

**59G-1.036 Clinical Trials.**

(1) This rule applies to any person or entity prescribing or reviewing a request for Florida Medicaid covered services and to all providers of Florida Medicaid covered services who are enrolled in or registered with the Florida Medicaid program.

(2) Definitions. Clinical Trials – Biomedical or behavioral research studies on human participants designed to answer specific questions about biomedical or behavioral interventions, including new treatments and known interventions that warrant further study and comparison.

(3) Coverage. Florida Medicaid reimburses for services as a result of a recipient participating in a clinical trial in accordance with the service-specific coverage policy when the services:

- (a) Are covered under the Florida Medicaid program.
- (b) Would otherwise be provided to a recipient who is not participating in a clinical trial.
- (c) Are related to complications or side effects arising during the clinical trial.
- (d) Are not expected or unique to the experimental or investigational treatment.
- (e) Are not covered by the clinical trial sponsor.

*Rulemaking Authority 409.919 FS. Law Implemented 409.902, 409.905, 409.906, 409.907, 409.908, 409.912, 409.913 FS. History—New 4-4-16.*