



June 27, 2016

Andrew M. Slavitt
Acting Administrator
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: 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

Submitted electronically via <http://www.regulations.gov>

Dear Mr. Slavitt:

UnityPoint Health (“UPH”) appreciates the opportunity to provide comments on the proposed rule related to MIPS and APM Incentives published in the Federal Register on May 9, 2016. UPH is one of the nation’s most integrated healthcare systems. Through more than 30,000 employees, our relationships with more than 290 physician clinics, 32 hospitals in metropolitan and rural communities, and home care services throughout our 9 regions, UPH provides care throughout Iowa, Illinois and Wisconsin. On an annual basis, UPH hospitals, clinics and home health provide a full range of coordinated care to patients and families through more than 4.5 million patient visits. In addition, UPH is actively engaged in numerous initiatives which support population health and value-based care. UPH participates in CMMI contracts under the Bundled Payment for Care Improvement Model 2 and the Medicare Care Choices Model. In addition, UnityPoint Health Partners (UPHP) is the ACO affiliated with UPH and has value-based contracts with multiple payers, including Medicare. UPHP is the largest ACO participating in the Next Generation ACO with roughly 77,000 beneficiaries attributed to this model. UPHP has providers that have participated in the Medicare Shared Savings Program as well as providers from the Trinity Pioneer ACO, which achieved two years of savings.

As an integrated healthcare system, we believe that patient-centered care is best supported by a value-based payment structure that enables healthcare providers to focus on population health, instead of episodic care. Section 101 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) repeals the Medicare sustainable growth rate (SGR) methodology for updates to the

physician fee schedule and replaces it with a new Merit-based Incentive Payment System (MIPS) for eligible clinicians as well as Advanced Alternative Payment Models (Advanced APMs). Together the proposed MIPS and Advanced APM frameworks encourage the transformation of health care to a value-based care delivery system. We appreciate CMS' outreach to the stakeholders, including the provider community, as it seeks to implement these provisions. We respectfully offer the following comments.

ADVANCED ALTERNATIVE PAYMENT MODELS

Advanced APMs is a subset of APMs that (1) utilizes Certified EHR Technology, (2) provides payment based on quality measures comparable to the MIPS quality performance category, and (3) bears more than a nominal amount of risk. Current APMs that may qualify for Advanced APM status include MSSP Tracks 2 and 3, Next Generation ACO, Comprehensive ESRD Care, Oncology Care Model, and Comprehensive Primary Care Plus.

Comment: *We applaud the SGR repeal and its replacement with a tiered approach towards recognizing those providers that have been progressive in testing innovative payment reform initiatives, represented by Advanced APMs. The CMS Office of the Actuary has estimated that 60% of physicians will elect the APM track in 2019. UPH urges CMS not to delay implementation of this vital and needed regulatory reform. This framework consolidates quality reporting, enables providers to assume responsibility for resource use, and promotes a transformation from volume to value-based care.*

We agree with the goals of CMS to “expand the opportunities for participation in APMs, maximize participation in current and future Advanced APMs, create clear and attainable standards for incentives, promote the continued flexibility in the design of APMs, and support multipayer initiatives across the health care market.” The proposed Advanced APM incentives align with these goals. UPH believes that the exclusion from MIPS reporting is appropriate for participation in Advanced APMs. Further, we support the 5% bonus payment for Advanced APM participation and advocate its extension to all participating providers, including Rural Health Clinics. This monetary incentive for participation recognizes in part the substantial investment and risk that providers have assumed in these innovative models. To assist with budgeting, we suggest that CMS establish a firm date for issuance of payment incentives, such as “payment will be issued to Advanced AMP Qualified Professionals no later the [date].”

❖ Advanced APM Entity Group Determination

For purposes of determining Qualified Professionals (QP), CMS proposes to group and assess all individual eligible clinicians through their collective participation in an Advanced APM Entity. To be included, individual eligible clinicians must be identified on an APM participation list on December 31st of the QP performance period (§414.1425).

Comment: *We support the proposed methodology to collectively assess the participation of individual providers within an Advanced APM. The proposed group determination recognizes that Advanced APMs contain a variety of professionals that are working together to promote access, increase quality and contain costs. It is through the collective, and not individuals, that results will be achieved in these programs. The proposed group determination permits implementation flexibility and enables the APM Entities to establish clinician relationships based on population*

health needs. It is the APM Entity that will provide a guide path for willing clinicians to learn and master the use of EHR technology, payments linked to quality outcomes and assumption of financial risk.

While we support the collective determination, we are concerned with the timing of this determination as it relates to existing APMs. Despite the fact that CMS proposes to use a finalized Advanced APM participant list on December 31st, this timeframe does not correspond with participant list submission dates in existing models. For instance, the NGACO is a split TIN model and individual TIN/NPI participant lists are required to be finalized in June for the next performance year. We urge CMS not to limit QP status decisions based on this alignment list. Foremost, this more than six-month time lag unduly restricts NPI participation in Advanced APMs. The alignment list is produced too early in the year to include all a TIN's NPIs who are actively billing that year and, because it is created specifically for attribution purposes, will generally be limited to primary care providers. This timing was particularly problematic in 2016 as new NGACO applicants were required to submit their TIN/NPI list on June 3. Fourteen days in advance of the list submission (May 20), NGACO applicants were required to notify providers. This timeframe gave NGACO Entities and individual providers (NPIs) less than a month to understand the proposed MACRA regulations. Further, the six-month time lag creates a dual reporting burden on Advanced AMP TINs – those NPIs excluded from MIPS reporting and those NPIs subject to MIPS reporting.

