

 <p><b>Release of HIV/AIDS and STD Data</b></p>	<i>Policy Number</i>	302.001
	<i>Effective Date</i>	April 9, 1999
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	<i>Subject Matter Expert</i>	Surveillance Specialist
	<i>Approval Authority</i>	Branch Manager
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## 1.0 Purpose

This policy describes guidelines for the release or publication of data associated with HIV/AIDS and STD surveillance, epidemiologic, public health follow-up, and the Texas HIV Medication Program (THMP). This policy aligns with requirements in the DSHS HIV and STD Program Operating Procedures and Standards (POPS) (<http://www.dshs.state.tx.us/hivstd/pops/default.shtm>), the Centers for Disease Control and Prevention's (CDC) Program Operations Guidelines for STD Prevention, (<http://www.cdc.gov/std/Program/overview/TOC-PGoverview.htm>), and the CDC's Technical Guidance for HIV/AIDS Surveillance Programs (Atlanta, GA; 2006) wherever possible and/or appropriate.

## 2.0 Authority

All information obtained and compiled by DSHS related to a disease report is confidential and may be used or released only as permitted by Health and Safety Code §81.046. Additionally, DSHS is legally bound by federal assurances of confidentiality (Sections 306 and 308(d) of the Public Health Service Act, 42 US Code 242k and 242m(d)) which prohibit disclosure of any information that could be used to directly or indirectly identify patients. This policy has been written in accordance with the Health and Safety Codes §81.046 and §81.103 and the Texas Administrative Codes §97.146 and §98.13 of Title 25.

## 3.0 Definitions

**Aggregate Data** - data which are based on combining individual level information; Aggregate data may contain potentially identifying information, particularly if the aggregated data are very detailed or for a small subset of individuals.

**Central Office** – the HIV/STD Program, Department of State Health Services (DSHS) main office located in Austin, Texas.

**Confidential Information** – any information which pertains to a patient that is intended to be kept in confidence or kept secret and could result in the identification of the patient should that information be released.

**Confidentiality** - the ethical principle or legal right that a physician or other health professional or researcher will prevent unauthorized disclosure of any confidential information relating to patients and research participants

**De-identified (Pseudo-anonymous) Data** - individual record-level data which has been stripped of personal identifiers (e.g., name, address, social security number) but may contain potentially identifying information (e.g., age, sex, race/ethnicity, locality information) that when combined with other information may identify an individual. If the combining of information could identify an individual, these data are considered confidential.

**Demographics** – refers to selected population characteristics, including race/ethnicity, sex, and age.

**External** – entities outside of the DSHS Central Office that the HIV/STD Program contracts with or works in association with to conduct public health activities related to HIV/STD surveillance, epidemiology, public health follow-up and the medication program.

**Fifty Rule** – refers to the acceptable threshold for the release of aggregate HIV/AIDS and STD surveillance, epidemiologic, and public health follow-up data. The underlying population of the statistic released must be a population of greater than fifty people. The underlying population must also be at least twice the number of cases.

**Geocode** - is a representation format of a geospatial coordinate measurement used to provide a standard representation of an exact geospatial point location at, below, or above the surface of the earth at a specified moment of time.

**Geographic Information System (GIS)** – is an information system capable of integrating, storing, editing, analyzing, sharing, and displaying geographically-referenced data.

**HIV/STD Program** – consists of the two branches of the DSHS Prevention and Preparedness Unit: the HIV/STD Comprehensive Services Branch and the HIV/STD Epidemiology and Surveillance Branch.

**Institutional Review Board (IRB)** - is a group that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the subjects.

**Local Responsible Party (LRP)** – an official who accepts responsibility for implementing and enforcing HIV/STD policies and procedures related to the security and confidentiality of HIV/STD surveillance, epidemiology, public health follow-up and medication program data and information and has the responsibility of reporting and assisting in the investigative breach process.

**Personal Identifier** - a datum or collection of data which allows the possessor to determine the identity of a single individual with a specified degree of certainty; a personal identifier may permit the identification of an individual within a given database. Bits of data, when taken together, may be used to identify an individual. Personal identifiers may include name, address or place of residence, social security number, telephone number, fax number, and exact date of birth.

**Population** - a group of people defined by demographic characteristics such as age, race, sex, or location of residence

**Potentially Identifying Information** – information which, when combined with other information, could potentially identify an individual or individuals. This includes but is not limited to such information as medical record/case numbers and demographic or locality information that describe a small subset of individuals (e.g., block data, zip codes, race/ethnicity data).

**Surveillance** - the ongoing and systematic collection, analysis, and interpretation of health data in the process of describing and monitoring a health event. This information is used for assessing public health status, triggering public health action, defining public health priorities and evaluating programs.

