

## **Non-Substantive Change Request to CMS-10052, OMB 0938-0857**

This is a non-substantive change request to Centers for Medicare and Medicaid Services (CMS) Recognition of Pass-Through Payment for Additional (New) Categories of Devices under the Outpatient Prospective Payment System and Supporting Regulations (CMS-10052) to allow CMS to identify each item has to qualify for pass-through status based on its individual characteristics on the CMS-10052 form. To keep pace with new technology we are making this application process more efficient. We are implementing an electronic application intake system called the Medicare Electronic Application Request Information System (MEARIS) for the CMS-10052 form. This form is currently near completion and is anticipated to go live in the electronic application in-take system by mid-December of 2021.

The electronic form is essentially identical to the paper application form (CMS-10052, OMB 0938-0857) except for a few minor, non-substantive changes to either accommodate the web format or further provide simplification or clarification of the existing questions. We are not requesting any new information. The modifications to the form include the following:

(1) Question D4 from the paper application, rather than being present for every applicant, is now only present if an applicant responds yes to, “Does the device replace or improve upon an existing device?”

(2) A question was added concerning the cost of the components of the device which was not entirely feasible without a digital format.

(3) An optional question was added about partial system components.

(4) A question about the cost significance test was reworded/reformatted so that it made sense in the context of the digital application.

(5) Question H3 was reworded to fit the digital application.

(6) Question H5 was removed from the digital application.

(7) A question was added which asks if applicants have completed other applications within the CARIS program.

Please refer to our crosswalk document for a more detailed comparison of the differences between the paper and electronic application. We consider all of the changes to be non-substantive since they do not constitute changes to the intent or substance of the Recognition of Pass-Through Payment for Additional (New) Categories of Devices, but only simplify or clarify the content and streamline the reporting process. These changes have no impact on the previously stated burden associated with this collection.