



## Licensure of Laboratory Personnel – the Journey

Kathy Hansen  
Minnesota Licensure Task Force Vice Chair  
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## History: Personnel Licensure Required

- California (1937)
- Florida (1967)
- Hawaii (1974)
- Louisiana (1992)
- Montana (1993)
- Nevada (1967)
- North Dakota (1990)
- Puerto Rico (1939)
- Rhode Island (1992)
- Tennessee (1967)
- West Virginia (1991)
- New York (2004)
- Facility Licensure (with personnel components)
  - Alaska
  - Georgia

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## Current Licensure Efforts / Activity

- Illinois
- Massachusetts
- Michigan
- Minnesota
- Texas-introduce bill in '08
- Vermont
- Washington
- New Jersey
- Iowa
- Georgia
- Utah
- South Carolina
- Wyoming
- Pennsylvania
- Virginia
- Delaware
- Missouri
- Alaska
- Mississippi
- Alabama
- Colorado
- Oklahoma

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## 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

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## Advantages of Personnel Licensure

- Licensure is a 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 at another laboratory.
- Increases public visibility and prestige for the profession; attracts students into the profession.
- Puts profession on a "level playing field" with other licensed healthcare professionals. Other healthcare professions value licensure. Our status is impacted by that mindset.

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## One side effect 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
- States collect data on nurses, pharmacists and physicians but are unable to collect similar data on our profession.
- Useful to have data for government funding initiatives, allied health program efforts, etc.

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## Making the case to legislators

- Unregulated practice will harm or endanger the public
- Existing protections are insufficient to protect public
- Regulation will mitigate existing problems (challenge: "proving" current problems exist)
  - Maryland General case
  - CMS CLIA data supports that regulation improves quality
  - Public awareness of medical errors
- Occupation requires possession of knowledge, skills and abilities that are teachable/testable (defined scope of practice exists)
- This profession is clearly distinguished from other licensed professions
- The economic impact is negligible

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## Concerns (*misconceptions*) regarding personnel licensure

- In times of a personnel shortage, a possible decline in availability of practitioners (especially in rural and underserved areas)
- Mobility of the practitioner may be limited. (It is essential to assure state-to-state reciprocity)
- Increased cost to the state
- Possible increase in the cost of testing
- The need to take a test to maintain a license
- Increased cost to the practitioner – only true statement on this list

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## Update on the Minnesota process



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## Minnesota process timeline

- 2003-2007: statewide education on the topic of licensure (almost 2000 laboratory professionals)
- 2005: ASCLS-MN appointed licensure task force to draft baseline model bill
- Assembled the licensure coalition members – asked for representatives from all laboratory professional organizations
- Coalition held first meeting - January 2006
  - Formal coalition commitment
  - Subsequent monthly meetings through 2006

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## Coalition represents:

- |                       |                         |
|-----------------------|-------------------------|
| ■ AACC (Clin. Chem.)  | ■ MSC (Cytology)        |
| ■ AGT (Genetic Tech.) | ■ MIMA (Microbiology)   |
| ■ AMT                 | ■ MABB (Blood Bank)     |
| ■ ASCP                | ■ MDH                   |
| ■ ASCLS-MN            | ■ Phlebotomy profession |
| ■ CLMA-MN             | ■ Molecular Diagnostics |
| ■ MSP (pathologists)  |                         |
| ■ MSH (Histology)     |                         |

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## Coalition members (putting a "face" to the process)

- |                                 |                                   |
|---------------------------------|-----------------------------------|
| ■ Beth Dahlmeier (AACC)         | ■ John Thon (CLMA)                |
| ■ Carol Johannes (ASCLS)        | ■ Julie Mumm (Phlebotomy)         |
| ■ Cathie Foster (Molecular)     | ■ Junell Peterson (ASCP)          |
| ■ Clara Boykin (AMT)            | ■ Karen Nelson (Phlebotomy)       |
| ■ Colleen Forster (MSH)         | ■ Kathy Hansen (ASCLS)-Vice Chair |
| ■ Curt Hanson, MD (MSP)         | ■ Leanna Erickson (AGT)           |
| ■ Dan McKeon (MSC)              | ■ Lizette Miller (MSC)            |
| ■ Dan Olson (ASCLS)             | ■ Marisa Peterson (MABB)          |
| ■ Donna Spannaus Martin (ASCLS) | ■ Sue Iddings (MIMA)              |
| ■ Edith Tefft (AMT)             | ■ Pat Ellinger (ASCP)             |
| ■ Heidi Sokolowski (MSC)        | ■ Paula Snippes (MDH)             |
| ■ Jean Robbins (CLMA)           | ■ Rick Panning (ASCLS)-Chair      |
| ■ Jeremy Angell (Phlebotomy)    | ■ Shelly Semerad (MSC)            |

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## Coalition

- Organizations initially agreed to participate in the “process”
- Organizations, at this point, did not commit to being part of the licensure bill. Each organization ultimately has decided to be “in or out” of the bill. All support the process and will support the bill as it moves forward.

