



April 4, 2012

Senator Dennis Egan
Chairman, Senate Labor and Commerce Committee
State Capitol Room 510
Juneau AK, 99801

Re: Opposition to Senate Bill 166 Unless Amended

Dear Chairman Egan:

I am writing on behalf of the Alaska Pathology Association (APA) and the College of American Pathologists (CAP) in opposition to Senate Bill 166, unless amended. The APA is a state medical specialty society representing many practicing pathologists in the state. CAP is a national medical specialty society, representing 18,000 physicians who practice clinical and anatomic pathology (laboratory medicine) in community hospitals, independent clinical laboratories, academic medical centers, and federal and state health facilities.

Our organizations are concerned with SB 166 that proposes to license medical laboratory science professionals in Alaska. We are not opposed to the concept of licensing laboratory personnel. However, we do believe that SB 166 has a number of flaws that need to be addressed and amended.

Of specific concern is the scope of practice definition in section 08.30.120 of SB 166. It is unclear if laboratory personnel are under the supervision of the medical laboratory director. The scope of practice contemplated for a medical laboratory scientist includes interpreting laboratory procedures and "establish and implement protocols, select or develop test methodology." It also confers on the medical laboratory scientist supervision of laboratory personnel. SB 166 does not distinguish a hierarchy in the laboratory setting, which may cause confusion and conflict among laboratory personnel, and potentially jeopardize quality laboratory testing. Therefore, the bill needs to clearly state that clinical laboratory personnel work under the "supervision, control, responsibility of the laboratory director."

In addition, we recommend that the definition of "independent judgment" in section 08.30.120 be clearly defined to differentiate from independent medical judgment as performed by a pathologist. This section authorizes a medical laboratory scientist to exercise independent judgment in the scope of his or her work. SB 166 should differentiate between the exercise of independent technical judgment and independent medical judgment since a medical laboratory scientist does not have the requisite medical training to exercise medical judgment in the diagnosis and treatment decisions related to clinical laboratory tests.

Furthermore, we believe the lack of clarity in the scope of practice definition is inconsistent with the Clinical Laboratory Improvement Amendment (CLIA) law of 1988. As you know, CLIA is a federal law regulating all laboratories to ensure quality laboratory testing. Pursuant to this law, CLIA regulations (CFR 493.1445) delineate the role and responsibility of a laboratory director who is "responsible for the overall operation and administration of the laboratory." This includes the responsibility of ensuring quality laboratory testing by establishing policies and procedures for laboratory personnel in conducting pre-analytical, analytical, and post-analytical phases of testing. We recommend that the legislation unequivocally state that the laboratory director has responsibility over laboratory personnel.

College of American Pathologists

We respectfully request the committee to consider the following during its deliberation of SB 166:

- **Clarify that all clinical laboratory personnel work under the supervision, control, responsibility of the laboratory director** including the medical laboratory scientist, medical laboratory technician, medical laboratory assistant, and phlebotomy technician as considered under SB 166.
- **Add technical to “independent judgment” under the scope definition for a medical laboratory scientist and define “independent technical judgment” and “independent medical judgment” to differentiate between the two.** Laboratory personnel considered for licensure under SB 166 do not have the requisite medical training to exercise medical judgment.
- **Include educational requirements for laboratory personnel not just scope of practice.** We recommend a minimum BA for technologists and AA for technicians and successful completion of a national certification exam.
- **Expand the 5-member board that has oversight of the licensure laboratory personnel program.** We believe the current 5-member board lacks diversity in representing laboratory personnel. We recommend that it increase to 7-members that include two pathologists and one non-physician medical director.
- **Create limited specialty licenses for personnel outside the licensure categorizations who perform specialty services in the laboratory.** We believe this will ensure continuity of the workforce in the laboratory since some educational programs do not cover specialty services provided by laboratory personnel. We recommend the legislation provides for either course curriculum completion for these positions or, alternatively, one year of on-the-job-training.

We appreciate the opportunity to comment on SB 166, and request the committee to consider our changes to the legislation.

Sincerely,



Kathryn Knight, MD, FCAP
Chair, Federal and State Affairs Committee

Cc: Alaska Pathology Association
Alaska State Medical Association
Senator Joe Paskvan, Alaska State Legislature
Senator Linda Menard, Alaska State Legislature
Senator Bettye Davis, Alaska State Legislature
Senator Cathy Giessel, Alaska State Legislature