National Application Process For Medicare Coverage Of IDE

Applies to IDE studies with FDA approval letters dated on or after 1/1/2015

- Applications are submitted to CMS/Medicare by the IDE study sponsor.
- The IDE study sponsor submits a single application to CMS/Medicare once there is a single IRB approval to include in the coverage application. Instructions for the national application are located on the Medicare Coverage Related to Investigational Device Exemption (IDE) Studies website. CMS/Medicare also has an optional, but recommended "checklist and sample crosswalk" application form available at this site.
- CMS/Medicare reviews the IDE study application and issues a national decision that applies to all study sites. Nationally approved studies are listed on the Medicare Coverage Related to Investigational Device Exemption (IDE) Studies website.

Note: CMS/Medicare does not require sponsors to seek Medicare coverage of their IDE studies. However, since UW Medicine will not host IDE studies with billing to patient accounts without Medicare approval, study teams should expect sponsors to initiate the national application process.

What the UW Medicine study team *must* do

Following national CMS/Medicare approval, UW Medicine must notify the local Medicare Contractor, Noridian Healthcare Solutions, about the IDE study. In order to facilitate this process, the IDE study team must provide the Clinical Research Budget and Billing Office (CRBB) – Clinical Trials Office (CTO) with the following information:

- IDE Study Name
- IDE Device Number
- National Clinical Trial (NCT) Number
- Facility Name: HMC (500064) and/or UWMC* (500008) where the IDE Study will provide services
  *Note: UWMC includes either UWMC-Montlake or UWMC-Northwest, or both
- The names of the Principal Investigator and all providers who will be billing for study-related services

Once all documents are received, CRBB-CTO notifies Noridian by submitting the required information and then, upon receiving Noridian confirmation, alerts the study team. At that point, the study is cleared from a CMS/Medicare Billing Compliance perspective; however, the study must still complete all of its IRB, CRBB-CTO, and CTA/Contract review processes before it will be cleared by the CRBB-CTO to begin subject enrollment."