Implementing Legal Interventions for the Control of Tuberculosis

New Jersey Medical School
National Tuberculosis Center
A Founding Component of the International Center for Public Health

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Preface

In 1995, the Advisory Council for the Elimination of Tuberculosis (ACET) stated, "TB control programs periodically should review applicable laws, regulations, and policies to ensure their consistency with currently recommended medical and public health practices. States and municipalities should create laws, regulations, and policies that provide support and a legal basis for…protecting the health of the public by isolating and treating persons who have infectious TB [and] detaining persons who, though not infectious, are unwilling or unable to complete treatment and who are at risk for becoming infectious again and acquiring drug-resistant TB."[1]

In 2001, the New Jersey Medical School National Tuberculosis Center surveyed state TB program representatives to determine how their programs implement legal interventions under state laws and regulations pertaining to TB nonadherence. The results of the survey suggested that different states utilize a variety of legal interventions and implement them in different ways.[2]

This resource is meant to help TB programs improve treatment outcomes by guiding the implementation of legal interventions. It describes a proven method suitable for replication in any jurisdiction, and should serve as a valuable resource for any healthcare worker (HCW) responsible for addressing TB patient nonadherence. The reader should keep in mind, however, that the successful implementation of legal interventions—determined by the attainment of one objective: to achieve patient adherence while ensuring due process—"depends upon the existence of appropriate laws, cooperative courts and law enforcement officials, and the availability of appropriate facilities."[3] These institutions must work together to promote patient adherence and thereby protect the public health.

Introduction

As Franklin D. Roosevelt stated, "Nothing can be more important to a state than its public health; the state's paramount concern should be the health of its people."[4] Although the United States enjoys a relatively low incidence of TB disease, the nature of the bacteria's transmission—via the air—makes it an ever-present potential threat to public health. To protect the public from TB exposure, the government promulgates laws and regulations to help ensure that all persons with **suspected or verified TB** disease are appropriately tested and treated. In some states, laws also mandate the testing of certain persons exposed to someone with confirmed TB disease, or who are otherwise considered at high risk of acquiring TB infection.

Almost any case of TB disease will be cured if the patient takes every dose of medicine as prescribed for the entire duration of an appropriate treatment regimen. This behavior is defined as **adherence**. For the purposes of this resource, "adherence" also means to follow mandates pertaining to TB control that are issued to individuals by TB programs and are backed by **statutes**, rules, or **regulations**.

ACET defines **nonadherence** as "the inability or unwillingness to follow a prescribed treatment regimen."[5] This includes not reporting for **directly observed therapy (DOT)**, refusing medication, or exhibiting evidence of not taking medications as prescribed. Nonadherence (or adherence to an inappropriate treatment regimen) can both prolong the patient's illness and give rise to **multidrug-resistant TB (MDR-TB)**, which can then be transmitted to others with even greater risk to public health. Treatment adherence, then, depends on the cooperation and ability of the patient to follow medical recommendations for the entire duration of his or her treatment regimen, while nonadherence places public health at undue risk.

There are many causes of nonadherence. For instance, the treatment regimen for TB disease is complex, involving multiple drugs prescribed over many months. As the patient's symptoms typically improve after a few weeks of treatment, overarching problems such as homelessness or drug addiction may take priority over treatment adherence. Likewise, the patient might experience unpleasant adverse effects as a result of taking medication, or might distrust healthcare providers or even Western medicine in general. Nonetheless, while many TB patients prove a challenge to treat, the TB program must make all reasonable efforts to promote adherence in the **least restrictive environment** possible. This includes providing the patient with **incentives, enablers**, or other social supports that make it easier to adhere to an entire course of TB therapy. **Legal interventions** should be implemented only as a last resort after all other reasonable efforts prove unsuccessful.[6]

When implementing legal interventions, all applicable laws must be followed in a manner that honors the rights of both the patient and the public. This first requires the TB program to uphold appropriate standards of care and to treat all patients within its jurisdiction equally. Next, program staff members should be familiar with the legal authority that exists in their jurisdiction, and they should fully understand how to implement legal interventions appropriately while ensuring **due process**. Likewise, clinical staff should understand what authority the TB program has to implement legal interventions. Ultimately, the TB program must be able and willing to carry out all proper measures—potentially including **involuntary confinement** of the patient—to help ensure that infectious patients complete a full course of TB therapy.

In keeping with this reasoning, this resource focuses on strategies that TB programs can use to promote patient adherence and to successfully implement legal interventions as a last resort. It includes the following:

- Discussion of elements a TB program should have and alternative strategies it should attempt prior to implementing legal interventions
- Description of the types of legal interventions and the appropriate times to use these interventions
- Teaching cases
- Sample warning letters and health officer's orders
- Glossary of key terms

As the implementation of legal interventions potentially results in the loss of liberty, these recommendations also provide the framework necessary to help ensure a successful legal outcome while protecting the patient's rights once legal interventions are implemented.

Statutes, Rules, and Regulations

Statutes are laws enacted by state legislatures, and they may be voided or modified only through the legislative process. Rules and regulations, on the other hand, are developed and implemented by individual state agencies. Like statutes, rules and regulations have the force of law, but they often carry sunset provisions that cause them to eventually expire. State agencies, then, must periodically review their rules and regulations according to state sunset law requirements. This allows agencies to make policy revisions, when necessary, through a rule-making process, rather than through the legislative process, which is often lengthier. Rules must be consistent with governing laws.

When applied to TB control, statutes, rules, and regulations provide TB programs with the legal authority to direct various activities, which guarantees the rights of the patient while protecting the public from TB exposure. These activities include:

- Ensuring patient confidentiality
- Mandating adherence to prescribed treatment regimens
- In some states, mandating skin testing and medical evaluation of contacts of infectious persons
- Confining nonadherent, infectious patients against their will to protect public health

However, TB programs should conduct their activities in the least restrictive environment possible. Legal interventions as a means to help ensure patient adherence should be utilized only as a last resort.

Patients' Rights and Due Process

Patients generally have the right to refuse to follow professional medical advice. Those with infectious TB disease, however, "may lose the right to refuse such advice if health officials believe these persons are putting the public at risk for infection."[7] As stated previously, state governments have the legal authority to enact laws regarding infectious persons, and it is incumbent upon TB program staff to have a working knowledge of these laws. Again, the program should exhaust all alternatives and document all efforts to help ensure adherence prior to implementing legal interventions.

When implementing legal interventions, patients' rights must be honored in keeping with the constitutional principle of due process. While due process requirements may be explicitly defined in a jurisdiction's laws or rules, a court will require provision of due process even if requirements are not so defined. In the event of a court hearing, the patient should be afforded the following:*

1. Ample written notice prior to a court hearing, detailing the grounds and underlying facts
2. The right to counsel and, if indigent, appointed counsel
3. The right to be present at the hearing and to present and cross-examine witnesses
4. The standard of proof to be by clear, cogent, and convincing evidence
5. The right to a verbatim transcript of the proceedings for purposes of appeal

In addition, all written correspondence with the patient—including **warning notices** and **health officer's orders**—should be given in the language the patient understands.

*Greene v. Edwards 263 S.E.2d 661 (1980).

Essential Services and Strategies that Promote Adherence

This section provides TB programs with a framework of guidelines for services and methodologies that will not only lessen the need for legal interventions, but will also ensure that programs can provide proper **documentation** should legal interventions become necessary. The Centers for Disease Control and Prevention (CDC) publication *Essential Components of a Tuberculosis Prevention and Control Program*, prepared by ACET, provides a "national standard by which policymakers, TB control program managers, and others evaluating TB programs can assess individual TB programs."[8] Among these essential components, as stated in the Preface, are laws, regulations, and policies that:

- Ensure that TB patients receive appropriate treatment until cured
- Protect public health by isolating and treating persons with infectious or potentially infectious TB disease
- Allow for the detainment of infectious or potentially infectious persons who refuse or otherwise cannot adhere to an appropriate treatment regimen

Moreover, TB programs should provide a variety of services to help ensure that the patient adheres to treatment. DOT should be the core of this treatment, supported by the offering of incentives and enablers, social and support services, interpreter services, and individualized health education. When offered together, these services promote a successful treatment outcome.

