

Clinical Trial Agreements and Unintended Compliance Issues

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Pitch Hitting for Ryan

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Goals

- What is a Clinical Trial Agreement (CTA)?
- Unintended consequences of language in the CTA
- CTA (and Budget) negotiation strategies

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SOME BASICS....

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What is a Clinical Trial Agreement?

.....it's just a contract

- The legal form of a CTA is no different from any other service agreement

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What is a Clinical Trial Agreement?

- Party 1 asks Party 2 to perform work
 - Party 1 pays Party 2 to do work
 - Party 2 performs work for Party 1
- The sponsor asks an institution/PI to conduct a clinical trial
 - The sponsor pays the institution to perform the clinical trial
 - The institution performs the clinical trial

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What is a "budget"?

- The "Budget" is just a collection of compensation terms associated with performing the services in the contract
- "Party 1 pays Party 2 to do work"
- The "CTA" and the "Budget" are in the same document
 - They are NOT two different documents
 - Language in one part can impact the other part
- The Budget Exhibit must always be read as part of the CTA
 - The Budget Exhibit is a sub-part of the overall CTA

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What makes a binding contract?

1. Offer
2. Acceptance
3. Something of value exchanged between the parties

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What makes a binding contract?

A note about legal obligations before signing a CTA

No one is obligated to do anything merely because an offer has been presented

CTAs (and budgets) are negotiable – just like all service arrangements

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COMPLIANCE ISSUES AND THE CTA

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Compliance Issues and CTAs

The most common compliance challenges in CTAs:

- Discussion of compensation terms in main body of the contract is in conflict with the Budget Exhibit (or is mismatched in some way)
- Language in the Budget Exhibit is not precise

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Compensation Terms

- Usually two places that money is discussed related to Protocol services:
 - Main section of the CTA contains “Compensation Terms” (or some similar title)
 - Budget Exhibit
- Also, subject injury provisions
 - Not Protocol services; not in Budget
- Tips:
 - Don’t have a 3rd section discussing money!

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Compensation Terms

- Possible neutral approach in the “Compensation Terms” section:
 - **“Compensation paid to Institution under this Agreement is set out in Exhibit B.”**
 - Statement of FMV
 - Say as little as possible! Kick the discussion of money to one section (Budget Exhibit).

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What happens if the language is unclear?

- The language appears as though the institution took money for something it billed insurance
- Worst case scenario: The government (or whistleblower) asserts the organization took the money from the sponsor, billed Medicare/Medicaid, and committed fraud
- Critical that the language is clear and everyone knows what the money is going for and what it is not going for

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Common Language Problems

1. Ambiguity – Unsure what sentence or phrase means and could be interpreted two or more ways
2. Contradictions – Two lines appear to contradict each other
3. Unintended Language – Clear language, but not written as the parties intended

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Ambiguity

- “The compensation set out in this exhibit covers research conducted during this study.”

– What is “research”?

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Contradictions

- “The compensation in this exhibit is payment for all services required by the protocol.”

- “The sponsor acknowledges that the institution will bill insurance for protocol services which meet Medicare’s NCD 310.1.”

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Clear...but with Unintended Consequences

- “The compensation in this exhibit is payment for all services required by the protocol.”

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Drafting Budget Language

- Are the terms clear? Not just to you, but to other people.
- Are there different ways to read language and terms?
- Are there definitions for terms?
 - Capitalized terms not defined

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Interpreting Budget Language

- Plain meaning of words used if not defined
- If CTA words are ambiguous, is there any ancillary evidence of intention of parties? (but let's try not to have this situation!)
- If words are clear that payment goes for clinical services, then service should be identified as not billable to insurance in the Coverage Analysis ("CA")

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Interpreting Budget Language

- **Difficult Terms**
- Pays for "research services", then CA assumes CTA is not paying for medically necessary clinical care
 - But, best practice is to clarify as "services only for research purposes"
 - Better – precisely identify services for which sponsor is paying
- Pays for "protocol services", then CA assumes CTA is paying for all scheduled services
- Pays for "study-related services", then CA assumes CTA is paying for scheduled services

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Budget Matrix for Mixed Billing Studies

- A best practice for clarity in the CTA when the study has some services billed to insurance and some to the study (a Mixed Billing Study) is to have a budget matrix as part of the CTA's Budget Exhibit.
- A budget matrix that replicates the schedule of events, sets out the time points, and identifies specifically which items and services are paid by the sponsor helps to achieve clarity in the CTA and speeds up the process for Coverage Analysis development.
- The budget matrix should state whether the sponsor is paying for the service
- A budget matrix can be proposed as an add-on to a Budget Exhibit to clarify those services for which the sponsor is paying

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Examples

- "Payment is inclusive of procedures required by the Protocol and in accordance with the Payment Schedule attached as Exhibit A."
- Exhibit A lists milestone payments
 - Are all services covered by the payments?

