



National Health Council

1730 M Street NW, Suite 500, Washington, DC 20036-4561 ■ 202-785-3910 ■ www.nationalhealthcouncil.org ■ info@nhcouncil.org

BOARD OF DIRECTORS

Chairperson
Tracy Smith Hart
Osteogenesis Imperfecta Foundation

Chairperson-Elect
Cynthia Zagieboylo
National Multiple Sclerosis Society

Vice Chairperson
Robert Gebbia
American Foundation for
Suicide Prevention

Secretary
Michael Rosenblatt, MD
Merck & Co.

Treasurer
Paul Pomerantz, FASAE, CAE
American Society of Anesthesiologists

Immediate Past Chairperson
Randy Beranek
National Psoriasis Foundation

Margaret Anderson
FasterCures –
A Center of the Milken Institute

Marcia Boyle
Immune Deficiency Foundation

Elizabeth Fowler, PhD, JD
Johnson & Johnson

James Greenwood
Biotechnology Innovation
Organization

Kevin Hagan
American Diabetes Association

Barbara Newhouse
The ALS Association

Ann Palmer
Arthritis Foundation

Harold Paz, MD, MS
Aetna

Richard Pops
Alkermes

Eric Racine, PharmD
Sanofi

Gary Reedy
American Cancer Society

J. Donald Schumacher, PsyD
National Hospice and
Palliative Care Organization

Susan Sherman
The LAM Foundation

Steven Taylor
Sjögren's Syndrome Foundation

Stephen Uhl
PhRMA

Ex Officio Member
Marc Boutin, JD
Chief Executive Officer
National Health Council

June 27, 2016

The Honorable Sylvia M. Burwell
Secretary, Department of Health and Human Services
200 Independence Ave SW
Washington, D.C. 20201

BY ELECTRONIC DELIVERY

RE: Medicare Program; Merit-Based Incentive Payment System and
Alternative Payment Model Incentive Under the Physician Fee Schedule, and
Criteria for Physician-Focused Payment Models; Proposed Rule [CMS–5517–
P] (Proposed Rule)

Dear Secretary Burwell:

The National Health Council (NHC) is pleased to provide comments on the proposed rule to implement the Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs), which together comprise the Quality Payment Program (QPP).

The NHC is the only organization that brings together all segments of the health community to provide a united voice for the more than 133 million people with chronic diseases and disabilities and their family caregivers. Made up of more than 100 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 professional and membership associations, nonprofit organizations with an interest in health, and representatives from the pharmaceutical, generic drug, insurance, medical device, and biotechnology industries.

The NHC supports the Centers for Medicare & Medicaid Services' (CMS) efforts toward improving the quality of care provided to Medicare beneficiaries while reducing costs to the Medicare program. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) represent a substantial refinement to Medicare incentives under the Physician Fee Schedule, replacing across-the-board annual payment reductions with practice-specific, value-based adjustments. The NHC recognizes the magnitude of effort required of CMS in implementing MACRA and the Agency's commitment to crafting a flexible framework of value-based incentives that can be adapted to evolving standards of care.

This letter provides overarching recommendations that should guide CMS' implementation of MACRA:

- Patient engagement activities must be strengthened and prioritized in the implementation of MACRA.
- The creation of a shared definition of value from the patient perspective must be the first step in implementing value-based payment systems.
- Quality measures must not penalize providers for providing care that is most relevant to an individual patient or for providing care to patients with high needs.
- APMs must include meaningful patient safeguards.
- Unintended consequences related to patient access must be monitored and addressed.

We also provide more specific recommendations and concerns:

- The weighting of the four MIPS categories must be evaluated to ensure the program is accurately rewarding high-quality care.
- Quality measures that are meaningful to patients, including cross-cutting measures, must be developed.
- Stakeholders must be engaged in developing patient-reported outcome-based performance measures (PRO-PMs).
- Additional APMs that address population health more holistically must be developed.
- Clinical practice improvement activities (CPIAs) that encourage patient engagement should be prioritized and promoted.
- The “one unique patient” threshold for the Advancing Care Information performance category should be increased.

