June 27, 2016

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–5517–P
P.O. Box 8013
Baltimore, MD 21244–8013

Re:

CMS–5517–P
RIN 0938–AS69

Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models

Dear Sir/Madam:

Thank you for the opportunity to comment on HHS's proposed rule implementing MACRA legislation. The National Health Law Program (NHeLP) protects and advances the health rights of low income and underserved individuals. The oldest non-profit of its kind, NHeLP advocates, educates and litigates at the federal and state level.

NHeLP endorses the comments of the National Partnership for Women and Families (NPWF), in addition to submitting our own additional comments below. We generally support this effort to improve quality and care coordination for Medicare and Medicaid enrollees. However, we also do not believe HHS should rush to accelerate transformation. Rather, we believe CMS should prioritize: confirming the actual capacity to achieve transformation every step of the way, ensuring continuity of care and quality for consumers, and only implementing reforms on a large-scale after there is certainty of their effectiveness for consumers. We underscore the following recommendations from the NPWF:

- We recommend that all Advanced APMs should be required to meet delivery requirements similar to medical homes, including features such as patient-centeredness and care coordination.
- We recommend that as HHS increases the risk on

providers, HHS should commensurately increase consumer protections to ensure that there is no stinting on care, cherry-picking or avoiding certain populations, reduced access to on-going care or providers, or reduced due process.

- We recommend that HHS include consumer stakeholders, and require states to include them as well, in all levels of delivery and payment system reform, including design, implementation, and oversight phases. This should be done, among other ways, through advisory bodies.
- We recommend that HHS improve the use of quality measurement by: (1) including more measures that are consumer reported and based on experience of care, and (2) acknowledging the current limitations in the field of quality measurement which require using measurement as *one* tool among many to assess whether consumers receive quality care; HHS must also look at complaint and appeals data, stratified reports on utilization data, and other sources of information to reach more robust conclusions on quality.

Advanced Alternative Payment Models Generally

Definition of Medical Home Model and Medicaid Medical Home Model

In the proposed regulatory definitions of Medical Home Models (at § 414.1305), both Medical Home Models must comply with two mandatory requirements as well as at least four out of seven additional elements. We have two recommendations with respect to these definitions:

- We recommend that all of the first six elements should be mandatory for all Medical Home Models. While we understand that HHS may not want to be overly prescriptive about what models of care should look like, the elements are broadly stated and all six elements are critical to any new model of care. We do not believe a model should ever qualify a provider for bonus payments if it does not comply with all six elements. For example, one element is "patient access and continuity of care." No model of care should qualify if it fails to provide patient access or ensure continuity of care. Failure on this element would, by definition, reduce access to high-quality health care, in contrast to the intent of MACRA.
- We recommend that the seventh element be deleted because it seems duplicative of the entire regulatory scheme, as well as the specific requirements at § 414.1415(c) and § 414.1420(a)(3).

Other Payer Advanced APMs

The objective of MACRA is to promote payment for value in Medicare. NHeLP recognizes that shifting risk onto providers is a method to accomplish this that is prioritized in MACRA. However, we are aware of no conclusive evidence that shifting risk onto providers is the best or *only* model to improve payment for value. The ACA and HHS's broader initiatives have – prudently – focused on testing diverse models of payment and delivery, to let the results of pilot initiatives inform the development of large-scale models of care. We are concerned that the MACRA regulation not only breaks with this approach, but also *undermines* it. Although various features of the

MACRA statute require some risk on some providers, HHS's regulation goes beyond those requirements and creates a regulatory framework that is excessively focused on risk. The ultimate consequence of this will be strong incentives to pursue heavily risk oriented models, to the exclusion of all other models of care, despite the minimal and uncertain evidence about what actually improves quality of care. We are particularly concerned in the context of Medicaid, where vulnerable consumers could be seriously harmed by models that fail to improve quality. HHS should not disrupt existing Medicaid models that are achieving improved quality, or discourage adoption of diverse types of models. Our recommendations are as follows:

Application of §414.1420(a)(3)(i) non-nominal risk standard

In addition to complying with EHR and quality requirements, an Other Payer Advanced APM (OPAAPM) must meet a non-nominal risk or "medical home" requirement (at §414.1420(a)(3)). Importantly, the MACRA statute does not apply the § 414.1420(a)(3)(i) risk standards to OPAAPM's meeting the medical home requirements. Therefore a model does not need to satisfy a risk requirement for Medicaid enrollees if it is "a medical home that meets criteria comparable to medical homes expanded under section 1115A(c)." Social Security Act § 1833(z)(2)(B)(iii)(II)(cc)(BB); proposed rule at §414.1420(a)(3)(ii)). We are concerned that HHS is interpreting this provision as non-applicable to any existing medical home models, because those models have not been "expanded" under the § 1115A(c) expansion authority (as opposed to, for example, "tested" under § 1115A(b) authority or simply implemented under some other authority). We believe this interpretation does not comply with the letter and intent of the statute. The statutory requirement is to meet *comparable criteria*. The baseline criteria for approving such models are clearly identified in § 1115A(c)(1) to (3). The fact that no model has not been implemented under that authority does not influence the content of the underlying criteria in § 1115A(c). Those criteria are plainly stated and can be applied immediately to HHS's implementation of MACRA and the regulations.[1] Essentially, those criteria require that the new model of care improve quality without raising costs, or decrease costs without reducing quality. HHS can and should apply that standard irrespective of whether models have actually been "expanded," and allow OPAAPMs to pass through the §414.1420(a)(3)(ii) pathway, as opposed to forcing all OPAAPMs to meet the risk standards in §414.1420(a)(3)(i).

