Clinical Research Billing Compliance Frequently Asked Questions

Clinical Study Billing Enterprise / Registration and documentation for research-related items/ services

1. How do we ensure clinical research billing information is shared across the Enterprise?
2. What documentation is required to be in the Medical Record to bill items/services related to research?
3. What is the required process for registering clinical research trial patients in Quest?

1. How do we ensure clinical research billing information is shared across the Enterprise?

Communications amongst the study team, Research Revenue Integrity (RRI), Sponsored Projects, IRB, Hospital Admission/Registration, and the Research Compliance Office is key to successful sharing of clinical research billing information.

Potential risks for non-harmonization of research documents:

1. Billing for services that are paid for by the sponsors.
2. Billing for services promised free in the informed consent.
3. Billing for services that are for research purposes only.
4. Billing for Non-Covered services during a non-Qualifying clinical trial.
5. Billing Medicare Advantage Plans for services that should be paid for by the Medicare Administrative Contractor.

"It takes a team" to get research reimbursement right. Here are just some of the people and groups to consider involving in the process.

1. Principal Investigator/Clinical Study Coordinator
2. IRB
3. Budget Negotiators
4. Research Revenue Integrity
5. Registration/Scheduling
6. Facility billing and coding
7. Professional billing and coding
8. Information Technology
9. Health Information Management

If you have any further questions, please contact Compliance & Privacy Office at 714-456-3466 or 714-456-8986.

2. **What documentation is required to be in the Medical Record to bill items/services related to research?**

   In addition to other routinely required documentation about the service, the Medical Record must include medically reasonable and necessary explanation for each item/service, unless it is being done solely for research data collection.

3. **What is the required process for registering clinical research trial patients in Quest?**

   Upon receipt of the informed consent signature page with Medical Record Number (MRN) from the study departments (via fax or OnCore), the plan description will be added at the patient level in Quest. The "R" Research Indicator will be added in the Patient Supplemental tab.

   By adding the plan description at the patient level, this will trigger an alert to the user checking in the patient to put the visit on "R" Bill Hold in the Visit Supplemental tab.

   If you have any further questions about how research patients are registered in Quest, please contact Research Revenue Integrity (RRI) at 714-456-6760.