# ACCEPTANCE OF AWARD

## Tuberculosis Control Local Assistance Funds

## COUNTY OF SAN MATEO

| FUNDING SOURCE | FEDERAL BASE | STATE BASE |
|---|---|---|
| AWARD NUMBER: | 2641BASE-F | 2641BASE-S |
| AWARD AMOUNT: | $124,434 | $147,335 |
| FUNDING PERIOD: | 7/1/2026-12/31/2026 | 7/1/2026-6/30/2027 |

I hereby accept this award. By accepting this award, I agree to the requirements as described in the FY 2026-2027 Tuberculosis Control Local Assistance Funds Standards and Procedures Manual and any other conditions stipulated by the California Department of Public Health, Tuberculosis Control Branch.

This award is contingent upon the availability of funds appropriated by the State of California and the federal government. The CDPH TBCB reserves the right to reduce, amend, or withdraw funding, in whole or in part, should funding from the state or federal government be reduced, delayed, or otherwise adjusted.

_____ _____
Authorized Signature Date

_____ _____
Print Name Title

* Federal funds fiscal information: Project Grants and Cooperative Agreements for Tuberculosis Control Programs; ALN number: 93.116; FAIN number: NU52PS910282

California Department of Public Health

Tuberculosis Control Branch

# Tuberculosis Control Local Assistance Funds Standards and Procedures Manual FY 2026-2027

Federal Budget Period: 7/1/2026–12/31/2026

State Budget Period: 7/1/2026–6/30/2027

Base Award Funding

Supplemental Funding

Civil Detention Funding

March 2026

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## Part 1 - Standards and General Terms and Conditions

### 1. Overview

The California Department of Public Health (CDPH) Tuberculosis Control Branch (TBCB) sets forth the following standards and procedures. These standards and procedures specify the conditions for receipt of CDPH TBCB local assistance funds.

The purpose of the tuberculosis (TB) local assistance funds is to assist the current efforts of local TB programs to prevent, control, and eventually eliminate TB in California. Financial assistance is provided to local TB programs to augment local support for TB prevention and control activities.

Local assistance allocations are made up of both state funds and federal funds with the exception of state funds-only allocations to three local health jurisdictions (LHJs) that receive federal funds directly from the Centers for Disease Control and Prevention (CDC). Federal funds fiscal information: ALN – 93.116; FAIN number – NU52PS910282.

### 2. Authority

California Health and Safety Code (H&SC) Sections 121450, 121451 and 121452 authorize CDPH TBCB to distribute for the purpose of TB control an annual subvention, paid quarterly, to any LHJ that maintains a TB control program consistent with standards and procedures established by the Department. The following conditions contained in this manual apply to LHJs that have accepted awarded funding.

### 3. Allocation of Local Assistance Funds

Fiscal year (FY) local assistance funds are allocated using a funding formula (see table Tuberculosis Local Assistance Allocation Formula FY 2026-2027 below). A multi-variable funding formula modeled after the national TB allocation formula was developed in 2009 in collaboration with the California TB Controllers Association (CTCA) and revised in FY 2012. In 2023, the allocation process was modified to incorporate low morbidity LHJs (averaging <6 cases annually) in the base award funding calculation starting in FY 2024-2025.

Allocations are calculated every two years using five years of surveillance data. Data from 2021-2025 was used to determine FY 2026-2027 and FY 2027-2028 allocations.

**Tuberculosis Local Assistance Allocation Formula FY 2026-2027**

| Variable | Weight |
|---|---|
| Incident cases | 32% |
| Non-U.S.-born persons and U.S.-born minorities | 30% |
| Pulmonary smear-positive | 15% |
| B-1 notification TB evaluations completed | 5% |
| HIV/AIDS co-infection | 5% |
| Substance Use | 5% |
| Homelessness | 5% |
| Multidrug-resistant (MDR) TB | 3% |

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amend, or withdraw funding, in whole or in part, should funding from the state or federal government be reduced, delayed, or otherwise adjusted.

## 4. Tuberculosis Control Branch Priorities and Guidelines for Tuberculosis Prevention and Control Activities

### 4.1. Tuberculosis Control Branch Priorities

CDPH TBCB priorities include national priorities and strategies established by CDC. Two of the strategies in the CDC Division of Tuberculosis Elimination Strategic Plan for 2022-2026 to reduce TB morbidity in the United States are:

**Strategy 1 – Maintain Control of TB:**

Maintain the decline in TB incidence through timely diagnosis of TB disease, appropriate treatment and management of persons with TB disease (both drug-susceptible and drug-resistant), investigation, appropriate evaluation and treatment of contacts of people with infectious TB disease, and prevention of further transmission through infection control.

**Strategy 2 – Accelerate the Decline:**

Advance toward TB elimination through appropriate regionalization of TB control activities, rapid recognition of TB transmission using genotyping methods, rapid outbreak response and targeted testing and treatment of persons with latent TB infection by engaging communities that experience high burden of TB disease and expanding partnerships with health care agencies, clinicians, and community organizations.

### 4.2. General Guidelines for Local Health Jurisdictions Receiving Local Assistance Funds

CDPH TBCB has historically taken a priority-based, graduated approach in conducting TB prevention, control and elimination activities. LHJs are now encouraged to conduct all TB prevention and control activities to both maintain control of TB and to accelerate the decline of TB. In California, more than 80% of cases reported each year are due to reactivation of LTBI among individuals with long-standing untreated infection (e.g., contacts to persons with TB disease, immigrants arriving with a class B notification, and other high-risk populations). Efforts to prevent future TB cases should include:

- Maximizing treatment initiation and completion for LTBI in high-risk populations
- Promoting the use of the shortest effective LTBI treatment regimens
- Increasing access to adherence technologies to enhance follow-up and treatment completion

LHJs experiencing success with certain strategies are encouraged to share best practices with CDPH TBCB and other TB programs.

## 5. Local Health Jurisdiction Responsibilities

LHJs agree to:

- Direct activities toward achieving the program objectives set forth by CDPH TBCB
- Use these funds in accordance with the CDPH TBCB Standards and Procedures Manual, and with any additional guidance set forth by CDPH TBCB regarding the granting, use and reimbursement of TB local assistance funds

- Use these funds to augment existing funds and not supplant funds that have been locally appropriated for the same purposes. Local assistance funds are intended to provide local entities with increased capabilities to address TB control needs. Supplanting of funds is defined (for the purposes of this agreement) as using local assistance award monies to "replace" or "take the place of" existing local funding. For example, reductions in local funds cannot be offset by use of CDPH TBCB dollars for the same purpose.
- Submit information and reports as requested by CDPH TBCB
- Abide by the most recent standards of care for TB treatment, control and prevention as promulgated by:
  - California Department of Public Health[1]
  - California Tuberculosis Controllers Association[2]
  - American Thoracic Society[3]
  - Centers for Disease Control and Prevention[4]

## 5.1. Reporting Requirements

### A. Case Reports

LHJs will comply with morbidity reporting requirements. All cases will be reported in California Reportable Disease Information Exchange (CalREDIE) using the Report of Verified Case of Tuberculosis (RVCT) form.[5] (Case outcome information for cases counted in 2021 and prior years will be reported on the 2009 RVCT form. For TB cases counted in 2022 and later, LHJs will report using the 2020 RVCT form. Additional information on all cases treated with multidrug-resistant (MDR) TB medications should be reported using the MDR supplemental form.

LHJs will submit complete TB case data within two weeks of case confirmation, participate in RVCT trainings, and conduct quality control procedures, including reconciliation of case counts. LHJs will participate in other activities as needed to ensure accurate reporting on the RVCT and MDR forms.

When the diagnosis and/or care of a patient with TB is shared between LHJs because of multiple residences or movement between LHJs, LHJs shall communicate with each other

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[1] CDPH TBCB TB Guidelines and Regulations (www.cdph.ca.gov/Programs/CID/DCDC/Pages/TB-Guidelines-and-Regulations.aspx)

[2] CTCA Guidelines (ctca.org/guidelines/cdph-ctca-joint-guidelines/#)

[3] American Thoracic Society, CDC, Infectious Diseases Society of America. (2016) Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis (cdc.gov/tb/publications/guidelines/pdf/clin-infect-dis.-2016-nahid-cid_ciw376.pdf)

[4] CDC TB Guidelines (https://www.cdc.gov/tb/hcp/clinical-guidance/?CDC_AAref_Val=https://www.cdc.gov/tb/publications/guidelines/default.htm)

[5] 2020 RVCT and MDR forms and reference materials are located in the Document Repository of CalREDIE. Log on and select Document Repository from the CDPH option on the menu bar. Under Report Forms & Documents, click on Tuberculosis Control Branch for a link to 2020 RVCT and MDR forms, revised manual, and TBCB guidance on CA fields.

to agree on the jurisdiction with appropriate case count authority, according to CDC case counting guidelines. When a decision cannot be reached between LHJs, CDPH TBCB will work with involved LHJs to assign a counting jurisdiction. Case counting guidelines are outlined in the CDC Report of Verified Case of Tuberculosis Instruction Manual.[1]

### B. Electronic Reporting

LHJs should enter RVCT case data for their jurisdiction directly into CalREDIE, the CDPH web-based reporting system for notifiable diseases, or a successor CDPH reporting platform if one is developed. For LHJs using CalCONNECT, data entry into fields that populate the RVCT in CalREDIE is also acceptable. Submission of hard copy RVCT for data entry into CalREDIE by CDPH TBCB will not be accepted. Direct entry of data into CalREDIE improves reporting processes including submission of case reports to CDC and tracking patients who have moved.

### C. Data Security and Confidentiality

LHJs shall comply with recommendations set forth in CDC's "Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs."[2]

### D. California Aggregate Report for Program Evaluation: Follow-up and Treatment for Contacts of TB Cases

LHJs will submit completed Preliminary and Final ARPE-Contact Investigation (CI) forms to CDPH TBCB annually. Reports are due March 19, 2027, for 2025 (Final) and 2026 (Preliminary). ARPE-CI instructions and forms can be found in the CalREDIE Document Repository and on the CDC DTBE ARPE webpage.[3] Each year by early February, CDPH TBCB will email all LHJs: 1) Instructions and the MS Word form; 2) Excel workbook with reported cases by smear and culture status; 3) invitation to instructional webinars in February. CDPH TBCB submits ARPE-CI data to CDC on behalf of California LHJs.

ARPE-CI reporting may be accomplished by using CalCONNECT. LHJs entering all active TB cases and their contacts into CalCONNECT do not need to submit an ARPE form but are encouraged to check data using the ARPE-CI dashboard in CalCONNECT. CDPH TBCB will download and submit ARPE-CI data for these LHJs. LHJs entering some but not all contacts into CalCONNECT may submit a partial ARPE-CI with contacts

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[1] CDC (2021) 2020 Report of Verified Case of TB (RVCT) Instruction Manual (cdc.gov/tb/programs/rvct/InstructionManual.pdf)

[2] CDC (2011) Data Security and Confidentiality Guidelines for HIV, Viral Hepatitis, Sexually Transmitted Disease, and Tuberculosis Programs: Standards to Facilitate Sharing and Use of Surveillance Data for Public Health Action (https://www.cdc.gov/program-collaboration-service-integration/php/data-security/?CDC_AAref_Val=https://www.cdc.gov/nchhstp/programintegration/Data-Security.htm)

[3] ARPE forms are located in the Document Repository of CalREDIE. Log on and select Document Repository from the CDPH option on the menu bar. Under Report Forms & Documents, click on Tuberculosis Control Branch for a link to the ARPE forms. ARPE forms and instructions are also available on the CDC DTBE ARPE (cdc.gov/tb/programs/evaluation/ARPE.html) webpage.

not entered into CalCONNECT, and CDPH TBCB will add the partial ARPE-CI data to the data from the ARPE-CI report in CalCONNECT.

### E. California Aggregate Report for Program Evaluation: Targeted Testing and Treatment for Latent Tuberculosis Infection

In 2020, CDC reintroduced the ARPE-TT as a required annual report. The requirement of LHJs to report to CDPH TBCB is being phased in by LHJ morbidity level over the next few years. LHJs reporting more than 5 TB cases per year, based on 2024-2026 average, shall submit the ARPE-TT to CDPH TBCB, by March 19, 2027, for 2025 (Final) and 2026 (Preliminary) data as available. ARPE-TT forms and instructions can be found on the CDC DTBE ARPE webpage.[1] Each year by mid-February, CDPH TBCB will email all LHJs: 1) Instructions and the MS Word form; 2) invitation to instructional webinars in February.

### F. Protocols for People Who Move

LHJs will use the most up-to-date National Tuberculosis Coalition of America (NTCA) forms for the transfer of patient care between LHJs in California or between states.[1]

All patients moving out of the United States should be referred to CureTB. Instructions and referral forms can be found on the CureTB webpage[2]. Note that referrals from California should be made to CureTB at (619) 542-4013 or by email at CureTB@cdc.gov.

Instructions for “Transfer Protocols - RVCT Reporting for Tuberculosis Patients that Move” can be found on the CDPH TBCB website.[3]

### G. Outbreak Reporting

The California Code of Regulations (Title 17, Section 2502[c]) directs local health officers to immediately report TB outbreaks to CDPH. Reports should be conveyed by calling the CDPH TBCB Outbreak Duty Officer at (510) 620-3000. California TB surveillance definitions for outbreaks can be found on the CDPH TBCB website.[4]

LHJs should not delay reporting while genotype results are pending if an outbreak is suspected.

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[1] NTCA protocol and forms can be found on the TB Reporting Forms and Instructions for Local Health Departments (cdph.ca.gov/Programs/CID/DCDC/Pages/TB-Reporting-Forms-and-Instructions-for-LHDs.aspx) webpage under Interjurisdictional Transfer Recommendations.

[2] CDC CureTB (https://www.cdc.gov/migration-border-health/php/cure-tb/index.html)

[3] CDPH TBCB. (2019) RVCT Reporting Instructions for Tuberculosis Patients that Move. Can be found on the TB Reporting Forms and Instructions for Local Health Departments (cdph.ca.gov/Programs/CID/DCDC/Pages/TB-Reporting-Forms-and-Instructions-for-LHDs.aspx) webpage under Interjurisdictional Transfer Recommendations.

[4] CDPH TBCB. (2023) Surveillance Definitions for TB Outbreaks. Can be found on the Resources for Local Health Departments (cdph.ca.gov/Programs/CID/DCDC/Pages/TB-Resources-for-LHDs.aspx) webpage under Tools and Trainings.

LHJs are encouraged to report TB occurrences in which CDPH TBCB assistance may be useful (e.g., suspected outbreak, an infectious case in a sensitive population, large or complex CI).

### H. Immigrants, Refugees, Parolees and Immigration Status Adjusters

LHJs will use the "Electronic Disease Notification (EDN) B-notification Follow-up Worksheet"[1] to report the results of U.S. evaluations of immigrants and refugees arriving with A/B-notifications. Evaluations should be completed and Worksheet results submitted within 120 days of notification of arrival in the U.S., or as soon as the American Thoracic Society TB classification has been assigned. Submission of treatment information, including outcomes, for persons diagnosed with ATS TB 2 or 4 is strongly encouraged. However, treatment outcomes should be submitted separately from evaluation outcomes, to prevent delayed evaluation reporting. LHJs receiving email notifications from EDN should enter the Worksheet results, including any LTBI treatment information, online into EDN. LHJs receiving secure email notifications from CDPH TBCB should submit the Worksheet, including any LTBI treatment information, by fax or secure email.

LHJs are strongly encouraged to work with civil surgeons in their jurisdiction to communicate reporting requirements and referral recommendations for immigration status adjustment applicants testing positive for LTBI, or with findings concerning for TB disease. All civil surgeons are required to use eMedical to report status adjusters with LTBI (not through CalREDIE provider portal). Data from eMedical will be transferred into the EDN system, and LHJs with EDN access will receive notifications of LTBI in EDN. LHJs are encouraged to refer or provide status adjusters with LTBI treatment, and report outcomes using the Follow-up Worksheet in EDN, or other state system if available. Please contact CDPH TBCB for questions, updates on reporting systems, and access to EDN.

## 5.2. Program Evaluation and Program Improvement

Program evaluation is a systematic review of priority program-area performance and improvement. LHJs are expected to be familiar with the California TB indicator reports, B notification and civil surgeon reports, National TB indicators reports, California performance objectives and local TB program performance.[2] Local assistance funding should be used to meet local and California TB performance objectives.

CDPH TBCB systematically reviews statewide data to decide which TB indicators to prioritize, and to inform work with select local TB programs. CDPH TBCB will contact LHDs based on their performance and contribution to statewide underperformance on prioritized indicators.

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[1] EDN B-notification Follow-up Worksheet and additional guidance can be found on the TB Reporting Forms and Instructions for Local Health Departments (cdph.ca.gov/Programs/CID/DCDC/Pages/TB-Reporting-Forms-and-Instructions-for-LHDs.aspx) webpage under A/B-Notification Reporting.

[2] Program evaluation and improvement resources can be found on the Tuberculosis Disease Data and Publications (cdph.ca.gov/Programs/CID/DCDC/Pages/TB-Disease-Data.aspx) webpage under TB Disease Data.

CDPH TBCB will collaborate with chosen LHDs on an annual basis to review their program performance summary data (provided by CDPH TBCB) and discuss opportunities for program improvement.

LHJs that receive annual performance reports from CDPH TBCB are expected to conduct internal reviews of their program performance summary data each year and consider opportunities for program improvement. CDPH TBCB sends performance reports to LHJs reporting an average of 15 or more TB cases per year, on most recent three-year average. CDPH TBCB staff are available upon request to provide consultation and technical assistance for program improvement.

LHJs reporting fewer than 15 TB cases annually are encouraged to review their TB data in the most recent "California TB Snapshot," California TB Dashboard" and "California Data Tables,"[1] and any other CDPH TBCB-provided data reports. CDPH TBCB staff are available upon request to provide consultation and technical assistance for program improvement.

For consultation regarding program evaluation and program improvement, please contact your assigned CDPH TBCB Program Liaison and/or Epidemiology Liaison (see Part 1 Section 5.8).

### 5.3. Rights of the Tuberculosis Control Branch

- CDPH TBCB reserves the right to modify the terms and conditions of all awards. Additional information and documentation may be required.
- CDPH TBCB reserves the right to use and reproduce all reports and data produced and delivered pursuant to the local assistance awards and reserves the right to authorize others to use or reproduce such materials, provided that the confidentiality of patient information and records is protected pursuant to California State laws and regulations.

### 5.4. Cancellation/Termination

- It is mutually agreed that if the Budget Act of the current year and/or any subsequent years covered under this agreement does not appropriate sufficient funds for the program, this agreement shall be of no further force and effect. In this event, CDPH shall have no liability to pay any funds whatsoever to LHJ or to furnish other considerations under this agreement and LHJ shall not be obligated to fulfill any provisions of this agreement.
- If funding for any fiscal year is reduced or deleted by the Budget Act for purposes of this program, CDPH shall have the option to either cancel this agreement with no liability occurring to CDPH or offer an agreement amendment to the LHJ reflecting the reduced amount.
- CDPH TBCB reserves the right to cancel or terminate this agreement immediately for cause.* LHJ may submit a written request to terminate a TB local assistance award only if CDPH TBCB substantially fails to perform its responsibilities.

[1] CDPH TBCB. California TB Snapshot and California Data Tables. Can be found on the Tuberculosis Disease Data and Publications (cdph.ca.gov/Programs/CID/DCDC/Pages/TB-Disease-Data.aspx) webpage under Annual TB Reports.

*The term “for cause” means that LHJ fails to meet the terms, conditions, and/or responsibilities of a TB local assistance award.

- Agreement termination or cancellation is effective as of the date indicated in the CDPH TBCB notification to LHJ. The notice stipulates any final performance, invoicing or payment requirements.
- Upon receipt of a notice of termination or cancellation, LHJ will take immediate steps to stop performance and cancel or reduce subsequent agreement costs.
- In the event of early termination or cancellation, LHJ is entitled to compensation for services performed satisfactorily under this agreement and expenses incurred up to the date of cancellation and any non-cancelable obligations incurred in support of the TB local assistance award.

### 5.5. Avoidance of Conflicts of Interest by Local Health Jurisdiction

LHJ agrees to make all reasonable efforts to ensure that no conflict of interest exists between its officers, agents, employees, consultants or members of its governing body.

- LHJ will prevent its officers, agents, employees, consultants or members of its governing body from using their positions for purposes that are, or give the appearance of being, motivated by a desire for private gain for themselves or others such as those with whom they have family, business or other ties.
- In the event that CDPH TBCB determines that a conflict-of-interest situation exists, any cost associated with the conflict may constitute grounds for termination of the TB local assistance award. This provision will not be construed to prohibit the employment of persons with whom LHJ’s officers, agents, or employees have family, business or other ties so long as the employment of such persons does not result in increased costs over those associated with the employment of other equally qualified applicants and such persons have successfully competed for employment with other applicants on a merit basis.

### 5.6. Indemnification

LHJ agrees to indemnify, defend and save harmless the State, its officers, agents and employees from any and all claims and losses accruing or resulting to any and all LHJs, subcontractors, suppliers, laborers, and any other person, firm or corporation furnishing or supplying work services, materials, or supplies in connection with the project, and from any and all claims and losses accruing or resulting to any person, firm or corporation who may be injured or damaged by LHJ in the performance of any activities related to a TB local assistance award.

### 5.7. Other

- TB Local Assistance Awards are not assignable by LHJ, either in whole or in part without a formal written amendment by CDPH TBCB.
- LHJ will act in an independent capacity and not as officers/employees/agents of the State.
- LHJ will notify CDPH TBCB prior to any public or media event publicizing project data.

### 5.8. Communicating with the Tuberculosis Control Branch

When communicating with CDPH TBCB, please contact your LHJ's assigned Program Liaison, Fiscal Analyst, Epidemiologist, or Outbreak Liaison.[1]

Fiscal questions should be directed to your assigned Fiscal Analyst. Programmatic questions should be directed to your assigned Program Liaison.

CDPH TBCB Civil Detention Coordinator Chris Keh may be reached at (510) 620-3000 or by email at Chris.Keh@cdph.ca.gov.

[1] CDPH TBCB. Program, Fiscal, Epidemiology and Outbreak Response Liaison Assignments. Can be found on the Resources for Local Health Departments (cdph.ca.gov/Programs/CID/DCDC/Pages/TB-Resources-for-LHDs.aspx) webpage under Liaison Assignments for Local Health Jurisdictions.

## Part 2 - Guidelines on Use of TB Local Assistance Funds

### 1. Use of Base Award Funds

Local assistance funds must be used exclusively for TB-related activities in accordance with the requirements set forth in Part 1 Section 4 and Part 1 Section 5. Allowable expenses include: salaries and benefits for personnel involved in TB control activities, equipment, supplies, TB-specific training and travel. **TB medication expenses are reimbursable from state funds only**. See Part 2 Section 1.1 for allowable expenditures and Part 2 Section 1.2 for non-allowable expenditures. Local assistance funds should be used to support licensed professionals only to perform services called for.

