



## **320-B AHCCCS MEMBER PARTICIPATION IN EXPERIMENTAL TREATMENT**

REVISION DATES: 07/01/12, 03/01/09, 06/01/07, 07/01/04, 10/01/01

INITIAL

EFFECTIVE DATE: 10/01/1994

### **DESCRIPTION**

AHCCCS members who are enrolled with a Contractor, or are receiving services on a Fee-For-Service (FFS) basis, may participate in experimental treatment, but AHCCCS will not reimburse for the experimental treatment.

### **AMOUNT, DURATION AND SCOPE**

If the experimental treatment provided to an AHCCCS member requires laboratory tests, imaging services, inpatient services, or other medical services that would not otherwise be required for non-experimental treatments provided to the member, AHCCCS will not cover the additional services. Coverage of care associated with complications resulting from the experimental treatment will be considered on an individual basis. Participation in experimental treatment will not result in the loss of the member's other benefits.

The member's primary care provider must not have any financial interest in the experimental treatment and cannot accept a finder's fee for referral of a member to participate in the experiment.

Any individual expected to assess the appropriateness of services for the member cannot have a financial interest in conducting the experimental treatment, or its outcome.

Participation in a U.S. Food and Drug Administration Phase I or Phase II clinical trial must be approved by the member's Contractor, or by the AHCCCS Chief Medical Officer. If a Contractor approves participation of one or more members in an experimental trial, it must provide notice to AHCCCS/Division of Health Care Management (DHCM), Medical Management Unit, which includes assurance that the member's rights are protected. FFS member participation will be evaluated for approval by the AHCCCS Medical Director. The basis for approval will include:

1. Verification that full financial liability for the experimental treatment is taken by the researcher or the sponsor, and documentation indicates that the costs associated with the experimental treatment and direct complications will not be charged to, or paid by, AHCCCS



2. The experimental treatment regimen is well designed, and adequate protection of the member's welfare is assured. The trial provides adequate participant information, assures participant consent, and
3. AHCCCS Contractor employees or network providers cannot receive fees, finder's fees or other payment for referring members.