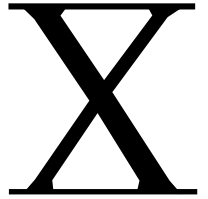


Clinical Research Billing and Compliance

Top 10 List



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.
 - OnCore 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 MM 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 MM 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 Charge Integrity Team (formerly Charge Capture and Revenue Optimization Team and CDM Team) for assistance.



For more information...

Calendar Review and Analysis Office

CR2-AO@umich.edu

CRBIssues-help@umich.edu

RVC-Charge-Capture-and Revenue-Optimization@med.umich.edu

Information on clinical research billing is also available at:

<https://research.medicine.umich.edu/our-units/calendar-review-analysis-office>



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
- CTA-Clinical Trial Agreement
- EAP-Epic All Procedures also known as CDM—Charge Description Master, codes utilized for billing
- IDE—Investigational Device Exemption
- IND—Investigational New Drug
- I/S—Items/Services
- Medicare part A & B—part A provides for inpatient care; part B provides for outpatient care
- MM – Michigan Medicine
- 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.

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