You may be aware that Medicare has revised its process for coverage application for IDE clinical trials. Application packets will now be processed by the Centers for Medicare & Medicaid Services (CMS) instead of the Medicare Administrative Contractors (MACs). An MLN Matters® article from CMS is available at [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8921.pdf](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8921.pdf) describing this change.

Below is a summary of the key items which will impact new Investigational Device Exemption (IDE) clinical trials.

**What is changing effective January 1, 2015?**

- Study sponsors who receive an FDA IDE approval letter, dated January 1, 2015 or later for IDE Category A or Category B studies that are seeking Medicare coverage, must submit a request packet to CMS.
- CMS commits to providing a response to applications within approximately thirty days of submission.
- Approved IDE studies will be posted on the Medicare webpage: [http://cms.gov/Medicare/Coverage/IDE/index.html](http://cms.gov/Medicare/Coverage/IDE/index.html).
- Providers are required to verify that the IDE study has been approved before submitting IDE-related claims. Therefore coverage must be established prior to implants initiating.

**What is staying the same?**

- Medicare approval for a Category A (Experimental) IDE study will allow coverage of routine care items and services furnished in the study, but not the Category A device.
- Medicare approval for a Category B (non-experimental/investigational) IDE study will allow coverage of the Category B device and the routine care items and services.
- IDE studies approved by MACs prior to January 1, 2015 are grandfathered and will continue to be administered by the MAC.
  - For these already approved studies, neither sites nor study sponsors need to go through the new process.
- Medicare claims for routine care items and services and Category B IDE devices should continue to be submitted to MACs.

**What will be done by Medtronic for studies approved after January 1, 2015?**

- New clinical trials, with expected FDA approval after January 1, 2015, will be submitted by Medtronic through the new process.

**Questions?**

For **Vascular studies**: Please contact the Vascular Reimbursement Team at 1 (877) 347-9662 or rs.cardiovascularhealth economics@medtronic.com.

For **(Cardiac Rhythm and Heart Failure) CRHF studies**: Please contact Steve St. George at 1 (855) 669-1860 or at steven.st.george@medtronic.com.

For **Structural Heart studies**: Please contact Angelica Oyugi at 1 (763) 505-8451 or at angelica.oyugi@medtronic.com.