

<u>Submitted via: https://www.regulations.gov</u>

May 29, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1744-IFC
Baltimore, MD 21244

Re: Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; CMS-1744-IFC

Dear Administrator Verma:

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to comment on CMS' rule ("IFC") making policy and regulatory revisions in response to the COVID-19 public health emergency ("PHE"). NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate nearly 40,000 pharmacies, and NACDS' 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit nacds.org.

I. Introduction

We are pleased to be able to provide our perspectives on a variety of policies and issues for which CMS seeks input. Our specific recommendations are detailed throughout our letter, as well as summarized immediately below:

- CMS should expand its interpretation of a "homebound" patient to include
 patients that travel to a CLIA-waived pharmacy's drive-through or parking lot
 site to obtain a COVID-19 test, but otherwise have not been determined by a
 physician that they are medically contraindicated from leaving the home.
- CMS should implement a specimen collection fee and an associated billing code that is not less than the payment to other practitioners such as physicians. Such fee and code should cover pharmacies' costs and incentivize pharmacies to participate in testing. CMS should work with pharmacies to assess their costs and interest in expanding testing.

II. Section M: Medicare Clinical Laboratory Fee Schedule: Payment for Specimen Collection for Purposes of COVID-19 Testing

In the IFC, CMS states that it is endeavoring to be as expansive as possible within the current authorities to have testing available to Medicare beneficiaries who need it. To do this, under separate rulemaking and guidance, CMS has reiterated that pharmacies may enroll in Medicare to bill for COVID-19 tests as clinical laboratories conducting such tests at the point of care (known as "CLIA-waived pharmacies"). In this IFC, CMS has changed Medicare payment policies during the PHE for the COVID-19 pandemic to provide payment to independent laboratories for specimen collection, but only for homebound patients. Our comments here relate to CLIA-waived pharmacies that are enrolled in Medicare as independent laboratories and plan to engage in specimen collection for COVID-19 testing.

CMS should expand its interpretation of a "homebound" patients to include patients that travel to a CLIA-waived pharmacy's drive-through or parking lot site to obtain a COVID-19 test, but otherwise have not been determined by a physician that they are medically contraindicated from leaving their homes. In the IFC, CMS specifically states that "a patient who is exercising 'self-quarantine' for his or her own safety, would not be considered 'homebound' unless it is also medically contraindicated for the patient to leave the home," but then goes on to recognize that "during the PHE for the COVID-19 pandemic, we expect that many Medicare beneficiaries could be considered 'homebound.'" Since CMS fully recognizes that many beneficiaries are "homebound" based on their underlying health conditions, we question the wisdom of forcing patients to pursue and obtain determinations by their physicians.

First, we question the policy that CMS should have to reimburse physicians to determine that a patient is "homebound" and then further reimburse for travel to the patient's home when a patient may be perfectly able to travel to a pharmacy testing site on their own. Second, in the spirit of social distancing, we question the policies of requiring a medical determination, which may necessitate a physician office visit, and sending personnel to multiple patients' homes that risks the health of the traveling personnel who may also unwittingly serve as vectors for COVID-19 transmission as they visit multiple patient homes. Instead, we believe CMS should encourage Medicare beneficiaries to seek testing through the most cost-efficient model, which is likely to be at a pharmacy site.

CMS' IFC provides that that clinical laboratories should use G codes 2023/2024 for specimen collection when a patient is homebound. Thus, it appears CLIA-waived pharmacies can only use the code if they send personnel to a patient's home. CMS explains that the G codes should be used to cover the expense of travelling to a homebound patient, including additional precautions to minimize exposure risks. CLIA-waived pharmacy personnel may not go to a patient's home but do participate in point-of-care COVID-19 testing to patients via drive-through or parking lot sites. To adequately reimburse CLIA-waived pharmacies, NACDS suggests these G codes or separate codes for a specimen collection "fee" may need to be created for

drive-through or parking lot locations due to the extra resources and personnel necessary to conduct tests at such location.

Furthermore, to facilitate and encourage more COVID-19 testing in this manner, we believe that CMS should implement the aforementioned specimen collection fee and an associated billing code that is not less than the payment to other practitioners such as physicians. Such fee and code should cover pharmacies' costs and incentivize pharmacies to participate in testing. CMS should work with pharmacies to assess their costs and interest in expanding testing.

We believe CMS can pay pharmacists in this manner because section 6002 of the *Families First Coronavirus Response Act* states that the payment will be "100 percent of the payment amount *otherwise recognized.*" Since this code will have to be billed using a modifier to denote that it is subject to the cost-sharing waiver, CMS could also use the legislative language to justify that all claims be paid at the full rate for this modified code, regardless of the provider administering them.

III. Conclusion

Again, NACDS thanks CMS for this opportunity to submit comments, and for your consideration of our recommendations. We look forward to continuing our work with you to further expand COVID-19 testing opportunities for Medicare beneficiaries as well as all Americans that may have been exposed to the SARS-CoV-2 virus. If we can provide any additional information, please do not hesitate to contact Kevin Nicholson, Vice President, Public Policy and Regulatory Affairs, at knicholson@nacds.org.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM President and Chief Executive Officer