United States Senate
WASHINGTON, DC 20510

December 22, 2014

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Dear Administrator Tavenner,

We are writing to express our interest in incorporating the new medical device identification system into electronic health information, including claims forms.

Medical devices are important tools for improving health and saving lives. These devices often provide significant patient benefit, but in rare cases, problems with medical devices can harm patients. Congress recognized that a medical device tracking system was necessary to better detect adverse events, improve product recalls, and enable robust post-market surveillance. The Food and Drug Administration (FDA) Amendments Act of 2007 (FDAAA) charged the FDA with creating a unique device identifier (UDI) system to accomplish these goals. Congress further expressed the importance of this system by setting a timeline for its implementation in the 2012 FDA Safety and Innovation Act (FDASIA).

In order to achieve all the benefits of the new UDI system for our nation's seniors, and accomplish the goals Congress intended, UDI information must be incorporated into electronic health information. The highest-risk devices are already required to start bearing UDIs, underscoring the importance of creating standard fields to document these identifiers in electronic health information as soon as possible.

There are many initiatives underway by HHS agencies to utilize the UDI and establish a robust medical device postmarket surveillance system in this country. First, the FDA has established two multi-stakeholder committees—the National Medical Device Postmarket Surveillance System Planning Board and the National Medical Device Registries Task Force—to develop a strategy for evaluating devices throughout their life cycle, including through the use of independent device registries linked to patient data. Second, the FDA and the Brookings Institution recently released a roadmap for successful UDI implementation and highlighted the importance of incorporating UDI information in claims to improve patient care. Third, a

subgroup to the Health Information Technology Policy Committee, an advisory committee to the Office of the National Coordinator for Health Information Technology (ONC), has already included UDI as part of preliminary recommendations for Stage 3 of the Meaningful Use program, which will encourage physicians to include UDIs in patients' electronic health records (EHR). Fourth, ONC has also committed to adding a field for UDI in the next updates to EHR certification criteria.

We commend the work done by the FDA and ONC, but believe that more needs to be done in order to ensure that UDIs are also included in claims data. In FDASIA, Congress specifically required that the Sentinel Initiative—a large electronic database of health information comprised primarily of claims data and designed to assess drugs and biologics—also evaluate devices. In response to Senator Warren's questions for the record, Department of Health and Human Services Secretary Burwell stated that "the Sentinel Initiative will ultimately benefit from these efforts by incorporating UDIs into its claims data sources." In addition, claims transactions provide longitudinal data on patient outcomes across healthcare institutions – a critical capability for implanted medical devices as problems might not emerge for several years and patients may seek care in facilities that did not perform the implant procedure. The FDA intended for UDIs to be incorporated into claims forms as it designed the UDI system, however, the FDA does not have jurisdiction over what fields are in claims forms, nor over what information is required in order for a claim to be processed. CMS, however, has the jurisdiction to require that this information be captured for Medicare claims, and the opportunity to incorporate UDI in claims forms if it will better protect the safety of Medicare beneficiaries.

Many private sector external stakeholders are working to incorporate UDI information into claims forms. The Accredited Standards Committee X12 (ASC X12), which sets standards for electronic claims and includes members from CMS, has voted to further explore how to use UDI information if it were provided payers, and the best vehicle for transmitting these data. An ASCX12 workgroup has already approved ways that UDI transmission could help achieve health care goals, referred to as "use cases," including to help confirm billing validity, derive quality measures, assist health plans with recalls, ensure appropriate follow-up care, provide data for research, and allow incorporation of device information into the Sentinel Initiative database.

A wide range of groups have been supportive of including UDI information in claims data, including the AARP, America's Health Insurance Plans, Brookings Institution, The Pew Charitable Trusts, Trust for America's Health, Society of Thoracic Surgeons, American College of Cardiology, Geisinger Health System, Aetna, Leapfrog Group, Pacific Business Group on Health, and Mercy Health System. We understand, however, that CMS has been a dissenting voice within ASC X12 in regards to the incorporation of UDI information in claims. Given that the same claims form is used by both public and private payers, CMS dissent could prevent other health plans from collecting and utilizing UDI data.

CMS plays a vitally important role in guiding what information is required in claims, and should be actively working with the FDA, ONC, and other stakeholders to promptly realize the UDI system's full benefits. CMS can—and has the responsibility to—help achieve the full public health benefits of the UDI system to improve care for Medicare beneficiaries and all U.S. patients.

