



HCCA's 12TH ANNUAL COMPLIANCE INSTITUTE

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“Complying with the CMS Clinical Trial Billing Rules”

Presented by

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Introduction



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Introduction – Background

- In response to a June 7, 2000 Executive Memorandum, issued by President Clinton, requiring Medicare to pay for routine care costs in clinical trials, the Health Care Financing Administration (HCFA)* implemented a Clinical Trial NCD on September 9, 2000.
- On July 10, 2006, CMS began the first reconsideration of the Clinical Trial Policy NCD.
- On December 13, 2006, CMS organized a Medicare Coverage Advisory Committee (MCAC)** public meeting at their head office in Baltimore, Maryland to re-evaluate the current Clinical Trial Policy.
- On April 10, 2007, CMS released their proposed revisions to the Clinical Trial Policy NCD with a 30-day public comment period.
- On July 9, 2007, CMS released their final decision memorandum on the Clinical Trial Policy NCD.

*Now Centers of Medicare and Medicaid Services (CMS)

**Now Medicare Evidence Development & Coverage Advisory Committee (MedCAC)



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Introduction – Background (cont'd)

- Within the July 9th decision memo, CMS indicated opening of a second reconsideration process for the clinical trial NCD to provide the public with additional opportunity to respond to the proposed changes.
- Ten days after the release of the decision memo, on July 19, 2007, CMS released their proposed decision memorandum for second reconsideration of the clinical trial policy with a 30-day public comment period.
- To facilitate discussions among the public, the stakeholders and the CMS on the proposed CRP NCD, CMS held a special open door forum (ODF) on August 7, 2007.
- The final decision memo for the second reconsideration process was issued on October 17, 2007.



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2007 Final Clinical Trial Policy (CTP) National Coverage Determination (NCD)



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Clinical Trial Policy NCD July 9, 2007 Coverage for Clinical Trials

The coverage remains the same.

- “Effective for items and services furnished on or after July 9, 2007, Medicare covers the **routine costs** of **qualifying clinical trials**, as such costs are defined below, as well as **reasonable and necessary** items and services used **to diagnose and treat complications** arising from participation in **all clinical trials**. **All other Medicare rules apply.**”



Source: CMS National Coverage Determination on Clinical Trials, 2007

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Clinical Trial Policy NCD July 9, 2007

Coverage – Key Tests

- **What are the Key Tests to Determine if the Costs of a Trial are Coverable?**
 - Is it a qualifying clinical trial?
 - Are the items and services routine costs?
 - Are the routine costs reasonable and necessary? (i.e., does Medicare generally cover the services outside a clinical trial?)



Source: CMS National Coverage Determination on Clinical Trials, 2007

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Clinical Trial Policy NCD July 9, 2007

Coverage – Is the trial a qualifying clinical trial (QCT)?

- Any clinical trial receiving Medicare coverage of routine costs must meet the following four requirements:
 1. The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
 1. The trial must have therapeutic intent. It cannot be designed to test toxicity or disease pathophysiology, exclusively. (Note: we discuss this in a greater detail later in the presentation...)
 2. Trials of therapeutic interventions must enroll patients with diagnosed disease. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.
 3. The clinical trial must be "deemed".

Source: CMS National Coverage Determination on Clinical Trials, 2007



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Clinical Trial Policy NCD July 9, 2007

Coverage – Is the trial a qualifying clinical trial (QCT)? (Cont'd)

- A trial is “deemed” to automatically meet the seven desirable characteristics if it is:
 - funded by NIH, CDC, AHRQ, CMS, DOD, or the VA;
 - supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD or the VA;
 - conducted under an investigational new drug application (IND) reviewed by the FDA; or
 - a drug trial that is exempt from having an IND under 21 CFR 312.2(b)(1).