As an example, consider Community Care of North Carolina. Numerous reports document that this Medicaid primary care case management (PCCM) program has saved money *and* improved health outcomes in North Carolina.[2] This model uses

[1] We note that if HHS does not use the criteria stated in § 1115A(c), it is difficult to know what the term "criteria" would refer to in the context of a § 1115A demonstration. Would it be the number of people enrolled? The quality metrics used? The definition of patient-centeredness used? And how would the endless possibilities for the term "criteria" be evaluated if there were numerous approved § 1115A demonstrations?

[2] Robert Cosway et al., *Analysis of Community Care of North Carolina Savings*, Milman Inc. Client Report (Dec. 2011); Stephen Somers et al., *Community Care of North Carolina: An Evolutionary Platform for Medicaid Innovation,* 74 N.C.MED. J. S16 (Mar. 2013); *see generally* Policy Forum,*Community Care of North Carolina: Building Medical Homes,* 70 N.C.MED. J.

medical homes without relying heavily on risk. Under the regulations, entities in such a model would not be eligible for bonuses under MACRA, because HHS's interpretation bars them from qualifying through §414.1420(a)(3)(ii), and they might lack the risk to meet the §414.1420(a)(3)(i) standard (discussed more below). As a result, such providers would have an incentive to *abandon* the successful PCCM model, and pursue bonuses through some untested risk model. Under our suggested approach, a model would qualify as an OPAAPM if it meets the criteria at §414.1420(a)(1), (2), and (3)(ii) – including the § 1115A(c) expansion criteria. We believe this approach more clearly implements the statutory language and intent, and further, we think it is more likely to promote testing of a diverse range of models of care as opposed to only testing high-risk models.

If, contrary to our recommendation, HHS maintains a narrow reading of §414.1420(a)(3)(ii) (and requires models to *actually* be expanded under § 1115(c)), then we commend HHS's attempt to create more flexible standards for Medicaid OPAAPM's at §414.1420(d)(2) and (d)(3)(ii). We agree that without such flexibility HHS would "create a significant challenge for [Medicaid] medical homes to serve their patients." 81 Fed. Reg. 28332. We make the following recommendations to improve this flexibility:

- We recommend the limitation to organizations "with fewer than 50 eligible clinicians" should be removed. While we appreciate the effort to protect smaller practices, we are aware of no evidence demonstrating that large practices require risk-based models to improve quality or reduce costs.
- We commend the language added at §414.1420(d)(2)(iv), and recommend that the language be adjusted to also be inclusive of upside-only (one-way) risk models.
- We also recommend that the criteria at (d)(3)(ii)(A) and (B) be adjusted by lowering the threshold to 1% and 2% respectively. We also recommend that HHS clarify whether the threshold is the *amount* of 4% or 5% of the Medicare Part A and B income, or, 4% or 5% of Medicare A and B payment in the model. For example, if the 4% threshold is exceeded in Medicaid payment risk (but not in Medicare payment), would that satisfy the requirement? We recommend that it should.

Advanced APMs

We apply the relevant analysis above for Other Payer Advanced APMs to Advanced APMs generally (described at § 414.1415). Advanced APMs have a similar option of qualifying through risk or as a medical home. See § 414.1415(c). We recommend that HHS not require models to actually have been expanded under § 1115A(c) to qualify; we again recommend that HHS apply the *criteria* at § 1115(c)(1) to (3).

Risk Thresholds

(May/June 2009).

For both Advanced APMs and Other Payer Advanced APMs, we are concerned that the marginal and total potential risk thresholds are too high. We are concerned this will exclude providers with lower risk levels that have improved quality and/or reduced cost. We believe CMS should set a lower entry standard and allow diversity among risk taking to inform conclusions on optimal effective risk levels.

State guidance on integration

States with Medicaid delivery and payment reform initiatives, or considering new initiatives, will need to understand how these current or proposed models of care interact with MACRA incentives. Providers in those states will need to understand whether they qualify for MACRA incentives based on participation, and/or what additional efforts might be needed to qualify. HHS should develop comprehensive guidance for states to assist them coordinate models of care with MACRA. Without such guidance, HHS runs serious risk of creating widespread confusion, disrupting existing initiatives, and obstructing future worthwhile initiatives.

Payment and Patient Count Methods for Thresholds

We do not have a recommendation, but we are concerned that the patient count methodology might be easier to game for providers seeking to hit qualifying targets. We encourage HHS to consider whether this might create problematic incentives.

Conclusion

In summary, we urge HHS to consider implementation policies that will be minimally disruptive to present and future models of care that may benefit Medicaid enrollees. If you have questions about these comments, please contact Leonardo Cuello at (cuello@healthlaw.org). Thank you for consideration of our comments.

Sincerely,

Leonardo D. Cuello
Director, Health Policy