



# Licensure of Laboratory Professionals 2011

# Certification

- Certification is for individuals
- Certification affirms that an individual has demonstrated that she/he possesses the knowledge to perform essential tasks in the medical laboratory.
- Requires that the individual pass some type of examination.
- Certification is offered by national non-profit organizations, such as the American Society for Clinical Pathology



# What is Licensure?

- Official or legal permission to do a specified thing, especially to practice a profession
- A license is granted by the state



# What is a Profession?

An occupational group characterized by:

- Extensive education and specialized training
- Use of skills based on theoretical knowledge
- Code of conduct
- An association that organizes its members
- Autonomy and tend to be highly resistant to control or interference in their affairs by outside groups



# History: Personnel Licensure Required



|             |        |                |        |
|-------------|--------|----------------|--------|
| *California | (1937) | *North Dakota  | (1990) |
| *Florida    | (1967) | *Puerto Rico   | (1939) |
| *Hawaii     | (1974) | *Rhode Island  | (1992) |
| *Louisiana  | (1992) | *Tennessee     | (1967) |
| *Montana    | (1993) | *West Virginia | (1991) |
| *Nevada     | (1967) | *New York      | (2004) |

## Facility Licensure (with personnel requirements)

- \*Alaska
- \*Georgia

## Current Licensure Efforts/Activity



- Illinois
- Massachusetts
- Michigan
- Minnesota
- Missouri
- Texas
- Vermont
- Washington
- New Jersey
- Iowa
- Georgia
- Utah
- S. Carolina
- Wyoming
- Pennsylvania
- Virginia
- Delaware
- Mississippi
- Alabama
- Colorado
- Oklahoma

## Licensure Efforts in Minnesota

- First clinical laboratory licensure effort was in 1937-1938, when a licensure bill was introduced, but was deferred
- Other licensure bills were introduced in 1949 and 1970
- Most recent licensure bill was drafted in 2005



## The Case for Personnel Licensure

- Protect the public health and safety (consumer protection).  
Assure quality of laboratory testing
- Identify and locate practitioners for workforce planning and mobilize for emergency preparedness.
- Protect the scope of practice by excluding those who have not acquired appropriate requisites for licensure



## Advantages of Personnel Licensure

- Licensure is cornerstone for quality and safety in laboratory medicine
- Licensure prevents our profession from being “dumbed down”
- A license can be revoked. Without licensure, a person can always work in another laboratory
- Increases public visibility and prestige for the profession;
- Puts profession on a “level playing field” with other licensed professions. Other professions value licensure. Our status is impacted by that mindset.



## Effects of NOT Being Licensed

- Lack of Data
  - Our profession is one of the most difficult healthcare workgroups to collect data on
  - In our current workforce shortage, the ability to define our profession with quantitative data is greatly hindered; workforce planning does not occur
  - Useful to have data for government funding initiatives, allied health program efforts, etc.



# Minnesota Process Timeline



- 2003-2007: statewide education on the topic of licensure
- 2005: ASCLS-MN appointed four person licensure task force to draft baseline model bill (Kathy Hanson, Daniel Olson, Rick Panning, Donna Spannaus-Martin)
- 2006: Assembled the Licensure Coalition – representatives from all laboratory organizations

# Licensure Coalition

- AACC
- AGT (Genetic Technologists)
- AMT
- ASCP
- ASCLS-MN
- CLMA-MN
- MSP (Pathologists)
- MSH (Histo-technologists)
- MSC (Cytologists)
- MIMA (Microbiology)
- MABB (Blood Bank)
- MDH
- Phlebotomy profession
- Molecular Diagnostics



# Minnesota Process Timeline



- January, 2006: First coalition meeting
  - Formal coalition commitment
  - Monthly meetings through 2006
- Sept.-Nov. 2006: Grass roots and stakeholder communication stepped up

# Making the Case to Legislators



- Unregulated practice will harm/hinder the public
- Existing protections are insufficient
- Regulation will mitigate existing problems (challenge: “proving” current problems exist)

# Making the Case to Legislators



- Occupation requires possession of knowledge, skills, and abilities that are teachable/testable (a defined scope of practice exists)
- This profession is clearly distinguishable from other professions
- The economic impact is negligible

