Modification to the Louisiana Register (Sanitary Code), May 2019

Frequently Asked Questions (FAQ)

On May 20, 2019, the Louisiana Sanitary Code was appended with the following language:

Electronic reporting by a laboratory/facility shall include any results, negative or positive, for all components of testing indicative of the following conditions:

1. hepatitis C virus;
2. human immunodeficiency virus (HIV), including nucleotide sequences; and
3. syphilis.

This reporting requirement is for laboratories only, and only for laboratories that report via electronic reporting mechanisms. These electronic laboratory reports are received at the Office of Public Health (OPH) and processed using the same secure and protected methods as all positive test results.

What are the reasons for modifying the Louisiana Sanitary Code?

The changes to the Louisiana Register began with a request for negative laboratory data for HIV and syphilis, and the request for HCV data was considered much later. This process did not begin due to HCV.

Louisiana determined the need for syphilis and HIV negatives due to the passage of the Third Trimester Testing law in 2014 and the national change in the HIV testing algorithm (to identify acute infections) in 2014. OPH requires the robust and proper screening of pregnant women and their newborns to work towards elimination of congenital syphilis and perinatal HIV transmission. In consultation with other OPH Programs and leadership, it was determined that negative reporting for HCV would allow the state to identify acute HCV infections, as well as persons cured of HCV.

OPH will use the negative laboratory reporting to improve public health understanding and practices related to the following:

- Determine if an individual is actively infected;
- Identify when someone is newly infected for more timely, targeted prevention and response efforts (The risk of disease transmission to others is highest when someone in newly infected);
- Differentiate acute/active versus treated/inactive cases by comparing positive screening tests with confirmatory tests (testing algorithms can include positive and negative components for persons who result as positive);

- Monitor screening rates using de-identified data and enhance prevention efforts among high-risk populations;
- Establish case definition;
- Identify false positive cases using subsequent negative testing;
- Reduce provider burden to respond to follow-up on cases missing relevant negative testing; and
- Identify providers or regions of the state that are not meeting screening standards and guidelines.

Prior to the changes in the Louisiana Sanitary Code, what efforts did OPH make to assess screening rates and identify acute stages of these health conditions?

In 2014, after the passage of Act 459 and the changes to the HIV testing algorithm, OPH established a number of internal practices to try and meet the identified needs. Beginning in 2014, OPH conducted repeat analyses with Medicaid to determine the screening rates for Medicaid clients and found the screening rates to be extremely low. Medicaid data is reliant on claims codes and does not include laboratory test results. The Medicaid match was only able to provide a limited understanding of pregnancy screening rates and could not be used to effectively plan, implement, and evaluate interventions, such as provider training and outreach that would result in improved outcomes.

Historically, OPH field staff who conduct chart abstractions on new diagnoses of HIV collect negative test results that occurred at the same time as the current positive testing, or negative tests that were conducted prior to the current positive testing. The negative test results are collected to complete a person's algorithm or to determine if a person is in an acute stage of infection because of a recent negative test. If the negative testing took place at a facility that is not the same as the current diagnosing facility, the negative laboratory data could not be found and abstracted. OPH field staff capture any prior negative HIV testing data from the medical record to ascertain how recent a person's new infection might be. In addition, OPH field staff were working cases based only on the receipt of undetectable viral loads and had to collect a negative screening test from the record in order to determine a person's HIV status as HIV negative.

These were the State's practices for many years but the results were incomplete and the efforts required a great amount of staff time. Under the changes to the Sanitary Code, staff time will no longer be used to collect missing laboratory test results and can be redirected towards enhanced provider education and more timely case ascertainment.

Why are negative test results being collected with identifying information for all persons? How will this benefit the overall population?

Names and date of birth must be reported on the laboratory results in order to match the test result to prior or subsequent test results with the same name and date of birth. The negative test results are being requested to allow OPH to receive all pieces of a person's testing algorithm,

identify acute infections and false positives, and assist with staging of a person's disease and the end of infectivity. In addition, negative testing will be used to generate screening rates.

People who are positive or are in an indeterminate status, may still have negative test results associated with their case (because they are in an acute stage, because they have been cured, or because some testing, such as HIV antigen testing, will result as negative for persons with longer periods of the virus.) Negative test results do not only belong to people who are negative for a condition.

