

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.



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8/18/15
Date



Selwyn Vickers

8/18/15
Date



Will Ferniany

8-20-15
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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)