



# *HCCA's 12<sup>TH</sup> ANNUAL* COMPLIANCE INSTITUTE

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## **HCCA: “Complying with the CMS Clinical Trial Billing Rules”**

Presented by

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# Introduction – Background

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- 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)

ASSOCIATION

# Introduction – Background (cont'd)

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- Within the July 9<sup>th</sup> 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.

# Clinical Trial Policy NCD July 9, 2007

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## 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  
[www.hcca-inc.org/06-080-0073](http://www.hcca-inc.org/06-080-0073)

## 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?

## Clinical Trial Policy NCD July 9, 2007

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### 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).



Source: CMS National Coverage Determination on Clinical Trials, 2007  
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## Clinical Trial Policy NCD July 9, 2007

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### 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



Source: CMS National Coverage Determination on Clinical Trials, 2007

## Clinical Trial Policy NCD July 9, 2007

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### 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



Source: CMS National Coverage Determination on Clinical Trials, 2007

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**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

# 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.a..

## 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

## Clinical Trial Policy NCD July 9, 2007

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### 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

Source: CMS National Coverage Determination on Clinical Trials, 2007  
www.cms.gov

## 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



# Clinical Trial Policy NCD July 9, 2007

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## 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



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



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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:



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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

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.”



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• **July 2007 Proposed CRP:** “The clinical

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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



# Local Medicare Contractor Role in Interpreting Therapeutic Intent

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- 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



## ~~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

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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?



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1. Every study must sort the protocol required

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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

## January 18 Clinical Trial Number Transmittal

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- 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



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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



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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

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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")



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3. The financial disclosure language of the

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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

## Operational Considerations for Research Billing Compliance

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- 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



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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**





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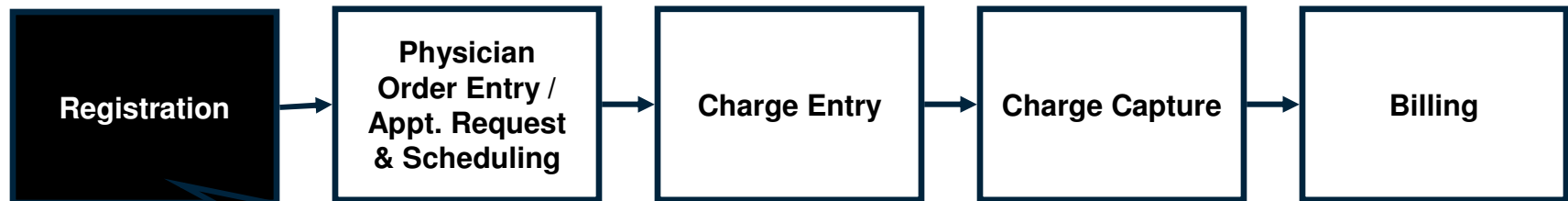
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# What We've Learned...

## 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**

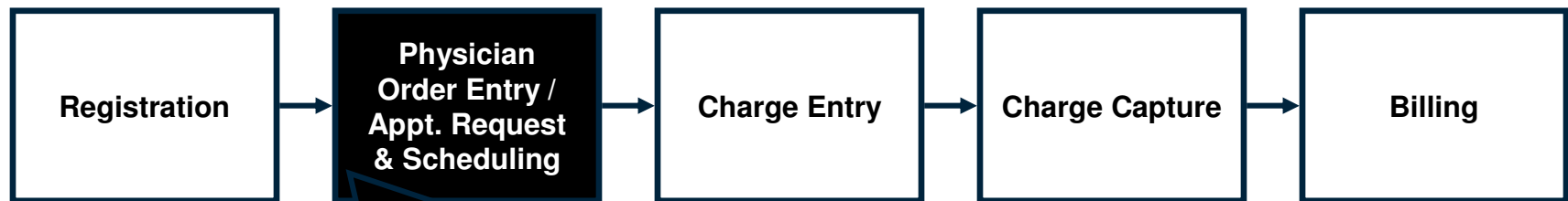


- Dual registration (e.g. SOC registration and R registration)
- One registration, two insurance provider codes
- Flag research patient in registration system

