

2015 Executive War College



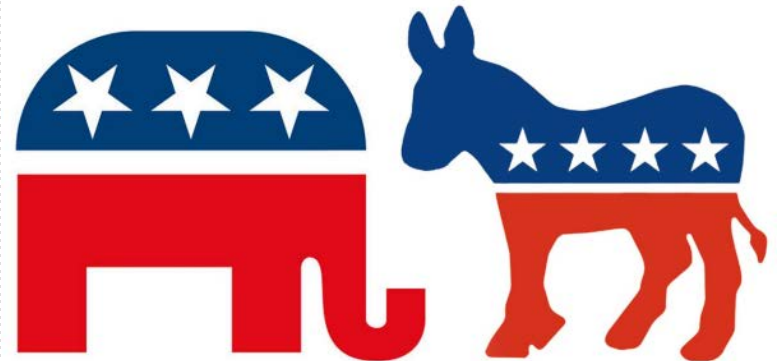
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Greetings from California

- ❑ The land of the fruits and nuts!
 - ❑ So leap for joy,
 - ❑ Be blithe and gay;
 - ❑ Or weep my friends with sorrow;
 - ❑ What California is today,
 - ❑ The rest will be tomorrow!
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Republican Voter Registration Continues to Erode in California

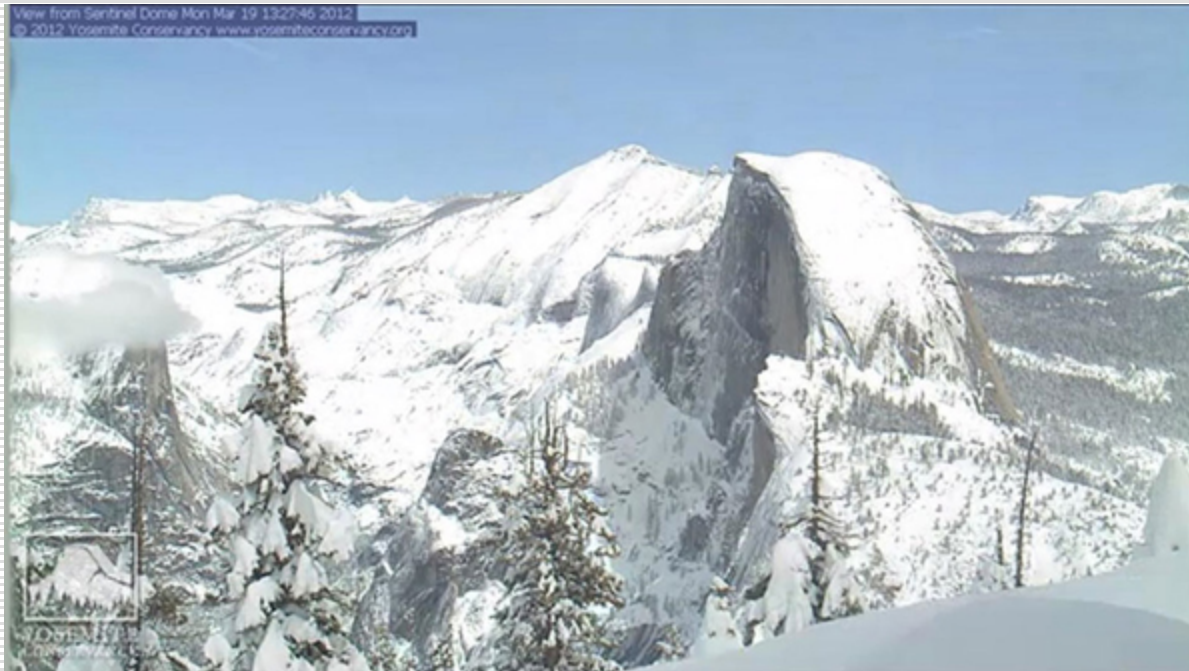
- Democrat: 43.15%
- Republican: 27.98%
- No Party Preference: 23.57%



Five pictures of Yosemite's Half Dome capture California's historic drought

- California is currently experiencing a severe drought.
- Photos from Phillip Reese, The Sacramento Bee March 24, 2015

March 19, 2012 - First Year of Drought



March 19, 2013 - Second Year of Drought



March 17, 2014 - Third Year of Drought



March 19, 2015 - Fourth Year of Drought



California Trends

- ❑ Reducing Medicaid lab reimbursement rates
 - ❑ More Medicaid enrollees. Now 12+ million! 30% of state's population! Budget: \$89 Billion.
 - ❑ New lab reimbursement methodology. Not good!
 - ❑ Moving patients to managed care
 - ❑ Covering more patients under the State Exchange—"Covered California"
 - ❑ "Personalized medicine" labs based in CA are upset with Medicare pricing and coverage decisions being made by the MACs through the LCD process
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Medi-Cal Lab Cuts—New Rate Development Methodology

- ❑ California lab rates for the Medi-Cal program are capped: **no more than 80%** of Medicare rates
 - ❑ Cut by 10% in 2011 and an additional 10% in 2012 (CMS has stopped the second 10% cut for now)
 - ❑ Department of Health Care Services is working on a new rate development methodology. When the new rates are complete, they will replace the old rates.
 - ❑ Bad news for labs. Even though based upon lowest rates for all payers
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AB (940 Ridley-Thomas and Waldron)

- Allows a licensed Bioanalyst with a Master's Degree to serve as an additional laboratory director in a laboratory performing high complexity testing as long as there is also a laboratory director meeting the requirements of the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA). State law permits laboratories to have more than one laboratory director.
- Allows an applicant for a bioanalyst license to obtain the required experience in any clinical laboratory certified under CLIA, rather than only a laboratory approved by the Department of Public Health. In other words, the change will allow an applicant for a bioanalyst license to obtain the required experience in an out of state CLIA-approved laboratory.
- Authorizes the Department of Public Health to issue limited clinical laboratory scientist licenses in the following additional two licensure categories: reproductive biology and biochemical genetics.

