Notification of Research Billing PGR

Effective: 02/02/2017
Reviewed: 02/02/2019

Name of Associated Policy: Palmetto Health Administrative Research Review Policy
Sponsored Research Award Policy

Definitions

1. **Investigator**: An individual having the background and training in scientific and administrative oversight necessary to conduct and manage research activities.

2. **Research Staff**: Individuals who assist in a research project overseen by an Investigator.

3. **Sponsor**: An individual, company, institution, government agency or organization responsible for the initiation, management and financing of research.

Responsible Positions

- Investigator and/or Research Staff
- Clinical Research Billing Analyst

Equipment Needed

- **Research Billing** form: A generic form is available on the Palmetto Health Research Compliance website, and study-specific are provided by the Research Compliance in conjunction with Palmetto Health Administrative Research Review approval (per Palmetto Health Administrative Research Review Policy) and/or at the request of the Investigator.

Procedure Steps, Guidelines, Rules, or Reference

1. Through the review of studies by the Palmetto Health Administrative Research Review
(PHARR) process, Research Compliance staff will determine if a Research Billing form is required for a study. The need for a Research Billing form will be noted in the PHARR approval.

2. As required, a Research Billing form must be completed for each subject encounter (subject visit) that occurs at Palmetto Health. The subject encounter may involve either research-related items/procedures/services that are paid by the Sponsor and/or not billable to the subject or routine item/procedures/services that are billable to the medical insurance or is required to ensure appropriate financial management of the study.

3. The information required on the Research Billing form includes, but is not limited to the following:

   3.1. Investigator/Research Staff name and contact information;
   3.2. Study information, including study title, PRO number, ClinicalTrials.gov number, the type of study (e.g. Investigational New Drug, Investigational Device Exemption, etc.), and Investigational Device Exemption number, if applicable;
   3.3. Study subject identifiers;
   3.4. Visit information, including date of the procedure/visit, type of visit, visit number, whether the patient is a series patient or not, and if the patient should be registered as research or if the subject’s insurance should be billed; and
   3.5. Procedures/items/services that must be removed from the subject’s bill (not billable to the subject), if applicable;
   3.6. Signature (electronic) of the Investigator and/or Research Staff completing the form.

4. The completed Research Billing form should be forwarded to Research Compliance electronically via email after the encounter and either within the same day as the encounter or the following day. See below for further definitions of the timing for submission. A Research Billing form should not be received prior to the encounter.
   4.1. A day is defined as beginning at 12:00 am through 11:59 pm.
   4.2. For Monday through Thursday encounters, Research Billing Forms should be received no later than the following day by 11:59 pm.
   4.3. For Friday, Saturday and Sunday encounters, Research Billing Forms should be received no later than the following Monday by 11:59 pm.

5. Emailing Research Billing Form
   5.1. It is the Investigator’s/Research Staff’s responsibility to ensure that the sent email is encrypted if sent from a non-Palmetto Health email address.

6. Payment of the identified research-related charges shall be payable to Palmetto Health. It is the Investigator’s responsibility to include such charges during the study budget negotiation process and/or identify a source of funding.

7. The Investigator and/or Research Staff must respond promptly to any Palmetto Health entity with questions related to the Research Billing form.
REFERENCES:
Palmetto Health Research Compliance website
Palmetto Health Administrative Research Review Policy