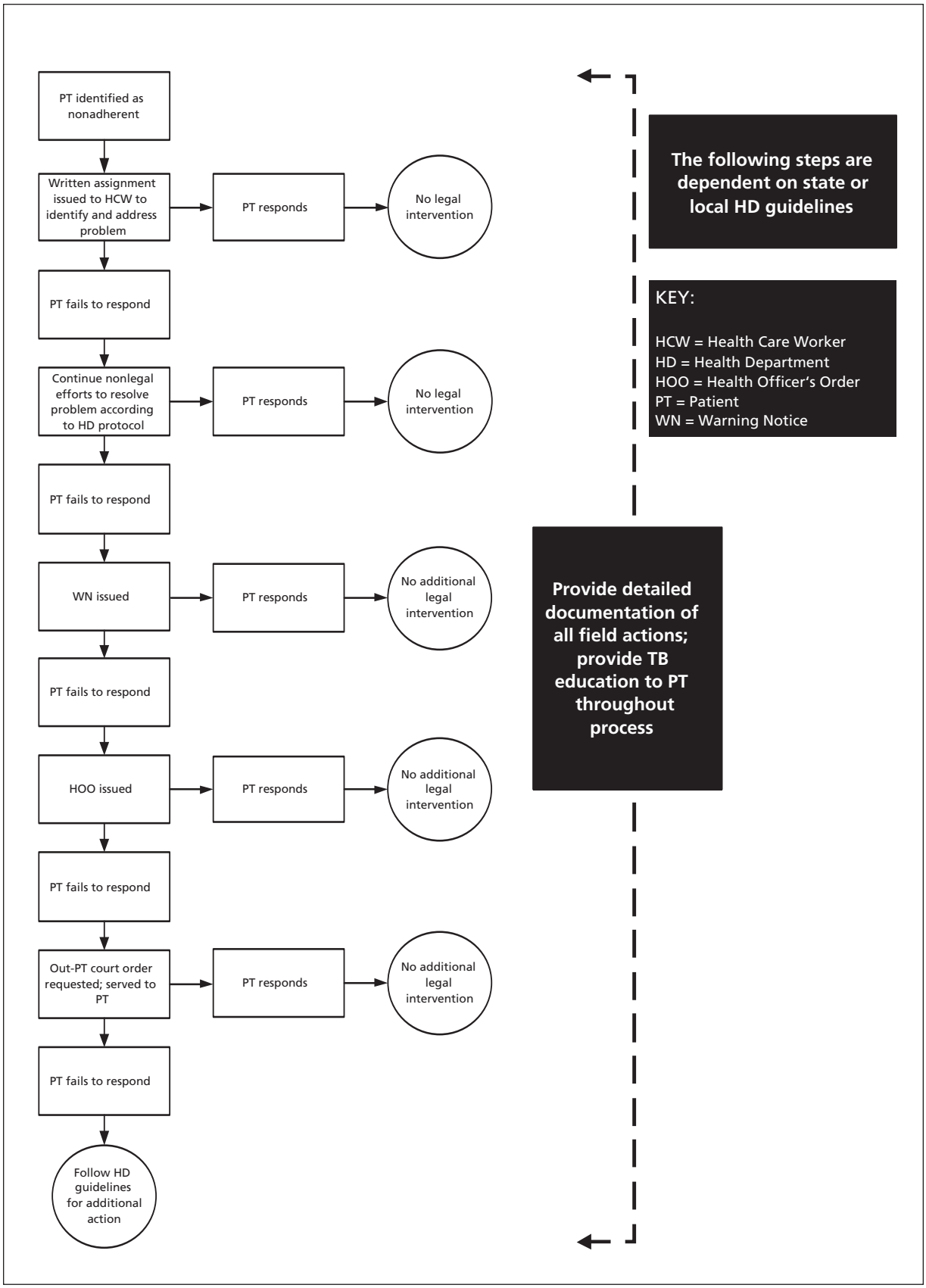
However, not all patients respond positively to these services. Therefore, when it fails to achieve treatment adherence, the TB program must have the capacity to utilize other options, including legal interventions (Figure 1).

CASE MANAGEMENT

As indicated in the CDC publication, *Improving Patient Adherence To Tuberculosis Treatment*, "several weeks or months can elapse between initiation of therapy and the discovery that sputum conversion has not occurred or that the chest radiograph does not show improvement. In the meantime, transmission of infection may continue, drug-resistant organisms may emerge, or serious complications may develop."[7] It is essential, then, that the patient's adherence be monitored for the duration of treatment.

Each patient with suspected or verified TB disease should be assigned a **case manager**, a TB program employee who takes primary responsibility for ensuring the patient's progression toward cure. The case manager plays an indispensable part in monitoring the patient's adherence to treatment, as he or she consults with other HCWs to identify and remove barriers to adherence. This includes removing language and cultural barriers, offering incentives and enablers, and recruiting the assistance of various social and support services.

Figure 1. Implementation of legal interventions for the TB outpatient



When the patient's condition exhibits signs of improvement—such as sputum conversion, chest x-ray improvement, and the lessening of signs and symptoms (especially cough)—it suggests that he or she is adhering to treatment. It is important to note, however, that these signs are not sufficient to indicate adherence when considered alone. To administer DOT under case management is the most effective way to monitor adherence.[8]

TRAINING

According to CDC, "Competent health care staff…should act as extensions of the clinician and nurse by locating patients, reminding them of their appointments, resolving basic problems, encouraging adherence…and identifying contacts. Such employees can greatly enhance the TB control effort amongst at-risk populations."[9] Therefore, it is essential that staff be trained in the fundamentals of TB control. Initially, HCWs must learn and demonstrate an understanding of the basic medical aspects of TB, as well as the fundamentals of fieldwork.

CDC's *Self Study Modules on Tuberculosis* contains 9 modules on the basic concepts of TB, providing an excellent foundation for HCWs.* These modules target specific aspects of field investigations (eg, Module 6 addresses field investigations related to contact investigations; Module 7 addresses confidentiality; Module 9 addresses TB treatment adherence). After mastering the information contained in these modules, it is strongly recommended that new HCWs receive practical training in the field with an experienced HCW. Training should also include basic skills training in communication, as the ability of a HCW to communicate and establish trust and rapport with a patient is important—and very often is the key—to maintaining the patient's adherence to treatment.

INCENTIVES AND ENABLERS

Incentives and enablers are used widely to encourage and assist patients to keep clinic and DOT appointments. They should be specific to the patient's needs, and, when used in concert with proper case management, they promote successful treatment outcomes. Incentives raise the priority of TB treatment by rewarding patients who adhere to therapy. Depending on the situation, incentives may range from food vouchers, to clothing, to housing homeless patients, to offering "special" items such as a toy to a child. Enablers are services or conditions that help the patient adhere to therapy. They range from minor services such as providing transportation to the clinic, to paying the patient's rent or mortgage while hospitalized or otherwise unable to work. A list of potential incentives and enablers can be found in the CDC publication, *Improving Patient Adherence to Tuberculosis Treatment*.[7] This list is summarized on page 9.

Incentives and enablers should be discussed with and offered to the patient during his or her first appointment. They can then be modified thereafter, depending on the patient's needs or behavior. Incentives should never be offered to a nonadherent patient, because the patient could interpret these incentives as rewards for nonadherence. If the patient becomes nonadherent, incentives should be withdrawn immediately. Once the patient returns to adherence, incentives can be offered again after a trial period. Enablers should be offered throughout treatment, even if the patient becomes nonadherent for a time.

* The modules can be downloaded at http://www.cdc.gov/nchstp/tb/pubs/ssmodules/default.htm.

All incentives and enablers offered to the patient should be documented. This documentation will become part of the supporting evidence in any legal hearing.

SAMPLE CATEGORIES OF INCENTIVES AND ENABLERS

- Money
- Food, food vouchers, nutritional supplements
- Clothing
- Personal care supplies (eg, shaving cream, nail polish)
- Transportation enablers (eg, bus or cab fare)
- Household items (eg, cooking utensils)
- Automotive supplies (eg, gasoline vouchers)
- Fishing supplies (eg, fishing rods)
- Garden supplies (eg, seeds, bulbs)
- Seasonal items (eg, Thanksgiving turkey)
- Children's items (eg, storybook, basketball)
- Miscellaneous personal services (eg, laundry service)

Adapted from *Using incentives and enablers in the tuberculosis control program*. Columbia: American Lung Association of South Carolina and South Carolina Department of Health and Environmental Control, Division of Tuberculosis Control, 1989. Cited in CDC, 1999.[7]

PATIENT EDUCATION

It is essential to provide educational services to patients and contacts, so each person is aware of not only the responsibilities that accompany his or her medical condition but also the consequences of failing to adhere to treatment. The patient must be educated that nonadherence can lead to prolonged illness (including MDR-TB), transmission to others, and legal interventions (including involuntary confinement). Patients should be educated regarding:

- How TB is transmitted
- How to prevent TB transmission
- How to take medications
- The patient's role in curing his or her disease
- The health consequences of nonadherence (eg, MDR-TB)
- The legal consequences of nonadherence (eg, involuntary confinement)

Maintaining Patients Under Medical Supervision

To be effective, each clinic must have an efficient, standardized method of scheduling and keeping appointments. Patients should be given precise appointment times for clinic visits, and a system must be in place to recognize when an appointment is missed. When a patient misses an appointment, measures to return the patient to medical supervision should be made within 24 hours or one business day.

Control measures include submitting a written work assignment to a HCW, requesting a specific service. In the case of a missed clinic or DOT appointment, when a patient is known to the clinic, he or she may be contacted by phone. If the patient cannot be reached by phone, then a written work assignment should be issued. The work assignment should provide basic locating information regarding the patient: type of patient (for example, active case or contact), patient identifiers (including unusual facial markings, height, weight, glasses), latest pertinent medical information (such as sputum result), hangouts, and the specific service required. The work assignment should be given to a field staff member, and a copy should be filed with the case manager or field supervisor. Thus, program staff members have a record of work pending in the field. All efforts to locate the patient and to have the patient receive required services must be documented on the work assignment, including the use of incentives and enablers. This documentation is extremely important, because, in the event legal interventions become necessary, it will serve as written proof that efforts were made to return the patient to medical supervision.

That the patient completes a recommended course of therapy within an established timeframe is a top priority of all TB programs. Therefore, for those patients on DOT, control measures as mentioned above should be initiated after a predetermined number of consecutively missed DOT appointments. This is necessary, because the issuance of the work assignment starts a paper trail that documents all field efforts to return the patient to treatment. Such documentation is essential in any legal proceedings brought against the patient.

Field Actions

It is extremely important to conduct field actions in a timely, professional, and confidential manner, while keeping proper documentation.

DOCUMENTATION

Documentation is the recording of information (including facts and insights) surrounding an investigation and all significant related events leading up to its closure. Documentation is important because it allows others to continue investigative activities in the HCW's absence. To promote accuracy, facts should be recorded as soon as possible after each event. Quality documentation consists of recording:

1. The name of the HCW responsible for actions taken
2. A detailed summary of each action, including date and time
3. Plans for future action

The use of standardized abbreviations in documenting events is encouraged and allows the investigator to save time and space on the work assignment form. Abbreviations should be understood by the entire staff.

