



# **Tuberculosis Control**

## **Legal Authority in the Commonwealth of Virginia**

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# Federal Authority

- 42 U.S.C. § 264; 42 C.F.R. Parts 70 and 71
  - CDC can issue a public health order to an international or interstate traveler with infectious TB.
  - CDC can also conduct public health prevention measures, such as inspection or disinfection and can require travelers to provide contact information.

# State Authority

- 10th Amendment to U.S. Constitution
  - *“The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States, respectively, or to the people.”*
  - *Jacobsen v. Massachusetts (1905)*  
States have the “police power” authority to enforce public health measures. (Case involved smallpox vaccine)  
Indirectly referenced quarantine

# Virginia Law

- Reporting
- Treatment and Management
- Isolation





# Definition of TB

- § [32.1-49.1](#). Definitions.
- "Active tuberculosis disease" means a communicable disease caused by an airborne microorganism and characterized by the presence of either (i) a specimen of sputum or other bodily fluid or tissue that has been found to contain tubercle bacilli as evidenced by culture or other definitive diagnostic test as established by the Commissioner, (ii) a specimen of sputum or other bodily fluid or tissue that is suspected to contain tubercle bacilli as evidenced by smear and sufficient clinical and radiographic evidence of active tuberculosis disease is present as determined by a physician licensed to practice medicine in the Commonwealth, or (iii) sufficient clinical and radiographic evidence of active tuberculosis disease as determined by the Commissioner is present, but a specimen of sputum or other bodily fluid or tissue containing or suspected to contain tubercle bacilli is unobtainable.
- "Tubercle bacilli" means disease-causing organisms belonging to the Mycobacterium tuberculosis complex and includes Mycobacterium tuberculosis, Mycobacterium bovis, Mycobacterium africanum or other members as established by the Commissioner.
- "Tuberculosis" means a disease caused by tubercle bacilli.

# Reporting of TB – Initial

- Report to local health department by laboratories, physicians, and directors of medical care facilities.
- Active TB to be reported immediately by the most rapid means available.

# Reporting of TB - Initial

- Laboratories required to report:
  1. Acid fast bacilli by microscopic examination;
  2. Mycobacterial identification—preliminary and final identification by culture or nucleic acid detection;
  3. Drug susceptibility test results for *M. tuberculosis*

# Initial Reporting

- Physicians and directors of medical care facilities are required to report:
  - Tuberculosis, active disease
  - Tuberculosis infection
- Details of report contained in 12 VAC 90-225.:

name; age; date of birth; gender; address; pertinent clinical, radiographic, microbiologic and pathologic reports, whether pending or final; such other information as may be needed to locate the patient for follow-up; and name, address, and telephone number of the treating physician.

# Secondary Report

- Secondary report by physicians and directors of medical care facilities simultaneously or within 1-2 weeks after initial report and includes:
  - Date and results of TST
  - Date and results of chest radiographs
  - Dates and results of bacteriologic or pathologic testing
  - The drug regimen
  - Date and results of drug susceptibility testing
  - HIV status
  - Contact screening info
  - Contact information for physician



# Subsequent Report

- Subsequent reports by physicians/directors of medical care facilities when:
  - Clinical status changes
  - Treatment regimen changes
  - Treatment ceases
  - Updates to lab results, treatment adherence
  - Updates to provider contact information
  - Other clinical information



# Reporting of TB

- Reports by laboratories – additional requirements. Submit sample to DCLS or other lab designated by the Board.



# Reporting of TB

- Person making report immune from civil liability or criminal penalty for making report unless acting with gross negligence or malicious intent.
- VDH shall not disclose to the public the name of any person reported or the name of any person making a report.



# Investigations: Records from Health Care Providers

- HIPAA allows “public health authorities” such as the CDC and VDH’s Office of Epidemiology and TB Control to access health records without patient authorization, 45 CFR 164.512(b)
- § 32.1-40 of Code of Virginia says:
  - Every practitioner of the healing arts and every person in charge of any medical care facility shall permit the Commissioner or his designee to examine and review any medical records which he has in his possession or to which he has access upon request of the Commissioner or his designee in the course of investigation, research or studies of diseases or deaths of public health importance. No such practitioner or person shall be liable in any action at law for permitting such examination and review.

