Clinical Research News You Can Use...

Coverage Analysis
Trae Rohan, Regulatory Specialist, Clinical Trials Resource Center

We have been talking a lot lately about the new CMS requirement to include NCT numbers on claims for items and services provided in a clinical trial. This has galvanized a lot of different groups within UT Houston to look at the clinical research billing process in general. At the heart of clinical research compliance billing is a process called coverage analysis. Coverage analysis means a review of all the procedures listed in the protocol’s schedule of events to determine which ones are ‘billable’. If the research sponsor is willing to pay for all the procedures in the study schedule – then a coverage analysis is not needed. Study teams have to make sure that all the study procedures are billed to the study account (EG Account) and not billed to the patient or third party payer.

Lately, we have been seeing more and more studies in which at least some of the services are considered routine (sometimes referred to as standard of care). A service would be considered routine if all the patients with that condition would have undergone that service whether or not they participated in the clinical trial. This service may be eligible for billing to Medicare and/or 3rd party payor if the clinical trial meets the criteria for ‘qualifying clinical trial’ or has been pre-approved, depending on the type of trial. We will focus initially on industry sponsored clinical trials. The plan is to make the process mandatory by June 1, 2014. Starting June 1, 2014, all industry sponsored clinical trials must have a formal coverage analysis before contract execution.

The Clinical Trials Resource Center is working with researchers and research staff to assist them in making these determinations. We identify studies when they are submitted via iRIS for CPHS review and reach out to the study team to offer assistance with the coverage analysis process. Some departments have already started working on a process to conduct coverage analysis at a departmental level. If you’d like to know more about this process or would like to learn how to conduct a coverage analysis for your research study, please contact clinicaltrials@uth.tmc.edu

CPHS Faculty Report

The CPHS Faculty Report for 2013 is here! As you can see from the report, the number of new submissions to CPHS has increased to over 900. At the same time, the median time to approval has reduced in all the review categories.

The median time for approval of an exempt application was 11 days, this is a reduction by half since 2009. For initial applications reviewed by expedited procedure, the median time was 36 days. Research applications that are greater than minimal risk are reviewed at a convened meeting. The time to approval for these protocols has also been almost reduced by over 40% to 59 days. You can review the complete report here.
UPCOMING TRAINING

Study Coordinator Monthly Forum
Objective: Discuss best practices in clinical research management and network with research administrators and staff from various research groups within UTHealth.
Date: March 25, 2014, April 28, 2014
Time: 11:30 a.m. – 1 p.m.
Location: MSB 2.135
Lunch provided to the first 40 participants
Registration is not required.
More information here.

Clinical Research Education
Objective – This educational program aims to promote excellence in clinical trial management for research nurses, study coordinators and other research staff. Day 1 and 2 focus on clinical trial management and day 3 on clinical trial finances and contracting.
Date: April 15 – 17, 2014.
Time: 8 am to 4 pm
Location: Cooley University Life Center.
Register here.

Orientation for Clinical Research Staff
Objective – This one day program provides an overview of clinical trial research at UTHealth. The first half of the day focuses on CPHS review and approval process, MHH hospital review process and clinical trial management. In the afternoon, the focus will be on clinical trial finances – including budgeting and billing.
Date: June 24, 2014; Aug 26, 2014
Time: 8 am to 3 pm
Location: MSB 2.104B
Registration is required. Register here.

iRIS Training
Objective: Hands on training in the iRIS system to submit research protocols involving human subjects to the IRB.
Date: April 9, 2014; April 29, 2014
Location: UCT 1160 (subject to change).
Register here.

About Clinical Trials Resource Center
It is the mission of the Clinical Trials Resource Center to provide a single portal of expertise, and best practices for the study team to facilitate efficient, compliant, and ethical study conduct and management. The CTRC office is located at UCT 790. Visit www.uthouston.edu/ctr for more information.

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