General Recommendations

Patient engagement activities must be strengthened and prioritized in the implementation of MACRA.

The NHC applauds CMS for recognizing the integral role of the patient¹ voice in defining health care quality and value. The NHC defines 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 people with chronic conditions at every point of contact – from the research bench to the bedside and everywhere in between.

CMS cannot achieve its goal of designing a patient-centered approach to MACRA implementation without meaningful patient engagement throughout the program development process. Meaningful engagement requires direct interaction with the patients, family caregivers, and patient organizations that is bidirectional, reciprocal, and continuous. Communications are open, honest, and clear. Engagement goals, participants, methods, desired impacts, and actual impacts are clearly outlined and transparent. While CMS' approach to MACRA implementation has been stakeholder-inclusive, the Agency has focused more of its outreach initiatives on the

¹ Throughout this letter, the term “patient” means both patients and their family caregivers.

clinicians who will be impacted by the financial incentives and reporting requirements rule than the beneficiaries whose care may be impacted.

CMS has demonstrated its ability to engage with patients through efforts such as initiatives such as the Partnership for Patient and Family Engagement and the ESRD (End-Stage Renal Disease) network. However, we believe that CMS must improve its processes by placing a stronger focus on patient engagement and patient centricity. In order to achieve this goal, we recommend:

- Expanding the language of the second strategic goal to state: “develop a program that is meaningful, understandable, and flexible for *patients and* participating clinicians.”
- Convening an Administrator-level Patient Engagement Advisory Panel to inform, advise, and guide the Administrator on improving the patient centeredness of CMS programs and initiatives across the board, including but not limited to the MIPS and APMs.
- Appointing patient representatives to all CMS committees, technical advisory panels, and similar groups, and creating training and tools to optimize their engagement.
- Involving patients and other stakeholders in the creation of all APMs that are developed by the Center for Medicare and Medicaid Innovation (CMMI), as evidenced in the creation of the Accountable Care Organization model.

We also urge the Agency to consider the six key domains of patient centricity identified in the NHC’s Patient-Centered Value Model Rubric, which was created in conjunction with its member organizations. These domains are: patient partnership; transparency to patients; inclusiveness of patient; diversity of patient populations; outcomes that matter to patients; and patient-centered data sources.²

The creation of a shared definition of value from the patient perspective must be the first step in implementing value-based payment systems.

In the proposed rule, CMS refers to the goal of the QPP as “paying for value and better care” without defining value. The NHC supports a payment system that incentivizes value-based care. However, at present, “value” is a concept that has no uniformly defined meaning or approach across the health care ecosystem. Patient perspectives on value can differ significantly from that of payers and their providers. Patients want clinically effective treatment options that are relevant given their personal circumstances and individual goals.³ The definition of value has different meaning among different patient populations; value also evolves with disease trajectory and is highly dependent on individual preferences.

The NHC urges CMS to engage in a meaningful dialogue with the patient and other stakeholder communities to jointly define value in terms of relevance to patients and their family caregivers. This consensus-based definition of value has the potential to provide a guidepost to evaluating the results of the QPP implementation. The NHC strongly encourages the inclusion of patients in the process of defining value and articulating how it will be operationalized and measured.

² The Patient Voice in Value: The National Health Council Patient-Centered Value Model Rubric.
<http://www.nationalhealthcouncil.org/sites/default/files/Value-Rubric.pdf>

³ Boutin, Marc. “The Patient Trifecta: A Basis for Truly Patient-Centric Health System.” American Journal of Pharmacy Benefits.
http://www.ajpb.com/journals/ajpb/2015/ajpb_septemberoctober2015/the-patient-trifecta-a-basis-for-a-truly-patient-centric-health-system.

Quality measures must not penalize providers for providing care that is most relevant to an individual patient or for providing care to patients with high needs.

