December 14, 2020

The Honorable Seema Verma
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-1850

Submitted electronically to www.regulations.gov

Re: Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency [CMS-9912-IFC]

Dear Administrator Verma:

The American Nurses Association (ANA) appreciates the Centers for Medicare & Medicaid Services' (CMS) continued efforts through rulemaking to provide support to the nation's health care delivery system throughout the COVID-19 public health emergency (PHE). ANA is pleased to provide comment on the above-captioned interim final rule, which includes provisions for coverage and payment for the COVID-19 vaccine when it becomes available. While largely supportive of the rule's provisions, through this comment letter we urge the agency to:

- Make available support and resources to providers, as well as clarity and education for patients, for successful compliance with requirements related to price transparency for COVID-19 diagnostic tests.
- Ensure states preserve access to comprehensive, essential health care services for all Medicaid beneficiaries throughout the PHE.
- Guard against any unintended consequences created by innovative payment approaches to provide incentives to decrease turnaround time of COVID-19 diagnostic tests.
- Adopt provider neutral language in current and future rulemaking.

ANA is the premier organization representing the interests of the nation's 4.2 million registered nurses (RNs), through its state and constituent member associations, organizational affiliates, and individual members. ANA members also include the four advanced practice registered nurse roles (APRNs): nurse practitioners (NPs), clinical nurse specialists (CNSs), certified nurse-midwives (CNMs), and certified registered nurse anesthetists (CRNAs). ANA advances the nursing profession by fostering high standards of nursing practice, promoting a safe and ethical work environment, bolstering the health and wellness of nurses, and advocating on health care issues that affect nurses and the public. RNs serve in multiple direct care, care coordination, and administration leadership roles, across the full spectrum of health care settings. RNs provide and coordinate patient care, educate patients and the public about various health conditions including essential self-care, and provide advice and emotional support to patients and their family members.

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The critical role of registered nurses in response to the COVID-19 pandemic cannot be overstated. This unprecedented public health crisis has challenged our health care delivery system—but our nurses remain on the frontlines fighting the spread of the virus and saving patients' lives. As a vaccine becomes imminently available, our nurses are also best positioned to not only educate and encourage uptake but are integral to widespread administration of the vaccine in their communities.

CMS must ensure providers have support and resources, as well as clarity and education for patients, to comply with all price transparency requirements for COVID-19 diagnostic tests.
In the interim final rule, CMS is implementing requirements related to price transparency for COVID-19 diagnostic tests as established by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). Providers of these diagnostic tests must make public on the internet the cash price—the amount a patient would pay if they self-paid with cash for a COVID-19 test. Providers without a website must give the same information in writing upon request. Failure to comply with all requirements can result in civil monetary penalties. ANA continues to be encouraged by the agency's price transparency efforts, which allow consumers to make informed decisions about their health care. However, the association urges CMS to provide support, clarity, and education to ensure successful implementation of the COVID-19 diagnostic test price transparency requirements.

ANA urges CMS to work closely with and offer support to providers as needed to comply with the price transparency requirements. The agency must provide clarity on how the cash price should be determined so that it accurately reflects fair market rates. This is important as services related to COVID-19 continue to be costly. This determination must also be transparent among all providers and facilities, preserving the ability of providers to negotiate fair rates that fully cover the costs of care. This will work to prevent price gouging, which is important for NPs as they negotiate rates for their practices and protect patients. CMS must also provide support and resources for the administrative aspects of compliance to make public the cash price, for example support to resolve IT issues. The association appreciates the agency's thoughtful exemption for providers that may not maintain a website by allowing them to provide the required information in writing. CMS should provide resources to these providers on best practices for written disclosure of the cash price. Ultimately, support from the agency will allow providers to comply with all requirements more easily, while preventing the need to impose monetary penalties and in lengthy appeals processes. This allows CMS and providers to keep focus on continued response to the pandemic and avoid adding administrative burden during the PHE.

Further, CMS defines which providers are required to comply with the price transparency requirements. The agency defines providers as those that have a Clinical Laboratory Improvement Amendments (CLIA) certificate or certificate of waiver, as applicable. We encourage the agency to provide additional clarity around its interpretation to ensure that this definition does not inadvertently prevent testing access for patients in communities that do not have access to providers that meet the definition. In addition, CMS must ensure a timely process to obtain any certifications and waivers, with clear indication of waiver lengths and/or timeframes.

Last, CMS must educate patients so that they may identify the lowest cost COVID-19 test in their community. This is important so that patients do not forego testing due to financial concerns. The

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agency should also work with private health insurance plans and issuers to do the same for their covered patient populations.

CMS must provide the support and resources needed to ensure that the price transparency requirements are effectively implemented. As the COVID-19 pandemic continues and testing needs increase, these requirements will only result in protecting all health care providers and, more importantly, consumers.

CMS must uphold the maintenance of effort (MOE) requirement as set forth in the Families First Coronavirus Response Act (FFCRA).

In passing the FFCRA, the U.S. Congress provided a temporary increase in federal funding for the Medicaid program to provide additional resources to state Medicaid agencies and, in turn, providers. States are eligible for this temporary increase if the MOE requirements for Medicaid beneficiary enrollment continue to be met throughout the duration of the PHE. CMS is reinterpreting the MOE requirement in this rule, effectively allowing states to adopt a tiered coverage approach that will allow restrictions to Medicaid benefit coverage, allow for changes to cost-sharing, and other program changes while maintaining eligibility for the enhanced federal funding.