# Minnesota Process Timeline



- Jan.-Feb. 2007: Found legislative authors and sponsors, lobbyist
  - Chief Senate sponsor is Senator Gary Kubly, a former medical technologist from Granite Falls
- March, 2007: Bill introduced, opposition lobbyist registers (CAP, MSP, AAB)
- Unable to get committee hearings in March, 2007, had to hold over until the 2008 session

# Minnesota 2008



- Feb. 12, 2008: 2<sup>nd</sup> year of biennial session began
- Opposition mounted a very effective last-minute “blitz”
- Senate Health Subcommittee on Licensing hearing, 2/18/08
  - Bill tabled to be reintroduced in 2009
  - Lobbyist recommendation: Don’t take a vote unless you have the votes to win

# 2007-2008 Opposition

- College of American Pathologists
- Minnesota Society for Pathology
- American Association of Bioanalysts
- Some hospitals
- Mayo Clinic (?)



# Minnesota Process Timeline



- December 2008: CAP revises its position on laboratory personnel licensure
- Following this and some changes in the bill, MSP supports licensure bill

# 2009-2010

- The bill was reintroduced with many of the same authors and supporters
- In the Senate, introduced as SF299 and in the House as 1249



# Bill Approval Process

- Senate
  - Health Committee
  - State/Local Government
  - Ways and Means
  - Finance
  - Floor vote

(red = passed)
- House
  - Licensure subcommittee
  - Health Committee
  - State/Local Government
  - HHS Finance
  - Finance
  - Ways and Means
  - Floor vote

(orange = key committees)



# Minnesota Process Timeline

- SF999
- In 2009:
  - Successful votes in three Senate committees
    - Health
    - State and Local Government Operations
    - Judiciary (State and Local Government)
  - Finance Committee is next
  - Full Senate vote



# Minnesota Process Timeline

- HF1249
- In 2009:
  - Was not heard in 2009
  - First hearing in Licensing Committee. This requires a 5-3 vote to pass and move forward. If a vote had been held, it was expected that the vote would be 4-4, which would have ended the bill for 2009, so no vote was called



# Licensure Standards

- Educational degree
- Approved experience and training
- Certification required



# Grandfathering Provisions

- 18 months to apply for this option
- Applies to those currently practicing who do not meet the new education and certification requirements of the legislation
- Practicing as of the effective date of the bill, OR
- Has worked for at least 6 months, at least half-time, within the last three years
- Submit current job description, attested to by employer
- Board determines which license to approve (ie., categorical, CLT, MLS)



## Exemptions (no license required)

- Other licensed professionals performing functions within their scope of practice
- Employed by the U.S. government (VA Hospitals)
- Research
- Education
- Pathology Assistants
- Students/trainees
- Phlebotomists
- Waived testing
- Point of Care under the direction of licensed laboratory professionals or laboratory directory



Opposition: Minnesota is experiencing a shortage and this bill creates one of the most restrictive licensure laws in the country



- All healthcare was (is) experiencing a shortage, but other professions are not backing away from strong personnel standards
- HRSA data
  - States which license baccalaureate and associate degree staff have a higher rate of professionals per 100,000 population than unlicensed states (114.7 versus 101.9)
  - Laboratory workforce growth is 20% higher in licensed states
- In times of shortage, it is even more important to hire qualified individuals

Opposition: There are no alternate routes to qualify as a MT, CLS, MLS other than a 4-year college degree. Military trained, MNSCU and alternate routes are not allowed



- The bill licenses 2- and 4-year degreed professionals
- Provides for alternate routes as allowed by the certifying agencies
- Does require a baccalaureate degree and passing a certification exam with the alternate routes to MLS
- Two-year associate degree professionals can, with additional education, become licensed at the 4-year level

Opposition: The bill encourages laboratory professionals who do not have a 4-year college degree to seek employment in other states bordering Minnesota



- North Dakota has had licensure since 1992 and has not seen this happen
- A number of Minnesota residents who work in Grand Forks and Fargo have obtained a ND license
- Other licensed states have not seen this occur

