Process to Request Medicare Administrative Contractor (MAC) A and B Letters

The Centers for Medicare & Medicaid Services (CMS) has replaced its former claims payment contractors, known as fiscal intermediaries and carriers, with new contract entities called Medicare Administrative Contractors (MACs).

For IDE & NSR studies, approval must be obtained from our MAC/Jurisdiction 8, which is the Wisconsin Physicians Service.

General IDE Coverage Considerations:

- Medicare does not cover Category A devices.
- Medicare covers IDE Category B devices only.
- Medicare covers Category B devices that have intent to treat ONLY.
- Medicare does not cover Category B devices for research.

*New IDE Submission Delivery Option (*as of 01/01/13):

Providers can now submit IDEs to WPS Medicare electronically. Electronic submission expedites the receipt and processing of IDE applications. You can send electronic submissions to: IDE.mailbox@wpsic.com

IDE Submission Requirements:

Hospitals or principal investigators should provide:

1. The FINAL Federal Drug Administration (FDA) letter (not redacted). If there is only conditional approval, please provide the entire series of FDA letters (not redacted) to the manufacturer.
3. The patient informed consent form.
4. A copy of the complete protocol.
5. Supporting articles ONLY if the IDE is a true new/unique technology. For example if the IDE is a coronary artery stent, we probably do not need more articles about coronary stents as we have seen many. However, if it is a new type of artificial heart, then we will need to review the additional literature.
6. **The type of coverage requested; Medicare A, Medicare B, or both.**
7. The site(s) of the hospital(s) is in our jurisdiction (Michigan is Jurisdiction 8). WPS Medicare must ensure the IDE submission is in our jurisdiction. Letters on a corporate letterhead that have a system, or a series of hospitals printed on it, do not always indicate the site of the hospital.
8. The name of the principal investigator and any sub-investigators.
9. The hospital's provider number (if the request is for Medicare A).
10. Contact email address and telephone number for any questions we may have or to request missing documentation.

As stated in the above information, the process to obtain these letters can begin AFTER IRB Approval has been received. The average time of receiving an approval from the MAC contract is 6 to 8 weeks.

Alternate IDE Submissions Delivery Option:

Providers can still send paper IDE submissions by US mail or commercial delivery to:

Ella M. Noel, D.O., F.A.C.O.I.
WPS Medicare
1717 W. Broadway
PO BOX 1787
Madison, WI 53701-1787