ALERT – LEGISLATIVE ALERT

CALL FOR LETTERS TO THE GOVERNOR

VETO SB 1481

Deadline is Friday, September 28th
Fax to 916-558-3177

SB 1481 (Negrete McLeod) as amended 8/20/12, will allow pharmacists at a community pharmacy to perform waived over-the-counter (OTC) tests for blood glucose, hemoglobin A1c and cholesterol testing upon a customer request provided the pharmacy:

1. Obtains a valid CLIA certificate of waiver and complies with all other requirements for the performance of waived clinical laboratory tests under applicable federal law.
2. Obtains a registration from the California Department of Health pursuant to Section 1265 and complies with all laws in Chapter 3.
3. Tests are performed only by a pharmacist as defined in BPC Section 4036.

Section 1265 (k) was added and says that in the case of a pharmacy applying for a registration the “laboratory director” means the pharmacist-in-charge, as defined in Section 4036.5, who is responsible for directing and supervising testing oversight and decision making.

REASONS WHY THE GOVERNOR SHOULD VETO THIS BILL

*note CAMLT’s and PPA’s formal veto request is posted at the end. DO NOT COPY.

- Why do pharmacists need to do testing? What will the pharmacist do with the result? Medication and treatment adjustments are the physician’s role.
- How are the pharmacies going to report results to the patient and to any requested physician? Licensed laboratories are reporting electronically to physician medical record systems.
- Over-the-counter tests are typically more expensive than traditional testing for the same analyte and would be repeated by the physician at a licensed laboratory for confirmation.
- California labs are already equipped to provide higher quality testing than waived methods and provide consistency in testing methodology for monitoring and reporting to physician offices.
- These tests can already be ordered (without a physician’s request) at a clinical laboratory where more accurate methods are utilized to produce accurate results that will be accepted by a physician without the need or expense of repeating them.
- Over-the-counter testing is not covered by insurance so the patient will be spending more for health care.
- Discuss potential harm to the patient if the test is done incorrectly. Even better, describe actual cases where there was harm to the patient.
WRITE A LETTER OF OPPOSITION TO THE GOVERNOR TODAY

- Letters must be professional, business-like, matter-of-fact, and courteous in tone and approach; do not rant or threaten.
- Letters must be pithy, to the point, and no more than one or two pages at the most. Do not be repetitive. Remember that you are writing to a lay person who is not in the clinical laboratory or scientific field.
- Do not copy sample letters or reasons verbatim, but develop individual letters.
- Use personal examples if you can.
- Fax your letter out no later than Friday, September 28th! The Governor only has between now and September 30 to veto this bill. If he doesn't veto it before then, it will become law with or without his signature. It is imperative that your letters get to him as far ahead of this deadline. Do not procrastinate.

FORMAT OF LETTER TO THE GOVERNOR

Date

Honorable Edmund “Jerry” G. Brown, Jr.
Governor
State of California
State Capitol, First Floor
Sacramento, CA 95814

RE: SB 1481 (Negrete McLeod) as amended 8/20/12 – OPPOSE – Veto Request

[Your OWN input as to why this bill should be vetoed.]

Sincerely,
[your signature]
Joe Smith
Your address

Fax your letter TODAY to 916-558-3177. Thank you!
September 12, 2012

Honorable Edmund E. Brown, Jr.
Governor
State of California
State Capitol, First Floor
Sacramento, CA 95814

RE: SB 1481 (Negrete McLeod) as amended 8/20/12 – OPPOSE – Veto Request

Dear Governor Brown:

As President of the California Association for Medical Laboratory Technology (CAMLT), I would like to inform you that we oppose SB 1481. CAMLT is a voluntary professional organization comprised of thousands of laboratory professionals such as licensed Clinical Laboratory Scientists (CLS), Medical Laboratory Technicians (MLT) and Certified Phlebotomy Technicians (CPT) in California. This bill would expand pharmacists’ scope of practice to include laboratory testing using FDA approved over-the-counter tests (OTC) for glucose, hemoglobin A1c and cholesterol without a laboratory director. We oppose this bill for the following reasons:

**Negative impact to the quality of testing**
In California, all clinical laboratory tests are performed under the overall operation and administration of the laboratory director, as described in Business and Professions Code, Section 1209. Since pharmacists are not qualified to be laboratory directors under California law and they are unwilling to hire a qualified laboratory director, they seek exemption from this requirement. Simply having a “pharmacist-in-charge” and obtaining a state registration from the Department of Public Health does not meet the requirement to have a qualified laboratory director as defined in BPC 1209. As a result, this bill will allow the “pharmacist-in-charge” to replace the laboratory director thus diluting existing personnel standards that may negatively affect the quality of testing with regard to glucose, hemoglobin A1c, and cholesterol tests performed at community pharmacies. Medical decisions based on erroneous test results can result in patient harm.

