Tuberculosis Control in a Changing Health Care System: Model Contract Specifications for Managed Care Organizations

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Increasingly, patients with tuberculosis are receiving clinical care in managed care organizations as a result of enrollment in Medicaid or Medicare, or coverage under privately purchased insurance policies or employee benefit plans. This represents a change from the system that has been in place for decades, where the clinical care and public health functions concerning treatment and control of tuberculosis occurred primarily in local health departments. The separation of individual patient care from the public health aspects of tuberculosis control has created challenges for managed care administrators, medical providers, and public health officials. To assist in the integration of the goals of managed care and public health with respect to the prevention and control of tuberculosis, we developed a set of model contract specifications for use by purchasers of managed care and by managed care organizations concerning the management of patients with tuberculosis and other related public health issues. These specifications can assist health officials in continuing their leadership roles by ensuring that managed care contracts address public health needs.

Background

Tuberculosis (TB) is a classic example of a communicable disease that is associated with both patient care and public health implications. The patient care component includes the diagnosis and treatment of active disease, the testing of high-risk individuals for latent Mycobacterium tuberculosis infection, and the treatment of infected individuals with preventive therapy. The goal of the public health approach in the United States is to ensure that patients with active disease are promptly identified and provided with the appropriate drug therapy, so that they are rendered noninfectious and cured and cannot transmit the disease to others. In addition, this approach includes the identification of populations at high risk for latent TB infections and the implementation of screening and preventive therapy programs among these groups [1]. Public health activities related to TB include surveillance, assurance that quality clinical and laboratory services are available, infection control, outbreak and contact investigations, implementation of screening and preventive therapy programs in high-risk populations, and quality assurance [2].

After the TB sanatoria were closed during the 1960s and 1970s, typically both clinical care and public health functions for TB control were carried out in the health department setting [3]. However, during the past 3 decades, there has been an increasing trend toward the provision of clinical care for patients with TB by the private sector. By 1995, ~50% of the care for patients with TB was provided either partially or totally by the private medical sector [4]. This separation of individual patient care from the public health aspects of TB control has created challenges for private health care providers and public health officials alike, and has provoked debates as to the optimal setting for the care of patients with TB [5].

More recently, the managed care transformation has increased this movement of patients with TB away from clinical care in health department settings [6]. Patients with TB may be enrolled in managed care organizations as a result of coverage under employee benefit plans, privately purchased insurance policies, or as a result of enrollment in Medicaid or Medicare programs. The Omnibus Budget Reconciliation Act of 1993 (OBRA) permitted states to extend Medicaid coverage to persons with TB, and some states have used this legislation to enroll such patients in their Medicaid programs [7]. In addition, as part of overall Medicaid managed care restructuring, a few
states have expanded coverage to include previously uninsured persons [8]. The vulnerable populations among the newly insured are likely to include persons at high risk for TB. By 1996, ~75% of all privately insured individuals, 40% of all Medicaid beneficiaries, and >10% of Medicare beneficiaries were members of managed care plans, and these numbers are expected to increase [9]. The shifting of the care of patients with TB into managed care plans, with the emphasis on management of costs, has raised new concerns in the public health community with regard to the ability to maintain adequate community TB control as well as to provide optimal management of patient care in light of these changes.

Because of the clinical care and public health components as well as the characteristics of an acute infectious disease and a chronic disease (long duration of treatment), TB is an ideal condition to demonstrate a model framework that integrates clinical care with public health care. The goal of managed care is to prevent and cure disease among members of the managed care plan. However, although the primary duty of managed care organizations is to their members, the organizations function within a larger community and their operations must be consistent with public health goals. On the other hand, the goal of public health is to ensure the health of the community-at-large, and public health officials see their duty as promulgating this approach among all health care providers in the community. The aim of the model contract specifications presented here (see appendix) is to unite these two visions of duty.

The Model Contract Specifications—Uses and Basic Assumptions

At the heart of the relationship between managed care purchasers and managed care organizations (contractors) lies the contract, or enforceable agreement, concerning what is being bought and sold. A recently completed comprehensive review of contracts between large group purchasers (e.g., state Medicaid agencies) and managed care organizations throughout the country revealed that, with very few exceptions, the contracts did not address issues that are pertinent to clinical care for patients with TB or the public health aspects of TB control. In light of this lack of TB-related contract specifications and the potential for critical issues in TB management to go unaddressed without clarity in written agreements, we undertook the development of model contract specifications for TB.

