

ORDER OF THE
DEPARTMENT OF HEALTH AND FAMILY SERVICES
AMENDING, REPEALING AND RECREATING RULES

To amend HFS 145.01 and to repeal and recreate HFS 145.08, HFS 145.09, HFS 145.10, HFS 145.11, HFS 145.12 and HFS 145.13, relating to control of communicable diseases.

Analysis Prepared by the Department of Health and Family Services

This order updates the Department's rules for prevention and control of tuberculosis based on changes made to ss. 252.07 and 252.10, Stats., as created or amended in 1999 Wisconsin Act 9. These proposed rules would modify subch. II of ch. HFS 145 to reflect and implement the changes to ch. 252, Stats., made by Act 9. The rulemaking order proposes principally the following changes:

- To specify laboratory procedures for identification of *Mycobacterium tuberculosis*;
- To specify how the Department will assist local health departments in administration and enforcement of confinement of patients with tuberculosis;
- To establish standards for certification of public health dispensaries;
- To specify services and reimbursement rates for public health dispensaries; and
- To specify record-keeping requirements for public health dispensaries.

The rulemaking order expands the sections on public health dispensaries for the diagnosis and treatment of persons with or suspected of having tuberculosis. The expanded sections specify how the Department will certify public health dispensaries and which dispensary services the Department will reimburse. Local health departments and the Department are authorized by s. 252.10 (1), Stats., to establish public health dispensaries and the Department is authorized by s. 252.10 (6) (b), Stats., to reimburse the dispensaries at the medical assistance program rate for services specified in rule.

Pursuant to s. 227.21, Stats., the Department has requested permission from the Attorney General and the Revisor of Statutes to incorporate three national standards by reference into administrative rule. These standards are listed in the proposed order.

The Department's authority to amend and repeal and recreate these rules is found in ss. 252.02 (4), 252.06 (1), 252.07 (1p) and (11), 252.10 (1) and (6) (a) and (b), and 254.51 (3), Stats. The rules interpret ss. 252.07 and 252.10, Stats.

SECTION 1. HFS 145.01 is amended to read:

HFS 145.01 Statutory authority. This chapter is promulgated under the authority of ss. 252.02 (4), 252.06 (1), 252.07 (1p) and (11), 252.10 (1), 252.10 (6) (a) and (b) and (f), 252.11 (1) and (1m), 254.51 (3) and 990.01 (5g), Stats.

SECTION 2. HFS 145.08, 145.09, 145.10, 145.11, 145.12 and 145.13 are repealed and recreated to read:

HFS 145.08 Definitions. In this subchapter:

(1) “Case management” means the creation and implementation of an individualized treatment plan for a person with tuberculosis infection or disease that ensures that the person receives appropriate treatment and support services in a timely, effective, and coordinated manner.

(2) “Confinement” means the restriction of a person with tuberculosis to a specified place in order to prevent the transmission of the disease to others, to prevent the development of drug-resistant organisms or to ensure that the person receives a complete course of treatment.

(3) “Contact” means a person who shares air with a person who has infectious tuberculosis.

(4) “Contact investigation” means the process of identifying, examining, evaluating and treating a person at risk of infection with *Mycobacterium tuberculosis* due to recent exposure to infectious tuberculosis or suspected tuberculosis.

(5) “Directly observed therapy” means the ingestion of prescribed anti-tuberculosis medication that is observed by a health care worker or other responsible person acting under the authority of the local health department.

(6) “Infectious tuberculosis” means tuberculosis disease of the respiratory tract capable of producing infection or disease in others, as demonstrated by the presence of acid-fast bacilli in the sputum or bronchial secretions, or by radiographic and clinical findings.

(7) “Isolate” means a population of *Mycobacterium tuberculosis* bacteria that has been obtained in pure culture medium.

(8) “Isolation” means the separation of persons with infectious tuberculosis from other persons, in a place and under conditions that will prevent transmission of the infection.

(9) “Licensed prescriber” means an advanced practice nurse prescriber, a physician assistant, or other person licensed to prescribe medication under Wisconsin law.

(10) “Public health dispensary” means a program of a local health department or group of local health departments to prevent and control tuberculosis disease and infection

by the identification, medical evaluation, treatment and management of persons at risk for tuberculosis infection or disease.

(11) “Repository” means a central location at the Wisconsin State Laboratory of Hygiene for receipt and storage of patient isolates of *Mycobacterium tuberculosis*.

