September 23, 2014

The Honorable Sylvia M. Burwell
Secretary, Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Findings from the June 2014 NCVHS Hearing on the Incorporation of the Unique Device Identifier (UDI) in Administrative Transactions

Dear Madam Secretary,

The National Committee on Vital and Health Statistics (NCVHS) is the statutory advisory committee with responsibility for providing recommendations on health information policy and standards to the Secretary of the Department of Health and Human Services (DHHS). Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), NCVHS advises the Secretary on the adoption of standards and code sets for the HIPAA transactions. The Patient Protection and Affordable Care Act (ACA) {Sec. 1104 (b) enacted on March 23, 2010, calls for NCVHS to assist in achieving administrative simplification to "reduce the clerical burden on patients, health care providers, and health plans."

Each year, NCVHS holds industry hearings to evaluate and review the standards, code sets, identifiers and operating rules adopted under the HIPAA and the ACA, and determine whether there is a need to update and improve any of these standards and operating rules. NCVHS is pleased to present in this letter, findings from our June 10, 2014 NCVHS Standards Subcommittee hearing regarding the incorporation and exchange of the Unique Device Identifier (UDI) in administrative transactions.

The Food and Drug Administration released in September, 2013 a final rule requiring that most medical devices distributed in the United States carry a unique device identifier, or UDI. A UDI system has many implications and potential benefits on quality, cost-effectiveness, patient safety and public health policies regarding medical devices. For example, collection and reporting of UDI could be used in monitoring and managing effectiveness and safety of medical devices, identify medical device issues faster, and improve effectiveness of targeted recalls.

The health care industry has offered recommendations at various industry fora, regarding the capture, exchange and use of UDI in electronic health records

(EHRs) that would facilitate the exchange of medical device information between providers, manufacturers and oversight agencies. Incorporation of UDI in EHRs is being considered as part to the certification criteria for Stage 3 of the Meaningful Use Program, scheduled to start in 2017.

Similarly, there have also been requests for the incorporation and reporting of UDI in administrative transactions between providers and payers, such that payers receive a UDI from providers, along with other medical device information, as part of certain administrative and financial transactions.

At the June, 2014 hearing, testifiers presented a variety of perspectives on the issue of adopting and using UDI in administrative transactions. There were a series of common themes, current barriers, and discussion on potential value, benefits and challenges of including UDI in health care transactions flowing from providers to payers. Identified benefits and value of recording and reporting UDI in administrative transactions included:

- Reporting UDI in administrative transaction could contribute to improving medical device safety and quality through improved post-market surveillance.
- Current medical device reporting systems have shown some limitations, including: (1) ability to quickly identify problems with medical devices; (2) incomplete recalls and limitations in the ability to reach all those exposed to a defective device; and (3) limited comprehensive data to establish long-term medical device outcomes. Including UDI in administrative transactions could help address these limitations.
- UDI data captured by payers could provide the 'denominator' for population-based data analytics.
- Having health plans collect UDI information linked to a member could serve as another mechanism to reach to consumers in the case of a medical device recall.

However, testifiers also expressed concerns with capturing and reporting UDI in administrative transactions, as follows:

- Incorporation of UDI in EHRs, if approved as a recommendation for Stage 3 of the Meaningful Use Program, would not start until after 2017, a key driver in UDI reporting across systems.
- The lack of a clear purpose and undocumented value and benefits for adding UDI to administrative transactions, and that is directly related to the purpose for which these transactions are used.
- Additional costs to providers to change existing systems to capture and maintain UDI throughout various internal information systems, from supply chain to materials management to the EHR, and then to the administrative and financial information systems.

- The need for providers to create internal workflows and processes to extract and report UDI in administrative transactions.
- Potential and undefined increased provider responsibilities for identifying and reporting device issues.
- Concerns about new expectations, roles and responsibilities of payers in post-market surveillance, if they were to receive UDIs from providers.

