L800

(Rev. 210; Issued:02-03-23; Effective:02-03-23; Implementation:02-03-23)

§418.116(b) Standard: Laboratory services.

(1) If the hospice engages in laboratory testing other than assisting a patient in self-administering a test with an appliance that has been approved for that purpose by the FDA, the hospice must be in compliance with all applicable requirements of part 493 of this chapter.

Interpretive Guidelines §418.116(b)(1)

Hospices holding a certificate of waiver are limited to performing only those tests determined to be in the waived category. Some tests that a hospice may perform that fall into the waived category include:

- Dipstick/tablet reagent urinalysis;
- Blood glucose by glucose monitoring devices cleared by the Food and Drug Administration (FDA) specifically for home use;
- Some prothrombin time tests; and
- Some glycosylated hemoglobin tests.

For a complete listing of waived tests, refer to CMS' website at http://www.cms.hhs.gov/CLIA/10_Categorization_of_Tests.asp#TopOfPage

Hospices holding a certificate for provider-performed microscopy procedures are limited to performing only those tests determined to be in the provider-performed microscopy procedure category or in combination with waived tests.

The tests in the provider-performed microscopy procedures category (e.g., wet mounts, urine sediment examinations, and nasal smears for granulocytes) are not typical of those performed in a hospice. However, if they are conducted by hospice staff under a certificate for provider-performed microscopy procedures, they must be performed by a practitioner as specified at §493.19 (i.e., a physician, nurse midwife, nurse practitioner,

physician assistant, or dentist). If not performed by these personnel, the hospice would require a registration certificate (which allows the performance of such testing until a determination of compliance is made), certificate of accreditation, or certificate of compliance.

For a complete listing of provider-performed microscopy procedures, refer to CMS' website at http://www.cms.hhs.gov/CLIA/10_Categorization_of_Tests.asp#TopOfPage

A registration certificate, a certificate of accreditation, or a certificate of compliance is required if the hospice performs any other testing procedures, (i.e., moderate or high complexity testing). While some prothrombin testing is in the waived category, as mentioned above, other prothrombin testing is considered moderate complexity testing depending on the skill level required to operate the instrument.

For a complete listing of moderate and high complexity tests, refer to CMS' website at http://www.cms.hhs.gov/CLIA/10_Categorization_of_Tests.asp#TopOfPage

Assisting individuals in administering their own tests, such as fingerstick blood glucose or prothrombin testing, is not considered testing subject to the CLIA regulations. However, if the hospice staff is actually responsible for measuring the blood glucose level or prothrombin times of patients with an FDA-approved blood glucose or prothrombin time monitor, and no other tests are being performed, request to see the facility's certificate of waiver, since glucose testing with a blood glucose meter (approved by the FDA specifically for home use) and some prothrombin time tests are waived tests under the provisions at 42 CFR 493.15.