

MORATORIUM ON THE ENROLLMENT OF CLINICAL LABORATORY PROVIDERS

October 2014

In accordance with Section 14043.55 of the California Welfare and Institutions Code, I, Toby Douglas, Director of the Department of Health Care Services (DHCS), Health and Human Services Agency, State of California, am implementing a 180-day state-wide moratorium, with exceptions as stated below, (1) on the enrollment of all clinical laboratories in the Medi-Cal program and (2) on the change or expansion of provider of service categories by a clinical laboratory provider that was allowed to enroll in the Medi-Cal program after March 2001. Any provider of service that enrolls subject to an exemption stated below shall be enrolled for a provider of service category defined by the specific laboratory specialty codes that the Medi-Cal program approves for that provider as part of the enrollment in question. Enrollment subject to an exemption does not include the authorization to add or expand provider of service categories by the change or addition of specialty codes, or to expand to serve beneficiaries outside any beneficiary group listed in the exemption, unless the exemption specifically states otherwise, except that such addition or expansion shall be allowed if it independently qualifies for an exemption at the time of the change or addition. Upon my approval of this moratorium, the clinical laboratory moratorium dated April 4, 2014, will be abolished and replaced by this new moratorium. This new moratorium will expire on April 6, 2015.

This moratorium does not apply to:

1. A clinical laboratory owned and operated by a physician or physician group so long as the physician or physician group only performs Provider-Performed Microscopy Procedures (PPMP) and/or waived clinical laboratory tests or examinations;
2. Current Medi-Cal enrolled clinical laboratory providers that have at least six actively enrolled locations, and seek to add a new business location, so long as the provider does not add new business activities, categories of service or billing codes other than those approved for enrollment at its existing locations; this exemption is only applicable to clinical laboratory providers who meet this criteria and all six locations have been continuously and actively enrolled and in good standing with Medi-Cal from February 12, 2007, through the date of application;
3. A clinical laboratory that is owned and operated by a general acute care hospital or psychiatric hospital licensed pursuant to Health and Safety Code Section 1250, et seq.;
4. A clinical laboratory that is owned and operated by a clinic licensed pursuant to Health and Safety Code Section 1200, et seq.;
5. A public health laboratory as defined in Business and Professions Code Section 1206(a) and certified pursuant to Health and Safety Code Section 101160;
6. The purchase of an existing clinical laboratory that is currently enrolled in the Medi-Cal program as a clinical laboratory, whether it constitutes a change of ownership or not; unless it is being sold by a laboratory provider who has expanded its location(s) and/or services under Exemption #13;

7. An out-of-state clinical laboratory requesting enrollment for the sole purpose of providing services to a Medi-Cal beneficiary on an emergency basis in accordance with the California Code of Regulations, Title 22, Section 51006;
8. The change of location of an existing clinical laboratory that is currently enrolled in the Medi-Cal program as a clinical laboratory, so long as it neither constitutes a change of ownership nor involves the change or addition of specialty codes;
9. A clinical laboratory that only seeks reimbursement for Medicare-cost sharing amounts;
10. Currently enrolled clinical laboratory providers that DHCS requires to submit an application for continued enrollment pursuant to California Code of Regulations, Title 22, Section 51000.55;
11. A clinical laboratory that performs a test or examination that is a Medi-Cal covered benefit and, the clinical laboratory is the only Clinical Laboratory Improvement Amendments (CLIA) approved clinical laboratory in the United States to perform that test or examination;
12. Applicants whose sole business is, and continues to be throughout the existence of this moratorium, a clinical laboratory performing only anatomic pathology services that are also Medi-Cal covered benefits, and the clinical laboratory has a laboratory director certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology;
13. A clinical laboratory that is owned and operated by a professional medical corporation or partnership of professional medical corporations, comprised of physicians that are certified by the American Board of Pathology or the American

Osteopathic Board of Pathology in clinical or anatomic pathology, who can provide evidence of a current contract to provide pathology services at a licensed and Medi-Cal certified acute care hospital in California, that currently is enrolled as a clinical laboratory provider and seeks approval for an additional location that will also perform clinical laboratory services, whether anatomic or clinical pathology services, and/or seeks to add new business activities, categories of service or billing codes other than those approved at its initial enrollment at its current business location. Exemption #13 only applies to those clinical lab providers who remain under the same common ownership and directorship, as defined above, for all of their business locations, throughout the period of this Moratorium.

14. A clinical laboratory that performs a test or examination that is a Medi-Cal covered benefit and, as of the date of application denial or approval, no Medi-Cal provider offers a test or examination that fills the same functional role. Multiple applications from providers asserting this exception will be granted or denied in the order they were submitted.
15. A clinical laboratory, licensed by the California Department of Public Health as a clinical laboratory, that will be providing services exclusively to California Medi-Cal beneficiaries placed through the Interstate Compact Placement of Children program (ICPC) in an out-of-state residential care facility approved by the California Department of Social Services, and for whom the residential care facility has provided a "letter of certification" that the facility is using the laboratory to provide services for ICPC placed Medi-Cal beneficiaries.

16. A CLIA- approved California Department of Public Health licensed clinical laboratory that, as of the date of the application, performs a test or examination that is not performed or available through an existing Medi-Cal provider.
Reimbursement shall be limited to the tests and examinations that form the basis of this exemption and that have been prior authorized by the Department.

This action is necessary to safeguard public funds and to maintain the fiscal integrity of the program.

Original Signed By Toby Douglas

Toby Douglas
Director
Department of Health Care Services
Health and Human Services Agency
State of California

10/8/14
Date