Patient centeredness is created by engaging, informing, and actively listening to people with chronic diseases. 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. As such, a patient's treatment plan may diverge from the treatment recommendations upon which quality measures are based. CMS must ensure that clinicians are not penalized for prescribing therapies that, based on clinician expertise and patient preferences and priorities, are most appropriate. Additionally, implementation of MACRA must be done with the understanding that many patients with progressive or degenerative conditions will likely see worsening health status despite receiving the highest quality care possible.

CMS must ensure that clinicians treating patients with chronic diseases and disabilities are rewarded for using their medical expertise to prescribe the most appropriate care for their patients rather than penalized for their patients' health status. 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.

APMs must include meaningful patient safeguards.

As CMS encourages increased development of and participation in APMs, it is imperative to incorporate meaningful, actionable patient protections such as quality measures, notification, and "opt out" opportunities that have previously been used in demonstration projects conducted or funded by CMMI. Under MACRA, providers have new incentives to participate in an APM, and we are concerned that some may manage their increased financial risk by limiting patient access. For this reason, we urge close monitoring of APMs and recommend that CMS consider additional advanced APMs in the early years of implementation that require less risk by providers.

Additionally, the NHC notes that CMS intends to grant substantial flexibility to APMs in selecting evaluation measures. We encourage CMS to ensure that any flexibility APMs have in choosing or developing evaluation measures is consistent with Section 1115A of the Social Security Act, which requires that models be evaluated on patient-specific outcomes and include patient-centered quality measures. While CMS' further development of patient-centered quality measures will be an important step toward this goal, the NHC recommends that CMS continue to engage the patient community to incorporate the patient voice in APM assessments, and ensure that any negative impacts on patient access or quality of care are rapidly addressed. One potential method to achieve this goal is to incorporate patient participation in the work of the Physician-Focused Payment Model Technical Advisory Committee.

Unintended consequences related to patient access must be monitored and addressed.

The NHC supports CMS' intent to streamline reporting programs through the MIPS, in an attempt to reduce the administrative burden on clinicians so they can spend more time on providing high-quality care. However, we are concerned that this intent may not be achieved

under the MIPS, and the new rule could potentially create unintended gaps in access. Specifically, we are concerned that:

- If the new reporting requirements outlined in the proposed rule are too onerous, some providers may either choose to exit the Medicare program, and those who remain may limit the amount of already-limited time that they can spend with their patients.
- Clinicians who have not participated in the various programs incorporated into MIPS, including non-physician providers, are even more susceptible to uncertainty surrounding the reporting requirements and may become less likely to treat Medicare patients with chronic conditions even if the provider continues Medicare participation generally.
- The stated expectation that 87% of solo practitioners and nearly 70% of small practices will experience a negative payment adjustment under MIPS may significantly impact Medicare participation among providers in rural and under-served areas. Similarly, specialties with a potential high percentage of clinicians subject to a negative payment adjustment (e.g., cardiology, endocrinology, family and general practice, immunology, physical medicine, etc.) may weigh the increased incremental burden of MIPS versus the likelihood of decreased payments when determining whether or not to participate in Medicare.

We urge CMS to continue its outreach and educational initiatives, including review and consideration of stakeholder comments to the Proposed Rule. CMS should also consider expanding eligibility for technical assistance. For example, technical assistance to non-physician providers who have not previously participated in the programs contained in MIPS but may voluntarily enter the program in 2017 may be needed. Additionally, many of the challenges faced by solo practitioners and small practices are not unique to those in rural and health professional shortage areas. As such, we recommend expansion of technical assistance eligibility to these practices in more urban areas.

Specific Recommendations and Concerns

The weighting of the four MIPS categories must be evaluated to ensure the program is accurately rewarding high-quality care.

