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P Clinical Trial Compensation

Policy

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Policy

Clinical Trial Compensation is payment received for taking part in a clinical trial researching and testing treatment of rare diseases or conditions that meets all of the following:

- Has been reviewed and approved by an Institutional Review Boards (IRB);
- It involves research and testing of medical treatments; and
- It targets a rare disease or condition.

Clinical trial compensation is treated as follows:

If the MA Program is...	Then the treatment is...
<ul style="list-style-type: none"> • ALTCS • SSI-MAO • MSP 	<p>The first \$2,000 paid during a calendar year is excluded for:</p> <p>This exclusion will expire on October 5, 2015.</p>
All other MA programs	Counted as unearned income.

NOTE Reimbursements for costs related to the clinical trial are not considered Clinical Trial Compensation. They are treated like any other reimbursement ([MA606.YY](#))

Definitions

Term	Definition
Clinical Trial Compensation	Income received for participation in a clinical trial researching and testing treatment of rare diseases or conditions as defined in Section 5(b)(2) of the "Orphan Drug Act".
Institutional Review Boards (IRB)	An IRB is a committee of persons responsible for ensuring that a clinical trial is ethical and protects the participants.
Rare disease or condition	Generally refers to any disease or condition that affects less than 200,000 people in the United States.

Proof

Proof that the income meets the requirements to exclude the first \$2,000 includes:

- The "informed consent form" from the clinical trial, which provides most of the information needed to determine whether the income exclusion applies.
- An official letter from the administrator of the clinical trial that provides all the relevant information of the informed consent in a summarized format.

IF THE PERSON DOES NOT HAVE EITHER OF THESE DOCUMENTS, SEE [DETERMINING CLINICAL TRIAL COMPENSATION](#) FOR INSTRUCTIONS ON DETERMINING IF THE CLINICAL TRIAL QUALIFIES FOR THE EXCLUSION.

Proof of the income amount and frequency of payment includes:

- Check stubs;
- Payment receipts;
- Informed consent form; and
- Other documents from the clinical trial administrator.

Programs and Legal Authorities

This requirement applies to the following programs:

Program	Legal Authorities
ALTCS SSI-MAO Medicare Savings Program	42 USC 1382a(b)(26) AAC R9-22-1909
Adult Caretaker Relative Pregnant Woman Child KidsCare	42 CFR 435.603 42 CFR 457.10, 300, 301 and 315



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