### 1.1. Allowable Expenditures FY 2026-2027

The following expenditures are usually approved when used to support CDPH TBCB Priorities I and II. This list is not comprehensive and the presence of an item on the Allowable list does not imply automatic approval. Please contact your assigned TBCB Fiscal Analyst for guidance.

**Equipment**
- Cell phones
- Computer hardware
- Computer software for data management of cases and contacts
- Printers, scanners, fax machines
- Video or eDOT equipment or services (see Part 2 Section 1.4)

**Fixed Assets**
- In-room air cleaners (HEPA filters)
- Laboratory or Radiographic equipment
- Sputum induction devices (booths or hoods)
- TB testing equipment

**Food, Shelter, Incentives & Enablers**
- Delivery services
- Food vouchers/Gift Cards
- Patient housing
- Personal products
- Rideshare services
- Transportation tokens or vouchers

**Indirect Costs (Optional)**
- LHJ specific rates are approved each year by CDPH
- Rates may not exceed 15% of total allowable direct costs or 25% of total personnel services costs

**Laboratory (TB-related)**
- Chest x-rays
- Culture, smear, drug susceptibility testing
- Rapid diagnostic tests
- Specimen transport

**Medications (anti-TB only)**
- Limited to state funds portion of award (see Part 2 Section 1.5)

**Personnel (conducting TB prevention and control activities)**
- MDs, NPs, Clinical RNs, Radiologists, PHNs, CDIs, Community Workers, Laboratory Staff, Clerks, Social Workers, Financial Screeners, Epidemiologists, Interpreters

**Supplies**
- Laboratory supplies
- Medical clinic supplies
- Office supplies

**Travel**
- In-jurisdiction for DOT, case management, CI
- Out-of-jurisdiction (in-state) associated with training
- Out-of-state travel only with prior CDPH TBCB approval

**Training (TB-related)**
- CTCA conference expenses
- Curry International TB Center training
- Educational materials
- Respirator fit testing

**Vehicle Leasing Fees**

**Other**
- Local detention activities as described in H&SC Section 121451
- Patient locating services

### 1.2. Non-Allowable Expenditures FY 2026-2027

The following expenditures will not be approved:

**Facility Leasing or Rental Fees**
- Building or office space

**Furniture**
- Desks
- File cabinets
- Modular furniture
- Tables

**General Building Renovation Fees**

**Laboratory Renovations**

**Patient Insurance Co-Pays**

**Promotional Items and Advertising**
- e.g., TB program or health department labeled pens, coasters, banners

**TB Clinic Renovations**

**Travel**
- Out-of-country
- Out-of-State without prior CDPH TBCB approval

**Other**
- Alcohol or Tabacco

### 1.3. State TB Mandates

In 2012, the Commission on State Mandates determined that Health and Safety Code (H&SC) Sections 121361,121362 and 121366 imposed a partially reimbursable state mandated program upon local agencies. To address these activities, the H&SC was amended to include Sections 121451 and 121452.

H&SC Section 121451 states that a local entity that receives funding from the state for the purposes of TB control shall first allocate the moneys received for the actual costs of the activities described below before allocating the moneys for any other purposes or activities.

#### A. Local Detention

When a person who has active TB or is reasonably believed to have active TB is discharged or released from a detention facility, LHJ may reimburse a detention facility for both of the following:

- Drafting and submitting notification to the local health officer
- Submitting the written treatment plan that includes the information required by Section 121362 to the local health officer (does not include drafting the written treatment plan)

When a person who has active TB or is reasonably believed to have active TB is transferred to a local detention facility in another jurisdiction, LHJ may reimburse the facility for both of the following:

- Drafting and submitting notification to the local health officer and the medical officer of the local detention facility receiving the person
- Submitting the written treatment plan that includes the information required by Section 121362 to the local health officer and the medical officer of the local detention facility receiving the person (does not include drafting the written treatment plan)

### B. Local Health Officer or Designee

Either of the following activities may be reimbursed with TB local assistance funds if those activities are carried out by a local health officer or their designee:

- Receiving and reviewing for approval within 24 hours of receipt only those treatment plans submitted by a health facility. This activity includes all of the following:
  - Receiving the health facility's treatment plan
  - Sending a request to a health facility for medical records and information on TB medications, dosages, and diagnostic workup; and reviewing records and information
  - Coordinating with the health facility on any adjustments to the treatment plan
  - Sending approval to the health facility
- Drafting and sending a notice to the medical officer of a parole region, or a physician or surgeon designated by the California Department of Corrections and Rehabilitation, if there are reasonable grounds to believe that a parolee has active TB and ceases treatment for the disease.

### C. Counsel to Nonindigent Patients with Tuberculosis

LHJ may reimburse costs for cities and counties to provide counsel to nonindigent patients with TB who are subject to a civil order of detention issued by a local health officer pursuant to Section 121365 upon request of the patient. Services provided by counsel include representation of the patient with TB at any court review of the order of detention required by Section 121366.

## 1.4. Equipment and Services for Electronic Directly Observed Therapy

LHJs using local assistance award funds to purchase equipment (e.g., cell phones or webcams) or services (e.g., cell phone service or eDOT vendor contracts) for electronic directly observed therapy (eDOT) will certify in writing that they have a written eDOT policy and procedures. LHJs are responsible for ensuring methods used are in compliance with the Health Insurance Portability and Accessibility Act of 1996 and any other applicable privacy laws.[1] LHJs should review the CDPH-CTCA "Joint Guidelines for Electronic Directly Observed Therapy (eDOT) Program Protocols in California"[2] and contact their assigned CDPH TBCB Program Liaison for assistance (see Part 1 Section 5.8).

## 1.5. TB Medication Expenditures

To comply with federal restrictions on fund use, reimbursement of medication expenditures is limited to the amount of the state fund portion of the award.

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[1] A link to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) can be found on the Health and Human Services (hhs.gov/hipaa/for-professionals/index.html) website.

[2] CDPH-CTCA Joint Guidelines for Electronic Directly Observed Therapy (eDOT) Program Protocols in California (ctca.org/wp-content/uploads/2018/11/CDPH_CTCA-eDOT-Guidelines-Cleared-081116.pdf)

### 1.6. Expense Allowability and Fiscal Documentation

LHJs will maintain records reflecting actual expenditures for applicable budget periods.

- Invoices, received from LHJ and accepted for payment by CDPH TBCB, will not be deemed evidence of allowable agreement costs.
- LHJs will maintain for review and audit and supply to CDPH TBCB upon request, adequate documentation of all expenses claimed pursuant to these TB local assistance awards to permit a determination of expense allowability for a minimum of 5 years after final payment.
- If the allowability of an expense cannot be determined by CDPH TBCB because invoice detail, fiscal records, or backup documentation is nonexistent or inadequate according to generally accepted accounting principles or practices, all questionable costs may be disallowed and payment may be withheld by CDPH TBCB. Upon request of adequate documentation supporting a disallowed or questionable expense, reimbursement may resume for the amount substantiated and deemed allowable.

### 1.7. Payment and Recovery of Overpayments

- CDPH TBCB reserves the right to question and re-negotiate reimbursement for any expenditure that may appear to exceed a reasonable cost for the service.
- Compensation provided for expenses incurred in the performance of the award (including travel, per diem, and taxes) will be considered as paid.
- Federal local assistance award funds may not be used for litigation costs.
- LHJ agrees that claims based upon a TB local assistance award or an audit finding and/or an audit finding that is appealed and upheld, will be recovered by CDPH TBCB by one of the following options:
  - LHJ's remittance to CDPH of the full amount of the audit exception within 30 days following a CDPH TBCB request for repayment
  - A repayment schedule that is agreeable to both TBCB and LHJ
- CDPH TBCB reserves the right to select which option will be employed and LHJ will be notified by CDPH TBCB in writing of the claim procedure to be utilized.
- Interest on the unpaid balance of the audit finding or debt will accrue at a rate equal to the monthly average of the rate received on investments in the Pooled Money Investment Fund commencing on the date that an audit or examination finding is mailed to LHJ, beginning 30 days after LHJ's receipt of the CDPH TBCB demand for payment.
- If LHJ has filed a valid appeal regarding the report of audit findings, recovery of the overpayments will be deferred until a final administrative decision on the appeal has been reached. If LHJ loses the final administrative appeal, LHJ will repay CDPH the over-claimed or disallowed expenses, plus accrued interest. Interest accrues from LHJ's first receipt of the CDPH TBCB notice requesting reimbursement of questioned audit costs or disallowed expenses.

## 2. Additional Guidance for Base Award Use

LHJs receive a single Letter of Award specifying amounts by funding source. The State Base Award includes Food, Shelter, Incentives and Enablers (FSIE) and Housing Personnel funding. All or part of an award can be used for FSIE expenditures.

### 2.1. Purpose of Housing Personnel Funds

Housing Personnel funding included in the State Base Award is not intended for FSIE expenditures. The State Base Award includes a separate amount for FSIE expenditures.

- Housing Personnel funds specifically support personnel that work directly with patients with TB who are:
  - Experiencing homelessness, or
  - At risk of experiencing homelessness, or
  - At risk for not completing treatment
- Eligible activities and expenditures for Housing Personnel funds included as part of the State Base Award are those that foster the use of less restrictive alternatives to decrease or prevent the need for detention. Some examples are:
  - Personnel salaries and benefits for personnel such as outreach workers, communicable disease investigators, social workers, or public health nurses that work with the specified population to attain the desired outcomes
  - Local mileage for personnel to perform directly observed therapy (DOT) or other services to ensure completion of therapy

### 2.2. Purpose of Food, Shelter, Incentives and Enablers Funds

FSIE funds are intended to improve adherence and motivate patients to successfully complete treatment. These funds may be used to provide food, incentives, and enablers for patients with confirmed or suspected TB, as well as their contacts. Additionally, funds may be used to provide shelter for patients with confirmed or suspected TB experiencing homelessness or at risk of homelessness (see Part 2 Section 2.2.B. for the definition of homelessness).

Incentives are tailored rewards that encourage or acknowledge patient treatment adherence (e.g., gift cards for gas, groceries, or meals, movie tickets, or children's toys). Enablers are practical resources that help patients overcome barriers to treatment adherence (e.g., clinic or treatment appointment transportation, social service referrals, assistance with rent, mortgage, or utility bills, or gift cards for gas, groceries, or meals. The specific types of incentives and enablers may vary based on local program policies and procedures.

For more information on strategies to help promote patient treatment adherence or questions about what qualifies as an incentive or enabler, please contact your assigned CDPH TBCB fiscal analyst (see Part 1 Section 5.8).

LHJs are expected to allocate FSIE funding included in their Base Award for FSIE expenditures before requesting Supplemental Funding.

#### A. Directly Observed Therapy (DOT) for Funds Used to Provide Shelter

LHJs will provide in-person DOT or eDOT for patients with confirmed TB and for patients suspected of having TB that are housed using local assistance award funds. For additional

requirements, please see "Policy for Housing Patients with Confirmed or Suspected Tuberculosis who are Considered Infectious."[1]

### B. Definition of Persons Experiencing Homelessness

This definition is taken from the CDC Report of Verified Case of Tuberculosis Instruction Manual.[2] A person experiencing homelessness may be defined as:

- An individual who lacks a fixed, regular, and adequate nighttime residence
- An individual who has a primary nighttime residence that is:
  - A supervised publicly or privately operated shelter designed to provide temporary living accommodations (including welfare hotels, congregate shelters, and transitional housing for the mentally ill); or
  - An institution that provides a temporary residence for individuals intended to be institutionalized; or
  - A public or private place not designated for, or ordinarily used as, a regular sleeping accommodation for human beings

A person experiencing homelessness may also be defined as a person who has no home (e.g., is not paying rent, does not own a home, and is not steadily living with relatives or friends). Persons in unstable housing situations (e.g., alternating between multiple residences for short stays of uncertain duration) may also be considered experiencing homelessness.

A person experiencing homelessness is someone who lacks customary and regular access to a conventional dwelling or residence. This includes persons living outdoors or in places not meant for housing, residents of homeless shelters or shelters for persons experiencing domestic violence, and residents of welfare hotels or single room occupancy (SRO) hotels. In rural areas where shelters are limited, experiencing homelessness may also include living in non-residential structures, substandard housing, or with relatives. Persons in a correctional setting are not considered to be experiencing homelessness.

### C. Using FSIE Funds for Hospitalization of Patients With TB Experiencing Homelessness

By providing funds to house patients with TB experiencing homelessness, it was the intent of the 1997-1998 State Budget Initiative to improve completion of therapy for TB, decrease the need for detention of patients with TB experiencing homelessness, and decrease the number of patients with TB experiencing homelessness that are lost to follow-up. The Initiative was also designed to reduce the need for hospitalization of patients with TB experiencing homelessness. CDPH TBCB recognizes, however, that when no other form of

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[1] CDPH TBCB. Policy for Housing Patients with Confirmed or Suspected Tuberculosis who are Considered Infectious. Can be found on the Tuberculosis Guidelines and Regulations (cdph.ca.gov/Programs/CID/DCDC/Pages/TB-Guidelines-and-Regulations.aspx) webpage under Guidelines and Regulations.

[2] CDC. (2020) Report of Verified Case of Tuberculosis (RVCT) Instruction Manual (cdc.gov/tb/programs/rvct/InstructionManual.pdf)

housing is available, or the patient is acutely ill, there may still be a need to hospitalize a patient with TB who is experiencing homelessness.

Use of FSIE funds for hospitalization may be approved when the following criteria are met:

- The patient is unhoused at the time of hospital admission.
- The patient is infectious or too ill to place in any other available housing. This must be clearly documented by the local health department in the patient's chart.
- All other payer sources have been explored and found inadequate or unavailable.
- The patient is not eligible for Medi-Cal and does not have other insurance.
- The patient is not under an order of detention as stated in H&SC Section 121365(d),(e)[1]. CDPH TBCB has a separate request and reimbursement process for Civil Detention funding (see Part 2 Section 5). Each proposed detention should be discussed with your assigned CDPH TBCB Program Liaison and/or Civil Detention Coordinator (see Part 1 Section 5.8) as soon as the need for detention arises. While both H&SC Section 121365(d) and (g) require the isolation of the patient, H&SC Section 121365(g) does not require that the patient be detained.

Additionally, as required by H&SC Sections 121361 and 121362, the hospital must submit a written treatment plan to the local health department of the county where the hospital is located and receive approval prior to discharging or transferring the patient. Approval is not required for transfer to a general acute care hospital when there is an immediate need for a higher level of care. The local health department should develop a plan for housing patients with TB experiencing homelessness. For consultation on developing a plan, please contact your assigned CDPH TBCB Program Liaison (see Part 1 Section 5.8). LHJs considering FSIE funding to cover part or all of the cost of hospitalization will contact their assigned CDPH TBCB Fiscal Analyst for approval.

## 3. Supplemental Funds Awards

Supplemental funding is available to LHJs that have not received funding, have expended awarded funding, or project to do so before the end of the fiscal year. Supplemental Funds Awards are intended to assist LHJs with urgent and/or increased needs related to treatment adherence and completion or acute non-enduring situations.

### 3.1. Treatment Adherence and Completion: Food, Shelter, Incentives, and Enablers

Supplemental funding intended to improve adherence and motivate patients to successfully complete treatment may be used to provide food, incentives, and enablers for patients with confirmed or suspected TB, as well as their contacts. Additionally, funds may be used to provide shelter for patients with confirmed or suspected TB experiencing homelessness or at risk of

[1] CDPH TBCB. Select California Health and Safety Codes (PDF). Can be found on the Tuberculosis Guidelines and Regulations https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/TBCB-Health-and-Safety-Codes-2017.pdf under Guidelines and Regulations.

homelessness. Circumstances warranting exceptions will be considered and approval will be made on a case-by-case basis. Exceptions may be in accordance with Part 2 Section 2.2 of this manual.

### 3.2. Acute Non-Enduring Situations: Special Needs

Supplemental funding intended to support LHJs with special needs associated with acute and non-enduring TB control activities such as outbreaks, extended contact investigations, and cases of multidrug-resistant (MDR) TB is typically funded for a maximum duration of six months:

- Eligible expenditures include support for additional personnel, benefits, travel, translation services, laboratory testing, supplies and services such as a portable X-ray van to conduct on-site screening of contacts for active TB disease and/or other allowable expenditures needed to assist with TB control activities.
- Ineligible expenditures include in-patient care, support for routine, on-going TB control activities, “not allowed” expenses under Part 2 Section 1.2 and any expenditure that can be covered by another source of funds.

CDPH TBCB is the funding source of last resort for supplemental funding needs. LHJs should attempt to find resources that allow the local TB control program to provide the necessary services to the patient with TB.

CDPH TBCB cannot ensure that sufficient funds will be available to pay every request. However, CDPH TBCB will endeavor to identify all appropriate available funds. Supplemental funding is awarded on a first come, first served basis, and made in accordance with merit of the request and availability of funds.

Available Supplemental Funds may be federal, state, or both. Approval of expenditures will be based on the most stringent applicable guidelines. LHJs that receive federal funds directly from CDC through a Tuberculosis Cooperative Agreement with CDC are only eligible for state funds, when available. **TB medication expenses are reimbursable from state funds only.**

LHJs may request supplemental funding as soon as the need has been identified. Requests will be reviewed and if approved, a letter of award will be issued. For instructions for submitting requests and invoicing for reimbursement, see Part 3 Section 2. For additional information, please contact your assigned CDPH TBCB Fiscal Analyst.

## 4. Civil Detention Funds Awards

Civil Detention Funds are made available when possible to LHJs that need resources to detain patients with persistent nonadherence to TB treatment. Funding is considered on a case-by-case basis. H&SC Section 121358(a) prohibits the use of these funds for detentions carried out in correctional facilities. See Part 2 Section 5.1 for allowable civil detention expenditures and Part 2 Section 5.2 for non-allowable civil detention expenditures.

CDPH TBCB is the funding source of last resort for civil detention expenditures. LHJs should attempt to find resources that allow the local TB control program to provide the necessary services to the patient with TB.

Civil Detention Funds may be requested by and awarded to LHJs in accordance with the following guidance:

- LHJs requesting Civil Detention Funds will file with CDPH TBCB a current "Plan for the Detention of Persistently Non-Adherent Patients With Tuberculosis." A template is available upon request.
- Reimbursement of up to $285 per day, based on the facility type, may be requested for the cost of detention for isolation (H&SC Section 121365[d]).
- Reimbursement may be requested for costs associated with the completion of therapy (H&SC Section 121365[e]).
- Reimbursement may be requested for the actual cost of counsel provided to a nonindigent patient with TB, upon request of the patient who is subject to an order of civil detention issued by the local health officer. Services provided by counsel include representation of the patient with TB at any court review of the order of detention required by H&SC Section 121366 (H&SC Section 121451[c]).

LHJs may request Civil Detention Funds as soon as the need has been identified, discussed with your assigned CDPH TBCB Program Liaison and/or Civil Detention Coordinator (see Part 1 Section 5.8), and recommended for approval.

Requests will be reviewed and if approved, a letter of award will be issued. For instructions for submitting requests and invoicing for reimbursement, see Part 3 Section 4.2. For additional information, please contact your assigned CDPH TBCB Fiscal Analyst.

### 4.1. Allowable Civil Detention Expenditures

All civil detention reimbursement requests are reviewed on a case-by-case basis. Proof of third-party payer non-eligibility must be provided to CDPH TBCB prior to invoice payment.

- **Room Accommodation**
  Including access to toileting and bathing, meals, housekeeping, laundry, provision of nursing care for administration of TB medication by DOT and visitation procedures
- **Health or Other Treatment Facility**
  - Acute Care Hospital (up to $285 per day)
  - Skilled Nursing Facility (up to $285 per day)
  - Alcohol and Drug Rehabilitation Facility ($50 per day)
  - Mental Health Rehabilitation Center (up to $285 per day)
  - Other Health Care/Treatment Facility (up to $285 per day)
  - Motel with elopement prevention measures (up to $285 per day)
- **Other Expenditures**
- **Additional Patient Services**
  - Provision of TB clinical services for medical evaluation, monitoring, and follow-up
  - Mental health, substance use and spiritual counseling
  - Counsel for a nonindigent patient with TB, upon request of the patient who is subject to an order of civil detention issued by the local health officer. Services provided by counsel include representation of the patient with TB at any court review of the order of detention required by H&SC Section 121451.
  - Recreation
  - Elopement prevention
    May include: 24-hour security, security guard, closed circuit television, electronic monitoring, alarm on doors, and electronic keypad for entry and exit

- **Medication**
  - Utilizing the most cost-efficient method of purchasing TB medication (i.e., third-party payer, or a discounted drug purchasing program)
- **Transportation**
  - Ground transportation to and from a regional civil detention site on a pre-approved case-by-case basis

### 4.2 Non-Allowable Civil Detention Expenditures

These expenditures will not be approved for reimbursement:

- **Detention in a correctional facility**
- **Personal monitoring devices (unless court-ordered)**
- **Detention in a private residence**
- **Air transportation**

## 5. Local Assistance Award Reimbursement

- CDPH TBCB reimburses LHJ in arrears for actual expenditures in accordance with an approved and accepted award.
- Reimbursement is contingent upon CDPH TBCB approval of LHJ expenditures submitted by invoice.
- Reimbursement will be withheld if CDPH TBCB determines that LHJ is not adhering to the terms and conditions described in the Standards and Procedures Manual.
- It is mutually agreed that if the State of California Budget Act of the current year or the federal budget covered under these TB local assistance awards does not appropriate sufficient funds for the TB program, the awards shall be of no further force and effect. In this event, CDPH TBCB has no liability to pay any funds whatsoever to LHJs or to furnish any other considerations under this agreement and LHJs are not obligated to perform any provisions of TB local assistance awards.
- If state or federal funding for any fiscal year is reduced or deleted for purposes of this program, CDPH TBCB has the option to either cancel this agreement with no liability occurring to the State or offer an amendment to LHJ to reflect a reduced amount.
- Total reimbursement will not exceed the sum specified in the letter of award for Base Award, Supplemental Funds Award or Civil Detention Funds Award.
- Payment will be made in accordance with, and within the time specified in, Government Code Chapter 4.5, commencing with Section 927.
- LHJs experiencing events that necessitate acute and non-enduring TB control activities for which no other funds are available, such as extended CIs, cases of MDR TB, and outbreaks may request Special Needs Funds (see Part 2 Section 4). Reimbursement for Base Award, Supplemental Funds Award and Civil Detention Funds Award will not be made more frequently than quarterly unless noted in the Letter of Award.
- A final undisputed invoice will be submitted for payment no more than 60 calendar days following the expiration or termination date of a TB local assistance award, unless a later or alternate deadline is agreed to in writing by your assigned CDPH TBCB Fiscal Analyst. Said invoice will be clearly marked “Final Invoice,” indicating that all payment obligations of

CDPH TBCB under this agreement have ceased and that no further payments are due or outstanding. CDPH TBCB may, at its discretion, choose not to honor any delinquent final invoice if LHJ fails to obtain prior written approval of an alternate final invoice deadline.

