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June 30, 2020

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue SW
Washington, DC 20201

RE: File Code CMS–5531–IFC

Dear Ms. Verma:

The Medicare Payment Advisory Commission (MedPAC) appreciates the opportunity to submit comments on the Centers for Medicare & Medicaid Services (CMS) interim final rule entitled “Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program” *Federal Register* 85, no. 90, 27550–27629 (May 8, 2020). We appreciate your staff’s continuous efforts to administer and improve the Medicare payment system, particularly given the competing demands on the agency.

We recognize the unique and difficult circumstances in which CMS currently operates under the COVID-19 public health emergency (PHE). In these interim final rules, as well as previous interim final rules and guidelines released over the past several months, CMS offers flexibilities that aim to allow providers to effectively respond to the public health threats posed by the spread of COVID-19. We understand that CMS has had to make these policy changes quickly. However, we are concerned about the broader implications of continuing these changes once the PHE has ended. When that time approaches, we urge CMS to carefully consider and weigh how making any of these changes permanent will affect the quality and safety of care beneficiaries receive, the willingness of providers to continue to participate in the Medicare program, and the already challenging fiscal solvency and program integrity of the Medicare program.

Beyond this general comment, we also have several comments on specific provisions in the interim final rule that follow.

Payment for audio-only telephone evaluation and management (E&M) services

In the April 6 COVID-19 interim final rule, Medicare began paying clinicians for three audio-only telephone evaluation and management (E&M) codes (99441, 99442, and 99443) in all locations.¹ Previously, Medicare did not cover these services. CMS began covering these services to reduce exposure risks to COVID-19, especially in cases in which two-way, audio and video technology required to provide telehealth services might not be available, such as in areas that lack high-speed internet. Providers have the option of waiving beneficiary cost sharing for these audio-only visits. In the April 6 interim final rule, CMS stated that it did not expect these audio-only services to fully replace a face-to-face visit. Initially, the payment rates for these codes were based on work relative value units (RVUs) and direct practice expense (PE) inputs recommended by the American Medical Association's Relative Value Scale Update Committee (RUC). Based on information that CMS learned from stakeholders since the April 6 interim final rule, the agency now believes that providers are using the audio-only services to manage more complex care than CMS had expected and that the current RVUs for these codes do not capture their intensity during the COVID-19 pandemic. CMS also asserts that these codes are being furnished as substitutes for office/outpatient E&M services. Therefore, in this interim final rule CMS is almost doubling the work RVUs and increasing the direct PE inputs for the audio-only codes so that they are equivalent to the work RVUs and direct PE inputs for analogous office/outpatient E&M codes (99212, 99213, and 99214).

Comment

We recognize that CMS substantially increased payment rates for audio-only E&M codes to ensure that providers have the resources to serve beneficiaries during the PHE. If, however, CMS continues to cover audio-only E&M codes after the PHE ends, the agency should quickly reinstate the previous payment rates for these services (which were based on the work RVUs and PE inputs recommended by the RUC) after the PHE because there is a lack of evidence that these services require the same level of resources as in-person E&M codes. Because clinicians cannot interact as fully with patients when they use audio-only technology as when they see a patient in person, we are skeptical that the level of intensity for audio-only services is the same as for in-person services. In addition, audio-only E&M services use fewer PE resources than E&M services provided in a clinician's office. Audio-only services do not require physical office space, medical supplies, medical equipment, or the same amount of clinical staff time as in-office services (e.g., clinical staff do not greet and gown patients, take vital signs, or prepare exam rooms for audio-only services). Therefore, continuing to pay audio-only E&M codes as much as in-person E&M codes after the PHE ends would distort prices for E&M services, which could lead providers to favor audio-only services over in-person E&M services, even when an in-person service may be more clinically appropriate. In the long run, there are better ways to financially support Medicare providers that do not distort prices for individual services.

¹ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2020. Medicare and Medicaid Programs; policy and regulatory revisions in response to the COVID-19 public health emergency. *Federal Register* 85, no. 66 (April 6): 19230–19292.

In addition, we are concerned that the high payment rates for audio-only services (e.g., \$46.19 for a 5-minute phone call) may increase the risk of overuse, fraud, and unnecessary program spending, particularly because clinicians can waive cost sharing for these services.² Although providers are prohibited from initiating these calls, they are allowed to market them to beneficiaries. Therefore, CMS should closely monitor the use of these services during the PHE to protect beneficiaries and the Medicare trust fund from providers who try to furnish unnecessary services.

Relocation of provider-based departments

Before 2017, all services furnished in off-campus provider-based departments (PBDs) of hospitals that are covered under the hospital outpatient prospective payment system (OPPS) were paid at OPPS rates. Section 603 of the Balanced Budget Act of 2015 (BBA15) established that services furnished in certain off-campus PBDs would be paid at rates that approximate physician fee schedule (PFS) rates while other off-campus PBDs would continue to be paid full OPPS rates. Those off-campus PBDs that are paid at the PFS-equivalent rates have been considered to be non-excepted from the provisions in BBA15, and those that continue to be paid at OPPS rates are considered to be excepted from BBA15.

