

L801

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

§418.116(b)(2) - If the hospice chooses to refer specimens for laboratory testing to a reference laboratory, the reference laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of Part 493 of this chapter.

Interpretive Guidelines §418.116(b)(2)

The hospice is required to comply with applicable State law and secure a CLIA certificate of waiver for any waived testing performed by staff. Lab specimens obtained in the patient's home must be taken to laboratories that meet CLIA and state law requirements.

The hospice should have a copy of the reference laboratory's CLIA certificate in its administrative records.