## 4.0 Policy

The policy of DSHS is to ensure that HIV/AIDS and STD data are released and/or published while maintaining patient confidentiality. The policy is also to ensure that individual record-level data containing personal identifiers are only released with proper legal authority. HIV/STD Program staff must assess the potential impact of proposed data releases on confidentiality, and staff responsible for the release of HIV/STD data must take steps to prevent the identification of individuals.

## 5.0 Persons Affected

Person affected are DSHS employees and external entities that have access to HIV/STD surveillance, epidemiologic, public health follow-up and THMP data.

## 6.0 Responsibilities

The Local Responsible Party (LRP) is responsible for implementing and enforcing these data release guidelines. For the HIV/STD program, the managers of the HIV/STD Epidemiology and Surveillance Branch and the HIV/STD Comprehensive Services Branch are the LRP, each responsible for the proper release of the information originating from that program area. The HIV/STD Epidemiology and Surveillance Branch Manager will be responsible for the proper release of HIV/STD surveillance and epidemiologic data. The HIV/STD Comprehensive Services Branch Manager will be responsible for the proper release of THMP data and information. The LRP are jointly responsible for the proper release of public health follow-up data.

Regional programs and agencies contracting with the Program for surveillance or public health follow up must designate an LRP to oversee the release of HIV/STD data from their program. Regional programs and contractors that handle HIV/STD surveillance, epidemiologic, and public health follow-up data must develop a policy that is at least as restrictive as the DSHS HIV/STD Program's policy outlining guidelines for the release of local HIV/STD data or they may choose to adopt the HIV/STD Program's policy.

## 7.0 Data Release Guidelines

### 7.1 Aggregate Data

#### 7.1.1 Fifty Rule

Aggregated HIV/AIDS and STD surveillance, epidemiologic, and public health follow-up data may be released if the underlying population consists of more than fifty people. Furthermore, the underlying population must be at least twice the number of cases. The size of the underlying population must be verified through the U.S. Census Bureau. Tables consisting of cells that do not satisfy the Fifty Rule are acceptable for release if those cells have been suppressed. Additional cells may also need to be suppressed to prevent the derivation of the suppressed data. Alternatively, data are acceptable for release if pooled to span a longer time period (i.e., 3 or 5 year periods). Another option is to collapse data categories if the data has been stratified by one or more categories, such as sex or age. All data released by DSHS at the zip code level or smaller and data that do not meet the fifty rule must be reviewed and approved for release by the DSHS HIV/STD Epidemiology and Surveillance Branch Manager. When population data are not available, the DSHS HIV/STD Epidemiology and Surveillance Branch Manager should be consulted. All data released by the regional programs and contractors can be released with the approval of the LRP at the local program.

#### 7.1.2 Geographic Data

Data depicted on a map should be consistent with the aforementioned Fifty Rule. Geographic areas with populations that do not satisfy the Fifty Rule must be aggregated

with data from one or more other geographic areas, although mapped data points with values of zero are acceptable for release.

The release of data in a map format created with GIS should not be accompanied by the individual layers and corresponding attribute tables used in the production of the map. The map should be released as a stand-alone image of a final product (e.g., JPEG format).

### **7.1.3 Medication Program Exception**

The THMP may release aggregate program utilization and cost data without adherence to the Fifty Rule. Sub-county level data or stratified data must be reviewed and approved by the THMP manager or designee prior to release. All requests for THMP aggregate data will be processed by THMP staff and tracked by the THMP manager.

## **7.2 De-identified Individual Record-Level Data**

The HIV/STD Program rarely releases de-identified individual record-level data. These data are only released for research or public health purposes, and these data shall only be released with a data sharing agreement in place and upon receiving approval from the LRP.

### **7.2.1 Geocoded Data**

Individual record-level data consisting of geocoded address data for release in a map format or data file should not contain the geographic coordinates of addresses. Instead, individual addresses will identify the geographic level (e.g. county, census tract) to which they were geocoded.

### **7.2.3 Registry Matching**

Confidential HIV/STD surveillance, epidemiologic, and public health follow-up data are routinely matched with data in other disease registries (e.g., cancer, tuberculosis) and data systems to improve data quality as a part of routine disease surveillance. HIV/AIDS and STD data may not be released to other programs for matching. Rather, the comparison of disease registries and other program data should be accomplished by the HIV/STD Program staff. The LRP is responsible for ensuring that data sharing agreements are in place when data are shared for matching purposes and are consistent with HIV/STD Program policies pertaining to the release of data.

## **7.3 Personally Identified Individual Record-Level Data**

The HIV/STD Program strongly discourages the release of individual patient records that contain personal identifiers. In very limited circumstances, a patient's personal records may be released to providers, legal entities, and/or directly to the patient. The HIV/STD Program may also disclose individual patient data for public health purposes.