The model contract specifications we present were designed primarily to be incorporated into agreements between state Medicaid agencies (purchasers) and managed care organizations. However, these specifications can serve as a prototype for any written agreement between managed care purchasers and contractors that concerns the clinical management and public health issues associated with patients with TB. These specifications may be used in contracts either as a self-contained set of provisions or as a series of requirements that can be incorporated separately into the preexisting sections of a contract (e.g., inclusion of the coverage provisions in the contract’s benefit section). These provisions are important to health officials because they attempt to address the multiple points at which public health agencies should interact with managed care organizations and the public health considerations which must be addressed in managed care settings. They are important to providers, who are the implementors of all negotiated agreements and must be aware of their responsibilities.

On one level, the model provides the contractor (managed care organization) with contract specifications on how to appropriately provide clinical care to patients with TB. The contract goes significantly further, however, in that each section includes specifications that are to ensure that the public health aspects of TB control are addressed. For example, with respect to services for inpatient treatment, the contract specifies that isolation rooms must be available for patients with TB who are infectious and that discharge should be planned in consultation with local health authorities who must consider where the patient will be living and whether he or she may pose a public health risk to the community (e.g., if living in a hospice for AIDS patients or in a nursing home). These considerations, although fundamental to the thinking of public health officials, must now be formalized because they are not intrinsic to the managed care model.

In developing these model contract specifications, we have assumed that all TB clinical and outreach services (tuberculin skin-test screening, laboratory-based and radiographic diagnosis, and drug treatment including directly observed therapy [DOT]) will be included within the scope of the agreement. In the case of Medicaid, where most state plans cover services that extend beyond the scope of the managed care agreement, a state agency may elect to exempt certain TB-related services from the contract. These services may remain the direct coverage responsibility of the state agency (e.g., DOT in some California counties, where the health department is reimbursed directly by the state Medicaid agency on a fee-for-service basis [10]) or may be incorporated into other managed care “ carve-out” agreements. In this case, the document should be modified to specify which services are the financial duty of the contractor and which are the duty of the state Medicaid agency, the local health agency, or another entity or agency that is paying for the services. Even in instances where financial responsibility for payment for care is carved out of the contract and remains the direct responsibility of the state agency, the managed care organizations may still have administrative responsibility for provision of the carved-out service for which they may be reimbursed on a fee-for-service basis.

An additional premise of these model contract specifications is that, although they can and should identify all recommended services and activities important to the treatment, prevention, and control of TB, the issue of risk sharing (i.e., the question of whether a managed care organization should be at full financial risk for some or all of these services) is a matter best
left to individual contract negotiations. For example, a buyer and contractor in a very low-risk state (i.e., low TB morbidity rates) might agree that the managed care organization should assume full risk for all TB-related services. On the other hand, in a high-risk state, the buyer and contractor might agree on a stop-loss arrangement (a ceiling for the amount of loss a seller will assume) or might provide for fee-for-service reimbursement as a general matter for certain services. The premiums for the different arrangements will vary accordingly.

Finally, in light of the variations in state law, a number of the issues described in this document may be addressed in state public health statues and regulations [11]. In this case, the document should be modified to reference such statues or regulations, as these would take precedence.

**The Model Contract Specifications**

The contract is divided into ten sections (table 1). The components of these sections were selected because they represent the principal elements of Medicaid managed care contracts. The numbering system conforms to standard contract practices.

Section 101 provides definitions, primarily of the medical terms used in the document. The readership of the document will include medical providers, Medicaid administrators, managed care administrators, and attorneys. This section is designed to ensure comprehension of and agreement on the meaning of key terms.

