December 21, 2020

Administrator Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9912-IFC
P.O. Box 8016
Baltimore, MD 21244-8016

Dear Administrator Verma:

On behalf of the National Independent Laboratory Association (NILA), thank you for the opportunity to submit comments in response to interim final rule with comment period CMS-9912-IFC (IFC) regarding Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency. NILA represents regional and community independent laboratories across the United States responding to the COVID-19 pandemic. Despite severe supply shortages and years of inadequate reimbursement following the Protecting Access to Medicare Act, NILA laboratories have responded swiftly to meet the testing needs of their communities during this unprecedented public health emergency.

While NILA recognizes the importance of pricing transparency to patients, the requirements of the IFC are more burdensome than necessary to meet the intent of the CARES Act. As written, the IFC requires all laboratories providing COVID-19 testing, regardless of their relationship to the patient, to post pricing information for COVID-19 tests. Many laboratories, however, do not provide patient-facing testing services. Instead, some laboratories provide reference service for other laboratories, who then have patient- or provider-facing contact. Because of the IFC, reference laboratories are now required to post the price of their services despite not having any patient-facing interaction. This is contrary to the expressed intent in the proposed interim final rule with comment. Instead, reference laboratories will be forced to post their negotiated rates with other laboratories, actions that are likely to have anticompetitive effects and open laboratories to additional legal risks.

In addition, broad-based price posting requirements for reference laboratories could have the unintended consequences of either deterring patients from receiving COVID-19 testing or misleading them about the availability of laboratory services to meet their COVID-19 testing needs. Under the CARES Act, health plans must cover a vast majority of COVID-19 tests without imposing cost sharing requirements, meaning that patients will have no out of pocket expense. In these circumstances, patient-facing pricing information could deter patients without the ability to pay for a test from pursuing testing. Discouraging testing not only runs contrary to the intent of the CARES Act but also represents a public health risk during an infectious disease pandemic. In the instance of reference laboratories, price posting requirements, including requirements for what words must be included on a laboratory's

website, also run the risk of misleading patients about the availability of testing. Because the price posting requirements apply to all laboratories who perform COVID-19 testing, including reference laboratories that provide no patient-facing services, patients may be mislead into believing that reference laboratories are able to meet their COVID-19 testing needs, when in fact the laboratory does not offer patient-facing services. In those circumstances, the provider collecting the patient sample is better equipped to communicate the price of COVID-19 testing, rather than the reference laboratory itself.

As for the requirements for what words must be included on a laboratory's website, NILA asks that the laboratories be given discretion to choose between "price" and "cost" and "COVID" and "coronavirus". The goal of having it on the website is to make it easily searchable and informational for consumers and insurers. Requiring all the words, which can be synonymous, may lead to confusion and inarticulateness in the effort to comply with the mandatory words. It is also our understanding that this will not benefit the actual search engine optimization results for users.

NILA also seeks clarity and revision to the definition of COVID-19 diagnostic tests. Under the current definition at 182.20, it only covers testing that has (1) FDA approval, (2) EUA approval from the FDA or (3) is in a state, such as New York, that oversees and approves tests by clinical laboratories. Many laboratories are offering COVID-19 tests that do not meet these criteria because they have developed laboratory developed tests (LDTs) and can no longer seek EUA approval after the Administration's rescission of guidance and other informal issuances concerning premarket review of laboratory developed tests. The change in the Administration's stance, however, does not preclude clinical laboratories from appropriately billing insurance and other payors for LDT COVID-19 tests. As such, there is an inherent conflict between the requirements of Section 3202(b) of the CARES Act and the proposed regulations. It also creates the potential impression to consumers and patients that laboratories providing COVID-19 LDTs are not authorized to do so, leading to confusion that this rule is intended to negate.

The IFC also sought comments on whether the definition for "provider of a COVID-19 diagnostic test" should be expanded to include the total cost of care. NILA urges the Centers for Medicare & Medicaid Services (CMS) not to require clinical laboratories to post the total cost of care, including costs of services that they do not provide. Given the various relationships that clinical laboratories have and the variety of sources from which they receive orders, it would be unduly burdensome for a laboratory to know or be involved in the total cost of care that a patient may face. Clinical laboratories should only be responsible for posting the price for their patient-facing testing.

Finally, while NILA recognizes the importance of preventing COVID-19 test price gouging, nothing in the CARES Act grants CMS or the Department of Health and Human Services the authority to regulate the price of COVID-19 tests charged outside the confines of the Medicare and Medicaid programs. To the extent that the IFC's definition of "cash price" by reference to "discounted cash price" is an attempt to place a ceiling on COVID-19 test prices, such an approach is beyond the authority granted to the Department under the CARES Act. Enforcement of price restrictions through the cash price posting requirements will limit access to COVID-19 testing and is outside the scope of the Department's regulatory authority. Through its own rate setting, CMS has enormous influence over the market rate for

COVID-19 testing, which is sufficient to set a reference point for COVID-19 test pricing. States are better positioned to address any price gouging activity through existing legislative authority, given their proximity to laboratories and their ability to assess the unique market for COVID-19 tests within a state's own boundaries. Moreover, depending on the entities that the laboratory may be billing, there are already federal laws and mechanisms in place to prevent inappropriate price gouging or steep discounts.

NILA laboratories are rising to meet the unprecedented challenge of the COVID-19 pandemic. The price posting and other requirements under this IFC are more burdensome than necessary to implement the requirements of the CARES Act and may deter patients from seeking laboratory services or mislead them about the availability of laboratory services. This approach places unneeded burden on laboratories responding to the COVID-19 public health emergency and forces laboratories to focus on compliance with arbitrary standards at the expense of the public health response. NILA respectfully asks that the CMS not impose unnecessary burdens on laboratories doing the demanding work of responding to the COVID-19 pandemic.

Sincerely yours,

Mark S. Birenbaum

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