# 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

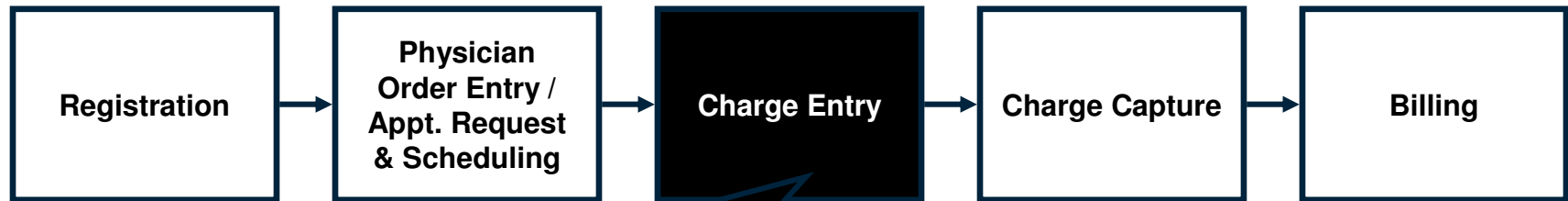
### **Scheduling**

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

# 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**

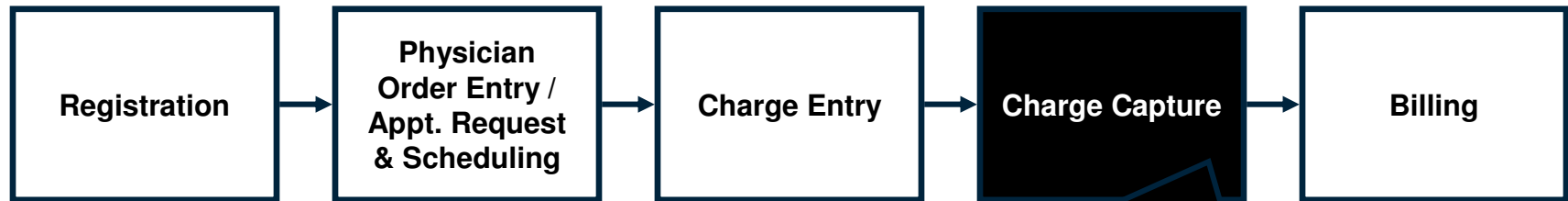


- **Flag SOC or R when coding encounter forms**
- **Modify Charge Description Master (CDM) to include research specific codes**

# 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**

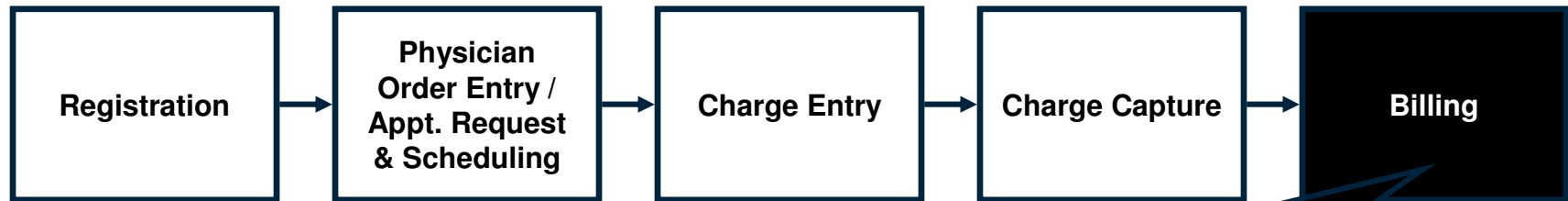


- **Review POE / appointment request against study grid**
- **Automate processes above via clinical research management system interface**

# 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**

## What We've Learned...

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### 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