Negative test data will also be used to generate screening rates for syphilis, HIV and HCV throughout the state. These screening rates will indicate where additional outreach, provider education, and testing need to occur. This focused public health effort will improve the health of Louisiana residents throughout the state.

The receipt of negative laboratory reporting for pregnant women and their newborns is of critical importance. In 2014, Louisiana passed Act 459 which requests that providers offer HIV and syphilis testing during the first prenatal care visit and repeat testing in the third trimester. Without the reporting of negative testing, it is unknown to what degree providers and facilities are screening pregnant women according to Act 459. Louisiana has the highest rate of congenital syphilis in the U.S. and the majority of cases result from missed opportunities of testing and treatment during pregnancy.

People who are truly negative will benefit from this change as part of the larger efforts to eliminate HIV, syphilis and HCV in our society and a reduction in the societal costs associated with those epidemics. For example, these individuals will directly benefit from not being erroneously contacted by a Disease Intervention Specialist (DIS) when the negative test result resolves any need for public health follow up.

What information is collected in an electronic laboratory test result? Is there any risk information include?

Negative test results transmitted from laboratories are reported with varying amounts of demographic information. There is no drug use or partner information within the electronic transmission of the laboratory result. Therefore, there is no information regarding sexual activity or injection drug use. At a minimum, electronic laboratory results include name, date of birth and sex at birth. In addition, laboratories may send race and/or SSN and/or address and/or medical record number. What is received by OPH is dependent on what a laboratory sends, but it never includes information on drug use or sexual activity.

How are these negative test results protected at the Office of Public Health?

All test results received at the Office of Public Health are protected with the same level of security and confidentiality, regardless of result. On a yearly basis, Louisiana's Overall Responsible Party (ORP) certifies that the data housed within the STD/HIV/Hepatitis Program (SHP) and the activities

of the STD/HIV/Hepatitis Program are in full compliance with the Centers for Disease Control and Prevention's 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 (2011). All data are physically protected and isolated by a network firewall with additional intrusion detection and prevention technology. All laboratory test results can only be accessed by STD/HIV/Hepatitis Program staff who have completed security and confidentiality training and HIPAA certification on an annual basis and whose job responsibilities specifically require access to confidential data. Personally identifiable data for all laboratory results are not released to any staff outside of the STD/HIV/Hepatitis Program. The negative laboratory results are not reported outside of the Program and are not stored for long-term use in any STD/Hepatitis/HIV database.

The recent changes to the Sanitary Code and related processes should not be confused with SHP's funded testing program. SHP has a long established history of collecting negative test results with complete identifying and HIV risk information from testing partners, including community-based organizations, correctional facilities and some healthcare clinics that are funded by SHP to conduct HIV, STI, and/or hepatitis testing. For decades, testing partners have submitted both positive and negative test results to SHP in accordance with established protocols. These test records are maintained by SHP indefinitely and there has never been a breach of this highly secured, confidential information. The recent changes to the Sanitary Code do not apply to the funded testing sites and no change in how they report test information has occurred.

What will happen to the negative test results?

Negative hepatitis C, HIV, and syphilis laboratory test results received due to changes to the Sanitary Code will be flagged for removal eighteen (18) months past their collection date. These laboratory results must not be associated with an open case under investigation or confirmed cases of a condition. Negative laboratory results willed be stripped of all identifiers and the remaining non-PHI negative lab data will be removed from the laboratory test tables. The information that will be fully deleted includes name, date of birth, medical record number if received, address if received, and SSN if received.

The process to identify and remove the negative laboratory test data will be generated in an automated data program. There will not be a manual review of the negatives. The data table with the de-identified negatives will not have any allowance for variables that include identifying information. Quality control procedures will be coded into the Program to ensure all identifying information is deleted when the laboratory results are moved after 18 months.

What plans are there to clearly inform those tested that their names and identifying information is being collected and stored?

OPH is continuing to share the Louisiana Department of Health (LDH) press release about the Sanitary Code change with agencies, providers, and community organizations statewide. It is the responsibility of each hospital, healthcare system, and provider to share information with their

patients/clients regarding personal health information and how it will be stored, used, and transmitted to the state health department. It is not in the purview of any Sanitary Code to mandate specific messaging that health care facilities or individual providers must use with their patients/clients.

What steps were taken to make the public aware of the Sanitary Code change before it went into effect?

