Research Billing Compliance Quality Assurance Training
Overview

• Navigating and complying with the numerous federal regulations around clinical trials billing is perhaps one of the most complex operational and regulatory challenges faced by academic medical centers and health care systems.

• Accurately billing for clinical trial services requires a tremendous amount of effort to coordinate operations and provide oversight to appropriately mitigate compliance risks.

• A lack of adequate controls can increase the risk for false claims and insurance fraud allegations, both of which can result in stiff penalties.
Federal clinical trials billing regulations mandate that payers should not be billed for services that are not considered to be directly related to patient care or are being paid by someone else (such as participation in a clinical trial).

In an effort to increase participation in clinical trials, former President Bill Clinton issued an executive memorandum directing the Secretary of Health and Human Services to: “Explicitly authorize [Medicare] payment for routine patient care costs ... and costs due to medical complications associated with participation in clinical trials”
Centers for Medicare and Medicaid Services (CMS), issued the Clinical Trial Policy National Coverage Determination (NCD) in response to the memorandum.

Effective July 9, 2007, Medicare covers the routine costs of qualifying clinical trials, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials.

Previously, Medicare did not cover patient care costs associated with enrollment in a clinical trial.

The NCD for Routine Costs in Clinical Trials (310.1) is now the standard by which commercial payers base clinical research coverage decisions.
Routine Costs

- Routine clinical trial costs include all items and services that would normally occur as part of the patient’s care outside of a clinical trial.

- Costs associated with the prevention, diagnosis and/or treatment of complications arising from participation in clinical trials are also covered.

- Standard Medicare billing rules apply to items deemed routine costs under the NCD.

- If Medicare covers the costs of items and services outside of the clinical trial, then they are covered during the clinical trial.

- A clinical trial must meet specific requirements under the NCD to receive Medicare coverage for routine costs.
Why is it important to know if a clinical trial is Medicare qualifying?

- Because if it is not, who is going to pay for the routine services?

Due to the complexity of clinical research billing and management, a Clinical Research Billing Taskforce was formed in 2018 and charged with the development and implementation of a research policy which would address all research studies identified with billable services as well as to identify the critical components involved with research billing compliance.
Effective April 1, 2019, all Medicare Qualifying Trials (MQT) will be required to adhere to the Yale Research Billing Compliance Policy which addresses all research studies with billable services.

Yale School of Medicine is committed to ensuring the appropriate billing of clinical procedures and services associated with its research studies. This commitment applies to all research studies regardless of the source of funds or Yale School of Medicine department performing the research study.

**Link for Policy:**
Yale School of Medicine Research Billing Compliance Policy
In addition to the Yale School of Medicine Research Billing Compliance Policy, an online manual was created in order to educate faculty and staff on the research billing compliance workflow and the critical components that encompass clinical trial billing and management.

Link: [Research Billing Compliance Manual](#)
Before billing 'routine costs' associated with a clinical trial to Medicare or other insurance carriers, YCCI determines if the trial meets the CMS qualifying criteria. There are 4 criteria to meet in order to be considered a Medicare “qualifying” trial:

1. The trial must have therapeutic intent. It cannot be designed to exclusively test toxicity or disease pathology.

2. Trials of therapeutic intervention must enroll people with diagnosed disease; and if healthy controls are enrolled, they must be assigned to a proper control group.

3. The purpose of the trial must be evaluation of an item or service that falls within a Medicare Benefit category and is not statutorily excluded from coverage (i.e. Medicare does not cover cosmetic surgery).

4. The clinical trial must be determined to meet the 7 desirable characteristics or “deemed” to meet the characteristics.

