Clinical Research Training Module

November 24, 2014
Why is this training important?

Coverage by insurance companies for patients in clinical trials was expanded under CT State law in 2012 and under the federal Patient Protection and Affordable Care Act in 2014. This is good news for Yale as a research facility! However, the expanded coverage is tied to additional billing requirements for clinical care services. In anticipation of the complex billing associated with patients in research studies, the Yale Medical Group has made a significant investment in software designed to facilitate correct billing of clinical care in research studies.

This tutorial will focus on:

- Insurance coverage and billing requirements for clinical care services for patients in clinical research studies
- OnCore and EPIC features to ensure billing compliance
- Consequences of non-compliance
This module will take about 30 minutes to complete. Please follow the instructions at the end of the tutorial in order to record and receive credit for the training.
What’s new in 2012?

CT Public Act 11-172 - Effective 1/1/2012

- Extends coverage of routine patient care costs associated with clinical trials to people with disabling or life threatening chronic disease by private insurers.

- This coverage was previously only available for Phase III therapeutic or palliative cancer clinical trials.

- Requires pre-authorization from private insurers for coverage of the standard of care (routine care) costs associated with the clinical trial.

- The routine patient care costs associated with clinical trials covered by Medicare’s Clinical Trial policy will qualify for private insurance coverage.
What’s new in 2014?

Patient Protection and Affordable Care ACT  Sec 2709 {42 U.S.C. 300gg-8} - Effective 1/1/2014

- Extends coverage of routine patient costs associated with ‘approved’ clinical trials for cancer and other life-threatening diseases or conditions to ‘qualified’ individuals insured by group health plans or another health insurance issuer nationally.

- Patients enrolled into insurance plans prior to March 23, 2010 that did not provide coverage of routine costs associated with clinical trials may not be entitled to these coverage provisions due to the plan’s ‘grandfathered status’.

- Routine patient costs include all items and services consistent with the coverage provided in the plan (or coverage) that is typically covered for a qualified individual who is not enrolled in a clinical trial.
What’s new in 2014?

CMS requires 8-Digit Clinical Trial Number on Claims - Effective 1/1/2014

As of January 1, 2014 the Department of Health & Human Services (DHHS) has made it mandatory to report a clinical trial number on claims submitted to Medicare for items/services provided in:

- ‘qualifying’ or ‘CMS approved’ clinical trials,
- ‘approved’ category A and B device IDE studies,
- CMS-approved registries, or under
- the Coverage with Evidence Development (CED) program.

This is the number assigned by the National Library of Medicine (NLM) ClinicalTrials.gov Website when a new study appears in the NLM Clinical Trials database.
What’s new in 2015?

CMS implements new regulations for Category A and B Investigational Device Exemption Studies - Effective 1/1/2015

Starting January 1, 2015 Medicare will be evaluating if the Category A and B Investigational Device Exemption (IDE) study meets 10 specific study criteria when determining if items and services associated study are allowed to be paid.

In addition, the new regulations establish a centralized review process for determining if the Category A and B IDE study should be considered Medicare ‘approved’.
“Routine costs” are considered services that are medically necessary and would be rendered absent a clinical trial.

Routine costs are also known as Standard of Care or Conventional Care.
What is already in place?

Connecticut Insurers must:

- Define the extent of coverage for clinical trials in their customer insurance policies.

- Cover services provided in a trial which has successfully completed Phase III of a FDA trial

- Cover routine costs associated with clinical trials approved by NIH, National Cancer Institute affiliated cooperative groups, the FDA, Department of Defense (DOD), the Veterans Administration (VA) or qualified to receive Medicare coverage under the Medicare Clinical Trial policy.
What is already in place?

Connecticut Insurers must:

- Respond to requests for coverage of routine care for clinical trial patients 5-10 days after the request for coverage information is received and any other reasonable supporting materials requested.

- Approve or deny requests for coverage of phase III clinical trials for the prevention of cancer within 14 business days.

- Denials may be appealed.

- Offer expedited appeals for patients denied coverage in studies that have less than a 2-year life expectancy.

- Respond to expedited appeals within 48 hours of receiving the request.
Check the Compliance Web Site under ‘Clinical Research’ for more information. This site includes the pre-authorization forms and can be found at URL:

http://ycci.yale.edu/comp\
y/index.aspx

Click: “Insurance Policies” and “Pre-authorization”
“Now that we have reviewed private insurance rules in Connecticut, let’s see what federal payer policies like Medicare cover.”
Medicare covers services in “qualifying” clinical trials.

- A “Medicare Qualifying Trial” is a trial in which Medicare will cover the standard of care (routine care) costs associated with the subject’s participation in the trial.

