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How Informed Consent Documents Can Affect Research Billing

University of California

Clinical Research Billing Education Series

September-October 2010

Session 4

9-21-2010

9-23-2010

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Structure of CRB Webinars

- Session 1: Opportunities & Challenges
- Session 2: CRB: A Team Effort
- Session 3: Clinical Trial Agreements
- **Session 4: Informed Consents**
- Session 5: Study Budgets & CRB Billing Rules
- Session 6: Medicare Advantage & CRB
- Session 7: Specific Issues in Billing & Coding

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Objectives

- Review basic regulations on what the informed consent form (ICF) must discuss about the financial dimension of the research study
- Discuss how the informed consent form fits into the information flow in a clinical research billing process
- Examine how language in the informed consent form could be misinterpreted to prevent billing during research studies
- Identify important sections of the informed consent form that could impact the clinical research billing process

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First things first: What is informed consent?

- Informed consent means that a legally competent prospective research participant volunteers to participate in a study after receiving information sufficient to make an informed decision, including information about the purpose of the study, risks, potential benefits, and alternatives
- Informed consent depends heavily on:
  - Full disclosure of facts
  - Legal/mental ability (capacity) to make decision
- In research, the informed consent is documented in writing and is specific to the research study
  - Note: There are limited occasions when informed consent can be obtained orally, but for purposes of this session, we will assume a clinical research study requiring written consent

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Research Informed Consent: Context

- U.S. HHS Office of Human Research Protection (OHRP) Informed Consent FAQ # 1:
  - "The informed consent process involves three key features:

    (1) disclosing to potential research subjects information needed to make an informed decision;

    (2) facilitating the understanding of what has been disclosed; and

    (3) promoting the voluntariness of the decision about whether or not to participate in the research."

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Research Informed Consent: Context

- OHRP & FDA Rules:
  - 45 CFR 46.116 & 21 CFR 50.20: "The information that is given to the subject or the representative shall be in language understandable to the subject or the representative."
  - Standard Practice: Language in 6th to 8th grade reading level
  - Government reviews and audits of ICF:
    - Interpreted from the perspective of the subject
    - The ICF means what it says: assumes plain meaning of the terms

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Why is the ICF important for the CRB process?

- CMS's view is that whatever is promised free in the ICF may not be billed to the patient or the patient's insurer
- If the ICF promises services free to subjects, the organization must live up to the promise
- The ICF is usually drafted concurrently with negotiating the budget and CTA – if ICF drafting is not coordinated with the CRB process, then the ICF may be out of sync with the sponsorship funding
- For example: "You or your insurer will not be charged for any services required by this research study."
  - This language promises all study required services free, which would likely be interpreted to include even standard of care which would otherwise be billable under Medicare or private payer reimbursement rules

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Medicare Coverage Analysis (MCA) & ICFS

- There are multiple parts of an ICF that can affect CRB – if the ICF is out of sync with the CTA and budget, then it could undo a carefully negotiated agreement with the sponsor
- If the IRB desires that the ICF list items and services provided without charge, then an MCA should be consulted before finalizing ICF language
- The MCA should be updated as negotiations with the sponsor progresses and what the sponsor will pay or won't changes – this could affect how the ICF is written
- IRBs have different approaches to assessing the financial dimensions of a study – some want MCAs submitted
- If an IRB wants to list the services provided without charge, be very specific which services and avoid over-promising