## Part 3 - Procedures

### 1. Process for Requesting and Invoicing Base Award Funds

### 1.1. Submitting Award Requirements

The following required documents shall be completed in accordance with the guidance provided in this document and submitted by the specified due date:

- TB Subrecipient Eligibility form, *signed* (required if accepting federal funds)
- Active SAM registration screenshot (required if accepting federal funds)
- Most recent Single Audit Report (required if accepting federal funds)
- Established eDOT Policy and Procedures certification, *signed* (required if requesting reimbursement)
- TB Base Award Budget workbook, in Excel format (submit with the following file naming convention: [**LHJ Name**]**-TB_Award-Budget-26**)
  - Program Contacts
  - Federal Detail Budget with Line Item Justifications (required if accepting federal funds)
  - State Detail Budget with Line Item Justifications
  - Funding Matrix
  - Summary Budget
- TB Base Award Budget summary page, *signed*
  - Copy of any subcontract (required if requesting reimbursement))
  - Official documentation of rate ≥53% and benefits breakdown (if applicable)
- Allocation of Personnel Matrix (submitted in Excel format)
- LHJ TB Control Program organizational chart
- Acceptance of Award, *signed*

TB Subrecipient Eligibility form, Established eDOT Policy and Procedures certification, TB Base Award Budget workbook, Allocation of Personnel Matrix, and Acceptance of Award are posted on the CDPH TBCB Extranet. Where required, authorized original signatures can be electronic or in blue ink.

Submit your package of all required documents electronically to TBCB.Awards@cdph.ca.gov, using the [**LHJ Name**]**-TB_BASE-26** naming convention to facilitate tracking.

For additional questions regarding the award requirements submission process, please contact your assigned CDPH TBCB Fiscal Analyst by telephone or email.

### 1.2. Completing Your Base Award Budget

#### A. Salary Savings and the Local Health Jurisdiction Initial Budget

Submitted budgets should not include projected salary savings. LHJs with local requirements to include salary savings in their budget should contact their assigned CDPH TBCB Fiscal Analyst for additional guidance.

### B. Medi-Cal Fee-for-Service Reimbursement of Directly Observed Therapy and Directly Observed Preventive Therapy, including eDOT

The use of directly observed therapy (DOT) as a strategy for improving completion of therapy and reducing adverse treatment outcomes is the standard of care. To the extent possible, DOT/eDOT services for Medi-Cal eligible patients should be reimbursed by Medi-Cal on a fee-for-service basis of $19.23 per encounter.

Note: DOT is not reimbursable through Medi-Cal Managed Care Plans (MCP), and it is not necessary to bill an MCP and have the claim denied first. DOT should be billed directly to DHCS through the fee-for-service process. Only local health departments are eligible for DOT reimbursement, not providers. DOT is reimbursable whether delivered in-person, or through telehealth: both synchronous *or* asynchronous modalities are reimbursable. In addition, more than one DOT service per day is reimbursable, if necessary and the need is documented (e.g., MDR-TB or other condition).

The following rules apply to claims for Medi-Cal reimbursement for DOT services:

- Medi-Cal fee-for-service reimbursement for administering DOT or directly observed preventive therapy (DOPT) can only be billed for personnel who are either fully or partially funded with local revenue dollars. Medi-Cal reimbursement is not allowed for services provided by personnel who are fully funded through CDPH TBCB local assistance funds.
- A county or local overmatch is required to claim the Federal Financial Participation reimbursement. LHJs should determine which position(s) will provide Medi-Cal fee-for-service DOT or DOPT, and structure their local and CDPH TBCB local assistance budgets to maximize this revenue stream. Reimbursement is limited to the amount of county or local overmatch budgeted for the personnel providing the service.

Suggested options for structuring your budget:

- Option A
  - Identify the number and type of personnel who will provide Medi-Cal reimbursable services
  - Budget these positions to be fully funded with local revenue dollars
- Option B
  - Identify the number and type of positions who will provide Medi-Cal reimbursable services
  - Estimate the amount of Medi-Cal reimbursement expected for services provided by each identified position
  - Each position should be funded with local revenue dollars for an amount equal to or greater than the expected amount of Medi-Cal reimbursement
  - Position costs in excess of the expected amount of Medi-Cal reimbursement may be included on the Base Award budget

### C. Federal Executive Level II Salary Cap

TB funding that consists of a combination of state and federal funds is subject to the Federal Executive Level II salary cap. The cap amount can be found at the Salary Cap

Summary (FY 1990 - Present) | Grants & Funding (grants.nih.gov/policy-and-compliance/policy-topics/nih-fiscal-policies/salary-cap-summary) webpage. On a federally funded award, LHJs may budget and invoice up to the salary cap amount. Any overage must be charged to a non-federal source such as local funds.

For Base Award budgets, LHJs will use the Federal Executive Level II amount for those staff members whose base salary is above the cap. The Total Annual Salary Amount is Base Salary times Effort on Project. The amount covered by local funds is the Total Annual Salary Amount minus the Capped Annual Salary Amount.

Below is an example for staff with a base salary of $226,000 and an Executive Level II salary cap of $225,700 for the award period:

| Base Salary | Effort on Project | Total Salary Amount | **Cap Amount** | **Amount Effort on Project** | **Capped Total Salary Amount** |
|---|---|---|---|---|---|
| $226,000 | 100% | $226,000 | $225,700 | 100% | $225,700 |

Example Base Award Detail Budget

| **Title/Name** | **New/Cont** | **Annual** | **FTE** | **Months** | **Amount** |
|---|---|---|---|---|---|
| 1. Medical Doctor/ Name | Cont. | $225,700 | 1.0 | 12 | $225,700 |

**Invoicing** for the Capped Total Salary Amount each quarter

| Base Salary | Effort on Project | Total Quarterly Salary Amount | **Cap Amount** | **Amount Effort on Project** | **Capped Total Quarterly Salary Amount** | Above Cap Quarterly Amount Covered by Local Funds |
|---|---|---|---|---|---|---|
| $226,000 | 100% | $56,500 | $225,700 | 100% | $56,425 | $75 |

For questions about the Federal Executive Level II salary cap, contact your assigned CDPH TBCB Fiscal Analyst.

### D. Personnel Costs (Benefited and Non-Benefited)

LHJs will provide budget information and line item justifications for CDPH TBCB funded positions on the Detail Budget tab (totals will populate into the Summary Budget tab):

- Detail Budget
  - Personnel (Benefited) line item category

    List and consecutively number each benefited position as a separate line item (see Example Personnel Costs Detail Budget below). For each position, enter:
    - Position title and name
    - Indicate if the position is new or continuing
    - Housing Personnel (HP checkbox if applicable)
    - Annual salary
    - Full time equivalent (FTE)

- Months
- Total Line Item Amount

- Personnel (Non-Benefited) line item category

  List and consecutively number each benefited position as a separate line item (see Example Personnel Costs Detail Budget below). For each position, enter:
  - Position title and name
  - Indicate if the position is new or continuing
  - Housing Personnel (HP checkbox if applicable)
  - Annual salary
  - Full time equivalent (FTE)
  - Months Total Line Item Amount

Example Personnel Costs Detail Budget

Personnel - Benefited

| Title/Name | New/Cont | HP | Annual | FTE | Months | Total |
|---|---|---|---|---|---|---|
| 1. Medical Doctor/Name | New | N | $203,700 | .05 | 12 | $10,185 |
| 2. Community Worker/Name | Cont. | N | $35,000 | 1.0 | 12 | $35,000 |
| 3. Community Worker/Name | Cont. | Y | $36,800 | 0.8 | 12 | $29,440 |
| 4. Epidemiologist/Name | New | N | $60,000 | 1.0 | 12 | $60,000 |
| Total Personnel (Benefited) | | | | | | $134,625 |

Benefits (rate, actual salary)

| Title/Name | | Rate | Salary | Total |
|---|---|---|---|---|
| 1. Medical Doctor/Name | | 32% | $10,185 | $3,259 |
| 2. Community Worker/Name | | 40% | $35,000 | $14,000 |
| 3. Community Worker/Name | | 40% | $29,440 | $11,776 |
| 4. Epidemiologist/Name | | 32% | $60,000 | $19,200 |
| Total Benefits | | | | $48,235 |

Personnel – Non-Benefited

| Title/Name | New/Cont | HP | Annual | FTE | Months | Total |
|---|---|---|---|---|---|---|
| 1. Community Worker/Name | New | N | $38,000 | 0.5 | 12 | $19,000 |
| 1. Bilingual Bonus | | | $80/mo | 9 | 12 | $8,640 |
| Total Personnel (Non-Benefited) | | | | | | $27,640 |

TOTAL PERSONNEL SERVICES **$210,500**

- Line Item Justification

  Include the following information for each position listed (see Example Line Item Justification below):
  - Position title

- Name(s) of the individual(s) filling the position. State “vacant” if position(s) is/are not filled
- Brief summary of the duties for the position; describe how the position contributes to conducting Strategy One and/or Strategy Two activities (see Part 1 Section 4)
- Identify personnel salaried above the Federal Executive Level II salary cap
- Identify personnel funded with Housing Personnel funds, their activities, and the amount of FTE that match the criteria for the use of these dollars
- Identify personnel fulfilling the duties of a Correctional Liaison (see Part 3 Section 1.2 O)
- Identify personnel fulfilling the duties of a Linkage to Care Liaison for civil surgeon referrals (see Part 3 Section 1.2 P)

Example Line Item Justification

- Personnel
  1. Medical Doctor (above salary cap)

     Allison Smith (0.05 FTE) Reviews hospital discharge treatment plans, coordinates treatment adjustments and approves discharge.
  2. Community Workers

     Henry Trevon (1.0 FTE) and Leo Segundo (0.8 FTE)

     Henry Trevon and Leo Segundo provide DOT along with other patient follow-up services in a public health clinic to ensure completion of therapy.
  3. Epidemiologist (Vacant)

     This individual analyzes RVCT form data and program records to identify disease trends, monitor patient outcomes, and program performance indicators.
  4. Community Worker

     Luther X. Ray (0.5 FTE)

     Luther X. Ray performs CI follow-up services in the field. He also provides DOT which is billed through the Medi-Cal TB Program fee-for-service DOT. He is supported for this portion of his effort by local revenue dollars.

**E. Benefits**

LHJs will provide budget information and line item justifications for CDPH TBCB funded position benefits on the Detail Budget tab (totals will populate into the Summary Budget tab):

- Detail Budget – Benefits line item category

  Enter the benefit rate, actual salary and the amount of benefits budgeted for each position listed in the Personnel (Benefit) category (see Example Personnel Costs Detail Budget on page 24).

  Benefit rates greater than 53% may be justified by submitting official documentation of the rate as well as a breakdown of the benefits.

### F. Personnel Non-Benefited

LHJs will provide budget information and line item justifications for miscellaneous personnel line items (i.e., nurse retention bonus, bilingual bonus) on the Detail Budget tab (totals will populate into the Summary Budget tab):

- Detail Budget – Personnel (Non-Benefited) line item category

  List any miscellaneous personnel line items as separate line items (see Example Personnel Costs Detail Budget on page 24).

- Line Item Justification

  For each miscellaneous personnel item listed in the Detail Budget, include the following information in the Line Item Justification:

  - Name of the line item
  - A brief justification describing how line items assist staff in meeting identified program needs

Example Personnel (Non-Benefited) Justification

| |
|---|
| Bilingual Bonus<br>These bilingual individuals provide direct services to non-English speaking persons. |

### G. Travel and Per Diem

Reimbursement for travel expenses shall be in accordance with California Department of Human Resources policies for state employees.[1] Out-of-state travel requires prior CDPH TBCB approval. LHJ travelers are expected to maintain receipts for all claimed expenses.

- Mileage

  Use mileage rate applicable to the period of travel. LHJs must maintain a travel log that includes traveler's name, purpose of the trip (e.g., DOT visit), date(s) of travel, and the total mileage for the trip.

- Lodging Rates

  Reimbursement is made for actual receipted expenditures not exceeding the applicable federal rate established by the U.S. General Services Administration for the travel destination, available on the GSA Per Diem Rates (gsa.gov/travel/plan-book/per-diem-rates) webpage. Lodging without a receipt will not be reimbursed.

- Meal and incidental Expenses

  Actual meal and incidental (M&I) expenses incurred while on travel status will be reimbursed in accordance with the maximum rates and time frame requirements outlined below:

  - For each full 24 hours of travel: Up to the federal standard rate for M&I expenses established by the U.S. General Services Administration
  - On the first and last day of travel: Up to 75 percent of the federal standard rate for M&I expenses established by the General Services Administration

[1] CalHR Travel Reimbursements (calhr.ca.gov/employees/Pages/travel-reimbursements.aspx)

| M&I Expense Total Daily | First & Last Day of Travel | Breakfast | Lunch | Dinner | Incidentals |
|---|---|---|---|---|---|
| Up to $68 | Up to $51 | $16 | $19 | $28 | $5 |

LHJs will provide budget information and line item justifications for travel on the Detail Budget tab (totals will populate into the Summary Budget tab):

- Detail Budget – Travel line item category

  List projected within jurisdiction travel separately from out-of-jurisdiction travel:
  - For within jurisdiction travel, indicate the number of miles and mileage rate
  - For out of jurisdiction travel, indicate travel expenses by category
- Line Item Justification

  For within jurisdiction and out of jurisdiction travel, briefly describe purpose of travel. If applicable, identify the dollar amount of Housing Personnel funds and how the proposed activities meet the criteria for the use of these funds (see Example Travel Justification using Housing Personnel Funds below and Part 2 Section 1.8 for guidance on the use of Housing Personnel funds).

Example Travel Justification using Housing Personnel Funds

| |
|---|
| Within jurisdiction travel is required for community outreach workers and public health nurses to perform DOT, patient interviewing, and CI.<br>Out of jurisdiction travel is required for medical, nursing and other health professional staff to participate in continuing education through the annual CTCA conferences. |

**H. Equipment**

Whenever the term equipment/property is used, the following definitions apply:

- Major equipment/property: A tangible or intangible item having a base unit cost of $2,500 or more with a life expectancy of one year or more and is either furnished by CDPH TBCB or the cost is reimbursed through this Agreement.
- Minor equipment/property: A tangible item having a base unit cost of less than $2,500 with a life expectancy of one year or more and is either furnished by CDPH TBCB or the cost is reimbursed through this Agreement.

LHJs are expected to document major equipment purchased with state funds. LHJs will request the “Equipment Purchased with CDPH TBCB Funds” form from their assigned CDPH TBCB Fiscal Analyst prior to invoicing and return the completed form to CDPH TBCB with the invoice for the purchase.

- Approval to purchase equipment is contingent upon LHJ’s ability to demonstrate that the purchase is a cost-effective means to meet a need related to the control and prevention of TB, best accomplished by clearly stating the purpose of the equipment.
- LHJ will contact Fiscal Analyst prior to any purchase of $2,500 or more for equipment and services related to such equipment. LHJ must provide in its request for approval all particulars necessary for evaluating the justification of incurring such costs.
- All equipment and products purchased should be American-made, to the greatest extent possible.

- LHJs using CDPH TBCB local assistance award funds to purchase video or other electronic equipment or services for electronic directly observed therapy are expected to have an eDOT policy and procedures in place and submit a signed "Certification of Established Electronic Observed Therapy (eDOT) Policy and Procedures" prior to equipment purchase. The eDOT certification is available on the CDPH TBCB Extranet or available upon request.

LHJs will provide budget information and line item justifications for CDPH TBCB funded equipment on the Detail Budget tab (totals will populate into the Summary Budget tab):

- Detail Budget – Equipment line item category

  Itemize equipment purchases and include:

  - The number of units, cost per unit, and total cost
  - Make and model number
- Line Item Justification

  Briefly describe how the equipment will enhance ability to conduct TB prevention and control activities.

### I. Supplies

Use this line item for office, clinic and laboratory supplies, such as tuberculin syringes.

LHJs will provide budget information and line item justifications for supplies on the Detail Budget tab (totals will populate into the Summary Budget tab):

- Detail Budget

  Itemize projected expenditures into three categories (see Example Supplies Detail Budget below):

  - Office Supplies: state the total amount to be expended for these supplies; It is not necessary to list all the types of office supplies
  - Clinic Supplies: state the total amount to be expended for these supplies; It is not necessary to list all the types of clinic supplies
  - Laboratory Supplies: itemize all supplies to be purchased with the unit price and number needed for each type

Example Supplies Detail Budget

| Line Item Category | Unit | Cost per Unit | Amount |
|---|---|---|---|
| Office Supplies | | | $500 |
| Clinic Supplies | | | $100 |
| Laboratory Supplies | | | |
| Reagents | 5 | $75.00 ea | $375 |
| Disposable pipets | 5 | $40.00 pkg | $200 |
| Centrifuge tubes | 8 | $35.00 pkg | $280 |
| Total Supplies | | | $1,455 |

### J. Anti-TB Medication

To comply with federal restrictions on fund use, reimbursement of medication expenditures is limited to the amount of the state fund portion of the award.

LHJs will provide budget information and line item justifications for anti-TB medication on the Detail Budget tab (totals will populate into the Summary Budget tab):

- Detail Budget – Anti-TB Medication line item category

  Itemize anti-TB medication you will purchase with the dollar amount for each drug (see Example of Anti-TB Medication Detailed Budget below):

Example Anti-TB Medication Detail Budget

| Anti-TB Medication | Units | Cost per Unit | Amount |
|---|---|---|---|
| Rifampin | 30 | $60 | $1,800 |
| Isoniazid | 30 | $20 | $600 |
| Pyrazinamide | 30 | $150 | $4,500 |
| Total Anti-TB Medication | | | $6,900 |

### K. Subcontracts

LHJs will include a copy of each subcontract with their budget submission. A final draft is acceptable, but a copy of the final signed contract must be submitted to CDPH TBCB as soon as the local contract process is completed.

LHJs will provide budget information and line item justifications for subcontracts on the Detail Budget tab (totals will populate into the Summary Budget tab):

- Detail Budget – Contractual line item category
  - Itemize each subcontract on the detailed budget sheet
  - List the name of each subcontract organization
  - Indicate the period of service
  - Specify total dollar amount of each subcontract
  - Specify personnel and/or services, equipment and other costs for each subcontract. Provide the same details for personnel, benefits, travel, equipment, supplies and other costs covered under the subcontract as is required for the Base Award detail budget section.
- Line Item Justification

  Briefly describe the following:
  - Purpose of the subcontract
  - Scope of work: Describe in outcome terms the specific services to be performed; Deliverables should be clearly defined.
  - Method of selection: State whether the contract is sole-source or competitively bid. If the organization is the sole source for the contract, include an explanation as to why this institution is the only one able to perform the service.
  - Method of Accountability: Describe how the progress and performance of the contractor will be monitored throughout the contract period. Identify who will be

responsible for supervising the contract. Include a schedule and description of the types and quantity of the services and/or product(s) to be delivered.

- If applicable, identify the dollar amount of Housing Personnel funds and how the subcontract meets the criteria for the use of these funds (see Part 2 Section 2.1) for guidance on the use of Housing Personnel funds).

### L. Other Line Items

This line item is used for other direct costs that have not been listed elsewhere, and local detention activities as described in Health and Safety Code Section 121451.

LHJs will provide budget information and line item justifications for other line items on the Detail Budget tab (totals will populate into the Summary Budget tab):

- Detail Budget – Other line item category

  Itemize each type of expenditure
- Line Item Justification

  Provide a brief justification for all items listed in the Detail Budget – Other category

### M. Food, Shelter, Incentives and Enablers

This line item is used for the Food, Shelter, Incentives and Enablers amount included with the Base State Award.

LHJs will provide budget information and line item justifications for FSIE expenses on the Detail Budget tab (totals will populate into the Summary Budget tab):

- Detail Budget

  Type the FSIE amount
- Line Item Justification

  Provide a brief justification for how FSIE funds will be used to improve adherence and to ensure that patients successfully complete treatment

### N. Indirect Cost

Indirect costs are the expenses of doing business not readily identified within a grant or contract but needed for the general operation of the organization. Reimbursement for indirect costs is generally expressed as a percentage called an indirect cost rate (ICR) and is applied to either the total of Personnel Services (Salary and Benefits) or the total Allowable Direct Cost of the contract.

LHJ will submit an application annually to CDPH Financial Management Branch (FMB) with their proposed ICR percentage based on either the total cost of personnel services or total allowable direct cost. CDPH FMB will review applications and approve rates for the upcoming fiscal year. ICR will be capped at the CDPH approved rate for each individual LHJ, but not to exceed 25% of total personnel services costs or 15% of total allowable direct costs. For more information regarding approved county indirect cost rates, please contact the FMB by email at CDPH-ICR-mailbox@cdph.ca.gov.

Reduced Indirect Costs

LHJs are **not required** to include an ICR in their TB local assistance award budgets. LHJs may choose to not include ICR in their award budget or may elect to include an ICR that is less than their approved rate.

### O. Designation of a Correctional Liaison

Ensuring continuity of care for patients with TB who transfer between correctional facilities and/or detention facilities and the community is an important TB prevention and control activity. Each LHJ should identify its needs and determine the duties most appropriate for their Correctional Liaison. The NTCA Public Health TB Corrections Liaison Model Duty Statement and Core Competencies[1] may be useful in determining these duties.

The designee should be LHJ's Correctional Liaison identified in the CTCA Directory[2] unless a recent change is not yet reflected.

To identify the designee in your submission package:

- If this position is supported through local assistance subvention funds, include the following statement in the line item justification: "Fulfills the duties of a Correctional Liaison."
- If the Correctional Liaison is supported through other funds, then indicate the name and position classification of the staff member responsible for fulfilling these duties in the cover letter included with the submission package.

### P. Designation of a Linkage to Care Liaison for Civil Surgeon Referrals

Ensuring linkage to care or referral of individuals with suspected TB and LTBI to care is an important TB prevention and control activity. Persons seeking adjustment of immigration status have TB testing performed by civil surgeons; civil surgeons are required to report those with LTBI to LHJ. Each LHJ should identify a Linkage to Care Liaison for civil surgeon referrals who is responsible for responding to inquiries from civil surgeons and helping persons with LTBI to be linked to treatment. The sites of care for LTBI treatment may include health department clinics, community clinics, primary care providers, or other providers designated by your program.

The designee would be a staff member who serves as a point of contact and lead for your program for responding to inquiries from civil surgeons. Reporting and care linkages may be handled by a number of persons but a point of contact or lead for TB prevention for civil surgeons should be identified.

To identify the designee in your submission package:

- If this position is supported through local assistance subvention funds, include the following statement in the line item justification: "Fulfills the duties of a Linkage to Care Liaison for civil surgeon referrals."

