

320-B - MEMBER PARTICIPATION IN EXPERIMENTAL SERVICES

EFFECTIVE DATES: 10/01/94, 10/01/18

REVISION DATES: 10/01/01, 07/01/04, 06/01/07, 03/01/09, 07/01/12, 09/20/18

I. PURPOSE

This Policy applies to AHCCCS Complete Care (ACC), ALTCS E/PD, DCS/CMDP (CMDP), DES/DDD (DDD), and RBHA Contractors; Fee-For-Service (FFS) Programs as delineated within this Policy including: Tribal ALTCS, TRBHA, the American Indian Health Program (AIHP); and all FFS populations, excluding Federal Emergency Services (FES). (For FES, see AMPM Chapter 1100). AHCCCS does not cover Experimental Services; however, this Policy establishes requirements regarding Member Participation in Experimental Service.

II. DEFINITIONS**EXPERIMENTAL SERVICES**

A service which is not generally and widely accepted as a standard of care in the practice of medicine in the United States and is not a safe and effective treatment for the condition for which it is intended or used as specified in A.A.C. R9-22-203.

FOOD AND DRUG ADMINISTRATION (FDA)

A federal agency of the United States Department of Health and Human which is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics and products that emit radiation.

III. POLICY

Members who are enrolled with a Contractor or who are receiving services on a FFS basis may participate in experimental service; however, AHCCCS will not reimburse for the experimental service as per A.A.C. R9-22-203.

If the experimental service provided to a member requires laboratory tests, imaging services, inpatient services, or other medical services, that would not otherwise be required for non-experimental services provided to the member, AHCCCS will not cover these additional services.

Coverage of care associated with complications resulting from an experimental service will be considered on an individual basis by the Contractor or AHCCCS DFSM for FFS. Participation in experimental service will not result in the loss of the member's other AHCCCS benefits.

Member or FFS member participation in a FDA Phase I or Phase II clinical trial shall be approved by the member's Contractor or by the AHCCCS Chief Medical Officer or

designee. If a Contractor approves participation of one or more members in an experimental trial, the Contractor shall provide notice to AHCCCS DHCM, Medical Management Unit, which includes assurance that the member's rights are protected. The basis for consideration will include:

1. Verification that full financial liability for the Experimental Services are taken by the researcher or the sponsor, and documentation indicating that the associated experimental service and any direct complications will not be charged to, or paid by, AHCCCS.
2. The experimental service regimen is well designed and adequate protection of the member's welfare is assured. The trial provides adequate participant information, assures participant consent.
3. Contractor employees and/or providers cannot receive fees, finder's fees or other payment for referring members for experimental service. The member's primary care provider shall not have any financial interest in the experimental service and cannot accept a finder's fee for referral of a member to participate in the experimental service.