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## Informational Meetings to gather input from Other Key Stakeholders

- Mayo Clinic laboratory leadership
- Minnesota Hospital Association
- Minnesota Medical Association
- Minnesota Department of Health
- Lobbyist
- Physical Therapy Practice Board

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## Minnesota process timeline

- Sept-Nov 2006: Grass roots and stakeholder communication stepped up
- Jan 2007: Selected lobbyist
- Jan/Feb 2007: Found legislative authors and sponsors
- March 2007: Introduced bill. Opposition lobbyist representing CAP, MSP, and AAB registered

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## Selecting a lobbyist

- Before looking for a lobbyist:
  - Establish a coalition of organizations representing laboratorians
  - Know which groups want to be licensed; which are in favor and which opposed
  - Have a draft bill in “close to final” format
  - Identify laboratorians who have contacts in the legislature (from campaigns, previous legislation, etc)

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## Selecting a lobbyist

- Look for lobbyist(s) with experience in healthcare and/or licensure legislation
  - Most large health systems have their own lobbyist – ask them for recommendations
  - Some laboratorians may know a lobbyist.
- Look for a lobbyist with experience with your legislature; contacts are essential

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## Selecting a lobbyist

- Select two or three independents or firms to interview.
- Provide them with the bill and information about the coalition and what grassroots support is in place
- Monthly retainer vs “session only” contract
- Party affiliation (Dem and Rep team)

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## Selecting a lobbyist

- 3 lobbyists were interviewed; Rider Bennett was selected
  - Our process and draft bill were thought to be very thorough and organized
  - Impressed with our “grass roots” experience
  - Likelihood of a two year process (2007 was the first year of the biennium – bills can be carried over to second year of MN session without starting over)
  - Vic Moore and Doug Franzen, our lobbyists, are now a private lobbying firm
    - Vic is former chief of staff for Senate majority leader Roger Moe (22 years)

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## What the lobbyist can do for you

- Help find authors and co-sponsors for the bill
- Help you understand committee processes, order of committee hearings, timing, deadlines
- Stay in frequent touch with supporters
- Monitor activity of opposition lobbyist(s)

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## What the lobbyist can't do for you

- Grass roots contacts with legislators by their constituents – statewide!
- Anticipate opposition points and refute them – the lobbyist can critique leave-behind literature and give guidance, but the burden is on you to make your case.

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## Funding

- ASCLS, ASCP and CLMA committed funding.
- Other coalition organizations were also asked to make a commitment.
- Some coalition members contributed honoraria to the licensure fund
- We have not yet had to have bake sales!

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## Recent timeline

- Unable to get committee hearings in March 2007, had to hold over until 2008 session
- 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 held a hearing on February 18, 2008
- Following that hearing, bill was tabled and will be reintroduced in 2009 – more on this later.

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## Professional Categories

- Medical Laboratory Scientist (CLS or MT)
  - Categoricals – Heme, Chem, Micro, Blood Bank
- Medical Laboratory Technician (CLT or MLT)
- Medical Laboratory Specialist
  - Cytogenetics
  - Molecular biology / pathology
  - Histocompatibility
  - other
- Cytotechnologist
- Histology Technician
- Histotechnologist

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## Licensure Standards

- Educational degree
- Approved experience and training
- Certification
  - We need flexible language regarding the names of the certification exams and the job titles for CLS/MT and CLT/MLT
  - Proposed merger of NCA and ASCP (BOR)

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## 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
  - i.e. If you were not certified or had formal CLS/MT education and have worked in microbiology for the last 10 years, would probably be granted a microbiology categorical license.

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## Exemptions (no license required)

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

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## Application procedures

- Reciprocity if licensed in another state (until renewal time)
- Temporary:
  - Eligible to take a certification exam, OR
  - Meets education requirements but is gaining working experience to be able to sit for a certification exam
  - 12 month temporary license – can renew 2 additional times.

