

# Medi-Cal Program Guide Letter (MPG) # 753

May 22, 2012

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**Subject** CLINICAL TRIALS ACT OF 2009

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**Effective** April 3, 2011

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**End Date** October 5, 2015

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**Reference** All County Welfare Director's Letter (ACWDL) # 12-07

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**Purpose** The purpose of this letter is to clarify how to treat compensation received for participation in a clinical trial involving research and testing of treatments for rare diseases or conditions.

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**Background** Public Law 111-255, provides for an income and resource exclusion that applies to the first \$2,000 of compensation received for participating in clinical trials that research treatment of a rare disease or condition. The \$2,000 income and resource exclusion will only be allowed once annually.

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**Highlighted Changes** Effective April 3, 2011 and expiring October 5, 2015, the first \$2,000 per year of compensation received for participating in clinical trials that research treatment of a rare disease or condition must not be counted as income and property.

The clinical trial must meet the following criteria in order for the exclusion to apply:

1	It must be approved by an Institutional Review Board (IRB).
2	It must involve research and testing.
3	It must target a rare disease or condition.

For instructions on how to determine if clinical trial meets the above criteria and instructions for treatment of:

- Income see [MPG 10.03.39](#)
- Property see [MPG 9.06.41](#)

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**Required Action**

Workers will apply the income and resource exclusion to:

- New applications
- Cases dated April 3, 2011 to present that have been denied or discontinued in error or assessed an incorrect SOC based on clinical trial income or property whenever:

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.

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**Automation Impact**

Case workers will follow the Steps outlined in:

- [MPG 10.03.39](#) when entering Clinical Trial Income in CalWIN
- [MPG 9.06.41](#) when entering Clinical Trial Resource in CalWIN

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**Forms Impact**

No Impact.

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**Access Impact**

No Impact.

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**Imaging Impact**

No Impact.

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**PA (CalFresh or CalWORKs) Program Impact**

Clinical Trials income is not exempt for CalFresh or CalWORKs programs. Please refer to section 44-100 of the [CPG](#) and section 63-223 of the [CFPG](#) for treatment of income for the CalWORKs and CalFresh programs. The worker will reasonably anticipate the income only if the client is reasonably certain of the amount and payment dates. For CalWORKs, please refer to [CPG 44-250-F](#) and [Special Notice 10-03](#). For CalFresh, refer to CFPG chapters [63-281](#) and [63-606](#).

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**QC/QA Impact**

Effective with the April 2012 review month Quality Assurance will cite the appropriate error on any case that does not comply with the requirements outlined in this letter.

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**Summary of Changes**

The table below shows the changes made in the MPG cites.

<b>Section</b>	<b>Summary of Change</b>
<a href="#">Article 10, Section 3</a>	<ul style="list-style-type: none"><li>• Infomapped the Article</li><li>• Added clinical trial income exemption criteria</li></ul>
<a href="#">Article 9, Section 6</a>	<ul style="list-style-type: none"><li>• Infomapped the Article</li><li>• Added clinical trial resource exemption criteria</li></ul>

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**Approval for Release**

A handwritten signature in black ink, appearing to be 'JRF', is written over a light yellow rectangular highlight.

CG

## 10.03.39 Clinical Trial Income

### A. Treatment

Effective April 3, 2011 and expiring October 5, 2015, income and resource exclusion will apply to the first \$2,000 of compensation received per year for participating in clinical trials that research treatment of a rare disease or condition.

MPG Letter #753 (05/12)

ACWDL  
12-07

### B. Clinical Trial Exclusion Criteria

Clinical trials must meet the following criteria in order to be excluded:

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1	Approved by an Institutional Review Board (IRB).
2	Involve research and testing.
3	Target a rare disease or condition.

To determine that payments meet the criteria workers must:

Step	Action						
1	Obtain the following: <ul style="list-style-type: none"> <li>• the informed consent form; or</li> <li>• an official letter from the administrator of the clinical trial, with the following information:               <ul style="list-style-type: none"> <li>– name and location of the clinical trial</li> <li>– name of disease or condition</li> <li>– name, phone, and address of the clinical trial administrator</li> </ul> </li> </ul>						
2	Use the information provided to determine if the clinical trial is IRB approved. Make this determination by locating the clinical trial in <a href="http://Clinicaltrials.gov">Clinicaltrials.gov</a> or <a href="#">results database</a> . <table border="1" style="margin-top: 10px;"> <thead> <tr> <th>If ...</th> <th>Then ...</th> </tr> </thead> <tbody> <tr> <td>yes</td> <td>go to step 3</td> </tr> <tr> <td>no</td> <td>the income exclusion does not apply</td> </tr> </tbody> </table>	If ...	Then ...	yes	go to step 3	no	the income exclusion does not apply
If ...	Then ...						
yes	go to step 3						
no	the income exclusion does not apply						
3	Look for the following details in the clinical trial information: <ul style="list-style-type: none"> <li>• type of clinical trial, which is usually listed under the primary purpose, the title, or stated in the purpose summary; and</li> <li>• name of the condition.</li> </ul> Use the information collected above to determine if the clinical trial involves research and testing. <table border="1" style="margin-top: 10px;"> <thead> <tr> <th>If ...</th> <th>Then ...</th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> </tr> </tbody> </table>	If ...	Then ...				
If ...	Then ...						