• Please note: The trial must meet all 4 of these criteria to be considered “qualifying”.
The 7 desirable characteristics needed to be considered Medicare “qualifying” trial:

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants’ health outcomes.
2. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;
3. The trial does not unjustifiably duplicate existing studies;
4. The trial design is appropriate to answer the research question being asked in the trial;
5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
6. The trial is in compliance with Federal regulations relating to the protection of human subjects; and
7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.
A trial is considered “deemed” to meet the 7 desirable characteristics by Medicare if it meets at least one of the following criteria:

1. Funded by NIH, CDC, AHRQ, CMS, DOD, or the VA.
2. Supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD, or the VA. (If the trial is not funded by one of these agencies, but is conducted by a center that is part of a cooperative group or receives funding from one of these agencies to conduct research, it still may be considered to be ‘deemed’. CMS assumes these centers will hold their non-funded trials to the same qualities as trials funded by one of these agencies.)
3. An investigational drug trial conducted under an IND.
4. A drug trial exempt from an IND under 21 CFR 312.2 (b)(1).

If you are conducting a trial that is not deemed to meet the 7 desirable characteristics, the local Medicare contractor may need to be contacted prior to billing them for the routine costs associated with the trial.
What is NOT covered by the Medicare Clinical Trial policy?

1. Investigational item or service itself (examples: many investigational drugs, devices and diagnostic tests), unless otherwise covered outside of the clinical trial.

2. Items and services provided solely for the purposes of determining eligibility and not related to medically necessary clinical care.

3. Items and services statutorily excluded under Medicare (example: cosmetic surgery).

4. Items and Services provided solely to satisfy data collection and analysis needs and not necessary for clinical management (example: Monthly CT scans for a condition usually requiring only a single scan).

5. Items and services provided by the research sponsors free of charge.
# Medicare Qualifying Trial (MQT) Process

<table>
<thead>
<tr>
<th>QCT Checklist</th>
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<tbody>
<tr>
<td>1. Does the study require items or services that are potentially billable to a subject or third party payer?</td>
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<td>2. Which type of research is the study?</td>
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<td>3. If Non-Device, does the investigational item or service fall under a Medicare Benefit Category?</td>
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<tr>
<td>a. If yes, what category?</td>
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<tr>
<td>b. If Non-Device, does the study have therapeutic intent as an objective?</td>
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<tr>
<td>i. If Yes, what is the objective?</td>
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<td>c. Does the study enroll patients with diagnosed disease?</td>
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<tr>
<td>i. If Yes, what is the disease?</td>
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<tr>
<td>d. Is the study a deemed trial?</td>
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<tr>
<td>i. If yes, list IND # or does the study meet one of the other requirements for a deemed trial?</td>
</tr>
<tr>
<td>4. If a Device study, does CMS allow coverage of the investigational device?</td>
</tr>
<tr>
<td>a. Is the device FDA approved and used on-label?</td>
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<tr>
<td>i. If no, does the device have an investigational device exemption (IDE) under 21 CFR 812.2(e) (1)?</td>
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<td>1. If Yes, what is the IDE number?</td>
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<td>2. If yes, what is the category for the IDE?</td>
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<tr>
<td>a. If Category A, has the contractor determined the device is used for diagnosis, monitoring or treatment of an immediate life-threatening disease or condition?</td>
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<td>b. If Category B, has the contractor approved the use of the device?</td>
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<tr>
<td>b. If device is investigational and does not have an investigational device exemption (IDE), does the device have a 510K exemption?</td>
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<tr>
<td>i. If yes, what is the 510K exemption number? Obtain contractor approval before billing for services?</td>
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<td>5. If Observational, what is the general purpose of the trial?</td>
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<td>a. What did you use to determine the study is observational?</td>
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<td>b. What is the implication for Medicare Billing for the observational trial?</td>
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<td>6. Is this a Qualifying Clinical Trial based on Medicare guidelines?</td>
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<td>7. Comments</td>
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Types of trials not meeting Medicare’s “qualifying” trial criteria

- **Example #1**: An investigational drug trial that will only give the drug to healthy volunteers to test for drug toxicity.

- **Example #2**: A diagnostic intervention study being performed in patients with disease, but not sponsored by one of the “deemed” agencies.

- The Medicare Coverage Office at Yale Center for Clinical Investigation (YCCI) should be contacted for guidance when a clinical trial does not meet the qualifying criteria and there are routine costs required under the trial.
Next Steps after MQT...

