New Federal Mandate Regarding Clinical Trial Billing Requirements Effective January 1, 2014

Nov 4, 2013

Effective January 1, 2014, the Centers for Medicare & Medicaid Services (CMS) will require inclusion of the 8-digit National Clinical Trial Number (NCT) on claims associated with clinical trial participation. Clinical trial related claims submitted to Medicare for dates of services on or after January 1, 2014, will be returned to the provider if the 8-digit clinical trial number is not present. VCUHS thinking ahead has decided to include this number on all clinical trial charges with the anticipation that other carriers will quickly follow suit.

The NCT number is an 8-digit number assigned to each trial registered in ClinicalTrials.gov. As mandated by federal law, Applicable clinical trials must be registered with ClinicalTrials.gov by the responsible party. Multisite commercially sponsored clinical trials are usually registered by the commercial sponsor of the trial. Investigator Initiated trials and Federally Funded trials must be registered by the Principal Investigator or designee in accordance with federal law and VCU policy. This 8-digit NCT number will be added to a list of other required data.

Study Teams (Investigator or Research Coordinator) will be required to furnish the NCT Number to VCUHS and Associated Physicians billing offices in order to bill Medicare for routine care items and services related to clinical trial participation. To obtain the NCT Number, contact the commercial sponsor of your clinical trial or visit, clinicaltrials.gov to determine if your clinical trial has been registered. If your investigator-initiated trial has not been registered, it will need to be registered promptly. If you do not have a ClinicalTrials.gov account, please fill out an account request form by visiting the following website: http://www.research.vcu.edu/forms/e-ct_account_creation_form.htm

For additional information regarding account set up or registration requirements, please contact Melanie Wiggins at mwiggins@vcu.edu.

Information regarding a standard process for collecting the NCT number and participant information will be coming shortly. In the interim please verify the NCT number for each of your clinical trials.