[1] NTCA. (2015) Public Health TB Corrections Liaison Model Duty Statement (tbcontrollers.org/docs/CoreCompetencies/Corrections_Liaison_Competencies_09-2015.pdf)

[2] CTCA Directory of Public Health Staff (ctca.org/wp-content/uploads/CTCA-Directory.pdf)

- If the Linkage to Care Liaison is supported through other funds, then indicate the name and position classification of the staff member responsible for fulfilling these duties in the cover letter included with the submission package.

### 1.3. Receiving Your Base Award

CDPH TBCB issues to LHJ a Letter of Award including the approved summary budget upon approval of the submission package.

### 1.4. Managing Your Base Award

#### A. Submitting Base Award Invoices

For services satisfactorily rendered, and upon receipt and approval of the invoices, CDPH TBCB agrees to reimburse LHJ for actual expenditures incurred in accordance with an approved TB local assistance award budget.

Invoices should be **separated by funding source**, signed by an authorized representative certifying that the expenditures claimed represent actual expenses, and submitted on LHJ letterhead quarterly (see Part 3 Section 1.4 A) in arrears, electronically to tbcb.awards@cdph.ca.gov.

The official signature(s) can be electronic or in blue ink.

##### 1. Guidance for Submitting Base Award Invoices by Funding Source

To facilitate timely reimbursement, use current Base Award invoice templates by funding source and include the following information:

- Invoice date
- Billing period
- Award number by funding source (see Letter of Award)
- Amount to be reimbursed by line item category:
  - Personnel (Benefited), include title, name, salary and benefits detail
  - Personnel (Non-Benefited), include title, name, and salary detail
  - Allowable travel and per diem expenses (in-state only) will be reimbursed using state rates. See Part 3 Section 1.2 G for details.
  - Equipment, provide item details (make, model, cost per unit, and number of units for each). CDPH TBCB reserves the right to request evidence of payment purchase, e.g., official county purchase order, and a brief description of the item(s) purchased including make and model number.
  - Supplies, include office, medical and laboratory supplies
  - Anti-TB medications, request for reimbursement must not exceed the State Base Award
  - Other Costs (including local detention activities as described in Health and Safety Code Section 121451), provide a description of each item
  - Food, Shelter, Incentives and Enablers, include amount by line item and provide the following detail:

- Shelter, include name or type of lodging and TB case RVCT or CalREDIE number or the local TB suspect ID number. Do not submit any patient identifiers, such as name, address, or birth date.
- Patients receiving housing assistance and/or shelter, verify and indicate that treatment was administered via DOT during the time housing was provided
- Food items, meals, incentives, enablers, itemize and cross-foot (e.g., 20 personal hygiene kits @ $3.50, total $70; 100 bus vouchers @ $1.00, total $100; 50 food coupons @ $3.00, total $150). If items such as gift cards included a discount, please include the discount as a separate line item (e.g. 50 food coupons discount @ ($0.50) total ($25.00).

It is not necessary to submit evidence of FSIE expenditures with the invoice. However, LHJs are required to maintain this documentation. Please contact your assigned CDPH TBCB Fiscal Analyst for more information regarding record retention requirements.

CDPH TBCB will review the balance of unexpended FSIE funds and redistribute these funds to LHJs in need of supplemental funding. By failing to contact CDPH TBCB to request a submission extension for second or fourth quarter invoices, LHJs risk not receiving full payment for the invoiced amount if submitted past the deadline. For information about requesting Supplemental Funds, see Part 3 Section 2.

- Remit to address, must match LHJ's organization mailing address indicated on LHJ's submitted budget workbook. For address changes, please contact your assigned CDPH TBCB Fiscal Analyst.

Invoices for the new fiscal year will not be processed if there are outstanding invoices from the previous year or unresolved stipulations from the Letter of Award.

### 2. Award Invoice Due Dates and Requests for Extensions

| Quarter | Period Covered | Due Date |
|---|---|---|
| First | July 1 through September 30 | November 16 |
| Second | October 1 through December 31 | February 15 |
| Third | January 1 through March 31 | May 17 |
| Fourth | April 1 through June 30 | August 16 |

- Award Invoices for TB control expenditures must be submitted quarterly per the schedule above. If an invoice will not be submitted by the quarterly due date, LHJ must contact CDPH TBCB in advance to request an extension.
- All requests for extensions must be submitted in writing via email by the invoice due date with an explanation of the barriers to timely submission. Requests for extensions longer than two weeks may not be granted if the date would delay CDPH TBCB fiscal closeout. Fiscal closeout begins on the first business day of

September of each year. LHJs granted a second or fourth quarter extension must submit a "not to exceed amount" by the last business day in August.

### B. Budget Revision Process

#### 1. General Standards

- A budget revision is required for any changes that:
  - Shift more than $10,000 or 25% of the total budget previously approved
  - Add personnel positions, equipment, or subcontract line items not previously included in the budget previously approved
- Budget revision requests are to be made four weeks prior to anticipated expenditures. Email TBCB.Awards@cdph.ca.gov to request a budget revision template.

#### 2. Requesting a Budget Revision

- Completing the Budget Revision Request:
  - Review the list of Allowable Expenditures (see Part 2 Section 1.1)
  - Complete the budget revision template and include the line item justification
  - If the budget revision includes addition of new staff positions, revise the Allocation of Personnel Matrix
  - Sign and date the Summary Budget with authorized signature
  - Submit the budget revision template, a PDF copy of the signed summary budget, Allocation of Personnel Matrix (if applicable) and subcontract (if applicable) electronically to TBCB.Awards@cdph.ca.gov for approval

#### 3. Notification of Action Taken on a Budget Revision Request

No reimbursements can be made for revised budget expenses until approval has been granted. CDPH TBCB does not give verbal approval for budget revision requests.

Approved or disapproved budget revision requests will be emailed to the contact person listed on the budget revision template or the person listed on the request cover letter if different from the person listed on the request template.

## 1.5. Additional Required Forms

- A "Local Health Jurisdiction Equipment Purchased with CDPH TBCB Funds" form must be submitted with the invoice for major equipment purchased with TB local assistance funds. Contact your assigned CDPH TBCB Fiscal Analyst for a form.
- A Local Health Jurisdiction's Release form will be emailed to LHJs prior to the end of the fourth quarter and must be submitted with the final Base Award invoice.

## 2. Process for Requesting and Invoicing Supplemental Funding

- As soon as the need for supplemental funding has been identified, contact your assigned CDPH TBCB Fiscal Analyst for the Supplemental Funding ADHC workbook. Requests must be in accordance with the use of these funds as described in Part 2 Section 3.
- If the request is approved, LHJ will receive a Supplemental Funds letter of award. As an official acknowledgement of receipt of the award, the Acceptance of Award must be

returned to CDPH TBCB with an authorized signature electronically or in blue ink. By signing the Acceptance of Award, LHJ agrees to the conditions of the award as set forth by CDPH TBCB. Invoices for Supplemental Funds expenditures will not be processed until the signed Acceptance of Award has been received.

- LHJs should provide a description and the outcome of attempts made to request funding from local or other sources (i.e., realignment funds). CDPH TBCB should be the payor of last resort for supplemental funding expenses.
- To facilitate timely reimbursement, use the current Supplemental Funds invoice template. The invoice must include the authorized original signature(s) electronically or in blue ink.
- Invoices for Supplemental Funds expenditures should be submitted electronically to TBCB.Awards@cdph.ca.gov on the same quarterly schedule and format as described in Part 3 Section 2 of this manual. Expenditures invoiced must have occurred within the scheduled time period.
- Fourth quarter invoices for Supplemental Funds expenditures must be submitted by August 15 following the award period (e.g., August 15, 2027 for the award period of July 1, 2026 – June 30, 2027). Invoices submitted after August 31 may not be considered for reimbursement.

## 3. Process for Requesting and Invoicing Civil Detention Funding

### 3.1. Requesting Approval and Submitting Documentation for Reimbursement for Civil Detention

- As soon as the potential need for civil detention of a persistently non-adherent patient with TB has been identified, contact your assigned CDPH TBCB Program Liaison and/or Civil Detention Coordinator (see Part 1 Section 5.8) for assistance. Available upon request, the "Procedure for Requesting Reimbursement for Civil Detention for a Persistently Non-Adherent Patient with Tuberculosis" provides a complete description of the request process and required documentation. LHJs should also refer to the CDPH-CTCA "Guidelines for the Civil Detention of Persistently Non-Adherent Tuberculosis Patients in California."[1]
- As soon as the need for Civil Detention Funds has been discussed and recommended for approval, contact your assigned CDPH TBCB Fiscal Analyst for assistance. Requests must be in accordance with the use of these funds as described in Part 2 Section 5.
- If the request is approved, LHJ will receive a Civil Detention Funds letter of award. As an official acknowledgement of receipt of the award, the Acceptance of Award must be returned to CDPH TBCB with an authorized signature electronically or in blue ink. By signing the Acceptance of Award, LHJ agrees to the conditions of the award as set forth by CDPH TBCB. Invoices for Civil Detention Funds will not be processed until the signed Acceptance of Award has been received.

[1] CDPH-CTCA. (2011) Joint Guidelines for the Civil Detention of Persistently Non-Adherent Tuberculosis Patients in California (ctca.org/wp-content/uploads/2018/11/FINLCivil_Detention092311_.pdf)

### 3.2. Invoicing for Civil Detention Funds once the Request is Approved

- LHJs should provide a description and the outcome of attempts made to request funding from local or other sources (i.e., application for health benefits). CDPH TBCB should be the payor of last resort for civil detention expenses.
- To facilitate timely reimbursement, use the current Civil Detention Funds invoice template. The invoice must include the authorized original signature(s) electronically or in blue ink.
- Invoices for Civil Detention Funds expenditures should be submitted electronically to TBCB.Awards@cdph.ca.gov on the same quarterly schedule and format as described in Part 3 Section 4 of this manual. Expenditures invoiced must have occurred within the scheduled time period.
- Fourth quarter invoices for Civil Detention Funds expenditures must be submitted by August 15 following the award period (e.g., August 15, 2027 for the award period of July 1, 2026 – June 30, 2027). Invoices submitted after August 31 may not be considered for reimbursement.

### 3.3. Detention Release Date Information

Within five working days of the detention release date, LHJ will submit the release date to the CDPH TBCB Civil Detention Coordinator.

## 4. Declining a Tuberculosis Local Assistance Award

- Any LHJ choosing to decline awarded TB local assistance funds shall notify the assigned Fiscal Analyst via email to TBCB.Awards@cdph.ca.gov.
- When declining TB local assistance funds, LHJ is authorizing CDPH TBCB to reallocate their award amount to other LHJs.

## Appendix

### Table 1. List of Abbreviations

| Abbreviation | Expansion |
|---|---|
| ARPE | Aggregate Report for Program Evaluation |
| CalREDIE | California Reportable Disease Information Exchange |
| CDC | Centers for Disease Control and Prevention |
| CDPH | California Department of Public Health |
| CI | Contact investigation |
| CTCA | California Tuberculosis Controllers Association |
| DOPT | Directly observed preventive therapy |
| DOT | Directly observed therapy |
| EDN | Electronic Disease Notification |
| eDOT | Electronic directly observed therapy |
| FMB | Financial Management Branch |
| FSIE | Food, shelter, incentives and enablers |
| FTE | Full-time equivalent |
| H&SC | Health and Safety Code |
| ICR | Indirect cost rate |
| LHJ | Local health jurisdiction |
| LTBI | Latent tuberculosis infection |
| MDR TB | Multidrug-resistant tuberculosis |
| NTCA | National Tuberculosis Coalition of America |
| PRUCOL | Permanent Residence Under Color of Law |
| RVCT | Report of Verified Case of Tuberculosis |
| SRO | Single room occupancy |
| TT | Targeted testing and treatment |
| TB | Tuberculosis |
| TBCB | Tuberculosis Control Branch |

# General Terms and Conditions for Non-Research Grants and Cooperative Agreements

**Incorporation:** The U.S. Department of Health and Human Services (HHS) grant recipients must comply with: all terms and conditions outlined in the Notice of Funding Opportunity (NOFO); their Notice of Award (NOA); grants policy contained in applicable HHS Grants Policy Statements; HHS grant administration regulations (2 CFR Part 200 and 2 CFR Part 300); requirements imposed by program statutes and regulations; applicable Executive Orders; HHS Administrative and National Policy Requirements; HHS policies, directives, and guidance; and requirements or limitations in any applicable appropriations acts. The term grant is used throughout these general terms and conditions of award and includes cooperative agreements.

**Note:** In the event that any requirement in the NOA, the NOFO, the HHS Grants Policy Statement, 2 CFR 200, 2 CFR 300, or applicable statutes/appropriations acts conflict, then statutes and regulations take precedence.

**CDC Priorities:** CDC serves the American public—individuals, families, and communities—who rely on accurate data, health guidance, and preventive measures. CDC's current Priority Statement: https://www.cdc.gov/about/cdc/index.html

**Compliance with Court Orders:** Any term or condition in this NOA, including those incorporated by reference, that HHS is enjoined by court order from imposing or enforcing shall not apply or be enforced as to any recipient or subrecipient to which that court order applies and while that court order is in effect.

## FEDERAL REGULATIONS AND POLICIES

**2 CFR 200 –** Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards. Referenced where indicated and applicable.
https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200?toc=1

**2 CFR Part 300 –** Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards.
https://www.ecfr.gov/current/title-2/subtitle-B/chapter-III/part-300

**HHS Administrative and National Policy Requirements**
https://www.hhs.gov/sites/default/files/hhs-administrative-national-policy-requirements.pdf

**HHS Grants Policy and Regulations**
https://www.hhs.gov/grants-contracts/grants/grants-policies-regulations/index.html

**HHS Grants Policy Statement**
https://www.hhs.gov/grants-contracts/grants/grants-policies-regulations/index.html

**Federal Funding Accountability and Transparency Act** (FFATA). https://sam.gov/fsrs. Refer to the section below on Reporting Requirements for more details.

**Trafficking Victims Protection**: Consistent with 2 CFR 175, awards are subject to the requirements of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. Part 7104(g)).
https://www.ecfr.gov/current/title-2/subtitle-A/chapter-I/part-175

## FUNDING RESTRICTIONS AND LIMITATIONS

**Cost Limitations as stated in Appropriations Acts.** Recipients must follow applicable fiscal year appropriations law in effect at the time of award and consistent with the specific funds provided under that award. The general provisions for grants, cooperative agreements and loans funded by the Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations Act is available at: https://www.congress.gov/resources/display/content/Appropriations+and+Budget.

Though Recipients are required to comply with all applicable appropriations restrictions, please find below specific ones of note. CDC notes that the cited section for each below provision may change annually.

A. Cap on Salaries (Division H, Title II, General Provisions, Sec. 202): None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II.

   Note: The salary rate limitation does not restrict the salary that an organization may pay an individual working under an HHS award or order; it merely limits the portion of that salary that may be paid with federal funds. The HHS Grants Policy Statement further explains the application of this salary rate limitation.

B. Gun Control Prohibition (Div. H, Title II, Sec. 210): None of the funds made available in this title may be used, in whole or in part, to advocate or promote gun control.

C. Lobbying Restrictions (Div. H, Title V, Sec. 503):

   - 503(a): No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111-148 shall be used, other than for normal and recognized executive- legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government itself.

   - 503(b): No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111-148 shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or

Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government.

- 503(c): The prohibitions in subsections (a) and (b) shall include any activity to advocate or promote any proposed, pending or future federal, state or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale of marketing, including but not limited to the advocacy or promotion of gun control.

For additional information, see Anti-Lobbying Restrictions for CDC Grantees at https://www.cdc.gov/grants/documents/Anti-Lobbying-Restrictions.pdf.

D. Blocking access to pornography (Div. H, Title V, Sec. 520): (a) None of the funds made available in this Act may be used to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography; (b) Nothing in subsection (a) shall limit the use of funds necessary for any federal, state, tribal, or local law enforcement agency or any other entity carrying out criminal investigations, prosecution, or adjudication activities.

E. Needle Exchange (Div. H, Title V, Sec. 526): Notwithstanding any other provision of this Act, no funds appropriated in this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

**Prohibition on certain telecommunications and video surveillance services or equipment** (2 CFR 200.216)**:** Recipients and subrecipients are prohibited from obligating or expending grant funds (to include direct and indirect expenditures as well as cost share and program funds) to:

1. Procure or obtain,
2. Extend or renew a contract to procure or obtain; or
3. Enter into contract (or extend or renew contract) to procure or obtain equipment, services, or systems that use covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. As described in 2 CFR 200.216, covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).
    i. For the purpose of public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).
    ii. Telecommunications or video surveillance services provided by such entities or using such equipment.
    iii. Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the

National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise, connected to the government of a covered foreign country.

President's Emergency Plan for AIDS Relief (PEPFAR) funding is exempt from the prohibition under 2 CFR 200.216 until September 30, 2028. During the exemption period, PEPFAR recipients are expected to work toward implementation of 2 CFR 200.216. The exemption may only be applied when there is no available alternative eligible source for these services.

**Cancel Year**: 31 U.S.C. Part 1552(a) Procedure for Appropriation Accounts Available for Definite Periods states the following: On September 30th of the 5th fiscal year after the period of availability for obligation of a fixed appropriation account ends, the account shall be closed and any remaining balances (whether obligated or unobligated) in the account shall be canceled and thereafter shall not be available for obligation or expenditure for any purpose.

## REPORTING REQUIREMENTS

**Annual Federal Financial Report (FFR, SF-425)**: The Annual Federal Financial Report (FFR) SF-425 is required and must be submitted no later than 90 days after the end of the budget period in the Payment Management System.

Additional guidance on submission of Federal Financial Reports can be found at: https://pms.psc.gov/grant-recipients/ffr-updates.html.

If more frequent reporting is required, the Notice of Award terms and conditions will explicitly state the reporting requirement.

**Annual Performance Progress and Monitoring Reporting:** The Annual Performance Progress and Monitoring Report (PPMR) is due no later than 120 days prior to the end of the budget period and serves as the continuation application for the follow-on budget period. Submission instructions, due date, and format will be included in the guidance from the assigned GMO/GMS via www.grantsolutions.gov.

Any change to the existing information collection noted in the award terms and conditions will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

**Data Collection and Sharing Under Award:** Consistent with strategies and activities expected and anticipated under this award, Recipient, either directly or indirectly, may be expected to collect or generate data for public health purposes. For purposes of this award, data for public health purposes may be administrative data or data commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation, but does not include preliminary analyses, drafts of scientific papers, plans for future research communications with colleagues, or physical objects, such as laboratory notebooks or laboratory specimens unless otherwise specified in the award.

2 CFR 200.315(d) states that the federal government has the right to: 1) obtain, reproduce, publish, or otherwise use the data produced under a federal award; and 2) authorize others to

receive, reproduce, publish, or otherwise use such data for federal purposes. In furtherance of various United States Government-wide initiatives and policies, the federal government seeks to make federally funded publications and data underlying them more readily available, and to make public health data more readily accessible within the federal government and to the public.

Consistent with grant regulations, CDC may legally obtain a copy of any data collected or generated under this award. Where CDC has determined that data collected or generated under this award must be shared with CDC, such direction will be further addressed in your Notice of Funding Opportunity, your Notice of Grant Award, or other specific grant guidance. Acceptance of funds under this award is an acknowledgement of this regulatory provision and its application to this award.

**Data Management Plan:** CDC requires recipients for projects that involve the collection or generation of data with federal funds to develop, submit, and comply with a Data Management Plan (DMP) for each collection or generation of public health data undertaken as part of the award. The DMP should take into consideration sharing data with CDC including: 1) the specific data that will be shared under the award, 2) the process and timing planned for such sharing, 3) and any legal limitations that the Recipient asserts would hinder CDC access to, or use of, the data collected or generated under the award. In addition, the DMP should address broader access to and archiving/long-term preservation of collected or generated data. Additional information on the Data Management and Access requirements can be found at https://www.cdc.gov/grants/additional-requirements/ar-25.html.

**Audit Requirement Domestic Organizations** *(including US-based organizations implementing projects with foreign components)*: An organization that expends $1,000,000 or more in a fiscal year in federal awards shall have a single or program-specific audit conducted for that year in accordance with the provisions of 2 CFR 200.501. The audit period is an organization's fiscal year. The audit must be completed along with a data collection form (SF-SAC), and the reporting package shall be submitted within 30 days after receipt of the auditor's report(s), or nine (9) months after the end of the audit period. The audit report must be submitted to the Federal Audit Clearinghouse at https://www.fac.gov.

**Audit Requirement Foreign Organizations:** A foreign organization that expends $300,000 or more in a fiscal year on its federal awards must have a single or program-specific audit conducted for that year. The audit period is an organization's fiscal year. The auditor shall be a U.S.-based Certified Public Accountant firm, the foreign government's Supreme Audit Institution or equivalent, or an audit firm endorsed by the U.S. Agency for International Development's Office of Inspector General. The audit must be completed in English and in US dollars and submitted within the earlier of 30 days after receipt of the auditor's report(s), or nine (9) months after the end of the audit period. The audit report must be sent to the Office of Financial Resources, Office of Grants Services, Audit Resolution Team (ART) at GrantsAudit@cdc.gov. After receiving the audit report, CDC will resolve findings by issuing Final Management Determination Letters.

**Domestic and Foreign organizations:** Audit requirements for Subrecipients to whom 2 CFR 200 Subpart F applies: The recipient must ensure that the subrecipients receiving CDC funds also meet these requirements. The recipient must also ensure to take appropriate corrective action within six months after receipt of the subrecipient audit report in instances of non-compliance with applicable

federal law and regulations (2 CFR 200 Subpart F and HHS Grants Policy Statement). The recipient may consider whether subrecipient audits necessitate adjustment of the recipient's own accounting records. If a subrecipient is not required to have a program-specific audit, the recipient is still required to perform adequate monitoring of subrecipient activities. The recipient shall require each subrecipient to permit the independent auditor access to the subrecipient's records and financial statements. The recipient must include this requirement in all subrecipient contracts.

**Federal Funding Accountability and Transparency Act (FFATA)**
In accordance with 2 CFR Chapter 1, Part 170 Reporting Sub-Award and Executive Compensation Information, Prime Recipients awarded a federal grant are required to file a FFATA sub-award report by the end of the month following the month in which the prime recipient awards any sub-grant equal to or greater than $30,000. Refer to 2 CFR Chapter 1, Part 170 Reporting Sub-Award and Executive Compensation Information at eCFR :: 2 CFR Part 170 -- Reporting Subaward and Executive Compensation Information and https://sam.gov/fsrs for reporting requirements and guidance.

**Unique Entity Identifier (UEI)**
The UEI is the official identifier for doing business with the U.S. Government as of April 4, 2022. The UEI is generated and assigned by the System for Award Management at SAM.gov. In accordance with 2 CFR part 25, Appendix A, a recipient must maintain current information in SAM.gov, through at least annual review, until it submits the final required financial report or receives the final payment, whichever is later.