Clinical Trial Billing QA Process and Workflow

1. Protocol Documents Received, MQT performed, if deemed qualifying
2. Calendar Build and coding
3. Coverage Analysis Completed in OnCore
4. Review Assessment Completed
5. Management Plan Activated
6. Budget Development
Coverage Analysis, AKA “SOC vs. RS” Designations:

Once a study is identified as an MQT and prior to budget determination, YCCI’s centralized coverage analysis unit will conduct a Medicare Coverage Analysis (MCA). The analysis will be completed by YCCI’s central unit regardless of who is responsible for the drafting and negotiation of the budget. As a result, any budgets performed outside of YCCI will undergo a QA process to confirm that the negotiations align with the analysis (which is represented in the OnCore calendar)

- Medicare coverage analysis (MCA) is the process of reviewing and mapping costs according to the study protocol as either routine costs or as costs billable to the study sponsors and/or a third-party payer
- It is dependent upon a systematic review of research related documents to determine the billing status of both the study itself and the items/services provided to the research participants that are outlined in the research documents over the course of the study
- Based on thorough research, supported by national and local guidelines which meet the standard and compliant government regulations
- Sources to be used and Cited: NIH, NCCN, ACC, JAMA, NEJM, CMS NCD and LCD, specialty societies, etc
- Yale today and future state per institutional recommendations
Once a research study is identified as a MQT, the Billing Compliance Quality Assurance Team completes a risk assessment determination as to whether a clinical trial is high, moderate, or low risk for research billing compliance purposes. Reviews will be based on the billing compliance risk to avoid billing discrepancies and adjustments.

Billing Assessment and Selection Process:

- Prospective reviews (before billing) on all clinical trials that have a MQT that results in a billable services designation.
- Retrospective reviews will be performed on sub-set of clinical trials based on risk assessment.
- Any protocol amendments that result in additional services or a change to the current schedule of events will be re-evaluated using the coverage analysis process.
** Protocol Billing Compliance Assessment Score Sheet **

** Billing Compliance Factors **

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<tr>
<td>1. Study Type</td>
<td>2. Intervention</td>
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<td></td>
<td>Oncology</td>
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<tr>
<td></td>
<td>Non-Oncology</td>
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<tr>
<td></td>
<td>Interventional</td>
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<tr>
<td></td>
<td>Non-interventional</td>
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<tr>
<td>3. Treatment Route</td>
<td>4. Phase</td>
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<td></td>
<td>IV, Injection, Procedure</td>
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<td></td>
<td>Oral or N/A</td>
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<td></td>
<td>Phase 3-4</td>
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<td>Phase 1-2</td>
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<td>5. Target Accrual</td>
<td>6. Billing Type</td>
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<td></td>
<td>&gt;=10</td>
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<td></td>
<td>&lt;10</td>
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<tr>
<td></td>
<td>Mixed Billing</td>
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<tr>
<td></td>
<td>All services are R or SOC only</td>
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<td>7. # of Clinical Services</td>
<td>8. Medicare Population</td>
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<tr>
<td></td>
<td>High volume</td>
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<td></td>
<td>Low volume or N/A</td>
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<tr>
<td></td>
<td>High volume</td>
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<td>Low volume or N/A</td>
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<th>9. Billing Compliance Total Score</th>
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<th>10. Billing Compliance Risk Level</th>
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<tr>
<td>High: Definitely included in protocol selection for routine CRB review</td>
</tr>
<tr>
<td>Moderate: May be included in protocol selection for routine CRB review</td>
</tr>
<tr>
<td>Low: Least likely to be included in protocol selection for routine CRB review</td>
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<th>11. Billing Compliance Review Date</th>
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<th>12. Team Reviewer:</th>
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Billing Review Process:

- Once the assessment is complete and the risk level determined, a prospective review will take place by a QA research analyst. If there are any findings identified, the research analyst will determine the source of the oversight as well as address any possible preemptive actions to mitigate any future risk.