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## Renewal

- Every three years
- Pay fee (to be determined)
- Submit documentation of 12 hours of continuing education annually

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## Costs of application/renewal

- Will be determined based on cost (a fiscal not must be completed)
- Other MN healthcare license costs:
  - Nursing: \$85 per 2 years
  - Physicians: \$192 per year
  - Physician Assistant: \$135 per year
  - Respiratory Care: \$90 per year
  - Athletic Trainer: \$100 per year
  - Midwife: \$100 per year
  - Pharmacist: \$105 per year
  - Physical Therapist: \$60 per year
  - Audiologist: \$200 per 2 years
  - Occupational Therapist: \$180 per 2 years
  - Occupational Therapy Assistant: \$125 per 2 years
  - Speech Pathologist: \$200 per 2 years

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## Advisory Council

- Initially proposed a separate board structure (like physical therapy or nursing)
  - Later amended to function within the Minnesota Department of Health structure
- Cost of license to cover cost of process
- Advisory Council members: (11 members)
  - 6 representing categories licensed in the bill, including a non-physician laboratory director
  - 2 pathologists
  - 1 non-pathologist physician
  - 1 public member
- 3 years terms - staggered

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## Minnesota Licensure Effort

- HF2109 and SF1830
- 14 House authors (chief author is Rep. Erin Murphy from St. Paul)
  - Including 13 of 20 members of the Health committee
- 5 Senate authors – the maximum allowed (chief author is Sen. Gary Kubly, former Medical Technologist, from Granite Falls).
  - Four of the five authors are on the Health Committee.
- All 6 nurse members of the legislature support the bill.

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## Bill Authors

- |   |  |
|---|--|
| <ul style="list-style-type: none"> <li>■ Senate File 1830           <ul style="list-style-type: none"> <li>□ Sen. Gary Kubly, principal author</li> <li>□ Sen. Paul Koering</li> <li>□ Sen. John Marty</li> <li>□ Sen. Linda Berglin</li> <li>□ Sen. Yvonne Prettner Solon</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>■ House File 2109           <ul style="list-style-type: none"> <li>□ Rep. Erin Murphy, principal author</li> <li>□ Rep. Patty Fritz</li> <li>□ Rep. Jim Abeler</li> <li>□ Rep. Laura Brod</li> <li>□ Rep. Neva Walker</li> <li>□ Rep. Tom Huntley</li> <li>□ Rep. Mary Ellen Otremba</li> <li>□ Rep. Ken Tshcumper</li> <li>□ Rep. Julie Bunn</li> <li>□ Rep. Cy Thao</li> <li>□ Rep. Maria Ruud</li> <li>□ Rep. Diane Loeffler</li> <li>□ Rep. Mindy Geiling</li> <li>□ Rep. Bud Heidgerken</li> </ul> </li> </ul> |
|---|--|

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## Bill Approval Process

- |  |   |
|--|---|
| <ul style="list-style-type: none"> <li>■ Senate           <ul style="list-style-type: none"> <li>□ Health Committee</li> <li>□ State/Local Government</li> <li>□ HHS Finance</li> <li>□ Finance</li> <li>□ Floor vote</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>■ House           <ul style="list-style-type: none"> <li>□ Licensure subcommittee</li> <li>□ Health Committee</li> <li>□ State/Local Government</li> <li>□ HHS Finance</li> <li>□ Finance</li> <li>□ Ways and Means</li> <li>□ Floor vote</li> </ul> </li> </ul> |
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## Summer/Fall Activity

- Coalition members asked laboratorians:
  - To contact legislators to re-affirm support or ask for support
  - To contact hospital administrators to ask for support and to communicate with MHA
  - We provided talking points, emailed to all society members and posted at [www.asclsmn.org](http://www.asclsmn.org)
- Senate Health Committee chair (Senator Marty) attended Nov 2 coalition meeting

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## Key stakeholders

- MHA
- MMA
- Mayo Clinic
- Minnesota Department of Health
- Pathologists:
  - CAP opposes and hired a lobbyist
  - ASCP supports

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## MHA (MN Hospital Association)

- AHA is historically anti-licensure
- Concerns:
  - Fear that shortages will worsen
  - Grandfathering provisions
  - No separate licensure exam
- Input:
  - Small Rural Health Committee
  - Human Resource Committee
  - Patient Safety Committee: quality concerns
  - Board
  - Policy and Advocacy

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## MHA (current status)

- Workforce Development committee recommended to support bill with changes
- Policy committee asked coalition for changes
  - Remove phlebotomists/CMAs from the bill
  - Address grandfathering language (i.e. length of time)
  - Exclude waived testing
- MHA position was neutral; did not lobby against bill
- However, two large health systems chose to oppose independent of MHA; fear higher costs due to higher wages

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## MMA: MN Medical Association

- Met with Policy Advisory Committee in October 2006
- Impact of hiring qualified professionals
  - Supply versus OJT
- What is the public risk?
- Important to maintain quality
- Impact:
  - Hospitals
  - Larger clinics
  - Small clinics

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## MMA (current status)

- Concern about phlebotomists and CMAs inclusion in the bill
- Wanted to understand where MHA would weigh in on this issue
- MMA stayed neutral, but would have actively opposed had we tried to have stronger standards for POLs.

