

Clinical Research Billing Compliance AudioCourse

Course Syllabus



All lectures are 60 minutes with a 15 minute Q&A session.
All lectures begin at 12 pm CT/1 pm ET.

September 22

Lecture 1: Overview of Medicare Clinical Research Billing Rules

- History of Rules: 1995, 2000 & 2007 rules and where to find them
- Conceptual framework of rules
- Qualifying clinical research study
- Routine Costs
- "All other Medicare rules apply"
- The reasonable & necessary rule and application to research
- Compliance risks of non-compliance
- Unique enforcement aspects of clinical research

September 24

Lecture 2: Device Studies

- Qualifying status based on type of device
 - » Category A IDEs
 - » Category B IDEs
 - » Post-marketing Approval device studies
 - » HUDs
 - » 510(k) approved devices
- Routine costs during device studies
- Dealing with imaging, labs and follow-ups during research studies
- The reasonable & necessary rule as default
- Medicare contractor medical director approval
- Claim submissions & the IDE

September 29

Lecture 3: Drug Studies

- Qualifying clinical trial criteria
 - » "Deemed" status
 - Government funded studies
 - IND status
 - » Medicare benefit category
 - » Diagnosed disease
 - » Therapeutic intent
- Routine costs during drug studies

- Identifying conventional care guidelines
- Documenting detection & prevention of complications

October 1

Lecture 4: Clinical Trial Agreement & Impact on Billing

- Structure & organization of clinical trial agreements
- Who should be a party to the agreement? Stark Law implications
- Options for sponsor budget/compensation structure
- Schedule of event payments
- Lump sum payments
- Milestone payments
- Documenting clinical event payments versus research-only payments
- Fair market value and sponsorship payments
- Government grants

October 6

Lecture 5: Research Informed Consent & Impact on Billing

- Regulatory requirements of the "added costs" section
- Statements on therapeutic benefit
- Avoiding overstating services without charge
- Statements on paying for research-related injury
- Interpreting added cost language in informed consents
- Discussing billing implications in informed consent with the IRB

October 8

Lecture 6: Medicare Secondary Payer Rules & Clinical Research Billing

- Overview of MSP statute and regulations
- Commentary by CMS on MSP
- MSP and research-related injury

- MSP and routine costs
- Impact on contract language

October 13

Lecture 7: Putting it All Together: Billing Rules & Study Documents

- Incorporating study documents and billing rules
- Identifying services that are required by research study
- Determining coverage for budgeting purposes
- Determining coverage for billing purposes
- Dealing with unscheduled visits & treating complications
- How to develop a process to manage coverage analyses

October 15

Lecture 8: Auditing & Monitoring Clinical Research Billing Compliance

- Two part process
 - » Testing coverage analyses
 - » Testing use of coverage analyses in billing process
- Charge capture process
- The role of modifiers
- Focusing resources on risks and building infrastructure