Clinical Research Billing and Compliance Top 10 List

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The top 10 things the CRAO does *NOT* advise you to do related to Clinical Research Billing and Compliance

Number 10…

- Do not bill insurance for anything that is not "reasonable and necessary."
  - Experimental and investigational items/services are not generally "reasonable and necessary."
  - Items/services solely for data collection or screening are not generally "reasonable and necessary."
- Items/services billed to insurance that are related to a study should be those items that are routinely provided to patients not in a study.

Number 9…

- Do not get paid by a sponsor more than "fair market value."

  - Compensation in excess of "fair market value" can be construed as "kickback" if one purpose is to generate business between the parties.

Number 8…

- Do not "GUESS" at your research budget.
  - Create your own internal research budget to identify how much it will cost you to do a particular study before you review a sponsor budget.
  - Make sure you use the research discount on charges when creating your budget.
    - MBECT reflects the 80% discounted clinical research
  - Assess the feasibility of completing the research and know how much money you need before you negotiate with a sponsor or make funding requests.

Number 7…

- Do not bill Medicare for items/services associated with an investigational device UNLESS you have written prior approval from the local Medicare contractor and carrier (Part A & B).
  - Submission must be made to the local Medicare contractor if anything related to a FDA category A or category B IDE research study is to be billed to Medicare or other insurance companies.
  - Contact the CRAO or go to the CRAO website if you would like guidance on this.

Number 6…

- Do not bill Medicare for any items/services provided within the context of a clinical research study if the study does not meet the Centers for Medicare & Medicaid Services (CMS) "qualifying" criteria.
  - This includes items/services considered standard of care or routine for the subjects enrolled in the study.

Number 6 cont'd…

- "Qualifying" clinical trials must meet the following criteria as established in the CMS National Coverage Decision (NCD).
  - The subject or purpose of trial must be the evaluation of an item or service that falls within a Medicare benefit category.
  - The investigational intervention must have therapeutic intent (not be designed exclusively to test toxicity or disease pathophysiology).
  - The study must enroll subjects with a diagnosed disease (trials of diagnostic interventions may enroll healthy patients as "controls").
  - Meet the seven desirable characteristics. Some studies have been deemed to meet these characteristics by CMS.

Number 6 cont'd…

- "Deemed" clinical trials are those studies:
  - Are funded by the NIH, CDC, AHRQ, DOD, DHHS, or the VA.
  - Or are supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, DOD, DHHS, or the VA.
  - Or are conducted under an IND or is a drugs trial that is exempt from having an IND.
  - Or reviewed and approved by a UMHS Pre-Review Committee (PRC).

Number 5…

- Do not use money from a sponsor for any non-trial related effort or anything other than the intended use
- **Example:** Funding is provided by Sponsor for a particular diagnostic test, the funding should be used for that purpose and not to cover research effort.
  - Read your clinical trial agreement (Contract) and review the budget in the agreement to see for which items the sponsor has agreed to pay.

Number 4…

- Do not bill insurance or the subject for any item or service that the informed consent form (ICF) says will be provided by the study or sponsor.

  – If the patient signed a consent that says “this test will be paid for by the study”, *even if the language was written in the consent in error,* it must be adhered to.

Number 3…

- Do not bill insurance or the subject for any item or service for which someone else has agreed to pay for.
  - This includes complications or adverse events (AE). Look for language related to this in the Contract/Clinical Trial Agreement (CTA).

Number 2…

- Do not bill insurance or the subject for any item that you receive for free.
  - If a sponsor provided a device or product for free, you must ensure that no bill is sent to the payer or subject related to that item.

Number 1…

- Do not keep money to which you know the institution is not entitled.
  - Reconcile your research accounts monthly
  - If the aforementioned items were billed to an insurance company or subject, the insurance company or subject must be refunded including any copayments or deductibles.
- Contact CRBIssues-help@umich.edu with any billing issues.

What Should I Do…

- **Do** make sure all of the five core study documents are consistent with each other.
- **Do** work with your UMHS Professional A/R Billing or the CRAO Coding & Audit Analysts, to make certain that items/services are coded correctly.
- **Do** contact the CRAO, the Med School Grants Office, or the CDM & Rate Setting Team for assistance.

For more information…

Calendar Review and Analysis Office

998-6880

CR2-AO@umich.edu

CRBIssues-help@umich.edu

BECT-coders@umich.edu

MBECT-Help@umich.edu

Information on clinical research billing is also available at:

http://www.med.umich.edu/medschool-crao/

Abbreviations

- A/R—Accounts Receivable
- CMS—Centers for Medicare and Medicaid Services
- CPT—Current Procedural Technology, a code utilized for indicating tasks and services provided by a medical practitioner to a patient
- CRAO– (Clinical Research) Calendar Review and Analysis Office, also known as CR2-AO
- CRB—Clinical Research Billing
- CDM—Charge Description Master, a code utilized for facility charges
- CTA-Clinical Trial Agreement
- IDE—Investigational Device Exemption
- IND—Investigational New Drug
- I/S—Items/Services
- MBECT—Michigan Budget, Enrollment, and Calendar Tool
- Medicare part A & B—part A provides for inpatient care; part B provides for outpatient care
- NIH, CDC, AHRQ, DOD, DHHS, COG, SWOG, the VA—these are each federal agencies which, when funding a study, allow the study to meet the deemed status.