

Opposition group	Opposition point	Response	Supporting Documents
<p>CAP</p>	<p>1) Clarify that all clinical laboratory personnel work under the supervision, control, responsibility of the laboratory director.</p>	<p>This is CLIA language so must be accepted by ASCLS.</p>	<p>http://wwwn.cdc.gov/clia/regs/toc.aspx</p>
	<p>2) Support state licensure for medical technologists and technicians with a defined scope of practice with a minimum education requirement of BA for technologists and AA for technicians and successful completion of national certification exam.</p>	<p>Scope of practice for CLS and CLT is defined in #4 and #5 on this list and is very close to the language in the ASCLS model bill, with the addition of the CLIA language about supervision found in #1.</p>	<p>26</p>
	<p>3) Support limited (specialty) licenses for specialized laboratory professionals that perform electron microscopy, histocompatibility, cytogenetics, stem cell processing, flow cytometry, cellular immunology and molecular diagnostics. Provide for either course curriculum completion for these positions or, alternatively, one year of on-the-job-training. Require competence certification by the lab director.</p>	<p>One concern about this point is that there is no educational level specified. On the strength of feedback from the state pathology society and the Mayo Clinic Laboratories, the MN bill has defined these subspecialists as requiring a BS/BA degree and competence certification by the lab director. This is consistent with practice in many academic health centers. The MN bill also provides for licenses for all categories for which certification exams are available (histocompatibility, cytogenetics, molecular biology). However, there are personnel working in subsets of these areas who would not have the experience required to take and pass an existing certification exam.</p>	<p>26</p>

4) Define the scope of practice for medical technologists as an individual eligible to perform any clinical laboratory test including those that require the exercise of independent technical judgment subject to the supervision, control, responsibility and direction of the clinical laboratory director. In addition this individual is responsible for, with oversight by the laboratory director, the establishment and implementation of protocols, quality assessment, method development and selection, equipment selection and maintenance, and all activities related to the pre-analytic, analytic, and post-analytic phases of testing. The medical technologist may also direct, supervise, consult, educate, and perform research functions that includes the establishment and implementation of protocols, quality assessment, method development and selection, equipment selection and maintenance, and all activities related to the pre-analytic, analytic, and post-analytic phases of testing.

Language is like that in the ASCLS model bill and some current state bills, with the addition of the supervision language.

	<p>5) Define the scope of practice for medical technicians as an individual eligible who is qualified to perform clinical laboratory tests pursuant to established and approved protocols which are performed under the supervision, control, responsibility and direction of the clinical laboratory director.</p>	<p>Language is like that in the ASCLS model bill and some current state bills, with the addition of the supervision language.</p>	<p>26</p>
	<p>6) Continue to oppose state licensure for cytotechnologists, histotechnologists, and pathologists assistants as unnecessary.</p>	<p>Despite #10 below, we have been told that CAP will oppose any bill that includes these groups even if the state pathology society supports their inclusion. While many states would prefer to include all laboratorians in a licensing bill, this decision is complicated by much dissension within the ranks of these professions as to whether they should be licensed. In the simplest sense, licensure bills make voluntary certification mandatory. Cytotechnologists are already required by CLIA to be certified; including them in a licensure bill is redundant. However, some cytology leadership is concerned about protecting their scope of practice, especially in the area of molecular testing where scope may overlap with that of other laboratorians. Support for state licensure by cytotechnologists seems to vary state by state and among practicing professionals within a state. One approach (used in MN) is to define the cytology scope of practice in the definitions section of the bill and then exempt CTs</p>	

		<p>from holding a license in the exemptions section.</p> <p>Histology also seems to be fractured in their opinions, with leadership generally favoring licensure and the rank and file not convinced. There is a very small number of certified pathology assistants in most states. We are not aware of any state that has licensed them (at least along with other laboratorians) or has included them in a proposed bill.</p>	
	<p>7) Incorporate definition of independent medical judgment that clearly establishes that in the laboratory only pathologists exercise independent medical judgment in the diagnosis and treatment decisions related to clinical laboratory tests.</p>	<p>The task force sees this definition as being somewhat presumptuous on the part of pathology since ultimately it is the clinician who diagnoses and makes treatment decisions. This may be an attempt to restrict the scope of the DCLS. However, even that individual would not make a final diagnosis or treatment decision.</p>	
	<p>8) Incorporate definition of independent technical judgment as the performance or conduct of clinical laboratory tests and assumption of responsibility for determination of the validity of clinical laboratory test results without intervention by or the supervision of another health care provider authorized by law to assume responsibility for the conduct and validity of clinical laboratory tests.</p>	<p>OK</p>	

