

Emory University Office of Sponsored Programs Policy on Sponsor Payment for Items that are: (a) Not Paid by Third-Party Insurers; or (b) For Uninsured Patients

Responsible Official: VP for Research Administration

Administering Division/Department: Office of Sponsored Programs

Effective Date: November 1, 2010

Last Revisions: New policy; no previous revisions

Policy:

- (1) In order to ensure compliance with applicable laws, regulations and contractual provisions regarding the submission of insurance claims for payment, Emory University will only submit for payment to insurers (whether government or private) a claim for which it has a reasonable and good faith basis to believe that the claim will be paid and/or the submission is otherwise appropriate. In making this determination and in handling any claims, Emory shall follow its standard billing practices and procedures. Emory University will not agree to any contract language that would in any way undercut or circumvent this policy (e.g., contract provisions that require a claim to be submitted and denied one or more times in order to trigger sponsor responsibility to pay the claim).

- (2) The Medicare *National Coverage Decision for Routine Costs in Clinical Trials* (310.1) does not provide Medicare coverage for “items and services customarily provided by the research sponsors free of charge for any enrollees in the trial.” In accordance with this rule, if a study Sponsor agrees in a clinical trial agreement or related informed consent form to pay a certain cost for any trial participant (whether insured by Medicare, Medicaid, private insurance or uninsured), then the study Sponsor will be expected to pay that same cost for all trial participants, even if any of the participants’ insurance (including Medicare or Medicaid) would have otherwise paid for the cost, unless the following exception applies:
 - (a) The sponsor may pay for costs for an uninsured study participant without paying the same costs for a Medicare/Medicaid beneficiary or private insurance beneficiary, **if** the uninsured person’s account is processed under the Emory’s standard indigent care policies and it is determined that (i) the uninsured person would not have any payment responsibility under those policies; or (ii) the uninsured person would have only partial payment responsibility under those policies. In the case of partial payment responsibility, the Sponsor would only be permitted to pay for those costs that were not deemed to be the responsibility of the uninsured person.

- (3) With some very limited exceptions for clinical trials sponsored by federal agencies, Medicare and Medicaid generally prohibit the waiver of co-payments, deductibles and/or co-insurance. Many private insurers also frequently prohibit such waivers. Accordingly, contract provisions for such waivers should not be included in clinical trial agreements or informed consent documents unless they are expressly approved in advance by the University’s Office of the General Counsel. Unless otherwise specifically approved in

advance by the Office of the General Counsel, contract reviewers should ***delete*** any provisions from the clinical trial agreement that state or imply that a subject's co-payment, co-insurance or deductible will be waived.

- (4) The clinical trial agreement and the informed consent document must contain only provisions that are consistent with the requirements specified in this policy. Any language that contradicts these requirements should be deleted.

Related Links:

Current version of this policy is at the following website: _____

Contact Information:

| Subject | Contact | Phone | Email |
|----------------------|---|----------------|---------------|
| Questions re. Policy | Director, Office of Research Compliance | (404) 727-2398 | orc@emory.edu |

Revision History:

None.