Source: CMS National Coverage Determination on Clinical Trials, 2007

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Clinical Trial Policy NCD July 9, 2007

Coverage – Is the trial a qualifying clinical trial (QCT)? (Cont'd)

- The four types of deemed trials are “deemed” to have the following seven desirable characteristics (self-certification was not adopted):
 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.

Source: CMS National Coverage Determination on Clinical Trials, 2007



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Clinical Trial Policy NCD July 9, 2007

Coverage – Is the trial a qualifying clinical trial (QCT)? (Cont'd)

- Alternative: CMS will cover the routine costs of clinical trials that are subject to the CED process:
 - The CED process can add additional requirements.
 - A special NCD will be issued for CED trials.

Source: CMS National Coverage Determination on Clinical Trials, 2007



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Clinical Trial Policy NCD July 9, 2007

Coverage – Are the items and services routine costs?

- Routine costs in clinical trials include items and services:
 - For which there exists a benefit category;
 - That are coverable by Medicare outside of a clinical trial;
 - That are typically provided absent a clinical trial (e.g., conventional care);
 - Required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
 - Needed for reasonable and necessary care arising from the provision of an investigational item or service--in particular, for the diagnosis or treatment of complications.

Source: CMS National Coverage Determination on Clinical Trials, 2007



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Clinical Trial Policy NCD July 9, 2007

Coverage – Are the items and services routine costs? (Cont'd)

- Routine costs in clinical trials exclude items and services:
 - That are investigational, *unless otherwise covered outside of the clinical trial*;
 - That are statutorily excluded;
 - For which there is a national non-coverage decision;
 - Provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
 - Provided by the research sponsors free of charge for any enrollee in the trial.
- As mentioned earlier, the italicized text is the new language added to the July 9, 2007 CTP.

Source: CMS National Coverage Determination on Clinical Trials, 2007



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Clinical Trial Policy NCD July 9, 2007

Coverage – Are the items and services routine costs? (Cont'd)

- Additional items of note:
 - **Complications:** Medicare will cover treatment of complications (even in a non-qualifying clinical trial) as long as the treatment of items and services are generally covered by Medicare.
 - **Non-covered items and services:** if an item or service is not covered by virtue of a national non-coverage policy and is the focus of a qualifying clinical trial, the routine costs of the clinical trial (as defined above) will be covered by Medicare but the non-covered item or service, itself, will not.

Source: CMS National Coverage Determination on Clinical Trials, 2007



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Clinical Trial Policy NCD July 9, 2007

Coverage – Are the routine costs reasonable and necessary?

- How to determine what is reasonable and necessary?
 - Whether an item or service is reasonable and necessary is the basis of most NCDs and LCDs.
 - NCDs and LCDs determine whether an item or service is reasonable and necessary.
 - If there is not an NCD or LCD addressing the item or service and the item or service is not statutorily excluded, then determining whether an item or service is reasonable and necessary is a question of clinical judgment and the physician should document in the medical record that the item or service is medically necessary



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Clinical Trial Policy NCD July 9, 2007

Coverage – Medical Devices

- CTP remains vague on the coverage for medical devices.
 - The CTP says the following about devices:

“This policy does not withdraw Medicare coverage for items and services that may be covered according to local medical review policies (LMRPs) or the regulations on category B investigational device exemptions (IDE) found in 42 C.F.R. §405.201-405.215 and §411.15 and §411.406.”
 - IDE devices should continue to follow the device trial regulations

Source: CMS National Coverage Determination on Clinical Trials, 2007



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Q&As by CMS

- On October 17, 2007, in addition to the decision memo, CMS posted seven frequently asked questions and answers.
- Within this document, CMS has encouraged providers to seek clarification from their local Medicare contractors (i.e., Medicare Carriers and Fiscal Intermediaries) for trials that do are meet CTP's qualifying criteria.
- In addition, CMS said that it will revise its policy through formal "rulemaking," which means through a formal regulations process (e.g. Code of Federal Regulations (CFR)) instead of the NCD process.
 - However, no timeline was provided by CMS.

