Research Billing Buzz

A Newsletter from the Office of Clinical Research Billing Compliance

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Clinical Research Billing Frequently Asked Questions
In this edition of Research Billing Buzz we answer some of the questions that we often receive from research teams.

Frequently Asked Questions

If all charges are billable to my study, why do I need a PRA?

A Prospective Reimbursement Analysis (PRA) is necessary for all research studies that have the potential to generate a Johns Hopkins Medicine patient bill and require participants to sign an informed consent.

The study might need a PRA even if all costs are covered by the study to ensure that participants are not billed inappropriately.

What happens if the PRA determines that some services are not
**Billable to insurance?**

The Principal Investigator (PI) must secure other appropriate source of funding and write offs are prohibited.

**My research population is not likely to have Medicare, why do we have to follow Medicare rules?**

Johns Hopkins follows Medicare rules and regulations for research billing and PRA development as they: 1) pose a bigger risk to the Institution if non-compliant, 2) are followed by most third party insurances, and 3) it is the standard among peer institutions.

In addition, Medicare excludes very few benefits and does have beneficiaries with other conditions that are younger.

**Why did the research charges bill to my participant?**

This can be due to various reasons:

- **The study does not have a PRA** – only studies with a PRA hold for CRBC review
- **The participant is not in CRMS** – therefore, there is no association between the patient and the study in Epic
- **The participant is not active in CRMS** - before the encounter is closed in Epic
- **The participant was taken “off study” too fast** – charges take from four days to two weeks to make it to the claim
- **The participant was registered incorrectly** – If the participant is registered as “self-pay” or with “do not bill insurance”, the charges bypass CRBC review
What do I do if my participant received a bill?

Send an email to CLINIRESBILLING@exchange.johnshopkins.edu and include as much information as possible, our intake staff will review and take action or reach out for follow up.

Who is responsible for research billing compliance?

The PI is ultimately responsible, but Johns Hopkins has a robust infrastructure to help with this complicated task. CRBC is responsible for working with the PI and study team to ensure compliance.

I received an insurance denial for one of my participants. Can I pay for that participant’s bills from my research budget?

No. According to Medicare’s Secondary Payor Rule, Medicare will not pay for an item of service to the extent that payment has been made or can reasonably be expected to be made by other health insurance, or in the case of clinical trials, a sponsor.

In other words, if the sponsor pays for one participant it must pay for all since
we cannot know or discriminate against a Medicare beneficiary or dependent that might enroll.

**What documentation is required in the electronic health record (EHR) to bill for items and services related to my study?**

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

Remember: “if it’s not documented, it wasn’t done”.

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We hope that these questions and answers are helpful to you. If you would like to see more questions answered about any aspect related to research billing compliance, please send them along to our email below. We love to hear from you!

**Need Help?**

If you need help, have questions or want to suggest topics for future newsletters you can email us at:

CLINIRESBILLING@exchange.johnshopkins.edu

For more information, visit the [Research Revenue Cycle Website](#)