	9) Establish a nine member clinical laboratory licensure oversight board that includes at least three pathologists and one non-physician laboratory director. Limit the regulatory authority of the board to modify or expand the personnel or scope of practice requirement defined by the state statute.	This composition of an oversight board could leave neither party with a majority vote. There might be four physicians, four laboratorians, and one public member. The laboratorians would have to convince one physician or the public member to vote with them. For many of the state bills now pending, the board is advisory in function, so the limitation of their authority seems to be a non-issue.	20 22 26
	10) The CAP Model Criteria are not binding on any State Pathology Society.	CAP initially accepted the revised language of the MN and MO bills but has now raised some additional concerns.	20
State Pathology Assns	CLIA is enough	Except for Cytology, the CLIA standards are a bare minimum and do not reflect how most laboratories select their staff.	21
	No guarantee that licensure improves quality and patient safety	Published papers establish the link between the qualifications of personnel and quality laboratory results	9 18 19 21 29 30
	Worsens personnel shortages	Published data shows that the supply of qualified laboratory personnel is as good or better in states with licensure than in those without.	1 6 7 15 18 21
	Does not address physician office laboratory quality issues	State bills address POLs that perform moderate complexity testing in different ways.	30
Hospital Associations (AHA or state)	Licensure will increase the cost of health care	Published data shows that there is no difference in salaries based on licensure or absence of licensure.	1 6 7 12 18 21

	Access in rural and underserved areas	Published date shows that the supply of qualified laboratory personnel is as good or better in states with licensure than in those without.	1 13 18 19 21
Individual hospitals or health systems	Licensure will increase the cost of health care	Published data shows that there is no difference in salaries based on licensure or absence of licensure.	1 21
	Access in rural and underserved areas	Published date shows that the supply of qualified laboratory personnel is as good or better in states with licensure than in those without.	1 6 15 18 21
State medical associations	Do not want licensure for phlebotomists	State bills address licensure for phlebotomists in different ways.	17
	Do not want regulation of physician office laboratory personnel	State bills address POLs that perform moderate complexity testing in different ways.	17
AAB	BS and AS level personnel can both perform high complexity testing under CLIA; there is no difference in their competencies and there should be one license for both.	The distinction between CLS and CLT levels has been accepted by all certification agencies except AAB and is incorporated into every state licensure bill. AAB's view is in the minority within the laboratory community.	26
	State bills require a BS to do high complexity testing; CLTs cannot perform	Not Correct	8

	Military trained personnel (veterans) should be granted a CLS license without a BS degree	State bills that mention military personnel generally require them to have an AS degree for CLT and BS for CLS. The NAACLS approved military programs (in 3 branches of the service) get the graduates within 3 credits of an AS degree, which could easily be completed on line. VA policy recognizes both AS and BS levels	32
Cytology groups	Some want to be included in licensure bills, despite CAP's opposition to this	Support for state licensure by cytotechnologists seems to vary state by state and among practicing professionals within a state. One approach (used in MN) is to define the cytology scope of practice in the definitions section of the bill and then exempt CTs from holding a license in the exemptions section.	27
	Some states do not want to be included in licensure bills	Cytotechnologists are already required by CLIA to be certified; including them in a licensure bill is redundant.	27
Histology groups	Some want to be included in licensure bills, despite CAP's opposition to this	Histology also seems to be fractured in their opinions, with leadership generally favoring licensure and the rank and file not convinced.	27
Legislators	Too much regulation		
	Increased cost of health care	Published data shows that there is no difference in salaries based on licensure or absence of licensure.	1 6 7 12 18 21
	Cost to the state	Licensure programs are designed to be self-supporting	26
	Access to care in rural and underserved areas		1 13 18 19 21

	No evidence that there is incompetent practice		2 24 31
Our own profession	A license will cost too much money	Surveys show that most clinical laboratorians support licensure.	19 25 27
	Confusion between certification and licensure	Stakeholder education needed	16
	Lack of understanding that licensure is a state by state issue and can't be solved at a national level.	Stakeholder education needed	16
Veterans groups	Military trained personnel (veterans) should be allowed to practice and their experience should be recognized	State bills that mention military personnel generally require them to have an AS degree for CLT and BS for CLS. The NAACLS approved military programs (in 3 branches of the service) get the graduates within 3 credits of an AS degree, which could easily be completed on line. A temporary license might be granted for a defined time period in order to allow veterans to complete an associate degree.	26