



# This is an official **DPH Health Advisory**

On July 1, 2024, the S.C. Department of Health & Environmental Control (DHEC) became two separate agencies: S.C. Department of Environmental Services (SCDES) and S.C. Department of Public Health (DPH).

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## Penicillin G Benzathine (Bicillin® L-A) Shortage Update

## **Summary**

On July 11, 2025, the Centers for Disease Control and Prevention (CDC) notified the South Carolina Department of Public Health (DPH) of a new voluntary recall by King Pharmaceuticals LLC., a subsidiary of Pfizer, of specific referenced lots of **Bicillin® L-A (Penicillin G Benzathine Injectable Suspension)**. This recall is compounding a severe nationwide shortage of penicillin G benzathine (Bicillin L-A®), which is the first-line recommended treatment for syphilis and the only recommended treatment option for some patients. DPH is also impacted by this shortage and does not have preferential access to obtaining the drug. DPH is monitoring supplies but does not have the ability to support referrals for high-risk patients as done with previous Bicillin shortages. DPH is providing guidance to mitigate the impact of this shortage to the extent possible.

#### **Recommendations for Health Care Providers**

During the time of this severe supply limitation, providers should do the following:

- Prioritize the use of Bicillin L-A® for treatment of pregnant women infected with or exposed to syphilis and infants with congenital syphilis.
  - Bicillin L-A® is the **only** treatment recommended for pregnant women that has been proven to prevent congenital syphilis.

- Pregnant women who are allergic to penicillin should be referred for desensitization and treatment per the 2021 CDC STI Treatment Guidelines (https://www.cdc.gov/std/treatment-guidelines/default.htm).<sup>3</sup>
- Review patients' syphilis testing and treatment history to confirm that patients with reactive syphilis serology have an active syphilis infection, especially patients with low nontreponemal titers.
- Alternative oral regimens are preferred for all non-pregnant patients, per the 2021 CDC STI Treatment Guidelines:<sup>3</sup>
  - Primary, secondary, or early latent syphilis
    - Doxycycline 100 mg orally twice daily for 14 days.
  - Late latent syphilis or syphilis of unknown duration
    - Doxycycline 100 mg orally twice daily for 28 days.
  - People who have had sexual contact with a person diagnosed with syphilis
    - Doxycycline 100 mg orally twice daily for 14 days.
- Consider prescribing doxycycline as post-exposure prophylaxis (doxy-PEP) to prevent syphilis infections among appropriate patients living with HIV and patients who are currently taking HIV pre-exposure prophylaxis (HIV PrEP). A single 200 mg dose of delayed-release doxycycline taken within 72 hours of possible exposure demonstrates significant reductions in syphilis, gonorrhea, and chlamydia infections in these populations. More information about doxy-PEP can be found here:
  - CDC Clinical Guidelines for DoxyPEP, June 2024
  - DPH Information on DoxyPEP
- Do **NOT** substitute Bicillin L-A® with Bicillin C-R®.
- During this shortage, Bicillin L-A® should **not** be used to treat conditions other than
  syphilis, such as streptococcal pharyngitis/tonsillitis, unless there are absolute
  contraindications to all other appropriate medications. Other drugs such as penicillin V,
  amoxicillin, or azithromycin should be used.

## **Further Actions if Continued Experience of Bicillin L-A Shortage:**

- Due to supply shortages, DPH is unable to accept patient referrals from providers that do not have access to a dose of Bicillin L-A.
- Effective immediately, Pfizer is implementing its Medical Request Process, prioritizing product only for patients with confirmed congenital syphilis and risk of congenital syphilis.
- The <u>medical request form</u> must be completed by the institution and authorized and emailed by the treating Health Care Provider or Director of Pharmacy on a per patient basis to receive product.
- Completed forms should be emailed to <a href="mailto:PISupplyContinuity@pfizer.com">PISupplyContinuity@pfizer.com</a>.

## **DPH Contact Information for Reportable Diseases and Reporting Requirements:**

Reporting of **syphilis and congenital syphilis** is consistent with South Carolina Law requiring the reporting of diseases and conditions to your state or local public health department. (State Law # 44-29-10 and Regulation # 61-20) as per the DPH 2025 List of Reportable Conditions available at: <a href="https://dph.sc.gov/sites/scdph/files/Library/00167-ENG-CR\_2025.pdf">https://dph.sc.gov/sites/scdph/files/Library/00167-ENG-CR\_2025.pdf</a>.

Federal HIPAA legislation allows disclosure of protected health information, without consent of the person, to public health authorities to collect and receive such information for the purpose of preventing or controlling disease. (HIPAA 45 CFR §164.512).

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#### References

 Pfizer Inc. (2025 July 10). Dear Customer Letter: Availability Update for Bicillin® L-A (penicillin G benzathine injectable suspension) 1.2 million Units/2 mL (600,000 units/mL) and 2.4 million Units/4 mL (600,000 units/mL) Prefilled Syringes. <a href="https://www.accessdata.fda.gov/drugsatfda\_docs/appletter/2025/BicillinLAAvailabilityUpdateCustomerLetter.pdf">https://www.accessdata.fda.gov/drugsatfda\_docs/appletter/2025/BicillinLAAvailabilityUpdateCustomerLetter.pdf</a>

- 2. U.S. Food and Drug Administration (2025 July 21). *Current and Resolved Drug Shortages and Discontinuations Reported to FDA: Penicillin G Benzathine Injectable Suspension.* 
  - https://www.accessdata.fda.gov/scripts/drugshortages/dsp\_ActiveIngredientDetails.cfm? AI=Penicillin%20G%20Benzathine%20Injectable%20Suspension&st=c&tab=tabs-1
- 3. U.S. Centers for Disease Control and Prevention (2025 July 21). *2021 STI Treatment Guidelines: Syphilis*. <a href="https://www.cdc.gov/std/treatment-quidelines/syphilis.htm">https://www.cdc.gov/std/treatment-quidelines/syphilis.htm</a>
- 4. U.S. Centers for Disease Control and Prevention (2025 July 21). *Availability of STI Testing and Treatment Products.*

https://www.cdc.gov/sti/hcp/clinical-guidance/availability-of-products.html?CDC\_AAref\_Val=https://www.cdc.gov/std/treatment/drug-notices.htm

#### Categories of Health Alert messages:

**Health Alert:** Conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: Provides important information for a specific incident or situation; may not require immediate action.
 Health Update Provides updated information regarding an incident or situation; unlikely to require immediate action.
 Info Service Provides general information that is not necessarily considered to be of an emergent nature.