Statement To
DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS
SUBCOMMITTEE ON STANDARDS

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Members of the Subcommittee, I am Jean Narcisi, Director of Dental Informatics at the American Dental Association and member of the WEDI Foundation Board of Trustees. I would like to thank you for the opportunity to present testimony today on behalf of WEDI Foundation concerning the Unique Device Identifier (UDI).

The WEDI Foundation is a charitable organization dedicated to scientific research and education in order to foster the improvement of healthcare. Through our activities, the WEDI Foundation works to improve the exchange of administrative and clinical healthcare information.

Background

The WEDI Foundation, with support of the Pew Charitable Trusts, recently completed a report regarding the capture and transmission of UDI. The goal of our recent work was to determine the best option for transmitting the UDI for non-dental high-risk implants among stakeholders to achieve the full benefits of a quality medical device postmarket surveillance system without adding significant cost and complexity.

To address this challenge, The WEDI Foundation conducted a series of meetings involving multiple stakeholders from the healthcare industry to discuss the many facets of postmarket surveillance with particular focus on the transmission of UDI from providers to payers. The focus of these discussions was high-risk implanted devices only. UDI transmission is not cost-effective, nor necessary, for all devices. Only those devices that are prone to failure and would cause substantial harm to patients should have the UDI transmitted. High-risk, implanted medical devices fit that definition.

The outcome of the discussions was recognition that a hybrid approach would be the optimum solution to enable the UDI to become an integral component of the postmarket surveillance system in the United States.

The hybrid approach was identified as a way to enable UDI to be accessible for postmarket surveillance and is comprised of the following combination of initiatives:

- The UDI should be added to the claim with a situational rule to enable interested providers and payers, on a voluntary basis, to transmit and use the UDI for high-risk implants.
- Providers should work to capture and electronically integrate the UDI into their internal systems so the UDI is available within their clinical systems, supply chains, and administrative systems
- Registries should be modified to add UDI and work to consolidate data from facilities
- All-payer claims databases should be modified to add UDI and work to consolidate data from multiple all-payer claim databases

- Further research should be done to evaluate if UDI should be included in the preauthorization transaction to enable interested payers and providers, on a voluntary basis, to transmit and use the UDI for high-risk implants
- With support of the FDA, pilot projects should be developed that demonstrate UDI being transmitted between entities (e.g., provider to payer, provider to registry, etc.)

This approach uses existing infrastructure and minimizes the burden on any individual stakeholder and enables each stakeholder to utilize UDI along its own timeline.

The WEDI Foundation also suggested that EHRs should eventually be able to transmit the UDI from providers to registries, payers, and other stakeholders; however, that capability will not be realized until well into the future. Achieving the benefits of UDI in the foreseeable future requires the inclusion of UDI in claims.

What is the current understanding of the purpose, value, and benefits of using UDI in administrative transactions, including Post-market surveillance, cost/payment, eligibility/prior authorization, utilization analysis, quality reviews and other?

The WEDI Foundation proposed a situational rule that establishes a voluntary approach to achieve the goals of postmarket surveillance to improve device safety and public health with minimal additional costs, complexities, and burdens. The situational rule suggested was as follows:

- The UDI will be used for reporting the unique device identifier when a health plan and hospital mutually agree to transmit this information or as deemed by the provider to enhance claim reporting.

Including the UDI in the claim with the proposed situational rule makes the inclusion of UDI voluntary, meaning providers would not be required to report it and payers would not be required to collect it, unless they have both agreed to do so. Providers would need to make changes to their charge master and billing systems to include UDI. The UDI pilot projects have made these changes, or are in the process of making these changes, because their evaluations indicated that the potential benefits and cost savings outweigh the costs of the changes.

Ultimately, through this situational rule, providers, payers, registries, and the FDA could compare the efficacy of similar devices to:

- Determine quality based on actual results in large patient populations
- Identify poorly performing devices and safety risks
- Assess differences in the performance of devices to improve competition among manufacturers and ensure that patients use the highest quality and most appropriate technologies for their conditions
- Assist with device recalls to ensure that all patients affected by failing technology receive appropriate follow-up care
- Payers and providers would be able to work together to identify the best-performing and cost-effective medical devices. Patients and providers would be able to make decisions regarding specific medical

Many benefits could result from the transmission of UDI to payers as part of a hybrid approach:

- Payers could assist with recalls by using UDI data to more quickly and efficiently reach the patient than the healthcare facility in which the procedure was performed, which in many cases could have been several years prior. Currently, many of the highest risk recalls end without all devices accounted for and identified, partially because hospitals and manufacturers lack up-to-date contact information. Health plans, on the other hand, are another stakeholder that can contact the patient and often will have more recent contact information.

- FDA's Sentinel system has successfully evaluated drug safety. Sentinel, though, lacks access to data on device quality and the specific devices used in care. UDI transmission to the health plan would enable Sentinel evaluations of device quality. According to Richard Platt, MD, MSc, Professor and Chair of the Harvard Medical School Department of Population Medicine at the Harvard Pilgrim Health Care Institute and the Sentinel Program Lead, the transmitting of the UDI in the claim is the least burdensome method for using Sentinel with devices.

- Payers would have access to detailed device information to conduct their own analyses on device quality and performance. As payers currently lack any information on the specific devices used, this information would provide them with previously unattained data to assess the care of beneficiaries. This information would support longitudinal analyses when patients see multiple providers or obtain follow-up care from a physician that did not conduct the initial procedure.

- Both existing and new registries could link with claims data to provide longitudinal analyses on medical devices. As registries often only house short-term outcomes data, this capability would ensure long-term data collection linked to detailed patient information.

What are the main challenges and issues in adopting and using UDI in administrative transactions

There are a number of challenges and issues identified in adopting and using UDI in administrative transactions related to system changes that would be required. Hospitals would be required to add UDI to their electronic healthcare record (EHR) systems in order to begin capturing the UDI at time of placement and then move that data over to the hospital revenue systems so that the UDI data could be submitted in the claim. There are a number of technical issues that the hospitals would have to address in including UDI in the administrative transactions, including integration of clinical EHR systems to billing systems, modifications to the hospital charge master to accommodate at least a portion of the UDI value (e.g. the DI portion of the UDI).

Payers as well would need to adjust their systems to accommodate the proposed change to the X12N standard and scrap the UDI data as it was accepted and adjudicated through their processes.

What is the current state of development of administrative transaction standards to accommodate for the capturing / reporting of UDI?

The WEDI Foundation delivered its whitepaper and related recommendations to X12 for further consideration as part of their development process. We defer to X12 to comment on the current state of development regarding current standards development efforts to address UDI.

Conclusion

In conclusion, the WEDI Foundation evaluated various avenues regarding UDI capture and transmission. In evaluating the alternatives, the WEDI Foundation came to the conclusion that a hybrid approach to capture UDI in order to improve postmarket surveillance is the most efficacious approach. As part of our suggested pathway, we believe that an initial step be made to modify the claim transaction to accept UDI. Given the postmarket surveillance system infrastructure that has already been built and operated by the FDA using large payer data, placing the UDI into the claim seems to be the most expeditious way to begin collecting and sharing UDI between partners.

The WEDI Foundation acknowledges that there are technical challenges and costs associated with this approach; however, we believe that combining this approach with a longer term registry-based approach will yield a much better understanding of the performance, quality and costs of implantable devices.

Members of the Subcommittee, thank you for the opportunity to testify and the WEDI Foundation offers our continuing support to help industry as we move towards implementation of UDI.