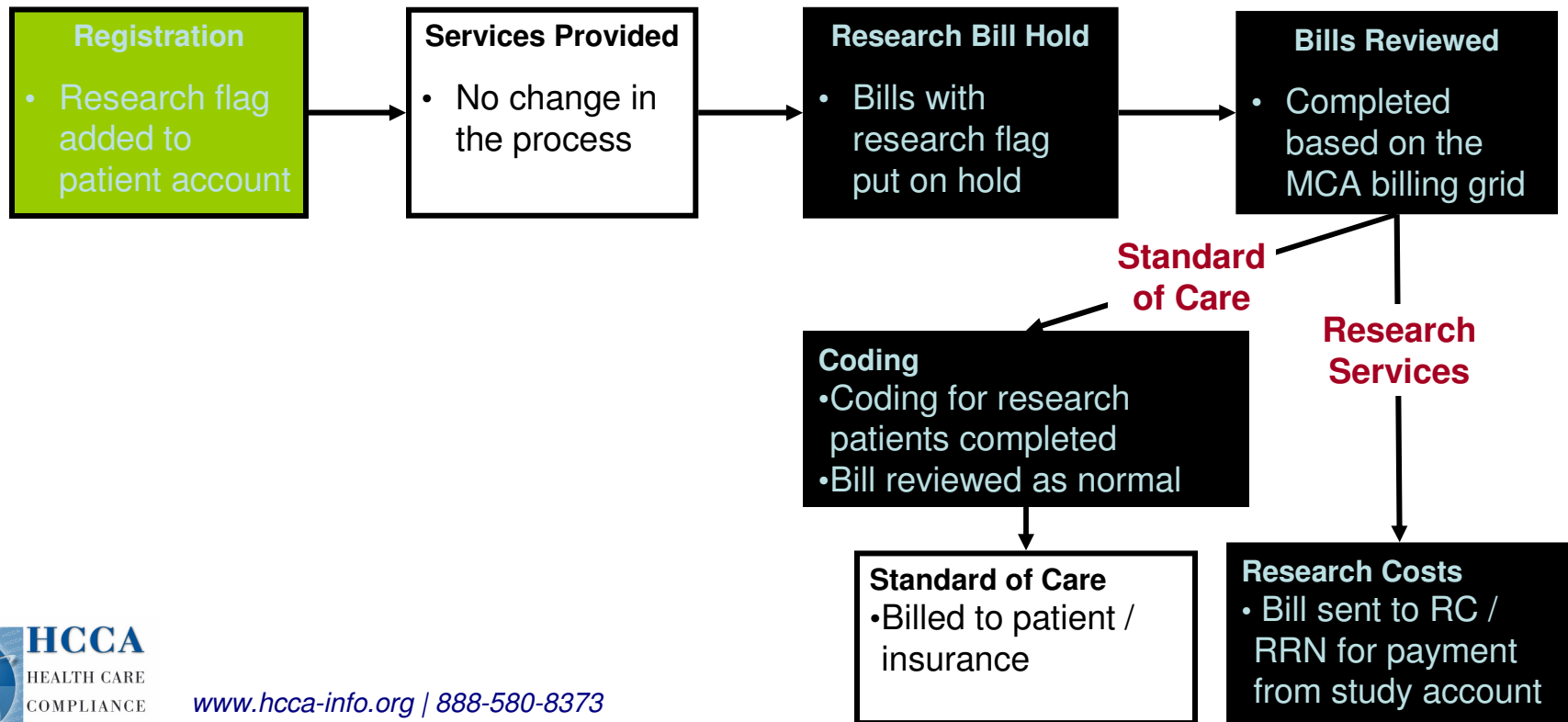
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Dual registration