CONTACTING THE PATIENT

After a work assignment has been issued, all field actions should be initiated promptly (within 24 hours if possible), and any follow-up field actions should be conducted within 48 hours. To initiate field actions in a timely manner is necessary to convey the matter's urgency, not only to the patient, but also to authorities should legal interventions become necessary. *To delay action is to forfeit the sense of urgency that must be conveyed to the patient and potentially to the court.*

When making contact, it is recommended that the HCW visit the patient in the field. Although telephoning the patient may be convenient, the face-to-face interaction afforded by a field visit fosters more effective communication between the patient and the HCW. When conducting fieldwork, however, all too often the HCW will arrive at a patient's residence, find no one there, leave an appointment slip, then repeat this process every few days. It is strongly recommended not to repeat a failed method of initiating patient contact by leaving appointment cards at the same address, repeatedly making phone calls, or visiting at the same times of day. If the patient is difficult to locate, vary the approach: make visits at different times, question neighbors, perhaps leave a sealed letter with a neighbor, and follow up on all leads as recommended in *Tuberculosis Field Investigation: A Resource for the Healthcare Worker*, available through the New Jersey Medical School National Tuberculosis Center.*

* Available from the New Jersey Medical School National Tuberculosis Center website, www.umdnj.edu/ntbcweb, or by contacting the Education and Training Unit at (973) 972-0979.

COMMUNICATING WITH THE PATIENT

Once the HCW has contacted the patient, he or she must clearly convey to the patient the purpose of his or her field visit, answering any questions that arise (without breaching confidentiality; see "Confidentiality" below). As previously mentioned in the section "Patient Education" (page 10), it is important that the HCW educate the patient about TB. Moreover, the HCW should instill a sense of urgency in the patient through persistent presentation of factual information, so he or she will respond in a positive, timely manner to the health department's mandates. The HCW should use nonthreatening language when discussing reasons for the visit or any legal ramifications that apply. During this interaction the HCW should determine if any barriers exist that might prevent the patient from keeping future appointments and should take steps to remove such barriers. Incentives and enablers should be considered and must be documented when offered. The patient's lack of cooperation or unwillingness to respond to specific interventions also must be documented.

As the field investigation progresses, unresolved problems should be discussed with either the field supervisor or case manager on an ongoing basis. Legal interventions should be considered after all reasonable attempts to return the patient to medical supervision have failed. Such actions should be initiated only with the knowledge and consent of the field supervisor or case manager.

CONFIDENTIALITY

The protection of a patient's identity has always been a fundamental principle of any public health program. This protection is extremely important in the field as well as in clinic settings. As such, even the most experienced HCW must be alert to the challenges of maintaining confidentiality in the field, especially when conducting contact investigations and dealing with third parties. Therefore, every TB program must be familiar with its jurisdiction's confidentiality laws.

It is highly recommended that confidentiality be discussed during the patient's initial encounter with the healthcare community, and the HCW assigned to the patient should reinforce the concept of confidentiality during subsequent encounters. However, depending upon the state, there may be instances in which the patient's right to confidentiality may be overridden to help ensure the protection of public health. In such instances, the HCW should proceed only with supervisory approval. For example, if a HCW has a non-adherent patient with active TB who works in a school setting, it may be necessary to share the name of the patient with the school administrator to conduct a proper contact investigation.

Implementation of Legal Interventions

When actions fail to achieve the desired outcome (ie, the patient fails to return to medical supervision, adhere to treatment, or undergo a required medical evaluation), it may become necessary to initiate legal interventions. The following categories of patients should be considered for legal interventions:

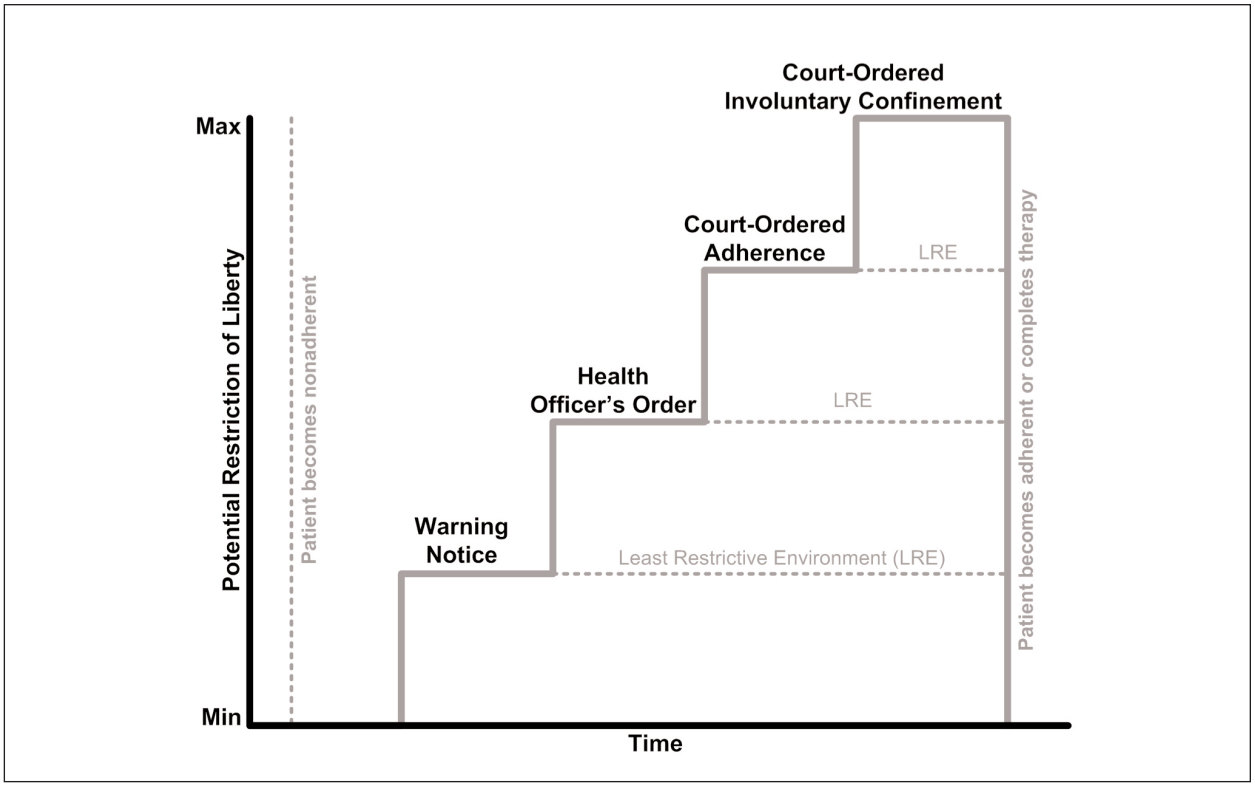
1. Patients with active pulmonary or laryngeal TB who refuse to follow a recommended course of treatment or refuse to submit to recommended periodic medical evaluations
2. Clinically suspected pulmonary or laryngeal TB patients who have refused to undergo a diagnostic examination or to adhere to a prescribed course of treatment
3. Contacts of active pulmonary or laryngeal TB patients who refuse to undergo a diagnostic examination (depending on state laws)

Once legal interventions are deemed necessary, the health official or agency responsible for TB control must be notified and provided with documentation of all previous attempts to help ensure appropriate care and treatment. This allows public health officials charged with enforcing the legal mandates of the TB program to have access to information demonstrating the program's efforts to achieve voluntary adherence, while ensuring the patient's rights in keeping with due process.

Prior to implementing legal interventions, it is recommended that a TB program representative communicate with the patient in hopes of achieving adherence. Communicating effectively with the patient, while ensuring convenient access to treatment, can reduce or even eliminate the need for legal interventions. However, legal interventions should be implemented after the TB program completes a predetermined number of failed attempts to gain patient adherence once contact with the patient has been made. When implemented, legal interventions should progress in increments from least to most restrictive to the patient, at all times being conducted in the least restrictive environment possible. This means implementing legal interventions in a way that minimally limits an individual's activities while it simultaneously ensures appropriate treatment and care of the patient, so that the risk to the public is balanced with the patient's right to due process (Figure 2). Progressive interventions include:

- Issuance of a warning notice
- Issuance of a health officer's order
- Court order for medical evaluation or treatment adherence
- Court-ordered involuntary confinement

Figure 2. Progressive steps in the implementation of legal interventions



These interventions are described as follows:

Warning Notice: The warning notice is a written letter issued by either the patient's healthcare provider or by the individual or agency responsible for TB control where the patient resides. It should be sent by certified mail and/or be hand delivered to the patient. Each notice must:

- Indicate the patient's name, medical status, and the reason(s) for its issuance (eg, the patient has missed DOT appointments, needs to be medically evaluated)
- List all efforts to contact, educate, counsel, and motivate the patient to cooperate and follow through with the healthcare provider's treatment plan and recommendations
- Indicate what specific actions the patient must perform, including the specific place, date, and time he or she should report for DOT or medical evaluation
- Provide a telephone number that the patient can call for clarification or to make alternative arrangements
- Be written in a language the patient can understand
- Clearly indicate that the patient's failure to respond appropriately will result in further legal actions

It is recommended that the warning notice cite all statutes, rules, or regulations that apply.

Health Officer's Order: A health officer's order should be sent if the patient fails to respond to the warning notice. It is similar to the warning notice, except that it is issued by the individual or agency with the *legal* responsibility for TB control in the patient's jurisdiction. It should include all elements found in the warning notice, plus a reference to the issuance of the warning notice.