The Office of Public Health followed all required activities for enacting modifications to the Sanitary Code. A Notice of Intent was published in the February 20, 2019 Louisiana Register (Sanitary Code). The deadline to request a public hearing was March 11, 2019 and no such request was received. Public Comment submission deadline was March 28, 2019. All public comments received were responded to by Dr. Billioux. OPH staff submitted the second oversight report to the Senate Health and Welfare Committee and the House Health and Welfare Committee on April 10, 2019. The oversight committees have the opportunity to call a hearing to question or stop the proposed rules within 30 days of the submission of the second oversight report. The oversight committees did not contact LDH OPH staff to call an oversight hearing and the proposed rules were submitted on May 10, 2019 for publication in the May 20, 2019 Louisiana Register.

Did LDH consider the potential to augment or create further stigma and its ramifications?

The state health department considered that this Sanitary Code change would decrease stigma for HIV, syphilis, and hepatitis C by normalizing and routinizing laboratory reporting for all results, just as routinizing testing itself reduces stigma. The health department recognizes that stigma persists in relation to all infectious diseases, particularly for HIV, syphilis, and hepatitis C, and by not singling out one specific type of result for laboratory reporting, OPH is supporting a status neutral approach to data collection, whereas in the past, only persons with positive results were shared with the health department.

How will this department work with advocates and communities to reduce HIV criminalization?

OPH, specifically the STD/HIV/Hepatitis Program (SHP) has worked for many years supporting efforts to address the criminalization of people living with HIV, such as those undertaken by the Louisiana Coalition on Criminalization and Health (LCCH) and will continue to participate in and provide support to this coalition. OPH plans to explore legislative change in this area, there may be an opportunity to do so in the future. OPH, in collaboration with LCCH and other advocates, will continue to educate staff and community partners about HIV criminalization and how it perpetuates the stigma and oppression of people living with HIV. In addition, OPH has a clear and unwavering stance of not participating in any investigation related to Louisiana's intentional exposure law unless specifically ordered by a court to provide information, but in the past, such orders have gone to the involved medical providers and not to OPH.

How will a negative test result assist in partner notifications?

Prior negative results are used to determine the stage of syphilis and HIV infections (to gauge how recently a person may have been infected), and help to better utilize resources for more timely and efficient follow-up. Acute HIV and early syphilis infections are amongst the highest priority for DIS follow-up because these are the most potentially infectious stages of those diseases. This is also the period where some tests may fail to detect early infections (producing some negative test results when a person is actually infected). Acute HIV infection often includes a period of high viral replication, resulting in a significantly higher viral load during this time although antibody tests will frequently produce negative results during this same period (known as the window period). DIS prioritize these clients in order to ensure they are linked to HIV care and can began antiretroviral medications as soon as possible. Persons exposed to acute HIV are of highest priority to refer to HIV/STD testing, post-exposure prophylaxis (PEP), and pre-exposure prophylaxis (PrEP) and receipt of their negative test results enables the DIS to close cases and not engage in further follow-up efforts.

Disease intervention is dependent on stopping the spread of disease through preventive treatment of persons currently in the inoculation phase and those newly infected and who are in infectious stages of syphilis. Prior negative syphilis results help DIS to determine the time of seroconversion and the critical period of partner exposure, which ensures timely follow-up for clients and exposed partners.

How will the additional capacity of DIS be redirected?

DIS currently depend on provider records and client self-reported medical history to determine stage of HIV and syphilis infections. Self-reported history has to be verified with provider or medical record review. The changes in the Sanitary Code that require negative lab reporting will reduce DIS time conducting these medical record reviews. This increased capacity will be redirected to additional prevention activities, including enhanced client services in areas such as linkage to care, STD treatment, and linkage to PrEP. The DIS will also have more capacity to participate in community outreach events, STD/HIV Taskforce meetings, and other community meetings.

What are the strategies of the health department to destigmatize HIV and does this help or hinder those efforts? Describe LDH's strategy/resources for reducing stigma/discrimination experienced by PLWH.

As noted above, the Sanitary Code change and collection of negative results from laboratories is understood as a way to destigmatize HIV in that it makes the collection of negative results equal to the collection of positive results already received. Stigma related to HIV is rooted in institutional racism, homophobia, and transphobia in that the communities hardest hit by this infection have been people of color, LGBTQ identified people, and people who use drugs. Stereotypes about people living with HIV and historically slow and insufficient systemic responses to the epidemic have been borne out of these oppressions. OPH has supported staff and partners' understanding of racism, homophobia, and transphobia through concentrated training efforts, which began in

SHP and have been elevated throughout OPH and LDH. This is done with the goal of applying an analysis of institutionalized oppression to programmatic decision-making and improving services offered through SHP supported programs.