We believe that evaluating clinicians in the four categories of the MIPS—quality, resource use, clinical practice improvement activities (CPIAs), and advancing care information—is a stepping stone to achieving a value-based health care system. However, we encourage CMS to critically review whether each provider’s MIPS score truly represents the value of care he or she provides. For example, CMS proposes to reduce the weighting of the quality category from 50% in Year 1 to 30% in Year 3 and after. While this weighting is statutorily defined, we encourage CMS to monitor the impact of the reduction of the weighting of this category to determine whether the scores are appropriate in Year 3. Further, we are concerned that the four categories have not been sufficiently delineated to ensure that certain measures or activities are over- or under-valued in a clinician’s Composite Performance Score. For example, efficiency of care could potentially be evaluated in not only the resource use category but also the quality category via appropriate use measures. It would be prudent to understand if there might be “double counting” magnified by

the weighting mechanism. Ensuring that the MIPS is accurately capturing data to reward high quality care is crucial to the success of the program and will help promote the best care possible.

Quality measures that are meaningful to patients, including cross-cutting measures, must be developed.

The quality measure component currently accounts for 50% of the MIPS and is, therefore, likely to have the most significant impact on clinician behavior in the short term. The NHC commends CMS for emphasizing the need to “measure performance on measures that are relevant and meaningful.” As CMS gathers information from measure developers and Qualified Clinical Data Registry (QCDR) developers, CMS should seek to address how individual measures are related to outcomes and/or if they impact patient care. In addition, existing quality measures should also be subject to ongoing rigorous review. CMS should closely evaluate quality measures that may not improve outcomes or address issues that are meaningful to patients. Measures that do not meet these criteria should be updated or retired.

Additionally, the NHC commends CMS in its proposal to require providers to report one cross-cutting measure through the quality category of the MIPS. Cross-cutting measures are needed to address the quality gaps for patients with conditions that currently lack effective quality measures. Additionally, because most quality measures are focused on a single-disease, they do not often adequately address patients with multiple chronic conditions, a population that makes up nearly two thirds of all Medicare beneficiaries.⁴

The NHC recommends CMS support the development and adoption of additional cross-cutting measures when clinically relevant to the care that patients receive from specific providers. These types of measures should be intended to capture a more holistic view of treatment and disease management. Specifically, the NHC recommends CMS adopt quality measures that evaluate the establishment of an individualized care plan specifically based on a discussion with the patient. Development and adoption of this type of cross-cutting measure should occur in addition to ongoing work to address the gaps in existing condition-specific measurement.

Stakeholders must be engaged in developing patient-reported outcome-based performance measures (PRO-PMs).

The proposed rule identifies the need for the development and testing of new outcome-oriented, patient-centric measures to be added to the quality measure list clinicians can select from. Patient-reported outcome measures are one type of measure that can play a significant role in ensuring that the patient voice is incorporated into medical decisions. This is particularly important in reimbursement models, such as MACRA APMs, that shift financial risk to providers.

The NHC understands that a large number of disease-specific PRO-PMs can be unwieldy for payers, providers, and patients, particularly people with multiple chronic conditions requiring multiple survey submissions. For these individuals, it is unlikely that metrics available to assess patient outcomes in general are sufficiently granular to capture the uniqueness of each patient

⁴ <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/chronic-conditions/downloads/2012chartbook.pdf>

and the quality of their care. PRO-PMs may be an effective tool to improve clinician communication with beneficiaries and enhance outcomes for patients with multiple chronic conditions. We encourage CMS to support the development and incorporation of PRO-PMs that address health-related quality of life, symptoms and symptom burden, function, perceptions, experience with care and treatments, and shared decision making. CMS should also be cognizant that simply because a measure is based upon a patient report, it is not necessarily patient centered. PRO-PMs must be created with the input of the patient community to ensure that they are measuring outcomes that are important to the patients impacted by them.

Additional APMs that address population health more holistically must be developed.

