

Dana Owen

From: Thomas Obermeyer
Sent: Thursday, April 05, 2012 10:27 AM
To: Dana Owen
Subject: FW: SB 166 documents

Thomas S. Obermeyer, MO Attorney, M.B.A.
Office of Alaska State Senator Bettye Davis
Chair, Senate Health & Social Services Committee;
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From: Heidi Mannion [mailto:heidi_mannion@hotmail.com]

Sent: Wednesday, April 04, 2012 6:05 PM

To: Thomas Obermeyer; Gloria A Tomich

Subject: RE: SB 166 documents

Tom,

Due to my work schedule, Gloria Tomich will be available to respond to testimony in opposition of the bill. In the event the Ms. Tomich gets disconnected, the following is in response to Mr. Will's letter:

1. Mr. Will is correct that I have not worked in the clinical laboratory on a daily basis since I began teaching in 1997. However I keep current with what is happening in the clinical labs through our advisory board, education coordinators and the professional organizations. I attend the state conference every year and I attend national conferences on a regular basis. If Mr. Will is not attending conferences and networking with laboratory professionals in the state, he may only be aware of what is happening at his facility. Ms. Jefson is currently working in a clinical laboratory and she sees the need for licensure.
2. Mr. Will stated under Alaska licensure laws with rare exception those groups subject to licensure are in a career where they are able to hang their own shingle-- nurses are licensed in this state and most are not allowed to hang their own shingle.
3. Like many others, Mr. Will is confusing terms (see definitions below), at one time ASCP was called the Board of Registry. It is now the Board of Certification because there are educational requirements and continuing competency requirements in order to obtain and maintain certification. CLIA 88 only requires cytotechnologists to be certified.

Although many facilities in Alaska require that their laboratory professionals be certified some do not. This bill would require that laboratory professionals be certified and maintain their certification. Mr. Will is correct that California has recently made changes to their licensure law. At one time California administered their own licensing exam, due to cost they have replaced their exam with the ASCP certification exam. SB 166 is also using certification exams approved by the Board instead of creating their own to reduce costs.

- License is formal permission, usually from the state, to engage in a specified occupation.
- Certification is recognition granted, usually by a non-government agency, to an individual who has met certain qualifications
- Registration is a very general term indicating that the title is controlled or that an individual in a given occupation must register with a designated agency.

Mr. Will states the following: Additionally, supervision occurs from several accrediting agencies, including CLIA, JCAHO, CAP and others- these organizations inspect facilities for compliance with regulations and standards and they license or accredit those facilities that are compliant. They do not supervise them.

5. Mr. Will's example of home pregnancy tests is only one example of waived test. There are numerous waived tests available which are not for home use and some of the tests that are available for home use are used for different purposes by the physician. The article I sent on POCT and POLs provided the example of a waived pregnancy test being done incorrectly. The pregnancy test was done to ensure that the patient was not pregnant before prescribing medication and ordering a radiologic procedure it was not done to confirm pregnancy as is the case with home pregnancy kits. The patient was given medication that would harm a fetus and sent for a radiology procedure which could also harm the fetus. It was later noted that the test had turned positive. A more sensitive test was done and the patient was found to be pregnant.

Ms. Jefson's letter stated that Fran Lehr, the Regional Inspector for CLIA programs in the NW said that Physician Office Labs that perform waived tests often do not follow manufacturer's directions compromising the quality of those results. Ms. Lehr made this statement at the state conference last week. This provides further evidence that this is an ongoing problem.

6. SB 166 does not require that a clinical pathologist be the laboratory director- page 8 (3) "medical laboratory director" means a person who is responsible for the administrative, scientific, and technical operation of a medical laboratory and who meets the requirements of a laboratory director as specified by CFR 42. 493.1443. This is what is currently required to be a medical laboratory director we have made no changes to the requirement.

It appears that Mr. Will did not review the current version of the bill even though it is available on the CLSA website. Mr Will did not have any credentials after his name. Either he is not certified or he does not place any importance on certification.

Heidi Mannion PhD, MLS (ASCP)
Chair, CLSA Licensure Committee

From: Thomas_Obermeyer@legis.state.ak.us
To: heidi_mannion@hotmail.com
CC: Senator_Bettye_Davis@legis.state.ak.us
Subject: FW: SB 166 documents
Date: Thu, 5 Apr 2012 00:36:32 +0000

Heidi,

I am sorry for the short notice on the attached letters provided for your review. Please be prepared to respond in hearing tomorrow to the letter of opposition by George Will, Jr. at hearing. His summary on page three is that "this seems to be a solution to a non-existent problem."

Tom Obermeyer

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From: Dana Owen
Sent: Wednesday, April 04, 2012 10:52 AM
To: Ann Krekelberg; Cathy Tilton; Dana Owen; Joan Klapperich; Jonathon Taylor; Kimberly Vanwyhe; Sharon Long; Thomas Obermeyer
Subject: SB 166 documents

Please add the attached documents to your SB 166 packet. My apologies if any of these are duplicates.

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