

Responsibility for Copays/Deductibles for Routine Care in a Clinical Trial

Subject: Responsibility for copays and deductibles for conventional or routine clinical care (e.g. items or services the participant would have received absent a clinical trial) provided to study participants

UAB Position Statement: UAB cannot accept any language in a clinical trial agreement or award where the sponsor agrees to pay for or reimburse a study participant’s copay or deductibles for conventional or routine clinical care services provided in a research study. UAB expects the study participant will be billed for any and all copays or deductibles associated with any clinical items and services billed to their insurance.

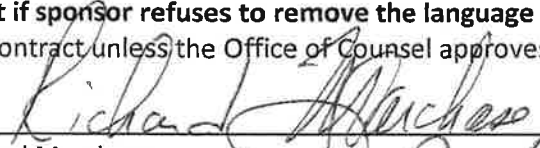
Acceptable CTA Language: The study participant is responsible for all copays or deductibles associated with protocol-required items and services that are identified as conventional care, i.e. services the patient would have received absent the clinical trial.

Basis: CMS (Center for Medicare and Medicaid Services) views sponsor payments or reimbursements for conventional or routine care copays/deductibles as an inducement to study participants.


Allowable Exception:

- Exception: Sponsors of trials that meet certain federal requirements may be allowed to pay for or waive copays/deductible. If this language is included in any award or agreement, refer the document to the office of counsel for review. The Office of Counsel is responsible for conducting these reviews and will evaluate the project to determine if the federal requirements have been met.
- If sponsor payment or waiver of copays/deductibles is approved by the Office of Counsel, this information must be immediately communicated to the PI/Study Team, OIRB and the Office of Clinical Billing Review.
 - The PI/Study Team and OIRB are responsible for ensuring that the consent form includes appropriate language about the responsibility for copays/deductibles.
 - The Office of Clinical Billing Review is responsible for ensuring that the information is included in the clinical trial management system to sufficiently inform the Health System billing offices about how to bill copays/deductibles.


What if sponsor refuses to remove the language from the contract? Sponsors must remove the language from the contract unless the Office of Counsel approves the study with the language included.



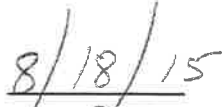
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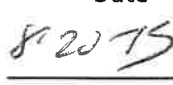
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Policy/Guidance References:

- CMS MLN SE0822, 1/9/09
- OIG Advisory Bulletin on Offering Gifts to Beneficiaries, 2002
- OIG Special Fraud Alert on Routine Waivers of Copayments and Deductibles, 1994)