<table>
<thead>
<tr>
<th>Component</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definitions</td>
<td>Define key medical/public health terms of the contract</td>
</tr>
<tr>
<td>Covered services</td>
<td>Diagnostic, treatment, and preventive services that the plan is obligated to cover and provide</td>
</tr>
<tr>
<td>Medical necessity</td>
<td>Standard that will be used to determine if a service will be covered</td>
</tr>
<tr>
<td>Prior authorization</td>
<td>Procedures used to determine coverage</td>
</tr>
<tr>
<td>Utilization review</td>
<td>A precondition to eligibility for coverage</td>
</tr>
<tr>
<td>Enrollment</td>
<td>The point at which coverage is no longer the responsibility of the plan</td>
</tr>
<tr>
<td>Disenrollment</td>
<td>Providers who are selected and authorized by the plan to deliver covered services</td>
</tr>
<tr>
<td>Provider network</td>
<td>Standards that govern the timeliness and reasonableness of services</td>
</tr>
<tr>
<td>Access standards</td>
<td>Relationships that promote coordination of tuberculosis-related activities between managed care organizations and health departments</td>
</tr>
<tr>
<td>Relationships with local health agencies</td>
<td>Process used to assure quality of care, including use of standard practice guidelines and evaluation of program performance</td>
</tr>
<tr>
<td>Quality assurance</td>
<td>Data that managed care organizations are required to furnish</td>
</tr>
<tr>
<td>Data and reporting</td>
<td>Procedures for ensuring the confidentiality of care and the management of patient records.</td>
</tr>
</tbody>
</table>

Section 102 delineates the services that the managed care organization is obligated to cover and provide. Provisions are included to ensure treatment completion, e.g., DOT, limiting or waiving cost-sharing for treatments and drugs for patients with TB, and addressing homelessness and drug addiction. Untreated or improperly treated patients are at risk for developing drug-resistant disease and for transmitting disease to others [12]. In addition, the provision of preventive therapy to persons with latent TB is addressed. As noted, this section is drafted to be as comprehensive as possible; individual purchasers may elect to exempt certain services from their contracts altogether or to incorporate certain services in separate carve-out agreements.

Section 103 addresses medical necessity, that is the standard that will be used to determine if a requested service will be covered. It is designed to ensure that in both coverage determinations for individual members and the general distribution of resources within the plan, managed care organizations will use a public health–oriented approach [2]. Herein, we include provisions to ensure prompt treatment (rapid authorization procedures) and the consideration of risks posed by the patient to the public’s health, which may necessitate additional vigilance in monitoring including quarantine of certain patients. The section also addresses the need to adhere to nationally accepted guidelines in managing patients [1–2, 13–23]. See table 2 for a summary of guiding principles for the management of patients with TB or tuberculous infection.

Section 104 describes enrollment and disenrollment provisions and emphasizes the importance of continuity of care for patients with active TB. Interruptions in the treatment of patients with TB place them at risk for developing drug-resistant disease and for becoming infectious to others.

Section 105 provides details on the providers and facilities that should be available to patients with TB. This section emphasizes the need for providers with expertise in the management of TB [24, 25]. It also points out the importance of using mycobacteriology laboratories with expertise in this field [26]. Special mention is given to the option of contracting with the local health department to provide clinical services to patients and of contracting with the public health mycobacteriology laboratory for laboratory services.

Section 106 covers access of members to services, emphasizing the importance of assuring that the patient gets immediate care when the diagnosis of TB is first suspected and that the services are located geographically such that care is readily available. Because the duration of treatment for TB is at least 6 months and therapy may involve daily supervision of treatment, geographic access is a major consideration. Health department services have often included transporting patients to the clinic or sending outreach workers to the patients’ homes to deliver daily or twice-weekly DOT. This section also introduces the concept that members who are contacts of patients with TB must be notified regarding exposure and provided timely access to medical evaluation.
Table 2. Summary of guiding principles for the management of patients with tuberculosis or tuberculous infection.