(12) “Sputum conversion” means the conversion of serial sputum cultures for *Mycobacterium tuberculosis* from positive to negative, in response to effective treatment.

(13) “Suspected tuberculosis” means an illness marked by symptoms, signs, or laboratory tests that may be indicative of infectious tuberculosis such as prolonged cough, prolonged fever, hemoptysis, compatible radiographic findings or other appropriate medical imaging findings.

(14) “Tuberculosis disease” means an illness determined by clinical or laboratory criteria or both to be caused by *Mycobacterium tuberculosis*.

(15) “Tuberculosis infection” means an infection with *Mycobacterium tuberculosis* in a person who has no symptoms of tuberculosis disease and is not infectious.

HFS 145.09 Laboratory procedures. (1) Any laboratory that receives a specimen for tuberculosis testing shall report all positive results as specified in s. HFS 145.04, including those obtained by an out-of-state laboratory, to the local health officer and to the department. The laboratory shall also submit an isolate from a patient with a positive culture to the state repository.

Note: Isolates for the state repository should be sent to: Mycobacteriology Laboratory, State Laboratory of Hygiene, Room 121, 465 Henry Mall, Madison, WI 53706.

(2) Any laboratory that performs primary culture for mycobacteria shall perform organism identification using an approved rapid testing procedure specified in the official statement of the Association of Public Health Laboratories, unless specified otherwise by the state epidemiologist. The laboratory shall ensure at least 80% of culture-positive specimens are reported as either *Mycobacterium tuberculosis* complex or not *Mycobacterium tuberculosis* complex within 21 calendar days of the laboratory’s receipt of the specimens.

Note: The official statement of the Association of Public Health Laboratory entitled “*Mycobacterium tuberculosis*: assessing your laboratory” is on file in the Revisor of Statutes Bureau and the Secretary of State’s Office, and is available from the Department’s Division of Public Health, P.O. Box 2659, Madison, WI 53701–2659.

(3) Any laboratory that identifies *Mycobacterium tuberculosis* shall ensure that antimicrobial drug susceptibility tests are performed on all initial isolates. The laboratory shall report the results of these tests to the local health officer or the department.

Note: Reports may be submitted to the Department's Division of Public Health, P.O. Box 2659, Madison, WI 53701-2659.

HFS 145.10 Restriction and management of patients and contacts. (1) All persons with infectious tuberculosis or suspected tuberculosis, and their contacts, shall exercise all reasonable precautions to prevent the infection of others, under the methods of control set out in section 9 under tuberculosis, pages 525 to 530, listed in the 17th edition (2000) of *Control of Communicable Diseases Manual*, edited by James Chin, published by the American Public Health Association, unless specified otherwise by the state epidemiologist.

Note: The handbook *Control of Communicable Diseases Manual*, 17th edition (2000), edited by James Chin, is on file in the Revisor of Statutes Bureau and the Secretary of State's Office, and is available for purchase from the American Public Health Association, 800 I Street, NW, Washington, DC 20001-3710.

(2) All persons with infectious tuberculosis or suspected tuberculosis shall be excluded from work, school and other premises that cannot be maintained in a manner adequate to protect others from being exposed to tuberculosis, as determined by the local health officer.

(3) Official statements of the American Thoracic Society shall be considered in the treatment of tuberculosis, unless specified otherwise by the state epidemiologist. Specific medical treatment shall be prescribed by a physician or other licensed prescriber.

Note: The official statements of the American Thoracic Society may be found in the Centers for Disease Control and Prevention's recommendations and report "Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection." The report may be found in the Morbidity and Mortality Weekly Report, June 9, 2000, Vol. 49, No. RR-6. The American Thoracic Society's "Treatment of Tuberculosis and Tuberculosis Infection in Adults and Children" may be found in the *American Journal of Respiratory and Critical Care Medicine*, vol. 149, 1994, pp. 1359-1374. These reports are on file in the Revisor of Statutes Bureau and the Secretary of State's Office, and are available from the Department's Division of Public Health, P.O. Box 2659, Madison, WI 53701-2659.

(4) (a) Any physician or licensed prescriber who treats a person with tuberculosis disease shall report all of the following to the local health officer:

1. The date of the person's sputum conversion.

2. The date of the person's completion of the tuberculosis treatment regimen.

(b) The physician or his or her designee shall immediately report to the local health officer when a person with tuberculosis disease does any of the following:

1. Terminates treatment against medical advice.
2. Fails to comply with the medical treatment plan.
3. Fails to comply with measures to prevent transmission.
4. Leaves the hospital against the advice of a physician.

