Requiring Reporting of Latent Tuberculosis Infection in Maryland: Process and Challenges

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PRECEPTORS

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Definitions – LTBI and TB

• **Latent TB infection (LTBI)**
  - Dormant TB infection in the lungs
  - No symptoms
  - Not infectious
  - TB skin test or blood test positive

• **TB Disease**
  - Occurs in about 10% of people with untreated LTBI
  - Symptoms
  - Infectious
Project Goal & Objectives

GOAL: Require all providers and laboratories in Maryland to report all positive LTBI test results to the DHMH TB Center.

• **Objective 1:** The Maryland Annotated Code of Regulations (COMAR), Title 10.06, Chapter 01.03: *The List of Reportable Diseases and Conditions*, will be amended to include that all patients with LTBI be reported.

• **Objective 2:** *To establish a surveillance system*, consistent with that being developed by the CDC for national LTBI surveillance system, to effectively identify patients with LTBI and their related risk factors.

• By May 2017.
Health Regulation Process

- Notify Office of Health Planning and Policy
- Meet with Office Director
  - Assigned Policy Analyst Contact (or regulations coordinator)
- Submit Regulation Package
  - Create "Redline"
  - Regulation Background Information Form
  - Proposed Regulation Publication Form
  - Notice of Regulations Development Form
- Pre Comment Phase
  - Contact key stakeholders for initial feedback
  - Be prepared to address concerns during Comment Phases
Objective 1: Amend Maryland Code of Regulations

• Worked with Office of Health Planning and Policy Director Jody Sheely and Policy Analyst Hannah Leker
  • “Redline” COMAR Proposal
  • Three Documents
• Reviewed by:
  • Infectious Disease Epidemiology and Outbreak Response Bureau Director Dr. David Blythe
  • TB Center Chief Nancy Baruch
• Submitted Proposal on January 11, 2017
Objective 1: Amend Maryland Code of Regulations

- Pre Comment Phase: Reach out to Stakeholders
  - Local health departments
  - Correctional facilities (federal, state, local)
  - Occupational health of hospitals
  - Federally-qualified health centers
  - Infection prevention
  - HIV clinics
  - Long-term care facilities
  - Private medical practitioners
  - Schools and Universities
Objective 1: Amend Maryland Code of Regulations

• Preliminary Positive Feedback
  • Necessary next step towards TB elimination
  • Not an anticipated increased burden for stakeholders
  • Most stakeholders are not opposed to the regulation change

• Preliminary Negative Feedback
  • Ethical concern regarding treatment responsibility

• Suggestions
  • Batched data collection
  • Specify roles for schools and universities
## Health Regulation Process

### Obtain and Submit Signatures
- Drafter of regulations
- Drafter’s supervisor
- Director of Proposed Unit
- Deputy Secretary of Proposed Unit

### Internal Comment Phase
- Governor’s Office
- Financial Management Administration
- Assistant Attorney General’s Office
- Office of Governmental Affairs
- Respond to Comments

### Public Comment Phase
- Posted on Website
- If necessary, hearing is set
- Respond to Comments
- Prepare Notice of Final Action

### Regulations Coordinator forwards Final Regulation Package
- Sent to Assistant Attorney General and Secretary of Health and Mental Hygiene
Objective 2: Establish LTBI surveillance system

- Local Health Department Survey
- Met with Deputy Chief for HIV Case Surveillance, Reshma Bhattacharjee
- Accessed Several Other Reportable Diseases/Conditions
- Compiled Different LTBI Surveillance Systems from 17 States
  - Confirmed LTBI System = LTBI Included on List of Reportable Diseases and Conditions AND LTBI Report Form
Objective 2: Establish LTBI surveillance system

- Worked with TB epidemiologists
  - Establish general surveillance protocols
  - Create LTBI data dictionary
- Data in alignment with CDC’s proposed Surveillance TB Elimination System (STEMS)
- Managed in Maryland’s National Electronic Disease Surveillance System (NEDSS)
- Pilot LTBI Data Assessment
  - 17 Fundamental Data Elements
Limitations and Challenges

- The formal process took more time than expected
  - Anticipated regulation change: 2018
- LTBI treatment responsibility
- Unknown volume of data and increased burden on DHMH
- Follow-up investigations – how and when to report
- Appropriate surveillance and data elements in the future
Conclusion and Next Steps

• Significant progress has been made
  • Completed initial steps in formal regulation change process
  • Drafted LTBI Surveillance System

• Next Steps:
  1. Obtain DHMH signatures of approval, Respond to stakeholder comments to the regulation
  1. Send out Pilot LTBI survey, Translate data dictionary into electronic system