AB 940 (Ridley-Thomas and Waldron) Continued

- ❑ Requires the Department of Public Health to issue a license for the following new categories where an application is properly submitted pursuant to department requirements: clinical reproductive biologist and clinical biochemical geneticist.
 - ❑ Allows persons licensed as clinical reproductive biologists or clinical biochemical geneticists to serve as laboratory directors in clinical laboratories limited to those specialties.
 - ❑ Allows the Department to charge a fee for licensure and license renewal for the following new categories of licensure: clinical reproductive biologist and clinical biochemical geneticist. Corrects existing law to allow a renewal fee for existing licensure categories of clinical cytogeneticist and clinical molecular biologist.
 - ❑ Requires the Department to issue a clinical laboratory scientist trainee license to individuals meeting Department requirements and seeking to become a clinical reproductive biologist scientist or a clinical biochemical geneticist scientist.
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AB 366 (Bonta) and SB 243 (Hernandez)

“Existing law requires, except as otherwise provided, Medi-Cal provider **payments** and payments for specified non-Medi-Cal programs to be reduced by 10% for dates of service on and after June 1, 2011.

These bills would restore the 10% cut for most providers. This would solve one problem we have with the new rate methodology—adding the 10% rate cut on to whatever average lowest price they determine.

ACA Implementation

- ❑ CA Exchange: Covered California
 - ❑ Operational January, 2014
 - ❑ “Qualified Plans” sell coverage through Covered CA with no pre-X exclusion
 - ❑ 2.6 million Californians qualify for discounts on their health coverage through Covered California
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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

CALIFORNIA CLINICAL
LABORATORY ASSOCIATION
1127 Eleventh Street, Suite 820
Sacramento, CA 95814, and

JANE DOE,

Plaintiffs,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,
200 Independence Avenue, SW
Washington, DC 20201,

Defendant.

COMPLAINT

COME NOW Plaintiffs California Clinical Laboratory Association (“CCLA”) and Jane Doe (collectively, “Plaintiffs”), by and through their attorneys Hooper, Lundy & Bookman, P.C., who bring this action against Defendant Secretary of Health and Human Services (“Secretary”), alleging as follows:

Does the SGR Act make the law suit less necessary?

"No." Congress is continuing to delegate authority directly to MACs to make LCDs. The LCD process, is not remedied by the new legislation. For example, the new law does not expand the criteria that MACs are limited to in determining LCD policy and does not excuse the MACs from the requirement to promulgate new coverage policy through the rulemaking requirements of the Administrative Procedure Act

The complaint, filed in federal district court in the District of Columbia, asserts

- ❑ Congress has unlawfully delegated regulatory power to the MACs
 - ❑ The MACs have implemented Medicare policy without following required federal rulemaking requirements
 - ❑ MACs have developed LCDs based on criteria they are not permitted to consider
 - ❑ HHS has eliminated any meaningful opportunity for laboratories to administratively appeal the application of LCDs and has not established a required mediation process
 - ❑ HHS has not developed an effective plan to evaluate the appropriateness of adopting new LCDs nationally, as noted recently by the Office of Inspector General
 - ❑ Bottom line: the MACs have virtually ignored input from the laboratory community in connection with the promulgation of LCDs. The CCLA Board felt that we were left with no other choice than to file suit.
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**CALIFORNIA
CLINICAL
LABORATORY
ASSOCIATION**

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FOR IMMEDIATE RELEASE, April 16, 2014
CONTACT: Michael Arnold, Executive Director

California Clinical Laboratory Association Files Suit To Prevent Medicare from Denying Coverage for Vital Laboratory Tests Needed by Medicare Patients

(Sacramento, CA) – The national law firm of Hooper, Lundy & Bookman, PC, today filed a complaint on behalf of the California Clinical Laboratory Association (CCLA) and a Medicare beneficiary against the U.S. Department of Health & Human Services, charging that Medicare Administrative Contractors (MACs) continue to develop and apply Local Coverage Determinations (LCDs) that result in policies depriving Medicare beneficiaries throughout the country of critical clinical laboratory tests.

Legislative Status Report

- Periodic listing of all bills being followed by the CCLA.
 - Shows bill, author, summary, location, hearing date, etc.
 - Available to any CCLA member, anytime.
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State Level Lab Issues 1

- Reimbursement from Public Programs
 - Frequency Limits
 - Staffing requirements and standards
 - Licensure regulations and fees
 - Moratorium on new lab provider numbers
 - Contracting for lab services
 - Operational issues - e.g. autoverification, use of personnel
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State Level Lab Issues 2

- ❑ Anti-mark up/direct billing legislation
 - ❑ Direct access testing for any test sold OTC—other tests
 - ❑ Safe needle mandate
 - ❑ Phlebotomy certification
 - ❑ Specimen lock box mandates
 - ❑ Cap on number of tests which may be provided to patients
 - ❑ Medicaid Lowest Price requirement
 - ❑ MoIDx Pricing
 - ❑ New Medi-Cal Rate Development Methodology
 - ❑ Etc., etc., etc....
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Thank you very much!





CALIFORNIA REPUBLIC