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## Opposition (March 2007)

- CAP/MN Society of Pathology/AAB
  - CAP (College of American Pathologists)
    - Consistently opposes licensure in all states
    - Reasons for opposition
      - CLIA regulations are sufficient to address quality issues in the laboratory
      - Licensure will exacerbate the current workforce shortage issue ("will make it harder to hire qualified staff")
      - Will make it "harder for pathologists to staff their laboratories"
      - Problems with licensure in New York State
  - MSP (Minnesota Society for Pathology): Board initially decided to join CAP and oppose the bill. Believe additional level of regulation unnecessary
  - AAB (American Association of Bioanalysts)
    - Opposes any bill which contains a requirement for formal degree for MT/CLS and CLT/CLS levels and opposed any continuing education requirement

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## Pathology stance

- In late September, MSP's executive board voted to separate from their coalition with CAP and to "not oppose" our bill
- We worked with MSP leadership to revise bill language and work toward active support.
- In late November we were informed by MSP that they had changed their position and would again support CAP in opposition to our bill
- Dec 14: CAP action alert to all CAP and MSP members asked members to contact hospital administrators contact MHA to oppose the bill

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## Current MSP issues:

- "Power" of the commissioner (Dept of Health)
- Make-up of the advisory council (would like pathologists to be equal or "+1")
  - Coalition would not agree to this.
  - Looked at make-up of all other health care profession licensure boards. Some had physician members, but none had a majority
- Build on CLIA – raise standards
- Concern re Molecular Biology certification
  - Bill does not require molecular biology certification to perform molecular testing
  - Molecular certification is one option available to achieve licensure

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## CAP/MSP Action Alert - issues

- Licensure will severely exacerbate the current laboratory personnel workforce shortage in **every area of the lab**. In general, states with laboratory personnel licensure have greater worker shortages.
- Licensure will greatly complicate and encumber the administration of the laboratory by pathologists and laboratory directors by **circumscribing scope of practice for all laboratory personnel**, making administration of the laboratory a greater challenge with many licensed practitioners **claiming professional autonomy**.
- Licensure will negatively impact the growing area of **molecular technology** due to workforce shortage and restriction of qualified individuals who may be considered experts in other parts the country, but who may lack the requisite licensure qualification.
- Licensure may **endanger the profession of histotechnology** due to exacerbation of workforce shortage and increased requirements to work in Minnesota. Thereby, licensure would deprive the laboratory of a critical pool of workers.
- Licensure may lead to diversion of laboratory work to out-of-state laboratories that are not encumbered by the regulatory requirements entailed with licensure regulations - exacerbating fragmentation of patient care and increasing lag time of diagnosis and treatment of patients.
- The proposed Minnesota licensure **legislation is rife with errors and ambiguities that will require protracted state regulatory interpretation**

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## Mayo issues (Oct 29 meeting):

- Make-up of the advisory council
- Concern re: advisory council housed within the Dept of Health
- Flexibility for an ever changing profession
- Do we need additional regulation?

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## Coalition successes

- Active participation by Mayo Clinic (Mayo said they would remain neutral, but ultimately testified against the bill)
- Active participation by MN Society for Pathology
  - Ultimately joined CAP in opposition
- Active participation by Department of Health
- Engagement of cytology and histology professions
- Stakeholder cooperation: Minnesota Hospital Association and Minnesota Medical Association
- Rank and file support
- Licensure has become a symbol of professional pride, quality and recognition
- Success with 2005 bill to "save the U of M Med Tech program" has served us well

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## Lessons learned from hearing

- Prepare legislators in advance as much as possible; one committee member thought that all we did was phlebotomy
- Put your most knowledgeable witness on first and let them answer questions. Our first witness was not heard because the committee had really not come to order.
- Be sure the grass roots has done its homework

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## Lessons learned

- Most effective arguments against us:
  - Weak point on regulation/quality of personnel in POLs
  - Cytology group had a written policy that they do not support licensure even though they were in the bill
  - Education does not guarantee quality!

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## How to make contacts

- **How to make an appointment with your state representative or senator:**
- Go to the Web site [www.leg.state.mn.us](http://www.leg.state.mn.us)
- Click on "Who Represents Me"?
- Click on District Finder
- This will bring you to a screen where you enter your address and ZIP code
- The next screen will show a map of the district where you live, along with pictures and contact information for your representative and senator.
- Click on the Web page beneath the picture of your legislator. The Web pages vary, but they always have the location and phone number of their office, and email.
- Emails and calls are good, but a personal visit is even better! This can be in the home district during the summer or fall, or at the office at the Capitol.
- To view recommended talking points and a sample letter to email to your senator or representative, go to [www.asclsmn.org](http://www.asclsmn.org) and select **licensure on the menu**

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## If you have questions or wish to assist, contact:

- Rick Panning
  - 651-291-6764
  - [panningri@usa.redcross.org](mailto:panningri@usa.redcross.org)
- Kathy Hansen
  - 612-273-5090
  - [khansen3@fairview.org](mailto:khansen3@fairview.org)

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