

A Multi-Pronged Approach to Addressing Syphilis

Starting in 2008, the Colorado Department of Public Health and Environment (CDPHE) observed a concerning rise in syphilis cases and has since pursued a number of policy solutions to reduce the rates. Unfortunately, in 2023 more than 3000 cases were reported, including 50 cases of congenital syphilis. Overall syphilis cases more than doubled since 2019, and the numbers were projected to rise even further without additional intervention. To address the escalating rates, in 2024 CDPHE pursued additional policy measures—including a public health order, legislation, and rulemaking—to increase syphilis testing with the hope of reversing the upward trend of disease.

Policy History

For many years, Colorado's syphilis case numbers were <u>relatively</u> <u>stable</u>. Then, <u>along with much of the United States</u>, <u>cases began to</u> <u>rise</u>. <u>Between 2018 – 2023</u>, syphilis cases in Colorado tripled and congenital syphilis cases rose seven-fold. In response to increasing cases, CDPHE put a number of initiatives in place, including a <u>Syphilis</u> <u>Review Board</u> to analyze trends and inform policy decisions, and grant-funded partnerships to increase facility-based screening.

Syphilis cases in the United States increased more than 700% from 2012 – 2021, with <u>missed</u> <u>opportunities</u> for appropriate testing noted as a factor in many cases.

<u>Provider outreach</u> was also key to CDPHE's syphilis strategy and included several Health Alert Network notifications, as well as additional provider communications, education, and technical assistance. CDPHE informed providers about the state's increasing case rates and recommended additional screening. Yet even with the investments in provider education and outreach, collaboration with the state Medicaid agency to understand gaps in screening and treatment, and active engagement with local public health experts and medical professionals, in the spring of 2024, CDPHE was projecting 150 cases of congenital syphilis.

With clear data and several policy solutions already in place, CDPHE leadership understood the need for further intervention to address the rising case numbers. On April 1, 2024, CDPHE issued <u>new syphilis screening recommendations</u>, including universal screening for the general population (e.g., all sexually active people ages 15-44), and recommended that pregnant people be screened three times—at the first prenatal visit, in the third trimester, and at delivery. In addition, because CDPHE data showed that pregnant people without prenatal care were accessing the healthcare system through emergency rooms and urgent care centers, the recommendations specifically addressed screening for pregnant people presenting to those facilities as well as in correctional settings (e.g., jails, detention centers).

While developing these updated recommendations, CDPHE's data suggested both that risk-based screening criteria was insufficient and that, for pregnant people, first semester screening alone might not be enough to prevent congenital syphilis. CDPHE wanted to formalize its recommendations to screen for syphilis three times during pregnancy. However, state statute limited syphilis screening to the first trimester and did not allow CDPHE to add additional testing requirements during pregnancy through rulemaking. This meant the statute would have to be changed to give CDPHE both the authority and flexibility to go beyond recommendations and instead issue regulations that increased screening requirements for pregnant people.

Syphilis is a sexually transmitted infection that can have serious health consequences, including organ damage and death, for an infected person if not treated. Syphilis can also be passed to a fetus at any stage of disease and at any time in pregnancy. This condition is known as congenital syphilis. Congenital syphilis can cause fetal death (stillbirth), and <u>babies born with syphilis</u> may have problems with their bones, brain, or internal organs, or may die from the infection.





While CDPHE hoped to pursue a legislative change to remove the time-limited screening language in statute and allow for future rulemaking by the CDPHE <u>Board of Health</u>, this could take a year or more to accomplish. Assuming statute could be changed to align with CDPHE's goals, the process of issuing rules would then take additional months. CDPHE wanted to address rising cases in the short term while pursuing the longer-term solution of changing the underlying statute and promulgating rules to increase screening during pregnancy. On April 18, 2024, CDPHE's executive director issued <u>Public Health Order 24-01</u> (Order), citing the need for immediate action to support further prevention and treatment of syphilis infections in pregnant people. Effective April 25, 2024, the Order applies to all healthcare facilities and providers that treat pregnant people as well as correctional facilities and urgent care centers. Pregnant people must be offered testing at three points during pregnancy: during the first trimester or at the patient's first prenatal visit, early in the third trimester, and at delivery. Exceptions include the existence of a documented syphilis case or patient refusal. In addition, the Order requires providers to offer testing where there is a fetal death after 20 weeks' gestation.

Fortunately, at this same time, the Colorado legislature considered changes with the support of CDPHE and other interested parties—to give the Board of Health additional legal flexibility for the longer term. As a result of that collaboration, on June 5, 2024, Colorado enacted <u>HB24-1456</u> to remove the first trimester screening requirement from state law and instead provide authority to the Board of Health to set prenatal screening requirements through rulemaking. The proposed rules were adopted by the state Board of Health on November 14, 2024 and will take effect on January 14, 2025, and at least until that time, the Order remains in place.

While executive branch agencies generally have the power to create, implement, and enforce their own laws—known as regulations—this authority must be specifically granted to the agency by the legislature.

Implementation and Impact

Overall, the Order has fostered collaboration across state agencies and healthcare partners, solidified the importance of creative and data-driven policy approaches to public health challenges, and proved to be an effective intervention to address rising cases. Specifically, while <u>CDPHE noted 25 cases of congenital syphilis</u> in the months prior to the Order, initial projections suggest that the overall case rate has decreased in the months following implementation. The Order does not require the reporting of negative syphilis test results, which may limit CDPHE's ability to determine the true positivity rate, but as of October 2024, CDPHE is now projecting 64 cases of congenital syphilis.

There have been other anticipated and unanticipated challenges associated with the Order. For example, while CDPHE staff expected that preparing for, implementing, and monitoring the Order would take a significant investment of time and resources, the added workload has been a challenge for an already strained public health workforce. In addition, while the Order has promoted increased testing and identification of cases, access to treatment remains a challenge, particularly for the uninsured. To address this need,

<u>CDPHE worked in partnership with other state agencies</u> to ensure that testing and treatment are covered and available for individuals with insurance, while actively exploring solutions to support treatment access for those who test positive but lack insurance or face barriers to care. And while CDPHE cannot legally require that individuals who test positive for syphilis be offered treatment, the agency does offer <u>Field Delivered Therapy</u> to help individuals access timely treatment and a <u>Bicillin Access Program</u> that helps get this necessary medication to diagnosing providers facing supply challenges.

Bicillin L-A is the first, and sometimes only, recommended <u>treatment</u> for people with syphilis. However, increased demand as a result of burgeoning syphilis cases resulted in nationwide shortage of Bicillin L-A in recent years. This shortage, which has since resolved, required actions by <u>CDC</u>, <u>FDA</u>, and jurisdictions to meet treatment needs.

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Finally, while CDPHE continues to provide technical support and education to healthcare facilities and providers, syphilis is a dynamic disease requiring providers to navigate a changing landscape. As a result, CDPHE is exploring how to incorporate local trends, experiences, and insights into training materials to enhance providers' practical understanding of syphilis in their communities and considering additional collaborations to support medical education.

The CDPHE experience emphasizes the need for comprehensive data, creative solutions, and engaged partners both inside and outside the agency. These factors helped CDPHE make the case for, and succeed in implementing, creative solutions to the state's public health challenges.

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