- Routine care services in a qualifying trial should be billed with **Modifier Q1**.

- **Modifier Q1** attests that the services are provided in a qualifying clinical trial.
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?

This information is vital for the budgeting process. The next few slides will tell you how to determine if the studies you are involved in are “Qualifying”.

There are 4 criteria to meet in order to be considered 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.
Want help in determining if your study is "Qualifying"?

There are several worksheets located on the Yale Medical Billing Compliance Website: [http://ycci.yale.edu/comply/index.aspx](http://ycci.yale.edu/comply/index.aspx)

Click: "Billing Information" and "Qualifying Trials".
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**.
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.
Other Medicare Qualifying Trial Facts

• the patient’s **medical record** must have the trial name, sponsor, and protocol number

• coverage extends to reasonable and necessary care arising from **complications** of a study

• the **Economic Consideration** section of the consent must clearly denote what the sponsor is paying for and the patient’s obligation
It is important that the protocol, budget and informed consent are consistent in regards to the financial obligations in the study.

The services that will be provided should be clearly spelled out along with who is paying for them.

Language such as “the sponsor will pay if the patient’s insurance does not” is NOT acceptable.

The next 4 slides cover device studies. If you don’t do device studies, please [click here](#).
Investigational Device Studies

Medicare has covered the cost of certain investigational devices and services incident to investigational device exemption studies (IDE) since November 1, 1995. Recently the Centers for Medicare and Medicaid Services (CMS) established new regulations related to Medicare coverage for investigational device exemption studies.

The new IDE regulations effective on January 1, 2015:

- define 10 specific criteria Category A and B IDE studies should exhibit for CMS to consider the study as ‘approved’ for purposes of Medicare coverage of the device and/or routine costs,
- establish a centralized review process for approval of the Category A and category B IDE studies that were approved by the FDA on or after January 1, 2015.
Medicare IDE Study Criteria

The 10 criteria that will be used by CMS to determine if the IDE study is ‘approved’ include:

(1) The principal purpose of the study is to test whether the device improves health outcomes of the appropriately selected patients.*

(2) The rationale for the study 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 study results are not anticipated to unjustifiably duplicate existing knowledge.*

(4) The study design is methodologically appropriate and the anticipated number of enrolled subjects is adequate to confidently answer the research question(s) being asked in the study.*

(5) The study is sponsored by an organization or individual capable of successfully completing the study.*

* Criterion also required under The National Coverage Determination (NCD) for Routine Costs in Clinical Trials § 310.0.
Medicare IDE Study Criteria

(6) The study is in compliance with all applicable Federal regulations concerning the protection of human subjects.*

(7) Where appropriate, the study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Studies of all medical technologies measuring therapeutic outcomes as one of the objectives may be exempt from this criterion only if the disease or condition being studied is life threatening and the patient has no other viable treatment option.*

(8) The study is registered with the National Institutes of Health’s National Library of Medicine ClinicalTrials.gov. (NCT#)*

(9) The study protocol describes the method and timing of release of results on all pre-specified outcomes, including release of negative outcomes and that the release should be hastened if the study is terminated early.

(10) The study protocol must describe how Medicare beneficiaries may be affected by the device under investigation, and how the study results are or are not expected to be generalized to the Medicare beneficiary population. Generalizability to populations eligible for Medicare due to age, disability, or other eligibility status must be explicitly described.

* Criterion also required under The National Coverage Determination (NCD) for Routine Costs in Clinical Trials § 310.0.
Coverage for Category B IDE Studies

• Medicare may pay for the costs of the **Category B** device and the routine care items and services furnished in an FDA-approved category B IDE study.

• Category B devices are generally a newer generation of a proven technology. These devices may be a refinements of existing technology or a replication of existing technology made by other manufacturers.

• Effective January 1, 2015 Medicare may make payment for a Category B (Nonexperimental/investigational) IDE device and routine care items and services furnished in an FDA-approved Category B IDE study if CMS (or its designated entity) determines prior to submission of the first claim that the Medicare coverage IDE study criteria described in the regulations are met.
Coverage for Category A IDE Studies

• Category A devices are not covered by Medicare.

• The absolute risk, safety and effectiveness has not established with the FDA for these types of devices.

• Effective January 1, 2015 Medicare covers routine items and services furnished in an FDA-approved Category A (Experimental) IDE study if CMS (or its designated entity) determines Medicare coverage IDE study criteria described in the regulations are met.
Investigational Device Studies

- For Category A and Category B IDE studies approved by the FDA prior to January 1, 2015, **pre-authorization** MUST be sought in writing from the local Medicare contractor by the PI before any charges (the devices or routine costs) can be billed to Medicare.

