September 10, 2018

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

Re: CMS-1693-P – Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Quality Payment Program [83 Fed. Reg. 35704 (July 27, 2018)]

Dear Administrator Verma:

We are writing collectively as members of the Patient Quality of Life Coalition, a group of over 40 organizations dedicated to advancing the interests of patients and families facing serious illness, with the overarching goal of providing these individuals with greater access to palliative care services. Members represent patients, health professionals, and health care systems.

Palliative care is specialized medical care for people with serious illnesses. It focuses on providing patients with relief from the symptoms and stress of a serious illness. Palliative care is appropriate at any age and any stage in a serious illness (ideally made available to patients upon their diagnosis) and can be provided along with curative treatment.[1] The goal is to improve quality of care and quality of life for both the patient and their family/caregivers.

Studies show that without palliative care, patients with serious illnesses and their families receive poor-quality medical care that is characterized by inadequately treated symptoms, fragmented care, poor communication with health care providers, and enormous strains on family members or other caregivers.[2,3] By focusing on priorities that matter most to patients and their families, palliative care has been shown to improve both quality of care and quality of life during and after treatment.[4,5] In one study, patients with metastatic non-small-cell lung cancer who received palliative care services shortly after diagnosis even lived longer than those who did not receive palliative care.[6] Another study found that the receipt of a palliative care consultation within two days of admission was associated with 22

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[1] Smith, TJ, Temin S, Alesi ER, Abernathy AP, Balboni TA, Basch EM, Ferrell BR, Loscalzo M, Meier DE, Paice JA, Peppercorn JM, Somerfield M, Stovall E, Von Roenn JH. American Society of Clinical Oncology Provisional Clinical Opinion: The Integration of Palliative Care Into Standard Oncology Care. J Clinical Oncol 2012; 30: 880-887.
[2] Teno JM, Clarridge BR, Casey V, Welch LC, Wetle T, Shield R, Mor V. Family perspectives on end-of-life care at the last place of care. JAMA. 2004 Jan 7; 291(1):88-93.
[3] Meier DE. Increased Access to Palliative Care and Hospice Services: Opportunities to Improve Value in Health Care. The Milbank Quarterly. 2011;89(3):343-380. doi:10.1111/j.1468-0009.2011.00632.x.
[4] Delgado-Guay MO, et al. Symptom distress, interventions, and outcomes of intensive care unit cancer patients referred to a palliative care consult team, 115(2) Cancer 437-45 (2009).
[5] Casarett D, et al., Do palliative consultations improve patient outcomes? 56 J Am Geriatric Soc'y 593, 597-98 (2008).
[6] Temel JS, Greer JA, Muzikansky A, et al. Early palliative care for patients with metastatic non-small-cell lung cancer. N Engl J Med. 2010;363:733-742.

percent lower costs for patients with certain comorbid conditions.[7] Furthermore, palliative care results in fewer crises, reducing hospital utilization and resulting in overall cost savings.[8]

Yet, despite the demonstrated benefits of palliative care, there remain millions of Americans who do not access such services. Many of these people are included in the five percent of patients who account for approximately 60 percent of all health care spending – those with multiple chronic conditions and functional limitations who have persistent high costs.[9]

The Coalition appreciates the opportunity to provide comments on the proposed rule that provides calendar year (CY) 2019 updates to the Medicare Physician Fee Schedule and revisions to the Quality Payment Program, as the proposed changes hold the potential to impact patients with serious illness and multiple chronic conditions and the providers who care for them.

Virtual Check-Ins

CMS proposes to reimburse for HCPCS code GVCI1, Proposed Brief Communication Technology-based Service ("Virtual Check-in"). This code would be billable when a physician or other qualified health professional has a brief non-face-to-face check-in with a patient via communication technology to assess whether the patient's condition necessitates an office visit. This proposal is intended to pay for 5-10 minutes of medical discussion. If related to a previous evaluation and management (E/M) service within the prior 7 days or next 24 hours, the virtual check-in would not be separately payable and would be bundled as part of that previous service. CMS proposes to pay $14 for this service (as compared with $92 for an in-person E/M visit). Virtual check-ins would only be available for established patients and CMS does not propose any frequency limitation.