# TB Investigation in a School

- FERPA: Family Educational Rights and Privacy Act, 20 U.S.C. 1232g and 34 C.F.R. Part 99
  - FERPA addresses the privacy and disclosure of educational records.
  - Public health can access school records if:
    - Consent (parent or student > age of 18)
    - Directory information
    - De-identified information
    - Health or safety emergency
  - Restrictions about re-disclosing info obtained under FERPA

# FERPA: Health or Safety Emergency

- Articulable and significant threat to health or safety of students or other individuals
- School must have rational basis for determining if current emergency exists
- Not a possible or eventual emergency (e.g. not determining whether emergency exists).
- Disclosure must be temporally limited.

34 C.F.R. 99.36

# Contact Tracing

- Local health director may
  - conduct contact tracing for active TB
    - Contact tracing is confidential.
  - recommend appropriate health control measures.

# Treatment of TB

- Any local health director may request one suspected of having active TB to be examined immediately by:
  - Physician or advance practice registered nurse at own expense  
if approved by the local health director or
  - By the local health director at no cost

# Treatment Plan

- Treating physician and medical care facility shall develop an individualized treatment plan with:
  - Patient address and name of provider
  - Planned course of drug therapy
  - Estimated date of completion
  - Means of ensuring successful completion

# Treatment Plan

- Plan submitted to local health director for approval.
- If disagreement between health director and provider, Commissioner shall have the authority to settle.
- Upon request, person in charge of medical facility or physician shall submit documentation of adherence to plan.

# TB Treatment Concludes

Active TB considered present until (i) the person has received a complete and adequate course of antituberculosis drug therapy as established by the Commissioner in accordance with guidelines developed by the American Thoracic Society and the CDC and (ii) three successive cultures of specimens of sputum or other bodily fluid or tissue collected at intervals of no less than one week, or other definitive diagnostic test as established by the Commissioner demonstrate no viable tubercle bacilli, or the Commissioner or his designee determines that the clinical, laboratory, or radiographic evidence leads to a diagnosis other than active tuberculosis disease. Va. Code § 32.1-50.1.



# Noncompliance

- Investigation
- Counseling Order
- Outpatient Treatment Order
- Emergency Order
- Isolation Order



