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Billing and compliance issues with devices

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Billing and Compliance Issues with Devices

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Regulatory Framework

- Primary responsibility for regulation of clinical trials rests with agencies of the U.S. Department of Health and Human Services (HHS).
- These are:
 - Office for Human Research Protections (OHRP)
 - Office of Civil Rights (OCR)
 - Food and Drug Administration (FDA)
 - Office of Research Integrity (ORI)
 - National Institutes of Health (NIH)
 - Centers for Medicare and Medicaid Services (CMS)
- Primary regulatory concern is: Protection and well-being of human subjects.

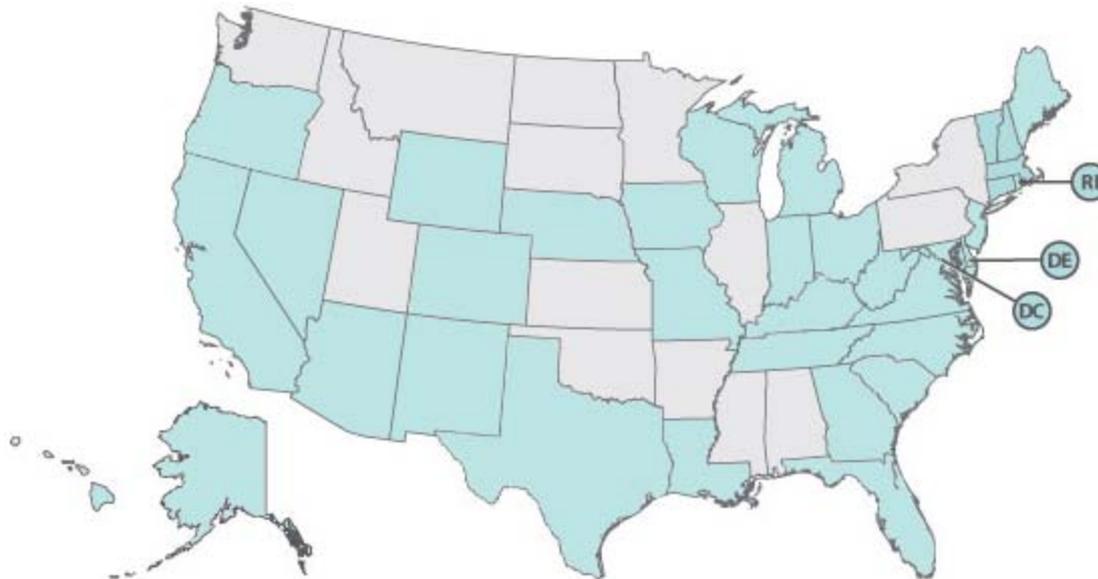
Regulatory Framework

- Three FDA centers regulate medical investigational products for human use:
 - Center for Drug Evaluation and Research (CDER)
 - Center for Biologics Evaluation and Research (CBER)
 - Center for Devices and Radiological Health (CDRH)
- FDA's Office of Regulatory Affairs (ORA) conducts onsite bioresearch monitoring inspections of sponsors, PIs and IRBs
- Enforcers: OIG/DOJ/FBI/State AGs/Health Care Fraud Prevention and Enforcement Action Team

Clinical Trial Billing

- Medicare Coverage Policy
 - NCD 310.1 states that Medicare will cover “routine costs of qualifying clinical trials...as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.” -NCD for Routine Cost in Clinical trials (310.1)
- Many commercial payers follow Medicare
- The NCD clinical trials policy **does not** address device studies. Organizations are required to work with their Medicare Administrative Contractor (MAC) to determine coverage for device studies.

States That Require Health Plans to Cover Patient Care Costs in Clinical Trials



Taken from the *National Cancer Institute* website, **MARCH 2011**
<http://www.cancer.gov/clinicaltrials/education/laws>



CMS Coverage of Medical Devices

- **WPS Medical Director review not required for**
 - Devices approved through FDA pre-market approval process
 - Devices cleared through FDA 510(k) process
- **WPS Medical Director approval is required for:**
 - FDA-approved IDE Category B devices
 - IRB-approved medical devices
- **Devices typically not covered include:**
 - FDA-approved Category A devices
 - EXCEPTION may be granted by CMS / WPS Medical Director for use in a “life threatening condition.”

