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November 2, 2020

Mr. Alex M. Azar, II
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
P.O. Box 8016
Baltimore, MD 21244-8016

Attention: CMS-3401-IFC

RE: Medicare and Medicaid Programs, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

Dear Secretary Azar Administrator Verma:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to its proposed rule, *“Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency,”* published on September 2, 2020. We appreciate the opportunity to leverage our members’ expertise in providing feedback on this proposed rule and helping the agency respond to the needs of Medicare beneficiaries during the COVID-19 public health emergency..

AMCP is the nation’s leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, the Academy’s 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

We appreciate the actions CMS has taken to address the current COVID-19 public health emergency. As addressed in previous comments on COVID-19 rulemaking filed by AMCP, pharmacists are continuing to play a vital role in ensuring that patients receive access to the care and medications that they need during the ongoing COVID-19 public health emergency. CMS’

policy in the interim final rule (IFC) to permit Medicare coverage for pharmacist-ordered COVID-19 and specified related tests is further evidence of CMS' ongoing recognition of the role the pharmacy community plays in response to COVID-19. Notwithstanding our support for the expanded role of pharmacists in responding to the pandemic as set forth in the IFC, we write to express our concerns regarding new limits placed on COVID-19 testing *without* an order.

As community spread continues to grow in this "third wave" of infections, frequent and accurate testing is more critical than ever. It is thus with concern and some confusion that we read CMS' revisions to the policy at 42 C.F.R. § 410.32(a)(3) placing new limits on COVID-19 testing and related orders for influenza and/or respiratory syncytial virus (RSV) without the order of a treating physician or other practitioner. In the IFC, CMS finalized a policy establishing that *only one* COVID-19 diagnostic test and one of each related test may be provided without an order from a physician or other healthcare practitioner. At a time when testing is more critical than ever, we fear this policy will erect unnecessary barriers that could hinder a robust response to this pandemic.

We write today urging you to keep in place the policy established in the May 8th COVID-19 IFC which includes no such limits, on the basis that the same (or greater) urgency related to the rapid expansion of COVID-19 diagnostic testing capacity exists today as it did five months ago. While AMCP is greatly appreciate of CMS' explicit recognition in the IFC that pharmacist and other health care practitioners, in addition to physicians, can order COVID-19 and other related diagnostic tests, we believe any barrier to testing are premature given current infection rates and community spread.

In the IFC, CMS notes that the May 8th policy was developed in response to an urgent need to expand testing capacity, and that recent concerns (including a heightened risk of fraud and abuse) now council in favor of a more narrow testing policy. While AMCP is similarly concerned about reports of fraud and abuse related to COVID-19 testing, we believe there are alternative policies (including enhanced enforcement and penalties) available to the agency, while ensuring new barriers to testing are not created. CMS similarly raises concerns that broad COVID-19 testing without the order of a healthcare professional could result in individuals forgoing needed medical attention. The agency points to statistics showing an increasing number of beneficiaries being tested more than once as evidence of a growing problem.

In general, more frequent testing does not present any safety or public health threats to Medicare beneficiaries, nor are we aware of any data or studies indicating that individuals receiving multiple tests are more likely to ignore or fail to seek medical attention. Instead, as CMS correctly points out, while we anticipate that the majority of Medicare beneficiaries will only have a single test performed, this figure (currently 83%) is likely to decrease solely on the basis that as the pandemic continues, chances of exposure similarly increase. So, too, we believe CMS' one-size-fits-all policy limiting tests without an order to a single COVID-19 and other related test fails to account for the fact that certain individuals are inherently more at-risk of exposure, and thus require more frequent testing. Medicare beneficiaries in the workforce, including in the service industry, may very well require more frequent testing in order to keep themselves, and those around them, safe. A clear unintended consequence of the policy adopted in the IFC is to discourage frequent testing, even when it is medically indicated.

AMCP is similarly concerned about the ability of pharmacist and other providers to meaningfully comply with this new rule given that there is currently no system tracking how many times a Medicare beneficiary has previously received a COVID-19 diagnostic test. While a provider is certainly able to place limits on the number of times *they*, as the individual provider, administer a test to a given Medicare beneficiary, there is currently no system available to determine if that Medicare beneficiary has received testing elsewhere. If CMS proceeds to keep in place the policy, we urge the agency to adopt a good faith or reasonable belief policy, such that a pharmacist or other healthcare practitioner administering a second COVID-19 test, without an order, is not penalized if they are unaware that a prior test was provided.

As noted above, AMCP is fully supportive and thanks CMS for their recognition of the expanded role pharmacists may play in ordering and administering COVID-19 and other specified vaccines, in accordance with state scope of practice and other pertinent laws. Under the policy in the IFR, an otherwise covered COVID-19 test (and other related tests) will be considered reasonable and necessary during the PHE for COVID-19 if ordered by a pharmacist or other healthcare professional who is practicing in accordance with applicable state scope of practice laws.

Conclusion

AMCP appreciates the opportunity to comment on the Interim Final Rule. We are committed to being a valuable resource to CMS as the agency seeks to respond swiftly to the COVID-19 pandemic. We continue to support efforts taken by the agency to increase pharmacist flexibility to ensure that all Medicare beneficiaries can access the care they need, where they need it. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-684-2600 or scantrell@amcp.org.

Sincerely



Susan A. Cantrell, RPh, CAE
Chief Executive Officer