ANA is concerned that CMS' interpretation will impact access to comprehensive care for Medicaid beneficiaries in the midst of an ongoing global pandemic. As the nation struggles with economic challenges resulting from response to the pandemic, the number of eligible Medicaid beneficiaries will continue to increase. Recent analysis shows a steady, significant increase in the number of Medicaid enrollments throughout the PHE, which is expected to continue as enrollment data lags changes in unemployment.[1] The safety net provided by the Medicaid program is vital for patients that lose health care coverage due to changes in employment. This is in addition to existing beneficiaries who rely on Medicaid for access and coverage of needed health care services. The association recognizes the pandemic's strain on state budgets, which are further challenged by increases in Medicaid enrollment. However, states should not mitigate those challenges at the expense of patient coverage and access to care.

By allowing the interpretation of the MOE as set forth in the interim final rule, states facing fiscal pressure will be able to retain the enhanced federal funding while carving out coverage of comprehensive services for Medicaid beneficiaries. ANA's concern is that programmatic changes under this interpretation will restrict beneficiary access to critical services—especially for those with chronic medical conditions. In addition, CMS is adopting the interpretation that the MOE requirements may not apply to certain circumstances, namely for state Medicaid programs that offer a narrow range of benefits. CMS cites COVID-19 testing and programs for tuberculosis and family planning as examples. Under this interpretation, beneficiaries covered in these narrow programs could find themselves at the point of care without coverage for the COVID-19 vaccine. Ensuring patient-centered coverage of the COVID-19 vaccine and other related services for all Medicaid patients cannot be overstated.

[1] Corallo B, Rudowitz R. Analysis of Recent National Trends in Medicaid and CHIP Enrollment. Kaiser Family Foundation. Nov. 5, 2020. Accessible at https://www.kff.org/coronavirus-covid-19/issue-brief/analysis-of-recent-national-trends-in-medicaid-and-chip-enrollment/.

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ANA believes that the MOE provisions set forth in the FFCRA intend that vaccine coverage to be as broad and far-reaching as possible—which is critical to addressing this unprecedented public health crisis and mitigating the spread of the virus. Moreover, as our nurses continue to stand on the frontlines of the PHE, healthcare workers will benefit from the added protection of having all patients vaccinated. As such, states must not be allowed to create barriers in coverage or payment of health care services and still retain increased federal Medicaid support.

Further, the agency has issued numerous regulations and guidance for the Medicare program to ensure that beneficiaries retain coverage and access for all health care services throughout the PHE. CMS is correct in taking those actions. As outlined in this rule, the agency's interpretation of the Medicaid MOE is inconsistent with that approach. It is imperative that the agency safeguard comprehensive health care services for Medicaid beneficiaries throughout the PHE, as it has for Medicare beneficiaries, and retain the MOE as written in the FFCRA.

Resulting unintended consequences from innovative payment approaches used to provide incentives aimed at decreasing turnaround time for COVID-19 tests must be mitigated.
The interim final rule encourages group health plans and issuers of group and individual health insurance coverage to explore alternative, innovative payment approaches that would provide incentives to decrease the turnaround time of COVID-19 diagnostic tests. The rule does note that any approach must not be at the expense of test accuracy or result in any unintended consequences. As these types of arrangements are created, ANA encourages the agency to actively guard against any unintended consequences resulting from any payment arrangements between plans and issuers and diagnostic labs.

Access to timely results from COVID-19 diagnostic testing is important to all patients and has larger public health implications. While using innovative payment approaches can lead to the desired result of shortening COVID-19 test result turnaround time, ANA is concerned that these arrangements could unintentionally favor patients with commercial coverage. During the PHE it is critical that all patients, regardless of their health coverage status, have access to accurate and timely diagnostic testing. Any unintended consequences from innovative, market-based payment arrangements must not result in a system that provides incentives that favor one patient population over another. It is imperative that the agency implement a process to monitor and ensure that these types of payment arrangements do not result in decreased access to timely COVID-19 diagnostic tests.

CMS must adopt provider neutral language in current and all future regulatory rulemaking.
ANA continues to request that CMS use provider-neutral language in all rulemaking and administrative guidance, including in this interim final rule. As our health care delivery system evolves, APRNs increasingly are integral to the primary care workforce in both urban and rural communities. The March 2019 Medicare Payment Advisory Commission (MedPAC) report notes that there was a 10 percent increase in APRNs and Physician Assistants billing Medicare, based on Medicare claims data from 2015 to 2017.[2] CMS must acknowledge this evolution and the important role of APRNs in the health care delivery system as it considers any rulemaking related to the provision of health care services.

[2] Medicare Payment Advisory Commission. Report to Congress: Medicare Payment Policy. March 2019. Accessible at http://www.medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec_rev.pdf?sfvrsn=0.

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ANA urges CMS to update all regulatory language with provider neutral language to reflect all health care practitioners able to provide primary care and other health care services as allowed by state scope of practice regulations. As noted above, ANA is the premier organization representing the interests of the nation's registered nurses, who not only have played a critical role in COVID-19 response but are vital to our health care delivery system to ensure all patients have access to comprehensive, quality care.

ANA appreciates the opportunity to submit these comments and looks forward to continued engagement with CMS as the nation responds to the COVID-19 pandemic. Please contact Ingrida Lusis, Vice President, Policy and Government Affairs, at (301) 628-5081 or Ingrid.Lusis@ana.org, with any questions.

Sincerely,

Debbie Hatmaker, PhD, RN, FAAN
Acting Chief Executive Officer / Chief Nursing Officer

cc: Ernest J. Grant, PhD, RN, FAAN, ANA President

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