LDH has recently launched equity efforts and hired full-time staff to support the implementation of an equity policy across the larger LDH. The use of this intentional equity lens to examine how services are offered and how LDH communicates internally and externally will impact not just the STD/HIV/Hepatitis Program, but all bureaus and programs within LDH and the community at large. One of the goals of this effort is to decrease health inequities for all people in Louisiana, including PLWH.

Additionally, staff within LDH, and SHP specifically, include the context of lived experience when sharing HIV related statistics in presentations or writing, in order to not re-stigmatize communities impacted by HIV or PLWH. This context is again impacted by issues related to racism, homophobia, transphobia and is explored, for example, in the Health Disparities introduction of the STD/HIV Annual Report.

Community and partner education related to issues impacting PLWH and the communities in which they live is another key strategy LDH uses to reduce HIV stigma and discrimination. SHP will host a statewide meeting this year that will include topics such as HIV criminalization, housing, employment, community violence, and U=U so as to support contractors and other partners in their journey of providing destigmatizing services and combating stigma and oppression in local communities. Marketing efforts will soon include U=U, which is a powerful tool to decrease stigma that impacts PLWH. LDH signed onto the U=U Consensus Statement earlier this year, making its support of this message unequivocal and clear.

What resources will support improved training and protocol design for routine opt out clinical screenings/expanded offerings of nontraditional community-based settings?

SHP provides ongoing capacity building and technical assistance to all of its testing partners. These partners undergo training around Louisiana's Counseling, Rapid Testing and Referral Services Quality Assurance and Procedural Protocol. Moreover, these partners are monitored by SHP to ensure compliance with this protocol, as well as to identify area of deficiency that require technical assistance from SHP.

What plans or strategies will LDH use to hold accountable any clinician or provider who does not follow standards of care or recommended screenings?

This change to the Sanitary Code is specific to laboratories; however, SHP does plan to use this information to determine screening rates at healthcare facilities statewide. Although SHP does not hold authority to direct the operations of healthcare facilities that do not have a contract or partnership with SHP, the plan is to share information about best practices and national screening recommendations, as well as offer technical assistance and training to any sites that are found to have deficient screening rates.

When will the Louisiana Commission on HIV, AIDS, Hepatitis C Education, Prevention & Treatment be re-convened? How will the commission be intentional and purposeful to ensure community representation of those affected be achieved on the commission?

There are nine seats for community members and representatives of community organizations on the Commission and a nomination process to fill those seats occurred from June 13-27. A list of names for these seats along with those representing the Ryan White Part A, B, C, and D grantees will be sent to the Office of the Governor for review no later than July 5th. The legislation pertaining to the Commission includes:

- Two persons living with HIV, at least one of whom represents a racial or ethnic subpopulation
- Two persons living with hepatitis C, one of whom is co-infected with HIV and at least one of whom represents a racial or ethnic subpopulation
- One representative from a community-based provider organization which provides services to people living with HIV, and which represents a racial or ethnic subpopulation
- One medically qualified representative from a medical provider or community-based provider organization which provides services to persons living with hepatitis C or HIV, and which represents a racial or ethnic subpopulation
- Two representatives from the faith-based community
- One representative from the HIV Planning Group/Statewide EtE Initiative

Please see the following link to read the legislation describing the entire Commission:

http://www.legis.la.gov/legis/law.aspx?d=98000

The first Commission meeting date has not been set, but appointments by the Governor are expected this Summer, with the first meeting following shortly after.

On behalf of LDH, OPH—and SHP in particular—appreciates this opportunity to answer your questions about these important issues. While we followed all procedures for public notification and engagement regarding changes to the Louisiana Register, including presenting this information at meeting with advocates for communities living with HIV/HCV/Syphilis, we recognize that more could be done to answer questions like those you have shared with us before the changes were made, rather than after. Dr. Billioux and OPH regret that and commit to ensure to do even more in the future to gather your input and gain your awareness before enacting policy that would impact your communities. We are hopeful that the re-establishment of the Louisiana Commission on HIV, AIDS, Hepatitis C Education, Prevention & Treatment will help facilitate that. We are grateful for all that you do to advocate for our communities, and we value the importance of our partnership and the trust that is its lifeblood.