July 2, 2020

To Whom It May Concern:

On behalf of the National Independent Laboratory Association (NILA), we are writing to express our concern and to provide comments on the proposed local coverage determination (LCD): Lab: Urine Drug Testing (DL38557) released on May 28, 2020. NILA represents community and regional clinical laboratories, including a number of laboratories that specialize in toxicology. NILA is committed to working with the Medicare Administrative Contractors (MACs), the Centers for Medicare and Medicaid Services (CMS) and the medical community to develop and support coverage policies that are based on strong scientific and clinical evidence and that enhance the physician's ability to detect and manage disease.

NILA is concerned that as drafted the proposed LCD will impair effective and appropriate use of laboratory testing for pain management and the treatment of addiction and substance use disorders. We urge the Palmetto MAC to revise the current draft policy and work with stakeholders to ensure that the LCD appropriately addresses coverage for toxicology testing that is based on clinical evidence and furthers the important task of reducing opioid abuse and deaths. The most important diagnostic tool available to manage patients who require chronic opioid therapy is periodic laboratory-based drug monitoring to ensure patient compliance with treatment.

Our concern with this LCD is several-fold. First, NILA is concerned about the focus on presumptive point of care testing and the assertation that it "may be the only mode of testing that is reasonable and necessary" (See Point III). While many health care professionals rely on point of care drug screens because they are convenient and inexpensive, these tests frequently produce higher incidences of false positive and false negative results. The American Society of Addiction

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Medicine (ASAM) confirmed such concern.[1] In addition, ASAM policy and guidance is clear that presumptive testing is frequently inadequate to advise clinical decision-making.[2] As such, many providers rely upon and seek results from liquid chromatography-mass spectrometry (LC-MS) or gas chromatography-mass spectrometry (GC-MS) drug tests performed by toxicology laboratories. This type of drug testing is superior to point of care drug screens because it provides clinicians with definitive quantitative results that go beyond reporting the presumptive presence or absence of a drug and avoids the risk of high incidences of false positives and false negative results. Point of care testing relies on the reactivity of an antibody to a drug, but not all drugs and/or their metabolites bind antibodies with strong affinity. Also, specific antibody tests have not been developed for all drugs, which limits the number and specificity of drugs detected. Some medications, such as fentanyl, gabapentin, tapentadol, and tramadol, are also not routinely detected in point of care testing. In addition, point of care testing cannot differentiate the parent compound from metabolites, which helps the healthcare provider determine medication compliance. Finally, point of care testing can produce false positive results due to the cross-reactivity with structurally related and unrelated compounds from prescriptions. As such, presumptive point of care tests are simply not reliable enough for many purposes, and definitive tests are necessary because (1) only definitive tests identify if the drug(s) in question is present, and not reflective of false negative and positive results; (2) only definitive tests can identify which drug(s) in a class are present; (3) only definitive tests can provide insight into whether a sample was tampered with or substances were otherwise diverted; (4) not all potential drugs of concern can be tested by point of care testing and (5) presumptive tests are inappropriate for many clinical applications.[3] Definitive testing of positive and unexpected negative results of presumptive tests, and for testing for which no presumptive test is available, has been the standard of care for decades and continues to be the

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[1] ASAM, *Public Policy Statement on the Ethical Use of Drug Testing in the Practice of Addiction Medicine, available at* https://www.asam.org/docs/default-source/public-policy-statements/2019-ethical-use-of-drug-testing-in-the-practice-of-addiction-medicine.pdf?sfvrsn=75bb4bc2_4

[2] *Id. See also*, Jarvis M, Williams J, Hurford M, et al. Appropriate use of drug testing in clinical addiction medicine. Journal of Addiction Medicine. 2017;11(3):163-173 ("If a provider expects the result of a presumptive test to be positive (eg, a patient reports recent use), and information regarding specific substance and/or quantity is desired, it may be appropriate to skip the presumptive test in favor of a definitive test."; "Definitive testing should be used when the results inform clinical decisions with major clinical or non-clinical implications for the patient (eg, treatment transition, changes in medication therapies, changes in legal status).").