Modifiable templates of warning notices and health officer's orders can be found in the Sample Letters section (pages 28-34).

Court Order for Medical Evaluation or Treatment Adherence (DOT): This order must be issued by the court system having jurisdiction over such matters in the TB program's state. This might be the municipal, probate, or county (superior) court. A court order should be sought only after an authorized HCW has documented the patient's refusal to respond appropriately to a health officer's order.

Court Order for Confinement: This order also must be issued by the court system having jurisdiction over such matters in the TB program's state. A court order for confinement should be sought only after all other legal interventions have failed to achieve patient adherence or, by judgment of the health director, if the patient poses a significant threat to public health.

At any court hearing, the health official, agency, or legal representative thereof responsible for TB control in the patient's jurisdiction must present:

- The TB program's rationale for its request of a court order, including specific cause for action
- Documentation of the patient's medical status, including evidence of infectiousness
- A record of the patient's nonadherence
- Documentation of all field actions performed

See "Patients' Rights and Due Process" (page 5) for information regarding rights that all patients must be afforded during legal proceedings.

UTILIZATION OF LAW ENFORCEMENT OFFICIALS

Depending upon state regulations, it is recommended that law enforcement officials serve or be present when serving legal documents or when implementing a confinement order. Law enforcement officials should be educated about TB so they understand that the infectious, nonadherent patient poses a threat to public health. They should also receive training in infection control procedures, so they know how to approach infectious persons without placing themselves at risk of exposure. Their assistance may be less forthcoming in the absence of this education. However, having a strong collaboration between the TB program and the local law enforcement agency can facilitate the safe and effective implementation of legal interventions.

Legal Interventions for the Nonadherent Tuberculosis Inpatient

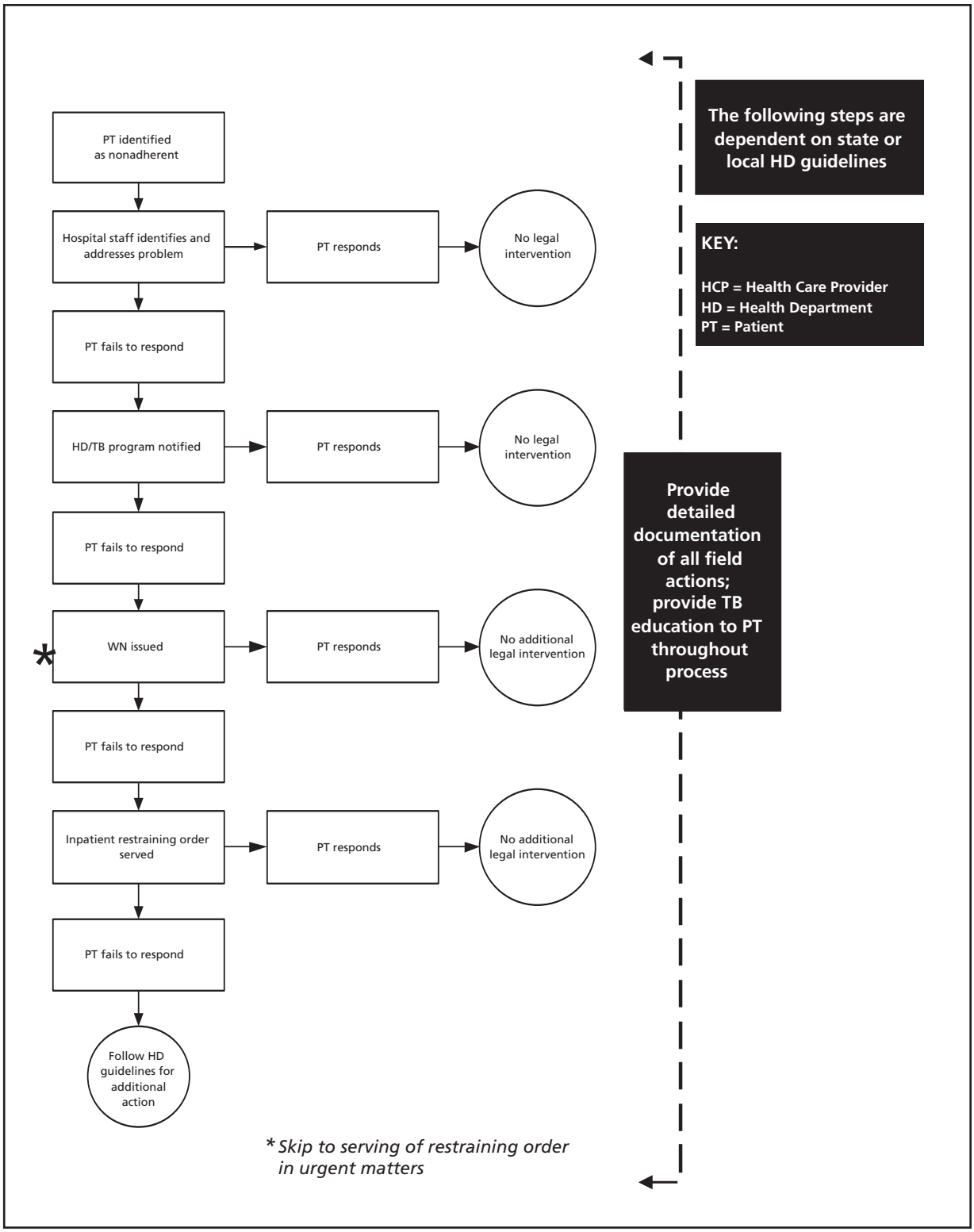
For a variety of reasons, TB patients sometimes become nonadherent while hospitalized. Reasons often include a desire simply to be out of the hospital, failure to accept a diagnosis of TB disease, having important matters to tend to outside the hospital, or emergencies. Taking prompt nonlegal action as a first step in addressing inpatient nonadherence can often prevent having to implement legal interventions at a later time. As with outpatients, any interventions must be implemented in accordance with state laws and regulations regarding TB patients (Figure 3).

When the patient's behavior compromises infection control procedures in the hospital (eg, the patient walks the halls without a mask, threatens to leave the hospital against medical advice [AMA]), it is crucial that the hospital immediately address the issue. If the issue cannot be resolved, the hospital should notify the health department as soon as possible. If such behavior cannot be brought to the attention of the health department promptly, or if the behavior is such that there is no time to do so (as in the case of a patient who threatens to leave the hospital AMA), then prompt implementation of legal interventions is appropriate.

When the patient's nonadherence is brought to the attention of the TB program, the same principles regarding outpatient nonadherent behavior apply. A representative should communicate with the patient as soon as possible to identify the cause of the behavior, and should first address the problem using nonlegal interventions. Depending on the nature of the situation, the problem can sometimes be resolved by listening to the patient and intervening on his or her behalf (for example, by providing the patient a television or telephone in his or her hospital room). The representative should reinforce TB education with the patient, focusing on his or her particular case, address and ease the patient's concerns, and make sure the patient understands his or her responsibility to adhere to medical recommendations. This one-on-one approach, utilizing all strategies available to the TB program (including incentives and enablers after discharge), can be effective in achieving patient adherence.

On the other hand, if the patient's nonadherent behavior continues, or if the health or safety of other patients or staff is jeopardized, it may be necessary to promptly implement legal interventions. Depending on the severity of the nonadherence, and assuming time is a critical factor, an inpatient warning notice or health officer's order issued by the health director to the patient should be considered. Either of these documents may be faxed or hand-delivered to the hospital and immediately issued to the patient. They should specify the nonadherent behavior exhibited by the patient, cite applicable statutes, rules, or regulations, and indicate that the patient must immediately become adherent to avoid being subject to further legal interventions. If this approach fails to resolve the problem, it may be necessary to seek an inpatient court order (often called an "inpatient restraining order") that prohibits the patient from leaving the hospital until discharged by the attending physician. Depending on laws and circumstances, hospitals sometimes have the right to physically restrain a patient for a limited time.

Figure 3. Implementation of legal interventions for the TB inpatient



Conclusion

The TB program must do whatever it takes to help ensure patient adherence. Taking a thorough medical history, communicating with the patient in a clear and nonthreatening manner, removing language barriers, acknowledging and understanding cultural barriers, offering incentives and enablers where appropriate, and providing other support services all promote a successful treatment outcome and reduce the likelihood of having to implement legal interventions. These program activities must work in concert to ensure convenient and accessible healthcare services for the patient.

However, when an infectious (or suspected-infectious) TB patient demonstrates that he or she is either unwilling or incapable of adhering to a prescribed treatment regimen, it may become necessary to implement legal interventions to achieve adherence and protect public health. For this reason, the TB program must be capable of effectively implementing legal interventions with due process, under applicable statutes, rules, and regulations.

The use of legal interventions can perhaps be described as a double-edged sword; properly implemented, they can help ensure adherence and promote the overarching goals of the TB program. Improperly implemented, however, they can violate the patient's right to due process or alienate the patient from the healthcare system. Either of these negative outcomes, of course, is detrimental to the overall goals of the TB program.

This resource provides the knowledge and tools necessary to take initial steps to prevent legal interventions, but, when necessary, to successfully implement those interventions. Ultimately, however, the success of a TB program rests with the day-to-day interactions between its staff and the patient, the patient's family, and others in the public health system. These interactions include coordination between the TB program and government institutions at all levels, including the health officer or commissioner, local and state administrations, the legislature, the judiciary, and law enforcement officials. Programs that only seldom implement legal interventions can benefit from advanced planning with these various participants within the system.

