



621216

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
03/22/2011	.	
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The Committee on Health Regulation (Latvala) recommended the following:

Senate Amendment (with title amendment)

Between lines 3085 and 3086
insert:

Section 78. Subsections (1) and (9) of section 483.051, Florida Statutes, are amended to read:

483.051 Powers and duties of the agency.—The agency shall adopt rules to implement this part, which rules must include, but are not limited to, the following:

(1) LICENSING; QUALIFICATIONS.—The agency shall provide for biennial licensure of all nonwaived clinical laboratories meeting the requirements of this part and shall prescribe the



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13 qualifications necessary for such licensure, including, but not
14 limited to, an application for or proof of a certificate under
15 Clinical Laboratory Improvement Amendments of 1988. A nonwaived
16 laboratory is a laboratory that has not been granted a
17 certificate of waiver by the Centers for Medicare and Medicaid
18 Services under the Clinical Laboratory Improvement Amendments of
19 1988 and the federal rules adopted thereunder.

20 (9) ALTERNATE-SITE TESTING.—The agency, in consultation
21 with the Board of Clinical Laboratory Personnel, shall adopt, by
22 rule, the criteria for alternate-site testing to be performed
23 under the supervision of a clinical laboratory director. The
24 elements to be addressed in the rule include, but are not
25 limited to: a hospital internal needs assessment; a protocol of
26 implementation including tests to be performed and who will
27 perform the tests; criteria to be used in selecting the method
28 of testing to be used for alternate-site testing; minimum
29 training and education requirements for those who will perform
30 alternate-site testing, such as documented training, licensure,
31 certification, or other medical professional background not
32 limited to laboratory professionals; documented inservice
33 training as well as initial and ongoing competency validation;
34 an appropriate internal and external quality control protocol;
35 an internal mechanism for identifying and tracking alternate-
36 site testing by the central laboratory; and recordkeeping
37 requirements. ~~Alternate site testing locations must register~~
38 ~~when the clinical laboratory applies to renew its license.~~ For
39 purposes of this subsection, the term "alternate-site testing"
40 means any laboratory testing done under the administrative
41 control of a hospital, but performed out of the physical or



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42 administrative confines of the central laboratory.

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44 ===== T I T L E A M E N D M E N T =====

45 And the title is amended as follows:

46 Delete line 249

47 and insert:

48 testing of employees and job applicants; amending s.
49 483.051, F.S.; requiring the Agency for Health Care
50 Administration to provide for biennial licensure of
51 all nonwaived laboratories that meet certain
52 requirements; requiring the agency to prescribe
53 qualifications for such licensure; defining nonwaived
54 laboratories as laboratories that do not have a
55 certificate of waiver from the Centers for Medicare
56 and Medicaid Services; deleting requirements for the
57 registration of an alternate site testing location
58 when the clinical laboratory applies to renew its
59 license; amending s.