

## Assembly Bill No. 2757

### CHAPTER 795

An act to add Sections 1241.1 and 1265.1 to the Business and Professions Code, and to add Section 14115.41 to the Welfare and Institutions Code, relating to clinical laboratories.

[Approved by Governor September 29, 2006. Filed with Secretary of State September 29, 2006.]

#### LEGISLATIVE COUNSEL'S DIGEST

AB 2757, Evans. Primary care clinics.

Existing law provides for the licensure and regulation of clinical laboratories and of primary care clinics by the State Department of Health Services. Under existing law, the department is required to approve a licensure application submitted by a primary care clinic meeting specified criteria for its affiliate clinic if, among other matters, both have the same corporate officers and are owned and operated by the same nonprofit organization with the same board of directors.

This bill would authorize a primary care clinic that submits an application for license with the department to, prior to, or concurrent therewith, also apply for licensure or registration of a clinical laboratory that would be operated by the primary care clinic. This bill would permit a primary care clinic that is operating within a network of primary care clinics, as defined, to be issued a license to operate a clinical laboratory pursuant to those provisions, which authorizes the conduct of clinical laboratory tests and examinations from its network of primary care clinics if specified conditions are met.

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Services and under which qualified low-income persons receive health care benefits.

Existing law generally regulates the reimbursement of providers for Medi-Cal program services.

This bill would provide that for services that are performed at a central laboratory pursuant to the above provisions, the department shall provide Medi-Cal reimbursement directly to the laboratory performing the services and submitting the claim for reimbursement. The bill would prohibit the department from denying payment to a laboratory created pursuant to provisions of the bill if the clinic and the laboratory are owned and operated by the same nonprofit corporation, and the laboratory services are performed on a specimen collected at the clinic for a clinic patient.

The bill would authorize the department to implement utilization controls or other cost-control measures to ensure that medically necessary services are appropriately rendered.

This bill would, until June 30, 2007, also authorize a licensed primary care clinic that is affiliated with a network of primary care clinics to submit to the Medi-Cal program claims for laboratory services until such time that the primary care clinic receives a provider number for the central laboratory if specified requirements are met.

*The people of the State of California do enact as follows:*

SECTION 1. Section 1241.1 is added to the Business and Professions Code, to read:

1241.1. (a) A primary care clinic, licensed pursuant to subdivision (a) of Section 1204 of the Health and Safety Code, that is operating within a network of primary care clinics, may be issued a license to operate a clinical laboratory pursuant to Section 1265, which authorizes the conduct of clinical laboratory tests and examinations from its network of primary care clinics, if all of the following conditions are met:

(1) The central laboratory's sole purpose is performing moderate or high complexity clinical laboratory tests and examinations, or both, for the patients of the clinics in the network.

(2) Prior to performing any tests or examinations, the central laboratory obtains a certificate under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) (CLIA) and a state laboratory license for the appropriate complexity level of clinical laboratory testing pursuant to Section 1265.

(b) For purposes of this section, "network of primary care clinics" means two or more primary care clinics operated by the same nonprofit corporation with the same board of directors and the same corporate officers, and operating under the same procedures and protocols.

SEC. 2. Section 1265.1 is added to the Business and Professions Code, to read:

1265.1. (a) A primary care clinic that submits an application to the State Department of Health Services for clinic licensure pursuant to subdivision (a) of Section 1204 of the Health and Safety Code may submit prior to, or concurrent therewith, an application for licensure or registration of a clinical laboratory to be operated by the clinic.

(b) An application for licensure of a clinical laboratory submitted pursuant to this section shall be subject to all applicable laboratory licensing laws and regulations, including, but not limited to, any statutory or regulatory timelines and processes for review of a clinical laboratory application.

SEC. 3. Section 14115.41 is added to the Welfare and Institutions Code, to read:

14115.41. (a) For services that are performed at a central laboratory as authorized pursuant to Section 1241.1 of the Business and Professions Code, the department shall provide reimbursement directly to the laboratory performing the services and submitting the claim for

reimbursement. Nothing in this section shall prohibit a primary care clinic network that utilizes centralized billing from submitting claims on the behalf of the network's central laboratory, if the claims are submitted with the central laboratory's provider number. The department shall not deny payment to a laboratory created pursuant to Section 1241.1 of the Business and Professions Code, for either of the following reasons:

(1) The clinic and the licensed central laboratory performing the services are owned and operated by the same nonprofit corporation with the same board of directors and the same corporate officers.

(2) The laboratory services are performed on a specimen collected at the clinic for a clinic patient.

(b) Nothing in this section shall be construed to allow a primary care clinic to submit a separate claim for central laboratory services currently reimbursed under the Medi-Cal program, utilizing the primary care clinic's provider number.

(c) The department may implement utilization controls or other cost-control measures to ensure that medically necessary services are appropriately rendered.

(d) (1) A primary care clinic licensed pursuant to subdivision (a) of Section 1204 of the Health and Safety Code that is affiliated with a network of primary care clinics may continue to submit claims for the laboratory services provided until such time that the primary care clinic receives a provider number for the central laboratory pursuant to this section, if all of the following requirements are met:

(A) The network of primary care clinics is operated by the same nonprofit corporation with the same board of directors and corporate officers.

(B) The primary care clinic operates under the same procedures and protocols as the affiliated clinics in the network, and the laboratory holds a valid Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) (CLIA) certificate and state laboratory license to perform moderate and high complexity laboratory services.

(C) The of primary care clinic has been providing laboratory testing services for the patients of the primary care clinic within the clinic network prior to August 1, 2006, and has been authorized by Medi-Cal to submit claims for those services.

(2) This subdivision shall remain operative until June 30, 2007.