Category B IDEs

- **FDA-approved IDE Category B devices**
 - Routine costs associated with these studies are covered if the study is approved by the local Medicare Medical Director
 - If approved, the device can be billed to Medicare if it is not provided for free by the sponsor or promised free in the informed consent form
 - Medicare coverage is based on the device continuing to meet criteria that led to the FDA category designation
 - Payment is limited to or less than what Medicare would have paid for a comparable device
 - Payment under Medicare for Category B devices will be based on information provided in the IDE submission and clearly stated in the IDE exemption letter

Category B IDEs

- **FDA-approved IDE Category B devices**
 - Providers are required to identify claims with the proper modifiers
 - Claims should include the IDE number assigned to the device

CMS Submission Requirements

- **Provider name and number (for Part A it would be the institution name and number, for Part B it would be the PI provider number along with the mailing address)**
- For Part B, all co-investigators that will bill for services must also be listed with the submission.
- Name and Number of the investigational device(s) utilized in the trial.
- A narrative description of the device(s).
- Signed copy of the FDA-approval letter demonstrating category A or B IDE status.

CMS Submission Requirements

- The FDA letter containing the most current approved number of institutions and subjects (may be 2 separate letters).
- Number of Medicare cases planned for the study at the specific institution.
- A copy of the final protocol from the sponsor.
- Additional items to be maintained at the site and readily available
 - The agreement between the company or manufacturer and the provider, furnishing the details of the provider participation.
 - At least 2 peer-review publications.
 - Any product literature illustrating the device and/or procedure.
 - IRB-approval for the protocol to be carried out at the institution.

BJC/ WUSM Approval Process

Step 1: Notification of Device Trial

- WUSM Contracts Department notifies BJH Research Billing Compliance and the WU Clinical Research Billing Support office via e-mail of any new device trial as it comes to that office. Documents available at that time are attached.
- Clinical Research Billing Support-Secretary (Jan Light) notifies BJH Research Compliance (Darlene Szczuka) via e-mail when she receives an IRB application for a new device trial and forwards the HRPO approval. Kelly Granda is copied on this e-mail transmission.

Step 2: Communication with Study Team

- Upon receiving knowledge of the trial, BJH will send an e-mail to the study coordinator informing them that she will be gathering the required documents and will send one packet including those documents and the request for coverage letter from both institutions. She will request the letter from the physician (or representative) be sent to her for mailing.



BJC/ WUSM Approval Process

Step 3: Gathering Documents

- BJH acquires required documents from CCS contracts, CCS Clinical Research Billing Support, department coordinators, and sponsors as appropriate.

Step 4: Sending the packet to WPS

- Upon receipt of all necessary documents and letters, BJH will write a cover letter to Dr. Stephen Boren (CMS) informing him that the packet includes requests from both entities. This letter is scanned and e-mailed to the coordinator listed on the device form along with the following individuals: the coordinator, the PI, Denise McCartney, Melanie Rowe, Deb Wierciak, William Woloszyn, and if the trial is within the Department of Surgery, Kathy Hoertel .

BJC/ WUSM Approval Process

Step 5: Review Process issues

- Any requests or questions coming from WPS will be directed to the appropriate entity.

Step 6: WPS Approval letter receipt

- BJH will inform the coordinator when approval is granted and will request that WU reciprocate and send the WU approval letter to her.

Quick Summary

- **Device Trial Coverage**: Medicare requires the MAC Medical Director's approval
 - **Category A IDE**: when studying a life-threatening condition
 - **Category B IDE**: when Medicare contractor approves coverage
 - **PMA**: generally covered with approval (if MAC requests)
 - Note: Carotid artery stent PMAs must be submitted
 - **Labeled Use**: generally covered with approval (if MAC requests)

Questions

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