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How Clinical Trial Agreements Can Affect Research Billing

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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

1. Discuss the connection between the study "budget" and the main body of the clinical trial agreement
2. Review how the clinical trial agreement and study budget fit into the information flow in a clinical research billing process
3. Examine how language in the budget or clinical trial agreement could be misinterpreted to prevent billing during research studies
4. Review best practice language in study budget exhibits that avoid misunderstandings of what is being paid for by the sponsor
5. Identify important common sections of the clinical trial agreement that could impact clinical research billing

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First things first: What is a clinical trial agreement?

- A clinical trial agreement (CTA) sets out the obligations of parties involved in a research study
- The CTA sets out:
  - ✓ what services are to be performed
  - ✓ "who <u>does</u> what"
  - ✓ "who <u>owns</u> what"
  - ✓ how much money will be paid for <u>which</u> services
  - ✓ "extra" regulatory obligations the parties will take on
  - ✓ the "rules of the road" between the parties

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Why is the CTA important for the research billing process?

- Whatever is paid for by the sponsor in the CTA cannot be billed to the subject or the subject's insurer
- If the CTA is not clear on what is being paid for by the sponsor, the document may be misinterpreted both by the sponsor and by regulators in the event of an audit
- The information in the CTA on what the sponsor is paying for must be communicated to the billing process
- Institutions may suffer unintended consequences based on what is written in the CTA

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The CMS Clinical Trial Policy (CTP) and sponsorship payments

- Medicare CTP excludes from coverage:
  - "Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial."
  - In other words.....
    - If the sponsor pays for an item or service; or
    - An item or service is provided "free of charge" to an enrollee, then Medicare cannot be billed for that service
  - Exception
    - Enrollees who qualify for assistance under an institution's indigent care policy

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Non-industry contracts

- The concepts in this presentation apply equally to contracts for funding support with non-industry sponsors
- Most CRB compliance risks can occur without respect to whether the sponsor is industry, government, or a private foundation
- Negotiators of government contracts should coordinate with the individuals who negotiate the budget and be cognizant of their impact on the CRB process
- Offices within organizations that deal with government contracts should be brought into the CRB process training

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MCAs can assist in the CTA negotiations

- A preliminary Medicare Coverage Analysis (MCA) can set out what is billable or not billable to Medicare assuming the sponsor pays for nothing
- Negotiations of the CTA and budget can utilize an MCA to ensure sponsor is paying for items and services not covered by insurance
- CTA and budget negotiators with sponsors should coordinate with the person developing an MCA for the study to ensure they have the appropriate information for negotiating funding specifics (Session 5 will discuss budgeting in more depth)

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Basic Parts of a CTA

- Parties
- Definitions
- Financial provisions
- Indemnification
- Confidentiality
- Publication rights
- Ownership/intellectual property
- Subject injury
- Compliance with law
- Governing law
- Termination
- Signatures

❖ Note: not an exhaustive list!

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What and where is the "study budget"?

- The study budget for industry-sponsored studies is typically an appendix or exhibit to the CTA and serves as the compensation detail
- The study budget and the main body of the contract are part of the same document – they will be interpreted together

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Operational issues that could impact the CRB process

- Many clinical trial agreements have been negotiated in "parts"
  - One person negotiates the main body
  - Another person negotiates the "budget"/compensation
  - Protocol is incorporated but may not be reviewed carefully by either person, particularly if there is no formal MCA process in place
- Fundamental principle of Clinical Trial Agreements – Singularity:
  - A CTA is one contract with many parts
  - Interpreted as a single legal document

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Bringing a CRB perspective early to a CTA

- Best practice CRB processes analyze both the main body of the CTA and the "study budget" exhibit from a billing perspective
- Goal: Clarity in the final documents
  - If sponsor is paying for all services, then the CTA and study budget should be clear and that should be reflected in a Medicare Coverage Analysis (MCA) or other communication tool to inform the CRB process
  - If sponsor is only paying for some of the protocol services, then the study budget should be clear as to which services are being paid for so there is no confusion in developing the MCA
- Ambiguities in the CTA and study budget will usually be interpreted by insurers to their benefit (i.e., no billing)