Comment: The Coalition supports the use of technology in improving the quality and availability of care and applauds CMS for this proposal. Clinicians that provide palliative care regularly furnish non-face-to-face services for patients that are routinely not reimbursed but that could have significant impact on patients' health and quality of life. Clinicians who devote the time and resources to assess patients to confirm that more resource-intensive in-person visits are unnecessary should be adequately compensated. We agree with CMS that frequency limitations on the use of this code are unnecessary.

The nature of palliative care services, in which patients often contend with a number of clinical conditions, means that there are likely to be significant opportunities for virtual check-in services to improve care coordination and reduce costs to the Medicare program. For example, where a patient's condition changes such that their prescribed medication is no longer adequately treating one or more conditions, a virtual check-in service would likely allow the patient to get guidance from clinicians

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[7] May P, et al. Palliative Care Teams' Cost-Saving Effect Is Larger For Cancer Patients With Higher Numbers Of Comorbidities. Health Affairs. January 2016.

[8] Agency for Healthcare Research and Quality: System-integrated program coordinates care for people with advanced illness, leading to greater use of hospice services, lower utilization and costs, and high satisfaction. www.innovations.ahrq.gov/content.aspx?id=3370.

[9] IOM (Institute of Medicine). 2014. Dying in America: Improving quality and honoring individual preferences near the end of life. Washington, DC: The National Academies Press.

sooner to receive appropriate symptomatic relief more quickly and potentially avoid a more expensive clinic or emergency department visit.

Given the potential cost-savings opportunities and the time and resources required for providing this service, we are concerned that the proposed payment for this service is so low that many providers will be hesitant to use it. An increased, more reasonable payment will encourage greater use of the code, and likewise offer greater opportunities for cost savings to the Medicare program.

With respect to the time-based provisions of this proposal, we believe it will be crucial for CMS to monitor the window of services furnished before and after the Virtual Check-In is provided. As currently proposed, the policy presents a risk that some clinicians would be incentivized to delay follow-up care in order to bill separate E/M services after the 7-day window has elapsed. Such a delay could be detrimental to a patient with serious illness, and could worsen health outcomes or increase spending for other Medicare services – consequences which are contrary to the stated policy goal.

At the same time, we are concerned that the use of the code would result in beneficiary cost-sharing obligation. We strongly encourage CMS to waive cost-sharing due to concern that the financial obligation may discourage beneficiary utilization, which is again contrary to the stated policy goal.

Remote Evaluation of Pre-Recorded Patient Information

CMS proposes to pay separately for services billed as HCPCS Code GRAS1, Remote Evaluation of Pre-Recorded Patient Information, and that such services would not be subject to Medicare's telehealth restrictions under Section 1834(m) of the Social Security Act (e.g. originating site requirements, etc.). These services would include "pre-recorded patient generated or still images," but would not include other types of patient-generated information such as data from heart rate monitors or devices that collect patient health marker data. Similar to CMS' virtual check-in proposal, this code would only be separately billable when there is no resulting E/M office visit and no related E/M visit within the preceding 7 days.

Comment: The Coalition supports this proposal and believes it represents an important effort in improving access to care for Medicare patients. Particularly in rural areas, where certain specialties may not be available, this service is likely to allow patients to receive medical care, including palliative care, that previously has not been available to them. While we agree with CMS that beneficiaries should be made aware of cost-sharing obligations, we strongly encourage CMS to waive beneficiary cost-sharing associated with this service to avoid undermining the policy goals of this code.

Interprofessional Internet Consultation

CMS proposes to make separate payment for assessment and management services conducted through telephone, internet, or other electronic health record furnished when a patient's treating physician or other qualified healthcare professional requests the opinion and/or treatment advice of a consulting physician or qualified healthcare professional with special expertise. The applicable CPT codes are 994X6, 994X0, 99446, 99447, 99448, and 99449. This payment would not be available when the consultation is for the benefit of the practitioner or as part of professional education; the service must be for the benefit of the beneficiary.

Comment: The Coalition supports this proposal. Clinicians providing palliative care are often asked to provide consultative services of this nature, particularly for Medicare beneficiaries in rural communities. Consultative services frequently suggested include pain and symptom management, prognostication, challenging patient and caregiver communication, psychological and/or spiritual distress, hospice eligibility, and end-of-life management.