The NHC supports CMS' efforts to transform the payment and delivery system to one that emphasizes value over volume by providing bonus payments to clinicians who participate in Advanced APMs. As the APM path of the QPP evolves, the NHC urges CMS to qualify additional APMs that address patient care more holistically. Disease-specific models (e.g., the Oncology Care Model) should evolve to take into consideration how the other health care needs of patients can be met either through the participating provider or through care coordination with other settings. Additionally, CMS should focus on qualifying disease-agnostic APMs that can apply to a broader population of people with chronic conditions. For example, APMs should address treatment of patients with multiple chronic conditions and integration of behavioral health into medical care.

Clinical practice improvement activities (CPIAs) that encourage patient engagement should be prioritized and promoted.

The NHC strongly supports CMS' efforts to use "a patient-centered approach to program development that leads to better, smarter, and healthier care" through the CPIA performance category. The NHC also commends CMS in its proposal to include a variety of CPIAs that aim to enhance patient access and engagement. We believe the diversity of the activities proposed in the rule will greatly enhance providers' flexibility to choose the most appropriate quality improvement initiatives to improve care for their patient populations. To further enhance the patient centricity of these activities, CMS should focus on areas of relevance to patients, as expressed by patients, as one of the criteria for CPIA inclusion.

We agree that "improved beneficiary health outcomes, patient engagement, and safety based on evidence" should be criteria required for the new CPIA subcategories, as proposed in the rule. We encourage CMS to apply this criterion to all existing subcategories moving forward. The NHC is concerned that the majority of activities proposed under the Beneficiary Engagement subcategory do not adequately address meaningful engagement with patients. For example, activities such as "participation in a QCDR that promotes collaborative learning network opportunities that are interactive" may not result in substantial improvement in engagement. The NHC is also concerned that the activity "engage patients, family, and caregivers in developing a plan of care and prioritizing their goals for action, documented in the certified EHR technology" is weighed as "medium." Individual care planning is a crucial element of patient-centered care and should be rewarded by being weighed as "high."

Finally, CMS must ensure that the CPIAs are more than just a "check-the-box" exercise and that clinicians continuously strive for improving patient outcomes and engagement. The proposed

rule does not include criteria or metrics for CPIAs. While we appreciate the flexibility given to clinicians for these activities, we encourage CMS to develop a set of metrics in order to ensure that CPIAs are truly improving patient care and patient engagement. One aspect of such metrics should relate to whether or not clinicians are engaging with patients in a meaningful way (bidirectional, reciprocal, and continuous).

The “one unique patient” threshold for the Advancing Care Information performance category should be increased.

The NHC strongly supports CMS in its proposal to expand into a more patient-focused health information technology (IT) program, “measuring more directly on how the use of health IT contributes to the overall health of their patients.” We believe demonstration of meaningful use should go beyond the measurement of infrastructure and process. The NHC commends CMS for its emphasis on the Coordination of Care Through Patient Engagement objective. However, the NHC is concerned that the currently proposed measures under this objective do not adequately evaluate patient centeredness and engagement. Specifically, the measures under the objective address the provision of infrastructure to support engagement rather than actual engagement between clinicians and patients. In addition, clinicians can achieve the base score for the category by meeting the requirements for at least one unique patient. We do not believe “one unique patient” is adequate to ensure meaningful patient engagement.

We strongly recommend CMS consider increasing such thresholds as we believe that in its current form, meeting the minimum requirements for this measure would neither constitute meaningful patient engagement nor would it be an effective means of measuring achievement of the health IT program objectives. While we understand the challenges associated with implementing health IT, we do not believe that measuring the experience of one patient would provide any indication of improved patient access and engagement.

Conclusion

The NHC appreciates the opportunity to submit comments on CMS’ proposed rule. As the voice for individuals with chronic diseases and disabilities and their family caregivers, the NHC encourages CMS to ensure that the patient voice is included in the implementation of MACRA and assure access to health care for patients by ensuring that providers have sufficient information and time to continue participating in Medicare. We are committed to working with CMS to ensure that Medicare beneficiaries receive quality care that improves and maintains the outcomes they care about.

Please do not hesitate to contact Eric Gascho, our Vice President of 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 M. Boutin, JD
Chief Executive Officer