**Clinical laboratories can perform the same tests with greater accuracy and cost effectiveness**
Glucose, hemoglobin A1c, and cholesterol testing are self referred tests that many clinical laboratories already provide to patients upon request without a healthcare provider’s order. Clinical laboratories typically do not employ FDA approved OTC methodologies due to their high cost and lack of accuracy and reproducibility when compared to traditional laboratory methodologies. Furthermore, these self administered OTC tests are rarely covered by insurance and need to be repeated at a licensed clinical laboratory before a healthcare provider will treat—adding to the cost of health care.
Pharmacists have no interest in complying with existing laboratory law
Since January, CAMLT has worked with the author’s office and sponsors to address our concerns about the quality of testing done at community pharmacies without a laboratory director and appropriate oversight of testing activity by the Department of Public Health. We thought these discussions were productive and even wrote amendments that would remove our opposition. As a result, we did not strongly oppose this bill between January and June which resulted in no “no” votes in both houses. It was not until May 31st that the author’s office and sponsors notified us that they had rejected our amendments, would continue to seek exemption from California laboratory law and asserted that the Board of Pharmacy should provide oversight instead of the Department of Public Health.

The CAMLT premise is that if pharmacists want to perform laboratory tests, they should adhere to the same state standards as everyone else. Instead of meeting state standards that all laboratory tests be performed under the overall operation and administration of the laboratory director as specified in BPC 1209, this bill will allow a pharmacist-in-charge to serve as a laboratory director without additional clinical laboratory science education and training. Since over 80% of medical decisions are based on test results, we feel that dilution of the current state standard jeopardizes the quality of care patients receive. “Simple tests” done incorrectly will produce erroneous results that may lead to dire consequences. In a recent case involving a community medical practice, a registered nurse performed a FDA approved OTC urine pregnancy test incorrectly that misdiagnosed the patient as not pregnant. The patient then consented to a procedure that led to the death of her fetus.

We believe that the real impetus behind this bill is to sell more OTC test kits and to charge a fee to perform these test(s). Therefore, we request your veto on SB 1481.

Respectfully,

Dora W. Goto, MS, CLS, MLS(ASCP)CM
President, CAMLT

Cc: Monica Wagoner, Deputy Director, Legislative and Government Affairs, CA. Dept. of Public Health
Lark Park, Deputy Legislative Secretary, Office of the Governor
September 6, 2012

Honorable Edmund “Jerry” G. Brown, Jr.
Governor
State of California
State Capitol, First Floor
Sacramento, CA  95814

RE:  SB 1481 (Negrete McLeod) as amended 8/20/12  - OPPOSE – Veto Request

Dear Governor Brown:

Our client, the California Association for Medical Laboratory Technology (CAMLT), representing thousands of licensed Clinical Laboratory Scientists in California, opposes SB 1481. This bill would permit pharmacists to conduct three specific clinical laboratory tests which are FDA approved over the counter tests (OTC) without prescription for sale to the public. The issue is not that pharmacists be permitted to do these tests, but that pharmacists are insisting in this bill to be exempt from state and federal requirements that apply to all professions doing clinical testing, namely, to have a designated laboratory director and be responsible to the Department of Public Health.

Department of Public Health – not the Pharmacy Board should oversee clinical lab testing
In California, oversight for clinical laboratory testing is provided by the Department of Public Health, Laboratory Field Services. Simply reporting to a public health officer or registering with the Department of Public Health that a pharmacist is doing testing does not meet the requirement to have a laboratory director or be subject to the Department of Public Health Laboratory Field Services. The Board of Pharmacy oversees the profession of pharmacy, not the profession of clinical laboratory science. Pharmacists should be subjected to the same oversight as any other discipline that wants to do clinical laboratory testing. Where do consumers complain if there is no state oversight? The Board of Pharmacy that is about pharmacy but not laboratory science? The local health officer or Department of Public Health that have no jurisdiction? A consumer is paying good money to get a reliable lab result. If the consumer sees someone in a white coat, there is an implicit assumption that he has the knowledge and authority. But he is not a professional laboratorian, he is a professional pharmacist operating a laboratory within a pharmacy. Will that translate to the consumer as a potentially false sense of confidence who may not see his physician as soon as he should?