# Models to Address Clinical Research Billing Compliance

## Model One: Patient-Level Research Flag

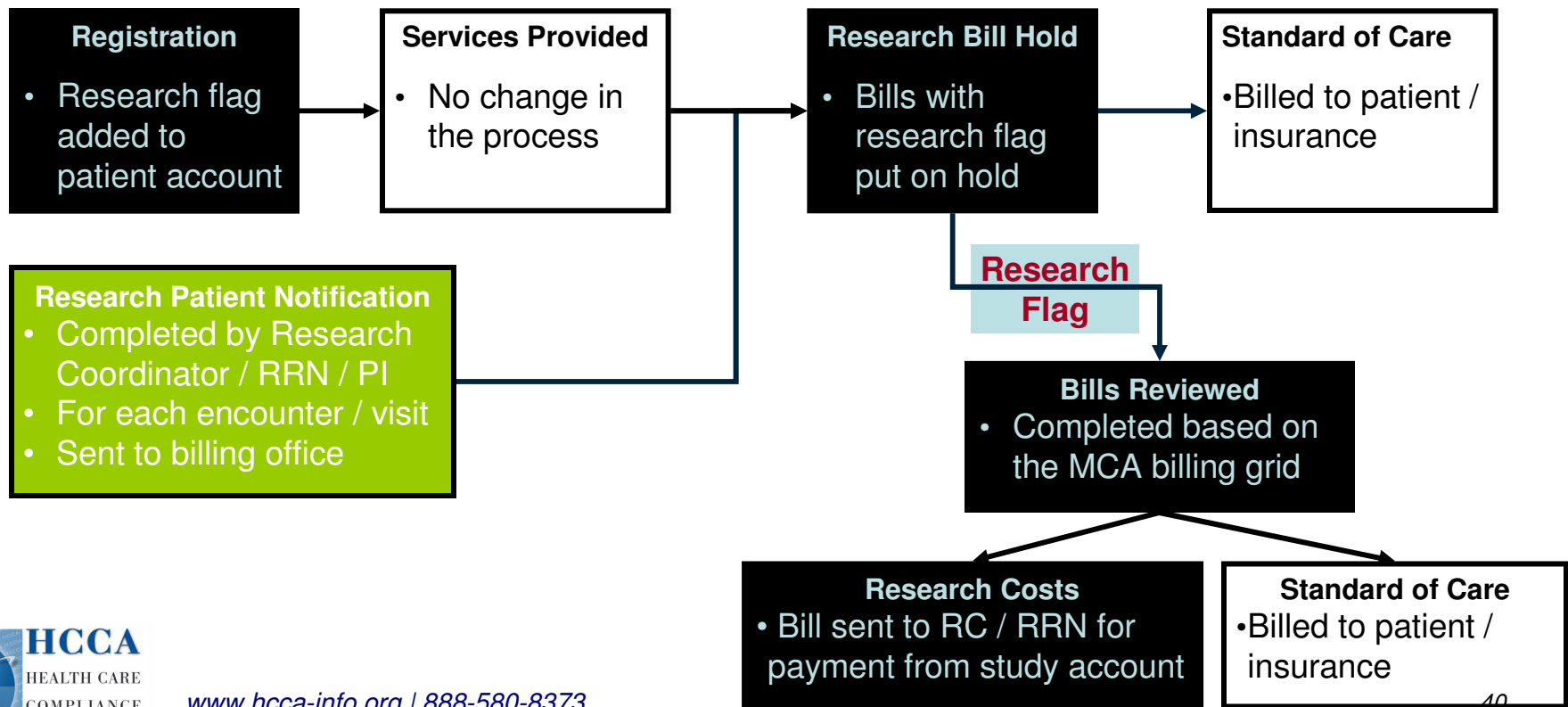
- Research study participants identified in the registration system via a patient-level research flag.
- Bills for these patients are forced into a separate bill hold queue until the bills have been reviewed



# Models to Address Clinical Research Billing Compliance

## Model Two: Visit-Level Research Flag

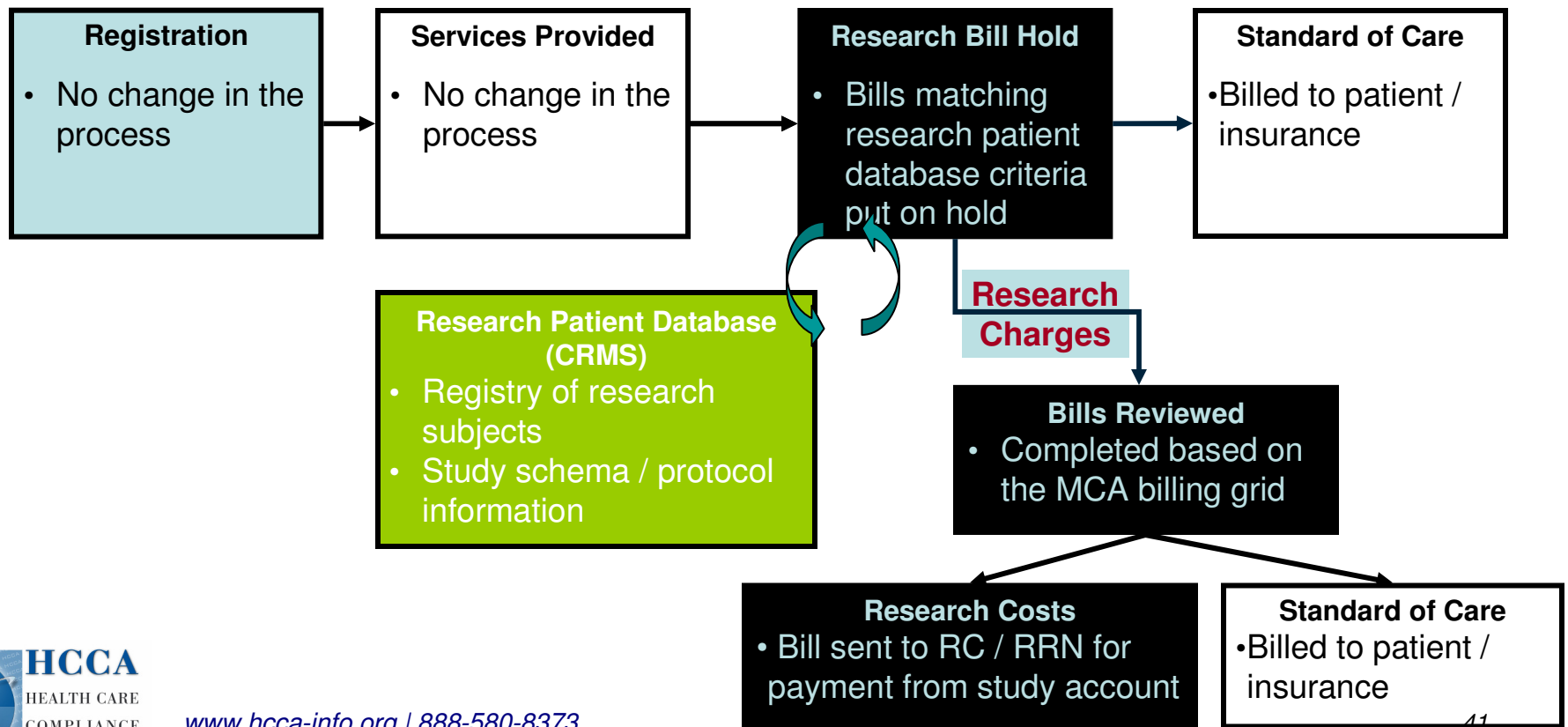
- Notification of research study VISITS sent to billing office
- Bills for these VISITS are forced into a separate bill hold queue until the bills have been reviewed