- Pre-approval may not be needed for Medicare’s coverage of items and services associated with non-category A or B IDE studies. The local Medicare contractor’s (i.e. National Government Services) IDE policy should be reviewed to determine if pre-approval of the study is needed.

- Effective for Category A and B IDE studies approved by the FDA on or after January 1, 2015, interested parties (i.e. study sponsors) that wish to seek Medicare coverage must submit a request for review and approval to CMS.

- Claims for items and services associated IDE trials may need a specific modifier (Q0 for the investigational item or service and Q1 for the routine care costs), diagnosis code (V70.7), the IDE number and the 8-digit clinical trial number assigned by the National Library of Medicine.
More detailed information regarding Medical Device Trials requirements may be found on the Medical Research Billing Compliance website.

http://ycci.yale.edu/comply/index.aspx

Click: “Devices”

Now it’s time for a quick pit stop to check our knowledge
1. Coverage of routine care services may be available to patients in clinical trials for:

A. Disabling or life threatening chronic disease

B. Phase III cancer studies

C. Trials that meet Medicare “Qualifying” criteria

D. All of the above
1. Coverage of routine care services may be available to patients in clinical trials for:

A. Disabling or life threatening chronic disease
B. Phase III cancer studies
C. Trials that meet Medicare “Qualifying” criteria
D. All of the above

The answer is “D’.

Remember that there is a worksheet on the Compliance website to assist in determining if the trial is qualifying.
2. Private insurers never require pre-authorization for patients in clinical trials.

True or False?
2. Private insurers never require pre-authorization for patients in clinical trials.

True or False?

Answer: FALSE.

Were you paying attention? Private insurers do want you to submit a request for pre-authorization for routine services for patients in research studies.
3. Routine care services in a clinical trial should be billed with modifier Q1.

True or False?
3. **Routine care services in a clinical trial should be billed with modifier Q1.**

True or False?

**The answer is True!**

**This modifier should be listed on your billing encounter form.**
4. Your budget, informed consent and protocol should be consistent about the services to be provided and who is financially responsible.

True or False?
4. Your budget, informed consent and protocol should be consistent about the services to be provided and who is financially responsible.

True or False?

The answer is ‘True’.

In the next section you will learn that these documents have to be specific enough so that items and services associated with the study are billed to the correct party.

Now on to the second section – OnCore and EPIC!
OnCore and EPIC

OnCore is Yale’s Clinical Trial Management System. Information in OnCore may interface with the EPIC billing system to assist investigators with appropriate clinical trial billing.

Information entered into a study’s billing calendar in OnCore can be used by EPIC billing system to identify patients enrolled in clinical trials and prevent clinical services paid by the study’s sponsor from being billed to the subjects and their insurers.
What studies may need a billing calendar built in OnCore?

Research studies with anticipated billable services that are rendered by Yale Medical Group and/or Yale New-Haven Hospital.*

- Billable services include **standard of care** services

- Billable services include **research specific services** that will be paid by the sponsor.

For example: studies with office visits conducted by an investigator or an ancillary department provider who may generate bills for patients encounters, x-rays, MRIs, CT scans, lab specimen collection/processing and/or testing, pathology fees, and/or ECGs may need to be entered into OnCore.

*For oncology trials involving investigational drugs the billing calendar may be built from the Beacon system.*
How do you get the billing calendar built into OnCore and ensure patients are billed appropriately?

• Inform the OnCore Team at Yale Center for Clinical Investigation (YCCI) of the protocol or the person responsible within your department. Build and activate the study’s billing calendar in OnCore system prior to enrolling the first subject. (For OnCore support contact: oncore.support@yale.edu or call 203-737-7039)

• Ensure each subject is identified in the OnCore system as a participant in the study as soon as they sign informed consent. Confirm each subject is denoted as enrolled in the trial in the EPIC system shortly after they have their first billable service performed.

• Maintain the subjects’ status in the OnCore system. Ensure the subjects’ visit dates are marked as completed in the system shortly after their visits are performed. Ensure the SOC designation for services as “standard of care” is appropriate. Ensure services not done or not applicable for marked appropriately.

• Inform the OnCore team when a subject deviates from the schedule of events (adverse events) and/or when the costs for a service needs to be charged to a different entity than was anticipated in the protocol level calendar.
What benefits does using OnCore and EPIC provide?

- Assists in billing the correct party for services provided in a research study.

- Ensures that correct modifiers such as the Q0 and Q1 are included on our bills.