Short and Long Term Considerations, Issues and Opportunities

Testifiers at the June, 2014 NCVHS hearing noted that current administrative transaction standards do not include a field designated for reporting UDI. Work-around solutions could be defined, while consideration is given to the incorporation of the UDI in the next version of the standards. Following are key short-term issues and opportunities identified by NCVHS through testimony and analysis:

- No requirement be issued at this time to have providers report UDI in administrative transaction.
- A more clear definition of the business case for incorporating UDI in administrative transactions should be developed, including the direct and indirect relationship to the purpose for which the transactions are used.
- The cost-benefit of reporting UDI should be better documented, including the additional cost implications to providers to change systems, develop new workflows to capture and report UDI to payers, and the potential health plan roles and responsibilities in post-market surveillance activities.
- Continue implementing industry pilots to test, document and analyze the effect of reporting UDI in administrative transactions, focusing initially on high-risk implantable devices.
- Incorporation of UDI in current transactions for purposes of implementing pilots should be done on a voluntary basis. Mutual agreement between trading partners should include guidelines for agreed-upon exchange policies and practices.
- To support such pilots, appropriate Standard Development Organizations (such as X12, NCPDP) should consider developing basic guidance that define the standardized work-around approach for reporting UDI in the current version of transactions.

Important long term activities related to the adoption and use of UDI in administrative transactions identified by testifiers at the June, 2014 hearing included:

- Standard development organizations should consider the incorporation of UDI in the next version of HIPAA-adopted administrative transactions.

Emphasis should be placed on defining the business purpose for such change, and not just on what the technical solution would be.
- As appropriate, consider replacing the current HCPCS codes with UDI.
- Define Operating Rules for the reporting of UDI in administrative transactions.

Recommendations

At the current time NCVHS does not recommend mandating the capture, reporting and use of UDI in administrative transactions. NCVHS does recommend the following:

Recommendation 1: HHS should continue to work with the Industry to better understand and document the value, benefits and costs of reporting UDI in administrative transactions, including:

- The business reasons for, and cost and benefits of including UDIs in administrative transactions, including the added burden for providers and payers to capture, report and receive/use UDI and the system and workflow changes required.
- Which transaction, if any, or other mechanism would be best to report UDI (e.g. claim or attachments).
- Potential post-market surveillance role of payers who receive UDI from providers via administrative transactions.

Recommendation 2: HHS should work with the Industry to consider implementing pilots to test and document the effect, value, cost, benefit and privacy implications of incorporating UDI in different administrative transactions, including claims, attachments, prior authorization, and others. Pilots should initially focus on the reporting of UDIs for high risk implantable medical devices and evaluating the future inclusion of additional devices.

Recommendation 3: Standard Development Organizations (SDOs) and Operating Rule Authoring Entities (ORAEs) should:

- Consider developing national standard guidance to support short-term UDI pilots. Guidance would define how to report UDI in current versions of administrative transactions.
- Explore the incorporation of UDI as a defined option in the next version of administrative transaction standards, specifically considering the business purpose and need for such change, and not just its technical approach.

- Consider the need to develop Operating Rules for reporting UDI in future administrative transactions, after appropriate consideration has been given by SDOs to the incorporation of UDI in future versions of the standards.

Recommendation 4: NCVHS suggests that the FDA and stakeholders work together to improve existing mechanisms for post-market surveillance of devices.

Closing Comments

NCVHS recognizes the challenges that the health care industry faces today and will continue to experience over the coming years as they adjust to these transformative changes. NCVHS also recognizes that reporting UDI in administrative transactions holds promising opportunities to help better meet industry needs for improved safety and quality of medical devices. At the same time, NCVHS acknowledges that there are a number of important policy, business, and technical issues that need to be addressed before considering adopting such reporting throughout the health care industry. NCVHS will continue to work with HHS and the industry to better understand and document these issues and develop cost-effective approaches to achieve the overall goals of administrative efficiency and improved safety and quality.

Sincerely,
/s/
Larry A. Green, M.D. Chairperson,
National Committee on Vital and Health Statistics

Cc: HHS Data Council Co-Chairs