# Models to Address Clinical Research Billing Compliance

## Model Three: Edit Checks via Research Patient Database

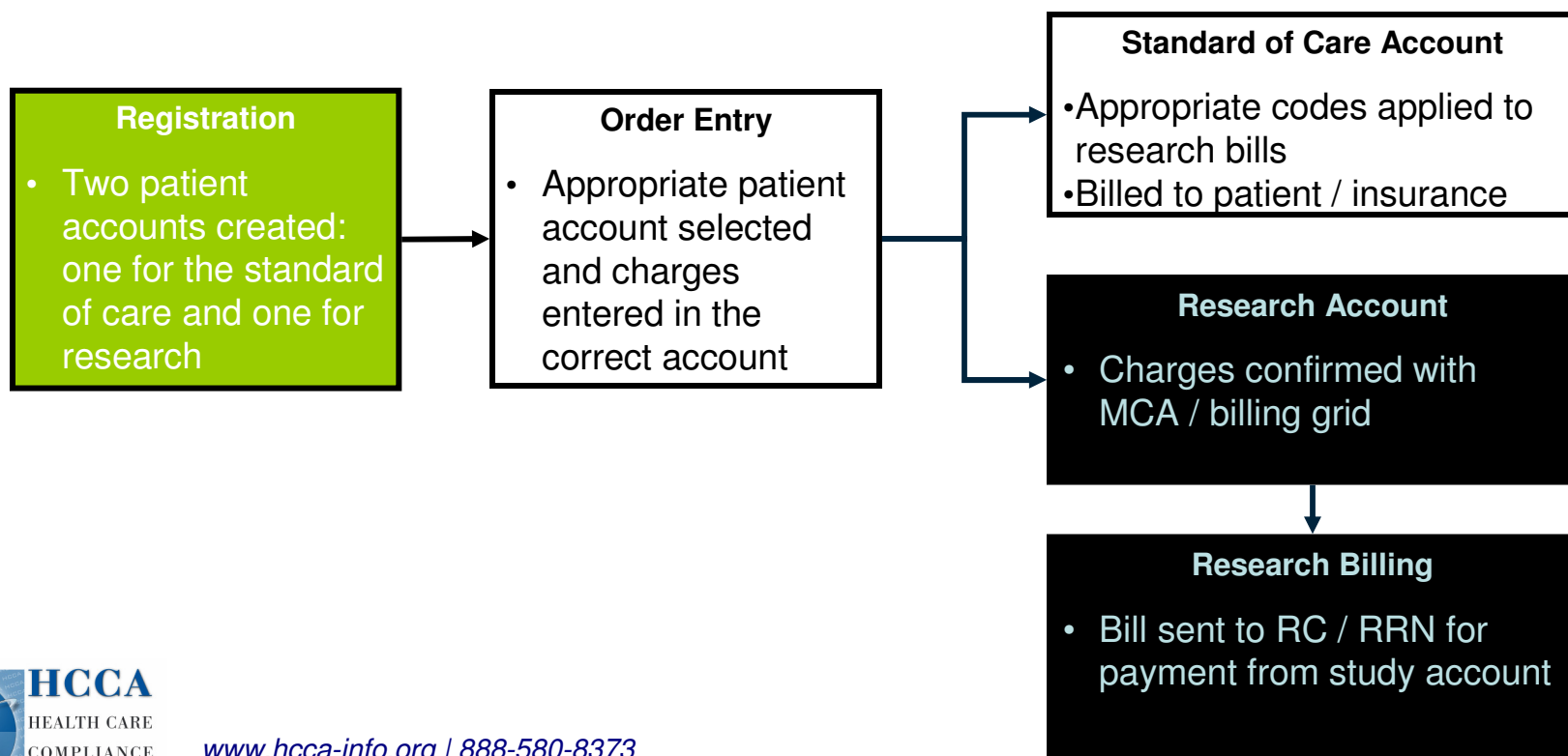
- **CRMS or patient database interfaces with billing systems to identify and tag potential research visits**
- **Bills for tagged are forced into a separate bill hold queue until the bills have been reviewed**



