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

In response to the PHE for the COVID–19 pandemic and in an effort to be as expansive as possible within the current authorities to have testing available to Medicare beneficiaries who need it, we are changing Medicare payment policies during the PHE for the COVID–19 pandemic to provide payment to independent laboratories for specimen collection for COVID–19 testing under certain circumstances.

In general, section 1833(h)(3) of the Act requires the Secretary to provide for and establish a nominal fee for specimen collection for laboratory testing and a fee to cover transportation and personnel expenses for trained personnel to collect specimens from homebound patients and inpatients (not in a hospital), in addition to the amounts provided under the Medicare Clinical Laboratory Fee Schedule (CLFS). Section 1833(h)(3)(A) of the Act provides that the Secretary must establish a nominal fee to cover the appropriate costs in collecting the sample on which a clinical diagnostic laboratory test was performed and for which payment is made under Medicare Part B, except that not more than one such fee may be provided with respect to samples collected in the same encounter. The HCPCS codes for the nominal specimen fees currently listed on the CLFS (HCPCS codes 36415, P9612, and P9615) have a payment rate of $3. Section 216(a) of the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93, enacted April 1, 2014) added section 1834A(b)(5) to the Act which increases by $2 the nominal fee that would otherwise apply under section 1833(h)(3)(A) of the Act for a sample collected from an individual in a skilled nursing facility (SNF) or by a laboratory on behalf of an HHA. Therefore, effective April 1, 2014, the nominal fee that would otherwise apply for a sample collected from an individual in a SNF or by a laboratory on behalf of a HHA is $5 (see § 414.507(f)), and the relevant HCPCS code is G0471.

In addition, section 1833(h)(3)(B) of the Act requires the Secretary to provide for and establish a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the sample, except that such a fee may be provided only with respect to an individual who is homebound or an inpatient in an inpatient facility (other than a hospital). In accordance with this provision, Medicare established a travel allowance for a laboratory technician to draw a specimen from homebound patients and non-hospital inpatients. Under current guidance, the travel allowance is intended to cover the estimated travel costs of collecting a specimen from a Medicare beneficiary and to reflect the technician's salary and travel costs. It is paid only when the nominal specimen collection is also payable and is not available if the technician is merely performing a messenger service to pick a specimen drawn by a physician or nursing home personnel. The methodology for determining the travel allowance varies depending on the round trip mileage to patients' homes. For instance, a per mile travel allowance methodology applies when the round trip to patients' homes is greater than 20 miles and a flat rate travel allowance methodology applies when the round trip to patients' homes is less than 20 miles. Medicare Part B MACs calculate the travel allowance for each claim. We have heard from stakeholders that in some cases the MAC requires them to maintain paper logs of miles traveled to receive the travel allowance.

CMS' current policies for payment of the nominal specimen collection fee and the fee to cover transportation and expenses for trained personnel to collect specimens from homebound patients and non-hospital inpatients are set forth in Pub. 100–04, Medicare Claims Processing Manual, chapter 16, section *60.* We also implemented the increased nominal specimen collection fee under section 1834A(b)(5) of the Act in our regulations at § 414.507(f). The manual instructions regarding payment of these fees are available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c16.pdf.* Neither the annual cash deductible nor the 20 percent coinsurance for Medicare apply to the specimen collection fees or travel allowance for laboratory tests.

This IFC is establishing the following changes to the specimen collection fee policy for the duration of the PHE for the COVID–19 pandemic. We will provide for Medicare payment of a nominal specimen collection fee and associated travel allowance to independent laboratories for collection of specimens related to COVID–19 clinical diagnostic laboratory testing for homebound and non-hospital inpatients. Stakeholders have informed us that access to COVID–19 testing in facilities especially is limited due to the resource costs associated with acquiring the samples in a manner that prevents exposure for patients and health care workers. With patients confined to their homes for their own safety or the safety of others, there is an additional need to have patients tested in their homes and minimize exposure to others. We believe that providing a specimen collection fee for COVID–19 testing during the PHE will provide independent laboratories with additional resources to provide this testing and at the same time help with efforts to limit patients' exposure to the general population and alleviate patients' unease with leaving the home.

