

## **Discontinuation of the Moratorium on the Enrollment of Clinical Laboratory Providers**

The Department of Health Care Services (DHCS) will not extend the moratorium on the enrollment of clinical laboratory providers after the moratorium expires on October 3, 2015. This bulletin provides information for clinical laboratory applicants applying for enrollment in the Medi-Cal Fee-For-Service Program during the six-month period following the expiration of the moratorium.

State Medicaid Agencies are required to collect fingerprints and conduct criminal background checks from applicants or providers screened at the “high” categorical risk level. (Title 42, Code of Federal Regulations [CFR] §§ 424.518, 455.434, and 455.450)

Title 42, CFR, Section 455.450(e)(2) and Welfare and Institutions Code (W&I), Section 14043.38(b)(4) specify that a provider that would have been prevented from applying for enrollment due to a moratorium that has been lifted in the past six months, be screened at the “high” categorical risk level.

A “high” risk screening requires a provider or applicant to submit proof that fingerprints for all the required individuals have been submitted to an authorized State Identification Bureau (Bureau of Criminal Information and Analysis, Department of Justice [DOJ] in California). Providers and applicants must attach a copy of a prefilled DOJ *Request for Live Scan Service* (BCIA 8016) form for each required individual with their application, date stamped and show verification that all fees have been paid by either a “PAID” stamp from the public Live Scan operator or a receipt of payment.

For more detailed information on which individuals are required to submit fingerprints, please review the ["Medi-Cal Requirement to Submit Fingerprints for a Criminal Background Check"](#) provider bulletin.

If you would have met one of the exemptions listed below, you do not need to be screened as “high” risk but you must submit a cover letter with your application advising which exemption you meet and include any necessary supporting documentation.

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 are 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 their 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, that is 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 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.

If the Department determines that you do not meet an exemption or if you do not want to go through an exemption review, you are required to be screened at the “high” categorical risk level and submit fingerprints for a criminal background check.

Failure to submit fingerprints for a criminal background check when required will result in the denial of the application package.(42 CFR § 455.416; W&I Code § 14043.26[f][4][E])

Additional information about the Medi-Cal requirements for submitting fingerprints is available in the [“Medi-Cal Requirement to Submit Fingerprints for a Criminal Background Check”](#) provider bulletin.

If you have any additional questions, please contact the Provider Enrollment Message Center at (916) 323-1945 or submit your question via e-mail at [PEDCorr@dhcs.ca.gov](mailto:PEDCorr@dhcs.ca.gov).

## **MORATORIUM ON THE ENROLLMENT OF CLINICAL LABORATORY PROVIDERS**

**April 2015**

In accordance with Section 14043.55 of the California Welfare and Institutions Code, I, Jennifer Kent, 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 October 8, 2014, will be abolished and replaced by this new moratorium. This new moratorium will expire on October 3, 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 Jennifer Kent**

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Jennifer Kent  
Director  
Department of Health Care Services  
Health and Human Services Agency  
State of California

4/1/15  
Date