1. Use bacteriologic confirmation to diagnose patients and to monitor response to therapy.
2. Obtain drug susceptibility results on all initial Mycobacterium tuberculosis isolates.
3. Provide HIV counseling and testing for all patients with tuberculosis and tuberculosis suspects. A suspect is an individual for whom active tuberculosis is suspected on the basis of clinical assessment and for whom drug-susceptibility testing is usually prescribed but for whom a confirmatory laboratory result has not yet been made.
4. Use only laboratories that have expertise in processing mycobacterial specimens for culture, identification, and drug susceptibility testing, from patients with tuberculosis or suspects.
5. Laboratories should use rapid laboratory methods, including fluorescent acid-fast staining procedures, inoculation of a liquid medium as primary culture, nucleic acid probes to identify M. tuberculosis, and, using radiometric or similar systems, testing of M. tuberculosis isolates for drug susceptibility to first-line drugs.
6. Use the standard three- or four-drug regimen in the initial phase of treatment including isoniazid, rifampicin, pyrazinamide, and ethambutol (or streptomycin), on the basis of drug-resistance prevalence information.
7. Treat continuously for a minimum of 6 months in patients with adequate clinical and bacteriologic response.
8. Extend the duration of therapy for HIV-infected patients if the response to treatment is slow or inadequate.
9. Modify therapy on the basis of drug susceptibility testing results.
10. Never add a single drug to a failing regimen.
11. Use directly observed therapy (DOT) (health care worker observes the patient taking medications) as a standard for treatment for all patients.
12. Suspect drug-resistant disease if patients do not respond appropriately to standard treatment (convert to acid-fast bacillus negative after maximum of 3 months of treatment).
13. Place tuberculosis patients and suspects who are in institutional settings (e.g., hospitals, correctional facilities, nursing homes, hospices, homeless shelters) in designated tuberculosis isolation rooms until they are not infectious.
14. Initiate contact investigations of patients with pulmonary or laryngeal tuberculosis or suspects immediately upon suspicion of the diagnosis.
15. Report all cases of tuberculosis and suspects to the health department immediately upon suspicion of the diagnosis, in order to ensure prompt investigation of contacts.
16. Screen patients who are at high risk for tuberculous infection with use of a Mantoux tuberculin test and ensure completion of a course of preventive therapy for infected persons when medically appropriate.

Section 107 provides guidance on formalizing the critical relationship between the managed care organization and the local health department. Several states include memoranda of understanding (MOU) requirements in service agreements with managed care contractors in order to promote working relationships between managed care organizations and local health agencies. Matters not resolved in these contract specifications but pertinent to the management of cases of TB can best be addressed through the use of this MOU process. However, the content of MOUs is typically outside the scope of the managed care contract and their provisions are not incorporated into the agreement. Thus, they are not binding documents, although they can play an important informal role in policy development.

Section 108 addresses quality assurance and emphasizes the use of standard practice guidelines, continuing medical education of medical providers, and evaluation of policies and practices. The collection and reporting of performance indicators are discussed, e.g., treatment completion rates for patients with TB. This section is especially important given that performance indicators for TB are not included in the Health Plan Employer Data and Information Set (HEDIS) quality assurance program—a widely used assessment tool for managed care organizations.

Section 109 describes health department reporting requirements for cases and suspect cases of active TB, including periodic treatment status updates during the course of therapy.

Section 110 provides for adherence to federal and state patient confidentiality requirements.

Discussion

The evolution to managed care represents one of the great transformations of the American health care system. Managed care, if properly designed and implemented, has the potential to improve the accessibility and quality of care and to promote overall public health objectives. This project was designed to identify the key issues that must be resolved in translating public health goals into a managed care environment. The model specifications that have been developed are intended to serve both as a technical service to managed care plan purchasers and contractors, as well as an articulation of the important issues that arise when the treatment and management of a communicable disease is in large part delegated to managed care.

More than ever the medical provider plays a pivotal role in the control of TB in this new era. He or she must not only manage the treatment of the individual patient, but must be knowledgeable about any contractual agreements under which he or she is operating. The provider will often be the middle man, first knowledgeable about problems with laboratory turnaround time, timely authorization of services, lapses in reporting cases and suspects to the health department, inadequate contact investigations, or gaps in the drug formulary for drugs to treat multidrug-resistant disease. In areas of high TB morbidity, a specially designated TB liaison in the managed care organization may monitor the quality of care and serve as the link between patient providers and the local health department to ensure that optimal patient care and public health functions of TB control are carried out. In most areas, however, medical providers will serve as the stewards of patient care and the link with public health authorities.

Infectious diseases physicians, particularly those with experience in health care epidemiology, may be particularly well-qualified to link the clinical and public health functions of population-based managed care [27, 28]. Such physicians al-
ready address infection control and employee risk issues for TB in both inpatient and outpatient settings [29, 30]. Managed care organizations and public health agencies may benefit from the involvement of infectious diseases physicians during contract negotiations and in assessing how well specific contract provisions are being implemented, particularly those which relate to the adequacy of clinical and laboratory services, as discussed in Section 105.