- Findings will be reviewed with the PI; will address billing opportunities and documentation recommendations in a proactive, educational manner.

- All findings will be accompanied with a corrective action plan and execution due dates.

- Follow-up on the CAP as well as continuing education, as needed, will be scheduled at the time of review meeting.
Clinical Trial Billing QA Process and Workflow

Identify Source(s) of Billing Data:

- Coverage Analysis
- Budget and Contract
- ICF
- Protocol
- HCFAs, UBs (PB vs HB claims)
- OnCore
- Epic WQ, Medical Record Documentation
- Sponsor Invoices (internally initiated, Auto-generated)
Identify source(s) of Error:

- Budget preparation and negotiation: Who pays for adverse events? What is the language related to subject injury?

- Informed consent language; Are there items/services promised free of charge and/or co-payments and deductibles.

- Scheduling Process: Are visits being linking and identified as research visits?

- Untimely Subject Management by coordinators; what can we do to be more pro-active?

- Rejections not managed
• Can result in federal investigations and settlements involving improper clinical trials billing

• A notable investigation involved Rush University Medical Center (Rush) in 2003

• Rush reviewed its clinical research billing practices and uncovered a number of errors in which Medicare was improperly billed for research services as routine costs

• As a result of the findings, all clinical trials at Rush must be reviewed under the Clinical Trials NCD before enrolling research participants to determine which services are considered “routine costs”
1. There are 4 criteria to meet in order to be considered a Medicare “qualifying” trial. The trial does not need to meet all 4 of these criteria to be considered “qualifying”.

True or False?
1. There are 4 criteria to meet in order to be considered a Medicare “qualifying” trial. The trial does not need to meet all 4 of these criteria to be considered “qualifying”.

True or False?

The answer is False...The trial must meet all 4 of these criteria to be considered “qualifying”.
2. A trial is considered “deemed” to meet the 7 desirable characteristics by Medicare if it meets at least one of the following criteria:

1. Funded by NIH, CDC, AHRQ, CMS, DOD, or the VA.
2. Supported by centers or cooperative groups that are funded by the NIH.
3. CDC, AHRQ, CMS, DOD, or the VA. (If the trial is not funded by one of these agencies, but is conducted by a center that is part of a cooperative group or receives funding from one of these agencies to conduct research, it still may be considered to be ‘deemed’. CMS assumes these centers will hold their non-funded trials to the same qualities as trials funded by one of these agencies.)
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5. A drug trial exempt from an IND under 21 CFR 312.2 (b)(1).

True or False?
2. A trial is considered “deemed” to meet the 7 desirable characteristics by Medicare if it meets at least one of the following criteria:

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4. An investigational drug trial conducted under an IND.
5. A drug trial exempt from an IND under 21 CFR 312.2 (b)(1).

True or False?

The answer is True. Remember if you are conducting a trial that is not deemed to meet the 7 desirable characteristics, the local Medicare contractor may need to be contacted prior to billing them for the routine costs associated with the trial.
3. Once a study is identified as an MQT and prior to budget determination, the Principal Investigator is responsible for conducting a Medicare Coverage Analysis (MCA).

True or False?
3. Once a study is identified as an MQT and prior to budget determination, the Principal Investigator is responsible for conducting a Medicare Coverage Analysis (MCA).

True or False?

The answer is False.

Once a study is identified as an MQT and prior to budget determination, YCCI’s centralized coverage analysis unit will conduct a Medicare Coverage Analysis (MCA).
4. One of the sources used for research billing quality assurance audits include which of the following?

a) Coverage Analysis
b) Budget and Contract
c) ICF
d) All of the above.
4. One of the sources used for research billing quality assurance audits include which of the following?

a) Coverage Analysis
b) Budget and Contract
c) ICF
d) All of the above.

The correct answer is D. Additional sources would include:

- Protocol
- HCFAs, UBs (PB vs HB claims)
- OnCore
- Epic WQ, Medical Record Documentation
- Sponsor Invoices (internally initiated, Auto-generated)
Questions?