Under this policy, the nominal specimen collection fee for COVID–19 testing for homebound and non-hospital inpatients generally will be $23.46 and for individuals in a SNF or individuals whose samples will be collected by laboratory on behalf of an HHA will be $25.46. Medicare-enrolled independent laboratories can bill Medicare for the specimen collection fee using one of two new HCPCS codes for specimen collection for COVID–19 testing and bill for the travel allowance with the current HCPCS codes set forth in section 60.2 of the Medicare Claims Processing Manual (P9603 and P9604). Our policy will also incorporate the clarification in the definition of homebound as discussed in section II.F. of this IFC, relating to the clarification of homebound status under the Medicare home health benefit.

In establishing a nominal fee for COVID–19 specimen collection, we considered the type of trained laboratory personnel required to collect the specimen and the resources this type of collection could require. As noted previously, the current specimen collection fee HCPCS codes on the CLFS for homebound and non-hospital inpatients are $3 and $5, but we recognize that these fees are not intended to address additional resources needed during the PHE for the COVID–19 pandemic. Absent concrete information regarding the costs associated with independent laboratories collecting such specimens for COVID–19 tests in the context of the PHE, we looked to similar services in other settings of care as a potential benchmark. In looking at other Medicare payment systems, we believe the PFS is the best source for a potential payment amount since physicians and other practitioners often bill for services that involve specimen collection by trained, non-institutional staff.

Under the PFS, a Level 1 office visit (CPT code 99211) typically does not require the presence of a physician or other qualified health care professional and the usual presenting problem(s) are minimal. This code is what is typically reported by physician practices when the patient only sees clinical office staff

for services like acquiring a routine specimen sample. CPT code 99211, describes an:

Office visit for E/M of an established patient that may be performed by clinical staff under supervision (may not require a physician's presence). Usually the presenting problem(s) are minimal and typically 5 minutes are spent supervising or performing the service.

The CY 2020 national PFS payment amount for Level 1 established patient office visits is $23.46 on the PFS. We also considered establishing a higher payment amount that considered the Level 1 E/M visit plus the payment amount for CPT code 89220, Sputum obtaining specimen aerosol induced technique, for a specimen collection fee of $40.06, but we believe there is likely overlapping costs in staff time for these two services and the Level 1 office visit payment rate is adequate.

For initial diagnostic testing for COVID–19, the CDC issued interim guidelines that recommend collecting and testing for the virus using an upper respiratory nasopharyngeal swab (NP). The CDC guidance also states that collection of oropharyngeal swabs (OP) is a lower priority and if collected should be combined in the same tube as the NP. The CDC guidance advises that collection of sputum should only be done for those patients with productive coughs. See *https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html.* Similar collection method types, that is, NP or OP swabs are also used in other laboratory developed tests for COVID–19.

Section 1833(h)(3) of the Act does not specifically describe the types of specimen collection methods that are eligible for the nominal fee and transportation and personnel expenses. However, section 1833(h)(3)(B) of the Act does refer to ''trained personnel'' that would collect the sample from homebound individuals and inpatients in non-hospital inpatient facilities. This suggests that to be medically necessary and for payment to be made for sample collection, the method of sample collection must require some training or skill on the part of the laboratory technician and cannot be conducted by the beneficiary, the beneficiary's caregiver, or facility staff if the facility does not have a laboratory, and therefore, is using an outside laboratory to perform its testing of patients. The Medicare Claims Processing Manual provides additional guidance on the medical necessity requirements for specimen collection. Specifically, the manual states that ''Medicare allows payment for a specimen collection fee when it is medically necessary for a laboratory technician to draw a specimen from either a nursing home patient or homebound patient'' and that ''the technician must personally draw the specimen.'' It also states that ''[t]his fee will not be paid to anyone who has not extracted the specimen'' and lists ''venipuncture or urine sample by catheterization'' as examples of a technician personally drawing the specimen. The manual further clarifies what it means for a specimen collection to be medically necessary stating that ''. . .where the specimen is a type that would require only the services of a messenger and would not require the skills of a laboratory technician, for example, urine or sputum, a specimen pickup service would not be considered medically necessary.''