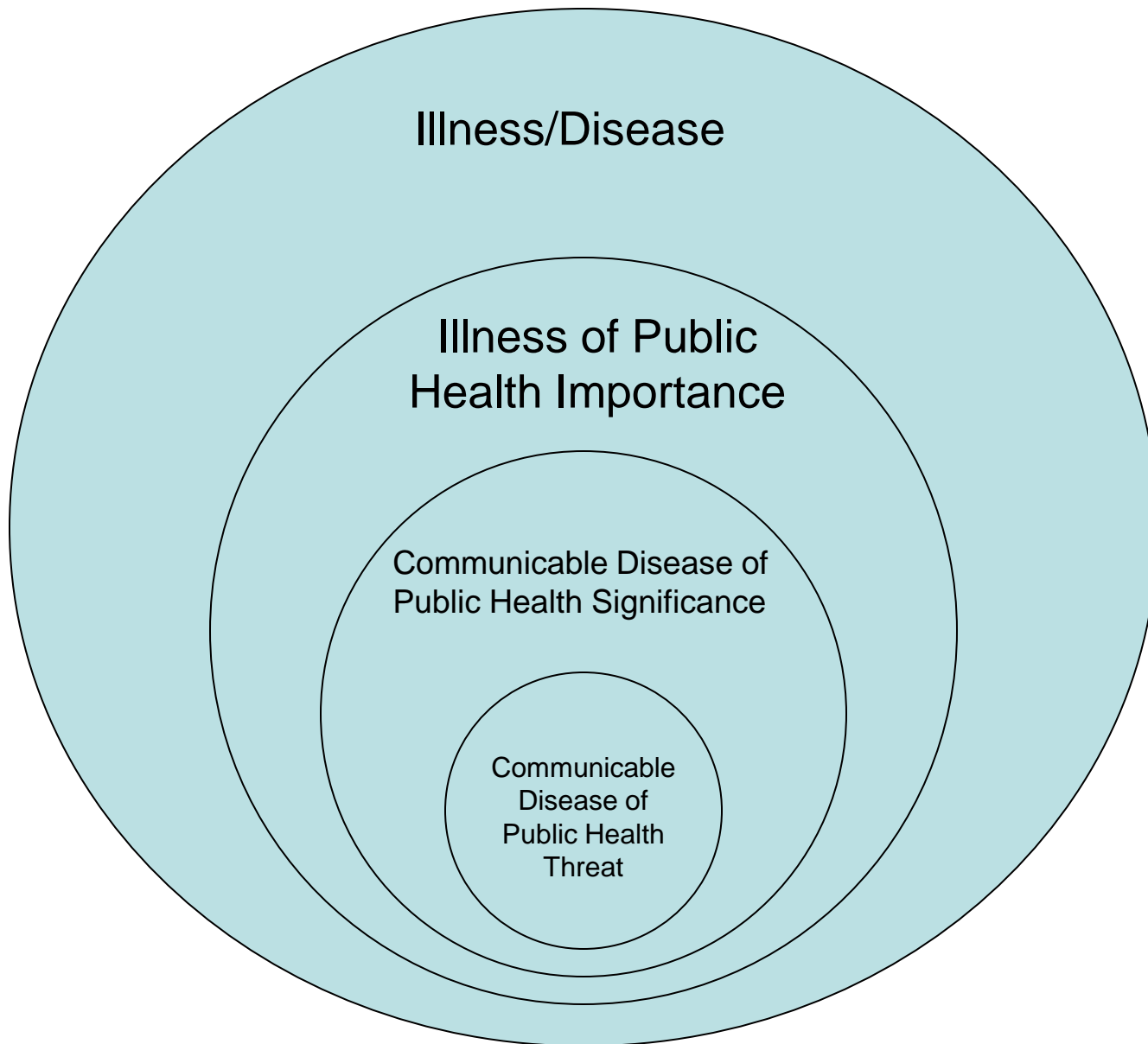
# Isolation vs. Quarantine

- Isolation: separation (for period of communicability) of known infected persons to prevent transmission of an infectious agent.



**QUARANTINE  
AREA  
NO ENTRY**

- Quarantine: restriction of activities during the incubation period of healthy persons exposed to a communicable disease to prevent transmission.



# Counseling Order

- If two verified reports or medical evidence that patient engaging in at risk behavior, Commissioner or designee may conduct an investigation of VDH and other medical records.
- Then, Commissioner or her designee may issue a counseling order
  - At risk behavior
  - Precautions and need to use

# Outpatient Treatment Order

- Outpatient Treatment Order if:
  - Person refused or failed to adhere to treatment and
  - Despite counseling is engaging in conduct that places uninfected persons at risk
- Orders person to:
  - Report to local health department to receive
    - Treatment
    - Education

# Temporary Detention

- If person counseled is still engaging in at-risk behavior, Commissioner or her designee may petition the general district court for the person to appear before the court.
- Order of temporary detention.
- Person held for period not to exceed 48 hours unless holiday or weekend.
- Not held in a jail – residence, “convenient and willing institution,” or “other willing place.”

# Emergency Isolation Order

- Emergency order by Commissioner if:
  - Documented and appropriate counseling
  - Conduct that places uninfected persons at risk and
  - Imminent threat to the health of others
  - Must also show:
    - Disobeyed outpatient treatment order
    - History of failure to adhere to treatment OR
    - Person indicated will not comply with treatment

# Emergency Isolation Order

- Emergency Order
  - Custody not to exceed 48 hours  
(or next day not weekend or holiday)
  - In least restrictive willing facility providing protection to others and appropriate treatment
  - Cannot be in a jail
  - All state and local law enforcement officers authorized to take custody of the subject of the order



# Order of Isolation



- Isolation hearing
  - Held in General District Court
  - Held within 48 hours of emergency detention or next business day if holiday or weekend
  - Person receives notice prior to hearing of basis for isolation and right of appeal
  - Right to counsel and interpreter

# Order of Isolation



- Order of isolation if show:
  - Person infected with TB
  - Engaging in at-risk behavior
  - Demonstrated an intentional disregard for the health of the public by placing others at risk for infection
  - No reasonable alternative means of reducing risk to public health

# Order of Isolation

- Order valid for
  - 120 days or
  - Shorter time if Commissioner, his designee, or the court find person no long poses a substantial threat to the health of others
- Order in:
  - Residence (may be with electronic device)
  - Institution
  - Other place

# Order of Isolation

- Order of isolation may include participation in counseling or educational programs
- After no longer a threat, order may be solely for counseling or education