	yes	go to step 4
	no	the income exclusion does not apply
4	Verify whether the clinical trial targets a rare disease or condition as outlined in <a href="#">MPG 10.03.39c</a> .	
	<b>If ...</b>	<b>Then ...</b>
	yes	the income exclusion applies
	no	the income exclusion does not apply

MPG Letter #753 (05/12)

**C.  
Determining  
Rare Disease  
or Condition**

Some commonly known rare diseases are:

ACWDL  
12-07

Amyotrophic Lateral Sclerosis (Lou Gehrig's disease)
Crohn's Disease
Cystic Fibrosis
Cystinosis
Duchenne Muscular Dystrophy
Huntington's Disease
Tourette Syndrome

If the condition listed in the summary:

- is not part of this list, and
- the documentation provided does not indicate the condition is a rare disease or condition.

Verify the disease or condition against the Office of Rare Disease Research's database at: <http://rarediseases.info.nih.gov/>.

MPG Letter #753 (05/12)

**D.  
Entering  
Clinical Trial  
Income in  
CalWIN**

Case workers will follow the Steps below when entering Clinical Trial Income in CalWIN.

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Step	Action	
1	The first \$2000 excluded Clinical Trial income will be entered in CalWIN as follows:	
	<b>If case consist of...</b>	<b>Then the income will be...</b>
	CalWORKs	entered in <b>Display Unearned Income Summary</b> as <i>net countable income for CalWORKs</i>
	CalFresh & Medi-Cal	entered as in <b>Display Unearned Income Summary</b> as <i>net countable</i>

	Combo	<i>income for Food Stamps</i>
	Medi-Cal Only	excluded from CalWIN entries
2	Document case actions in Case Comments.	
3	Set a CalWIN Case Alert to monitor when the beneficiary has reached the maximum \$2000 exclusion for Medi-Cal.	
	<b>When ...</b>	<b>Then the worker must...</b>
	the maximum \$2,000 exclusion is reached	Follow Steps 4 through 6 below to begin counting Clinical Trial Income being received.
4	Add a new <b>Net Countable Income for Medi-Cal</b> record in CalWIN to enter countable income for Medi-Cal.	
5	Follow QR/PB regulations for changes to this type of income for CalWORKs and CalFresh.	
6	Document case actions in Case Comments.	

MPG Letter #753 (05/12)

## 09.06.41 Clinical Trial Resource

### A. Treatment

Effective April 3, 2011 and expiring October 5, 2015, resource exclusion will apply to the first \$2,000 of compensation received per year for participating in clinical trials that research treatment of a rare disease or condition.

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MPG Letter #753 (05/12)

### B. Clinical Trial Exclusion Criteria

Clinical trials will have to meet the following criteria in order to be excluded:

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1	Approved by an Institutional Review Board (IRB).
2	Involve research and testing.
3	Target a rare disease or condition.

To determine that payments meet the criteria workers must:

Step	Action						
1	Obtain the following: <ul style="list-style-type: none"> <li>• the informed consent form; or</li> <li>• an official letter from the administrator of the clinical trial, with the following information:               <ul style="list-style-type: none"> <li>– name and location of the clinical trial</li> <li>– name of disease or condition</li> <li>– name, phone, and address of the clinical trial administrator</li> </ul> </li> </ul>						
2	Use the information provided to determine if the clinical trial is IRB approved. Make this determination by locating the clinical trial in <a href="http://Clinicaltrials.gov">Clinicaltrials.gov</a> or <a href="#">results database</a> . <table border="1" style="margin-top: 10px;"> <thead> <tr> <th>If ...</th> <th>Then ...</th> </tr> </thead> <tbody> <tr> <td>yes</td> <td>go to step 3</td> </tr> <tr> <td>no</td> <td>the resource exclusion does not apply</td> </tr> </tbody> </table>	If ...	Then ...	yes	go to step 3	no	the resource exclusion does not apply
If ...	Then ...						
yes	go to step 3						
no	the resource exclusion does not apply						
3	Look for the following details in the clinical trial information: <ul style="list-style-type: none"> <li>• type of clinical trial, which is usually listed under the primary purpose, the title, or stated in the purpose summary; and</li> <li>• name of the condition.</li> </ul> <p>Use the information collected above to determine if the</p>						

	clinical trial involves research and testing.	
	<b>If ...</b>	<b>Then ...</b>
	yes	go to step 4
	no	the resource exclusion does not apply
4	Verify whether the clinical trial targets a rare disease or condition as outlined in <a href="#">MPG 9.6.41c</a> .	
	<b>If ...</b>	<b>Then ...</b>
	yes	the resource exclusion applies
	no	the resource exclusion does not apply

MPG Letter #753 (05/12)

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Rare Disease  
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Some commonly known rare diseases are:

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MPG Letter #753 (05/12)

**D.  
Entering  
Clinical Trial  
Resource in  
CalWIN**

The first \$2000 of excluded Clinical Trial resource will be entered in CalWIN as follows:

ACWDL  
12-07

<b>If case consist of...</b>	<b>Then the resource will be...</b>
CalWORKs	entered in CalWIN as appropriate for CalWORKs
CalFresh & Medi-Cal Combo/ Medi-Cal Only	excluded from CalWIN entries by subtracting the first \$2,000 from the resource value and manually calculating the net countable resource amount

MPG Letter #753 (05/12)