Over time it will become increasingly important to develop model specifications for a range of other communicable diseases. Regardless of whether the issue is the management of tuberculosis, the management of vaccine-preventable diseases, or the management of sexually transmitted diseases, aligning managed care practices with public health imperatives is essential to the integration of public health priorities into managed care practices. The George Washington University Center for Health Policy Research, in collaboration with the Centers for Disease Control and Prevention (CDC), is currently developing model specifications for additional communicable diseases, as well as a number of other diseases and conditions.

The managed care industry and public health community are working to address the issues outlined in this document [31–33]. The pace of change is rapid, however, and it is not possible at this point for purchasers, medical providers, and affected health officials to simply rely on "industry practice." As purchasers of managed care, medical providers and health officials increasingly direct efforts to address these issues, industry practice can be expected to evolve. The model contract specifications described in this document are designed not only to meet a current pressing need, but to assist in pointing the way toward further industry development.

Appendix: Recommended Contract Specifications for Tuberculosis

Section 101. Definitions

a. Active tuberculosis (TB)—An individual is presumed to have active TB if he or she is considered to be infected with Mycobacterium tuberculosis, has clinical or radiographic evidence of disease, and qualifies for drug therapy [34]. Also known as tuberculosis.

b. Contact—any individual who is identified as having been exposed to someone with active TB (shared "air space").

c. Case management—services that (i) assist an individual in gaining access to medical, social, educational, and other services (including housing and posthospital discharge services) and (ii) promote the continuity of care and completion of treatment.

d. Directly observed therapy (DOT)—a direct, face-to-face contact in any location (including a community setting other than a health professional’s office) between an individual with TB and a health care worker who is trained to observe patients with TB take each dose of medication and remove barriers to completion of treatment.

e. Fixed-dose combination drugs—drug formulations that combine two or more drugs into one capsule or tablet. Useful in preventing the development of drug-resistant TB.

f. High morbidity area—an area designated by a health agency as having a high prevalence of TB.

g. Infectious TB patient—an individual who has active TB and who is determined to be capable of clinically transmitting the disease.

h. Latent tuberculosis (also tuberculous infection)—an individual is presumed to have latent TB if he or she is infected with M. tuberculosis but does not have clinical or radiographic evidence of disease (usually has a positive tuberculin skin test).

i. Local public health agency—the public health agency whose service area includes part or all of the service area served by the Contractor and has jurisdiction to address threats to the public health. It is possible that a managed care contractor’s service area may encompass the service area of more than one local health agency.

j. Mycobacterium tuberculosis—the bacteria that causes TB.

k. Source case—an individual with infectious TB who may have infected one or more individuals.

l. Tuberculosis suspect—an individual who is suspected of having active TB on the basis of a clinical assessment and for whom multiple drug therapy is usually prescribed but for whom (i) confirmatory laboratory results have not yet been received or (ii) clinical diagnosis has not yet been made. This definition is designed to ensure appropriate management at the earliest possible date for all active TB cases. Thus, the definition includes suspects who may eventually not be officially counted as cases for surveillance purposes.

Section 102. Covered Services

a. TB-related screening services—Contractor shall cover and provide or arrange (subcontractors are bound by contract terms, unless otherwise specified) for the following TB-related screening services (which shall include a medical history, physical examination, and tuberculin skin test, as indicated in the professional judgement of the health professional furnishing the screening service):

(1) screening examinations for asymptomatic children and adults who are identified as high risk. Examinations shall be conducted in accordance with the most recent guidelines [18, 21]. For both children and adults, Contractor shall ensure use of the Mantoux tuberculin test, with results read by trained personnel and recorded in millimeters of induration.

b. TB-related diagnostic services—Contractor shall cover and provide or arrange for the following diagnostic services (which shall include evaluation of members who may be TB contacts under Section 106):

(1) examinations by health professionals who are competent in the diagnosing of TB;
(2) laboratory tests including microscopic smears, bacteriological cultures (or equivalent tests);
(3) other diagnostic services and procedures medically necessary for the accurate diagnosis of TB including but not limited to x-rays, bronchoscopies, sputum induction, tuberculin skin testing, and biopsies of affected organs [14];
(4) HIV counseling and serodiagnostic services.