¹Director of Coverage and Analysis Group at CMS



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The CTP's Lingerin Issues:

- Interpretation
- New Transmittals
- Risks



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What is “therapeutic intent”?

- A study that does not have therapeutic intent is not a qualifying clinical trial.
- Whatever “therapeutic intent” is, a study must have it in order to be a qualifying clinical trial.
- There are two discussions of therapeutic intent in the CTP:
 - “The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.”
 - “The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes.”



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What is “therapeutic intent”?

- A host of unanswered questions:
 - Do these two criteria stand on their own?
 - Do they inform each other?
 - Should they be interpreted together and reconciled as like a single criteria?
 - Is there a national interpretation of therapeutic intent or are local Medicare contractors allowed to interpret these criteria?
- These questions are not academic; they have direct impact on drug studies that are Phase I and Phase II that may measure therapeutic benefit as a secondary objective but not a primary objective.
 - Impacts going-forward budgeting for research costs
 - Impacts potential past liability
- Cancer studies have the most at stake since most Phase I drug studies have therapeutic benefit as one of the objectives, but may not be a primary objective.



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Sidenote on the 2007 Attempted Reforms:

Do revised standards that weren't adopted tell us something about the standards that remain?

- **April 2007 Proposed CRP:** "The clinical research study is not designed to exclusively test toxicity or disease pathophysiology. Research studies, including some Phase I trials, whose protocols commit to measuring therapeutic outcomes as one of the objectives, may meet this standard only if the disease being studied is chronic, life threatening, or debilitating."
- **July 2007 Proposed CRP:** "The clinical research 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 meet this standard only if the disease or condition being studied is life-threatening as defined in 21 CFR 312.81(a) and the patient has no other viable treatment options."
- **NOTE:** CMS adopted neither of these revised standards. CMS was clear in several forums that the revised therapeutic intent standard in the hoped-for CRP is not a clarification of the CTP therapeutic intent standard.



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CMS Commentary on Therapeutic Intent

- **June 2006 Conference:** At Forum on Regulation of the Association of Academic Health Centers (AAHC), CMS official states that in order to meet the therapeutic intent standard, the "primary objective" of the research study must be measurement of therapeutic benefit
- **December 2006 MedCAC Hearing:** "...there is in general the assumption that many Phase Ones, if not most Phase Ones, currently aren't covered in the clinical trial policy." Steven Phurrough, MD, Director of CMS Coverage & Analysis Group (CMS Transcript, p. 182)
- **August 2007 Open Door Forum:** [In response to a question on the therapeutic intent standard] "For those trials that are currently under way, they will have to live under whatever confusion they think there is around the current policy, the 2000 and the July 9th policy, and we will not attempt to clarify that any more than it is currently clarified." Dr. Phurrough (CMS Audio recording)



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Local Medicare Contractor Role in Interpreting Therapeutic Intent

- Local Medicare contractors have the authority to determine if an item or service is “reasonable and necessary” to diagnose or treat illness or injury (i.e., covered by Medicare) if the item or service is not excluded by statute or CMS has not issued a non-coverage determination.
- Various local Medicare contractors have applied the “primary objective” test
- In the absence of clarity from CMS, local Medicare medical directors have the authority to interpret and make “reasonable and necessary” determinations
- October 17 CMS FAQ # 4: A provider with “trials that do not meet the existing criteria for deemed trials should contact their local Medicare contractors to determine whether items and services will be covered in that geographic area.”



