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October 5, 2020

The Honorable Seema Verma Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1734-P P.O. Box 8016 Baltimore, MD 21244-8016

Re: CMS-1734-P

CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; etc.

Dear Administrator Verma:

The National Health Council (NHC) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule referenced above.

Created by and for patient organizations 100 years ago, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, sustainable health care for the more than 160 million people with chronic diseases and disabilities, and family caregivers that we represent. Made up of more than 140 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses representing biopharmaceutical, device, diagnostic, generic drug, and payer organizations.

The NHC has commented in support of CMS' focus throughout the COVID-19 Public Health Emergency (PHE) on increasing the modalities through which individuals can access needed health care and minimizing the burden on NHC Comments – Medicare Fee Schedule and QPP October 5, 2020 Page 2 of 8

providers as they navigate how to enable clinically appropriate options for their patients to receive necessary treatments and services. We appreciate that the Agency seeks to continue many of its flexibilities through the PHE, and that it has leveraged its experience during the pandemic to identify and propose permanent changes that will enable broader use of telemedicine. Similarly, the NHC applauds CMS' measured approach to updating and evolving the Quality Payment Program (QPP), including its proposal to increase the complex patient bonus to account for challenges to patient health and care delivery during the PHE, and the decision to delay implementation of the MIPS value pathway initiative.

Individuals with chronic diseases and disabilities, have been disproportionately impacted by the PHE, by virtue of the challenges associated with accessing health care needed to manage their conditions, as well as increased morbidity and mortality for those contracting the novel coronavirus. The pandemic has also magnified and illuminated health disparities associated with race, socioeconomic status, and geographic factors that have long impeded adequate management of chronic conditions in these subpopulations. Experiences over the past several months underscore the importance of addressing the care needs of complex patients and the dire consequences to patients unable to access appropriate interventions to adequately address their health care needs. Our comments focus on ensuring that CMS' policy refinements continue to facilitate the ability of individuals with chronic diseases and disabilities and their providers to design, implement, and continue treatment plans that align with the patient's health care goals and needs.

The NHC supports CMS' proposal to expand access to Telehealth services.

The NHC has joined with other patient organizations to identify key principles to implementing telehealth to ensure access, enable quality care, and protect patients. We call for regulations concerning telehealth to meet the following principles:

- **Improve Access through Equitable Coverage:** Telehealth services should be covered by all health plans including, but not limited to, Medicare, Medicaid, the ACA Marketplace, and other federal and state regulated commercial health plans.
- Improve Access by Easing Technology Barriers: Telehealth services should be equitably available through easily accessible and usable technologies that are accessible to people with disabilities, limited English proficiency, and limited technology access and experience. The option of audio-only communication is especially important for rural and low-income populations, as many of these patients lack internet access.
- **Preserve and Promote Patient Choice:** A patient should have the opportunity and flexibility to choose whether they will access care in-person or via telehealth technologies.
- **Remove Geographic Restrictions:** Geographic restrictions, such as requiring both the patient and provider to be in the same state, places a burden on and

NHC Comments – Medicare Fee Schedule and QPP October 5, 2020 Page 3 of 8

can limit both patients and providers when evaluating treatment options for optimal care and should be removed.

- **Protect Patients and Provider Legal Rights:** Health plans should clearly define what telehealth services are covered. Providers must use technology compliant with patient privacy, disability access, and civil rights law. This information should be transparent and easy to understand for consumers.
- Increase the Evidence Base for Telehealth: As telehealth becomes more common, data must be collected, and more research must be conducted on the use and outcomes of telehealth. Special attention should be given to promoting health equity to determine how telehealth technologies should be designed and implemented so all populations have equal access to the potential benefits.

Our comments on the proposed rule's telehealth provisions reflect these principles, and we urge CMS to keep them in mind when promulgating a final rule.

The NHC continues to support CMS' initiatives to ensure Medicare beneficiaries have a robust set of options for accessing needed health care. Expanded access to telehealth services can be particularly important to individuals with chronic diseases and disabilities who may require more frequent interactions with providers, and benefit from consultation specialists. We believe appropriate use of telehealth services requires a balanced approach and should be based on patient preferences, needs and goals, and that it should be used in tandem with face-to-face clinician visits when patients and providers determine in-person visits are the more appropriate setting to manage chronic conditions and achieve health care goals.

The NHC fully supports CMS' proposals to:

- Extend telehealth flexibilities through the calendar year in which the PHE expires. The NHC agrees with CMS that abruptly ending the PHE-related temporary expansion in telehealth services upon resolution of the PHE would present a disruption in coverage and inject uncertainties for providers. More importantly, we also believe an additional period beyond the PHE is crucial to protect people with chronic conditions. Even when the PHE expires not all people can safely relax social distancing behaviors. For example, people who are immunocompromised will benefit from the ability to continue at least some level of isolation that telehealth services will help facilitate.
- Permanently add several codes that were temporarily added to the Medicare telehealth list, including the codes for group psychotherapy; domiciliary, rest home, or custodial care services for established patients; home visits for established patients; cognitive assessment and care planning services; visit complexity inherent to certain office/outpatient evaluation and management services; prolonged services; and psychological and neuropsychological testing.
- Permanently permit physicians to supervise rural non-physician providers through telehealth.