(5) Upon receiving a report under sub. (4) (b), the local health officer shall immediately investigate and transmit the report to the department.

(6) The local health officer or the department may do any of the following:

- (a) Order a medical evaluation of a person.
- (b) Require a person to receive directly observed therapy.
- (c) Require a person to be isolated under ss. 252.06 and 252.07 (5), Stats.

(d) Order the confinement of a person if the local health officer or the department decides that confinement is necessary and all of the following conditions are met:

1. The department or local health officer notifies a court in writing of the confinement.
2. The department or local health officer provides to the court a written statement from a physician that the person has infectious tuberculosis or suspected tuberculosis.
3. The department or local health officer provides to the court evidence that the person has refused to follow a prescribed treatment regimen or, in the case of a person with suspected tuberculosis, has refused to undergo a medical examination under par. (a) to confirm whether the person has infectious tuberculosis.
4. In the case of a person with a confirmed diagnosis of infectious tuberculosis, the department or local health officer determines that the person poses an imminent and substantial threat to himself or herself or to the public health. The department or the local health officer shall provide to the court a written statement of that determination.

(e) If the department or local health officer orders the confinement of a person under par. (d), a law enforcement officer, or other person authorized by the local public health

officer, shall transport the person, if necessary, to a location that the department or local health officer determines will meet the person's need for medical evaluation, isolation and treatment.

(f) No person may be confined under par. (d) for more than 72 hours, excluding Saturdays, Sundays and legal holidays, without a court hearing under sub. (7) to determine whether the confinement should continue.

(7) (a) If the department or a local health officer wishes to confine a person for more than 72 hours, the department or a local health officer may petition any court for a hearing to determine whether a person with infectious or suspected tuberculosis should be confined for longer than 72 hours. The department or local health officer shall include in the petition documentation that demonstrates all the following:

1. The person named in the petition has infectious tuberculosis; the person has noninfectious tuberculosis but is at high risk of developing infectious tuberculosis; or that the person has suspected tuberculosis.

2. The person has failed to comply with the prescribed treatment regimen or with any rules promulgated by the department under s. 252.07 (11), Stats.; or that the disease is resistant to the medication prescribed to the person.

3. All other reasonable means of achieving voluntary compliance with treatment have been exhausted and no less restrictive alternative exists; or that no other medication to treat the resistant disease is available.

4. The person poses an imminent and substantial threat to himself or herself or to the public health.

(b) If the department or a local health officer petitions the court for a hearing under par. (a), the department or local health officer shall provide the person who is the subject of the petition written notice of a hearing at least 48 hours before a scheduled hearing is to be held. Notice of the hearing shall include all the following information:

1. The date, time and place of the hearing.

2. The grounds, and underlying facts, upon which confinement of the person is being sought.

3. An explanation of the person's rights under sub. (8).

4. The proposed actions to be taken and the reasons for each action.

(8) A person who is the subject of a petition for a hearing under sub. (6) (a) has the right to appear at the hearing, the right to present evidence and cross-examine witnesses and the right to be represented by counsel. At the time of the filing of the petition, the court shall assure that the person who is the subject of the petition is represented by counsel. If the person claims or appears to be indigent, the court shall refer the person to the authority for indigency determinations under s. 977.07 (1), Stats. If the person is a child, the court shall refer that child to the state public defender who shall appoint counsel for the child without a determination of indigency, as provided in s. 48.23 (4), Stats. Unless good cause is shown, a hearing under this paragraph may be conducted by telephone or live audiovisual means, if available.

(9) An order issued by the court under sub. (6) (a) may be appealed as a matter of right. An appeal shall be heard within 30 days after the appeal is filed. An appeal does not stay the order.

(10) If the court orders confinement of a person under sub. (6) (a), the person shall remain confined until the department or local health officer, with the concurrence of a treating physician, determines that treatment is complete or that the person is no longer a substantial threat to himself or herself or to the public health. If the person is to be confined for more than 6 months, the court shall review the confinement every 6 months, beginning with the conclusion of the initial 6-month confinement period.

(11) (a) If the administrative officer of the facility where a person is isolated or confined has good cause to believe that the person may leave the facility, the officer shall use any legal means to restrain the person from leaving.