Collectively, legal interventions provide TB programs with a tool that works within a larger strategy of TB elimination. By promoting treatment adherence and completion, including treatment for latent TB infection, and maintenance of effective prevention programs for those at high risk of exposure, TB can be controlled and ultimately eliminated.

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7. Centers for Disease Control and Prevention. Improving patient adherence to tuberculosis treatment. 1994. Available at: http://www.cdc.gov/nchstp/tb/pubs/adherence/predicting.htm. Accessed January 6, 2004.
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9. Centers for Disease Control and Prevention. Prevention and control of tuberculosis in US communities with at-risk minority populations. *MMWR Recomm Rep.* 1992;41(RR-5):1-11.

Teaching Cases

The following teaching cases describe scenarios in which HCWs implemented legal interventions to address patient nonadherence. Adapted from actual cases, each describes the patient's background, the challenges that the HCW faced regarding nonadherence, and the manner in which the HCW implemented legal interventions. A description of outcomes and a brief description follow. Discussions focus on the effectiveness with which legal interventions were implemented, and they discuss alternative strategies for those cases in which legal interventions were not implemented effectively.

Case 1: Pablo

Background: Pablo, a Mexican immigrant who worked odd jobs as a day laborer, was 33 when he began to experience weight loss, fever, chills, and a frequent cough. These symptoms persisted for nearly 2 months before Pablo's brother in law brought him to a local TB clinic. Pablo was diagnosed with suspected pulmonary TB and, after a short hospitalization, placed on DOT with a standard 4-drug regimen. After drug susceptibility testing showed resistance to three first-line drugs (MDR-TB), his regimen was modified accordingly.

Challenge: Pablo admitted to frequently using both intravenous and nonintravenous drugs, most often with other laborers when jobs were scarce. Pablo's DOT worker noted his excessive alcohol use, which sometimes led to verbal abuse and behavior bordering on violence during routine DOT visits. Although the DOT worker was able to work within his schedule and provide various incentives and enablers, Pablo soon began to miss clinic appointments and was often absent for routine DOT visits. His absences became more frequent as summer approached and jobs became more available.

Intervention: As a first step in returning Pablo to adherence, a HCW from a local health department delivered a warning notice and educated Pablo on the importance of adhering to his treatment regimen. Also, the clinic worked to its greatest extent to schedule DOT visits and clinic appointments around Pablo's somewhat erratic work schedule, and it continued to offer enablers, including transportation to and from the clinic. After Pablo still failed to consistently keep his DOT appointments, the local health officer issued a written outpatient order to keep all DOT and clinic appointments, and the HCW again visited Pablo to educate him about the importance of taking every dose of his medicine. Although Pablo kept his next clinic appointment, he was absent for his next two DOT visits. At this point the TB program requested a court order for Pablo to adhere to his prescribed treatment regimen.

Outcome: The court order was effective in convincing Pablo to adhere to his treatment regimen.

Discussion: *Timely implementation of legal interventions* – In large part, this case demonstrates the proper implementation of legal interventions: The clinic treating Pablo first worked within its limits to provide convenient access to care. When that failed, legal interventions were progressive.

However, Pablo was infrequently keeping DOT appointments for several weeks, during which time he was receiving sporadic treatment for MDR-TB. The HCW should have implemented legal interventions soon after Pablo first demonstrated nonadherent behavior. Those interventions should have progressed in steps after each time that Pablo missed a predetermined number of DOT appointments.

Case 2: Richie

Background: Richie was a homeless man who abused alcohol and suffered mental illness. One afternoon he passed out on a sidewalk and was transported by ambulance to a local hospital. When a chest x-ray (CXR) showed cavitary disease, a tuberculin skin test (TST) was taken that measured 16 mm in induration, and a sputum smear tested positive for acid-fast bacilli (AFB).

Challenge: Shortly after being diagnosed with suspected pulmonary TB, Richie left the hospital AMA without having begun treatment for TB disease. Nearly a month after leaving the hospital, Richie again presented with TB at a clinic in a neighboring state. The clinic placed him on a 4-drug regimen, but Richie left the area unannounced after only 1 month of DOT. He soon presented to a clinic in a third state, which placed him back on DOT.

After 2 months of treatment, Richie was transferred back to his hometown but failed to report to the health department there. The health department found him via an inter-state referral system within 2 months and resumed DOT. He was assigned a case manager, and a HCW educated Richie at each DOT appointment, giving him cash every week that he adhered to treatment. The health department also provided Richie free ancillary health services, transportation to and from the clinic, and fast-food meals as incentives. Despite this, Richie began to miss his DOT appointments.

Intervention: While Richie continued to frequently miss his DOT appointments, he received 3 verbal warnings that nonadherence could result in his being involuntarily confined. After the third warning proved ineffective, a representative from the city health department read Richie a letter of "intent to commit," which he refused to sign. He disappeared again immediately after.

From that point, all attempts to locate Richie were documented in preparation for a court-ordered involuntary confinement. The health department's legal representative presented the confinement letter and documentation to a circuit court judge, who issued a warrant for his arrest. Three months later, TB-program workers spotted Richie napping on a bench in a public park. When approached he said he had just completed a 1000-mile bus ride, returning from a seasonal job picking fruit with his brother. He was arrested and given a court hearing, for which he was provided a lawyer, and he heard the charges against him.

Outcome: At the behest of a court ruling, Richie was confined in the medical ward of a state correctional facility, where he successfully completed 9 months of DOT.

Discussion: *Progressive implementation of legal interventions* – The TB program treating Richie went to great lengths to provide convenient access to care, including offering an array of incentives and enablers. However, rather than repeating an intervention strategy—namely, the issuance of 3 verbal warnings—the program should have implemented progressive legal interventions, beginning with a written warning notice.

In this case, the TB program could not have a made a compelling argument that it implemented legal interventions in the least restrictive environment possible. Because of this, had Richie not had a history of disappearance, the judge at his court hearing might have found on the side of the patient and refused to issue an order for involuntary confinement.

Case 3: Luis

Background: Luis was a second-grade student who lived with his parents and 2 siblings. When his teacher was diagnosed with suspected pulmonary TB, all the students in Luis's class were classified as high-priority contacts. TB control laws in Luis's state mandated the taking of a CXR for all high-priority contacts with a positive TST result. Luis was referred for a CXR when his TST induration measured 17 mm.

Challenge: Luis received a Bacille Calmette-Guérin (BCG) vaccine as an infant in Peru, 3 years before his family immigrated to the United States. Luis's primary care physician advised against the patient receiving the CXR. Rather than interpreting Luis's TST reaction as an indicator of TB infection, the physician saw it as the result of his patient having received the BCG vaccine. Following the physician's advice, a CXR was not done.

The TB program conducting the congregate setting contact investigation provided culturally and linguistically-appropriate TB education to Luis and his parents. The program also enlisted the help of Luis's school nurse, who provided additional TB education to the family. Both a pediatrician and pediatric nurse from the local chest clinic discussed Luis's need for a CXR with his physician, but he still advised against the procedure.

Intervention: The TB program issued a warning notice instructing Luis to report for a CXR within 5 days. The notice was written in both English and Spanish and explained the state regulations mandating a CXR for all TB contacts with a positive TST result. The notice also clearly stated that failing to report would force the city health department to issue an outpatient health officer order.

Outcome: Within 3 days of receiving the warning notice, Luis's parents brought him to the TB clinic to receive a CXR. Results of the CXR revealed abnormalities consistent with pulmonary TB.

Discussion: *Addressing health beliefs* – HCWs appropriately addressed Luis's parents' health beliefs and provided culturally and linguistically appropriate health education. However, the parents' initial refusal to consent to the CXR suggests that their response to the warning notice was likely due to their desire to avoid further legal interventions, and not due to their understanding of the risk to Luis's health. HCWs should see this as a potential barrier to treatment adherence and should provide further health education.

Case 4: Hector

Background: Hector, a 51-year-old homeless, unemployed factory worker, suffered a productive cough and significant weight loss before presenting at a local emergency department. Upon being diagnosed with pulmonary TB, he began an appropriate treatment regimen and was released after a 10-day hospital stay.

Challenge: Although a criminal history made Hector ineligible for public housing, the local TB program found a room at a nearby boarding house where he could stay for the length of his treatment. This residence provided a stable meeting place for DOT, and he was given food and bus passes for transport to and from the clinic. Preferring to live in his car, however, within a month Hector left the boarding house without notifying the public health nurse.

Hector was lost to follow-up until he returned to the hospital when his symptoms worsened. Less than 24 hours into his hospitalization, Hector suffered a stroke and was later transferred to an area nursing home for long-term care. After a partial recovery, he left the nursing home AMA and was again lost to follow-up. A month later, Hector presented a third time to a local emergency department with TB symptoms, where he was hospitalized again.

Intervention: Based on Hector's history of nonadherence, the local health officer issued an inpatient restraining order, which mandated that he remain in the hospital until discharged by the attending physician.

Outcome: Hector successfully completed treatment while confined to a hospital room.

Discussion: *Communicating with the patient* – Although the TB program offered Hector free housing as an incentive, Hector in fact saw his placement in the boarding house as confining. Had a HCW communicated with Hector to address his needs from the outset of his new living arrangements, efforts could have been made to accommodate him. Even the provision of a telephone or television might have made the difference between his staying and completing therapy, or leaving, being lost to follow-up, and eventually being involuntarily confined to a hospital room. To ensure a successful outcome the legal authority worked closely with the medical provider in this case.