NHC Comments – Medicare Fee Schedule and QPP October 5, 2020 Page 4 of 8

• Extend its geographic and site-of-service originating-site flexibilities for Medicare telehealth services through at least 2021. Ideally, CMS would extend this flexibility until Congress has had the opportunity to remove or ease the existing statutory restrictions.

The NHC offers recommendations and comments for CMS implementation and finalization of the telehealth-related proposals identified below:

- We support CMS' proposal to identify a new "Category 3" track for adding telehealth services "for which we could foresee a reasonable potential likelihood of clinical benefit when furnished via telehealth outside the circumstances of the PHE." We agree that identifying these services separately will better enable stakeholders to engage CMS through the rulemaking cycle on the need for continued/permanent coverage of these services. We believe, however, that CMS should permit coverage through the calendar year on which the PHE terminates for all the services temporarily covered as telehealth services. This would minimize the disruption to provider practices that would occur if any of CMS' telehealth flexibilities were abruptly terminated upon the Administration's announcement that the PHE has ended.
- We generally support CMS' proposal to maintain additional services on the list of Medicare telehealth services through the end of the calendar year in which the PHE ends. The NHC appreciates that CMS intends to utilize this additional time to examine the benefits to patients and the Medicare program by providing these services through telecommunications technology outside the context of a pandemic. We urge the Agency to examine access to and impact of these services through telemedicine and in-person care, for patients with chronic diseases and disabilities as well as across socioeconomic and racial subpopulations. Specifically, we ask you to work directly with patients to identify how telehealth has improved those outcomes most important to them.
- The NHC agrees that a set of billable codes to enable payment for audio-only telehealth services that would enable patients to access health care providers from their own home. This may be the only option that some people have or are comfortable with. The brief check-in codes that currently exist do not offer sufficient payment for services beyond a very brief call in follow-up to or anticipation of an in-office encounter. We urge CMS to develop measures and safeguards while enabling appropriate payment for audio-only visits that are of similar duration to the time required for evaluation and management services.
- We similarly support CMS' proposal to extend the temporary policy of allowing practitioners to satisfy direct supervision requirements virtually using real-time, interactive audio and video technology until the later of the end of the calendar year in which the PHE ends or December 31, 2021.

The NHC appreciates CMS' implementation of PHE flexibilities to allow patients with complex care needs to access care from specialists across the country, and to do so from their homes so they can maintain continuity of care when they are unable to safely participate in office visits. We urge CMS to examine its claims data to ascertain

NHC Comments – Medicare Fee Schedule and QPP October 5, 2020 Page 5 of 8

the extent to which patients have relied on this PHE-related flexibility and the impact on their care and outcomes.

The NHC Supports CMS' Efforts to Clarify Requirements for Remote Patient Monitoring (RPM) Services.

The NHC has supported CMS' temporary revision of its Medicare payment policies to loosen RPM reimbursement requirements during the PHE, removing a barrier to promote the health and safety of patients. RPM services permit collection and analysis of patient physiologic data so that providers that develop and manage a patient's treatment plan are more fully informed on the patient's current condition. In its Proposed Rule, CMS acknowledged it has received frequent questions from stakeholders on use of the RPM service codes. The NHC appreciates the Agency's efforts to provide guidance to stakeholders.

The NHC supports CMS' proposals to permit auxiliary personnel to furnish certain RPM services under the general supervision of the billing physician or nonphysician practitioner. We also support expanding RPM eligibility to patients with either acute or chronic conditions, and we urge the Agency to ensure that the duration requirements are sufficiently flexible to permit use of this service to address monitoring needs related to acute conditions.

We also appreciate that CMS is seeking comment on the 20-minute "interactive communication" monthly thresholds for RPM services, and urge the Agency to ensure that clinicians are adequately reimbursed for both the real-time conversation with synchronous, two-way interactions, and the clinician's review and analysis time. The NHC believes that a CMS interpretation that excludes time required for data review and analysis would discount the importance of clinician use of RPM information in treatment planning.

The NHC appreciates that CMS has determined to double the Complex Patient Bonus from 5 points to 10 points for Performance Year 2020 and urges the Agency to consider applying this enhanced bonus until sufficient quality measures are developed to account for patient complexity.

The NHC appreciates CMS' recognition that:

"The overall goal, when considering a bonus for complex patients, is twofold: (1) To protect access to care for complex patients and provide them with excellent care; and (2) to avoid placing MIPS-eligible clinicians who care for complex patients at a potential disadvantage while we review the completed studies and research to address the underlying issues."

We strongly support CMS' proposal to increase the value of the complex patient bonus from 5 points to 10 points. The NHC shares CMS' concern that the complex patient bonus represents a short-term solution to an inherent and unrelenting reality that

NHC Comments – Medicare Fee Schedule and QPP October 5, 2020 Page 6 of 8

patients with complex conditions require more costly care, and clinicians should not be penalized for delivering the care these patients need. 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 but in the meantime support CMS' goal to ensure this temporary bonus appropriately rewards providers for caring for more complex patients.

Given the bright light the PHE has cast on health care disparities and their potentially catastrophic impact on communities of color, rural communities, and other vulnerable subpopulations, we urge CMS to also include a separate focus on vulnerable subpopulations. Individuals within these subpopulations who suffer from chronic diseases and disabilities face additional challenges in maintaining access to quality, affordable, sustainable health care to promote their best possible health outcomes. The QPP and its set of quality measures should reflect interventions and recommendations relevant to all Medicare patients, including those at greatest risk of poor health outcomes both during and after the PHE.

The NHC agrees with CMS' proposal to delay implementation of the MVP initiative under the QPP and urges the Agency to engage the patient community and other stakeholders to address complex patients and reduce health care disparities through the QPP.

The NHC appreciates CMS' commitment to transforming the health care delivery toward patient-centered care, innovation, and outcomes that are important to patients, and has previously commented in general support of the Agency's proposed Merit-based Incentive Payment System (MIPS) Value Pathways (MVP) initiative. We also agree with CMS' proposed decision to delay implementation of the MVP initiative until 2022 and seek further stakeholder input. The overarching goal of the MVP initiative is to enable providers to spend less time on paperwork and reporting requirements and more time on the clinician-patient relationship. We believe achieving that goal will enable patients to have a greater opportunity for improvement on health outcomes most important to them.

The NHC believes that at its core, a successful value-based reimbursement framework must be designed to improve value to patients, reduce burden, help patients compare clinician performance, and better inform patient choice in selecting providers. 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. We previously requested that CMS delay MVP implementation and further engage the stakeholder community, particularly patients, to ensure that considerations related to individuals with chronic conditions and disabilities are incorporated into the MVP transition. We continue to urge CMS to:

• Meaningfully engage patients in planning and implementing the transition;

NHC Comments – Medicare Fee Schedule and QPP October 5, 2020 Page 7 of 8

- Adopt a methodical transition to MVPs that starts on an opt-in basis, has significant oversight to support providers during the transition to MVPs, and avoids any potential negative impact on access for patients;
- Ensure providers are not overburdened by having to participate in an MVP for one disease while reporting in traditional MIPS for other patients;
- Recognize that individuals with chronic conditions, particularly Medicare patients with multiple chronic conditions, are uniquely vulnerable to changes in clinician behavior resulting from incentive shifts in performance and value-based payment strategies. Linking quality measures with cost measures too broadly could have the unintended effect of disincentivizing providers from appropriately treating Medicare's most vulnerable patients.
- Consider the unique needs of patients with chronic conditions and ensure measures related to care for these patients are not disproportionately removed from MIPS or excluded from MVPs due to a perceived inability to link quality measures with cost measures.
- Recognize that 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. Often these guidelines are based upon clinical-trial literature that captures outcome endpoint relevant to researchers and clinicians but not to patients (e.g., a biomarker versus functional abilities).

As the NHC has previously noted, patient perspectives on desired outcomes and views on quality can differ significantly from that of payers and providers. We urge CMS to work directly with the patient community to identify outcomes relevant to patients and family caregivers. The NHC has outlined a set of domains of patient centeredness we recommend CMS adopt to ensure the measures driving performance data capture outcomes patients care about:

- **Patient Partnership:** Patients should be involved in every step of the process, including planning and dissemination.
- **Transparency:** All activities should be conducted openly, and assumptions, inputs, processes, and results need to be disclosed to patients in plain language and 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. It refers to "who" and "how many" individuals to include in an interaction in order to, as closely as possible, engage with individuals that represent the broader, target patient population.
- **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 research, policy, or care delivery oriented, the outcome(s) being measured should include those that patients state are most important to them.
- **Patient-Centered Data Sources and Methods:** Having a variety of credible sources can facilitate timely incorporation of new information and account for the

NHC Comments – Medicare Fee Schedule and QPP October 5, 2020 Page 8 of 8

diversity of patient populations and patient-centered outcomes, especially those from real-world settings and reported by patients directly.

The NHC believes that CMS' strategic initiative to transform the MIPS program provides a unique opportunity to more fully address what value means, and the perspective from which it is identified, assessed, and quantified. Patient engagement, together with feedback from other stakeholders, will allow CMS to better align the QPP with the Agency's overarching goal of empowering patients, increasing patient centeredness, and reducing provider burden.

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,

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Marc Boutin, JD Chief Executive Officer National Health Council