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Examples

- "Payment is inclusive of procedures, overhead and other indirect costs."
- Billing?

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Examples

- “Neither Institution nor Principal Investigator shall bill any third party for any Study Drug or other items or services furnished by Sponsor in connection with the Study, or any services provided to patients in connection with the Study for which payment is made as part of the Study including, but not limited to, Laboratory Tests, ECG evaluations, CT scans, Bone Marrow Biopsy, and MRI.”

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Examples

- “Sponsor shall also provide financial support in an amount not to exceed \$X for the Study, which shall be provided as follows...”
- The next paragraph provides schedule for timing of payments but includes no further information detailing what the payments are for.

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Clarity in language

- Medicare asks for “most favored nation” status – the best deal given to any subject in the study
- Avoiding variable payments
 - The sponsor should either pay for a service or not pay for a services
 - Avoid “SOC/INV”
 - This minimizes risk of the sponsor paying for Service X for Patient 2 when Service X has been billed to Medicare for Patient 1

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Clarity in language

- What about an item or service in a budget listed as "Invoice upon occurrence"?
- Are there any qualifiers to the term?
 - If no qualifiers, then it appears the sponsor is agreeing to be invoiced when the service occurs
 - An obligation to pay under the CTA is treated under CRB rules as if the sponsor has already paid

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Clarity in language

- What about an item or service in a budget listed as "Invoice"
- Fewer words than "Invoice upon occurrence" but is it any different?
- Are there any qualifiers to the term?
 - If no qualifiers, then it appears the sponsor is agreeing to be invoiced when the service occurs

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Clarity in language

- What about an item or service in a budget listed as "Invoice when not Standard of Care"
- The obligation to pay is not triggered when the service is "standard of care"
 - Who decides?
 - What if it's SOC and insurance won't pay?
 - Leads to inconsistent approaches to subjects?
 - Best practice - avoid this statement or restrict its use to unscheduled events

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Clarity in language

- "Invoiceable"
 - Means that when the service occurs it will be invoiced to the sponsor and the sponsor will pay for the service
- Payment for a clinical service/procedure
 - Assumption that payment is for the clinical service
 - Payment associated with a CPT code will be interpreted in CAs as payment for a clinical service
 - If payment is only for data transmission, then it should clearly state so

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If you need a clarifier....

- Despite considerable effort, it's possible the sponsor will not modify its template and will not budge from lump sum payments
- If the intention is for the sponsor's money to not cover everything, consider adding a qualifier:
 - "Payments by the Sponsor do not cover items and services that are billable to third-party payors under the definition of Routine Cost in Medicare National Coverage Determination 310.1 or other Medicare coverage policies."

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Examples Needing Clarification

- "The Per Patient Visit Cost includes study-related costs for each patient as required in the Protocol, including procedure costs, site personnel fees (including electronic data entry), administrative fees during performance of the study (copying, shipping preparation, labels, etc.), lab draws, and indirect costs and overhead. All of the study-related costs are included in the costs outlined above. The Per Patient Visit Costs section of the budget represents

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Examples Needing Clarification

- “The payments set forth in the Chart of Payments for Subject Visits cover all laboratory services, testing services, scans and other services described in the Protocol and Study Addendum at the applicable visit unless described in this Study Addendum.”

- There is nothing wrong with this language; it’s a question of whether the language meets the budget goals

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Zingers

- “If Institution chooses to seek payment from Medicare for any routine treatment cost that is offered to be paid by Sponsor, Institution acknowledges that the Sponsor may be providing payment for the same costs to other trial sites.”

- Conditional payment language
 - Sponsor will pay if insurance denies
 - Re: Protocol-required services
 - Re: subject injury language

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Summary Tips

1. Keep main legal clauses neutral and talk about money/dollar amounts in one place: the Budget Exhibit
2. Do not assume you know what the sponsor means – be clear and do not be afraid to ask the sponsor what it means
3. If possible, use CA or schedule of events and place \$\$ in cells for services paid by sponsor and put \$0 in cells in which sponsor pays nothing

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Summary Tips

- 4. Add definitions if there is any doubt about what a term means
- 5. Define acronyms!
- 6. Avoiding using the term "standard of care" or "SOC"
- 7. Try exchanging Budget Exhibit document with colleagues to see if they are reading the language the same way

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Summary Tips

- 8. Avoid variable billing
- 9. Don't be afraid to negotiate
- 10. Know who is negotiating the main body of the CTA and make sure you are "on the same page"

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QUESTIONS?

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