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Approaches to dealing with therapeutic intent

- Approach 1: Apply the primary objective test and consider a study a QCT only when one of the primary objectives is to measure therapeutic benefit
 - Do not bill Medicare for items and services required by a non-QCT
 - Negotiate sponsor to cover all costs of Phase I non-QCTs
- Approach 2: A provider should ask its local Medicare medical director what test should apply in the region
 - If CMS is not going to issue any more clarifications, then with full disclosure of CMS statements, providers can make argument to medical director that therapeutic intent can be met by any objective
 - After the issuance of the October 2007 CTP, if a provider does not adopt Approach 1, the prudent approach is to consult the provider's local Medicare medical director



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January 18, 2008 Coding Changes

- On January 18, 2008 CMS issued transmittals eliminating the QV, QA and QR modifier – retroactive to January 1, 2008.
- New modifiers:
 - Q0: “investigational clinical service”
 - Q1: “routine clinical service”
- What should providers do?
 - 1. Every study must sort the protocol required services to determine which are the “investigational clinical services” and which are the “routine clinical services”
 - 2. Institute a process to appropriately place modifiers on claims
 - 3. Consult Medicare contractor to determine if the contractor can accept the modifiers yet



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January 18, 2008 Coding Changes

- Definitions from January 18:
 - “Investigational clinical services are defined as those items and services that are being investigated as an objective within the study. Investigational clinical services may include items or services that are approved, unapproved, or otherwise covered (or not covered) under Medicare.”
 - “Routine clinical services are defined as those items and services that are covered for Medicare beneficiaries outside of the clinical research study; are used for the direct patient management within the study; and, do not meet the definition of investigational clinical services. Routine clinical services may include items or services required solely for the provision of the investigational clinical services (e.g., administration of a chemotherapeutic agent); clinically appropriate monitoring, whether or not required by the investigational clinical service (e.g., blood tests to measure tumor markers); and items or services required for the prevention, diagnosis, or treatment of research related adverse events (e.g., blood levels of various parameters to measure kidney function).”



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January 18 Clinical Trial Number Transmittal

- Encourages providers to place clinical trial number on claim – this is voluntary for providers
- Requires Medicare contractors to accommodate receiving clinical trial number
- Requires contractor to “generate one monthly report...to CMS data center” that identifies:
 - use of the clinical trial numbers
 - use of the new modifiers
 - number of clinical trial claims
 - number of patients



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January 18 Transmittals

- Contractor Local Guidance
 - Modifier Transmittal: “Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.”
 - Clinical Trial Number Transmittal: “CMS expects that within 90 days of publication of this instruction, contractors will have instructed providers and suppliers on the proper billing methods to use and encouraged them to voluntarily participate.”



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Managing Research Billing Compliance

- **Clinical research billing compliance involves:**
 - Identifying clinical research services that can or cannot be billed to third-party payors
 - Ensuring processes are in place to bill to third-party payors only services that billing rules allow to be billed
 - Harmonizing relevant portions of study documents in accordance with billing rules



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Managing Research Billing Compliance

Coordination is Key to Compliance

1. The protocol's schedule of events
2. The compensation arrangement in the sponsorship contract or grant (the "budget")
3. The financial disclosure language of the study's informed consent



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Research Billing Compliance Risks

- Ignoring clinical research billing rules can lead to:
 - Billing for services that are already paid by the sponsor (double billing)
 - Billing for services promised free in the informed consent
 - Billing for services that are for research-purposes only
 - Billing for services that are part of a non-qualifying clinical trial



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Operational Considerations for Research Billing Compliance

- What types of research studies are performed at or by your organization?
- Is the hospital informed that services are being ordered for research patients?
- If the hospital is not a party to the research contract with the sponsor, is there a contract between the hospital and the physician? (to invoice physician group for research services)



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Take Away Points -- Tasks

- **Develop a database of all research studies performed at or by your organization**
- **Develop a database of patients who are enrolled in the research studies**
- **Require coverage analyses before research study is agreed to in order to determine whether the study is financially viable**
- **Require coverage analyses that reflect the billing posture for items and services before billing for services is done**
- **Establish safeguards to ensure that claims are appropriately either directed to an internal research account or to third-party payor**
- **Develop an education program for investigators and study coordinators**
- **Develop an auditing and monitoring program that samples billing for services during research studies**



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Practical Tips for Developing and Implementing a **Compliant Clinical Research Billing Process**



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What We've Learned...