- Ensure that correct diagnosis codes are included on our bills, such as V70.7 ICD.9 code which indicates “examination of participant in clinical trial”.

- Ensure that the correct National Clinical Trial # associated with the trial/study/registry is included on claims released to Medicare.

- Assist departments in paying ancillary providers for research services they have rendered and in collecting payments from sponsors.
The information in OnCore and EPIC is shared with Yale New Haven Hospital (YNHH) to assist them in appropriate billing for clinical research services as well.

For example, when a MRI is ordered for research purposes only YNHH should bill the technical component of the MRI to the sponsor, just as Yale Medical Group would bill the sponsor for the interpretation of the MRI.

Now let’s address the last part of our presentation – “What are the consequences of not billing correctly?"
Why should you be concerned about billing processes for clinical trials?

- Billing appropriately is ethical.

- It is bad public relations for Yale and researchers for inappropriate billing to take place.

- It could negatively impact our credibility as a premier research institution.
In addition, clinical trial billing is under more scrutiny

- The Fraud Enforcement and Recovery Act of 2009 (FERA) gave federal government agencies more power and money to detect those who misuse federal grant monies and money obtained through federal programs such as Medicare and Medicaid.

- The 2010 Patient Protection and Affordable Care Act (PPACA) dedicated approximately $1.5 billion for fighting health care fraud.

- In 2011, U.S. Department of Health and Human Services (HHS) recovered over 4 billion dollars as a result of efforts to prevent fraud, waste and abuse.
There are several tools in the government’s arsenal of fraud fighting remedies for those who present false claims. The first is the False Claims Act which:

- Makes it illegal to submit false or fraudulent claims for payment to Medicare, Medicaid, NIH and other agencies run by our government.

- May be applicable if the Investigator received payment from the patient’s insurer and the sponsor for the same service.

- May be invoked if a consent form indicates study visits will be provided free of charge, but the study visit is billed to the insurer.

- May be invoked if a principal investigator misrepresents that their trial met the necessary qualifying criteria in order to gain Medicare coverage of routine costs.
In order to avoid violating the False Claims Act:

- Identify the services in the Clinical Trial budget that will be covered by the sponsor and the services that will be considered part of routine care.

- The clinical trial budget, HIC application form, and informed consent form must be consistent in terms of who is responsible for the costs of services and items.

- The investigator should consult with their department’s clinical practice specialist (CPS) to ensure invoices capture information needed to identify the patient as participating in a clinical trial.

- Clinical research record keeping and billing practices should be clear and known to the research and billing team up front.
The second is the Anti-Kickback Statute:

The federal anti-kickback statute prohibits any provider from knowingly and willfully paying remuneration to any person to induce that person to purchase, prescribe, recommend or refer a person for the furnishing of items and services payable under a federal healthcare program.
Under the Anti-Kickback Statute:

- Investigators may be prosecuted for waiving research subjects co-payments or deductibles.

- Waiving co-pays may carry the appearance of a financial inducement to utilize healthcare services.

**Note:** The co-pay can be waived if the waiver is “unadvertised” and based on an individualized determination of financial need or exhaustion of reasonable collection efforts.
The consequences of having improper financial transactions can also hit you in the “old pocketbook”.

Here are some examples of institutions and fines that have been paid.
Consequences of Inappropriate Clinical Trial Billing

- **Spectranetics**: $5 million settlement over Medicare false claims
- **New York University Medical Center**: $15.5 million for inflated research grants cost.
- **University of Alabama**: $3.4 million for double billing
- **Palm Beach Imaging**: $7 million for anti-kickback violations
- **Scripps Memorial Hospital**: $29 million for violation of the False Claims Act
- **Rush University Medical Center**: $1 million to settle allegations of overbilling with oncology trials

(Source: AAPC Coding Edge October 2011 and FDA News Billing Medicare for Clinical Trials Costs: Avoiding Noncompliance and Budgeting Accurately 2010)
Fines and Exclusions

- The Office of Inspector General (OIG), Department of Justice and FDA may fine or disqualify a research center, investigator and staff if they repeatedly or deliberately fail to comply with applicable regulatory requirements.

- We also could face exclusion from participation in federal health care programs.
The Compliance Department at the Yale Medical Group (YMG) screens all Yale employees against the OIG’s excluded persons list.

Part of Yale’s agreement to accept Medicare, Medicaid payments and NIH funds is to not employ persons who are on the “excluded list”.
That concludes our presentation of Research Billing training. Questions regarding the content can be directed to the YMG Compliance Department at 785-3868.

To receive credit for this module, please click on the link below or click slide to print paper attestation.

http://ycci.yale.edu/comply/ctc/attestation.aspx