August 15, 2023

Jonathan Blum
Principal Deputy Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Delivered via email to: jonathan.blum@cms.hhs.gov

Re: National Correct Coding Initiative Edit for Presumptive and Definitive Drug Tests

Dear Mr. Blum,

We are writing on behalf of the National Independent Laboratory Association (NILA) to request a meeting and to provide our perspective on the recent implementation of a National Correct Coding Initiative (NCCI) edit for the coverage and payment for presumptive and definitive drug testing.

NILA represents independent community and regional clinical laboratories that collaborate with physician practices, hospitals, outpatient care settings, skilled nursing facilities, and homebound patients. NILA's member laboratories range in size from small community laboratories to large multi-state regional laboratories. There are over ninety members of NILA, and many provide a full range of testing services, while others are focused primarily on providing routine and emergency (STAT) diagnostic services to allow physicians to manage chronic diseases. Many NILA members offer drug testing to their clients, and for some NILA members toxicology testing is the primary focus for their laboratory.

We respectfully request a rescission of the NCCI edit that prohibits reporting and payment for presumptive urine drug testing on the same date of service as definitive urine drug testing. This edit was implemented on July 1, 2023, without warning and without the public comment period that typically occurs prior to NCCI edit implementation.

Per the policy, a NCCI procedure to procedure (PTP) edit disallows the use of a modifier to bypass the edit, hence payment for the definitive drug test (codes G0480, G0483 and G0659) will not be made when performed on the same patient with the same date of service as the presumptive drug test (CPT® codes 80305, 80306 and 80307).

After hearing from stakeholders, we understand that the agency has modified the policy to allow the use of a modifier to bypass the edit and allow payment when billing the presumptive and definitive drug testing together under certain circumstances. The agency has noted that the special or certain circumstances are "generally defined by the Medicare Administrative Contractors (MACs) using local coverage determinations."

However, payment using this modifier will not be eligible until October 1, 2023, unless individual MACs allow for exemptions to issue payment prior to this date. We also note that the procedural change to the modifier to bypass the edit was made quite hastily, and we believe the MACs may be unable to implement this quickly. Finally, allowing the use of the modifier accomplishes nothing, as the modifier will always be used to bypass the edit, with the rationale for using it defended identically for each claim.

Putting the coverage and payment decision into the hands of the MACs will create disjointed coverage policies that will lead to access to care issues. The policy may create inequity of care across the country simply by the geographic location of a patient who may live in a MAC jurisdiction that may not cover the testing, even if the modifier to bypass the edit is used correctly. We thank the agency for amending the edit and allowing the use of a modifier to bypass the edit. However, this does not go far enough, and we request that the edit be removed completely.

If this edit is not rescinded, patient care will suffer. It is not typical (or recommended) for a patient to provide a urine sample for the presumptive drug test, only to then return the next day, or even several days later, to provide another sample for the definitive drug test. It is best practice to use the same sample for both presumptive and definitive drug testing. It is the standard of practice in drug abuse testing to use two distinctly different methodologies to prevent random errors or interference errors that may be detrimental to patient care. To prevent significant patient harm, it is essential to test for drug metabolites and specific dangerous illicit drugs which are detectable only by the more sensitive and advanced capabilities of definitive testing methodologies. Considering the often-critical consequences of errors that are possible in performing this essential testing, one test is clearly not enough in most circumstances. In cases of suspected illicit drug use, using the same sample to perform both tests is essential. If patients return, if they return at all, to provide another sample for the definitive test, the drug(s) being abused may have already cleared their system.

There are many instances when it is clinically appropriate to perform both a presumptive and definitive drug test on the same day, particularly for a patient suspected of illicit drug use or when a presumptive test inadequately detects a medication. This is particularly vital as we are amid a fentanyl epidemic and there are very few presumptive tests available for this drug. Not only is presumptive and definitive drug testing important for suspected illicit drug use, but many types of conditions, such as chronic pain and behavioral health issues often seen in the Medicare population, require drug testing to monitor the appropriate use of therapeutic drugs and to ensure appropriate care. It is simply not feasible for a patient, particularly frail, elderly patients with an already heavy burden of traveling to a physician's office, to return a day later to provide another sample for the definitive test.

NILA's member laboratories perform tests that are ordered by physicians and in accordance with best practices. The edit implementation, even with the change of a modifier now being allowed, creates undo administrative burden on laboratories that have already been stretched thin and are just now recovering from the COVID-19 pandemic.

We urge you to remove this edit that disallows presumptive and definitive drug testing to be billed for the same patient on the same day.

NILA thanks you for your attention to this matter. We would also like to request a meeting with you to discuss this policy and better understand the agency's goal in implementing it. Please let us know your availability to do so. If you have questions, and to set up a time to meet, please contact Kay Moyer, Director of Regulatory Affairs, CRD Associates, kmoyer@dc-crd.com.

Sincerely yours,

Mark S. Birenbaum, Ph.D. | *Executive Director*
National Independent Laboratory Association (NILA)

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