# 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**





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# How to Conduct a Medicare Coverage Analysis

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## 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.



# How to Conduct a Medicare Coverage Analysis

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## 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.

# How to Conduct a Medicare Coverage Analysis

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## 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

# How to Conduct a Medicare Coverage Analysis

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## 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

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# How to Conduct a Medicare Coverage Analysis

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## 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  
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# How to Conduct a Medicare Coverage Analysis

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## 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



# How to Conduct a Medicare Coverage Analysis

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## 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?

# How to Conduct a Medicare Coverage Analysis Memo Example



Privileged and Confidential

### Issues Summary

**Protocol Related Items**  
A review of the documents provided has led to the determination that this is a "Qualifying Clinical Trial" and "routine care" items are billable to Medicare as described in the attached Billing grid.

**Informed Consent Form Related Items**  
XXXX

**Contract Related Items**  
XXXX


**Budget Related Items**  
XXXX

### Study Identifying Information

Name of Study (Protocol Name): XXXX  
 Phase of Study: XXXX  
 CRD Number: XXXX  
 IRB Number: XXXX  
 Grant Number: XXXX  
 Budget Number: XXXX  
 Department: XXXX  
 Principal Investigator (PI): XXXX  
 Sponsor: XXXX  
 Status of Study: Open to Accrual / Closed to Accrual / Terminated  
 Contract Status: XXXX  
 Informed Consent Status: IRB Approved DATE  
 Study Documents (IND/IDE): XXXX

### Documents Received for Coverage Analysis Review

- Study Protocol
  - XXXX
- Clinical Trial Agreement / Notice of Grant Award



Privileged and Confidential

- XXXX
- Informed Consent Document
  - XXXX
- Communications Letters / Emails
  - XXXX

### Qualifying Clinical Trial Analysis

Does the Clinical Trial meet the necessary Requirement?

Requirement	Yes	No	Comment
Does the Investigational Item or service fall into a Medicare benefit category?	X		The Investigational product is a member of Medicare benefit category "drugs, biologics, and therapeutics."
Does the study have therapeutic intent in the primary objective?	X		The therapeutic intent of this trial is to ...
Does the study enroll patients with diagnosed disease?	X		This protocol enrolls patients that ...
Is the study deemed IRB?	X		
Is the study a qualifying clinical trial?	X		

### Investigational Item or Service Analysis

Analysis Questions	Answer
What is the Investigational Item or service?	
What is the FDA's status of the Investigational Item or service?	The IND number is ...
Does a CMS Benefit Policy, NCD, or LCD allow coverage of the Investigational Item or service?	Yes/No, however the sponsor is providing the drug free of charge

# How to Conduct a Medicare Coverage Analysis

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## 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

# How to Conduct a Medicare Coverage Analysis

## Billing Grid Example

Privileged and Confidential: Attorney Work Product and Attorney-Client Communication		Protocol Number							Protocol Title	
		Cycle 1							Cycle 2	Cycle 3
Items and Services	Pre-Treatment	Day 1	Day 8	Day 15	Day 21	Day 1	Day 1			



## Practical Scenario 1

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- Phase III study of off-label use of XYZ drug to treat breast cancer patients. XYZ drug is commercially approved to treat uterine cancer.
- What are the important points to focus on for billing compliance?

## Practical Scenario 2

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- 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.

## Practical Scenario 3

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- 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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