Update 2012-4: Medi-Cal
Clinical Trial Act of 2009

Background

Public Law 111-255, signed October 5, 2010 provides for an exclusion under the Supplemental Security Income program and the Medicaid program for compensation provided to individuals who participate in clinical trials for rare diseases or conditions.

Policy

The first $2,000 per year of compensation received by the client and/or his/her spouse for participating in clinical trials that research treatment of a rare disease or condition must not be counted as income and property.

Note: Any compensation over $2,000 per year should be counted as unearned income. Interest income earned (as a result of keeping the funds in a bank account) from these payments is counted as unearned income in the month the interest is posted.

The trial must meet ALL three criteria in order for the exclusion to apply:

• It must be reviewed and approved by an Institutional Review Board (IRB).

• It must involve research and testing of medical treatments.

• It must target a rare disease or condition.

For instruction on how to verify if clinical trial meets the above criteria refer to [Refer to “Compensation for Participating in Clinical Trials,” page 46-51] for treatment of property and [Refer to “Compensation for Participating in Clinical Trials,” page 54-18] for treatment of income.
This exclusion is effective April 3, 2011, and will expire on October 5, 2015.

The EW must rescind and reevaluate any discontinuance, denial and/or increase in SOC that occurred on or after April 3, 2011 as a result of counting this payment. It must be done in the following situations, whichever occurs first:

- A case is known to the county to have been denied or discontinued in error or assessed an incorrect SOC.
- A case is brought to the county’s attention.
- A case is processed at reapplication, a change in circumstances or annual redetermination.
- When reopening a case that was closed since April 3, 2011.

Reminder:
Appropriate Notice of Action (NOA) must be sent.

This income and property type is currently not programmed in CalWIN. The EW must document the amount and the reason for exemption in the "Maintain Case Comments" window. The EW must select "Clinical Trial Exclusion" as a case comment type in the drop down menu. This will be used as a monitoring tool to prevent exclusions over $2,000.

Note:
EWs must review all comments entered under "Clinical Trial Exclusion" type in the "Maintain Case Comments" window in CalWIN every time client reports this type of income or property, and assure that total excluded compensation does not exceed $2,000 per calendar year.

Changes in this Update affect Medi-Cal program only.

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