices over a seven-year period that begins October 1, 2014. The goal was to create a standard for recording medical devices manufactured by suppliers together with the corresponding production lot for that device. As hospitals and other providers acquire or purchase these devices they will be able to track and consistently record the acquisition or purchase of these devices from the supplier. We support the UDI for this purpose. We also recognize that as medical devices are provided to patients, the ability to reference the UDI in the patient's electronic health record (EHR) will improve care, support reporting of adverse events, and allow for efficient and effective response to recall notices.

These positive outcomes for patient safety and care improvement will also require that the purchasing and patient record systems maintained by providers change in order to incorporate the recording of the UDI, and will occur as the UDI requirement on manufacturers begins in FY2015, and rolls out over the next seven years. These systems will support the public health benefits that underlie the deployment of UDI – better tracking of adverse events to improve post-market surveillance, and more efficient and efficacious response to recalls. They will likely also be more suited to supporting the collection of clinical data that would support post-market research on devices.

The final rule for UDI also speaks to the important roles for both the manufacturer of the device and the Food and Drug Administration (FDA) in enhancing our knowledge of medical device safety, and acting quickly when problems are identified. Manufacturers of medical devices are asked to maintain records of the devices they sell or supply to providers, monitor performance, and report problems to the FDA In addition, the UDI final rule also added a requirement on all device user facilities (such as hospitals and ambulatory surgery centers) that they include the UDI when they submit mandatory adverse event reports to the FDA under the Medical Device Reporting regulation (21 CFR 803.32). Under the MDR Act, user facilities must provide both situation-specific and annual reports to the FDA, as well as reporting device issues to the manufacturer.

The NUBC recommends that a task force be established to study the extent to which the deployment of the UDI, which includes mandatory reporting requirements on both manufacturers and providers, will improve on the existing surveillance systems to monitor the safety of medical devices, and what additional steps FDA should take to leverage the deployment of the UDI to improve its surveillance

systems. The FDA will need to evaluate its role and serve as a source of information and dissemination of findings for the public, providers, and others interested in monitoring medical devices. For the reasons discussed above, he NUBC does not believe that the health care claim should be the principal mechanism for this purpose, or even one of the first.

Again, the NUBC respectfully asks that efforts to include UDI reporting on the HIPAA claim standard be suspended until a thorough examination and vetting by the public occurs through the notice-and-rule-making process.

Should you have any additional questions or concerns you may contact me at 312/422-3398 or garges@aha.org

Sincerely

George Arges
Chair NUBC