As noted in our comments above, we would also encourage CMS to waive any beneficiary cost-sharing related to the use of these codes so as not to discourage their use.

Allowing Payment for Same-Day Services Delivered within the Same Specialty and Practice

CMS is soliciting comment on eliminating the current restriction on more than one provider in the same specialty and same practice from billing for E/M services on the same day.

Comment: We strongly support elimination of this existing billing restriction. This change acknowledges the modern reality of subspecialization within practices, which has led to a much broader array of services being available 'under one roof.' This is particularly valuable for beneficiaries with serious illness, who often face limited mobility, caregiving and transportation challenges, and symptoms that make multiple visits on multiple days a great burden. Palliative care subspecialists can train in any one of 10 primary specialties, and many of them continue to practice palliative care within their primary specialty group (e.g. oncology, cardiology, neurology, etc.). Such 'embedded' services can often be delivered on the same day as other care, which is of great value to beneficiaries. As a result, we urge that this provision be included in the final rule.

Bundled Episode of Care for Substance Use Disorders

CMS is considering the creation of a separate payment for a bundled episode of care for treatment of substance use disorders (SUD), aimed at preventing the need for more acute services. CMS is requesting comments regarding the structure, coding, and payment of such a bundled SUD treatment model and solicits feedback on details such as the number and duration of counseling sessions, the types of practitioners who could participate, and incident-to rules specific to opioid treatment.

CMS also invites comments on regulatory and sub-regulatory changes to prevent opioid use disorders, specifically methods for identifying non-opioid alternatives for pain treatment and management, along with identifying barriers that may inhibit access to these non-opioid alternatives including barriers related to payment or coverage.

Comment: The Coalition appreciates CMS' prudent approach in soliciting information from the clinician community before drafting regulations responding to the complex problem of opioid misuse.

With respect to CMS' proposal for bundling payments for SUD treatment, the Coalition supports the development of innovative payment approaches to improve access to care and services connected to SUD. As CMS further considers this bundled payment approach, it will be crucial for CMS to balance the desire to achieve cost savings through the use of bundled payments with the need to adequately compensate comprehensive care, particularly for patients with complex needs. For example, if the bundled payment amount is set too low, that may potentially decrease access to care, which could in turn increase emergency department visits and lead to increased costs.

Similarly, we hope that any forthcoming proposals involving bundled payments for SUD treatment ensure that the changes to payment do not limit Medicare beneficiaries' access to appropriate care, particularly for those patients with concurrent serious illnesses, such as advanced cancer, or for individuals of limited means who may be price sensitive to services that will impose additional cost-sharing on beneficiaries.

Finally, we recommend that CMS consider linking bundled payments for SUD treatment to performance on certain quality measures in order to incentivize accountability for delivery of appropriate care within the episode of care.

With respect to CMS' request for comments regarding non-opioid alternatives, the Coalition commends CMS on this focus. We support this focus, as we support palliative care clinicians having more options to effectively treat their patients' symptoms, which will hopefully lead to better outcomes for seriously ill individuals. Many patients are not able to use currently-available non-opioid treatments because they are not covered by insurance – or are covered at much higher costs – and therefore not affordable. The Coalition encourages CMS to carefully consider expanding coverage of non-opioid alternatives, including medication and non-medication alternatives, in fee-for-service coverage and Medicare Advantage. However, we urge CMS to maintain timely access to opioids for patients who require these medications and can safely use them. We also encourage CMS to ensure that any new or adjusted coverage be provided with cost-sharing that is no more burdensome than the cost-sharing for opioid treatments.

Evaluation & Management (E/M) Visits

CMS' proposals for revising current E/M coding and payment policies, if finalized, would present a significant change in payment for many clinicians. CMS is proposing a new, single blended payment rate for new and established patients for office and outpatient E/M level 2 through 5 visits, as well as a series of add-on codes to reflect resources involved in furnishing primary and specialty care. Based on the estimates provided by CMS in the proposed rule, the impact of these changes to payment for E/M visits would vary by physician specialty. CMS is also proposing to apply a new minimum documentation standard where Medicare would require information to support a level 2 CPT visit code for history, exam and/or medical decision-making in cases where practitioners choose to use the current framework, or, as proposed, medical decision-making (MDM) to document E/M level 2 through 5 visits.