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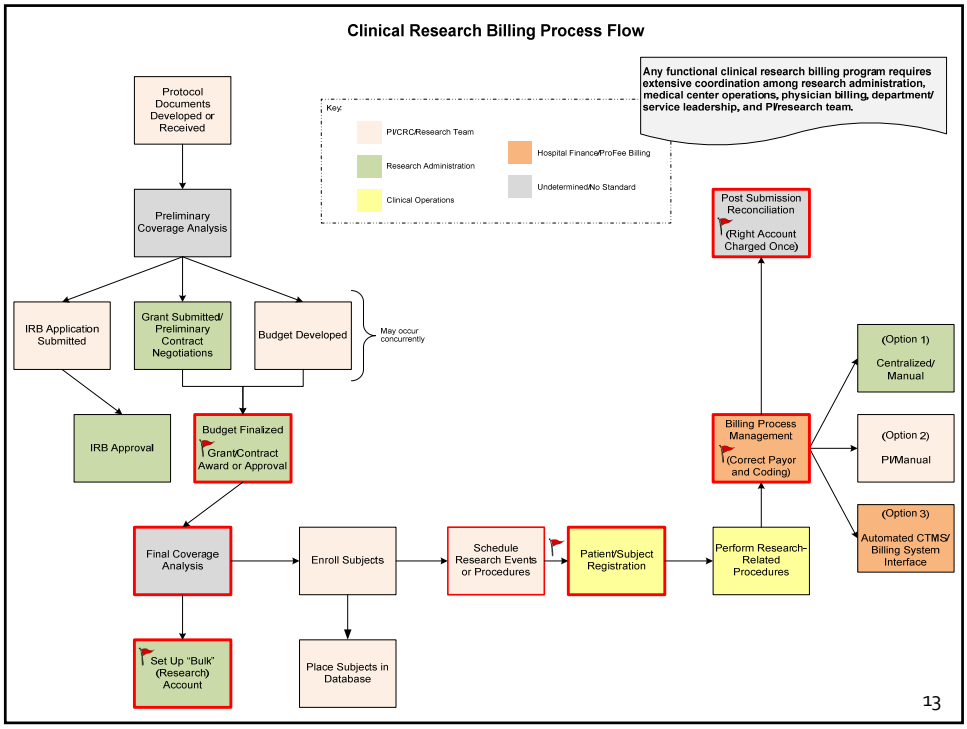

Structure of Financial Provisions: Main Body of CTA

- The main body of the CTA typically has a clause which links to an appendix (or exhibit) which is the study budget
- **Compliance risk:** If the main clause indicates that "Exhibit A" sets out payment for all costs for the services required by the protocol and "Exhibit A" provides general milestone payments, this could render none of the protocol services billable
- **Best practice:** The main clause is "neutral" with respect to what is set out in "Exhibit A" and defers to the exhibit as setting forth the payment terms under the CTA
- **Negotiating suggestion:** Keep the compensation discussion in the main body of the CTA simple and short

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Structure of Financial Provisions: Main Body of Master CTAs

- Master agreements pose an additional challenge since they are designed to cover multiple research studies
- Master agreements may or may not address the funding terms for the individual research studies; clarity in how they approach funding provisions is essential
- **Approach 1:** If the master agreement is designed to allow each research study maximum flexibility to negotiate the individual budgets, then the master agreement should have "neutral" language on compensation and defer to each research study that is covered by the master agreement.
- **Approach 2:** The master agreement may want to restrict how much financial negotiation is done for each research study and then should be precise in what can or cannot be negotiated for each research study (for example, the sponsor may be required to pay for all research-only services).

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Main body of the CTA: Case studies of language

Examples of clauses (risky language):

- "Payment for Study services are set out in Exhibit B. Such compensation constitutes payment for all of the Institution's costs for conducting Study services."
- "Sponsor agrees to pay Institution in accordance with Exhibit B. Institution agrees not to bill any third-party payer for services required by the Study."
- "Exhibit A sets out the payment schedule to Institution for Study services. Unscheduled imaging services shall be invoiced to sponsor at $350 per service."