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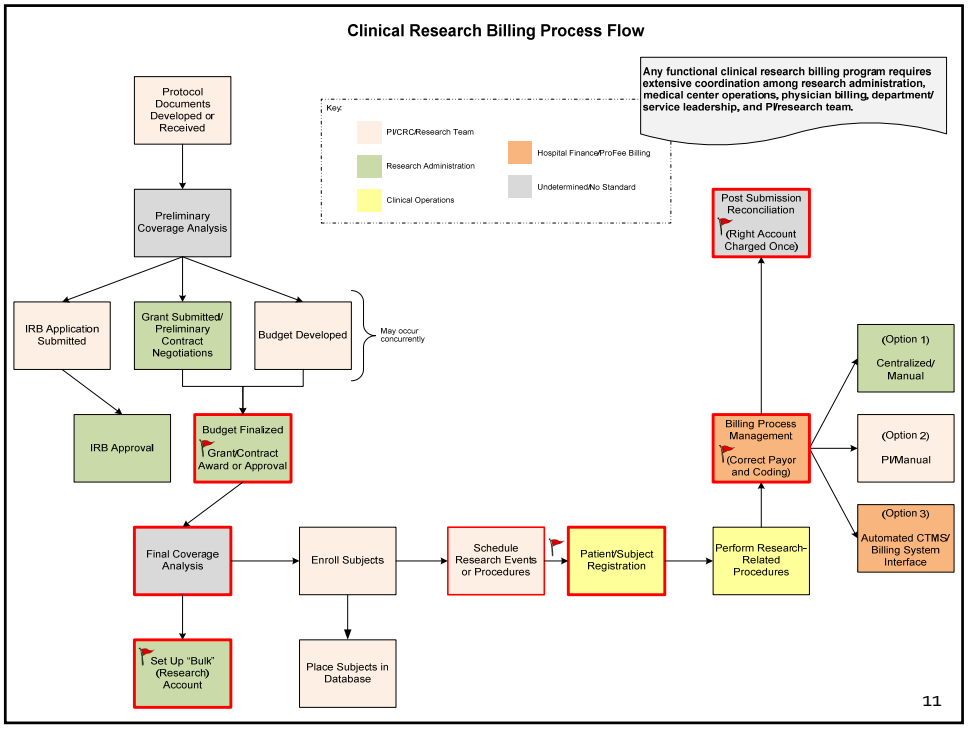
Clinical Research Billing Process Flow
Any functional clinical research billing program requires extensive coordination among research administration, medical center operations, physician billing, department/ service leadership, and PI/research team.
Key:
PI/CRC/Research Team
Research Administration
Clinical Operations
Hospital Finance/Pro Fee Billing
Undetermined/No Standard
Protocol Documents Developed or Received
Preliminary Coverage Analysis
IRB Application Submitted
Grant Submitted/ Preliminary Contract Negotiations
Budget Developed
May occur concurrently
IRB Approval
Budget Finalized
Grant/Contract Award or Approval
Final Coverage Analysis
Enroll Subjects
Schedule Research Events or Procedures
Patient/Subject Registration
Perform Research-Related Procedures
Billing Process Management
(Correct Payor and Coding)
Post Submission Reconciliation
(Right Account Charged Once)
(Option 1)
Centralized/ Manual
(Option 2)
PI/Manual
(Option 3)
Automated CTMS/ Billing System Interface
Set Up "Bulk" (Research) Account
Place Subjects in Database
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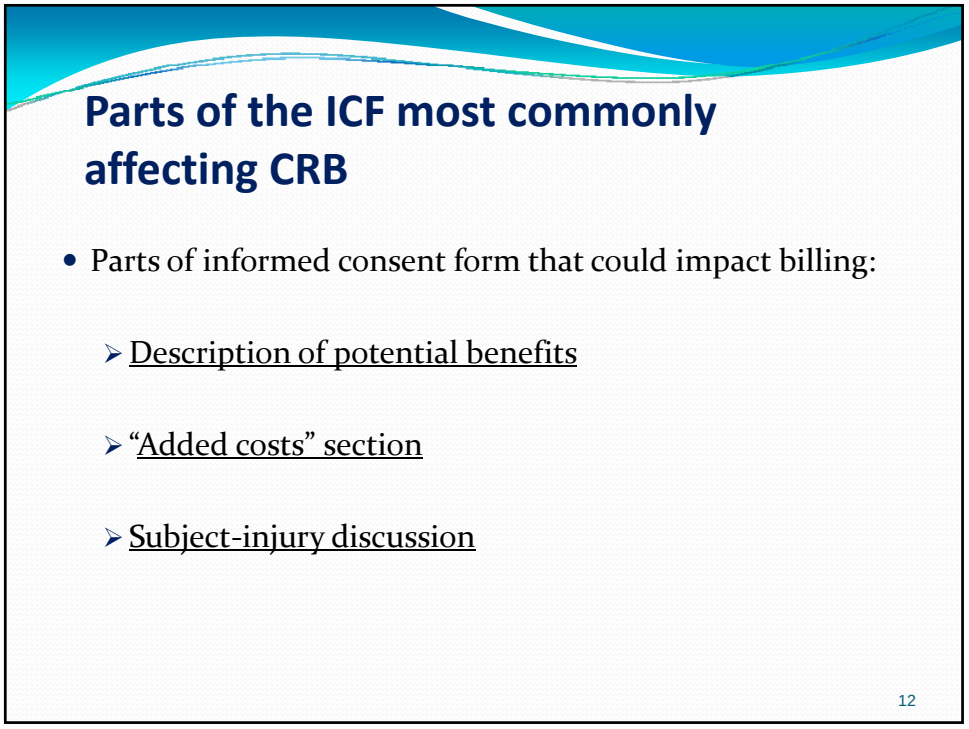
Parts of the ICF most commonly affecting CRB
• Parts of informed consent form that could impact billing:
➢ Description of potential benefits
➢ "Added costs" section
➢ Subject-injury discussion
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Benefits Section

- Regulation:
  - 45 CFR 46.116(a)(3) & 21 CFR 50.25(a)(3) require the ICF include "a description of any benefits to the subject or to others which may reasonably be expected from the research"
- If benefits section indicates that the subject will not receive any benefit for participating in the study, then the study will not meet the "qualifying clinical trial" criteria of the CMS Clinical Trial Policy

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Benefits Section

- The language of the benefits section should be checked carefully
- Example of language which may not allow billing
  - "There will be no direct benefit to you for participating in this research study."
- Example of language which supports that the study has therapeutic intent (and therefore may be billable to Medicare):
  - "The study will test whether the study drug improves [YOUR CONDITION]. However, you personally may not benefit from taking part."

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ICF & Added Costs Section

- Regulation:
  - 45 CFR 46.116(b)(3) & 21 CFR 50.25(b)(3) require the ICF include, when appropriate, "any additional costs to the subject that may result from participation in the research"
- If the "added costs" section of the informed consent form states that an item or service will not be charged to the patient, then the provider cannot bill for that service
- Note: The regulation does not require that the ICF list the services that are or are not charged, rather it requires the ICF to list the "additional costs" the patient will incur as a result of participating in the study (many routine costs are not costs resulting from participation)

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Problematic Added Costs Language

- "You or your insurer will have no costs for participating in this research study."
  - *(Subject/insurer may not be billed for any protocol-required items or services, nor for complications/injuries or other costs associated with participation.)*
- "Your routine medical care will be billed in the usual way. However, you will not be charged for any study visits or services."
  - *(Inconsistent terms within the same document.)*
- "You will be responsible for the costs of any services you would have received if you did not enroll in this research study. However, you will not be billed for any lab services or imaging services."
  - *(Inconsistent terms within the same document.)*

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Added Costs Section Contemplating the CRB Process

- Language which keeps the ICF "neutral":
  - "You will be responsible for the costs of services required by the research study that are routine to treat your condition. You will not be responsible for the costs of services that are required only because you are enrolled in the research study."
- Language which specifically identifies services that will not be billed (if IRB desires specifics)
  - "You will be responsible for costs for care you would have received if you were not enrolled in this research. However, you will not be responsible for the costs of the CT scan conducted at the start of each drug cycle."

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ICF & Subject-injury

- Regulation:
  - 45 CFR 46.116(a)(6) & 21 CFR 50.25(a)(6) require the ICF include "[F]or research involving more than minimal risk,…an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained."
- How this language is crafted is important for CRB because ICFs may differ in the scope of what may be considered "injury"
- Each IRB may have a different approach to defining the scope of "injury" under this regulation

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ICF & Subject-injury

- Practical implication for CRB process:
  - Whatever is the scope of payment for "injury" needs to be identified to the billing process if it occurs
  - If treatment of injury is promised free, then if the subject suffers "injury" the services must be flagged in the billing process
- Example of language which is very broad and goes beyond promising treatment for injury:
  - "If you suffer any complications or side effects during your participation in this research study, then ABC Institution will pay for your treatment."

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ICF & Subject-injury

- Examples of language which limits billing restrictions to injury:
  - "If you suffer injury from the study drug, the Sponsor will pay for health care to treat your injury."
  - "If you suffer injury from the study device, ABC Institution will pay for health care to treat your injury."
- Example of language which disclaims payment for subject-injury care:
  - "No money has been set aside for treating any complication or injury that you may experience because you have participated in this research study. You will be responsible for costs associated with treating any complications you may experience."

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Tackling ICF & the CRB Process

- Questions to ask when analyzing ICF impact on CRB:
  - Who drafts the ICF in each department?
  - Does the institution have a template informed consent form?
  - Does the IRB have a template informed consent form?
  - How does the PI deal with a template from the sponsor?
  - Does investigator merely "tinker" with the sponsor's proposed template informed consent?

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Operational Suggestions for Tackling ICF & the CRB Process

1. Determine how ICF is developed at your institution
2. Consider educating IRB members on how language in ICF could impact billing
3. Develop a process for administrative review of ICF language against MCA before final approval
4. Obtain copies of approved ICFs for all active research studies for development of MCAs and access for auditing

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The ICF as a "trigger" in the CRB process

- The point of consenting is a "trigger" for the CRB process – at that point services may need special coding if billed to Medicare or may need to be charged to study account
- Determine where consenting is occurring
  - In hospital?
  - In physician's office?
- Develop a process to flag subject as a research patient at point of consenting
- Enter subject information into central databases

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Take-away Points

- Be conscious that ICF is interpreted from the perspective of the subject
  - Ask yourself: "How would a typical patient interpret the words?"
- Be clear; be precise
- Do not over-promise
- Understand the development and approval process
- Identify a way to flag patients at consenting
- Identify a way to flag services covered by the subject-injury section

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References for further reading

National Coverage Determination 310.1 ("Routine Costs in Clinical Trials")

OHRP Human Subject Protection Rules: 45 CFR Part 46

FDA Human Subject Protection Rules: 21 CFR Part 50

AAHRPP Accreditation Standards, see Domain II generally (www.aahrpp.org/www.aspx?PageID=319)

42 USC 1395y("Exclusions from Coverage and Medicare as Secondary Payer")

- 1395y(a)(1)(A): "Reasonable and necessary" clause
- 1395y(b): Medicare Secondary Payer provisions

"Exculpatory Language in Informed Consent," OHRP Guidance (1996)

Lutz, H. (2007) "When Does a Sponsor's 'Promise to Pay' in the Clinical Trial Setting Trigger Medicare Secondary Payer Liability?" BNA Medical Research Law & Policy Report (6:20)

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Comment by HHS-OIG referencing ICF

May 18, 2010 settlement posting by OIG:

> "After it self-disclosed conduct to the OIG, Tenet Healthcare Corporation and Tenet HealthSystem KNC, Inc., (collectively Tenet), California, agreed to pay $1.9 million for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Tenet submitted claims to the Federal health care programs for clinical research-related items or services rendered at a hospital that were billed to or reimbursed by the Federal health care programs, including…2) items or services that were indicated as free of charge in the research informed consent…."

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- Questions