CMS has established that if an excepted off-campus PBD moves to a new location (relocates), that PBD loses its excepted status and begins to be paid at PFS rates unless the facility faces extraordinary circumstances outside of hospital control such as natural disasters, significant seismic building code requirements, or significant public health or public safety requirements. A relocating PBD must apply to its CMS Regional Office for an extraordinary circumstances waiver.

In response to the COVID-19 PHE, CMS in this interim final rule announced that it wants to give hospitals that provide services to Medicare beneficiaries the flexibility to respond effectively to the serious public health threats posed by the COVID-19 PHE. Many hospitals are repurposing existing clinical and non-clinical space for use as temporary expansion sites to furnish inpatient and outpatient care during the PHE for the COVID-19 pandemic. CMS is concerned that if an excepted off-campus PBD (paid at OPPS rates) relocates off-campus due to the COVID-19 PHE, some hospitals would have difficulty maintaining operations for necessary services during the COVID-19 PHE at the off-campus PBD if they were paid at PFS-equivalent rates because that excepted location became a non-excepted location. In response, CMS is adopting an expanded temporary relocation exception policy specific to the COVID-19 PHE so that hospitals can maintain treatment capacity and deliver needed care. This expanded policy includes both on-campus PBDs and excepted off-campus PBDs that relocate off-campus for the purposes of addressing the COVID-19 pandemic. Specifically, excepted PBDs that relocate on or after March 1, 2020 through the end of the PHE for the purposes of addressing the COVID-19 pandemic may seek an extraordinary circumstances relocation exception so that they may bill at OPPS rates, as long as the relocation is not inconsistent with the state's emergency preparedness or pandemic plan.

This temporary extraordinary exceptions policy is time limited to the PHE for COVID-19, which enables short-term hospital relocation of excepted off-campus or on-campus PBDs to improve

² This amount is the national non-facility payment rate.

access to care for patients. CMS anticipates that most, if not all, PBDs that relocate will return to their original location prior to, or soon after, the COVID-19 PHE concludes. Hospitals that choose to permanently relocate these PBDs to new off-campus sites will be considered new non-excepted off-campus PBDs, and would be paid at PFS-equivalent rates. Hospitals that permanently relocate may seek an extraordinary circumstances waiver, but those hospitals would have to follow the extraordinary circumstances application process that CMS adopted in 2017.

CMS is taking steps to streamline the process for the extraordinary circumstances relocation exceptions for purposes of addressing the COVID-19 pandemic. Both excepted off-campus *and* on-campus PBDs may relocate to off-campus locations during the COVID-19 PHE and begin furnishing and billing for services under the OPPS in the new location prior to submitting documentation to their regional office to support the extraordinary circumstances relocation request. In place of the standard process established in 2017 in which off-campus PBDs can apply for extraordinary circumstance relocation exceptions, all hospitals that relocate excepted on- and off-campus PBDs to off-campus locations in response to the COVID-19 PHE should email their CMS regional office information about the relocated PBD that will allow CMS to determine whether the relocation meets the criteria for extraordinary circumstances and allow CMS to identify the new locations.

During a relocation, hospitals may divide their PBD into multiple locations. In addition, hospitals may relocate part of their excepted PBD to an off-campus location while maintaining the original PBD location. CMS points out that dividing locations would be helpful to hospitals that want to separate COVID-positive and COVID-negative patients.

CMS anticipates most multi-relocations or partial relocations would be to a limited number of locations as needed to respond to the COVID-19 PHE in a manner not inconsistent with the state's preparedness and pandemic plan, with the exception being multiple relocations to accommodate care in patients' homes. CMS also expects hospitals exercising this flexibility to be able to support that the excepted PBD is still the same PBD, just split into more than one location. For example, if the excepted PBD was an oncology clinic, CMS expects that the relocated PBD(s) during the COVID-19 PHE would still be providing oncologic services.

Comment

The Commission fully recognizes the benefit of modifying regulations to provide hospitals with flexibility to effectively address the COVID-19 PHE. The Commission also commends CMS for creating an application process that allows hospitals to quickly transfer resources to new off-campus locations and also provides CMS with the data necessary to identify the locations of new off-campus PBDs. However, the Commission is not as confident as CMS that most, if not all, of these locations will return to their original location when the COVID-19 PHE is over. Therefore, we encourage CMS to maintain the information from the application about the excepted PBDs that relocate. Also, we encourage CMS to be diligent in identifying which of these excepted PBDs return to their original location and which remain in their new location and ensure these providers are paid at rates that are consistent with section 603 of BBA15.

Requirement for facilities to report nursing home resident and staff infections, potential infections, and deaths related to COVID-19

The interim final rule dated April 30, 2020, expanded reporting requirements for nursing homes to report data to the Centers for Disease Control and Prevention's National Healthcare Safety Network. Nursing homes are required to report: suspected and confirmed COVID-19 case counts among residents and staff, deaths attributable to COVID-19 among residents and staff, the available personal protective equipment and hand hygiene supplies in the facility, ventilator capacity and supplies available in the facility, resident beds and census, access to COVID-19 testing, staff shortages, and other information specified by the Secretary. This information will be shared with CMS and publicly reported. In addition, nursing facilities are required to inform residents, their representatives, and their families of confirmed and suspected cases among residents and staff within specific timeframes. They must also provide updates if there is a subsequent reported case or if there are 3 or more staff or residents with new onset of symptoms within 72 hours of each other. Facilities must include information on the mitigating actions taken to prevent or reduce the risk of transmission, including whether normal operations will be altered or limitations to visitation or group activities will be imposed.

