Department of Justice

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Lexington Laboratory Agrees to Pay $2.1 Million to Resolve Allegations of False Claims for Urine Drug Testing Services

LEXINGTON, Ky. – LabTox, LLC, a clinical laboratory in Lexington, has agreed to pay $2,101,335 to resolve civil allegations that it violated the False Claims Act, a federal law that prohibits submitting false or fraudulent claims to the federal government.

The allegations relate to urine drug testing services LabTox provided to Medicare and Kentucky Medicaid beneficiaries. According to the settlement agreement, from January 2014 to March 2015, LabTox billed Medicare and Kentucky Medicaid for qualitative urine drug screens completed by a high complexity method. The United States alleged that these claims were false because LabTox misrepresented the complexity of its testing method: the method was actually low complexity, not high complexity, as LabTox claimed. By billing the screens as high complexity, LabTox secured higher reimbursements to which it was not entitled.

The United States further alleged that LabTox billed Medicare for specimen validity testing, a quality control process used to analyze a urine specimen to ensure that it has not been diluted or adulterated. Since January 2014, Medicare's guidance has been explicit that specimen validity testing should not be separately billed to Medicare. The United States alleged that LabTox nonetheless submitted claims to Medicare for specimen validity testing during the period January 2014 to February 2016.

"Millions of Americans count on the medical benefits they receive from the Medicare and Medicaid programs," said Robert M. Duncan Jr., United States Attorney for the Eastern District of Kentucky. "Ensuring that improper billing practices and payments do not deplete the limited resources available to these health care programs is absolutely critical. We will continue to combat inappropriate billing of claims and endeavor to protect the critical resources of these taxpayer-funded programs. That truly benefits us all."

In addition to agreeing to pay the $2,101,335 settlement amount, LabTox also entered into an Integrity Agreement with the U.S. Department of Health and Human Services Office of Inspector General. The Integrity Agreement requires, among other things, that LabTox appoint a Chief Clinical Officer to oversee issues related to clinical decision-making, ensure that requisition forms provide clarity about medical reasonableness and necessity and programmatic payment amounts, and retain an Independent Review Organization to conduct quarterly claims reviews.

"LabTox allegedly sent false and fraudulent bills to Medicare and Kentucky Medicaid. Such actions could drain critically-needed resources from these taxpayer-funded health plans," said Derrick L. Jackson, Special Agent in Charge for the Office of Inspector General of the U.S. Department of Health and Human Services. "The OIG's settlement in the LabTox case is designed to ensure such alleged behavior will not be repeated."

The matter arose from an affirmative investigation following a tip reported to the U.S. Department of Health and Human Services hotline. The United States encourages anyone with information about potential fraud, abuse, or mismanagement of Medicare or Medicaid funds to contact the hotline at 800-HHS-TIPS (800-447-8477). False Claims Act allegations can also be brought under the *qui tam* provisions of the Act, which encourage whistleblowers to bring suit on behalf of the United States and share in any financial recovery.

The investigation was conducted by the Kentucky Attorney General's Office of Medicaid Fraud and Abuse Control, the U.S. Department of Health and Human Services Office of Inspector General, and the U.S. Attorney's Office for the Eastern District of Kentucky. The United States was represented by Assistant United States Attorney Christine Corndorf.

The claims resolved by the settlement are allegations only, and there has been no determination of liability.

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