November 9, 2020

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Dear Tamara,

Thank you for meeting with us September 17, 2020, to discuss the interim final rule (CMS–3401–IFC) that further revised CMS' ordering requirements for COVID–19 diagnostic testing. We appreciate your time and commitment to addressing our concerns and ensuring reasonable and necessary access to diagnostic testing during this unprecedented time.

The undersigned organizations remain concerned that the CMS's revised policy that allows for one COVID-19 diagnostic test and one other related test, without an order from a physician or other practitioner, as described in the preamble of the IFC includes language allowing for a local coverage determination (LCD) to override the policy. While we appreciate CMS' attempt to develop a policy that strikes an appropriate balance in providing the flexibility necessary to ensure beneficiaries have prompt and equal access to important COVID-19 and related diagnostic testing during the public health emergency, while simultaneously preventing unnecessary add-on testing, the inclusion of the caveat allowing a LCD to override the policy represents a serious flaw in ensuring beneficiaries have equal access to this important diagnostic testing.

However, CMS's list of "COVID-19, Influenza, and RSV Clinical Diagnostic Laboratory Tests for which Medicare Does Not Require a Practitioner Order During the PHE"[1] includes a caveat that "*Other Medicare conditions of coverage and payment continue to apply, including any applicable local coverage determinations."* What appeared as a regulatory flexibility for improving access to and coverage for diagnostic testing while also reducing provider burden, is effectively negated by CMS's deference to local coverage policy. In fact, CMS's policy hinders comprehensive testing for beneficiaries in regions where the local policy is more restrictive than allowed under the aforementioned IFC[2], impeding providers' ability to rapidly diagnose and manage patients with COVID-like symptoms and creating gross inequities for seniors. Further, CMS policy is in direct contrast with this Administration's *Testing Blueprint: Opening Up America Again*, which states:

> *"Finally, the Administration will update diagnostic testing algorithms and protocols in order to account for seasonality of influenza and other diseases that may occur concurrently. This effort is needed because, in Fall 2020, COVID-19 could co-circulate with influenza or other respiratory viruses.* ***Under this scenario, anyone with an influenza-like illness may be recommended to undergo a testing sequence, a dual antigen test, or a dual nucleic acid test to enable effective diagnoses of COVID-19 even in the context of a co-circulating disease.****"* [emphasis added][3]

We contend that *uniform national coverage* of COVID-19 and other related diagnostic tests are essential to providing appropriate patient care and is consistent with direction from this

[1] https://www.cms.gov/files/document/covid-ifc-2-flu-rsv-codes.pdf
[2] The Palmetto GBA Molecular Diagnostic Services Program (MolDX) established the Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (RVPs) local coverage determination (LCD), which has been adopted by Medicare Administrative Contractors (MACs) covering 28 states, as well as American Samoa, Guam and the Northern Mariana Islands. This LCD was established prior to the COVID-19 pandemic and is based on clinical assumptions that are superseded by the clinical circumstances of our public health emergency.
[3] https://www.whitehouse.gov/wp-content/uploads/2020/04/Testing-Blueprint.pdf

Administration, guidance from this agency[4], the Centers for Disease Control and Prevention (CDC)[5], and other leading organizations[6] during this national emergency. State health departments have also encouraged testing algorithms that include respiratory viral panel (RVPs) and COVID-19 testing. For example, the Nebraska Department of Health and Human Services issued an Advisory through its Health Alert Network explaining that,

- *"Clinicians should consider and test for infectious agents known to be circulating for which testing is readily available:*
  - *rapid influenza tests*
  - *multiplex PCR respiratory viral panels.*
- *Anyone with a severe respiratory disease of unclear etiology, especially with a negative flu and respiratory viral panel multiplex PCR test (RVP) (e.g., Biofire respiratory panel) should be tested for COVID-19."*[7]

The Maryland Department of Health also encourages simultaneously testing as part of its guidance to nursing homes and assisted living facilities.[8]

Given how easily COVID-19 spreads, it is imperative to ensure that providers cohort patients appropriately and are confident in the COVID test results. The many COVID tests that have been created have varying degrees of specificity and sensitivity and there have been numerous cases where clinical suspicion for a false negative test is high in a patient with a COVID-like illness. In this scenario, providers need the ability to rapidly identify the pathogen causing the patient's symptoms to ensure they are in fact COVID negative, and then appropriately isolate or cohort a patient accordingly. As an example, respiratory virus panels are a critical tool for clinicians during this pandemic. They provide a crucial adjunct in determining the etiology of patients' symptoms who present with flu-like illnesses. Many respiratory pathogens present similarly in patients and it is difficult to delineate between influenza, coronavirus, rhinoviruses, and many other pathogens without accurate testing. Individual tests take too long to process and once COVID and influenza have been eliminated, there are too many options to individually test each pathogen. Ensuring rapid results is essential to triaging patients and minimizing disease transmission.

Uniform access to and coverage for appropriate tests is essential to diagnose and manage patients with acute respiratory illness. The coverage caveat would seem to imply that the availability of the additional add-on testing deemed to be appropriate by the CDC might be available in some MAC jurisdictions but not in others as some LCDs limit the availability of testing based on pre-pandemic circumstances. We request that CMS recognize the potential for inconsistent LCDs to be out of step with current treatment approaches and that the IFC language, as implied, override Medicare coverage policy with regard to COVID-19 and related tests. **Based on this information, we recommend that CMS provide uniform coverage for the clinical diagnostic laboratory tests that may be performed without a practitioner order, by removing the local coverage barrier during the COVID-19 public health emergency.**

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[4] Centers for Medicare & Medicaid Services FAQS about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 42, available at https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf.

[5] Centers for Disease Control and Prevention, Evaluating and Testing Persons for Coronavirus Disease 2019 (COVID-19), available at https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html.

[6] In addition to this guidance, the Society for Post-Acute and Long-Term Care Medicine and State health departments strongly encourage the use of molecular RVP same-day testing for other causes of respiratory illness, including infections such as influenza and pneumonia.

[7] http://dhhs.ne.gov/han%20Documents/ADVISORY03112020.pdf

[8] https://phpa.health.maryland.gov/IDEHASharedDocuments/Preparing-for-and-Responding-to-COVID-19-in-LTC_final.pdf

Sincerely,

American College of Emergency Physicians
Association for Molecular Pathology
Association of Public Health Laboratories
College of American Pathologists
Infectious Diseases Society of America
Pan American Society for Clinical Virology

cc: Seema Verma, Administrator, Centers for Medicare & Medicaid Services

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