Comment: The Coalition is deeply concerned that these proposed changes may adversely impact the time and quality of care furnished to patients receiving palliative care. As currently proposed, analysis conducted by the American Medical Association (AMA) estimates that Hospice and Palliative Medicine specialists would receive the largest percent change in payment for office visits, with an average reduction of 20 percent, if the proposals are finalized. This reduction inevitably means that palliative care services will be less available for the sickest, most vulnerable patients. In the short term, the proposed E/M changes also are likely to increase provider burden and create confusion, given that they will require providers to deviate from the standard billing practices of other payers.

Additionally, since the E/M codes would not provide sufficient reimbursement to address multiple chronic conditions in a single visit, some providers might choose to address one condition at a time rather than treating the patient holistically. Incentivizing multiple visits for a single patient creates

additional burden for the patients and their families/caregivers, extra demand on the system, and results in poorer outcomes. This change could result in a perverse incentive to provide disjointed care.

Looking longer term, these proposed changes to established E/M billing practices are likely to dis-incentivize the provision of palliative care. The average palliative care patient requires more time and involvement from a treating provider, which is not equivalent to the time and effort of a traditional level 2 visit. Where providers are faced with reduced reimbursement for these services, we fear that fewer providers will provide palliative care, or will specifically exclude palliative care for Medicare patients. This problem is likely to be particularly acute in rural areas, where smaller physician practices may not be able to justify the time and involvement in furnishing palliative care reimbursed at the consolidated payment level. Thus, these proposed changes would likely negatively impact the providers furnishing care to the most complicated and vulnerable patients – impacts that would very likely be passed on to seriously ill patients in the form of reduced access to this crucial care.

CMS notes in the Proposed Rule that it does not believe that the current E/M visit definitions and the associated documentation burdens are the most accurate descriptions of the variation in work. Rather, CMS believes that certain types of clinicians that frequently bill higher level E/M visits have been burdened by the documentation requirements, and that the corresponding medical treatment is described imperfectly by the visit codes. Thus, CMS appears to believe that reductions in documentation burden justify reductions in E/M reimbursement, and supports this with an analysis suggesting that reductions in reimbursement by specialty would only reach a maximum of -4 percent.

With respect to palliative care, this conclusion is inaccurate. As noted above, AMA's analysis shows that Hospice and Palliative Medicine providers would see a 20 percent reduction in E/M revenue under the proposed rule. While that reduction may be partially mitigated by other revenue in the fee schedule, we are very concerned that such a reduction will threaten the viability of palliative care practices, particularly those focused primarily in the outpatient setting.

We are also concerned that documentation reduction will not materially offset the proposed losses in E/M revenue. While certain documentation requirements do indeed pose burdens, the corresponding medical treatment for palliative care patients is complex given the many comorbidities this patient populations experiences. As a result, meaningful documentation will be still necessary for appropriate care coordination and communication among treating providers, so any modest reduction in documentation for palliative care clinicians will not enable a sufficient increase in patient volume to offset the E/M revenue losses.

We are encouraged that CMS has proposed add-on payments to E/M visits that include both prolonged services codes as well as complexity codes. However, we have several concerns regarding these proposals. First, it is not clear how the prolonged services codes will be implemented with respect to the time thresholds required to bill the codes, specifically, 'typical time' vs. the CPT convention of 'more than half' of a time-based code interval. Many palliative care providers report E/M codes based on time, so this is a critical issue for professionals in the field, and the beneficiaries they serve.

Second, we are concerned that only specific physician specialties are proposed to receive the complexity add-on payments. Hospice and Palliative Medicine is **not** among the specialties proposed to be eligible, which is surprising given the specialty's sole focus on patients with serious, life-limiting illness (like

advanced cancer, advanced heart failure and advanced dementia) who are, by their nature, extremely complex. More importantly, we believe that payments for complexity should be based on the characteristics of the patient—not the specialty of the billing provider—to more accurately account for the time and intensity of services provided. Not all patients seen by any limited list of specialists are complex enough to require additional payment; conversely, not all providers who care for complex patients will fall on any limited list of specialties.