Contractor shall provide or arrange for hospitalization which may be medically necessary (in accordance with Section 103) to carry out one or more diagnostic tests.

c. TB-related treatment services for persons diagnosed with active TB—Contractor shall provide or arrange for medically necessary care for individuals who are diagnosed with active TB. Treatment shall be available for both TB suspects and individuals whose diagnoses have been confirmed either clinically or through laboratory tests. Covered benefits shall include the following care and services:

(1) inpatient hospital services in facilities with TB isolation capabilities and that are otherwise appropriately equipped and staffed to treat persons with clinically active TB [16]. Inpatient treatment (including isolation treatment) shall continue until public health authorities conclude that discharge of the individual is warranted;
(2) physician services including the services of physicians with expertise in the treatment of TB;
(3) continuing diagnostic and evaluation services (including repeat evaluation of drug susceptibility where deemed medically necessary) which are designed to assess the progress of treatment and the presence of drug-resistant TB. Provider must provide or arrange for at least monthly sputum smear examinations and cultures from patients with active TB until culture results are documented as negative [15];
(4) pharmaceutical services (including isoniazid, rifampin, pyrazinamide, ethambutol [or streptomycin] and drugs to treat drug-resistant TB when necessary)—Contractor shall cover all prescribed drugs in both regular and fixed-dose combination forms and shall not dispense a dosage format or amount which is different from the one prescribed by the treating professional. Cost-sharing requirements should be waived if necessary in the case of persons with active TB;
(5) discharge planning for hospitalized patients;
(6) for patients with conditions that could complicate recovery, including but not limited to mental illness and addiction disorders, homelessness or unstable housing and HIV/AIDS, referral to providers and agencies that furnish housing and social services;
(7) DOT. Because DOT is designed to assure continuity and completion of treatment and thus lessen the potential for the spread of the disease in the community, contractors are expected to cover the service unless not deemed medically necessary by the local health agency;
(8) case management services throughout the course of treatment to reduce the risk of missed visits and to assure completion of patient’s pharmaceutical treatment schedule without interruption;
d. tuberculosis-related treatment services for persons diagnosed with latent TB.

In the case of persons diagnosed with latent, but not active, TB, contractors shall furnish preventive therapy, based on current guidelines [15].

Performance Measure for Covered Services—Contractor shall:

- Submit all provider manuals, memoranda, and other information which set forth covered screening, diagnosis, treatment, and preventive therapy services described in this section including, in the case of Medicaid, services for which the state agency has retained residual coverage and payment responsibility.
- Submit written memoranda of understanding with each local health agency in its service area regarding the consultation procedures that will be followed in determining coverage of services in the case of TB-related diagnosis, treatment, and preventive therapy services.

Section 103. Medical Necessity, Prior Authorization, and Utilization Review

a. No prior authorization for screening services—Contractor shall not require prior authorization for TB screening services furnished in accordance with the standards set forth in this document.

b. TB-related services not included in calculating provider consumption of resources—in reviewing and calculating resource consumption patterns of network providers, Contractor shall not count consumption of TB-related screening, diagnosis, or treatment services, whether furnished directly or through referral or prescription. (In some cases managed care plans establish across-the-board upper limits on network provider resource consumption, with economic sanctions applied for providers who exceed such upper limits. In light of the public health importance of TB control, such disincentives to use screening, diagnostic, or treatment resources would be deemed inappropriate.)

c. TB-related medical necessity standard—in making determinations regarding the medical necessity of coverage and provision of TB-related screening, diagnosis, and treatment services (including determinations regarding the modification of an oral or written treatment plan which is in effect at the time of enrollment), Contractor shall use nationally accepted guidelines [1–2, 13–23] and shall take into account:

(1) the patient’s overall health status including evidence of addiction disorders, mental illness, HIV infection, and other health and social factors (including living arrangements) that could adversely affect or complicate successful treatment of the patient;
(2) clinical evidence of TB (including the presence of drug-resistant TB);
(3) the risks posed by the patient to the public’s health (this definition is designed to ensure that decisions concern-
ing coverage and treatment are made in consultation with state and local public health authorities and specifically consider the risks posed to public health by the patient.)

d. Determinations of medical necessity by public health agencies—determinations of medical necessity by a public health agency shall be binding for the Contractor with respect to any TB-related screening, diagnosis, or treatment service covered under this agreement.