### **7.3.1 Patient Records**

For requests through the HIV/STD Epidemiology and Surveillance Program, providers, patients and/or their lawyers may request only data relating to the patient. HIV/STD public health follow-up data will not be released to patients, providers, or legal entities under any circumstances, as those data contain partner information.

### **7.3.2 Public Health Purposes**

Following routine matching of confidential HIV/STD surveillance, epidemiologic, and public health follow-up data with data in other disease registries, the HIV/STD Program may provide the other program with data on persons who are also diagnosed with an STD, including HIV. The LRP is responsible for ensuring that data sharing agreements are in place when data are shared and are consistent with HIV/STD Program policies pertaining to the release of data and maintaining confidentiality of the data.

### **7.3.3 THMP**

Due to statutory provisions protecting the confidentiality of the manufacturers' drug pricing data (Federal Omnibus Budget Reconciliation Act of 1990 and in Section 340B of the Public Health Services Act, 42 U.S.C. 256B), drug pricing lists are considered restricted and cannot be released. Client records containing personal identifiers may be released to treating physicians, servicing pharmacies, contractors, the patient, or other programs as necessary for the client to obtain services. THMP routinely shares THMP data with pharmacy benefit manager contractors, Medicare, and Medicaid. The LRP is responsible for ensuring that data sharing agreements or appropriate contracts are in place when THMP data are shared.

## **8.0 HIV/STD Program Procedures**

### **HIV/STD Epidemiology, Surveillance and Public Health Follow-Up Data**

#### **8.1 Responding to Requests for Aggregated Data**

Requests for data present an opportunity for direct interaction between the HIV/STD Program and our customers in the public, the media, the legislature, and other public health agencies. DSHS staff handling data requests should extend the most professional, courteous, accurate and rapid service available. The following procedure provides guidance for fulfilling data requests. DSHS recommends that regional and contracting programs create procedures for handling and tracking data requests that are similar.

Customers commonly initiate data requests via telephone or e-mails. An assigned staff member will work with the customer to complete the data request by clearly defining the specifics of the data requested. For requests of data that the HIV/STD Program does not have, program staff should refer the customer to other sources when possible. Key criteria for defining data requests may include:

- Disease(s) or diagnosis
- Reported cases versus diagnosed cases
- Number of cases, rates, or both
- Time period
- Geographic location(s)
- Demographic crosstabs (e.g., age, sex, race, risk group, etc) or restrictions (e.g., living cases, male cases, female cases, etc)
- Date the data request must be completed

Occasionally, the customer may not know how to define the data needed. In such cases, the assigned staff member may help define the request based on the question(s) the customer is trying to answer. For formal Public Information requests, assigned staff members are **not** permitted by state law to inquire about why the request is being made.

The assigned staff member will gather the customer's contact information, including e-mail address or fax number, in order to send the data. In general, assigned staff members should accept and meet the customer's deadline for receiving the data. If the deadline is unusually short, cannot be met, and/or another deadline cannot be negotiated, consult the LRP.

When completing data requests, assigned staff members should save the syntax and output files in a folder for future reference. These files are recorded in the data request tracking log to allow others to use or modify them for future requests. The requested data are most often saved in an electronic file format (e.g., Excel, Word, html, etc) and e-mailed to the customer. All data files should be clearly annotated, including titles and notes to thoroughly describe what the data represent. Additional notes should also be included to describe any special circumstances or limitations of the data, such as why some cells are suppressed.

If the data results are complete and follow the guidelines described in this policy, they may be sent to the customer along with the staff member's contact information.

If the data require further approval from the LRP due to issues with the data results, such as small underlying populations, then the results may only be sent upon approval. Staff must not send questionable data through e-mail to the LRP for approval. Until it is approved, the data should be treated as confidential information and may not be e-mailed, even internally. Questionable data are to be hand-delivered.

## **8.2 Data Request Tracking**

### **8.2.1 HIV/STD Surveillance Data**

During and/or immediately following a request for data, the assigned staff member completing the request will document the request in the EpiDiv Request Log. Providing documentation of data requests in a centralized location allows the HIV/STD Program to quantify who its customers are and how they are being served. In addition, by identifying contact names and file information, future requests for repeat or similar data can be fulfilled more efficiently.

The Request Log is located on the public network in S:\Requests\Epidiv New Request Log.xls. Requests are organized by date. Select the appropriate tab for the year and scroll down to the month that the request was completed. Complete as many of the fields as possible.

### **8.2.2 Handling Requests from Special Customers**

Staff should respond to requests from the media by following Policy Number AA-5007 (<http://online.dshs.state.tx.us/policy/agency/aa%2D5036.htm>).