**Required Disclosures for Responsibility and Qualification (R/Q) (SAM.gov):** Consistent with 2 CFR 200.113, applicants and recipients must disclose in a timely manner, in writing to the CDC, with a copy to the HHS Office of Inspector General (OIG), all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Subrecipients must disclose, in a timely manner in writing to the prime recipient (pass through entity) and the HHS OIG, all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Disclosures must be sent in writing to the assigned GMS/GMO identified in the NOA, and to the HHS OIG by email at grantdisclosures@oig.hhs.gov or by mail to the following address:

U.S. Department of Health and Human Services
Office of the Inspector General
ATTN: Mandatory Grant Disclosures, Intake Coordinator
330 Independence Avenue, SW
Cohen Building, Room 5527
Washington, DC 20201

Recipients must include this mandatory disclosure requirement in all subawards and contracts under this award.

Failure to make required disclosures can result in any of the remedies described in 2 CFR 200.339. Remedies for noncompliance include suspension or debarment (See 2 CFR parts 180 and 376, and 31 U.S.C. 3321).

CDC is required to report any termination of a federal award prior to the end of the period of

performance due to material failure to comply with the terms and conditions of this award in the OMB-designated Responsibilities and Qualifications (R/Q) accessible through SAM (2 CFR 200.340(c)). CDC must also notify the recipient if the federal award is terminated for failure to comply with the federal statutes, regulations, or terms and conditions of the federal award (2 CFR 200.341(a)).

1. *General Reporting Requirement*

   If the total value of currently active grants, cooperative agreements, and procurement contracts from all federal awarding agencies exceeds $10,000,000 for any period of time during the period of performance of this federal award, the recipient must maintain the currency of information reported to the System for Award Management (SAM) and made available in the designated integrity and performance system (currently the Responsibility/Qualification (R/Q) through SAM.gov) about civil, criminal, or administrative proceedings described in section 2 of this award term and condition. This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for federal procurement contracts, will be publicly available.

2. *Proceedings About Which You Must Report*

   Submit the information required about each proceeding that:

   a. Is in connection with the award or performance of a grant, cooperative agreement, or procurement contract from the federal government;

   b. Reached its final disposition during the most recent five-year period; and

   c. If one of the following:

      (1) A criminal proceeding that resulted in a conviction, as defined in paragraph 5 of this award term and condition;

      (2) A civil proceeding that resulted in a finding of fault and liability and payment of a monetary fine, penalty, reimbursement, restitution, or damages of $5,000 or more;

      (3) An administrative proceeding, as defined in paragraph 5 of this award term and condition, that resulted in a finding of fault and liability and your payment of either a monetary fine or penalty of $5,000 or more or reimbursement, restitution, or damages in excess of $100,000; or

      (4) Any other criminal, civil, or administrative proceeding if:

         (i) It could have led to an outcome described in paragraph 2.c.(1), (2), or (3) of this award term and condition;

         (ii) It had a different disposition arrived at by consent or compromise with an acknowledgement of fault on your part; and

         (iii) The requirement in this award term and condition to disclose information about the proceeding does not conflict with applicable laws and regulations.

3. *Reporting Procedures*

Enter in the SAM Entity Management area the information that SAM requires about each proceeding described in section 2 of this award term and condition. You do not need to submit the information a second time under assistance awards that you received if you already provided the information through SAM because you were required to do so under federal procurement contracts that you were awarded.

4. *Reporting Frequency*

   During any period of time when you are subject to this requirement in section 1 of this award term and condition, you must report proceedings information through SAM for the most recent five-year period, either to report new information about any proceeding(s) that you have not reported previously or affirm that there is no new information to report. Recipients that have federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10,000,000 must disclose semiannually any information about the criminal, civil, and administrative proceedings.

5. *Definitions*

   For purposes of this award term and condition:

   a. Administrative proceeding means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (*e.g.*, Securities and Exchange Commission Administrative proceedings, Civilian Board of Contract Appeals proceedings, and Armed Services Board of Contract Appeals proceedings). This includes proceedings at the federal and state level but only in connection with performance of a federal contract or grant. It does not include audits, site visits, corrective plans, or inspection of deliverables.

   b. Conviction, for purposes of this award term and condition, means a judgment or conviction of a criminal offense by any court of competent jurisdiction, whether entered upon a verdict or a plea, and includes a conviction entered upon a plea of nolo contendere.

   c. Total value of currently active grants, cooperative agreements, and procurement contracts includes—

      (1) Only the federal share of the funding under any federal award with a recipient cost share;

      (2) The value of all expected funding increments under a federal award and options, even if not yet exercised.

## GENERAL REQUIREMENTS

You will administer your project in compliance with the HHS Administrative and National Policy Requirements found at https://www.hhs.gov/sites/default/files/hhs-administrative-national-policy-requirements.pdf.

**Antidiscrimination Compliance:** By applying for or accepting federal funds from HHS, recipients certify compliance with all federal antidiscrimination laws and these requirements and that complying with those laws is a material condition of receiving federal funding streams. Recipients are responsible for ensuring subrecipients, contractors, and partners also comply.

**Assurance of Compliance**: The applicant hereby agrees that it will comply with Title VI of the Civil Rights Act of 1964, as amended (codified at 42 U.S.C. 2000d et seq.), and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 CFR Part 80); Section 504 of the Rehabilitation Act of 1973, as amended (codified at 29 U.S.C. 794), and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 CFR Part 84); Title IX of the Education Amendments of 1972, as amended (codified at 20 U.S.C. § 1681 et seq.), and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 CFR Part 86); The Age Discrimination Act of 1975, as amended (codified at 42 U.S.C. § 6101 et seq.), and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 CFR Part 91); and Section 1557 of the Patient Protection and Affordable Care Act, as amended (codified at 42 U.S.C. § 18116), and all requirements imposed by or pursuant to the Regulation of the Department of Health and Human Services (45 CFR Part 92).

**Termination:** This award is subject to the termination provisions at 2 CFR 200.340. Pursuant to 2 CFR 200.340, the recipient agrees by accepting this award that continued funding for the award is contingent upon the availability of appropriated funds, recipient satisfactory performance, compliance with the Terms and Conditions of the award, and may also otherwise be terminated, to the extent authorized by law, if the agency determines that the award no longer effectuates program goals or agency priorities.

**Travel Cost**: In accordance with HHS Grants Policy Statement, travel costs are allowable when the travel will provide a direct benefit to the project or program. To prevent disallowance of cost, the recipient is responsible for ensuring travel costs are clearly stated in their budget narrative and are applied in accordance with their organization's established travel policies and procedures. The recipient's established travel policies and procedures must also meet the requirements of 2 CFR 200.475.

**Food and Meals**: Costs associated with food or meals are allowable when consistent with applicable federal regulations and HHS policies. See https://www.hhs.gov/grants/contracts/contract-policies-regulations/spending-on-food/index.html. In addition, costs must be clearly stated in the budget narrative and be consistent with organization approved policies. Recipients must make a determination of reasonableness and organization approved policies must meet the requirements of 2 CFR 200.432.

**Prior Approval**: All requests which require prior approval, must bear the signature (or electronic authorization) of the authorized organization representative. The recipient should submit these requests no later than 120 days prior to the budget period's end date to ensure ample time remains to process and carry out the request. Additionally, any requests involving funding issues must include an itemized budget and a narrative justification of the request.

The following types of requests are examples of actions that require prior approval, unless an expanded authority, or conversely a high-risk condition, is explicitly indicated in the NOA.

- Use of unobligated funds from prior budget period (Carryover)
- Lift funding restriction

- Significant redirection of funds (i.e., cumulative changes of 25% of total award)
- Change in scope
- Implement a new activity or enter into a sub-award that is not specified in the approved budget
- Apply for supplemental funds
- Extensions to period of performance

Templates for prior approval requests can be found at: https://www.cdc.gov/grants/already-have-grant/prior-approval-requests.html.

Additional information on the electronic grants administration system CDC non-research awards utilize, GrantSolutions, can be found at: https://www.cdc.gov/grants/grantsolutions/index.html.

**Recipient Contractual/Consultant Cost Agreements: I**n accordance with 2 CFR 200.325, all supporting documentation related to the elements outlined in the Budget Preparation Guidelines must be maintained by the recipient and available upon request. Recipients may submit supporting documentation via GrantSolutions Grants Management Services (GSGMS) Grant Messages to the assigned Grants Management Specialist.

**Key Personnel**: In accordance with 2 CFR 200.308 and 2 CFR 300.308, CDC recipients must obtain prior approval from CDC for (1) change in the project director/principal investigator, authorized organizational representative, business official, financial director, or other key persons specified in the NOFO, application or award document; and (2) the disengagement from the project for more than three months, or a 25 percent reduction in time devoted to the project, by the approved project director or principal investigator.

**Inventions**: Acceptance of grant funds obligates recipients to comply with the standard patent rights clause in 37 CFR Part 401.14.

**Acknowledgment of Federal Funding**: When issuing statements, press releases, publications, requests for proposal, bid solicitations and other documents --such as toolkits, resource guides, websites, and presentations (hereafter “statements”) --describing the projects or programs funded in whole or in part with U.S. Department of Health and Human Services (HHS) federal funds, the recipient must clearly state:

1. the percentage and dollar amount of the total costs of the program or project funded with federal money; and,
2. the percentage and dollar amount of the total costs of the project or program funded by non-governmental sources.

When issuing statements resulting from activities supported by HHS financial assistance, the recipient entity must include an acknowledgement of federal assistance using one of the following or a similar statement.

If the HHS Grant or Cooperative Agreement is NOT funded with other non-governmental sources:

> This [**project/publication/program/website, etc**.] [**is/was**] supported by the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling **$XX** with 100 percent funded by CDC/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by CDC/HHS, or the U.S. Government.

If the HHS Grant or Cooperative Agreement IS partially funded with other non-governmental sources:

> This [**project/publication/program/website, etc.]** [**is/was**] supported by the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling **$XX** with **XX** percentage funded by CDC/HHS and **$XX** amount and **XX** percentage funded by non- government source(s). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by CDC/HHS, or the U.S. Government.

The federal award total must reflect total costs (direct and indirect) for all authorized funds (including supplements and carryover) for the total competitive segment up to the time of the public statement.

Any amendments by the recipient to the acknowledgement statement must be coordinated with the HHS Awarding Agency.

If the recipient plans to issue a press release concerning the outcome of activities supported by HHS financial assistance, it should notify the HHS Awarding Agency in advance to allow for coordination.

**Copyright Interests Provision:** This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available without any embargo or delay after publication. Also, at the time of submission, Recipient and/or the Recipient's submitting author must also post the manuscript through PubMed Central (PMC) without any embargo or delay after publication. The recipient must obtain prior approval from the CDC for any exception to this provision.

The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted article reserve adequate right to fully comply with this provision and the license reserved by CDC.

The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public

Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

**Disclaimer for Conference/Meeting/Seminar Materials:** If a conference/meeting/seminar is funded by a grant, cooperative agreement, sub-grant and/or a contract, the recipient must include the following statement on conference materials, including promotional materials, agenda, and internet sites:

> Funding for this conference was made possible (in part) by the Centers for Disease Control and Prevention. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services, nor does the mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.

**Logo Use for Conference and Other Materials:** Neither the Department of Health and Human Services (HHS) nor the CDC logo may be displayed if such display would cause confusion as to the funding source or give false appearance of Government endorsement. Use of the HHS name or logo is governed by U.S.C. Part 1320b-10, which prohibits misuse of the HHS name and emblem in written communication. As a general matter, a non-federal entity is not authorized to use the HHS name or logo. Moreover, the HHS Office of the Inspector General has authority to impose civil monetary penalties for violations (42 CFR Part 1003). The appropriate use of the HHS logo is subject to review and approval of the HHS Assistant Secretary for Public Affairs (ASPA), and if granted would be governed by a logo license agreement setting forth the terms and conditions of use.

Additionally, the CDC logo cannot be used by the recipient without the express, written consent of CDC, generally in the form of a logo license agreement setting forth the terms and conditions of use. The Program Official/Project Officer identified in the NOA can assist with facilitating such a request. It is the responsibility of the recipient to request consent for use of the logo in sufficient detail to ensure a complete depiction and disclosure of all uses of the Government logos. In all cases for utilization of Government logos, the recipient must ensure written consent is received.

**Equipment and Products**: To the greatest extent practical, all equipment and products purchased with CDC funds should be American made. CDC defines equipment as tangible non-expendable personal property (including exempt property) charged directly to an award having a useful life of more than one year AND an acquisition cost of $10,000 or more per unit. However, consistent with recipient policy, a lower threshold may be established. Please provide the information to the Grants Management Officer to establish a lower equipment threshold to reflect your organization's policy. The recipient may use its own property management standards and procedures, provided it observes provisions in applicable grant regulations found at 2 CFR 200.

**Federal Information Security Management Act (FISMA):** All information systems, electronic or hard copy, that contain federal data must be protected from unauthorized access. This standard also applies to information associated with CDC grants. Congress and the OMB have instituted laws, policies and directives that govern the creation and implementation of federal information security practices that pertain specifically to grants and contracts. The current regulations are pursuant to the Federal Information Security Management Act (FISMA), Title III of the E-

Government Act of 2002, PL 107-347.

FISMA applies to CDC recipients only when recipients collect, store, process, transmit or use information on behalf of HHS or any of its component organizations. In all other cases, FISMA is not applicable to recipients of grants, including cooperative agreements. Under FISMA, the recipient retains the original data and intellectual property, and is responsible for the security of these data, subject to all applicable laws protecting security, privacy, and research. If/When information collected by a recipient is provided to HHS, responsibility for the protection of the HHS copy of the information is transferred to HHS and it becomes the agency's responsibility to protect that information and any derivative copies as required by FISMA.

For the full text of the requirements under Federal Information Security Management Act (FISMA), Title III of the E- Government Act of 2002 Pub. L. No. 107-347, please review the following website: https://www.govinfo.gov/content/pkg/PLAW-107publ347/pdf/PLAW-107publ347.pdf.

**Whistleblower Protections:** As a recipient of this award, you must comply with the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2013 (Pub. L. 112-239, 41 U.S.C. § 4712) "Enhancement of contractor protection from reprisal for disclosure of certain information," and 48 CFR part 3 subpart 3.9, "Whistleblower Protections for Contractor Employees." For more information see: https://oig.hhs.gov/fraud/whistleblower/.

**Cybersecurity Requirements**: Recipients shall develop plans and procedures, modeled after the NIST Cybersecurity framework, to protect HHS and CDC systems and data, if the following conditions are met: 1) recipients, subrecipients, or third-party entities have ongoing and consistent access to HHS owned or operated information or operational technology systems and 2) recipients, subrecipients, or third-party entities receive, maintain, transmit, store, access, exchange, process, or utilize personal identifiable information (PII) or personal health information (PHI) obtained from the awarding HHS agency for the purposes of executing the award. Where both conditions exist, recipients must develop cybersecurity plans and procedures modeled after the NIST Cybersecurity framework (https://www.nist.gov/cyberframework) to protect HHS systems and data.

## PAYMENT INFORMATION

**Fraud Waste or Abuse:** The HHS Office of the Inspector General (OIG) maintains a toll-free number (1-800-HHS-TIPS [1-800-447-8477]) for receiving information concerning fraud, waste, or abuse under grants and cooperative agreements. Information also may be submitted online at https://tips.oig.hhs.gov/ or by mail to U.S. Department of Health and Human Services, Office of the Inspector General, Attn: OIG HOTLINE OPERATIONS, P.O. Box 23489 Washington DC 20026. Such reports are treated as sensitive material and submitters may decline to give their names if they choose to remain anonymous. For additional information, see: https://oig.hhs.gov/fraud/report-fraud/.

**Automatic Drawdown (Direct/Advance Payments):** Payments under CDC awards will be made available through the Department of Health and Human Services (HHS) Payment Management System (PMS), under automatic drawdown, unless specified otherwise in the NOA. Recipients must comply with requirements imposed by the PMS on-line system. Questions concerning award payments or audit inquiries should be directed to the payment management services office.

PMS Website: https://pms.psc.gov/
PMS Phone Support: +1(877)614-5533
PMS Email Support: PMSSupport@psc.gov

**Payment Management System Subaccount**: Funds awarded in support of approved activities will be obligated in an established subaccount in the PMS. Funds must be used in support of approved activities in the NOFO and the approved application. All award funds must be tracked and reported separately.

**Exchange Rate**: All requests for funds contained in the budget, shall be stated in U.S. dollars. Once an award is made, CDC will generally not compensate foreign recipients for currency exchange fluctuations through the issuance of supplemental awards.

**Acceptance of the Terms of an Award:** By drawing or otherwise obtaining funds from PMS, the recipient acknowledges acceptance of the terms and conditions of the award and is obligated to perform in accordance with the requirements of the award. If the recipient cannot accept the terms, the recipient should notify the Grants Management Officer within thirty (30) days of receipt of the NOA.

**Certification Statement**: By drawing down funds, the recipient certifies that proper financial management controls and accounting systems, to include personnel policies and procedures, have been established to adequately administer federal awards and funds drawn down. Recipients must comply with all terms and conditions in the NOFO, outlined in their NOA, grant policy terms and conditions contained in applicable HHS Grant Policy Statements, and requirements imposed by program statutes and regulations and HHS grants administration regulations, as applicable, as well as any regulations or limitations in any applicable appropriations acts.

## CLOSEOUT REQUIREMENTS

In accordance with 2 CFR 200.344, recipients must submit all closeout reports identified in this section within 120 days of the period of performance end date. The reporting timeframe is the full period of performance. If the recipient does not submit all reports in accordance with this section and the terms and conditions of the Federal Award, CDC may proceed to close out with the information available within one year of the period of performance end date unless otherwise directed by authorizing statutes. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI). If recipients do not submit all closeout reports identified in this section within one year of the period of performance end date, then CDC must report recipients' material failure to comply with the terms and conditions of the award with the OMB-designated integrity and performance system (currently Responsibility/Qualification section of SAM.gov). CDC may also pursue other enforcement actions per 2 CFR 200.339.

**Final Performance Progress and Evaluation Report (PPER):** This report should include the information specified in the NOFO and is submitted upon solicitation from the GMS/GMO via www.grantsolutions.gov. At a minimum, the report will include the following:

- Statement of progress made toward the achievement of originally stated aims;

- Description of results (positive or negative) considered significant; and
- List of publications resulting from the project, with plans, if any, for further publication.

All manuscripts published as a result of the work supported in part or whole by the grant must be submitted with the performance progress reports.

**Final Federal Financial Report (FFR, SF-425):** The FFR should only include those funds authorized and expended during the timeframe covered by the report. The Final FFR, SF-425 is required and must be submitted no later than 120 days after the period of performance end date through recipient online accounts in the Payment Management System. The final FFR will consolidate data reporting responsibilities to one entry point within PMS which will assist with the reconciliation of expenditures and disbursements to support the timely close-out of grants.

The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. Remaining unobligated funds will be de-obligated and returned to the U.S. Treasury.

Every recipient should already have a PMS account to allow access to complete the SF-425.

Additional guidance on submission of Federal Financial Reports can be found at https://pms.psc.gov/grant-recipients/ffr-updates.html

**Equipment and Supplies - Tangible Personal Property Report (SF-428):** A completed Tangible Personal Property Report SF-428 and Final Report SF-428B addendum must be submitted, along with any Supplemental Sheet SF-428S detailing all major equipment acquired or furnished under this project with a unit acquisition cost of $10,000 or more. Electronic versions of the forms can be downloaded by visiting: https://www.grants.gov/forms/forms-repository/post-award-reporting-forms.

If no equipment was acquired under an award, a negative report is required.

The recipient must identify each item of equipment that it wishes to retain for continued use in accordance with 2 CFR 200. The awarding agency may exercise its rights to require the transfer of equipment purchased under the assistance award. CDC will notify the recipient if transfer to title will be required and provide disposition instruction on all major equipment.

Equipment with a unit acquisition cost of less than $10,000 that is no longer to be used in projects or programs currently or previously sponsored by the federal government may be retained, sold, or otherwise disposed of, with no further obligation to the federal government (see 2 CFR 200.313(e)(1)).

## CDC STAFF RESPONSIBILITIES

**Roles and Responsibilities:** Grants Management Specialists/Officers (GMO/GMS) and Program Officials (PO) work together to award and manage CDC grants and cooperative agreements. From the pre-planning stage to closeout of an award, grants management and program staff have specific roles and responsibilities for each phase of the grant cycle. Award specific terms and conditions will include contact information for the PO/GMO/GMS.

**Program Official:** The PO is the federal official responsible for monitoring the programmatic,

scientific, and/or technical aspects of grants and cooperative agreements including:

- The development of programs and NOFOs to meet the CDC's mission;
- Providing technical assistance to applicants in developing their applications, e.g., explanation of programmatic requirements, regulations, evaluation criteria, and guidance to applicants on possible linkages with other resources;
- Providing technical assistance to recipients in the performance of their project; and
- Post-award monitoring of recipient performance such as review of progress reports, review of prior approval requests, conducting site visits, and other activities complementary to those of the GMO/GMS.

For Cooperative Agreements, substantial involvement is required from CDC. The PO is the federal official responsible for the collaboration or participation in carrying out the effort under the award. Substantial involvement will be detailed in the NOFO and award specific terms and conditions and may include, but is not limited to:

- Review and approval of one stage of work before work can begin on a subsequent stage;
- Review and approval of substantive programmatic provisions of proposed subawards or contracts (beyond existing federal review of procurement or sole source policies);
- Involvement in the selection of key relevant personnel;
- CDC and recipient collaboration or joint participation; and
- Implementing highly prescriptive requirements prior to award limiting recipient discretion with respect to scope of services, organizational structure, staffing, mode of operation, and other management processes.

**Grants Management Officer:** The GMO is the only official authorized to obligate federal funds and is responsible for signing the NOA, including revisions to the NOA that change the terms and conditions. The GMO serves as the counterpart to the business officer of the recipient organization. The GMO is the federal official responsible for the business and other non-programmatic aspects of grant awards including:

- Determining the appropriate award instrument, i.e., grant or cooperative agreement;
- Determining if an application meets the requirements of the NOFO;
- Ensuring objective reviews are conducted in an above-the-board manner and according to guidelines set forth in grants policy;
- Ensuring recipient compliance with applicable laws, regulations, and policies;
- Negotiating awards, including budgets;
- Responding to recipient inquiries regarding the business and administrative aspects of an award;
- Providing recipients with guidance on the closeout process and administering the closeout of grants;
- Receiving and processing reports and prior approval requests such as changes in funding, budget redirection, or changes to the terms and conditions of an award; and

- Maintaining the official grant file and program book.

**Grants Management Specialist:** The GMS is the federal staff member responsible for the day-to-day management of grants and cooperative agreements. The GMS is the primary contact of recipients for business and administrative matters pertinent to grant awards. Many of the functions described in the GMO section are performed by the GMS, on behalf of the GMO.