Case 5: Svetlana

Background: Svetlana, who emigrated from Russia, had an abnormal CXR result that suggested old TB disease. To determine the extent of her disease, Svetlana was required by law to submit to a medical evaluation shortly after arriving in the United States. An outreach worker and interpreter from the local TB program visited Svetlana in the field, at which time they provided TB education and set up an appointment for her evaluation.

Challenge: During their field visit, the HCWs assigned to Svetlana's case identified 2 potential barriers to adherence: she spoke limited English and was asymptomatic. Indeed, because she felt well and had received clearance to travel, Svetlana saw little reason to be evaluated further. Although the TB program gave her a voucher for taxi service to and from the clinic, Svetlana failed to report for her evaluation. A second appointment was scheduled, but she failed to report for that one as well. Despite being offered both enablers and culturally and linguistically appropriate health education, Svetlana was nonadherent.

Intervention: The TB program overseeing TB control in Svetlana's jurisdiction issued her a warning notice, which explained the program's responsibility to see that she be evaluated for TB disease. A third appointment was scheduled, and this time it was agreed that an outreach worker from the TB program would transport Svetlana to and from the clinic. When Svetlana was absent at the time of her pick-up, an outpatient health officer order was requested from the city health department. The health department representative issuing the health officer order provided additional TB education through an interpreter, who explained that further nonadherence would bring legal action in the form of an outpatient court order.

Outcome: After receiving the health officer's order, Svetlana reported to the clinic for her medical evaluation. She was diagnosed with Class IV TB disease and placed on appropriate therapy.

Discussion: *Progressive implementation of legal interventions* – This case represents the proper implementation of legal interventions. The field worker assigned to Svetlana's case brought an interpreter with her on the initial field visit, and together they provided linguistically and culturally appropriate health education. After identifying potential barriers to adherence, they offered Svetlana an appropriate enabler: paid transportation to and from the clinic. After Svetlana missed 2 consecutive clinic appointments, the TB program implemented progressive legal interventions in the least restrictive environment.

Sample Letters

Being able to effectively communicate with patients both verbally and in writing can be the difference between having a successful outcome and having to implement legal interventions. Just as the need to maintain quality documentation of all efforts to manage the patient's care is crucial in any legal undertaking, the need to correspond in writing is also imperative in preparing the legal case against the patient.

Following are *sample* warning notices and health officer's orders, which can be modified to align with local or state regulations. Two scenarios are offered, one for a TB patient not adhering to therapy or clinic appointments, and the other for a nonadherent contact in need of an initial medical evaluation. Both scenarios are common. These 2 examples provide the framework mentioned in this resource for such letters and incorporate the required elements. They can also easily be altered to reflect other scenarios that require legal interventions (such as a follow-up evaluation for a contact needing a second TST, or a TB patient refusing to follow health precautions).[4]

Since the authority for originating and sending warning notices to patients may vary across jurisdictions, this resource provides 2 sample warning notices for each of the above-mentioned scenarios. The first is sent to the patient from the healthcare provider and the second from the health officer or TB program director. Health officer's orders should be sent from the health officer or director having legal responsibility for TB control in the jurisdiction in which the patient resides.

WARNING NOTICE FROM HEALTHCARE PROVIDER FOR INITIAL CONTACT EVALUATION

<Clinic Letterhead>

<Date>

<Patient name/address>

Re: Warning Notice for Contact Evaluation

Dear *<Patient's name>*:

This letter is to inform you that you have been exposed to someone with *<pulmonary (lung) tuberculosis (TB)/other>*. Public health regulations in the state of *<state>* (*<cite regulation>*) require that a person identified as a high-priority contact to an *<active/suspected active>* tuberculosis patient must submit to a complete medical evaluation, which may include a tuberculin skin test and chest x-ray, if necessary. To date, despite repeated visits and telephone calls to your home on the following days *<dates and times>*, and letters mailed to your home on *<dates>*, you have not yet had this evaluation.

Be advised that this evaluation is mandatory. This letter is to inform you that the *<name of clinic>* is able to give you this evaluation *<specify at no cost, if applicable>*. It is extremely important that you contact the *<clinic/agency>* at *<telephone #>* within *<#>* days of receiving this letter to arrange for the evaluation or discuss other means of getting the evaluation. Please be assured that the *<clinic/agency>* staff is prepared to assist you if necessary to ensure you receive this evaluation.

If you do not respond to this **warning** and do not get this evaluation, you will be subject to legal actions **ordering** you to get the evaluation.

Your cooperation in this matter is appreciated.

Sincerely,

<Name>
<Title>

C: *<Health director's name>*

WARNING NOTICE FROM HEALTH OFFICER/DIRECTOR FOR CONTACT EVALUATION

<Health Officer/Director/Municipal Letterhead>

<Date>

<Patient name/address>

Re: Warning Notice for Contact Evaluation

Dear *<Patient's name>*:

I have been informed by *<name of physician or clinic director>* that you have been exposed to someone with *<pulmonary (lung) tuberculosis (TB)/other>*. Public health regulations in the state of *<state>* (*<cite regulation>*) require that a person identified as a high priority contact to an *<active/suspected active>* tuberculosis patient must have a complete medical evaluation, which may include a tuberculin skin test and chest x-ray, if necessary. I have also been informed by the staff of the *<name of clinic/agency>* that, despite repeated visits and telephone calls to your home on the following days *<give dates and times>*, and letters mailed to your home on *<dates>*, you have not yet had this evaluation.

Be advised that this evaluation is mandatory. This letter is to inform you that the *<name of clinic>* is able to give you this evaluation *<specify at no cost, if applicable>*. It is extremely important that you contact the *<clinic/agency>* at *<telephone #>* within *<#>* days of receiving this letter to arrange for the evaluation or discuss other means of getting the evaluation. Please be assured that the *<clinic/agency>* staff is prepared to assist you if necessary to ensure you receive this evaluation.

If you do not respond to this **warning** and do not get this evaluation, you will be subject to legal actions **ordering** you to get the evaluation.

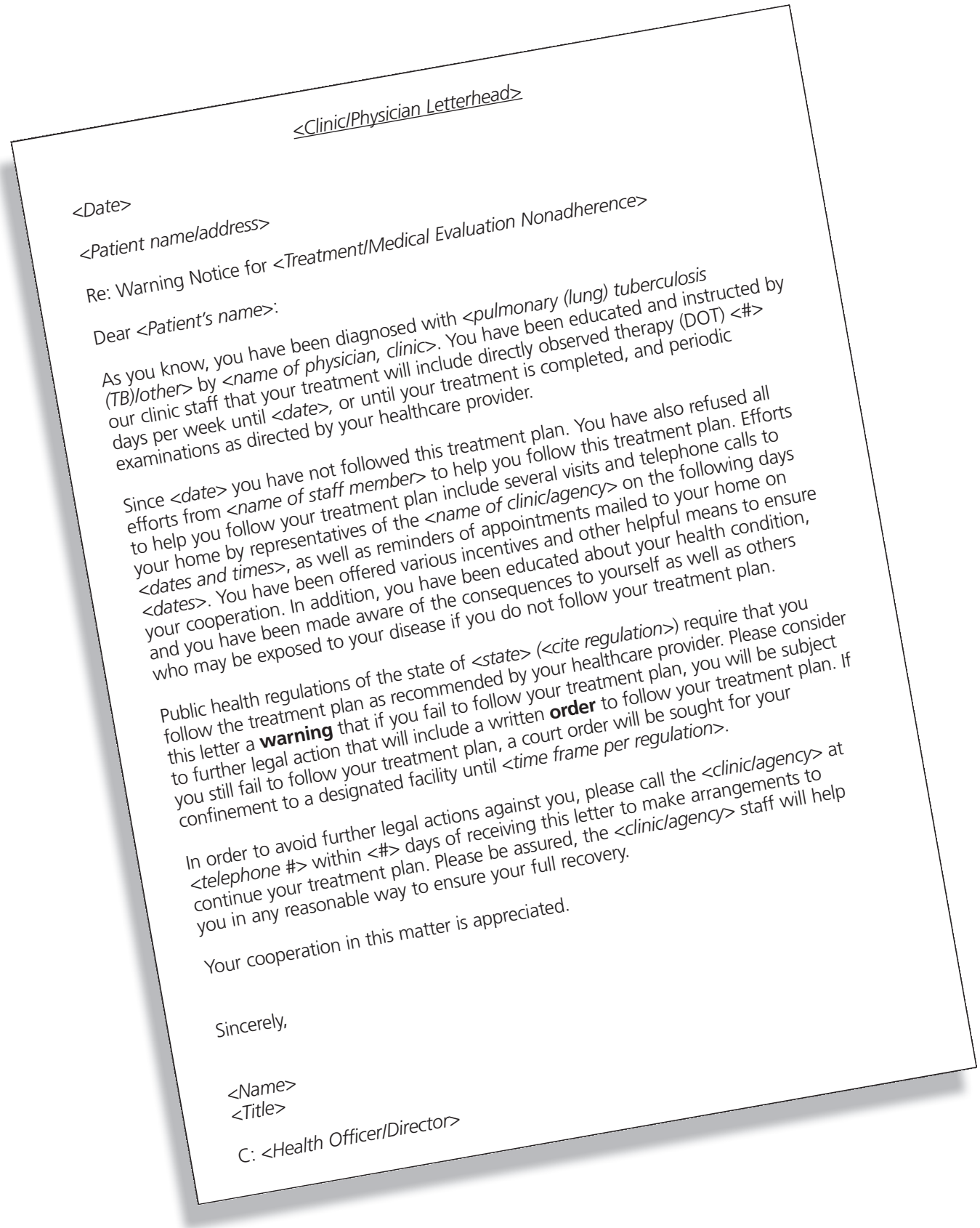
Your cooperation in this matter is appreciated.