(b) The local health officer or a person designated by the local health officer shall monitor all persons under isolation or confinement as needed to ascertain that the isolation or confinement is being maintained.

(c) The local health officer or a person designated by the local health officer shall monitor all persons with tuberculosis disease until treatment is successfully completed.

(12) The local health officer or the department may order an examination of a contact to detect tuberculosis. Contacts shall be reexamined at times and in a manner as the local health officer may require.

HFS 145.11 Discharge from isolation or confinement. The local health officer or the department shall authorize the release of a person from isolation or confinement if all the following conditions are met:

(1) An adequate course of chemotherapy has been administered for a minimum of 2 weeks and there is clinical evidence of improvement, such as a decrease in symptom

severity, radiographic findings indicating improvement, or other medical determination of improvement.

(2) Sputum or bronchial secretions are free of acid-fast bacilli.

(3) Specific arrangements have been made for post-isolation or post-confinement care.

(4) The person is considered by the local health officer or the department not to be a threat to the health of the general public and is likely to comply with the remainder of the treatment regimen.

HFS 145.12 Certification of public health dispensaries. (1) A local health department or 2 or more local health departments jointly may be certified by the department as a public health dispensary under s. 252.10, Stats., if the public health dispensary provides or ensures provision of all of the following:

(a) Tuberculin skin testing.

(b) Medication for treatment of tuberculosis disease and infection.

(c) Directly observed therapy.

(d) Tuberculosis contact investigation.

(e) Case management.

(f) Sputum specimen collection and induction.

(g) Medical evaluation by a physician or nurse.

(h) Chest radiographs.

(i) Collection of serologic specimens.

(2) A local health department that meets the requirements under sub. (1) and wishes to be certified as a public health dispensary shall submit a request for certification to the department. The request for certification shall include a list of the tuberculosis-related services provided or arranged for and a plan for tuberculosis prevention and control at the local level, including tuberculin skin testing of high-risk groups as defined by the Centers for Disease Control and Prevention.

Note: "High-risk groups" are defined in the Centers for Disease Control and Prevention report, "Targeted Tuberculin Testing and Treatment of Latent Tuberculosis

Infection.” The report may be found in the Morbidity and Mortality Weekly Report, June 9, 2000, Vol. 49, No. RR-6, and is on file in the Revisor of Statutes Bureau, the Secretary of State’s Office, and is available from the Department’s Division of Public Health, P.O. Box 2659, Madison, WI 53701–2659.

(3) Upon authority of s. 252.10, Stats., the department shall review the request for certification as a public health dispensary and the related local health department operations within 6 months of receiving the application. The department shall either issue a written certificate signed by the state health officer or deny the application and provide a written explanation of the recommendations for improvement needed before the department reconsiders the request for certification.

(4) (a) The department shall review the operations of the public health dispensary at least every 5 years.

(b) The department may withhold, suspend or revoke its certification if the local health department fails to comply with any of the following:

1. Applicable federal or state statutes, or federal regulations or administrative rules pertaining to medical assistance, occupational safety, public health, professional practice, medical records and confidentiality.

2. The official statement of the national tuberculosis controllers association.

Note: The official statement of the National Tuberculosis Controllers Association entitled “Tuberculosis Nursing: a Comprehensive Guide to Patient Care” is on file in the Revisor of Statutes Bureau and the Secretary of State’s Office, and is available from the National Tuberculosis Controllers Association, 2951 Flowers Road South, Suite 102, Atlanta, GA 30341-5533.

3. The official statements of the American Thoracic Society.

Note: The official statements of the American Thoracic Society may be found in the Centers for Disease Control and Prevention’s recommendations and report “Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection.” The report may be found in the Morbidity and Mortality Weekly Report, June 9, 2000, Vol. 49, No. RR-6. The American Thoracic Society’s “Treatment of Tuberculosis and Tuberculosis Infection in Adults and Children” may be found in the *American Journal of Respiratory and Critical Care Medicine*, vol. 149, 1994, pp. 1359-1374. The American Thoracic Society’s “Diagnostic Standards and Classification of Tuberculosis in Adults and Children” may be found in *American Journal of Respiratory and Critical Care Medicine*, vol. 161, 2000, pp.1376-1395. These reports are on file in the Revisor of Statutes Bureau and the Secretary of State’s Office, and are available from the Department’s Division of Public Health, P.O. Box 2659, Madison, WI 53701-2659.

