NUCC
National Uniform Claim Committee

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American Academy of Physician Assistants

American Association for Homecare

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Accredited Standards Committee
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Public Health Data Standards Consortium
Federal Perspective
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State Medical Association
Minnesota Medical Association
Texas Medical Association

Veterans Health Administration

May 9, 2014

Karen DeSalvo, MD, MPH, MSc, National Coordinator for Health Information Technology
Margaret Hamburg, MD, Commissioner, Food and Drug Administration
Marilyn Tavenner, RN, Administrator, Centers for Medicare & Medicaid Services

**RE: Unique Device Identifier**

Dear National Coordinator DeSalvo, Commissioner Hamburg, and Administrator Tavenner:

The National Uniform Claim Committee (NUCC) is writing to express our concerns about current discussions that would require reporting of the Unique Device Identifier (UDI) in health care claim transactions. While we recognize the merits of capturing and reporting the UDI for patient safety and post-market surveillance efforts, we believe there are other methods that should be used instead of claim transactions.

The NUCC has been aware of and has discussed the work that has taken place over the last several years by the Food and Drug Administration (FDA) to develop the UDI system. We are also aware of current activities by the FDA, The Pew Charitable Trusts, and the Workgroup for Electronic Data Interchange (WEDI) to identify a methodology to capture and report the UDI of a device that has been implanted in a patient.

In our maintenance of the NUCC Data Set, which is the set of data to be reported in professional/non-institutional claim transactions, we work closely with the Accredited Standards Committee X12 Insurance Subcommittee (ASC X12N) due to their role as the developer of the electronic standards adopted under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Our joint efforts in identifying data to be reported in claim transactions have focused on the need for the data in adjudication of the claim. Reporting of the UDI for patient safety tracking and post-market surveillance efforts does not contribute to the claims adjudication process and is, therefore in our opinion, not appropriate for inclusion. Because the electronic claim transactions are widely used and produce a large set of data does not mean that they are the most appropriate vehicle to support non-claims adjudication needs.

The NUCC has concerns that including the reporting of UDI on the claim will impose huge costs on provider organizations to develop and implement system interfaces that currently do not exist between clinical or supply management systems and revenue cycle management systems. Payers will also need to develop and implement systems to store the UDI. Finally, software vendors will need to develop solutions for capture and reporting UDI.

The NUCC is aware that work is underway to develop the capability to capture UDI in electronic health records (EHR) and potentially incorporate this process into the future certification requirements for the EHR Meaningful Use Incentive Program. We believe that efforts would be best spent on focusing on the collection of data and extraction of UDI directly from the EHR where other clinical data relevant to the medical device will also be available.

Also being debated in the industry is a "hybrid" approach that would require payer, provider, and vendor organizations to devote time, money, and staff to developing various systems without a clear focus on which process will be used to capture and report UDI. This work will also need to take place at a time when these organizations are being overwhelmed by the need to meet regulatory requirements of the Affordable Care Act of 2009, the EHR Meaningful Use Incentive Program, and ICD-10, to name a few. We request that the FDA take a closer look at the current process used to capture medical device information and identify ways to improve that system for UDI reporting as a short-term measure until the EHR reporting capability is fully developed.

The NUCC is concerned about the burden and costs this requirement will impose on the health care industry and believes the business case is lacking for reporting the UDI in claim transactions. While we recognize the important role this number can play in patient safety and post-market surveillance efforts, we ask that you carefully consider other options for capturing and reporting the UDI.

If you have any questions, please do not hesitate to contact me directly at (202) 789-4586 or nancy.spector@ama-assn.org.

Sincerely,

[redacted]

Nancy Spector
Chair, National Uniform Claim Committee

cc: Robert Tagalicod, Director, Office of eHealth Standards and Services, Centers for Medicare & Medicaid Services
Walter Suarez, MD, Co-Chair, National Committee on Vital and Health Statistics Subcommittee on Standards
W. Ob Soonthornsima, Co-Chair, National Committee on Vital and Health Statistics Subcommittee on Standards
Devin Jopp, Ed.D., President & CEO, Workgroup for Electronic Data Interchange
Margaret Weiker, Chair, Accredited Standards Committee X12 Insurance Subcommittee