Comment

The Commission fully supports these new requirements for the duration of the PHE. The reporting requirements will support the national, state, and local surveillances of COVID-19 cases. Further, the identification of equipment and staffing shortages could facilitate the distribution of needed resources as they become available or help redistribute existing resources. Requiring communication with the residents, their representatives, and families will keep them up to date on the nursing facility's circumstances. Such transparency will keep all interested parties abreast of the facility's evolving conditions and explain why the facility may need to take new actions.

Excluding COVID-19 episodes from Medicare Shared Savings Program financial calculations

Shared savings and losses for accountable care organizations (ACOs) in the Medicare Shared Savings Program (MSSP) are determined by comparing per capita Part A and Part B expenditures of beneficiaries assigned to an ACO with its financial benchmark. CMS estimates a benchmark for each ACO in each agreement period, which are five years in length as of July 2019. Benchmarks use the three years prior to an ACO's agreement period as the baseline years. CMS computes the Part A and Part B expenditures for the beneficiaries who would have been assigned to the ACO during the baseline years. For ACOs that either started a second agreement as of 2017 or started an agreement period as of July 2019, baseline expenditures are a blend of the ACO's historical spending and all of the fee-for-service spending in an ACO's region. These expenditures are retrospectively trended forward to an ACO's performance year to reflect a blend of the actual growth in the ACO's regional per capita expenditures and national per capita expenditures. For all months during the PHE, ACOs will have the opportunity for shared savings but will not be liable for shared losses. To avoid using 2020 as a baseline year, no new ACO agreement periods will

begin in 2021, and ACOs with expiring agreement periods will have an optional one-year extension.

This interim final rule proposes to change the MSSP financial methodology during the PHE by removing spending for COVID-19 episodes of care from benchmark and performance expenditures. This removal of COVID-19 spending includes payment amounts used to calculate trend factors based on national and regional expenditures. An episode of care for treatment of COVID-19 will be triggered by an inpatient service for treatment of COVID-19. The episode will start in the month in which the inpatient stay begins and will end in the month following the end of the inpatient stay. CMS will also remove affected months from annualized per capita expenditures.

Comment

We commend CMS for seeking a solution that helps mitigate the potential for windfall shared savings or losses due to COVID-19. During this challenging time, we understand the desire to retain program participation even if the measures put in place to retain ACO participants increase program spending. However, for the reasons we discuss below, we believe that CMS's proposal to remove COVID-19 episodes from ACOs' performance assessment is problematic and may not be an effective way to accomplish that goal.

Adjusting alternative payment model (APM) benchmarks for the effects of COVID-19 is extraordinarily challenging. There are concerns with accurate coding of COVID-19 diagnoses, and the impact of COVID-19 on spending is highly variable and extends beyond COVID-19. As a result, the removal of spending from COVID-19 episodes of care is difficult, and we believe that attempting to adjust 2020 spending and benchmarks for COVID-19 will be impractical and possibly inequitable. Specifically, removing spending for COVID-19 is unlikely to produce a reasonable estimate of what spending would have been without COVID-19. For example, because COVID-19 disproportionately affects patients with certain chronic conditions, removing spending for COVID-19 treatment may underestimate the services those patients would have used had they not been admitted for COVID-19. The uncertainty of whether this would be beneficial or unfair to an ACO, in particular relative to regional and national spending that factor into benchmarks, increases the possibility that CMS will be rewarding ACOs for random variation. During 2020, there will be greater uncertainty than in other years that an ACO's care management is the reason for any reduction in spending relative to the ACO's region.

An alternative strategy would be to avoid imposition of downside risk for all of 2020 and cap shared savings paid to an ACO. The cap should be large enough to cover an ACO's administrative expenses (e.g., 2 percent of benchmark). In addition, because uncontrollable factors from the PHE may negatively bias an ACO's performance relative to its benchmark, CMS could consider giving a small bonus payment (e.g., 0.5 percent of benchmark) to ACOs that do not earn shared savings in 2020 but have MSSP participation agreements for 2021. Looking ahead, benchmarks for new agreements in performance year 2022 could either use 2017–2019 data or combine 2019 and 2021 data.

Seema Verma
Administrator
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Conclusion

MedPAC appreciates your consideration of these issues. The Commission values the ongoing collaboration between CMS and MedPAC staff on Medicare policy, and we look forward to continuing this relationship.

If you have any questions regarding our comments, please do not hesitate to contact James E. Mathews, MedPAC's Executive Director, at 202-220-3700.

Sincerely,

A handwritten signature in black ink, appearing to read "m. chernew", with a horizontal line extending to the right from the end of the signature.

Michael E. Chernew, Ph.D.
Chair