views of the protocol, proposed budget, informed consent, and sponsor contract, are required to determine all the items and services needed for the conduct of the clinical trial. Documenting these items on a spreadsheet provides a visual template which assists with this analysis. Review each item or service and note if the sponsor is providing funding or goods, such as the investigational agent. Under this methodology, a line item budget is used. For the items in which there is no coverage, list the items and note if they are conventional care or if they are being conducted for research purposes only (the NCD on Routine Costs associated with clinical trials excludes coverage for items or services conducted for research purposes only). For the conventional care items, review NCDs and LCDs to determine coverage. If the clinical trial involves "off-label" use of an agent or agents and a LCD does not exist for coverage, coverage may be granted by the local fiscal intermediary or local Medicare carrier if the use is determined to be medically accepted.[28] For anticancer chemotherapeutic agents, coverage may occur if its use is supported in any of the three drug compendia or, if not, noted in specific peer-reviewed journal articles.[29] For any questions pertaining to coverage or non-coverage of an item or service, it is prudent to contact the local fiscal intermediary or local Medicare carrier for a coverage determination. Finally, before starting the study, it is important to review the informed consent document, the negotiated study budget, and contract to ensure concordance regarding which party is financially responsible for the items and services required to conduct the clinical trial.[30]

If the coverage analysis is conducted after the contract is executed and the study has commenced, the focus of the coverage analysis is what items and services the sponsor is covering. These items and services need to be noted and not billed to a third-party payer. It is important also to review the informed consent document to note what has been promised to the subjects at no charge and what items will be charged to the subject or a third-party payer. If the informed consent promises an item or service at no charge, neither the subject nor a third-party payer can be billed regardless of what the negotiated budget states.[30]

F. Clinical Research Coding and Billing Adjudication

Determining how to bill third-party payers and adjudicate claims for clinical trial care is a complex task that requires collaboration of a wide range of individuals working closely to develop a process that will work in their practice setting. The steps in the process are as follows: (1) Coverage Analysis; (2) Budgeting and Contracting; (3) Identifying Research Patients; (4) Registration and Admission; (5) Charge Segregation; (6) Coding; (7) Claims Processing and Invoicing; (8) Study Close-out and Residual Balances (Figure 5.10)[31] All of these steps require communication and collaboration of the clinical research teams and revenue cycle personnel.

Figure 5.10 *Clinical Research Billing and Coding Cycle Copyright Huron Consulting Group Inc. (2007)*[31]

Following completion of a coverage analysis and development a billing plan, when patients are consented and enrolled they must be identified in the financial system as research subjects to allow for a detailed review of claims. Charge segregation, coding, processing of claims, and invoicing the sponsor are billing processes that follow as patients take part in the study. All claims submitted for a patients treated under a clinical trial protocol must include secondary diagnosis code V70.7 (ICD-9) and Z00.6 (ICD-10), examination of participant in clinical trial, as a secondary or subsequent diagnosis code. This diagnosis code is reported on all treatments, imaging studies, laboratory tests and other procedures performed during the time period that the patient participates in the clinical trial.

In addition, Medicare requires, and other payers may utilize modifiers for clinical trial services on outpatient hospital and freestanding center claims for all services provided to a clinical trial patient. Each procedure or service billed must include one of the modifiers as outlined in Table 5.2 below.[32] Also, effective January 1, 2014, CMS requires healthcare providers to report the 8-digit trial number on all claims during the time period the beneficiary participates in the trial.[32] Additional coding requirement exist for facility/institutional claims (e.g., condition codes, IDE device number, revenue codes, etc.) Further instructions for proper coding for routine items and services for clinical trials can