AMERICAN CLINICAL LABORATORY ASSOCIATION

July 18, 2023

Dr. Rahul Gupta, Director
Office of National Drug Control Policy
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

Submitted electronically

Dear Dr. Gupta,

The American Clinical Laboratory Association (ACLA) commends the Office of National Drug Control Policy (ONDCP) for formally designating fentanyl adulterated or associated with xylazine as an emerging drug threat, pursuant to 21 U.S.C. § 1708,[1] and for taking subsequent steps, including last week's release of the Fentanyl Adulterated or Associate with Xylazine Response Plan ("Response Plan").[2] ACLA appreciates that the Response Plan recognizes the critical importance of testing to ensure a robust response. While the Response Plan notes that the FDA has not cleared or approved any diagnostic manufacturer-developed tests for the detection of xylazine in human specimens, the nation's leading clinical laboratories are at the forefront of driving diagnostic innovation to meet the country's evolving drug testing needs, now providing vital clinical laboratory tests for xylazine and fentanyl to allow clinicians to provide informed patient care.

As ONCDP takes the next steps of issuing Implementation Guidance to agencies and thereafter accepting agencies' Agency Implementation Reports, ACLA strongly encourages ONDCP to ensure that policy across all federal agencies is optimized to recognize the critical role of laboratory-based testing in achieving the goals of the Response Plan. Specifically, we urge ONCDP to include in its Implementation Guidance policy on how drug testing procedures are coded to ensure broad patient access to presumptive and definitive drug testing, specifically by providing clear directions for the Centers for Medicare & Medicaid Services (CMS) to reverse a policy issued this month that will have the effect of severely curtailing laboratory testing for fentanyl, fentanyl analogs, and xylazine. More information on this policy is included below. Respectfully, I request the opportunity to meet with you to discuss this matter, committing the support of the ACLA membership to protect the public health and health care of all Americans as we face this increasingly devastating synthetic drug scourge.

ACLA is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers by advocating for policies that

[1] The emerging threat designation, made under the authority provided by The Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018, 21 U.S.C. § 1708.

[2] Fentanyl Adulterated or Associated with Xylazine Response Plan (July 2023), *available at* https://www.whitehouse.gov/wp-content/uploads/2023/07/FENTANYL-ADULTERATED-OR-ASSOCIATED-WITH-XYLAZINE-EMERGING-THREAT-RESPONSE-PLAN-Report-July-2023.pdf.

expand access to the highest quality clinical laboratory services, improved patient outcomes, and advance the next generation of personalized care. All ACLA members are high-complexity laboratories subject to Clinical Laboratory Improvement Amendments (CLIA) and accredited by the College of American Pathologists (CAP). Serving patients in every state, territory, and tribal land across the country, ACLA members perform millions of drugs of abuse laboratory tests each year and furnish services that are critical to the nation's response to the urgent public health threats posed by fentanyl, xylazine, and other drugs of abuse.

CMS recently implemented a National Correct Coding Initiative (NCCI) policy, effective July 1, 2023, that is preventing clinical laboratories from being paid for both presumptive drug testing and definitive drug testing performed on the same Medicare or Medicaid beneficiary on the same day.[3] The policy contravenes the American Medical Association (AMA) CPT coding guidelines for presumptive and definitive drug testing, and the standard of patient care in drug testing. CMS's stated reason for the policy is that the two types of testing are "mutually exclusive procedures." The policy fails to account for the circumstances in which it is clinically appropriate and necessary for a laboratory to perform both presumptive testing and definitive testing on the same day. For example, a clinician may suspect that a patient is using cocaine and/or fentanyl, and the clinician may order a presumptive test for cocaine and a definitive test for fentanyl (for which there is no presumptive test available). Even if the presumptive test result is negative for cocaine, it still is necessary for the laboratory to perform the ordered definitive test for the fentanyl. Moreover, many community health care providers who treat those with substance use disorders are not equipped to perform point of care testing, so they must rely on a laboratory to perform both presumptive and definitive testing for their patients.

ACLA has appreciated engagement with CMS on this matter, and we continue to urge the agency withdraw the NCCI edit policy. While CMS has offered to put a generic edit "modifier" in place on or after October 1 that would allow payment for both presumptive and definitive testing "in those circumstances when billing these codes together is allowable," ACLA firmly believes that withdraw of the policy is essential to patient access. A modifier would lead to subjective determinations made by the Medicare Administrative Contractors (MACs) and state Medicaid agencies. Again, the association continues to urge CMS to withdraw the NCCI edit policy.

Importantly, CMS's NCCI policy will have a deleterious effect on Medicare and Medicaid beneficiaries' ability to access medically necessary testing to treat substance use disorders. Under the policy, a laboratory can be reimbursed by Medicare or Medicaid for presumptive testing or definitive testing, but not for both. If a laboratory submits a claim for both types of testing for the same beneficiary on the same day without a claim modifier, the claim for one of the tests will be denied.[4] However, the impact of CMS's NCCI policy is far broader than Medicare and Medicaid,

---

[3] *See* National Correct Coding Initiative (NCCI) version 2023 Q3 Procedure-to-Procedure (PTP) edit files released on June 1, 2023, for implementation July 1, 2023 (for presumptive and definitive drug testing CPT codes 80305-80307 and HCPCS codes G0480-G0483, G0659) , *available at* https://www.cms.gov/license/ama?file=/files/zip/ccipra-v292r0-f1.zip.

[4] CMS has represented to ACLA that if a laboratory submits a claim with a certain modifier, it could get paid for both presumptive and definitive testing "in those circumstances when billing these codes together is allowable," which is a subjective determination made by the Medicare Administrative Contractors (MACs) and state Medicaid agencies. Furthermore, laboratories cannot be paid for use of this claim modifier until at least October 1, 2023; until then, laboratories are left without payment for both types of testing on the same day. It is unclear to what extent

because the vast majority of commercial insurers adopt NCCI claim edits. Simply put, few laboratories can bear the costs associated with testing that they actually perform for a patient but for which no reimbursement is available. Some laboratories will cease or limit toxicology testing because they cannot be paid for services they provide.

ACLA commends the Response Plan's calls for increased testing as a core component of a fulsome national response to the increasing threat posed by fentanyl adulterated by or associated with xylazine. Unfortunately, CMS's NCCI policy undoubtedly will result in less testing available in the communities that desperately need it, running counter to the goal of the Response Plan. **Accordingly, and respectfully, we urge the ONDCP to include in the forthcoming Implementation Guidance direction to CMS to: (1) immediately withdraw the NCCI policy on non-payment for both presumptive and definitive substance abuse testing, and (2) provide retroactive reimbursement for any claims that were denied under the policy beginning on July 1.** The NCCI policy is inconsistent with the Response Plan's xylazine-related testing action steps, particularly with the plan for making testing more available in community settings where it is needed, and it is not consistent with the reality of substance use disorder testing today.

Thank you very much for your leadership and for your attention to ACLA's request. I request the opportunity to meet with you about this request and more broadly about how ACLA members can continue to contribute meaningfully and impactfully in the nation's overall response to this emerging drug threat. I can be reached at (202) 637-9466 and at svanmeter@acla.com.

Sincerely,

Susan Van Meter, President
American Clinical Laboratory Association

commercial insurers who adopt NCCI claim edits will also adopt the CMS modifier policy.