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Main body of the CTA: Case studies of language

Examples of clauses (neutral language):

- "During the term of the Study, Sponsor agrees to provide financial support for the Study in accordance with the budget set out in Exhibit A."
- "Payment to Institution for items provided and services performed by Institution during the Study are set out in Exhibit A."

Negotiations will not always be able to produce completely neutral language in the main body of the CTA; if the main body contains discussion of specifics of the financials, then be precise and ensure that the main body of the CTA and the study budget language do not contradict each other

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Structure of Financial Provisions: Compensation Exhibit/"Study Budget"

- There is no standard approach to the Compensation Exhibit – each sponsor tends to have its own format
- Some structures utilized:
  - Payments for "research service" at milestones
    - Note: Is "research service" defined? Be clear which services are considered research services
  - Spreadsheet with payments based on schedule of events
    - Note: Best practice
  - Prose discussion of circumstances

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Structure of Financial Provisions: Compensation Exhibit/"Study Budget"

- Consider adopting a consistent approach for the compensation exhibits: the more detail on which services are being paid for, the better
- The MCA can serve as a tool for budgeting and lends itself to be used as the compensation exhibit
- Negotiating Suggestion: Watch out for footnotes! Avoid footnotes in the study budget, if possible

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Case Study on Compensation Exhibit/Study Budget: A hypothetical schedule of events

	Screening	Infusion 1	Infusion 2	2 weeks	12 weeks	24 weeks	Every 6 month
Physical Exam	X		X	X	X	X	X
EKG	X	X	X	X			X
Drug 123		X	X				
Infusion			X				
Urinalysis	X		X	X			X
Ultrasound				X			X
Patient Diary	X		X	X	X	X	X

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Compensation Exhibit – Example 1

	Screening	Infusion 1	Infusion 2	2 weeks	12 weeks	24 weeks	Every 6 month
Physical Exam	$75		$0	$0	$0	$75	$0
EKG	$100	$0	$0	$0			$100
Drug 123		Provided by Sponsor	Provided by Sponsor				
Infusion			$250				
Urinalysis	$45		$45	$45			$45
Ultrasound				$350			$350
Patient Diary	$50		$50	$50	$50	$50	$50

Note: The following examples are simplified to emphasize concepts

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Compensation Exhibit – Example 2

Sponsor shall pay the following amounts:

- Screening: $1000
- Infusion 1: $750
- Infusion 2: $750
- 2 weeks: $400
- 12 weeks: $400
- 24 weeks: $400
- Every 6 months for 3 years: $250

Question: For what services is the sponsor paying?

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Compensation Exhibit – Example 3

	Screening	Infusion 1	Infusion 2	2 weeks	12 weeks	24 weeks	Every 6 month
Physical Exam	X		X	X	X	X	X
EKG	X	X	X	X			X
Drug 123		X	X				
Infusion			X				
Urinalysis	X		X	X			X
Ultrasound				X			X
Payment	$1000	$750	$750	$450	$450	$450	$250

Question: Is the sponsor paying for everything with an X?

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Negotiating the format of the compensation exhibit

- Best practices:
  - To the extent possible, develop a standard format
  - Use a spreadsheet identifying exact services being paid and when during the study the payments will occur
  - Utilize the Medicare Coverage Analysis spreadsheet
  - Add qualifying statement to exhibit indicating that payments are only for the services identified in the spreadsheet at the frequencies indicated
- If not feasible to negotiate organization's standard format, then
  - be as clear as possible
  - be as precise as possible

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Dealing with conditional payment clauses

- Some sponsors want to pay for services only if the subject's insurance has denied the claim
- Example of a conditional payment clause: "Institution will invoice sponsor for any imaging service not covered by the subject's insurer."
- Sponsors may propose this language across-the-board for study-related services or focused just on specific services or focused just on treatment for subject "injury" – the concepts of the clauses are the same
- Medicare concern:
  - If a non-Medicare patient (or the patient's insurer) is not charged for a study-related service, then Medicare believes it should be treated the same and not be charged