We respectfully request a response to the below questions by January 20, 2015.

1. Proponents of the UDI system—including FDA and ONC—have identified several uses of this new tool to improve the safety, quality and efficiency of patient care. CMS, on the other hand, has expressed concerns about utilizing this new tool to improve patient outcomes while reducing health care costs.

    a. The Government Accountability Office has found that more than half of high-risk device recalls conclude without all devices corrected or removed from the market. UDI transmission in claims could help payers—which often have up-to-date contact information for beneficiaries—inform beneficiaries affected by recalls and ensure that they obtain appropriate follow-up care. How could CMS collect and utilize UDI to assist with recalls?

    b. UDI transmission on the claim would provide CMS with additional information to detect fraud, waste and abuse for billed services. How could CMS utilize UDI data to identify and curb waste and fraud?

    c. Claims data are often utilized to assess long-term outcomes, and UDI data submitted in the claim could provide CMS with better information on the safety, quality and performance of medical devices over time. How could CMS utilize the UDI system to improve the quality and safety of devices used by Medicare beneficiaries?

    d. Claims data are often utilized by registries to enhance longitudinal analyses of patient outcomes. UDI transmission as part of the claim would give device information to registries and enable better patient matching capabilities to improve assessments of patient outcomes. How could CMS support the use of UDI in claims to improve the ability of registries to evaluate patient outcomes and enhance care quality?

    e. Do you agree with Secretary Burwell that the Sentinel Initiative would benefit from UDIs being captured in claims forms—especially in order to provide robust data on device safety in seniors?

    f. CMS has recently prioritized the release of aggregate Medicare claims data on utilization and payments for services and procedures; however, CMS is currently unable to provide any information on devices reimbursed through Medicare. How

could CMS use UDIs to produce aggregate data on the utilization and payments for medical devices through Medicare?

g. How could CMS ensure that UDI and specific device information is available to patients, such as through the Blue Button initiative that allows patients to view and utilize their health data to improve outcomes?

2. What are the current and/or planned collaborations between CMS and the FDA or ONC to help facilitate the collection of UDIs into electronic health information in order to improve the safety of devices for seniors?

3. If a field for UDI existed in electronic claims forms, do you currently have the authority to require this field be completed in order to process and pay the claim?

4. There are several private sector organizations—such as Aetna and Geisinger—that expressed an interest in incorporating UDI information into claims to improve patient safety and outcomes. How could CMS support the exchange of UDI data in claims between private sector organizations that are interested in using this information to improve patient safety, outcomes and the efficiency of care?

5. CMS will need to update its claims processing systems to reflect standard scheduled revisions made by ASC X12. For some claims form revisions, CMS must make changes to its claims adjudication systems, while other revisions only require CMS to validate the data and forward it to trading partners, which is less costly.

a. How much, on average, does it cost CMS to update its claims processing systems each time the electronic claims form standards are revised by ASCX12?

b. As part of the next revision, what is the incremental cost of adding a field for UDI, (1) as part of claims adjudication systems and, (2) if CMS only validated and forwarded UDI data to trading partners without including this information in the adjudication process?

c. Should CMS decide, or be mandated to, collect UDI in claims after the standard claims form revision, how much would it cost CMS to add a field for UDI in, (1) claims adjudication systems, and (2) only for validation and forwarding?

d. Aside from collecting UDI for adjudication or as part of a validation and forwarding of claims data, are there other ways that CMS could collect UDI information on claims and make those data available to registries, researchers and other stakeholders to improve patient safety and outcomes?

6. What actions has CMS taken and what actions does CMS plan to take as a member of ASC X12 in regards to the incorporation of a field for UDIs in claims?

If you have any questions, please do not hesitate to contact Remy Brim in Senator Warren's office (remy_brim@warren.senate.gov) and Rodney Whitlock in Senator Grassley's office (rodney_whitlock@grassley.senate.gov). Thank you for your prompt attention.

Sincerely,

Elizabeth Warren
United States Senator

Charles E. Grassley
United States Senator

CC:

Patrick Conway, M.D., CMS Deputy Administrator for Innovation & Quality, and Chief Medical Officer
Margaret Hamburg, M.D., Commissioner, Food and Drug Administration
Sylvia Burwell, Secretary, Department of Health and Human Services
Karen B. DeSalvo, M.D., M.P.H., M.Sc., Acting Assistant Secretary for Health, National Coordinator for Health Information Technology