Conflicts with AB 761 before you
Another bill before you is AB 761 (Roger Hernandez) that permits optometrists to do certain waived tests. CAMLT does not oppose this bill because the optometrists are willing to comply with existing law. Pharmacy sponsors have indicated that they don't want to have a lab director, nor do they want to be designated as the lab director for these tests, unlike the optometrists. We would suggest that federal law specifically requires the designation of a lab director, as does California law. Moreover, if pharmacists want to do waived lab testing, then they should be willing to take the responsibility of being the lab director and be subject to the Department of Public Health like the optometrists. Lab directors function to ensure that the manufacturer's instructions are followed in doing the waived test.

These aren’t “simple little tests.”
The three over the counter tests, glucose, A1c, and cholesterol are not necessarily "simple" just because they are waived and available for sale to the public. Normally, persons buying these tests are already being treated by their physician for their
condition and have experience. They are working with their physicians to monitor this condition. These test kits should come with quality control (QC) requirements and manufacturer's instructions. One recent example of these "simple" tests not being so simple occurred at a major tertiary hospital emergency room in northern California at which the nurses could not figure out how to run the quality control process in order to test patient gluoses--the nurse, a health care practitioner, in a hospital setting, was unable to figure out the QC process in this OTC kit available to the public for sale or understand the manufacturer's instruction, hence punted to the laboratory personnel specifically trained in clinical laboratory testing. If a nurse whose profession is to provide direct patient care has difficulties, would not a pharmacist whose primary role is to fill prescriptions rather than provide patient care also have difficulties, particularly if there is no designated lab director to trouble shoot?

Another example occurred when a Clinical Laboratory Scientist (CLS) purchased three OTC gluometer kits for her Medical Laboratory Technician (MLT) students to practice with. The manufacturer's instructions were followed, the devices set up, the quality control functions followed. The students performed finger sticks on each other. When their gluoses were run on the three different devices, the same student had widely ranging glucose values, even though conducted in the same time proximity of fifteen minutes. None of the three students were diabetic, yet the same student was falsely classified as hypoglycemic on one device and diabetic on another device. In the case of the device that was reading too low, a diabetic not in glycemic control could be misdiagnosed as in glycemic control, and their insulin dose would not be adjusted in a timely manner.

A third recent example occurred in a San Diego pharmacy. As in the example above, a CLS teaching in an MLT training program bought three OTC test kits for his students to practice with, all with varying results. The kits did not contain the quality controls despite the manufacturer's instructions to use controls to ensure results. When the CLS took the kits to the pharmacist, he was told to take it up with the manufacturer because the pharmacy did not carry the controls in stock. Interestingly, the greatest number of violations for which CMS cites waived labs is for not following manufacturer's instructions. Why would pharmacists be any different--especially without the same State oversight that everyone else must have if doing clinical laboratory testing?

**What will pharmacists do with the results?**

We are confused about what the pharmacist intends to do with test results. Medication and treatment adjustments? That would be the physician's role. Greater access to simple, safer tests? Over the counter tests are typically more expensive than traditional lab testing for the same analyte. California labs are already equipped to provide higher quality testing than waived methods in a timely manner. Physicians are more likely to make appropriate adjustments to treatment with results from a licensed California lab than from a community pharmacy--whose results would be repeated anyway before the physician would treat. Plus, the patient is now out of pocket for the OTC kit which won't be covered by insurance.

CAMLT's opposition is not based on the fact that a pharmacist wants to do these tests, only that pharmacists want to be exempt from the oversight and lab director requirements that every other profession that does lab tests must adhere to. We would submit that the driving force behind this bill is to sell more kits rather than provide for the public good. We request your veto on SB 1481.

Sincerely,

Russell W. Noack            Kathryn C. Rees

Cc:  Monica Wagoner, Deputy Director, Legislative and Government Affairs, CA. Department of Public Health
     Lark Park, Deputy Legislative Secretary, Office of the Governor