Sincerely,

<Name>
<Title>

C: *<Clinic Director/Agency>*

WARNING NOTICE FROM HEALTHCARE PROVIDER REGARDING TREATMENT/EVALUATION NONADHERENCE



<Clinic/Physician Letterhead>

<Date>

<Patient name/address>

Re: Warning Notice for *<Treatment/Medical Evaluation Nonadherence>*

Dear *<Patient's name>*:

As you know, you have been diagnosed with *<pulmonary (lung) tuberculosis (TB)/other>* by *<name of physician, clinic>*. You have been educated and instructed by our clinic staff that your treatment will include directly observed therapy (DOT) <#> days per week until *<date>*, or until your treatment is completed, and periodic examinations as directed by your healthcare provider.

Since *<date>* you have not followed this treatment plan. You have also refused all efforts from *<name of staff member>* to help you follow this treatment plan. Efforts to help you follow your treatment plan include several visits and telephone calls to your home by representatives of the *<name of clinic/agency>* on the following days *<dates and times>*, as well as reminders of appointments mailed to your home on *<dates>*. You have been offered various incentives and other helpful means to ensure your cooperation. In addition, you have been educated about your health condition, and you have been made aware of the consequences to yourself as well as others who may be exposed to your disease if you do not follow your treatment plan.

Public health regulations of the state of *<state>* (*<cite regulation>*) require that you follow the treatment plan as recommended by your healthcare provider. Please consider this letter a **warning** that if you fail to follow your treatment plan, you will be subject to further legal action that will include a written **order** to follow your treatment plan. If you still fail to follow your treatment plan, a court order will be sought for your confinement to a designated facility until *<time frame per regulation>*.

In order to avoid further legal actions against you, please call the *<clinic/agency>* at *<telephone #>* within <#> days of receiving this letter to make arrangements to continue your treatment plan. Please be assured, the *<clinic/agency>* staff will help you in any reasonable way to ensure your full recovery.

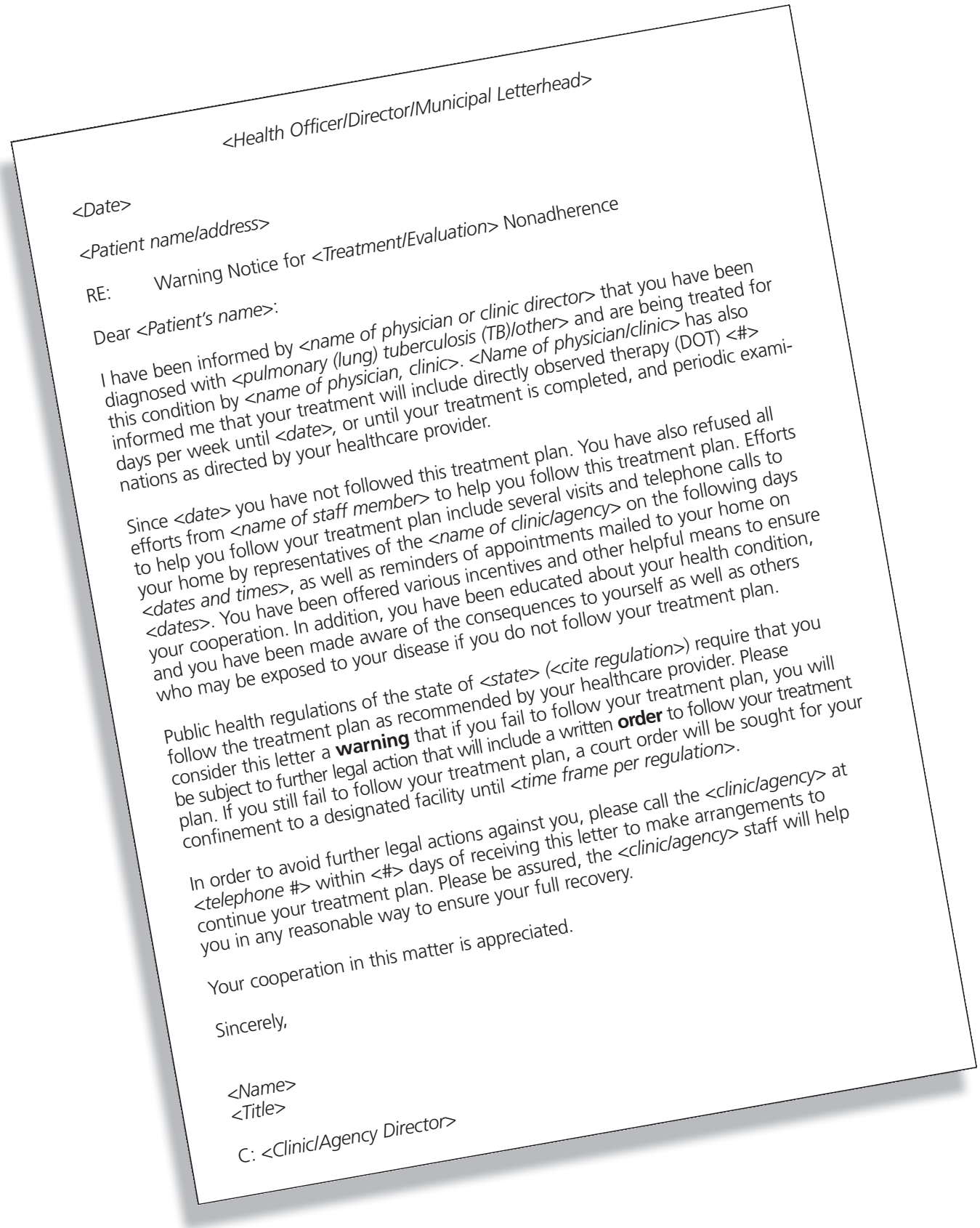
Your cooperation in this matter is appreciated.

Sincerely,

<Name>
<Title>

C: *<Health Officer/Director>*

WARNING NOTICE FROM HEALTH OFFICER/DIRECTOR REGARDING TREATMENT/EVALUATION NONADHERENCE



<Health Officer/Director/Municipal Letterhead>

<Date>

<Patient name/address>

RE: Warning Notice for *<Treatment/Evaluation>* Nonadherence

Dear *<Patient's name>*:

I have been informed by *<name of physician or clinic director>* that you have been diagnosed with *<pulmonary (lung) tuberculosis (TB)/other>* and are being treated for this condition by *<name of physician, clinic>*. *<Name of physician/clinic>* has also informed me that your treatment will include directly observed therapy (DOT) *<#>* days per week until *<date>*, or until your treatment is completed, and periodic examinations as directed by your healthcare provider.

Since *<date>* you have not followed this treatment plan. You have also refused all efforts from *<name of staff member>* to help you follow this treatment plan. Efforts to help you follow your treatment plan include several visits and telephone calls to your home by representatives of the *<name of clinic/agency>* on the following days *<dates and times>*, as well as reminders of appointments mailed to your home on *<dates>*. You have been offered various incentives and other helpful means to ensure your cooperation. In addition, you have been educated about your health condition, and you have been made aware of the consequences to yourself as well as others who may be exposed to your disease if you do not follow your treatment plan.

Public health regulations of the state of *<state>* (*<cite regulation>*) require that you follow the treatment plan as recommended by your healthcare provider. Please consider this letter a **warning** that if you fail to follow your treatment plan, you will be subject to further legal action that will include a written **order** to follow your treatment plan. If you still fail to follow your treatment plan, a court order will be sought for your confinement to a designated facility until *<time frame per regulation>*.

In order to avoid further legal actions against you, please call the *<clinic/agency>* at *<telephone* #> within *<#>* days of receiving this letter to make arrangements to continue your treatment plan. Please be assured, the *<clinic/agency>* staff will help you in any reasonable way to ensure your full recovery.