Decision Points for Charge Segregation

Based on our experience working with other academic health centers and hospitals, we believe there are a limited number of places in the continuum to segregate research charges from standard of care charges



- Dual registration (e.g. SOC registration and R registration)
- One registration, two insurance provider codes
- Flag research patient in registration system



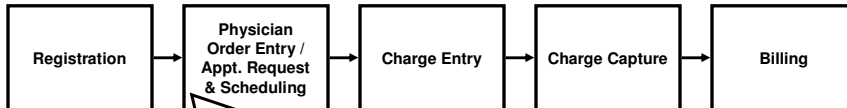
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What We've Learned...

Decision Points for Charge Segregation

Based on our experience working with other academic health centers and hospitals, we believe there are a limited number of places in the continuum to segregate research charges from standard of care charges



POE / Appointment Request

- Identify and segregate SOC versus R via:
 - Different color paper / online forms
 - Pre-populate paper / online form with items and services of each study
 - Research check boxes on the paper / online forms
 - Integrate with a clinical research management system

Scheduling

- Research flag utilized for R procedures in scheduling system
- Separately schedule research and SOC

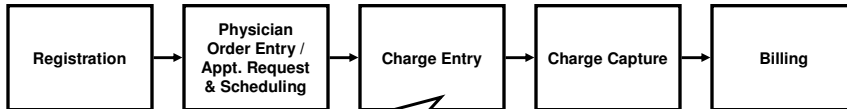


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What We've Learned...

Decision Points for Charge Segregation

Based on our experience working with other academic health centers and hospitals, we believe there are a limited number of places in the continuum to segregate research charges from standard of care charges



- Flag SOC or R when coding encounter forms
- Modify Charge Description Master (CDM) to include research specific codes



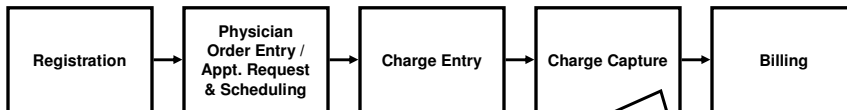
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What We've Learned...

Decision Points for Charge Segregation

Based on our experience working with other academic health centers and hospitals, we believe there are a limited number of places in the continuum to segregate research charges from standard of care charges



- Review POE / appointment request against study grid
- Automate processes above via clinical research management system interface



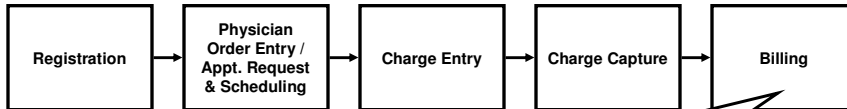
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What We've Learned...

Decision Points for Charge Segregation

Based on our experience working with other academic health centers and hospitals, we believe there are a limited number of places in the continuum to segregate research charges from standard of care charges



- Manual back-end bill hold
- IT Systems modified to accommodate above suggestions



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What We've Learned...

Models for Addressing Clinical Research Billing Compliance

- Given the logical points for segregating charges in the process, several models have emerged
 1. Patient-level research flag
 2. Visit-level research flag
 3. Edit checks via patient registry / CRMS
 4. Dual registration



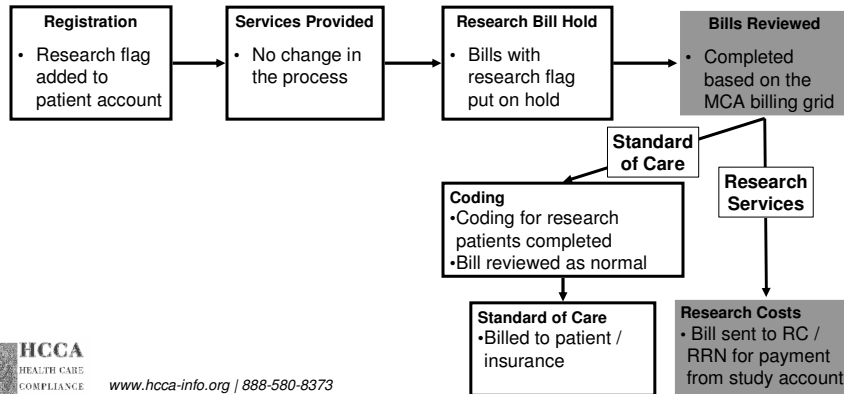
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Models to Address Clinical Research Billing Compliance

Model One: Patient-Level Research Flag

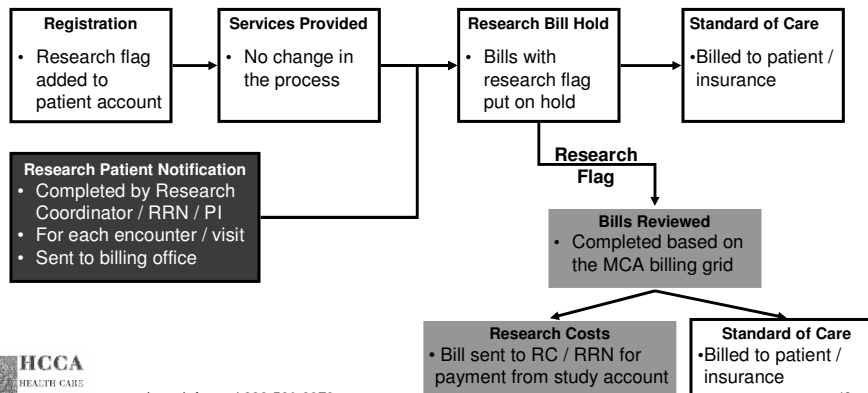
- Research study participants identified in the registration system via a patient-level research flag.
- Bills for these patients are forced into a separate bill hold queue until the bills have been reviewed



Models to Address Clinical Research Billing Compliance

Model Two: Visit-Level Research Flag

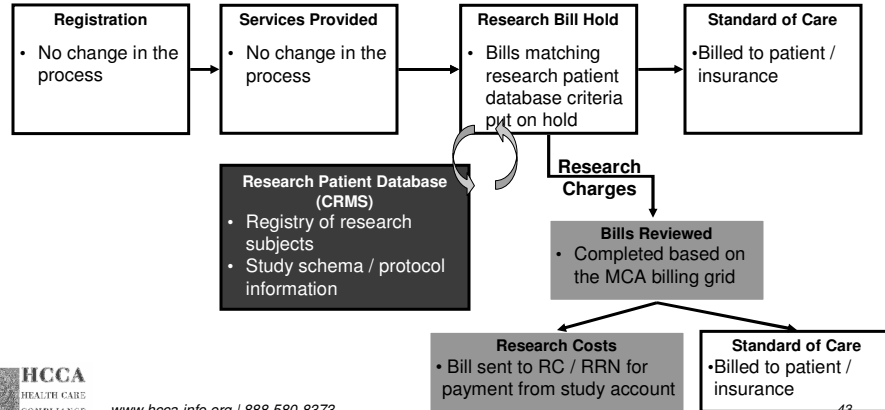
- Notification of research study VISITS sent to billing office
- Bills for these VISITS are forced into a separate bill hold queue until the bills have been reviewed



Models to Address Clinical Research Billing Compliance

Model Three: Edit Checks via Research Patient Database

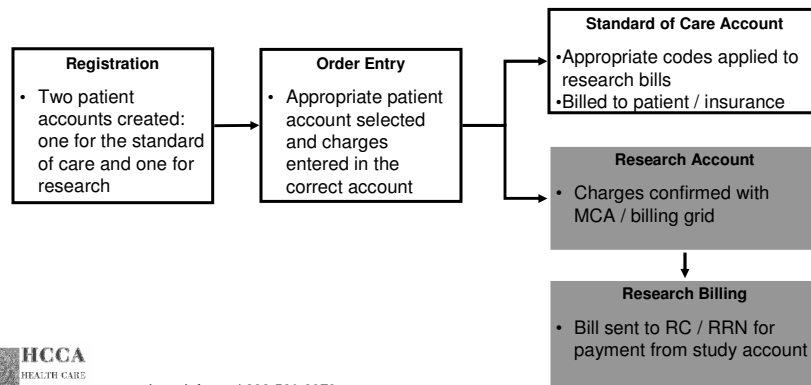
- CRMS or patient database interfaces with billing systems to identify and tag potential research visits
- Bills for tagged are forced into a separate bill hold queue until the bills have been reviewed



Models to Address Clinical Research Billing Compliance

Model Four: Dual Registration

- Two separate registrations created; one for research charges / one for standard of care charges
- Bills for these patients are forced into a separate bill hold queue until the bills have been reviewed



How to Conduct a Medicare Coverage Analysis (MCA)



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How to Conduct a Medicare Coverage Analysis

Overview

- Gather all of the relevant documents
- Determine if the trial is investigating a device, a drug, or a service
- Apply the appropriate criteria for coverage of the trial (for drugs and services reference the NCD on Clinical Trials).
- Determine which items are paid for by the study sponsor in the contract and which items are promised free of charge to the participant in the informed consent form.
- Determine which of the remaining items are “routine care” and their billable status.
- Document the results of the analysis.



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How to Conduct a Medicare Coverage Analysis

Necessary Documents

- Research Protocol
- Protocol Specific Informed Consent Form
- Clinical Trial Agreement/Contract (or Notice of Grant Award)
- FDA IND or Device letters
- Carrier and/or Fiscal Intermediary Letter documenting approval for billing of the device and/or protocol related services.



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How to Conduct a Medicare Coverage Analysis

Overview-Research Protocol

- When conducting an MCA, the sections of the protocol that are most relevant are:
 - Study procedures (i.e. study design, methodology, research plan, etc.)
 - Schedule of events (i.e. activity flow chart, calendar, etc.)
 - Participant population (i.e. inclusion criteria, participant selection, etc.)
- The protocol cover page usually contains basic information:
 - Study title, study sponsor, the lead principal investigator locally or nationally, and other key items.
 - It may list the IND number, version and the Institutional Review Board (IRB) approval date.



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How to Conduct a Medicare Coverage Analysis

Overview- Informed Consent Form

- ICFs contain financial language useful for conducting MCAs:
 - The costs section of the ICF (usually) describes what items and services will be charged to participant and/or his/her insurer (standard of care), and what items are promised at no cost to the participant.
 - It is a violation of CMS NCD 310.1 to charge the participant or his/her insurer for items and services promised free of charge.
- Additional Evidence of Therapeutic Intent
 - The benefits section of this document should provide insight into the therapeutic intent of the trial. If this section says there is no potential benefit to participants in the trial, it is likely that evidence of therapeutic intent cannot be found.



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How to Conduct a Medicare Coverage Analysis

Overview- Clinical Trial Agreement

- A Clinical Trial Agreement (CTA) is a contract between the Study Sponsor and the Institution for the conduct of the research.
- CTAs list the types of support provided by the sponsor:
 - Items and services that will be paid by the Sponsor
 - Items and services that will be provided by the Sponsor
 - Payment schedule
 - Indemnity
 - Payment for subject injury



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How to Conduct a Medicare Coverage Analysis

Overview- Device Studies

- Medicare may reimburse for some devices and associated items and services used in research:
 - Post-marketing approved (PMA) devices
 - 510-K approved devices
 - Hospital IRB approved devices
 - IDE Category B devices
 - IDE Category A devices used in a life-threatening situation
- Medicare Contractors must approve billing for devices and associated items and services used in research **prior to the initiation of the study.**