4. The directives of the state health officer made under s. 252.02 (6), Stats.

(c) The department shall provide the local health department with at least 30 days notice of the department's decision to withhold, suspend or revoke its certification.

(5) (a) A department action under sub. (3) or (4) is subject to administrative review under ch. 227, Stats. To request a hearing under ch. 227, the public health dispensary shall file, within 10 working days after the date of the department's action, a written request for a hearing under s. 227.42, Stats. A request is considered filed on the date the division of hearings and appeals receives the request. A request by facsimile is complete upon transmission. If the request is filed by facsimile transmission between 5 P.M. and midnight, it shall be considered received on the following day.

Note: A hearing request should be addressed to the Department of Administration's Division of Hearings and Appeals, P. O. Box 7875, Madison, WI 53707. Hearing requests may be delivered in person to that office at 5005 University Avenue, Room 201, Madison, WI. Hearing requests may be faxed to 608-264-9885.

(b) The division of hearings and appeals shall hold an administrative hearing under s. 227.44, Stats., within 30 calendar days after receipt of the request for the administrative hearing, unless the public health dispensary consents to an extension of that time period. The division of hearings and appeals shall issue a proposed decision to the department no later than 30 calendar days after holding the hearing, unless the department and the public health dispensary agree to a later date.

(6) Public health dispensaries or the department may contract with other agencies, institutions, hospitals, and persons for the necessary space, equipment, facilities and personnel to operate a public health dispensary or for provision of medical consultation.

(7) If a public health dispensary charges fees for its services, the dispensary shall do all the following:

(a) Establish a fee schedule that is based upon the reasonable costs the public health dispensary incurs.

(b) Forward a copy of the fee schedule and any subsequent changes to the department.

(8) (a) Public health dispensaries and branches thereof shall maintain records containing all the following:

1. The name of each person served.

2. The date of service for each person served.
3. The type of service provided to each person.
4. The amount the dispensary billed and received for providing service to each person.

(b) The department may audit the records of public health dispensary and branches specified under par. (a).

HFS 145.13 Dispensary reimbursement. (1) REIMBURSEABLE SERVICES. Public health dispensary services reimbursable by the department shall include at least the following:

(a) Tuberculin skin testing of high-risk persons as defined by the Centers for Disease Control and Prevention. The administration and reading of a tuberculin skin test shall be considered one visit. Tuberculin skin tests administered to persons who are not defined as high-risk by the Centers for Disease Control and Prevention, such as school employees, are not reimbursable.

Note: “High-risk persons” are defined in the Centers for Disease Control and Prevention report, “Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection.” The report may be found in the Morbidity and Mortality Weekly Report, June 9, 2000, Vol. 49, No. RR-6, and is on file in the Revisor of Statutes Bureau, the Secretary of State’s Office, and is available from the Department’s Division of Public Health, P.O. Box 2659, Madison, WI 53701–2659.

(b) One chest radiograph for a person with a newly identified significant skin test result, including interpretation and consultation services.

(c) One follow-up chest radiograph, including interpretation and consultation services, to document response to therapy.

(d) An initial medical evaluation and one interim medical evaluation, as needed.

(e) Blood specimen collection for one baseline and up to 3 follow-up liver function tests.

(f) Visits to collect initial diagnostic sputum specimens, either freely coughed or induced, and follow-up specimens to monitor successful treatment, up to a total of 3 initial and 6 follow-up specimens.

(g) Sputum induction for collection of up to 3 specimens for initial diagnosis and 3 for documentation of sputum conversion.

(h) Case management visits and visits to provide directly observed therapy to persons with tuberculosis disease up to a maximum of 66 visits.

(2) REIMBURSEMENT RATE. (a) The department shall reimburse public health dispensaries on a quarterly basis for services provided under sub. (1) to clients who are not recipients of medical assistance until the biennial appropriation under s. 20.435 (5) (e), Stats., is totally expended. Reimbursement shall be at least at the medical assistance program rate in effect at the time of the delivery of the service.

(b) Public health dispensaries may claim reimbursement from the medical assistance program under ss. 49.43 to 49.497, Stats., and chs. HFS 101 to 108 for services under sub. (1) provided to persons eligible for medical assistance under s. 49.46 (1) (a) 15., Stats.

The repeal and rules contained in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, as provided in s. 227.22 (2) (intro), Stats.

Wisconsin Department of Health
and Family Services

Date: February 1, 2002

By: _____
Phyllis J. Dubé
Secretary

Seal: