September 27, 2019

BY ELECTRONIC DELIVERY

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244-8013

RE: CY 2020 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies - CMS-1715-P

Dear Administrator Verma:

The National Health Council appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services’ proposed rule revising payment policies under the Medicare Physician Fee Schedule (the Proposed Rule).

Founded in 1920, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. The NHC provides a united voice for the more than 160 million people with chronic diseases and disabilities and their family caregivers. Made up of more than 125 diverse national health-related organizations and businesses, the NHC’s core membership includes the nation’s leading patient advocacy organizations, which control its governance and policy-making process. Other members include health-related associations and nonprofit organizations including the provider, research and family caregiver communities; and businesses representing biopharmaceutical, device, diagnostic, generic, and payer organizations.

We support CMS’ proposed initiatives to refine the Quality Payment Program (QPP); enable appropriate payment for clinicians managing patients with one or more chronic condition; and expand coverage, coding, and payment mechanisms for opioid use disorder (OUD) treatment in opioid treatment programs (OTPs) and physician offices.

Our comments focus on ensuring that CMS’ policy refinements will facilitate, rather than impede, the ability of individuals with chronic conditions and their providers to design, implement, and continue treatment plans that align with the patient’s health care goals.
Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs) – General Goals and Guiding Principles

The NHC appreciates CMS’ commitment to transforming the health care delivery system and shares its stated goal of putting an increased focus on patient-centered care, innovation, and outcomes. We agree that when providers spend less time on paperwork and reporting requirements, and more time on the clinician-patient relationship, patients have a greater opportunity for improvement on the health outcomes that are most important to them. The Agency’s measured approach toward implementing the Quality Payment Program (QPP) has enabled it to balance the inherent burdens and uncertainties for clinicians with the QPP’s programmatic goal of transitioning to a value-based Medicare reimbursement framework. We appreciate CMS’ engagement with stakeholders throughout the QPP phase-in and support its “strategic vision to further transform MIPS by empowering patients and simplifying MIPS to improve value and reduce burden.”

The NHC agrees that a value-based reimbursement framework should be designed to improve value, reduce burden, help patients compare clinician performance, and better inform patient choice in selecting providers. While the flexibility CMS has afforded to clinicians participating in the MIPS pathway was an important element in the QPP phase-in to minimize clinician uncertainties and burden, the resulting diversity in quality measure reporting, even within specialties, has complicated the ability of CMS or patients to reliably assess performance. The MIPS value pathways (MVP) proposal would, ideally, involve CMS engagement with patients, caregivers, and providers to identify smaller sets of condition- or specialty-specific groups of cost, quality, and improvement measures. CMS’ proposed transition to MVPs is intended to make reporting simpler and more uniform, and to generate more meaningful results for patients and the Medicare program.

The NHC also recommends a methodical transition to MVPs with significant oversight to support providers during the transition to MVPs and avoid any potential impact on access for patients. It will take substantial time and resources to develop, refine, and educate physicians on this new QPP track. We further advocate for an opt-in policy, which would allow physicians to opt-in to CMS’ suggested MVP, or to choose an alternative MVP, or to continue to report measures through the traditional MIPS pathway. We are concerned about physician burden during this transitional period, and CMS should ensure that providers do not have to participate in an MVP for one disease but report in traditional MIPS for other patients that do not fit in the CMS MVP. In addition, as part of this transition period, we urge CMS to meaningfully engage patients in planning and implementing the transition.

CMS has also proposed that, beginning with the 2020 call-for-measures process, MIPS quality-measure stewards must link their MIPS quality measures to existing, related cost measures and improvement activities, as applicable and feasible.

Individuals with chronic conditions, particularly those encountered in the Medicare population with multiple chronic conditions, often are uniquely vulnerable to changes in clinician behavior resulting from incentive shifts in performance and value-based
payment strategies. The NHC is concerned that CMS’ proposal to link quality measures with cost measures could, if implemented too broadly, have the unintended effect of disincentivizing providers from appropriately treating Medicare’s most vulnerable patients.

The NHC encourages CMS to include in this process considerations related to patients with chronic conditions and ensure that measures related to care for these patients are not disproportionately removed from MIPS due to an inability to link quality measures with cost measures.

The NHC appreciates that CMS has identified and seeks comment on a set of “guiding principles” that would drive MIPS’ transition to MVPs. The NHC agrees that MVPs should:

- Consist of limited sets of measures and activities that reduce or eliminate clinician burden related to selection of measures and activities, simplify scoring, and lead to sufficient comparative data and
- Include measures and activities that:
  - Provide comparative performance data that is valuable to patients and caregivers in evaluating clinician performance and making choices about their care. To assist in this, the NHC and the Pharmacy Quality Alliance have created the Patient-Engagement Rubric for Quality Measurement. The rubric is a standardized tool for involving the patient community in the quality-measure lifecycle enhances the development of measures that are easily understood, meaningful, and useful for addressing quality issues important to the public;
  - Encourage performance improvements in high priority areas; and,
  - Are part of alternative payment models (APMs) where feasible.

In addition to supporting the principles above, the NHC recommends some additional modifications that will benefit patients. The NHC urges CMS to:

- Incorporate patient-centeredness into measures and activities so that measure sets capture the outcomes that are most important to patients, and scoring reflects patient priorities. This means engaging patients in measure development and selection and utilizing approaches such as those outlined in the Patient-Engagement Rubric for Quality Measurement;
- Ensure that patients with chronic conditions and complex patients are appropriately identified as high priority;
- Avoid rigidly linking cost and quality measurement. Clinical guidelines that generally drive value-based payer strategies tend to be population-based and do not account for an individual’s goals and personal circumstances, or the unique medical needs of complex patients with multiple chronic conditions. A patient’s treatment plan may, therefore, diverge from the treatment recommendations.

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upon which quality measures are based. We urge CMS to ensure that clinicians are not penalized for prescribing therapies that, based on clinician expertise and patient preferences and priorities, are most appropriate; and

- Adopt a guiding principle of designing MVPs to incorporate a holistic view of the patient that takes into account how health care needs outside a particular MVP or specialty measure set are met, either through the reporting provider or through care coordination with other practices and/or settings.

**CMS should engage patients to better define “value” for the purposes of implementing the Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs)**

The NHC continues to support payment system refinements and reforms that incentivize value-based, patient-centered care. In its proposed rule, CMS stated that:

> [F]or purposes of this discussion, we define ‘value’ as a measurement of quality as related to cost, ‘value-based care’ as paying for health care services in a manner that directly links performance on cost, quality, and the patient's experience of care, and ‘high value clinicians’ as clinicians that perform well on applicable measures of quality and cost.

The NHC is concerned that by defining value, based on quality alone, which implies quality measures, ignores aligning value with patient-preferred outcomes. CMS has over-simplified an elusive, highly variable concept. Patient perspectives on desired outcomes and views on quality can differ significantly from that of payers and providers.

CMS’ strategic initiative to transform the MIPS provides an opportunity to more fully address what value means and the perspective from which it is identified, assessed, and quantified in a manner that aligns with CMS’ overarching goal of empowering patients and increasing patient centeredness. In devising an MVP, we urge CMS to work with the patient community to create a shared and agreed-upon definition of value in terms of outcomes relevant to patients and family caregivers. Failing to address this fundamental informational gap could deprive the Agency, providers, and the patients they serve, of core information that should drive payment and care delivery transformation, including the QPP and could ultimately undermine our shared goal of increasing patient centeredness, improving outcomes, and reducing costs.

**Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs) should engage the patient community.**

The NHC appreciates CMS’ MVP Request for Information (RFI) on patient engagement. The issues CMS has asked stakeholders to weigh-in on are both relevant and meaningful to the Agency’s MVP strategic initiative. Our responses to the RFI focus on CMS’ interest in ensuring meaningful stakeholder engagement as it develops MVPs. First and foremost, the NHC believes that the patient community should be involved in
measure development and selection, as well as identification and/or development of patient experience/satisfaction measurement tools and patient-reported outcomes.2

As a voice for individuals with chronic diseases and disabilities, the NHC devotes significant attention to devising and improving mechanisms for engaging patients and incorporating their perspectives into policies and decisions likely to impact availability of and access to high-quality medical care. The MVP initiative is particularly well-suited to patient engagement. Our “Rubric to Capture the Patient Voice” (Rubric) was devised as a tool to guide health care stakeholders on meaningful patient engagement.3 The Rubric includes level-setting definitions and two main sections:

Section I: Meaningful Patient Engagement Processes. This section outlines characteristics of direct, meaningful patient engagement.

Section II. General Patient-Centeredness Considerations. This section focuses on approaches that enhance patient centeredness throughout an activity but are not direct patient engagement.

We define patient-centered health care as care that is respectful of and responsive to individual patient preferences, needs, and values in the context of their own social worlds. Patient centeredness is created by engaging, informing, and actively listening to patients at every point of contact. Over the past few years, the NHC has held several multi-stakeholder roundtables to more fully capture what it means to be patient centered, and identified the following domains representing hallmark characteristics of patient centeredness:

Patient Partnership - Patients should be involved in every step of the process, including planning and dissemination. Consideration should be given as to whether tools or other resources are needed to support patient partners (e.g., training on terminology).

Transparency - All activities should be conducted in an open way, and assumptions, inputs, processes, and results need to be disclosed to patients in plain language and in a timely fashion.

Representativeness - Representativeness connotes that a sufficient number and types of people are included in the engagement activity to ensure that those engaged can speak on behalf of the target population. In practical terms, this means that those engaged - patients, caregivers, advocates, and advocacy organizations - should be representative of the set of Medicare beneficiaries likely to be impacted by a particular MVP in order to deliver sufficient insight into what constitutes value and how it should be measured.

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Diversity - The activity should consider differences among patients, including patient subpopulations, trajectory of disease, and stage of a patient's life.

Outcomes that Patients Care About - Whether the activity is oriented around research, policy, or care delivery, the outcome(s) being measured should include those that are important to patients. Patient-centered (patient-prioritized) outcomes can only be identified by patients. A common misconception is that all patient-centered outcomes are patient-reported outcomes (PROs), and all PRO’s are patient centered. Neither is true. Patients often prioritize outcomes such as pain or fatigue, which can only be captured through PRO measures, but they may prioritize other outcomes that are captured using clinical measures such as biomarkers.

Patient-Centered Data Sources and Methods - Having a variety of credible sources can facilitate timely incorporation of new information and account for the diversity of patient populations and patient-centered outcomes, especially those from real-world settings and reported by patients directly.

Timeliness - The engagement should happen in alignment with the given objective of the activity. For example, engagement toward the MVP initiative should occur well before MVPs or quality measures have been identified.

The NHC supports CMS’ Care Management Services proposals.

The NHC applauds CMS for prioritizing the care management services crucial to addressing the health care needs of complex patients. We believe that the best way to support the clinician-patient relationship and facilitate patients reaching their goals is to incentivize treatment planning and shared decision-making throughout the patient journey. This means clinicians should be encouraged to provide covered care management and treatment-planning services when they can be most useful, including when a new diagnosis is received, a new medication is given, or the patient experiences life changes that might impact their care and goals. We share CMS' concern that chronic care management (CCM) services, and in particular, complex CCM services continue to be underutilized.

The NHC supports CMS’ proposals to:

- Clarify that the transitional care-management (TCM) code can be reported with an evaluation and management (E&M) visit or with another care-management code if all reported services are medically necessary;
- Implement additional codes for complex and non-complex CCM services with 20-minute increments to ensure that payment is adequate to facilitate appropriate utilization;
- Increase reimbursement for TCM services;
- Create two new codes for principal care-management (PCM) services to appropriately reimburse clinicians treating patients for a single, serious chronic condition requiring substantial care management.
The NHC believes that the proposed changes provide greater granularity with respect to the time required to provide these services and should reduce any current disincentives to treat Medicare’s most complex and vulnerable patient populations. We encourage CMS to also explore ways to utilize the CCM codes as a means of differentiating patients likely requiring higher resources so that clinicians treating these patients are not penalized for providing appropriate care.

**NHC supports CMS’ proposal to maintain the complex-patient bonus for 2020.**

The NHC strongly supports the proposal to maintain the complex-patient bonus for clinicians treating high-complexity patients. We remain concerned, however, that this remains a short-term solution to an inherent and unrelenting reality. We strongly urge CMS to engage the patient community in developing system-wide quality measures and resource-use methodologies that capture the clinical realities associated with caring for patients with chronic diseases and disabilities. This will offer a better long-term solution to ensure that clinicians are rewarded – not punished – for providing care to the most complex patients.

**The NHC supports CMS’ proposal to refine coverage payment mechanisms for opioid use disorder (OUD) treatment services.**

The NHC appreciates CMS’ efforts to ensure that individuals suffering from OUD have access to evidence-based, medication-assisted treatment (MAT) to increase their chance for recovery. According to the American Society for Addiction Medicine:

> Relative to treatment without medication, office-based opioid treatment with buprenorphine improves six-month treatment engagement, significantly reduces cravings, illicit opioid use and mortality, and improves psychosocial outcomes. Importantly, agonist therapy has been shown to decrease mortality by approximately 50% among persons with opioid-use disorder.

We agree that individuals seeking treatment for OUD should be able to receive what they need for recovery quickly and in the setting most suited to their individual needs, circumstances, and goals. CMS has proposed changes intended to expand access to MAT in both opioid-treatment programs and the physician-office setting. Opioid-treatment programs (OTPs) must be certified by SAMHSA and accredited by an independent, SAMHSA-approved accrediting body to dispense opioid treatment medications. OTPs have historically dispensed doses of methadone to patients on a daily basis as well as ancillary social and counseling services based on a treatment plan. Physician offices that provide MAT services generally prescribe buprenorphine-based medications for take-home use and provide or coordinate counseling and other services the patient needs throughout recovery.

The NHC supports CMS’ goal of refining payment mechanisms to enable increased Medicare beneficiary access to MAT for OUD. We are concerned, however, that without implementation tailored to the needs of patients and providers, access gains may be limited. With respect to CMS’ OTP proposal, the NHC supports proposals to:
Set patient responsibility at zero copayment. The NHC urges CMS to apply the zero-copayment policy to OUD treatment to both the OTP and physician-office settings to ensure that patients have access to the care most appropriate for their needs and circumstances;

- Permit OTP use of two-way interactive audio-video communication technology, as clinically appropriate, in order to increase access to care for beneficiaries; and

- Not propose a maximum treatment duration.

The NHC urges CMS to:

- Reconsider the requirement patients must have had OUD for at least a year to be eligible for OTP services; and
- Set payment rates for the medicines that allow physicians to adequately provide the services in the bundle.

CMS has also proposed a set of refinements to OUD treatment reimbursement in the physician-office setting. The NHC supports CMS' efforts to ensure that Medicare beneficiaries have access to MAT services provided by clinicians in their communities. We are concerned, however, that bundled payments that include treatment planning, prescribing, care management, care coordination, psychotherapy, and counseling activities do not align with the realities of practices outside psychiatric offices and addiction specialists. CMS could expand access to office-based primary-care settings by creating bundles that enable MAT-prescribing clinicians to refer their patients to other settings for counseling services while retaining treatment planning, care management, and coordination responsibilities associated with prescribing MAT.

Conclusion

We thank CMS for the opportunity to provide comments on the Proposed Rule. Please do not hesitate to contact Eric Gascho, Vice President of Policy and Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202-973-0545 or via e-mail at egascho@nhcouncil.org.

Sincerely,

Marc Boutin, JD
Chief Executive Officer
National Health Council