

MDH NBS Rule "Plan"

Stakeholders/Contacts:

1. Internal Contacts
 - a. Public Health Laboratory Division
 - b. Commissioner's Office
 - c. Governor's Office

2. External Contacts
 - a. Birthing Hospitals
 - b. Minnesota Labs (private/public)
 - c. Doctors, Nurses, Health Care providers (FPs and Ped)
 - d. Misc. Health Care Professionals
 - e. March of Dimes
 - f. Parents
 - g. Privacy advocates

3. Legislators/Staff Contacts
 - a. Chairs of Health and Human Services Policy Committee
 - b. Committee administrators for above committees
 - c. House/Senate Staff Research for these committees
 - d. Revisor

Timeline: (All dates are subject to change)

1. Begin internal discussions with staff: August – October 2005
 - a. Hold group and individual meetings
 - b. Review draft of suggested changes

2. Send Administrative Rule Preliminary Proposal Form to Governor's Office: August 2005.

3. Select an Advisory Committee: August 2005
 - a. Solicit input from MDH staff
 - b. Send letters inviting selected individuals to participate
 - c. Possibly include legislators or their staff. If not included, at least meet with them to let them know what we are doing
 - d. Possible press release

4. Hold Advisory Committee meetings: Late November – End of January (*Maybe longer-it depends on how much agreement or opposition we have on the changes.*)
 - a. Set dates for meetings (number undetermined depending on controversy)
 - b. Give members summary of proposed changes
 - c. Take input and redraft proposed rules so that we can publish the request for comments

5. Publish Request for Comments:
 - a. Have to wait 60 days before we can publish dual notice of hearing
 - b. Write the Rules and SONAR
 - c. Review comments and decide how to proceed and what changes to make to the draft rules.
 - d. Press Release
 - e. Meet with legislators

6. Publish Notice of Dual Hearing or Notice of Hearing:
 - a. Review comments and decide how to proceed and what changes to make to the draft rules.
 - b. Possible Press Release

SUMMARY OF COMMUNICABLE DISEASE REPORTING RULE TIMELINE

Task	Entails	Drop Dead Date	Other
Contact Revisor	Cindy Maxell: 651- 296-0955		
Advisory Task Force	Selecting Individuals Setting up Meeting Times		Meet before publishing request for comments.
FIRST FORMAL STEPS IN RULEMAKING PROCESS			
Notify Gov. Office that dept. is working on the rule (<i>need MDH commissioner approval too</i>)	Complete Preliminary Proposal Form and submit to governor		Do this before publishing Request for Comments. But, don't need governor's approval to publish.
Publish Request for Comments	Publish request in registry and notify other interested parties of intent to write a rule (mail, e-mail, listserv, etc)		Advisory council will meet before request for comments published is published
Draft Communicable Disease Reporting Rule	Revisor does final draft		
Draft SONAR			Include why we didn't do something and opposing concerns. If bill passes legislature may need to do fiscal note too.
<i>Don't forget Commissioner approval to do next steps</i>			
Notify Governor Before Publishing Notice of Intent to Adopt	Complete Proposed Rule & SONAR Form & submit to governor		Governor will review within 3 weeks. Cannot publish Notice of Intent to Adopt without governor's approval.
ALJ Approval of Notice of Intent to Adopt	Send to ALJ, also request hearing date & get approval of additional notice plan		They have to respond in 5 working days.
Publish Notice of Intent to Adopt	Publishing in registrar/1 st public viewing, additional notices sent out		
Dual Notice of Hearing	Publish in Registry & send out additional notices	Same day as Notice of Intent	At least 25 responses Should do it this way so you'll know who is going to be at the hearing.
Prepare for Hearing	Meet with agency staff		
Hearing			
Comment Period After Hearing	Send to ALJ agency comments	Up to 20 days	All sides can submit comments to Judge
Rebuttal to Comments	Send to ALJ comments	5 days later	
ALJ Submits Their Order			
Agency Makes Revisions	Only done if needed		
Final Governor Approval	Complete Final Rule Form		Cannot formally submit the Order Adopting Rules to OAH without approval
Final ALJ Approval			After governor's approval
Adopt Rules			

Draft 8/15/2005

Task	Start Date	Completion Date	Person
During 60 Day Waiting Period			
Get approval from commissioner's office			
Prepare Final Rule			
Draft Statement of Need/Reasonableness			
Internal Agency Review of SONAR staff, manager, AC, commissioner			
Add new rule language from advisory group			
Draft Dual Notice, Notice Plan			
Manager & AC review of dual notice and notice plan			
Notify governor of notice of intent to adopt (form #2)			
Send to ALJ for approval (intent to adopt)-everything must be done			
Send Sonar to Legislative Library			
Send dual notice, rules to register			
Prepare mailing of dual notice & rules to affected parties			
Mail Notice to legislature			
Publish Dual Notice, rules in register			
Proceed according to comments			
Review comments, decide on changes to rule if necessary			
If 25 or more requests			
Prepare for hearing			
Hearing			
Post-hearing meeting to decide response- 3 weeks			
Prepare response during 20 day comment period			
Submit responses to ALJ			
Prepare rebuttle response (5 days)			
Submit responses to ALJ			
Task	Start Date	Completion Date	Person

FORMAL STEPS: NEWBORN SCREENING RULE TIMELINE

Task	Entails	Drop Dead Date	Other
Contact Revisor	Cindy Maxell: 651- 296-0955		
Advisory Task Force	Selecting Individuals Setting up Meeting Times		Convene advisory task force before
FIRST FORMAL STEPS IN RULEMAKING PROCESS			
Notify Gov. Office that dept. is working on the rule (<i>need MDH commissioner approval too</i>)	Complete Preliminary Proposal Form and submit to governor	DONE: August 2005	Do this before publishing Request for Comments. But, don't need governor's approval to publish.
Publish Request for Comments	Publish request in registry and notify other interested parties of intent to write a rule (mail, e-mail, listserv, etc)		If work with advisory council then public will give input earlier too.
Draft Immunization Rule	Revisor does final draft		
Draft SONAR			Include why we didn't do something and opposing concerns. If bill passes legislature may need to do fiscal note too.
<i>Don't forget Commissioner approval to do next steps</i>			
Notify Governor Before Publishing Notice of Intent to Adopt	Complete Proposed Rule & SONAR Form & submit to governor		Governor will review within 3 weeks. Cannot publish Notice of Intent to Adopt without governor's approval.
ALJ Approval of Notice of Intent to Adopt	Send to ALJ, also request hearing date & get approval of additional notice plan		They have to respond in 5 working days.
Publish Notice of Intent to Adopt	Publishing in registrar/1 st public viewing, additional notices sent out		
Dual Notice of Hearing	Publish in Registry & send out additional notices	Same day as Notice of Intent	At least 25 responses Should do it this way so you'll know who is going to be at the hearing.
Prepare for Hearing	Meet with agency staff		
Hearing			
Comment Period After Hearing	Send to ALJ agency comments	Up to 20 days	All sides can submit comments to Judge
Rebuttal to Comments	Send to ALJ comments	5 days later	
ALJ Submits Their Order			
Agency Makes Revisions	Only done if needed		
Final Governor Approval	Complete Final Rule Form		Cannot formally submit the Order Adopting Rules to OAH without approval
Final ALJ Approval			After governor's approval
Adopt Rules			

Stuff I need to do:

1. Logistics each step of the way
2. Get bill that didn't pass in 2001
3. Are rules defined in statute or do we need to define them
4. get other sonars and rules.

Other Discussion Points

1. Set up Advisory Council: proponents and opponents, representatives from CFL, DHS, MNSCU, Chairs-legislators.
2. Must decide how we want to use advisory council. Do we want to have a rule already drafted (rough outline) for advisory council or start from scratch with them.
3. Advisory council should meet after request for comments so the council can see the comments. How much public input do we want?
4. Who from MDH will be working on the rule with me?

Draft 8/15/2005

Get ALJ decision			
Make appropriate changes to decision			
Commissioner signs order			
Notify governor (form #3)			
Publish rules in register			
Rules effective 5 days later			
If Less Than 25 Responses			
Make any necessary changes to rule			
Prepare notice of adoption			
Review notice of adoption			
Send to ALJ for decision			
React to ALJ decision			
Publish rules in register			
Rules effective 5 days later			

Detailed Agency Rule Timeline <i>Not Necessarily In This Order</i>			
Task	Start Date	Completion Date	Person
Contact Revisor			
Meet with agency staff			
Draft Rule			
Put Rule together			
Internal Review by lead writers			
Review by Supervisor			
Review by Director/A.C.			
Review by commissioner			
Send to Revisor			
Request for Comments			
Notify Governor's Office (form#1) --- Get comm approval/signature			
Write Request for Comments			
Review Request for Comments			
Get approval from Commissioner's Office to Publish			
Review of Notice Plan-internal only			
If you have a SONAR and Rule at this time you can forward to the governor's office too			
Send Request to State Registrar			
Prepare request for comment mailing			
Publish Request in Register-60 day waiting period			
Advisory Group			
Select members w/staff input			
Send preliminary ltr to advisory group			
Meeting logistics for advisory group			
Send letter to group with proposed rules			
Hold Meetings			

7. Hold hearing if more than 25 people request it. (Must be at least 30 days after publication.)

For detailed timelines see attached.

Communications Plan: *(Exact details will be developed at a later date, see stakeholder/contact list also)*

1. Internal Contacts

2. External Contacts

- a. Press Releases
- b. Meetings with legislators
- c. Mailings and e-mail listservs to affected parties
- d. Advisory Committee meetings

3. Talking Points:

- a. Benefits:

- Overall, this rulemaking process will update Minnesota's Newborn Screening Rules to reflect changes in the 2003 law, changing roles of participants and
- The Rule has not been revised in 2000..
 - Revision is critical to effectively conduct Newborn Screening of infants.
 - Implement appropriate treatment options
 - Keep Minnesotans healthy, medically and economically
- With the increased risk of bioterrorism the rule needs to be updated to require:
 - submission of specimen to identify the disease agent; and
 - reporting of disease related to bioterrorism, including unexplained respiratory illness.
- For more specific details see governor's preliminary proposal form

- b. Opponents Concerns

- Personal Privacy. Government should not have the right to get information on individuals and keep blood spots.

Response:

- Newborn screening is well-established in this state (since ?????) and MDH has a good record of protecting people's privacy. There are state and federal laws protecting privacy, while in addition MDH has data privacy procedures in place.