Ms. Courtney Yohe, MPP
Director of Government Relations
The Society of Thoracic Surgeons
20 F St., NW, Suite 310C
Washington, DC 20001

Dear Ms. Yohe:

Thank you for your letter regarding the recent report by the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) on the costs to taxpayers and patients resulting from recalled and faulty medical implants. In your letter, you expressed your support for the OIG’s recommendation to add device identifiers to claims forms. I appreciate you sharing your position on this issue.

The information you shared, the information from the OIG and the Medicare Payment Advisory Commission, and the various letters we have received both supporting and opposing adding the device identifier (DI) to claims forms have been very helpful. In addition, the Accredited Standards Committee (ASC) X12 workgroup meetings where this issue has been discussed at length have also been very helpful. We are aware of the competing points raised by stakeholders from these various perspectives regarding collection on claims as compared to collecting it in other ways, such as via registries, electronic health records, and claims attachments, as well as the burden to providers for the various potential collection methods.

It is my understanding that the ASC X12 proposed package for the next version of the claims form will include the DI for high risk implantable devices between willing trading partners. After ASC X12 moves forward the package for the next version of the claims form, the process continues with consideration by the National Committee on Vital and Health Statistics (NCVHS). NCVHS may hold hearings and obtain input from stakeholders in preparation for development of its recommendations to HHS. The Centers for Medicare & Medicaid Services (CMS) looks forward to receiving recommendations from NCVHS and the completion of the standards development process. CMS would then consider whether to proceed with notice and comment rulemaking, which would be necessary to adopt the standards.
Thank you again for taking the time to provide us with valuable feedback that we can use to inform our process. I would appreciate your sharing this response with the co-signers of your letter. Please contact me if you have any further thoughts or concerns.

Sincerely,

Seema Verma