# CDPH - CTCA Joint Guidelines

***Guidelines for Electronic Directly Observed Therapy (eDOT) Program Protocols In California***

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## 1. Abbreviations

| | |
|---|---|
| ADR | Adverse Drug Reaction |
| AES | Advanced Encryption Standard |
| BA | Business Associate |
| BAA | Business Associate Agreement |
| CDC | Center for Disease Control and Prevention |
| CDPH | California Department of Public Health |
| CTCA | California Tuberculosis Controller's Association |
| DOT | Directly Observed Therapy |
| eDOT | Electronic Directly Observed Therapy |
| EMR | Electronic Medical Record |
| GPS | Global Positioning Satellite |
| HIPAA | Health Insurance Portability and Accountability Act of 1996 |
| LVN | Licensed Vocational Nurse |
| MDR-TB | Multi-Drug Resistant Tuberculosis |
| PHI | Protected Health Information |
| PHN | Public Health Nurse |
| RN | Registered Nurse |
| RVCT | Report of Verified Case of Tuberculosis |
| TB | Tuberculosis |
| TBCB | California Department of Public Health Tuberculosis Control Branch |
| VDOT | Video Directly Observed Therapy |
| WHO | World Health Organization |
| WOT | Wirelessly Observed Therapy |
| XDR-TB | Extensively Drug Resistant Tuberculosis |

## 2. Administration

### 2.1 Preface

The following guidelines were developed collaboratively by the California Tuberculosis Controllers Association (CTCA); the California Department of Public Health (CDPH), Center for Infectious Diseases, Tuberculosis Control Branch; the University of California, San Diego School of Medicine; and the Center for Connected Health Policy. These guidelines provide statewide recommendations for tuberculosis (TB) control in California. If these guidelines are altered for local use, then the logo should be removed and adaptation from this source document acknowledged.

These guidelines pertain specifically to statewide uses of Electronic Directly Observed Therapy (eDOT), an approach to remotely monitoring patient adherence to medication during the course of treatment through the use of mobile and electronic technologies.

While eDOT is not intended to replace in-person Directly Observed Therapy (DOT) for all patients undergoing TB treatment, there is growing evidence from epidemiological studies showing that eDOT is an acceptable alternative to in-person DOT for many patients and is associated with comparable or higher adherence. As technologies and systems for eDOT become increasingly comprehensive, TB providers may have the ability to incorporate elements beyond simply documenting adherence, including providing patients with reminders, motivators and expanded means of communicating medication side effects to their providers.

The practice of medicine is an integration of both the science and art of preventing, diagnosing, and treating diseases. Accordingly, it should be recognized that these guidelines cannot guarantee successful outcomes with respect to the treatment of individual patients, and CDPH/CTCA disclaims any responsibility for such outcomes. These guidelines are provided for informational and educational purposes only and do not set a legal standard of medical or other health care. They are intended to assist practitioners in providing effective and safe medical care that is founded on current information, available resources, and patient needs. The practice guidelines and technical standards recognize that safe and effective practices require specific training, skills, and techniques, as described in each document, and are not a substitute for the independent medical judgment, training, and skill of treating or consulting practitioners.

### 2.2 Background

One-third of the world's population harbors the bacteria that causes TB, 10 percent of whom will develop the disease over their lifetime. TB causes 1.2 million deaths worldwide each year[1]. In 2014, a total of 9,412 new TB cases were reported in the United States, an incidence of 3.0 cases per 100,000 population, representing a drop in incidence from 3.4 cases per 100,000 population from just 2011. The progress made in TB control may have plateaued, however, as the decline noted between 2013 and 2014 (2.2%) was the smallest decrease in a decade, a concern given that rates of tuberculosis still far exceed the 2020 target of reducing TB incidence to 1.4 cases per 100,000[2].

California, Texas, New York, and Florida now account for over 50% of the TB cases nationally despite only containing a third of the nation's population. In California, 2,137 new TB cases were reported in 2015 compared to 2,134 cases in 2014. The decline in California's TB incidence has slowed over the past decade and has now stopped [3, 4, 5]. Novel interventions, including eDOT, are needed to keep pace with societal expectations and to provide patient-centered strategies to maintain and accelerate declines in TB incidence.

### 2.2.1 TB Treatment

Strict adherence to TB treatment regimens must be maintained otherwise illness may persist, patients can remain infectious, and selective pressure can result in the emergence of bacteria that are resistant to TB treatment. While standard TB treatment is usually required for six to nine months, multi-drug resistant TB (MDR-TB) treatment currently takes 18-24 months. This length of treatment is indicated because of the necessity to use second and often third line agents. Directly observed therapy is recommended for all TB patients and is required for patients with MDR-TB.

Currently, drug resistant TB has been reported from every country in the world, which includes nearly 500,000 new cases of MDR-TB each year. Many countries have detected cases of extensively drug resistant TB (XDR-TB), defined as TB that is resistant to the two most effective first line antibiotics, plus a fluoroquinolone and at least one injectable antibiotic. Furthermore, some countries have reported cases of TB that are resistant to all currently available anti-TB medications [6,7,8,9].

### 2.2.2 Costs of TB Treatment in the United States

Treating uncomplicated TB for at least six months and drug resistant TB for up to two years places a substantial burden on healthcare systems. Although direct costs vary by drug regimen, non-resistant TB treatment is estimated to cost $17,000 per patient (outpatient management estimated at $3,419). Given the longer therapy, more expensive drugs, increased drug reactions, increased hospitalizations and numerous other factors, treatment for MDR- and XDR-TB are significantly higher: although costs vary, it is estimated to cost $134,000 per case of MDR-TB and $430,000 for XDR-TB [10].

### 2.2.3 Directly Observed Therapy (DOT)

Patients cite drug side effects, feeling drugs are unnecessary after symptoms resolve, and treatment fatigue as reasons for poor adherence to treatment. To improve adherence, health departments in the United States use DOT when possible. Through DOT, patients are observed ingesting each medication dose maximizing the likelihood that patients will complete therapy. DOT is typically performed in the patient's home or workplace, but also may be done in a clinic or other mutually agreed upon location. Studies have shown that DOT is effective in achieving adherence to TB treatment and reducing TB mortality, especially when combined with individualized care. While DOT is effective, individual and structural factors make in-person DOT challenging to provide for all patients. For example, DOT is often precluded by transportation and resource limitations. It also requires the patient to be in a specific place at a stated time and does

not easily allow for last minute changes. Vacation days or holidays also can limit DOT. Thus, eDOT offers potentially viable solutions for monitoring treatment in settings already using in person DOT and increasing access to DOT in places where it is performed inconsistently or not at all.

### 2.2.4 Definition of Electronic Directly Observed Therapy (eDOT)

Electronic Directly Observed Therapy (eDOT) refers to the use of mobile technologies to remotely monitor patient medication adherence during the course of treatment. Different forms of eDOT are available for remote patient monitoring. The choice of eDOT modality will depend upon the TB program's aims and resources, as well as patient characteristics and preferences.

Investigational research is underway on emerging technologies, such as ingestible sensors, that are embedded into medication tablets or placed into capsules. These sensors are detected by a patient-worn external device that wirelessly transfers data to the patient's mobile phone. Termed Wirelessly Observed Therapy (WOT), ingestion data are transmitted securely to a server for a healthcare provider to monitor. WOT is still in trial stages, but one company recently received FDA clearance for WOT as a medication adherence monitoring device.

Facial recognition is another mechanism to assist health care providers and patients monitor therapy. As these technologies evolve, their application may be considered by health departments for eDOT.

Video Directly Observed Therapy (VDOT) utilizes mobile video conferencing or video recording technology to monitor patients taking medications. Two VDOT modalities that are already in use by a number of TB programs in California and elsewhere may be referred to as asynchronous and synchronous VDOT.

eDOT modalities are emerging that can safely and effectively monitor TB treatment while increasing patient autonomy. Unless otherwise stated, this guidance document will focus on VDOT given that it is the eDOT modality at the time of this writing with sufficient evidence of use and formalized development [11]. As stressed in these guidelines, although some technologies might not be appropriate for every patient, different eDOT mechanisms have innate strengths that can increase patients' access to care, which should be balanced against the benefits of in-person DOT.

#### 2.2.4.1 Synchronous VDOT

With synchronous VDOT, TB care providers observe patients taking their medications via videophone, smartphone, tablet or computer. Synchronous VDOT is a form of VDOT which allows the patient and provider to see and hear each other in real time. This approach is sometimes referred to as "live streaming" or "video conferencing". Synchronous VDOT can be implemented using fixed phone lines, the Internet or cellular networks.

1. Landline Videophones: Videophone equipment is installed in both the patient's home and at the health department through telephone landlines, allowing secure, reliable real-time conversation and observation. This method requires that the patient has a landline and is present at the landline site at the agreed upon time to take medications during the DOT worker's normal working hours. These systems are reliable, but require landline telephones, which are becoming increasingly less common and, thus, may not accommodate some patients.
2. Internet or Cellular Networks: Various options are available to provide video and audio on desktops, laptops, tablets or mobile phones equipped with a microphone and camera that allow real-time conversations and observation. These systems have the advantage of not depending on wired telephone connections and may be mobile. However, reliable network connectivity and transmission security are important considerations.

#### 2.2.4.2 Asynchronous VDOT

With asynchronous VDOT, patients record themselves taking their medications and care providers subsequently observe the recordings to document that medications were ingested. This can be accomplished using smartphones, tablets or computers that can record videos and securely forward them electronically to the TB program to be viewed at a time chosen by the DOT worker. This approach is also be referred to as "store-and-forward" or "recorded" VDOT.

1. Store-and-Forward/Recorded Video. A smartphone or tablet is used by patients to record themselves ingesting each medication dose. The video is then transferred securely to a protected server or Cloud where it can be retrieved immediately or at a later time for viewing by the DOT worker. Similar to synchronous VDOT, asynchronous VDOT requires network connectivity and secure data transmission; however, asynchronous VDOT does not require network connectivity at the time the patient ingests his/her medication.

### 2.2.5 Evidence Basis of VDOT

Research studies have shown that implementation of VDOT can be feasible, acceptable, and cost-saving. For example, Gassanov, et al[12] and Miraseidi, et al[13], found synchronous VDOT to be patient-friendly and simple to use. Another study involving synchronous VDOT found a cost-savings of nearly $2500/patient when videophones were used for the administration of TB medications[14]. In a study of asynchronous VDOT, researchers found that over 93% of the expected doses were observed through recorded videos, and that patient satisfaction with this method of DOT was high[15].

### 2.2.6 Comparison of VDOT to In-Person DOT

Given that different modalities of patient monitoring have unique attributes; one or more approach could be employed by a TB program to provide options for client-centered care. Some of these attributes with relative strengths are listed in Table 1.

| Table 1 – Attributes of VDOT Methods and In-Person DOT | | | |
|---|---|---|---|
| **Characteristic** | **Synchronous VDOT** | **Asynchronous VDOT** | **In-person DOT** |
| **QUALITY ASSURANCE AND SAFETY** | | | |
| • Allows repeat viewing of ingestion event | | ✓✓✓ | |
| • Quality assurance using duplicate observers | ✓✓ | ✓✓✓ | ✓ |
| • Allows DOT worker to make visual assessment of patient's health | ✓✓ | ✓ | ✓✓✓ |
| • Allows DOT worker to actively evaluate for medication side effects | ✓✓ | ✓ | ✓✓✓ |
| • Ease of verifying correct medications and dosages | ✓✓ | ✓ | ✓✓✓ |
| • Ability to provide concomitant case management, i.e. contact investigation, social support, teaching | ✓✓ | ✓ | ✓✓✓ |
| **PATIENT CONVENIENCE** | | | |
| • Allows DOT worker to monitor doses taken on weekends, holidays, and after hours | ✓✓ | ✓✓✓ | ✓ |
| • Allows patients the opportunity to ask questions before medication administration | ✓✓ | | ✓✓✓ |
| • Ability to observe patient during travel | ✓✓ | ✓✓✓ | |
| • Suitable for patients in unstable living circumstances (e.g. homelessness, shelters, drug treatment programs) | ✓ | ✓✓ | ✓✓✓ |
| **PROGRAM TIME AND COSTS** | | | |
| • Ability to decrease DOT worker travel time and expense | ✓✓✓ | ✓✓✓ | ✓ |
| • Ability to simplify scheduling logistics for patients | ✓✓ | ✓✓✓ | ✓ |
| • Program costs currently well-established | ✓ | ✓ | ✓✓✓ |
| • Decreased initial upfront costs and technology requirement | | | ✓✓ |
| **TECHNOLOGY AND FUTURE DIRECTIONS** | | | |
| • Provides a gateway to future mobile health application use | ✓✓ | ✓✓✓ | |
| • Ability to monitor without reliance on consistent internet or cellular connectivity | | ✓ | ✓✓✓ |

## 2.3 Funding for eDOT

In California, federal and state funding sources may be available for local health departments to support electronic DOT arrangements. Laws regarding reimbursement in California and other states can be found on the Center for Connected Health Policy website www.cchpca.org .

## 3. Eligibility

### 3.1 Considerations for eDOT Use

eDOT may be considered for all patients with TB treatment regimens that call for DOT. A patient-centered approach should be taken by the TB program in determining which DOT modality is the best fit for each individual. It is advised that eDOT patients be selected using policy and procedures established by the TB program. In addition to the recommendations in the CDPH-CTCA Joint Guidelines for DOT[16], the following criteria should be considered when determining whether eDOT is suitable for each patient.

#### 3.1.1 Patient Eligibility Considerations for eDOT

- Patient has successfully completed initial weeks of in-person DOT with close to 100% adherence.
- Patient is experiencing no major side effects and has tolerated a stable medication regimen for at least two to three weeks.
- Patient is willing to accept and follow eDOT procedures.
- Patient is able to accurately identify and swallow his/her own medication independently, or patient has a stable caregiver who can provide consistent assistance.
- Patient can recognize side effects associated with TB treatment and is instructed about what to do if side effects occur.
- Patient speaks a language that can be accommodated by eDOT personnel, or the TB program can coordinate with language interpretation services to provide consistent care for the patient.

#### 3.1.2 Additional Considerations for eDOT

Before concluding that a patient is a candidate for eDOT, consider the following:

A. Network connectivity at patient's residence which may be relevant for many forms of eDOT.

   i. Check the cellular/internet coverage in the area where the patient and DOT worker will be using their mobile devices.
   ii. If connectivity coverage is poor, determine whether the patient can bring their device/phone to another location with satisfactory coverage (e.g., work, school, or hotspot) during the day that medications were taken in order for videos/data to be sent.

B. Patient literacy.

   i. Ensure patient is capable of using required equipment without help from a DOT worker before starting the program.

C. Patient disabilities

i. Ensure patient has no cognitive and/or physical disabilities that could prevent them from using required equipment properly (e.g., diminished hearing or vision, severe arthritis), or has support from a responsible and trained individual.

D. Patient mobility (e.g., binational)

i. Determine if the patient plans on being out of town, and if so, the frequency, duration and location of travel, and access to cellular or Wi-Fi networks.
ii. Determine whether the patient is willing and able to handle accommodations for continual connectivity.

E. Patients who are younger than 18 years-old, frail, have comorbid conditions, misuse alcohol or drugs, undergoing TB treatment re-challenge or adjustment due to toxicity/side effects or resistance, or have missed clinic appointments should be assessed individually to determine whether eDOT is a suitable option for them. For example, patients whose lifestyles are not conducive to monitoring them with in-person DOT could demonstrate better adherence using eDOT because this modality is not subject to some of the constraints that exist with in-person DOT. Additionally, patients should be considered on a case-by-case bases when they cannot make their own medical decisions and have an appointed designated power of attorney.

## 4. Roles and Responsibilities

### 4.1 TB Staff and Procedures

#### 4.1.1 TB Controller Role

Oversight, direction, and size of TB programs vary by jurisdiction; however, TB controllers should identify DOT modalities available and operational considerations for implementing eDOT as an option for treatment monitoring. TB controllers should also assure policy and procedures are in place for determining how patients will be assessed to determine which mode of treatment monitoring they should receive. When patients are placed on eDOT, the TB controller should be made aware of concerns or problems that occur during treatment in order to participate in decisions regarding changes to the mode of DOT. Regardless of the method chosen for adherence monitoring, TB controllers should participate in continual quality assurance.

#### 4.1.2 Program Supervisor Role

Supervision of TB programs may vary by local jurisdiction; however, it remains important to ensure the safe, appropriate and effective use of eDOT. Program supervision may be performed by TB controllers, program or case managers, clinical or public health nurses (PHN), or other personnel who are equipped to provide oversight and evaluate

effectiveness. TB programs should have procedures in place to monitor equipment (e.g., smartphones, tablets, video phones, and computers) and service plan usage (e.g., phone, text message, and data charges) when these items are provided by the program. Access to protected health information (PHI) should be managed according to local health department standards based on federal and state guidelines. Specific considerations will vary depending on the method of eDOT service (cloud based server, smartphone application, in-house software, etc.). A protocol should also be in place for deleting all patient information at the end of treatment from devices and resetting devices to their factory settings before devices are redistributed to other patients.

### 4.1.3 Program Staff Role

Careful observation of medication ingestion each time a dose is scheduled is central to the success of a DOT program. The specific personnel responsible for daily viewing and recordkeeping can vary according to the local jurisdiction and community needs, but may include licensed and non-licensed workers (health technicians, LVNs, RNs, etc.). Thus, supervision per the local jurisdiction is important to ensure safety, accuracy and completeness of therapy. Duties of these workers may include:

A. Documenting whether the medications were ingested as directed using the mechanism provided by the eDOT method and/or TB program procedures.
   i. For asynchronous VDOT, videos should be reviewed frequently (e.g., daily during the workweek and on the first day back following a weekend or holiday) to document doses ingested and promptly identify patients who require assistance.
B. Contacting the patient to identify and resolve problems when scheduled medications were not observed/confirmed being ingested.
   i. For side effects, assessing as per protocol and referring to appropriate clinical/management personnel for resolution.
   ii. For technical problems, assessing whether patient training or technical support is needed to resolve the problem and implement steps to resolve it.
   iii. For patient adherence problems, working with patient according to local protocols.
C. Maintaining patient confidentially, as per local procedures, with all encounters.
D. Assisting patient with obtaining and completing laboratory tests, x-rays, transportation, and referrals to needed resources such as additional health care, social services, and housing.
E. Assessing and reporting symptoms concerning for adverse drug reactions to medication per local protocol appropriate to the chosen eDOT method.
F. Identifying issues that affect successful eDOT implementation or maintenance and reporting them to supervisors/management for review and resolution.
G. Reinforcing counseling and educational messages provided by the patient's case manager.
H. Disbursing DOT incentives and enablers as per local department procedures.

TB programs may consider incentives or enablers throughout the course of treatment. As eDOT often includes the use of additional technologies (e.g., telephones, SMS text messaging, GPS, and internet access), these may in-themselves be seen as an enabler.

For a list of additional incentives/enablers, refer to the CDPH/CTCA Joint Guidelines for DOT[16].

#### 4.1.3.1 Patient Setting

As many eDOT modalities require visualization, patient positioning and lighting should be adjusted to maximize patient comfort, yet produce clear viewing conditions for the DOT worker. The patient should be trained how to videoconference or video record their actions in a manner that allows the DOT worker to unambiguously determine that medications were ingested. For example, patients should ensure that the quality of their image is not obscured by backlighting or glare from windows and room lights. Patients should place their cameras on a secure, stable platform to avoid wobbling and shaking during the videoconferencing session. To the extent possible, cameras should be placed at the same elevation as the patient's eyes with their face clearly visible at all times. The same should apply to the DOT worker in the case of synchronous VDOT. The DOT worker, or designated program staff member, and the patient should also discuss concerns and strategies to maximize privacy. For example, during synchronous VDOT, if other persons are present in either the patient's or the DOT worker's room, both the DOT worker and patient should be made aware and agree to their presence.

### 4.1.4 Documenting Treatment Observation

Documenting treatment observation should ideally ensure that all members of the TB program team (e.g., case manager/PHN, physician, DOT worker) have the same information for a patient. Each encounter is an opportunity to document relevant information about the patient's treatment progress. Having the documentation available to case managers and providers ensures best practice treatment decisions can be made. The documentation should also promote teamwork between the TB program staff and the patient.

Documentation may vary in each jurisdiction and by method of eDOT, according to the program design, needs, personnel and policies. If the eDOT application/method is capable of capturing and storing DOT elements (e.g., treatment adherence, side effects reported, etc.), these data could be used to complete the jurisdiction's DOT record for each patient. TB programs must decide whether medication adherence will be captured and stored within the eDOT application or on a separate encounter form (See Appendix I – Sample DOT Encounter Form).

#### 4.1.4.1 Measuring Adherence

Adherence means that the patient:

A. took all medication doses continuously as prescribed; and
B. executed eDOT procedures which allowed the DOT worker to observe or verify that the medications were ingested.

Observation rate means the number of observed medication doses divided by the number of expected doses during the period of observation.

#### 4.1.4.2 Procedures for Non-adherent Patients

Procedures must be in place that guide the DOT worker when the patient is non-adherent.

Example 1 – the patient records a video, but the DOT worker cannot clearly see the patient swallowing the pills.

Example 2 – no electronic documentation is received by the scheduled time and the patient does not notify the DOT worker regarding a technical problem.

Appropriate monitoring of therapy is vital to accurately document completion of treatment. In the event that TB staff members are not able to clearly document that medications were swallowed, the patient should be contacted immediately. This contact provides an opportunity to troubleshoot possible problems with the technology or treatment and resolve them. In the event of technology problems or unacceptable adherence that cannot be resolved, procedures should be in place to guide the TB program's response, which may vary by local jurisdiction (see Section 4.3).

### 4.2 Enrollment Procedures

#### 4.2.1 Patient Enrollment

Once eligibility for eDOT is determined, the following procedures should be reviewed with the patient by an authorized TB staff member (e.g., TB supervisor, TB coordinator, PHN, case manager) for continuation of therapy via eDOT.

A. Present the different eDOT methods that are locally available to the patient (availability may vary by health jurisdiction).
   i. If patient is interested, continue to next item.
   ii. If not, assess for concerns about eDOT and answer questions. If patient refuses, maintain patient on in-person DOT.
B. Assess the patient's literacy.
   i. If literate, continue to next step.
   ii. If not, the program should have procedures in place to confirm the patient understands system procedures and/or the consent, if required.
C. Ensure information is provided in a language that the patient understands.
D. Review overall procedures with patient, and ensure they are understood.
   i. Answer any questions the patient has about the procedures.
E. Review possible risks/discomforts and benefits of using eDOT with patient.
F. Review confidentiality statement with patient.
G. Review expectations from the TB program regarding treatment adherence and explain possible reasons for returning the patient back to in-person or another form of DOT.
H. Coordinate TB medication delivery/pickup with patient to ensure continuous supply (e.g. extended travel or hospitalizations).
I. Provide instructions to contact case manager/supervisor or provider if patient suspects he/she is having adverse drug reactions/side effects.