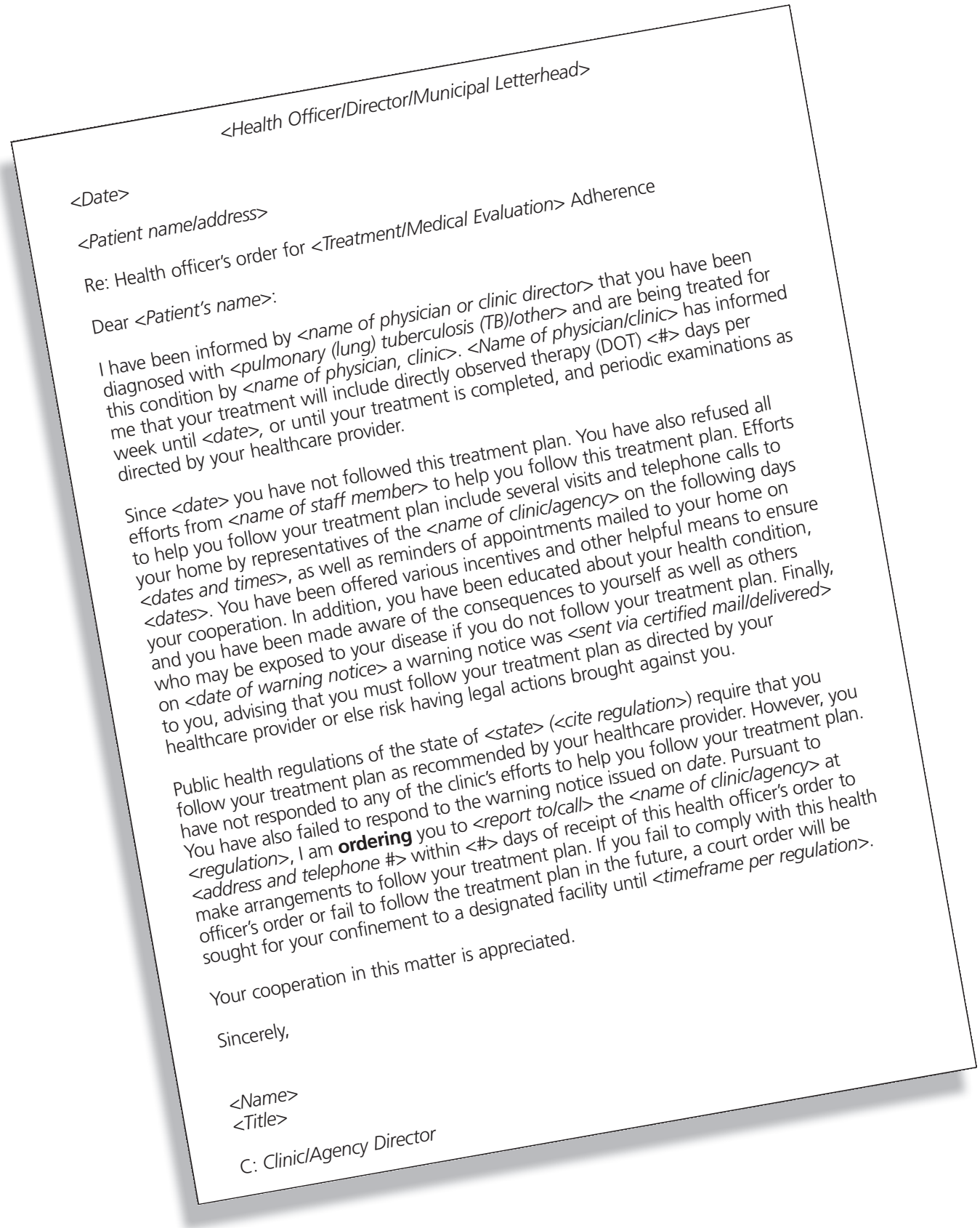
Your cooperation in this matter is appreciated.

Sincerely,

<Name>
<Title>

C: *<Clinic/Agency Director>*

ORDER FROM HEALTH OFFICER/DIRECTOR FOR TREATMENT/EVALUATION ADHERENCE



<Health Officer/Director/Municipal Letterhead>

<Date>

<Patient name/address>

Re: Health officer's order for *<Treatment/Medical Evaluation>* Adherence

Dear *<Patient's name>*:

I have been informed by *<name of physician or clinic director>* that you have been diagnosed with *<pulmonary (lung) tuberculosis (TB)/other>* and are being treated for this condition by *<name of physician, clinic>*. *<Name of physician/clinic>* has informed me that your treatment will include directly observed therapy (DOT) *<#>* days per week until *<date>*, or until your treatment is completed, and periodic examinations as directed by your healthcare provider.

Since *<date>* you have not followed this treatment plan. You have also refused all efforts from *<name of staff member>* to help you follow this treatment plan. Efforts to help you follow your treatment plan include several visits and telephone calls to your home by representatives of the *<name of clinic/agency>* on the following days *<dates and times>*, as well as reminders of appointments mailed to your home on *<dates>*. You have been offered various incentives and other helpful means to ensure your cooperation. In addition, you have been educated about your health condition, and you have been made aware of the consequences to yourself as well as others who may be exposed to your disease if you do not follow your treatment plan. Finally, on *<date of warning notice>* a warning notice was *<sent via certified mail/delivered>* to you, advising that you must follow your treatment plan as directed by your healthcare provider or else risk having legal actions brought against you.

Public health regulations of the state of *<state>* (*<cite regulation>*) require that you follow your treatment plan as recommended by your healthcare provider. However, you have not responded to any of the clinic's efforts to help you follow your treatment plan. You have also failed to respond to the warning notice issued on *date*. Pursuant to *<regulation>*, I am **ordering** you to *<report to/call>* the *<name of clinic/agency>* at *<address and telephone #>* within *<#>* days of receipt of this health officer's order to make arrangements to follow your treatment plan. If you fail to comply with this health officer's order or fail to follow the treatment plan in the future, a court order will be sought for your confinement to a designated facility until *<timeframe per regulation>*.

Your cooperation in this matter is appreciated.

Sincerely,

<Name>
<Title>

C: *Clinic/Agency Director*

ORDER FROM HEALTH OFFICER/DIRECTOR FOR CONTACT EVALUATION

Health Officer/Director/Municipal Letterhead

<*Date*>

<Patient name/address>

Re: Health officer's order for Contact Evaluation

Dear <*Patient's name*>:

I have been informed by <*name of physician or clinic director*> that you have been exposed to someone with <*pulmonary (lung) tuberculosis (TB)/other*>. Public health regulations in the state of <*state*> (<*cite regulation*>) require that a person identified as a high-priority contact to an <*active/suspected active*> tuberculosis patient must have a complete medical evaluation, which may include a tuberculin skin test and chest x-ray, if necessary. I have also been informed by the staff of the <*name of clinic/agency*> that, despite repeated visits and telephone calls to your home on the following days <*give dates and times*>, and letters mailed to your home on <*dates*>, you have not yet had this evaluation. Finally, on <*date of warning notice*> a warning notice was <*sent via certified mail/delivered*> to you, advising that you must have this evaluation or risk having legal actions brought against you.

Be advised that this evaluation is mandatory. This letter is to inform you that since you have not responded to any of the above efforts or the warning notice issued on <*date*>, pursuant to <*regulation*>, I am **ordering** you to <*report to/call*> the <*name of clinic/agency*> at <*address and telephone* #> within <#> days of receipt of this letter to make arrangements for this mandatory medical evaluation. If you fail to comply with this health officer's order, a court order will be sought for your confinement to a designated facility until the evaluation is completed (<*cite regulation*>).

Your cooperation in this matter is appreciated.

Sincerely,

<*Name*>
<*Title*>

C: *Clinic/Agency Director*

Glossary

adherence – 1. taking every dose of medicine as prescribed for the entire duration of an appropriate treatment regimen 2. following mandates pertaining to TB control that are formally issued to individuals by TB programs and are backed by statutes, rules, or regulations

case manager – a healthcare worker (HCW) who monitors and helps ensure that the patient adheres to treatment, and who also helps the patient obtain services from appropriate social service agencies

court order for involuntary confinement – issued by the court system having jurisdiction in a state; should be sought only after all other legal interventions have failed to achieve patient adherence or if, by judgment of the health director, the patient poses a significant public health threat

court order for examination or treatment – issued by the court system having jurisdiction in a state; should be sought only after the patient's refusal to respond to a health officer's order has been documented (see documentation)

directly observed therapy (DOT) – a methodology for promoting patient adherence in which a healthcare provider or trained designee witnesses the patient ingest each dose of his or her medication

documentation – the recording of information (including facts and insights) surrounding an investigation and all significant related events leading up to its closure

due process – the administration of justice according to established rules and principles; based on the principle that a person cannot be deprived of life, liberty, or property without appropriate legal procedures and safeguards

enabler – anything that helps the patient receive treatment or adhere to medical recommendations, including, but not limited to, providing transportation

health officer's order – written document sent by certified mail and/or hand delivery to the patient by the person or agency with the legal responsibility for TB control in the area where the patient resides; should be sent if the patient does not respond to a warning notice

incentive – anything that motivates a patient to adhere to treatment (eg, food vouchers)

involuntary confinement – isolation for inpatient treatment resulting from failure to respond appropriately to the warning notice and/or health official's order

least restrictive environment – any surrounding or condition(s) that limits an individual's activities the least while simultaneously ensures appropriate treatment and care of a patient so that the risk to the public from TB is balanced

legal interventions – actions taken by a governmental agency to ensure an individual(s) adhere(s) to a law or regulation

multidrug-resistant TB (MDR TB) – disease that is resistant to at least isoniazid (INH) and rifampin (RIF); usually caused by incomplete or inadequate treatment; more difficult to treat than drug-susceptible TB

nonadherence – not taking TB medications as prescribed or not following the recommendations of the healthcare provider for the management of TB disease

work assignment – a written document to a HCW requesting a specific service, including bringing a patient back under medical supervision. The work assignment includes patient's physical description, medical information, and the specific service required

regulation – an order issued by an executive authority of a government and having the force of law; can be amended through the rule-making process by the particular governmental agency; usually has a sunset provision

statute – law enacted by a state legislative body; can be removed only by legislative action

suspected tuberculosis – a preliminary diagnosis based on bacteriologic and/or radiographic findings and/or clinical presentation, which suggests infectiousness or potential infectiousness

verified tuberculosis – 1. having one of the following: (a) a positive culture identified as *Mycobacterium tuberculosis* or *M. tuberculosis* complex taken from gastric aspirates, sputum, pleural fluid, cerebrospinal fluid, urine, other body fluids, or a biopsy specimen and having not completed a recommended course of therapy; (b) a specimen taken from an extrapulmonary source indicating the presence of acid fast bacilli (AFB) or confirmation of *M. tuberculosis* or *M. tuberculosis* complex and having no clinical evidence or clinical suspicion of pulmonary TB; or (c) sputum smears or cultures are unobtainable or negative, and radiologic, epidemiologic, or clinical findings are sufficient to establish a diagnosis of pulmonary tuberculosis

warning notice (letter of notice) – a written document sent by certified mail and/or hand delivery to the nonadherent patient by the healthcare provider responsible for managing the patient's care

New Jersey Medical School
National Tuberculosis Center
A Founding Component of the International Center for Public Health
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