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Dealing with conditional payment clauses

- Medicare rules implicated:
  - "No legal obligation to pay" rule
  - Medicare Secondary Payer Statute (for treatment of subject-injury)
- Controversial issue in which CMS has attempted unsuccessfully to clarify whether existence of conditional payment clauses defacto prohibits Medicare billing
- CMS has stated that Medicare billing is not prohibited if sponsor pays for non-Medicare patient if patient is indigent or under-insured such that the patient would be considered indigent under charity care policy if collection pursued
- Developments in this area must be monitored closely as they are subject to change without advance notice by CMS

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Dealing with conditional payment clauses

- Best practice approach: Avoid conditional payment clauses. If the sponsor is willing to pay for a service when an insurer denies coverage, then ask the sponsor to pay for the service for all subjects in the study.
- Language which could still allow Medicare billing: "Institution may invoice sponsor for services required by the research study which are not covered by the subject's insurance if the subject is eligible for a reduction in charges under the Institution's charity care policy."
  - Note: If this language is adopted, then the organization must have an active charity care policy. Before invoices are sent to the sponsor, a process should be developed to document that the patient meets the charity care policy.

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Dealing with conditional payment clauses

- What happens if the sponsor will not agree to pay for all services and continues to insist on a conditional payment clause?
- The organization must think through the following:
  - Whether it will accept the language but be prepared not to bill Medicare patients
  - Determine if the study is highly unlikely to enroll Medicare patients (due the study population) and therefore not impact Medicare
  - Consider whether accepting the conditional payment language does not run afoul of standard managed care agreements

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Subject Injury Issues

- CTAs should deal with how the sponsor will pay for treatment of injuries which are directly caused by the investigational item
- Organizational policies that require institutions to provide subject-injury services free of charge to the subject should negotiate with the sponsor to have these paid
- The same CRB principles for scheduled protocol services apply to subject-injury costs – if the language is broader than treatment of injury directly caused by the investigational item, then the CRB process must be told what the scope of the coverage is
- Subject injuries must be flagged in the CRB process

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Negotiating Goal to Minimize Impact on CRB: Clarity

- Tips for drafting language :
  - Ask yourself: If you had to pick up the CTA and "budget" 3 years from now, would you be able to know what the money is paying for without referencing your notes?
  - Ask yourself: If someone else had to read the CTA and "budget" 3 years from now, would that person know what the money is for?

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Managing CRB Compliance Risk from CTAs

- Identify a process that will review CTAs (and budget exhibits) for consistency and conformance with the organization's policies – this could be a centralized office or a standardized process for individual departments
- Consider establishing an initiative to collect all existing CTAs and centrally house future CTAs
- Create a database of CTAs
- Who has the final, executed documents?
- Find the parts! Make sure the compensation exhibit/study budget is in the same place as the main body of the CTA

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Take-away Points

- Negotiators of the CTA and the study budget must work closely together in order to ensure that language does not overstate what it desires to pay
- Be as clear and precise as possible in the CTA
- Include all of the services in a protocol into the study budget so that they can be negotiated
- The financial terms of the final CTA and study budget must be incorporated into a final MCA before billing occurs

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References for further reading

- National Coverage Determination, NCD 310.1 ("Routine Costs in Clinical Trials")
- MLN Matters SE0822 ("Clarification of Medicare Payment for Routine Costs in a Clinical Trial") January 7, 2009
- 42 USC 1395y(a)(2) ("no legal obligation to pay" clause)
  - Medicare Benefit Policy, Ch. 32, Sec. 40 ("No Legal Obligation to Pay for or Provide Services")
- 42 USC 1395y(b)(7) & (8) (Medicare Secondary Payer Mandatory Reporting) (Also known as, Medicare, Medicaid, and SCHIP Extension Act of 2007, Sec. 111)
  - "CMS Alert: Clinical Trials & Liability Insurance (Including Self-Insurance),No-Fault Insurance, and Workers' Compensation" (May 26, 2010)

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•Questions

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