Third, we are concerned that the proposed add-on payments are too small to offset the anticipated 20 percent loss in E/M revenue to palliative care providers, who already struggle to support high-quality service delivery under current payment. Such a loss would further limit access to vital services by seriously ill, often vulnerable beneficiaries. It would also diminish the proven value of palliative care to the Medicare program detailed at the beginning of these comments, including improved care quality, decreased hospitalization, and reduced overall costs. While these savings do not accrue specifically to the fee schedule, we urge CMS to take broad consideration of the potential negative impact of the payment changes to the overall Medicare program, and the overall beneficiary experience.

Given these concerns, rather than move forward with these changes regarding the E/M codes the coalition urges CMS to not finalize the payment changes proposed for the E/M codes in the 2019 MPFS proposed rule.

Quality Payment Program Merit-based Incentive Payment System Measures

CMS proposes to designate quality measures related to opioids as high priority in the Quality Payment Program (QPP), and asks for comments on what aspects of opioids should be measured – for example, whether it should focus solely on overuse of opioids.

Additionally, as part of the Merit-based Incentive Payment System (MIPS) Promoting Interoperability performance category, CMS proposes to add two new measures recording whether the clinician checked the Prescription Drug Monitoring Program (PDMP) for a patient receiving opioids, and whether the clinician verified that a patient receiving opioids had a signed Opioid Treatment Agreement. CMS specifically asks for comments on whether such agreements could create a burden on clinicians and patients, particularly clinicians who serve patients with cancer or those practicing in hospice, as well as the patients they serve.

Comment: The Coalition appreciates CMS' prudent approach in soliciting information from the clinician community before drafting regulations responding to the complex problem of opioid overuse. In general, the Coalition emphasizes the need for any opioid-related regulations to appropriately balance concerns about opioid abuse, misuse, and diversion with the need for timely, safe and appropriate access to opioid therapy by patients with serious illnesses with opioid-responsive pain. For example, clinicians furnishing hospice and palliative care regularly treat patients whose care includes treatment with opioids to improve their quality of life, manage pain, and/or address end-of-life needs. Thus, CMS must recognize that high frequency or quantity of opioid prescribing does not necessarily reflect inappropriate prescribing, especially for clinicians treating seriously ill patients.

The Coalition appreciates CMS' consideration of how the two new proposed opioid-related quality measures could impact patients, and we ask CMS to include patients receiving palliative care in this

consideration. Regarding the first proposed measure, the Coalition supports the use of PDMPs to reduce misuse and abuse of opioids, and also as a care coordination tool for patients with multiple prescribers. We are concerned, however, that at a time when many PDMPs are not integrated seamlessly into providers' EHRs, requiring a clinician to check a PDMP every time they prescribe an opioid could be overly burdensome, and lead to gaps in essential treatment for seriously ill beneficiaries with severe pain. If CMS finalizes the two new opioid measures detailed above, the Coalition urges CMS to monitor implementation closely to ensure that these measures do not cause seriously ill patients to lose access to palliative care by placing an undue burden on palliative care providers or other clinicians involved in the treatment of seriously ill patients.

Conclusion

On behalf of the Patient Quality of Life Coalition, we thank you for the opportunity to comment on the proposed updates to the Medicare Physician Fee Schedule and Quality Payment Program. If you have any questions, please contact Keysha Brooks-Coley, Executive Director of the Patient Quality of Life Coalition, at 202-661-5720 or Keysha.Brooks-Coley@cancer.org.

Sincerely,

Academy of Integrative Pain Management
Alzheimer's Association
Alzheimer's Impact Movement
American Academy of Hospice and Palliative Medicine
American Association of Colleges of Nursing
American Cancer Society Cancer Action Network
American Psychological Association
Association of Oncology Social Work
Association of Pediatric Hematology/Oncology Nurses
Cancer Support Community
Catholic Health Association of the United States
Center to Advance Palliative Care
Coalition for Compassionate Care of California
Motion Picture & Television Fund
National Patient Advocate Foundation
Oncology Nursing Society
Pediatric Palliative Care Coalition
Physician Assistants in Hospice and Palliative Medicine
ResolutionCare Network
Supportive Care Coalition