Opposition: The bill will make it more difficult for small rural hospitals, physician office laboratories and community independent laboratories to staff their facilities



- This bill is about assuring that people with the necessary education, experience, and certification are hired to perform laboratory testing
- JAMA has published studies which show that more stringent personnel standards result in lower error rates

Opposition: The Minnesota bill is rife with errors and ambiguities that will complicate the administration of the laboratory



- There were continued references to the situation in New York State – NY bill was not written by laboratory professionals, which resulted in many problems when it was enacted
- MN bill compared to NY bill to show how problems were addressed

## Opposition: CLIA standards are adequate

- Several JAMA studies document that the training and qualifications of laboratory personnel correlate with the quality of testing (3 references in the ASCP position paper)
- CLIA personnel standards are lower than what is required to assure quality
- Support for more stringent personnel standards from the Joint Commission





“Finally, while the GAO’s lengthy and detailed review addresses many issues associated with laboratory quality, it fails to address a long acknowledged shortcoming of CLIA requirements – the qualifications and supply of lab personnel. **The Joint Commission believes that the personnel standards currently required by CLIA are insufficient to adequately protect patients and the public health.** For example, CLIA requires only an Associate degree and minimal lab training to perform tests of high complexity and has no personnel requirements for waived tests. Today, the problems underlying failures in laboratory performance that are most commonly cited by experts in the field are the growing shortage of laboratory technologists and the inadequacy of their training. These shortcomings become especially glaring in the face of the expanding array and increasing complexity of laboratory tests in hospitals. By not addressing this serious regulatory shortcoming in the scope of its review, GAO has missed an opportunity to leverage potential improvements in laboratory performance and protect the public interest.”

Dr. Dennis O’Leary

President and CEO of The Joint Commission

# Lessons Learned

- “It is easier to kill a bill than to pass one”
  - One legislator acknowledged that we had done a better job of providing facts and making our case. That was not enough to counter the “scare tactics”
- “All politics is local”
  - Grass roots support and contact can make a difference



# Lessons Learned

- Hard to balance the needs/ opinions of stakeholders. MSP wanted the bill to be stronger in regulating POL testing; MMA would have actively opposed the bill if we had done this



# What next?

- Lobbyists are expensive but necessary
- The legislators and party in power in the legislature have changed
- The bill will probably not be reintroduced in this biennium



# What now?

- ASCLS-MN web site for updates  
[www.asclsmn.org](http://www.asclsmn.org)
- Talk about the profession
- Contact your legislators
  - [www.leg.state.mn.us](http://www.leg.state.mn.us)
  - E-mail, call, visit
  - Legislative Day



## Survey Results (n= 1,074)

Before reading the introduction to this survey, were you aware the Laboratory Licensure Coalition was working towards personnel licensure in Minnesota?



- Yes - 76.7%
- No - 23.3%

## Survey Results (n= 1,074)

Do you think that laboratory professionals should have a required minimum education level?



- Yes - 97.0%
- No - 1.9%
- No opinion - 1.1%

## Survey Results (n= 1,074)

Do you think that Clinical Laboratory Scientists (CLS/MT) and specialists, Cytotechnologists (CT), and Histotechnologists (HLT) should be required to have a baccalaureate degree?



- Yes - 80.5%
- No - 14.5%
- No opinion - 4.9%

## Survey Results (n= 1,074)

Do you think that laboratory professionals should be certified by a national certification agency?



- Yes - 86.6%
- No - 10.1%
- No opinion - 3.4%

## Survey Results (n= 1,074)

Do you think that laboratory professionals should be required to complete a specified number of continuing education hours each year?



- Yes - 83.8%
- No - 11.9%
- No opinion - 4.3%

## Survey Results (n= 1,041)

Based on what I currently know, I support licensure of laboratory personnel.



- Strongly agree - 39.1% (41%)
- Agree - 28.1% (28%)
- Neutral - 16.7% (14.3%)
- Disagree - 8.5% (10.2%)
- Strongly disagree - 7.6% (5.4%)
- (2005 ASCP national data in red)



“If we don’t fight hard enough for the things we stand for, at some point we have to realize that we don’t really stand for them. Passion is not enough, action is required.”

~ Senator Paul Wellstone