All DSHS staff who receives a legislative contact should notify the appropriate Branch Manager immediately. Before responding to a legislative request, staff must obtain approval from appropriate Branch Manager prior to release of data. Immediately following the completion of a legislative request, a Legislative Contact Report should be e-mailed. At minimum, this report will be submitted to the assigned staff member's supervisor, the Branch Managers of the HIV/STD Epidemiology and Surveillance Branch and the Comprehensive Services Branch, the Unit Manager of the Epidemiology and Surveillance Unit, the Director of the Prevention and Intervention Section, the Assistant Commissioner for Prevention and Preparedness, the Office of Governmental Relations, and the individual responsible for legislative liaison at the Division of Prevention and Preparedness.

This report should contain the following information:

- Who made the request – which Legislator's office, contact person's name, telephone number and other contact information
- When the request was received
- What the question or issue was that prompted the request
- Summary of the response or copy of data released
- Any future follow-up required
- Name and contact information for the employee that responded to the request

Staff who receive an Open Records or Public Information Act request should follow Policy Number AA-5007 (<http://online.dshs.state.tx.us/policy/agency/aa%2D5007.htm>).

## **8.3 De-identified Data Requests**

De-identified individual record-level data are only released upon approval by the LRP. Customers commonly initiate data requests via telephone or e-mail. For HIV/STD surveillance, epidemiologic, and public health follow-up data requests, customers must sign

Data Release and Confidentiality Agreements prior to receipt of data. The Data Release and Confidentiality Agreements will specify:

- the permitted uses, disclosures, and final disposition of the data
- who is permitted to use or receive the data
- that the data recipient will use appropriate safeguards to prevent use or disclosure of the information outside that specified by the Data Release and Confidentiality Agreements

The dataset will be prepared by assigned staff and provided to the customer via secured means upon approval by the LRP. The LRP or designee will file the paperwork associated with the request and enter the request in the Data Release Tracking Log. The LRP or designee will provide the customer with a signed copy of the Data Release Agreement and must store hard copies of the agreement. Follow-up will be conducted with customers who receive individual record-level data to ensure that the data and any additional data files created have been properly destroyed on their stated project completion date.

All THMP data requests will be processed by THMP staff and tracked by the THMP manager.

External sites should develop and use their own data release agreement for local individual record-level requests, or the external sites may choose to use the DSHS Data Release Agreement.

#### Handling Requests for Research Purposes

Requests for individual record-level data from the HIV/STD Epidemiology and Surveillance Branch for research purposes must be reviewed and approved by the DSHS Institutional Review Board (IRB) and the Local Responsible Party. Procedures for submitting data requests to the DSHS IRB can be found at <http://www.dshs.state.tx.us/irb/default.shtm>. The requestor must also obtain approval from an IRB at the institution responsible for oversight of the research program. Prior to releasing datasets, all personal identifiers must be removed. Datasets that contain potentially identifying information must be maintained by the recipient in a manner consistent with the most current DSHS confidentiality and security guidelines regarding physical and electronic security. The staff of the research institution must comply with all security and confidential training requirements.

Upon approval by the IRBs, Data Release and Confidentiality Agreements must be signed prior to releasing the data (See Appendix A). The Data Release Agreement must specify the length of time that the research institution will maintain the data. All the data must be removed from all electronic files and hard copies at the conclusion of the timeframe specified in the Data Release Agreement. The research institution must provide documentation that these data have been destroyed in a confidential manner. Requests for THMP individual record-level data for research purposes must be reviewed by the DSHS IRB.

## **8.4 Personally Identified Individual Record-Level Data**

### 8.4.1 Requests From Legal Entities

Requests for individual HIV/STD surveillance, epidemiologic, or THMP patient records initiated via court orders, subpoenas, or legal counsel for a patient must be directed to the DSHS Office of General Counsel. Patients and/or their lawyers must sign a medical record release form before any data are released. The LRP must see the medical record release form and approve before data is released.

### 8.4.2 Requests by Patients or Providers

Providers requesting patient records or patients requesting their own records through the HIV/STD Epidemiology and Surveillance Branch must be directed to the DSHS Office of

General Counsel. A medical record release form must be signed by the patients and the LRP must see the medical release form and approve before data is released. Requests for THMP client records do not need to be directed to the DSHS Office of General Counsel.

## 9.0 Revision History

Date	Action	Section
11/09/2009	Clarification that local policy must be at least as restrictive as DSHS policy  Clarification that the local LRP can approve data released at the local program level	6.0  7.1.1
07/02/2008	Extensive revision too numerous to list, therefore treated as new policy. Previously, this policy was numbered as 020.061	NA