J. Read the elements of a eDOT agreement out loud to the patient and have him/her sign the form, which should include:
   i. how eDOT will be performed;
   ii. how confidentiality will be maintained;
   iii. how to contact their provider directly in the event of adverse drug reactions or side effects;
   iv. what the patient should do in the event of an emergency (e.g. they must leave the jurisdiction suddenly or become hospitalized) or equipment failure;
   v. how to maintain and care for equipment (if supplied by health department); and
   vi. instructions for returning equipment (if supplied by health department) upon cessation of eDOT treatment, either from completion of therapy or reversion to in-person DOT. Note, in the event the patient is able to use their own device/computer/phone, limitations of the health department's role in covering internet/data plan fees should be clearly outlined.

K. Where required by local TB program policy, have patient sign and date a Consent Form to use eDOT.
   i. File the signed and dated consent form in the patient's medical record.

#### 4.2.1.1 Patient Consent Form

Where required by local health jurisdiction policy, an informed consent process covering the chosen modality should be conducted with the patient in the language that can be easily understood at the start of eDOT (see Appendix II – Sample Consent Forms). Local, state and federal laws regarding verbal or written consent may impact which procedures to follow. Topics to consider include: the limits to confidentiality in electronic communication; an agreed upon emergency plan, particularly for patients in settings without clinical staff immediately available; process by which patient information will be documented and stored; the potential for technical failure; procedures for coordination of care with other professionals; and conditions under which eDOT services may be terminated and a referral made to in-person treatment.

### 4.2.2 Handling Equipment and Managing Technical Problems

Use of an eDOT system will require both the TB care providers and the patients to have access to needed equipment and software, which may vary by jurisdiction. Depending upon the eDOT modality selected, patients may personally own or have access to devices that are suitable for the chosen eDOT system. This should be considered on a case-by-case situation depending on local jurisdiction policy. Personal equipment, if used, should meet all standards established by the local jurisdiction. Regardless of whether the equipment is owned by the patient, or provided TB program, the following should be considered before initiating treatment with an eDOT system:

A. Plan for possible equipment malfunction (e.g., lost, stolen or broken phone, chargers, etc.). In the event the equipment is distributed by the TB program, limitations should be outlined regarding how hardware should be utilized. For patients who use their own equipment, there should also plan for the possibility that patients stop paying for service. A Phone Use Agreement form should be completed and signed by the patient as documentation that they understand the

conditions of the use of the equipment (see Appendix III Sample Phone Use Agreement Form for examples of both phone check out and return).

B. Define limitations of equipment use by the patient (e.g., data use, personal telephone use, long distance calls, texting) when the equipment is provided by the TB program. Terms of use for all equipment should similarly be described to the patient and documented in their treatment record.
C. Establish procedures for ending the use of eDOT, which includes the return of equipment (e.g., phone, charger, phone case), if it was provided by the TB program.

Patients should be provided with the following in writing: instructions on installation and use of equipment; what to do in an emergency; who to call with questions; how to troubleshoot technical problems; patient's responsibilities for damage or loss of equipment (may vary by jurisdiction); and limitations of equipment use/data use parameters if appropriate (see Appendix IV – Sample Patient Recording Procedures Pamphlet).

Prior to allowing patients to use eDOT, the TB program staff should conduct a 'test run' to ensure appropriate function of the equipment and thorough understanding by the patient.

### 4.2.3 Patient Training for Synchronous VDOT

A. Patient and DOT worker agree to a regular time for live videoconference calls;
B. Patient and DOT worker activate video equipment and assure proper functioning;
C. Patient's position is clearly visible on device display by DOT worker;
D. DOT worker can confirm patient's identity;
E. DOT worker talks to patient prior to observing medication ingestion, (e.g., asks how they are feeling, if they experienced medication side effects, if they have encountered problems);
F. Patient states the name and dosage of each TB medication and holds it in front of the camera long enough for it to come into focus before placing the pill in his/her mouth and swallows it while on camera. Note: patient should be instructed to take pills one at a time to make ingestion easier to confirm. Patients may be provided with a pill placement tool to help them organize their medications before starting to ingestion (see Appendix V – VDOT Medication Layout Tool);
G. Patient opens mouth after swallowing and shows DOT worker that the pills were swallowed; and
H. DOT worker and patient confirm the day and time for the next VDOT session.

### 4.2.4 Patient Training for Asynchronous VDOT

A. Patient and DOT worker activate video equipment and assure appropriate function and visualization;
B. Patient clearly identifies him/herself (e.g., states name or unique ID depending upon confidentiality requirements specified by the local jurisdiction);
C. Patient states whether he/she is having problems with the medicines or reports any new symptoms (e.g., nausea, vomiting, abdominal pain). Note: TB program

protocols should be provided in advance to the patient indicating whether or not the patient should take medications in the event of symptoms;

D. Patient states the name and dosage of each TB medication and holds it in front of the camera long enough for it to come into focus before placing the pill in his or her mouth and swallows them while on camera. Note: patient should be instructed to take pills one at a time to make ingestion easier to confirm. Patients may be provided with a pill placement tool to help them organize their medications before starting to ingestion (see Appendix V – VDOT Medication Layout Tool);
E. Patient opens mouth after swallowing and shows DOT worker that the pills were swallowed;
F. Patient states when the next video will be made and ends session; and
G. DOT worker communicates with patient regularly (e.g., at least weekly) by phone or in-person to ensure no side effects or concerns exist, and that patient has appropriate quantities of medication on hand. Follow TB program protocol for managing potential medication side effects and notifying the patient's case manager or healthcare provider.

### 4.3 Terminating eDOT

A patient may be returned to in-person DOT, or switched to another eDOT modality, if their healthcare provider or the TB controller believes that it is in the best interest for assuring adherence. Examples of situations that might compel the DOT worker to suggest reversion to in-person DOT include: eDOT equipment/technology malfunction which is unable to be resolved in a timely manner; patient is non-adherent to eDOT procedures; patient repeatedly misses medication doses; or patient loses or damages the eDOT equipment, or exceeds allowed service usage limits.

As with in-person DOT, the DOT worker should notify the patient's TB case manager (or other person responsible for patient adherence) when doses are missed. Stopping rules should be established in written protocols indicating when the eDOT method is failing and the patient should be returned to in-person DOT or another form of patient monitoring.

Patients can be re-considered for eDOT later in treatment if their circumstances change. These decisions may be left to the discretion of the TB controller.

## 5. Technology and Data Management

In choosing an eDOT system, factors to be considered include the software application, characteristics of the required devices(s), network connectivity options, and data security. The eDOT system and associated devices must also comply with the health department's information technology policies.

### 5.1 HIPAA Compliance

Efforts to safeguard patient PHI is mandated by the federal Health Insurance Portability and Accountability Act (HIPAA). In eDOT modalities, as in any electronic exchange of health information, only required information that is essential to successfully accomplish

safe and effective care should be included. Proper environments for recording, encryption, safe transfer, appropriate documenting and storage, and processing of health data should comply with HIPAA. Local health departments should consult with their HIPAA compliance officer, Information Technology manager, and/or local legal counsel when assessing whether an eDOT product is HIPAA-compliant in their jurisdiction.

Additional information can be found at: http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html

### 5.2 VDOT Applications

Video conferencing applications must have the appropriate verification, confidentiality, and security features necessary to meet HIPAA requirements. Where practical, health departments may recommend the preferred video conferencing software and/or video and audio hardware to the patient, as well as providing any relevant software and/or hardware configurations to ensure the security of patients' PHI. When choosing a VDOT application, consider whether it runs on Android, iOS, Windows or other device operating systems, and ensure it is suitable for the type(s) of devices that will be used by the patients.

### 5.3 Equipment Characteristics

Many eDOT devices require front-facing cameras and microphones, which allow the patients to see themselves on the screen while taking their medications. For synchronous VDOT, the device will also need a speaker so the patient can communicate with the DOT worker. The components of the device must be of high quality to ensure the audio is clear and the video resolution is high enough to read the text on a pill bottle or medication tablet. Most smartphones and tablet computers provide these features; laptop and desktop computers may require peripheral devices such as cameras or microphones. Devices used by the patient should be equipped with up-to-date operating systems and antivirus software to ensure data security.

If the patient's device is a smartphone or tablet, it should be equipped with a holster or stand that allows the patient to position the device in an upright orientation to facilitate hands-free operation with the patient's face and hands clearly visible on the device screen. Personal computers should have cameras that can be positioned to provide the same functionality.

### 5.4 Network Connectivity

Devices used for eDOT may transmit video, audio and other information to the DOT worker via cellular or internet connections. Devices that are capable of using both cellular and internet connections will maximize the likelihood that the patient will consistently be able to communicate with the DOT worker. eDOT services provided through personal computers or mobile devices that use internet-based videoconferencing software programs for synchronous VDOT should provide such services at a bandwidth of 384 Kbps or higher in each of the downlink and uplink directions. Such services should provide a minimum resolution of 640 X 360 at 30 frames per second. Because different

technologies provide different video quality results at the same bandwidth, each end point shall use bandwidth sufficient to achieve at least the minimum quality for appropriate drug adherence monitoring. A connectivity test (e.g., bandwidth test) between the patient and DOT worker should be conducted before formal eDOT sessions occur to troubleshoot possible problems or assess feasibility in a given area.

Since synchronous VDOT systems require a consistent, active connection throughout the patient/provider interaction showing the patient taking his/her medications, network connectivity requirements are more stringent for this method than asynchronous VDOT and other eDOT methods.

## 5.5 Privacy and Security

Efforts must be taken to make eDOT data transmission secure by using point-to-point encryption that meets the most updated standards. Currently, FIPS 140-2, known as the Federal Information Processing Standard, is the US Government security standard used to accredit encryption standards of software and lists encryption such as AES (Advanced Encryption Standard) as providing acceptable levels of security. Health department IT staff should be familiar with the technologies available regarding computer and mobile device security, and help select eDOT applications that meets these standards.

When the patient and/or DOT worker uses a mobile device, special attention should be paid to ensuring the privacy of information being communicated over such technology. Mobile devices should have security features available and enabled. Although specifics may vary according to local standards, health departments should consider software capable of blocking caller ID; software that prohibits more than one concurrent video session at a time; and a timeout function requiring a passphrase or re-authentication to access the device should be enabled after a period of inactivity (e.g., 15 minutes). Unauthorized persons must not be allowed access to sensitive information stored on the device, and the device must not be used to access sensitive applications or network resources.

eDOT systems should have features to assure patient contact information is restricted. Additionally, electronic equipment should have the capability to remotely disable or wipe a patient's mobile device in the event it is lost or stolen. Applications for performing these functions are available from cellular service providers and third party vendors. Some of these applications also allow users to locate a phone when its GPS function is enabled.

## 5.6 Data Storage

Cloud services that do not meet HIPAA compliance standards are not recommended for PHI or confidential data. Patients should be informed that using unapproved applications to capture, store or transmit PHI could result in inadvertent disclosure of their data. Health departments may choose to provide guidance to patients on how to best protect their own privacy. Recordings should be encrypted for maximum security. Access to the recordings should only be granted to authorized users. Applications that stream (display only) videos and other data to the DOT worker provide greater security than applications that download this information to the DOT worker's computer or other device.

To communicate expectations for both the patient and the health department, written agreements may be appropriate pertaining to the health department's policy regarding the patient sharing portions of his or her own information.

## 5.7 Data Management

### 5.7.1 Minimum Data Requirements

Regardless of the DOT method used, treatment records must be maintained for each patient. The information captured in a treatment record should include: dates of each expected dose; medication type and dosage of each medication expected; dates of treatment initiation and completion/termination; date of each dose observed; medication type and dose observed; doses held; method of DOT (e.g., eDOT, in-person DOT); and self-administered (not observed) doses.

If the chosen eDOT modality does not capture these data elements in a manner that can be extracted for monitoring and reporting purposes, a paper form may be used and kept in the patient's medical record (see Appendix I – Sample DOT Encounter Form). Alternatively, the eDOT application may be used solely to observe the patient taking his/her medication and the adherence data can be captured in a separate electronic medical record or similar database.

Software, devices and network service should be selected to minimize technical problems, but TB programs should also have written procedures for documenting the outcome in the event that a medication dose could not be observed. The DOT worker or designee should immediately contact the patient by any acceptable means once a missed dose is determined. For synchronous VDOT, this would be when the patient fails to join a scheduled videoconference. For asynchronous VDOT, a missed dose would be determined when the DOT worker sees that no video was received within a predetermined number of hours after the patient's scheduled medication time or if a video is received but does not show the patient ingesting his/her medications. Depending on the outcome of the DOT worker's investigation, the disposition of the expected dose (e.g., self-administered, failed, held, etc.) should be recorded in the patient's adherence record.

Immediate follow-up is necessary with patients who fail to connect to a videoconference or send videos to minimize the number of unobserved and failed doses. Since the reason could have to do with technical problems, resolving the problem quickly will allow the DOT worker to resume normal observation. In addition, patients using asynchronous VDOT may have videos stored on their phones that can be used to document ingestion. Unlike in-person DOT, audio or video quality, connection problems, lighting, background noise, or software glitches could make it difficult or impossible for the DOT worker to confidently determine whether the patient swallowed his/her medications. Pre-determined procedures should be established to document these events. For example, when a videoconference loses connection or a recorded video stops prematurely, but part of the dose was observed, the DOT worker may consider that an observed dose with a qualifier (e.g., "partial dose observed") entered into the database or record. Note that the frequency of these exceptional doses should be monitored and used to consider

reversion to in-person DOT. Thus, it is important to rule out technical problems quickly so that the DOT worker can detect and address problems with compliance.

### 5.7.2 Data Integration and Reporting

eDOT data allows for the possible synchronization in a health department's electronic medical record (EMR). As EMR systems and eDOT technologies evolve, efficiencies of integration should be considered. Further integration of EMRs and TB surveillance reporting systems (e.g., the CDC's Report of Verified Case of Tuberculosis [RVCT]) should also be considered.

eDOT data may also be used for standardized treatment reporting for program evaluation and surveillance. In addition, these data can be used by TB program supervisors to monitor the quality of DOT. For example, tracking the frequency of technical problems could indicate bugs in the eDOT application, or patients who are attempting to avoid taking their medications.

### 5.7.3 Data storage

For both asynchronous and synchronous VDOT, videos may be recorded and stored. Applications on smartphones, tablets and computers may allow for uploading videos to a TB program's EMR or other database. Depending on the needs and policies of the TB program, videos may be deleted as soon as they are watched, deleted after a fixed period of time (e.g., 30 days, 6 months, etc.), deleted after the patient completes treatment, or stored indefinitely.

Currently, there is no mandate for storing video captured for VDOT. However, TB programs may consider storing videos for a specified time period for quality assurance procedures, training purposes, or legal actions. The cost of keeping long term data, patient approval, and data security should be addressed by health departments considering video storage. Local and state policies should also be considered.

## 6. Supervision and Quality Assurance

As with in-person DOT, a licensed healthcare professional should provide supervision for eDOT related activities.

A yearly formal performance review should be written into the program protocol, and include:

- chart review;
- regular and ongoing supervision with DOT worker that covers setup of eDOT equipment, patient training, observation of medication ingestion, and documentation of ingestion events; and
- case management/review meetings at least monthly to identify eDOT issues and concerns.

### 6.0.1 Quality Assurance for Synchronous VDOT

Synchronous VDOT can allow for more than one DOT worker or TB provider to access the same video. While videos are streamed in real-time, the viewing atmosphere can allow more than one viewer. Supervisors or other licensed personnel can be summoned by the DOT worker if concerns exist in real-time. Further, because viewings are pre-scheduled, audits or random check-ins on DOT workers can allow for quality assurance, safe and effective care, and protocol adherence. Policies should be established for regular quality assurance procedures.

### 6.0.2 Quality Assurance for Asynchronous VDOT

Asynchronous VDOT provides the ability to continually monitor and improve the quality of DOT. Because the medication ingestion event is recorded, the videos can be viewed more than once by more than one TB worker, which allows for record verification, quality control, event monitoring, and consistent supervision. In addition, every event is recorded so post hoc reviews are possible when more quality assurance is required than originally scheduled. Inter-rater reliability can be assessed by having two or more staff members view the same videos and compare their interpretations. Policies should be established for regular quality assurance procedures.

#### 6.0.2.1 Continuous Quality Improvement

Since medication doses observed via synchronous or asynchronous VDOT should be documented on a daily basis, continuous quality improvement is possible For example, problems in viewing the patient, connectivity issues, setting/atmosphere deficits which compromise the ability to definitively view the medications, and concerns from DOT workers can and should be addressed promptly so that subsequent doses may be properly observed. Responses may include patient re-training, device repair or replacement, software updates, and changing the patient's location to improve network connectivity. eDOT methods should be employed as a tool for improving patient/provider interaction, rather than relying on eDOT to replace continual patient monitoring.

#### 6.0.2.2 Monitoring Adverse Effects of Therapy

eDOT systems, like in-person DOT, should aim to provide care without compromising safety. Identification of medication side effects is key to preventing serious adverse events during treatment. If the patient or the DOT worker has suspicion for a possible drug side effects, videos can be re-reviewed to assess clinical concerns and early warning signs.

Prior to initiating eDOT, patients should be monitored using in-person DOT until the patient's ability to tolerate his/her medications has been established. In the unlikely and undesired event of a true allergy, adverse event, or drug reaction, videos or other electronic data may be audited to explore deficits in monitoring programs in identifying problems beforehand. Lessons learned may prove beneficial towards adapting system changes to ensure safer administration, documentation, and completion of TB therapy.

#### 6.0.2.3 Assurance of Appropriate Supervision

Stored videos or electronic information may be viewed by various personnel in the health department to ensure safe, appropriate and consistent care from all patients being monitored. TB controllers, program and case managers, PHNs, LVNs, and other DOT workers can work together to provide the highest quality care for the patient, while maximizing patient autonomy. If concern exists from any stakeholder—the patient to the TB controller—archived videos or electronic information can be reviewed to assess for deficits. Further, audits can provide insight into a highly successful program, which can showcase high quality care from DOT workers and supervisors alike.

### 6.0.3 Assessing Patient Satisfaction with the eDOT Experience

eDOT programs should strive to provide not just safe and effective care, but also patient-centered care. This can serve to promote treatment adherence and reporting of problems or concerns with systems, personnel, or technology which may allow for improvement in delivery. TB programs should consider including surveys, especially with the introduction of eDOT modalities to highlight strengths and discover weaknesses. In addition to assessing adherence, side effects, and patient concerns, DOT workers may also ask about overall patient experience. This should be documented for review in aggregate to note deficiencies or areas needing more attention. DOT workers should also note concerns with eDOT programs and provider experiences.

## 6.1 Personnel Training

In addition to in-person DOT training and experience[16], initial and ongoing training in the use of eDOT provided by properly trained and licensed staff should be documented for all personnel in the program.

### 6.1.1 Initial Training of Supervisors

Personnel responsible for supervising eDOT programs may vary by jurisdiction; however, supervision remains important for the successful and safe treatment of patients. Supervisors must ensure appropriate treatment regimens, maintain the capacity to successfully troubleshoot problems experienced during treatment, and provide continual quality improvement. Thus, supervisors must be comfortable with any and all software and hardware used by an eDOT program. In the case of a new eDOT program, a supervisor may find it helpful to orient themselves to new systems before enrolling patients. Additionally, training and awareness of required equipment maintenance, inventory systems and management, and information technology changes/updates is advisable. Supervisors should also review privacy compliance, local procedures, and policy per department and jurisdiction. Once comfortable, supervisors should conduct a ‘test run’ to ensure any major impediments have received attention.

### 6.1.2 Initial Training of DOT Workers

DOT workers are responsible for the day-to-day video viewing tasks, and serve as the frontline for observing patients ingest their medication doses. DOT workers should be

trained on the use of both the hardware and software selected by the program. Supervisors should work with new trainees to orient them to local system interfaces, including how to access applications/websites/cloud servers to access patient videos (uploaded or streamed). For quality assurance, reviewing documentation and videos should be performed until the supervisor is confident in the independence of the DOT workers. Supervisors should continuously monitor DOT workers to assess for problems encountered, either technological or with patient communication.

Training procedures will vary depending upon the type of hardware and software used. It is important for DOT workers to be comfortable with these systems, or know who to contact when problems arise (i.e., eDOT software/hardware provider, health department's information technology provider, etc.).

Similar to in-person DOT, DOT workers should have at least the minimal training and competencies to assure consistent, safe and effective care. For details regarding the recommended minimal qualifications, consult the CDPH/CTCA Joint Guidelines for DOT[16].

## 7. Special Circumstances

### 7.1 Patient Travel while on eDOT

If a patient must travel during TB treatment, eDOT may be the only option to maintain continuous observation. TB staff and patients should have a shared discussion regarding equipment use (see section 4.2.2). Specifics may vary depending upon the device characteristics and the location of travel; however predefined allowances should be discussed (e.g. if the patient is traveling internationally, data-use and cellular coverage, including limitations should be defined). Additionally, backup means of communication should be established in the event of equipment malfunction or connectivity issues.

If the patient and the DOT worker—under the guidance by the TB controller—have identified an appropriate scenario for travel, an agreement documenting the shared discussion about the limitations of data use, the care of medications, the backup agreed upon means of communication, and the plan in the event of suspected medication side effect is advisable. This agreement should be placed in the patient's chart.

Travel may not be appropriate for patients who have recently initiated therapy, or who have had recent changes to their medical regimens, until their risk of side effects has been assessed by a provider.

#### 7.1.1 Asynchronous VDOT while Traveling

Depending upon the software application used, asynchronous VDOT may be considered appropriate for some patients. If the VDOT application allows patients to record videos even when their device lacks a cellular or Internet connection, and each date/time stamped video is stored on the device until connectivity is restored, then this VDOT modality would allow documentation of every medication dose ingested even when

patients travel to regions with no or low connectivity. Patients should be trained in advance of travel to continue recording each medication dose regardless of whether their videos are uploading, because the videos can be retrieved upon their return to document all doses taken. Recognizing medication side effects should be emphasized before travel in the event observation and communication becomes problematic and a predefined plan should be discussed.

### 7.1.2 Synchronous VDOT while Traveling

Depending upon the software applications used, synchronous VDOT may be a consideration for patients during travel. Specified parameters should be discussed beforehand, with considerations of time zone changes. Backup communication plans should be emphasized in the event connectivity problems arise. Given the high cost of international roaming rates for cellular phones, patients should be trained to connect via the Internet whenever possible.