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How to Conduct a Medicare Coverage Analysis

Step-by-Step

- Provide the relevant study information (Identify the study):
 - Study Title and Version
 - IRB Number (and IRB approval if applicable)
 - PI
 - IND or IDE number
- **Qualifying Clinical Trials Analysis:**
 - Review the study protocol and determine whether the trial qualifies under CMS NCD 310.1:
 1. Does the investigational item or service fall into a Medicare Benefit Category?
 2. Does the study have therapeutic intent? (study purpose and objectives)
 3. Are the participants diagnosed with a disease or condition? (inclusion/exclusion)
 4. Is the study deemed? (Operating under an IND, IND Exempt, or sponsored by a recognized federal agency)

All four answers must be YES.



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How to Conduct a Medicare Coverage Analysis

Memo Example

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Issues Summary

Protocol Related Item : XXXX

Aspects of the document provided heretofore to be reviewed for this a Qualifying Clinical Trial and you're can't see an issue is the date of the document in the attached being use.

Investigational Consent Form Related Item : XXXX

Contract Related Item : XXXX

Budget Related Item : XXXX

Study Identifying Information

Name of Study/Protocol Name: XXXX

Phase of Study: XXXX

CFR Number: XXXX

IRB Number: XXXX

Grant Number: XXXX

Budget Number: XXXX

Department: XXXX

Principal Investigator (PI): XXXX

Sponsor: XXXX

Study of Study: Open to Actual / Closed to Actual / Threshold

Contract ID#: XXXX

Investigational Consent Form: IRB Approval DATE

Study Documents #XXXX#: XXXX

Documents Received for Coverage Analysis Review

- Study Protocol
- XXXX
- Clinical Trial Agreement / Notice of Origin Form

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- Investigational Consent Form
- XXXX
- Consentation Letter / IRB
- XXXX

Qualifying Clinical Trial Analysis

Does the Clinical Trial meet the necessary Prerequisites?

Requirement	Yes	No	Comment
Does the trial involve the use of a service within a Medicare benefit category?	X		The trial involves products, a number of them are covered by Medicare, but not all of them are.
Does the study have a primary objective for primary efficacy?	X		The primary objective of this study is ...
Does the study meet criteria for Investigational Services?	X		This protocol meets criteria for ...
Is the study covered by IRB?	X		
Is the study a qualifying clinical trial?	X		

Investigational Item or Service Analysis

Investigational Item or Service	Is it covered?
XXXX: XXXX	
XXXX: XXXX	
XXXX: XXXX	



How to Conduct a Medicare Coverage Analysis

Step-by-Step

- Locate all items and services that occur as part of the research
 - Review the protocol schedule of events section
 - Review the protocol methodology or procedures section
 - Cross reference the ICF methodology or procedures section
- List all items and services on the billing grid:
 - Name of item/service (or procedure)
 - Visit date when items/service is to occur
- Items and Services Analysis:
 - Review the Protocol, CTA, and ICF to determine which items are provided by the sponsor or promised free of charge
 - For all other items, determine whether they are considered routine or standard of care:
 - Use objective, nationally recognized treatment guidelines
 - Use attestation provided by Principal Investigator or Department Head
 - For routine care items, review Medicare billing rules for reimbursement
 - The Medicare Benefits Policy and Claims Processing Manuals
 - National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs)



Practical Scenario 2

- Phase I study of non-FDA approved drug to treat schizophrenia.

Alternative:

- Phase II study of off-label use of FDA-approved drug for treating schizophrenia. The drug is not approved use in treating schizophrenia.



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Practical Scenario 3

- Community hospital as site for research that is being conducted by a private physician group.
 - Who signs the contract?
 - Who takes the funding?
 - How does the hospital know who is a research patient?
 - Does the hospital invoice the practice group?



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