[3] *See* Jarvis M, Williams J, Hurford M, et al. Appropriate use of drug testing in clinical addiction medicine. Journal of Addiction Medicine. 2017;11(3):163-173

drug testing standard of care for pain management and the treatment of substance use disorders. NILA urges the modification of the LCD to reflect this practice.

Secondly, NILA believes that precluding coverage of testing for unreported substances and limiting testing for controlled substance therapy (See Section II(C)), can be a detriment to the patient and an obstruction to the healthcare provider. In some patients, the long-term use of substances can build a tolerance that may inhibit the patient from showing signs or symptoms that would fall under the defined category B. As such, there may be patients that can avoid detection and continue to take substances or engage in diversionary practices that mask their compliance with the treatment regimen that would be impossible to detect without definitive testing at a higher frequency than may be permitted by this LCD. In addition, definitive drug testing is a useful tool to monitor the effectiveness of treatment for those engaging in chronic controlled substance therapy. The proposed LCD precludes such testing under Section II(C) as it limits it to therapy changes, unexpected results or annual testing. However, it may be necessary to test more than annually to effectively monitor the patient based on an individualized assessment by the treating clinician. In fact, studies have concluded that more frequent definitive drug testing is a vital component in the mitigation of opioid-related morbidity and mortality as it can help in terms of early detection of opioid aberrancy. This has significant implications as early detection will ideally result in earlier implementation of treatment of the emotional and behavioral factors causing aberrant drug and alcohol use. Such early intervention is more likely to be successful in terms of reducing substance misuse in a chronic pain population, providing a higher degree of patient adherence and safety, and producing superior overall patient outcomes. Finally, economic benefits may include substantial savings through avoidance of the necessity for drug rehabilitation and the empirically established higher costs of treating opioid misuse comorbidities.

Finally, NILA is concerned regarding the parameters for the use of definitive testing (See Section IV). As discussed above, point of care testing has many drawbacks, including that it is problematic for use in clinical decision-making,[4] may hinder the most appropriate care that is in the best interest of the patient, and may jeopardize patient safety. Definitive laboratory testing, on

[4] ASAM, *Public Policy Statement on the Ethical Use of Drug Testing in the Practice of Addiction Medicine, available at* https://www.asam.org/docs/default-source/public-policy-statements/2019-ethical-use-of-drug-testing-in-the-practice-of-addiction-medicine.pdf?sfvrsn=75bb4bc2_4 ("It is problematic to make any clinical decision based on results from presumptive (screening) tests which have not been confirmed by the patient or through the use of definitive testing methods.").

the other hand, provides highly specific and sensitive results, detects a wide range of drugs, differentiates between classes of drugs, and produces quantitative concentrations of parent drugs and their metabolites that provide accurate information about medication compliance, which is essential in pain management and addiction treatment practices. Definitive testing can also demonstrate whether levels of used substances are decreasing over time and accurately identify dangerous drug interactions, such as with benzodiazepines and alcohol. Also, clinical laboratories can offer definitive test algorithms that detect the increasing trend of "simulated compliance," or patient sample tampering, whereby patients adulterate urine samples to modify the results of a test. Point of care technology and presumptive testing simply cannot provide this level of sophistication and, for that reason, is frequently inadequate to care for patients with addiction and substance use disorders. The currently proposed LCD parameters for definitive testing essentially require that the presumptive testing not generate a false negative and precludes the known fact that only definitive testing can differentiate between classes of drugs and parent drugs and their metabolites.

NILA appreciates the focus on individualized assessment and is sensitive to the fact that the MACs need to ensure that appropriate and medically necessary tests are ordered for Medicare beneficiaries at the appropriate time. However, while the LCD makes progress in recognizing the individualized need for treatment, NILA believes that portions of the LCD fail to take into account clinical evidence. NILA firmly supports the importance of laboratories working in conjunction with clinicians to order the appropriate tests, and that clinician decision-making should determine the course of clinical care for patients.

We would be pleased to connect you with NILA member laboratories with expertise in this field to address any questions. Thank you for your consideration of our comments.

Sincerely yours,

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