e. Court or executive agency-ordered treatment—Contractor shall be bound by any treatment order that is issued by a court of competent jurisdiction or an agency with the administrative authority to order treatment of individuals with infectious disease.

f. Prior authorization procedures for TB-related coverage or referral requests—in the case of requests for TB-related diagnosis or treatment services or for referrals to providers experienced in the diagnosis and treatment of TB, Contractor shall determine the medical necessity of the diagnosis or treatment request and shall communicate its determination to the member’s provider, the patient, and the local health agency within 24 hours of receipt. Denials of requests for diagnosis or treatment services by Contractor shall be in writing and shall state the reasons for such denial. At the request of the provider, the patient, or a public health agency, Contractor shall provide an expedited review (within 24 hours) of a coverage denial. Such review shall be carried out by an impartial decision-maker who was not involved in the initial decision to deny coverage.

g. Free or discounted care not a factor in coverage determinations—in making coverage determinations under this part, Contractor may not deny or reduce coverage for covered services on the ground that such services are available at a substantial discount or free-of-charge through a local health agency or other program, provider, or agency.

h. Treatment of quarantine plans—Contractor shall provide or arrange for care and services which are identified in a quarantine plan developed by a state or local health agency and which are contained in the Contractor’s service agreement. If the quarantine facility is a medical facility, all costs of institutionalization are covered under this agreement.

i. Consideration of bacille Calmette-Guérin (BCG) immunization status—in reviewing requests from health care providers for diagnosis or preventive therapy services, Contractor shall not use BCG immunization history as a sole basis for denying such requests.

j. Drug substitution—Contractor shall engage in drug substitution practices for TB-related prescribed drugs and biologics only if the substitution is approved by the public health agency.

Performance measure—Contractor shall:

- Submit all provider manuals and information transmittals that describe for providers the medical necessity standard applicable to TB-related reviews as well as manuals explaining Contractor’s procedures for making medical necessity determinations and reviewing denials of coverage.

- Submit all written memoranda of understanding with each local health agency in Contractor’s service area regarding the consultation procedures that will be followed in making coverage determinations for members receiving TB-related services.

Section 104. Enrollment and Disenrollment of Members

a. Enrollment of members receiving treatment for TB—In the event that Contractor enrolls an individual who is receiving TB-related treatment at the time, Contractor shall adhere to any treatment plan which has been developed for the member prior to enrollment until treatment is completed. Contractor may modify the treatment plan only in accordance with the terms of this agreement.

b. Disenrollment of members receiving treatment—in the event that an individual ceases to be an enrolled, Contractor shall immediately notify the public health agency and shall continue to furnish treatment until completed or for 30 days, whichever occurs first.

Section 105. Provider Network

a. Network requirements—Contractor’s provider network shall include the following classes of providers:

(1) hospitals equipped with (AFB) isolation capabilities for persons with TB;

(2) clinical providers with experience in treatment of individuals with TB;

(3) referral providers specializing in the treatment of TB for individuals who, in the opinion of experienced providers, have complex cases of TB requiring subspecialty consultation or management (e.g., TB plus a complicating morbidity, a complex case of TB, or multidrug-resistant TB).

(4) laboratories for the provision of both diagnosis and treatment-related testing services that maintain expertise in mycobacteriology and that conform to national guidelines [17] (laboratories must be able to comply with the timeliness requirement applicable to laboratory services as specified in Section 106 (e));

(5) all other providers necessary to the proper execution of this section, including appropriately trained case managers and DOT specialists.

b. Payment of local health agencies—in the event that enrollees receive TB-related services covered under this contract from a provider identified in this subsection, Contractor shall reimburse such provider (regardless of provider’s network status) for services furnished at the same rate that would be paid to a network provider for the same service, unless Contractor can demonstrate through written information that the member has received or is receiving the same service from a network provider. Providers covered under this subsection are those working in local health agencies, the Indian Health Service, federally qualified health centers, and clinics operated by disproportionate share hospitals.
Performance measure—Contractor shall:

- Submit a list of participating hospitals, laboratories, and physicians that conform to the specifications of this section. Identify the referral providers and programs that will be utilized for complex cases of TB. Submit all information furnished by Contractor to network providers that indicates sources of specialty care for persons suspected of having active TB.