We note that venipuncture and urine sample by catheterization are currently provided in the Medicare Claims Processing Manual as examples of a technician personally drawing a specimen, however, they are not an exhaustive list of all possible scenarios that require trained personnel to collect a specimen. In the case of collecting a specimen for COVID–19 testing, we believe that in the context of and for the duration of the PHE for the COVID–19 pandemic, collecting specimens using NP or OP swabs or collection of sputum will require a trained laboratory professional, as well as additional precautions that must be taken to minimize exposure risks in handling specimens that are suspected or confirmed for COVID–19. Thus, we believe that collecting a specimen for COVID–19 testing will incur higher costs than similar specimen collection services which require a trained laboratory professional but not additional precautions, to minimize exposure risks. The CDC advises that specimen collection must be performed correctly the first time the specimen is collected. A focus of the response to the PHE for the COVID–19 pandemic is to quickly identify individuals who are infected so that appropriate treatment for the patients being tested is provided in a timely manner. At the same time, another goal is to appropriately isolate those patients and quarantine those exposed to the patients to prevent further spread of the virus. We believe laboratory personnel will need to be trained on how to handle the specimen to maximize accurate test results for COVID–19. Laboratory personnel also will need to be trained on how to minimize risks for spreading the virus to themselves and/or others in the chain of handling the specimen before it arrives at the laboratory for analysis. The CDC guidance states that specimens should be collected as soon as possible once a person under investigation (PUI) is identified, regardless of the time of symptom onset, and that proper infection control must be maintained when collecting specimens. We believe that specimens for COVID–19 testing using NP, OP, or sputum must be collected by trained laboratory personnel, and the specimens are a type that would not require only the services of a messenger or specimen pick up service. The manual currently lists collection of sputum as a type that would require only the services of a messenger, and therefore, is not considered medically necessary. However, for the PHE for the COVID–19 pandemic only, we believe a specimen collection fee for sputum collection would be warranted and medically necessary due to the reasons discussed previously. If in the future other types of COVID–19 tests are available, such as serological tests or point of care tests, we note that the specimen collection fee would apply if the specimen collection method must be performed by trained laboratory personnel. However, COVID–19 tests that allow patients to collect the specimen themselves would not be eligible for the specimen collection fee.

To identify specimen collection for COVID–19 testing, we are establishing two new level II HCPCS codes. Independent laboratories must use one of these HCPCS codes when billing Medicare for the nominal specimen collection fee for COVID–19 testing for the duration of the PHE for the COVID–19 pandemic. These new HCPCS codes are:

- G2023, specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV–2) (Coronavirus disease [COVID–19]), any specimen source.
- G2024, specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV–2) (Coronavirus disease [COVID–19]), from an individual in a SNF or by a laboratory on behalf of a HHA, any specimen source.

We created the second Level II HCPCS code, G2024, because section 1834A(b)(5) of the Act and our regulations at § 414.507(f) require a higher fee for collecting a specimen from an individual in a SNF or by a laboratory on behalf of an HHA, as described previously in this section of the IFC. We will issue guidance when the PHE for the COVID–19 pandemic is over and when these codes are no longer valid and terminated in the HCPCS file and/or the CLFS as appropriate.

In addition, Medicare payment for transportation and expenses for trained personnel to collect specimens from homebound patients (as discussed in section II.F. of this IFC, relating to the clarification of homebound status under the Medicare home health benefit) and inpatients (not in a hospital) for purposes of COVID–19 testing will be made in accordance with existing instructions found in the Medicare Claims Processing Manual. Independent laboratories must use the existing level II HCPCS codes when billing for the travel allowance, that is, the per mile travel allowance as described by HCPCS code P9603 and the flat rate travel allowance as described by HCPCS code P9604. Additionally, we are clarifying that paper documentation of miles traveled is not required and laboratories can maintain electronic logs with that information. However, laboratories will need to be able to produce these electronic logs in a form and manner that can be shared with MACs. Asstated previously, we have heard from stakeholders that maintaining paper logs of miles is burdensome, especially with the development of GPS systems and various applications for cellular phones in recent years that can track miles traveled. Thus, we are clarifying that there is no requirement that laboratories maintain logs on paper to document travel, and that laboratories may use digital documentation of this information if preferred. The MACs may provide more information on acceptable formats.