# Order of Isolation

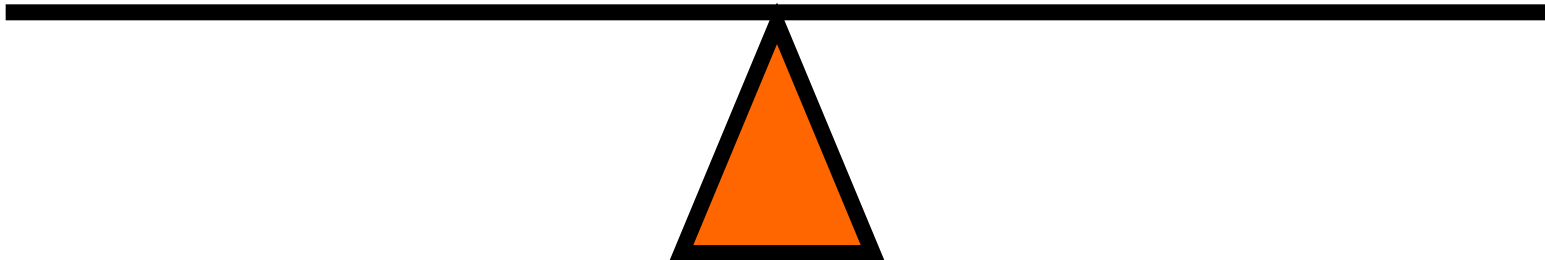
- Order of isolation
  - Appeal to the circuit court within 30 days
  - Right to counsel
  - Interpreter
  - Responsible for expenses of treatment

# Conditions for Invoking Isolation

- Implemented in “least restrictive means.”
- “Least restrictive” means the minimal limitation of the freedom of movement and communication of an individual while under an order of isolation or an order of quarantine that also effectively protects unexposed and susceptible individuals from disease transmission.

**Public Good**

**Civil Liberties**



# Health Records Privacy

- The Commissioner has the authority to examine any health records of any person subject to an order of quarantine or isolation. A covered entity may disclose protected health information to the Commissioner without obtaining consent from the patient pursuant to this article.
- The Commissioner may re-disclose health information pursuant to HIPAA or Va. Code § 32.1-41.
- FOIA exemption: health records are confidential and shall not be disclosed pursuant to the provisions of § 2.2-3705.5.

# Process of Building Case

- Extensive documentation
  - Counseling
  - Treatment Orders
  - Noncompliance
- Call AG's Office and TB Control to discuss





# Arrange Details

- Arrange for site of isolation
  - Appropriate site
  - Payment
  - Medication and treatment
- Arrange for pick up of patient
  - Which law enforcement
  - Legal duty to inform public safety officer of risk of exposure. Va. Code § 32.1-116.3
  - Personal protection



# Hearing

- Thoroughly documented medical records

Va. Code § 8.01-390

- Witnesses
  - Physician/expert
  - Nurse/outreach worker

# Hearing Structure

- Expert witness (possibly health director)
  - Qualify the expert
  - Explain disease
    - What causes it, how it progresses, how it is transmitted, how it is cured, incubation period, how managed and prevented
  - Review of patient's record, conclusions, and recommendations
- Fact witnesses (nurse, outreach worker)
  - Details of patient's noncompliance
- Defense case

# Isolation

- Arrange for treatment and medication
- Payment
- Rights of patient
  - Phone, letters
  - Clothing
  - Other

*No Entry*  
*Isolation Procedures*  
*In Process*

*Do not Enter*

# Voluntary Compliance

- Most important part of TB control
- Outreach workers
- Flexibility with medication and isolation sites
- Bonds with nurses/outreach workers

# Principal Resources

- Virginia Code
  - §§ 32.1-48.02 to 32.1-48.04, 32.1-49 to 32.1-54, 32.1-35 to 32.1-41
- Virginia Administrative Code
  - 12 VAC 5-90 et seq.
  - Other (see infra)
- Federal law
  - 42 U.S.C. § 264
  - 42 C.F.R Parts 70-71

# Other TB Laws: EMS

- Transferring health care facility shall alert EMS agency of the condition of a patient with a communicable disease and the types of precautions to take.
- Physician who later determines transported patient has communicable disease shall notify EMS agency.
- Any person requesting a public safety agency to transfer or take custody of one with a communicable disease shall inform the employee of the potential risk of exposure.

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