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BULLETIN

To: **Health Maintenance Organizations Operating in Maryland**

Re: **Clinical Trials Mandate--§15-827, Insurance Article**

Date: **March 25, 2005**

Bulletin: **Life and Health # 05-4**

The purpose of this bulletin is to notify Health Maintenance Organizations (HMOs) operating in Maryland of a recent problem that has been observed in the administration of the clinical trials mandate found in the Insurance Article, §15-827, Annotated Code of Maryland.

The MIA has investigated several complaints where an HMO has denied authorization for a covered member to participate in a clinical trial because the services were being provided by a provider who was not participating with the HMO or because the service was provided outside of the HMO's service area.

An HMO may not deny the "patient costs" the HMO member incurs when the member is receiving care in a clinical trial on the basis that the HMO does not have a contract with the entity participating in the clinical trial or on the basis the benefits are being provided outside the HMO's service area.

Specifically, an HMO must cover the "patient costs" as defined in §15-827(a)(7) of the Insurance Article when all of the following are satisfied, even if the care is received outside the HMO's service area or from a non-HMO provider:

1. The member is participating in a clinical trial for cancer or for a life-threatening condition as described in §15-827(e)(1);

2. The treatment is being provided in a clinical trial approved by:
    a. one of the National Institutes of Health;
    b. an NIH cooperative group or an NIH center;
    c. the FDA in the form of an investigational new drug application;
    d. the federal Department of Veterans Affairs; or

e. an institutional review board of an institution in the State which has a multiple project assurance contract approved by the Office of Protection from Research Risks of the National Institutes of Health;

3. The facility and personnel providing the treatment are capable of doing so by virtue of their experience, training, and volume of patients treated to maintain expertise;
4. There is no clearly superior, noninvestigational treatment alternative; and
5. The available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as effective as the noninvestigational alternative.

Contract Review

As the Maryland Insurance Administration reviews HMO contracts for compliance with §15-827 of the Insurance Article, we will be looking for the following:

- For closed panel HMO contracts, i.e. those that limit benefits to those provided only by HMO providers within the service area, the contract must indicate that the service area and network restrictions will not apply to the clinical trial benefit.

- For HMO contracts that permit members to receive benefits from both in-network and out-of-network providers, but which require that non-emergency and non-urgent care be provided in the service area, the contract must indicate that the service area requirements will not be applied to the clinical trial benefit.

Any questions about this bulletin should be directed to the Life/Health Section of the Maryland Insurance Administration at 410-468-2170.

signature on original

Howard Max
Associate Commissioner