In defining an individual who is homebound for purposes of the specimen collection fee and the travel allowance under section 1833(h)(3) of the Act, the manual refers to Chapters 7 and 15 of Pub. 100–02, the Medicare Benefit Policy Manual. The definition of ''homebound'' in Chapters 7 and 15 of Pub. 100–02 originate from the statutory definition of ''confined to the home'' (that is, ''homebound'') under sections 1814(a) and 1835(a) of the Act. As discussed in section II.F. of this IFC, relating to the clarification of homebound status under the Medicare home health benefit patients are considered ''confined to the home'' (that is, ''homebound'') if it is medically contraindicated for the patient to leave the home. When it is medically contraindicated for a patient to leave the home, there exists a normal inability for an individual to leave home and leaving home safely would require a considerable and taxing effort.

As an example for the PHE for COVID–19 pandemic, this would apply for those patients: (1) Where a physician has determined that it is medically contraindicated for a beneficiary to leave the home because he or she has a confirmed or suspected diagnosis of COVID–19; or (2) where a physician has determined that it is medically contraindicated for a beneficiary to leave the home because the patient has a condition that may make the patient more susceptible to contracting COVID–19. 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. Determinations of whether the patient is homebound must be based on an assessment of each beneficiary's individual condition. For the PHE for the COVID–19 pandemic, the CDC is currently advising that older adults and individuals with serious underlying health conditions stay home (CDC's guidance is interim and is expected to continue to be updated as warranted).[14] As such, during the PHE for the COVID–19 pandemic, we expect that many Medicare beneficiaries could be considered ''homebound''. In light of this clarification regarding the definition of homebound, we are noting this clarification pertains to the specimen collection fee and travel allowance in the PHE for COVID–19 pandemic testing for homebound patients; that is, a patient is considered homebound for purposes of the fees under sections 1833(h)(3) and 1834A(b)(5) of the Act if it is medically contraindicated for the patient to leave home.

In summary, to address the PHE for the COVID–19 pandemic, we are using this IFC as a vehicle to provide additional payment during the PHE in the form of a specimen collection fee of $23.46 generally, and $25.46 for an individual in a SNF or by a laboratory on behalf of a HHA, for COVID–19 testing and to provide a travel allowance for a laboratory technician to collect a specimen for COVID–19 testing from a non-hospital inpatients or homebound patients under section 1833(h)(3) of the Act.

N. Requirements for Opioid Treatment Programs (OTP)

In the CY 2020 PFS final rule (84 FR 62645 and 62646), we finalized allowing the use of interactive two-way audio/video communication technology to furnish the counseling and therapy portions of the weekly bundle of services furnished by OTPs. In light of the PHE for the COVID–19 pandemic, during which the public has been instructed to practice self-isolation or social distancing, and because interactive audio-video communication technology may not be available to all beneficiaries, we are revising § 410.67(b)(3) and (4) to allow the therapy and counseling portions of the weekly bundles, as well as the add-on code for additional counseling or therapy, to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology during the PHE for the COVID–19 pandemic if beneficiaries do not have access to two-way audio/video communications technology, provided all other applicable requirements are met. We believe this change is necessary to ensure that beneficiaries with opioid use disorders are able to continue to receive these important services during the current PHE.

O. Application of Teaching Physician and Moonlighting Regulations During the PHE for the COVID–19 Pandemic

a. Background

In context of the PHE for the COVID–19 pandemic, we have been asked by stakeholders to relax supervision requirements related to the provision of teaching physician services under the PFS. For teaching physicians, section 1842(b) of the Act specifies that in the case of physicians' services furnished to a patient in a hospital with a teaching program, the Secretary shall not provide payment for such services unless the physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which payment is sought. We have also been asked to allow residents to independently furnish services in their capacity as fully licensed physicians outside of the scope of their approved GME residency in the inpatient setting of the hospital at which they provide services.

b. Revisions to Teaching Physician Regulations During a PHE for the COVID–19 Pandemic

Regulations regarding PFS payment for teaching physician services and moonlighting are codified in 42 CFR part 415. Under § 415.172, if a resident participates in a service furnished in a teaching setting, PFS payment is made only if the teaching physician is present during the key portion of any service or procedure for which payment is sought. The provisions in § 415.174 exempt certain office/outpatient E/M services provided in the outpatient department of a hospital or another ambulatory care

[14] *https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/high-risk-complications.html.*