## 7.2 eDOT for Pediatric Patients

Under certain circumstances, pediatric patients may be considered for eDOT. In these instances, local, state and federal laws/policies should be followed to assure appropriate informed consent is conducted with the parent or guardian (see section 4.2.1.1). Depending upon the patient, the parent or guardian may need to be involved in the medication administration. In this case, the parent or guardian should follow all procedures outlined for the appropriate eDOT modality (i.e., identifying the date, the patient, the medicine, showing the medicine, having the patient clearly in view of the camera, etc.). As with all TB treatment, if problems arise because of adherence, technologic failure, or medication side effects, the parent or guardian and patient should be contacted, supervisors should be notified and corrective action taken.

## 7.3 Monitoring Patients with Drug Resistance

Patients with drug resistant TB require longer periods of treatment and may also require administration of injectable medications. Patients with twice daily medication administration may be considered for eDOT for one of the doses allowing for in-person DOT for the other doses. Given its potential to reduce patient burden, TB patients should not be precluded from eDOT based solely on drug resistance; however, TB programs may consider using higher adherence thresholds for reverting patients to in-person DOT and monitoring the status of these patients more closely.

# 8. Policy and Legal Considerations

### 8.0.1 Confidentiality

In selecting an eDOT modality, the TB program should ensure compliance with provisions regarding the management of PHI contained in HIPAA. A program should initiate a risk assessment to determine where PHI will be stored and how it will be accessed. Such an assessment would also assist health departments in determining

who may need to sign a Business Associate's Agreement (BAA) to ensure that third parties who are given access to patient PHI are also complying with HIPAA regulations.

## 8.1 Security and Privacy

### 8.1.1 Secure lines and end points

When using eDOT, patients will potentially transmit information over unsecured, public Wi-Fi. Therefore, the eDOT modality selected should ensure the transmitted information, such as a recorded video in the case of VDOT, is encrypted to ensure that intercepted files are not viewable.

Both the user and the TB program must ensure precautions are taken to protect PHI. Passwords should be employed at both ends before a device or information can be accessed. If storing PHI on the physical device is unavoidable, the information should be encrypted and/or password protected. If a patient opts to use their own device, the TB program may wish to discuss further safeguards like additional password protection for opening applications pertaining to eDOT.

For VDOT, TB programs should be mindful of the DOT worker's environment when he or she is viewing recorded videos or live transmissions. The DOT worker should ensure that he or she is in a private location where unauthorized persons cannot see or hear the information being received from the patients.

### 8.1.2 Business Associates

Be aware of who may be potential Business Associates (BA). A BA is a person or entity other than a workforce member (e.g., a member of your office staff) who performs certain functions or activities or services on the behalf of the TB program, when the services involve the access to, or the use or disclosure of, PHI. In the case of eDOT, this may include third party vendors that provide eDOT applications.

## 8.2 Other Legal Topics

### 8.2.1 Ethical Considerations

Devices issued by TB program should be limited in what they can be used for beyond what is involved in eDOT. As incentives for patients are sometimes provided for in-person DOT, TB programs may also consider incentives to participate and comply with eDOT. Examples may include data usage, text messaging abilities, domestic calls, or other functions as permitted by the program in the context of loaned devices. Before offering such incentives, TB programs should carefully consider possible negative outcomes such as the phone being used for illicit or illegal activities.

### 8.2.2 Use of GPS to Locate a Patient

Devices used for eDOT may have locating capabilities, such as a Global Positioning Satellite (GPS) technology on smartphones, which can potentially be used by the TB

program to locate a participant using eDOT. For example, a program might use location data to locate a lost or stolen device. TB programs should establish, and share with patients, clear policies regarding the collection and use of location data.

## ACKNOWLEDGEMENTS

The authors wish to thank the following people for contributing their firsthand expertise conducting eDOT to these guidelines: Jazmine Cuevas-Mota, MPH, Kelly Collins, PhD, Fatima Munoz, MD and Valerie Mercer, MPH (University of California, San Diego, School of Medicine); Jaspreet Sidhu, RN, BSN (Imperial County Public Health Department); Stephanie Le, PHN, Monica Wong, RN, PHN, MSN, Cynthia Haines, PHN and May Miller, PHA, (Santa Clara County Health Department); Krystal Liang, RN, PHN, BSN and Pamela Kennedy, RN, BSN, PHN (San Diego County Health and Human Services Agency); Teresita J. Ampie, MEA, Laura Romo, MPH and Rocio Agraz-Lara, RN, PHN (San Francisco Department of Public Health); and Tasnim Masood, BS, Tivoli Walker, MPH and Carmencita Oliva, BS, (San Joaquin County Public Health Department). We also wish to thank Mario Gutierrez, MPH, Mei Wa Kwong, JD, Lois Ritter, EdD, MS, MA, MS-HCA, PMP, CHDA (Center for Connected Health Policy) for providing their policy expertise to these guidelines.

Funding for guideline development was provided by the California HealthCare Foundation to the University of California, San Diego (R. Garfein) and the Center for Connected Health Policy (M. Gutierrez).

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# Appendix Table of Contents

## I. Sample DOT Encounter Form

Total doses - previous med sheet

**DIRECTLY OBSERVED THERAPY MEDICATION BILLING RECORD**

MONTH/YEAR: TOTAL # DOT DOSES TO DATE: Q.D. BIW TIW SAT

Location of DOT: «Location» Date Last Med Fill: DOT Start Date: «DOT_Start_Date»

| MEDICATIONS AM/PM (circle one) | | DATE: | Mon | Tue | Wed | Thu | Fri | | Mon | Tue | Wed | Thu | Fri |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| «Medication1» «Med1_dose» | «No_Pills1» | «Med1_Freq» | | | | | | | | | | | |
| «Medication2» «Med2_dose» | «No_Pills2» | «Med2_Freq» | | | | | | | | | | | |
| «Medication3» «Med3_dose» | «No_Pills3» | «Med3_Freq» | | | | | | | | | | | |
| «Medication4» «Med4_dose» | «No_Pills4» | «Med4_Freq» | | | | | | | | | | | |
| «Medication5» «Med5_dose» | «No_Pills5» | «Med5_Freq» | | | | | | | | | | | |
| «Medication6» «Med6_dose» | «No_Pills6» | «Med6_Freq» | | | | | | | | | | | |
| «Medication7» «Med7_dose» | «No_Pills7» | «Med7_Freq» | | | | | | | | | | | |
| «Other1» «Strength1» «Dose1» «Amount1» «Frequncy1» | | | | | | | | | | | | | |
| «Other2» «Strength2» «Dose2» «Amount2» «Frequncy2» | | | | | | | | | | | | | |
| DOT By - Initials | | | | | | | | | | | | | |
| Loc: 1-8516, 2-8517, 3-N512,4-N514,5-N513, 6-TBC, 7-8518, 8-Video C-Clinic | | | | | | | | | | | | | |

S=self administered* F=failed dose* H=held dose* X=special circumstances* (Include comment on S, F, H, X)

**POSSIBLE SIDE EFFECTS**: (abdominal pain, ↓ appetite, ataxia, bruising, dark urine, diarrhea, dizziness, fever, headache, impaired hearing, impaired vision/color vision, jaundice, joint pain, nausea, numbness, skin rash, tinnitus, vertigo, vomiting, weakness, weight loss)

**Ask patient weekly by: Week 1** **Week 2**

IMMEDIATELY REPORT SIDE EFFECTS AND All S, F, H, X, to NURSE CASE MANAGER. **Preferably Monday/Date**

| DATE | COMMENTS | Initials | Signature/Title |
|---|---|---|---|
| «Date» | «Comments» | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

«Justification_for_2nd_dailyt_DOT_encount»

Site Of Disease: «Site_CodeSite_of_Disease» Billing Code: «Billing_Code»

| | | |
|---|---|---|
| Insurance: «Insurance» | ID #: «ID» | Issue Date: «Issue_Date1» |
| Other Insurance: «Other» | ID # «ID2» | Issue Date: «Issue_Date» |
| CASE MANAGER: «Case_Manager» | | |
| Pt. name: LAST: «Last_Name» FIRST: «First_Name» | D.O.B: «DOB» | CASE #: «Case» |

HHSA: TB-71 (8/14) Original: P576 Registry Clerk County of San Diego Health and Human Services Agency

# II. Sample Consent Forms

## i. San Diego Health and Human Services Consent English and Spanish

County of San Diego

NICK MACCHIONE, FACHE
DIRECTOR

HEALTH AND HUMAN SERVICES AGENCY
PUBLIC HEALTH SERVICES
TUBERCULOSIS CONTROL BRANCH
3851 ROSECRANS STREET, MAIL STOP P-576
SAN DIEGO, CA 92110-3134
(619) 692-5565 • FAX (619) 692-5650

WILMA J. WOOTEN, M.D., M.P.H.
PUBLIC HEALTH OFFICER

**CELL PHONE VIDEO DIRECTLY OBSERVED THERAPY (DOT) CONSENT FORM**

Patient Name _____

I am aware that I have been diagnosed with tuberculosis (TB.) It is the standard in San Diego County for TB medications to be observed in order to assure adherence to therapy. The use of cell phone video technology may have certain benefits to me in providing greater flexibility in time of therapy.

I understand that observation of my treatment will be performed using a cell phone video. The cell phone, loaned to me, will be password protected. TB Control staff will have access to my videos and the information in them. I agree to allow TB Control staff to view my videos. I understand that TB Control will do its best to keep the videos private. It is possible that someone who should not have this information may see it. TB Control cannot ensure complete privacy. In order to protect my privacy, the cell phone number will be used instead of my name in the videos. I understand that cell phone transmission will let TB Control know where I took the medications.

It will not be used to locate me personally. I agree to let TB Control staff view the street level location ____ or city level location ____ or I do not agree to let the TB Control staff view any location data sent with my videos ____. In the event that the phone is lost or stolen, the staff will track the phone and erase the data on the phone remotely.

I understand that I may switch back to standard in-home observed therapy at any time during the treatment. I also understand that I may be removed from participation and return to standard in-person DOT if the cell phone is lost or stolen or the TB Program, or my doctor, decides that it is better to continue my TB treatment by in-person DOT.

I understand that the cell phone and all peripherals/cables are not my personal property. I agree to return all the equipment to the San Diego County Health and Human Services Agency within four business days of the end of treatment.

_____ _____
Signature of Patient Date

_____ _____
Signature of Witness Date

HHSA: TB-291 (9/14)

County of San Diego

NICK MACCHIONE, FACHE
DIRECTOR

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WILMA J. WOOTEN, M.D., M.P.H.
PUBLIC HEALTH OFFICER

## FORMULARIO DE CONSENTIMIENTO PARA VIDEO CELULAR DE TERAPIA DE OBSERVACION DIRECTA (DOT)

Nombre del Paciente _____

Estoy consciente de que he sido diagnosticado(a) con tuberculosis (TB.) En el Condado de San Diego, la observación de la toma de medicamentos es práctica estándar para asegurar el cumplimiento con el tratamiento. El uso de la tecnología de vídeo por teléfono celular puede tener ciertos beneficios para mi al proporcionar una mayor flexibilidad en el horario de tratamiento.

Entiendo que la observación de mi tratamiento se llevará a cabo por medio de un vídeo del teléfono celular. El teléfono celular que se me preste, estará protegido por una contraseña. El personal de Control de Tuberculosis tendrá acceso a mis videos y a la información que contienen. Estoy de acuerdo en que el personal de Control de Tuberculosis pueda vea mis videos. Entiendo que el personal de Control de Tuberculosis hará todo lo posible por mantener los videos confidenciales. Es posible que alguien que no debiera tener acceso a esta información pudiera verlos. El personal de Control de TB no puede garantizar privacidad absoluta. El número de teléfono celular se puede utilizar en lugar de mi nombre en los videos con el fin de proteger mi privacidad. Entiendo que la transmisión del teléfono celular le permitirá al personal de Control de Tuberculosis saber donde tomé los medicamentos. No se utilizará para localizarme personalmente. Acepto permitir al personal de Control de Tuberculosis ver la localización a nivel de la calle ____ o a nivel de ciudad____, o NO acepto que el personal de Control de Tuberculosis vea los datos de ubicación enviados con mis videos_____. En el caso de que el teléfono se pierda o sea robado, el personal podrá rastrearlo y borrar los datos en forma remota.

Entiendo que puedo regresar al tratamiento observado domiciliario estándar en cualquier momento. Entiendo también que puedo ser retirado(a) de la participación para regresar a DOT estándar en persona si el teléfono se pierde, es robado o si el Programa de TB, o mi médico, decide que es mejor continuar mi tratamiento de tuberculosis por DOT en persona.

Entiendo que el teléfono celular y todos los accesorios/cables no son de mi propiedad personal. Estoy de acuerdo en devolver todo el equipo a la Agencia de Servicios Humanos y de Salud del Condado de San Diego en un plazo de cuatro días hábiles al finalizar el tratamiento.

_____ _____
Firma del Paciente Fecha

_____ _____
Firma del Testigo Fecha

HHSA: TB-291 (9/14)

## ii. San Francisco Department of Public Health Consent

City and County of San Francisco
Department of Public Health

Tuberculosis Control Section
Julie Higashi, MD, PhD – Director

Edwin M. Lee
Mayor

**CELL PHONE VIDEO DIRECTLY OBSERVED THERAPY (DOT) CONSENT FORM**

Patient Name _____

I am aware that I have been diagnosed with tuberculosis (TB). It is standard in the City and County of San Francisco for TB medications to be observed in order to assure adherence to therapy. The use of cell phone video technology may have certain benefits to me in providing greater flexibility in time of therapy.

I understand that observation of my treatment will be performed using a cell phone video. TB Control staff will have access to my videos and the information in them. I agree to allow TB Control staff to view my videos. I understand that TB Control will do its best to keep the videos private. Videos will be uploaded to a HIPAA-compliant secure server, and will only be accessed by staff members with a unique username and password. In order to protect my privacy, my patient number will be used instead of my name in the videos.

I understand that I may switch back to standard in-person directly observed therapy (DOT) at any time during the treatment. I also understand that I may be removed from participation and return to standard in-person DOT if the cell phone is lost or stolen, or if the TB Program or my doctor decides that it is better to continue my TB treatment by standard in-person DOT.

I understand that the cell phone and all peripherals/cables are not my personal property. I agree to return all the equipment to the San Francisco General Hospital Tuberculosis Clinic as per program request.

_____ _____
Signature of Patient Date

_____ _____
Signature of Staff Member Date

San Francisco General Hospital • Ward 94
1001 Potrero Avenue, San Francisco, CA 94110
Phone: (415) 206-8524 • Fax: (415) 206-4565 • Web: www.sftbc.org

Updated 7/8/14

## iii. Riverside County Synchronous VDOT Consent

**COUNTY OF RIVERSIDE**
**DEPARTMENT OF PUBLIC HEALTH**
**DISEASE CONTROL**

Video Directly Observed Therapy
Therapy (DOT) Consent Form

**Serial number:** _____

I am aware that I have been diagnosed with tuberculosis (TB). I will need a long course of medication for cure. I will be receiving my treatment from Riverside County Department of Public Health Disease Control. Direct observation of medication dosing is normally done in the patient's home or at the treating facility.

During my treatment, observation of dosing will be performed using a computer WebEx link. I understand that a laptop and/or a webcam with software will be placed in my home. I agree to allow the TB nurse watch me take my medicines over the computer at a prearranged time either daily or twice weekly.

I understand that I may request to switch back to standard in-home observed therapy at any time. The use of video technology may have certain benefits to me. It is hoped that Video Directly Observed Therapy will be less intrusive and allow greater flexibility in time of therapy. The use of video technology is not believed to carry any risk for me.

I understand that the laptop and/or webcam are the property of Riverside County Department of Public Health Disease Control. I agree to return all equipment to Disease Control staff, within two business days of the end of my treatment, or upon their request.

I will notify Disease Control at (760) 863-8172 if I have any problems logging on, or if I need to change the scheduled time for Video DOT.

_____ _____
Signature of Patient (Parent/Guardian) Date

_____ _____
Signature of Nurse Date

Specific Procedure:

1. Turn on computer and go to: https://countyofriverside.webex.com
2. Log in by using the password given by your TB Case manager
3. Obtain meeting number to join by calling DOT staff
4. Face webcam
5. Display face and confirm your identity with DOT staff
6. Report any problems with medications
7. Display pills
8. Swallow pills

**9/11 East**

## III. Sample Phone Use Agreement Form

### *i. San Francisco Department of Public Health Cell Phone Check Out Form*

City and County of San Francisco
Department of Public Health

Edwin M. Lee
Mayor

Tuberculosis Control Section
Julie Higashi, MD, PhD – Director

# VDOT Cell Phone Sign Out Form

I, _____ have been given a _____
(participant Name) (brand)

cell phone on ____ / ____ / ____ for use during my treatment at the San Francisco Department of Public Health TB Controlin the Video Directly Observed Therapy (VDOT) program.

*Participant please write your initials besides each statement below to indicate that you understand and agree:*

____ I am aware that this phone is only to be used to upload videos of myself taking my medication and to make phone calls or text messages directly related to my TB treatment.

____ I am aware that I am the only person authorized to use this cell phone.

____ I am aware that if I use this phone for unapproved purposes, I may be withdrawn from the VDOT program and return to being watched taking my TB medications in person.

____ I am aware that if this phone is lost, stolen, or damaged, I may incur a $20 fee and also have to return to being watched taking my TB medications in person.

____ I am aware that the VDOT phone app, website, and server where videos are stored meet San Francisco Department of Public Health security requirements for patient privacy, but there is always a small risk that my image or voiceprint may become public.

____ I am aware that at the end of my participation in the VDOT project I will have to return the phone, charger and holster to the County TB program.

____ I am aware that the SF TB Program reserves the right to use certain information about my use of the wireless service, including details of when I use data services and about telephone calls. This information will be used in the event the telephone is lost, stolen, or the SF TB program cannot locate me through the usual channels.

_____ _____
Participant Signature Date

_____ _____
Staff Member Signature Date
AND Witness Signature (needed for patient unable to read/or of consenting age)

San Francisco General Hospital • Ward 94
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Phone: (415) 206-8524 • Fax: (415) 206-4565 • Web: www.sftbc.org

## ii. San Francisco Department of Public Health Cell Phone Return Form

City and County of San Francisco
Department of Public Health

Edwin M. Lee
Mayor

Tuberculosis Control Section
Julie Higashi, MD, PhD – Director

# VDOT Cell Phone Return Form

I, _____ have received a;
(Staff Member Name)

*Staff member – Please check mark each item returned by participant.*

____ _____ (brand) cell phone

____ Cell phone charger

____ Cell phone holster

from _____ on _____/_____/_____.
(Participant Name)

_____ _____
Staff Member Signature Date

_____ _____
Participant Signature Date

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1001 Potrero Avenue, San Francisco, CA 94110
Phone: (415) 206-8524 • Fax: (415) 206-4565 • Web: www.sftbc.org

### iii. San Francisco Department of Public Health VDOT App Checkout

City and County of San Francisco
Department of Public Health

Edwin M. Lee
Mayor

Tuberculosis Control Section
Julie Higashi, MD, PhD – Director

## VDOT Phone App Sign Form

I, _____ am being given acces to the
(participant Name)

VDOT phone App on ____ / ____ / ____for use on my personal phone during my treatment at the San Francisco Department of Public Health TB Control in the Video Directly Observed Therapy (VDOT) program.

*Participant please write your initials besides each statement below to indicate that you understand and agree:*

____ I am aware that this phone App is only to be used to upload videos of myself taking my medication.

____ I am aware that I am the only person authorized to use this phone App.

____ I am aware that if I use this phone App for unapproved purposes, I may be withdrawn from the VDOT program and return to being watched taking my TB medications in person

____ I am aware that the VDOT phone app, website, and server where videos are stored meet San Francisco Department of Public Health security requirements for patient privacy, but there is always a small risk that my image or voiceprint may become public.

____ I am aware that at the end of my participation in the VDOT program I will have the Staff at TB control Delete the Phone App from my phone.

____ I am aware that the SF TB Program reserves the right to use certain information about my use of the Phone App, This information will be used in the event the SF TB program cannot locate me through the usual channels.

_____ _____
Participant Signature Date

_____ _____
Staff Member Signature

AND Witness Signature (needed for patient unable to read/or of consenting age)

San Francisco General Hospital • Ward 94
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# IV. Sample Patient Recording Procedures Pamphlet



## Video Cell Phone Direct Observed Therapy (VDOT)

### Important Phone Numbers

If you are experiencing problems with your medication, or you are experiencing new or uncomfortable side effects call your TB Case Manager or health care provider immediately. If this a medical emergency, call 9-1-1.

TB Control Department:
Name:_____
Phone:_____

TB Case Manager:
Name:_____
Phone:_____

Private Doctor:
Name:_____

DOT Monitor:
Name:_____

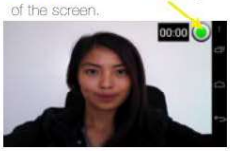
University of California, San Diego
School of Medicine
Division of Global Public Health
Phone: 619-767-9602
Email: rgarfein@ucsd.edu

### Patient Recording Procedures

### Recording Procedures

1. Gather medications, water, and cell phone in well-lit location.
2. Turn phone on and set it up horizontally in front of your face on a flat surface.
   a. Note: Phone must be horizontal to record videos.
3. Press the VDOT icon on the Home Screen.
4. In the application, press the "Record" button. Make sure you can see your face clearly on the screen.

5. To begin recording, press the **GREEN** button on the top right of the screen.




6. Video script: Say your participant ID# and location. Specify the number and type of medication by name, shape, size and/or color.
7. Hold first pill in front of camera. Say the name and dosage. Swallow pill.

8. Repeat Step 7 until all pills are taken.
9. Say when the next dose will be taken.
10. To end the recording, press the **RED** button on the top right of the screen.


### Video Confirmation

11. When recording stops, video is automatically sent to the DOT Monitor.
12. A status bar will appear showing the progress of your video upload.

12. To check the status of you video, from the home screen press the "Status" button.

Your video uploads will appear as follows:


Note: For privacy, you can view the status, but not the video themselves. If you video does not upload successfully, first check that your Wi-fi is "ON" and if so, take your phone to a new location for better connection.

# V. Sample VDOT Medication Layout Tool

**Video DOT Medication Layout Tool**

**Today is** _____(mm/dd/yy)

| | | | | |
|---|---|---|---|---|
| **Place Pills Here:** | | | | |
| **Name of Pill:** | _____ | _____ | _____ | _____ |
| **Number:** | ___ pills | ___ pills | ___ pills | ___ pills |

**If you are experiencing any of the following side effects, contact your TB care provider at: _____ before taking any medication.**

| | | |
|---|---|---|
| - Abdominal pain/stomach ache | - Dark urine | - Numbness hands/feet |
| - Decreased appetite | - Diarrhea | - Skin rash/Itching |
| - Nausea | - Bruising | - Fever |
| - Vomiting | - Headache | - Dizziness |
| - Yellow skin | - Change in vision/color vision | - Muscle / joint pain |

Version 1.0, Last modified 06/14/2016

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