Section 107. Relationships with Local Health Agencies

a. Memorandum of understanding required—For each local health agency serving some or all of Contractor’s service area, Contractor shall enter into a written memorandum of understanding (this document assumes that a memorandum of understanding is mandatory, as is the case in several state Medicaid programs) which shall address the following matters:

1. the status of the local health agency as a provider of one or more covered TB-related screening, diagnosis or treatment services;
2. procedures for conferring on matters related to the diagnosis and treatment of TB cases including coverage determinations;
3. exchange of treatment plans between Contractor and the public health agency;
4. procedures to be followed by the local health agency and other providers, agencies, institutions, and individuals when referring to the Contractor for diagnosis and treatment members who are suspected of having TB or who are suspected contacts;
5. data relating to individuals receiving TB-related diagnosis or treatment services which will be furnished by Contractor and its providers to the local health agency as well as data to be furnished to Contractor by the local health agency;
6. procedures to be followed when the local or state health agency conclude that quarantine of a member of Contractor is necessary;
7. responsibilities of the parties for notifying members who are suspected contacts;
8. role and responsibility of the Contractor during an investigation of an outbreak by a local health agency;
9. procedures for ongoing discussions of current cases by Contractor and the local health agency;
10. individuals who will be designated by Contractor and the local health agency as TB-related liaisons;
11. procedures for addressing issues related to non-compliant patients or patients who have missed appointments for one or more treatment services.

Performance measure—Contractor shall:

- Submit a signed memorandum of understanding along with all relevant appendices and attachments prior to commencing services.

Section 108. Quality Assurance

a. Practice guidelines—Contractor shall disseminate to all network providers TB-related practice guidelines that are to be based on nationally accepted guidelines [1–2, 13–23] and which are to be updated as such guidelines are updated.

b. Clinical studies—in assessing the quality of its TB program, Contractor shall conduct clinical studies which are designed to measure the timeliness and appropriateness of its
diagnosis and case management services. Such studies shall, at a minimum, consider the following factors:

- (1) percentage of patients with active TB who are placed on the recommended three or four-drug TB treatment regimen [15];
- (2) the percentage of patients with active TB whose initial specimens were evaluated for drug susceptibility;
- (3) the number and percentage of patients whose initial specimens were evaluated for drug susceptibility; and placed on preventive therapy and who complete an appropriate preventive therapy regimen.

Performance measure—Contractor shall:

- Submit all practice guidelines disseminated to providers as well as the results of all clinical studies and drug formulary assessments.
- Submit the percentage of all members who are contacts of infectious cases who have been recommended for and placed on preventive therapy and who complete an appropriate preventive therapy regimen.
- Continuing medical education—Contractor shall ensure that network providers that furnish TB-related services receive continuing education in the proper identification, treatment, and management of TB.

Performance measure—Contractor shall:

- Submit all practice guidelines disseminated to providers as well as the results of all clinical studies and drug formulary assessments.
- Submit the percentage of all members who are contacts of infectious cases who have been recommended for and placed on preventive therapy and who complete an appropriate preventive therapy regimen.
- Continuing medical education—Contractor shall ensure that network providers that furnish TB-related services receive continuing education in the proper identification, treatment, and management of TB.

**Section 109. Data and Reporting**

a. Public health reporting:

- (1) for members who are diagnosed or suspected of having active TB, Contractor shall notify public health authorities within 24 hours of identification of the case or suspect case;
- (2) for members receiving treatment for TB (cases of active TB or TB suspect), Contractor shall file periodic clinical reports on the status of the individual with local health department (as specified in the memorandum of understanding) until treatment has been completed.

Performance measure—Contractor shall:

- Submit the number and percentage of all members diagnosed with active TB or who are TB suspects, who are reported to the local health agency within 24 hours of identification.
- Submit the number and percentage of all members receiving treatment for TB whose reports, as required in this subsection, have been submitted to the local health agency.

**Section 110. Confidentiality**

a. Safeguarding patient confidentiality—in treating persons who are receiving TB-related services, Contractor shall comply with all federal, state, and local laws relating to protection of patient confidentiality and the management of medical records.

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**References**

7. Pub L No. 103-66, Sec. 13603 (e)(I).
10. Request for Application, Medi-Cal Managed Care, addendum #3, Section 9.7.3.R.7 Contractual Requirements, December 14, 1994.