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October 5, 2020

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1734–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: Medicare Program; CY 2021 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies [CMS-1734-P]

Dear Administrator Verma:

On behalf of the Coalition for 21st Century Medicine (C21), we appreciate the opportunity to comment on the Medicare Physician Fee Schedule (MPFS) Proposed Rule for Calendar Year 2021.

C21 comprises many of the world's most innovative diagnostic technology companies, clinical laboratories, physicians, venture capital companies, and patient advocacy groups. C21's mission is to improve the quality of healthcare by encouraging research, development, and commercialization of innovative diagnostic technologies that will personalize patient care, improve patient outcomes, and substantially reduce healthcare costs. For fifteen years, C21 has worked with CMS on the development, promulgation, and implementation of policies intended to facilitate appropriate patient access to high-quality clinical laboratory tests.

In furtherance of this goal, C21 offers the following comments on the above-captioned proposed rule for the agency's consideration:

1. **Facilitating Access to Telehealth Services**

C21 thanks CMS for expanding Medicare beneficiary access to telehealth services during the pandemic, and supports CMS's proposal to maintain such access on a more permanent basis (where possible under existing authorities). Access to reasonable and necessary telehealth services facilitates appropriate patient access to medically necessary diagnostic and screening tests by:

- Increasing patient access to health care providers (HCPs), allowing HCPs to identify patients who might otherwise miss medically necessary screening/testing services (e.g., patients in rural and other traditionally under-served communities, patients with

mobility/transportation issues, and patients who may otherwise be uncomfortable coming into a physician office during a pandemic); and
- Facilitating HCPs' ability to follow-up with patients (e.g., providing HCPs' with a mechanism to quickly communicate results and provide accurate interpretive information to patients).

Expanding access to telehealth services also reduces patient and provider exposure to infectious disease, and preserves stockpiles of personal protective equipment (PPE) and other medically necessary supplies.

In light of these considerations, C21 encourages CMS to continue using all of the tools at its disposal – e.g., waivers, temporary policies – to enhance beneficiary access to telehealth services. In particular, C21 encourages CMS to use its waiver authority under section 1135 of the Social Security Act to give Medicare beneficiaries access (via telehealth) to certified genetic counselors. Genetic counselors can facilitate the delivery of complex genetic information to individuals in a manner that allows them to understand what test results mean for themselves and their family members. Moreover, genetic counselors can facilitate appropriate genetic test utilization by reviewing and assessing the appropriateness of ordered testing, developing protocols, and increasing communication with ordering providers.[1]

2. <u>Payment for specimen collection</u>

In response to the COVID-19 outbreak, CMS created unique HCPCS codes G2023 and G2024 to report specimen collection for SARS-CoV-2 testing.[2] CMS assigned prices to these HCPCS codes of $23.46 and $25.46, respectively. CMS assigned a higher price to these codes than is typically paid to laboratories for specimen collection because collecting a specimen for SARS-CoV-2 testing requires special efforts and protective equipment beyond that ordinarily required to protect the healthcare worker performing the collection.

C21 commends CMS for recognizing the special efforts that go into specimen collection for SARS-CoV-2 testing during the pandemic, and that protection of specimen collection staff and patients requires greater resources. However, C21 notes that specimen collection of many other tests present similar risks, particularly if they are performed in a population that has a significant risk for catching COVID-19.

The Centers for Disease Control and Prevention has recommended special infection control measures for routine care furnished during the pandemic that is not related to evaluation or diagnosis of patients suspected of COVID-19.[3] Some of these mitigation measures involve avoidance of care that can be delayed and physical distancing in as much as possible. However, for some patients with chronic disease that require ongoing management, care cannot be delayed in spite of the pandemic. For example, transplant patients on immunosuppressive therapy

[1] Kotzer KE, Riley JD, Conta JH, et al. Genetic testing utilization and the role of the laboratory genetic counselor. Clin Chim Acta 2014; 427:193-5.

[2] CMS-1744-IFC

[3] https://www.cdc.gov/coronavirus/2019-ncov/hcp/framework-non-COVID-care.html. Accessed August 18th, 2020

continue to require management of their immunosuppressive treatment. Likewise, patients with cancer who are undergoing treatment continue to require diagnostic testing for not only cancer treatment response, but also often toxic side effects of cancer treatment.

At the outset of the epidemic, it was unknown how long SARS-CoV-2 would pose a meaningful threat to public health, and many had hoped that mitigation plans for SARS-CoV-2 would not need to become a long-term part of the routine clinical care of patients being seen for medical conditions unrelated to or comorbid to COVID-19. As such, it originally seemed unnecessary to adjust payment rates for specimen collection services rendered to patients that were not directly related to COVID-19. However, since that time, it has become clear that healthcare institutions must develop sustainable care processes to prevent spreading of the disease (particularly among patients who are at a high risk of suffering from a severe case of COVID-19) and protect healthcare workers. A key component of a sustainable response is sufficient funding.

For specimen collection, whether a healthcare provider is performing nasopharyngeal swab, or a blood draw, close contact with the patient is required. As such, the measures required to minimize the chance of COVID-19 transmission – e.g., wearing PPE, and the utilization of more extensive cleaning procedures between patients – must be used regardless of whether the specimen is collected for SARS-CoV-2 testing or for the management of another condition. The implementation of these measures reduces patient throughput. As such, C21 recommends that CMS develop a payment rate to appropriately reimburse for specimen collection of non-SARS-CoV-2 testing specimens, particularly in patients for whom the risks related to COVID-19 are particularly high, including the elderly, the immunosuppressed, those with cancer, and those with comorbid cardiac or pulmonary conditions.

3. Increased flexibility for pharmacist orders of testing

C21 applauds CMS for allowing pharmacists – where consistent with state law – to order COVID-19 testing during the public health emergency.[4] C21 encourages CMS to consider extending this policy to other types of tests – e.g., pharmacogenomic tests – for which a pharmacist may appropriately be involved in medication management decisions. By enabling pharmacists to order such tests, collect specimens, and interpret results, CMS can improve patient access to critical healthcare services in underserved communities and rural areas where retail pharmacies exist, but healthcare infrastructure may otherwise be inadequate.

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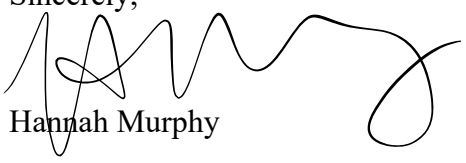
Thank you for considering our comments. Please contact me at hmurphy@c21cm.org or (916) 835-5117 should you have any questions or if we can provide you with further information.

Sincerely,



Hannah Murphy

[4] *See* 42 C.F.R. § 410.32(a)(3).