We request that CMS not limit QP determination for NGACO Entities to providers included on the TIN/NPI list created for alignment purposes and submitted in June or July of the preceding year. For the MIPS reporting exclusion, we suggest that Advanced APMs have the ability to submit a revised participant list for new NPIs within existing participant TINs as late in the measurement year as feasible to account for all NPIs billing under that TIN. This resubmitted list would be limited to quality reporting requirements and not impact beneficiary attribution.

❖ **Advanced APM Qualified Professional Performance Period**

The QP Performance Period is the full calendar year that aligns with the MIPS performance period. For both Advanced APMs and MIPS, the initial performance period is 2017 for the 2019 QP incentive payment or the 2019 MIPS payment adjustment. In the “gap” year (e.g. 2018), the initial MIPS reporting submission occurs between January 2nd and March 31st and the QP notification takes place that summer.

Comment: *The MIPS reporting deadline occurs prior to the QP notification. To avoid penalties for failing to report MIPS if an Advanced APM does not meet the Threshold Score, it is probable that Advanced APMs will engage in MIPS reporting (Clinical Practice Improvement Activities and Advancing Care Information) to assure compliance. We do not believe that Advanced APMs should have this additional reporting burden. We recommend that CMS consider presumptive QP status in the first performance year and, in subsequent performance years, use prospective notification of QP status based on the prior year thresholds.*

❖ **Advanced APM Minimum Loss Ratio (MLR)**

CMS sets the MLR at no more than 4%.

Comment: *We are uncertain how CMS determined this level of minimum loss. UPH would recommend a MLR equivalent to the MSSP standard of 2%.*

❖ **Advanced APM All-Payer Combination QP Threshold**

For payment years 2021 to 2024, CMS proposes an all-payer combination option for QP determinations. The threshold option allows eligible clinicians to become QPs by meeting a relatively lower threshold based on Medicare Part B covered professional services through Advanced APMs and an overall threshold based on services through both Advanced APMs and Other Payer Advanced APMs.

Comment: *UPH has participated in value-based contracts with Medicare, Medicaid and commercial payers. Streamlining quality measures and reporting requirements across multiple payers would reduce administrative burdens on providers and allow efforts to more appropriately focus on patient care. We support the inclusion of Medicare Advantage within the calculation of All-Payer Thresholds – both payment amount and patient count.*

While we support the multipayer concept in theory, we have concerns related to the willingness of commercial payers to support value-based arrangements with Advanced APMs. We implore CMS to mandate that commercial payers share full claims data sets to allow providers to manage risk and their patient population. In the absence of a mandate, we fear that commercial payers will have no motivation to provide timely or complete claims data sets to providers.

❖ **Advanced APM Participation by Rural Health Clinics (RHCs)**

CMS proposes that professional services furnished at stand-alone RHCs that meet certain criteria be counted towards the QP determination. In particular, professional services furnished at stand-alone RHCs that participate in ACOs and are reimbursed under the RHC All-Inclusive Rate will be counted towards the QP determination calculations under the patient count method but not under the payment amount method. As proposed, RHC payments are not considered part of the amount upon which the APM 5% incentive payment is based.

Comment: UnityPoint Health Partners, our ACO, has more than 30 stand-alone RHCs participating with the Next Generation ACO model throughout Iowa and Illinois. We have a large geographic spread and, in some of our geographic regions, RHCs represent the majority of our attributed patients. In these rural areas, the residents are primarily elderly with a high prevalence of multiple chronic conditions and other socioeconomic risks. RHCs provide needed safety net access and enable Medicare beneficiaries to remain in their communities.

Since RHCs are a vital component of our service delivery, we urge CMS to consider equal treatment for our rural providers that choose to participate in an Advanced APM. This would equate to recognizing RHCs in both QP threshold determinations (payment amount and patient count) as well as allowing them to receive the Advanced APM 5% incentive payment. While we understand that RHCs have a different reimbursement scheme, there should be a concession that this revenue be credited to the Advanced APM Entity to determine QP status. Without this, there is little incentive for RHCs to participate in Advanced APMs, particularly ACO models that rely on integrated and coordinated care across the care continuum. Further eligibility for the 5% payment incentive for RHCs would recognize the commitment that these providers have already made to participate in an Advanced APM – heightened quality standards, additional reporting requirements (Meaningful Use and PQRS), and willingness to be subjected to risk-bearing relationships. We encourage CMS to revise both the QP threshold payment amount method and

the eligibility for the 5% payment incentive to include RHCs. Since the revenue would be credited to the ACO (or Advanced APM Entity) for purposes of QP determination, we also recommend that the incentive payment be paid to the ACO for distribution to RHC providers.

MERIT-BASED INCENTIVE PAYMENT SYSTEM

❖ MIPS Benchmark Calculations

For the resource performance measures, CMS proposes to use data from CY17—the performance period—as the baseline period to derive benchmarks. In addition, the proposed rules are silent as to the applicable trend factor.

Comment: *We strongly believe that providers need to understand benchmarks prior to delivering service under a contract in order to appropriately perform and meet/surpass expectations. While we support the concept that providers must own some responsibility for managing utilization and healthcare resources, we oppose holding providers to unclear or unknown standards. Further, we urge CMS to specify a trend factor and suggest that the MSSP trend be used. This trend was recently confirmed in the MSSP final rule, it is straight-forward, and it does not provide a disincentive for Advanced APMs participants (or alternatively an advantage to MIPS participants).*

FRAUD AND ABUSE WAIVERS

The proposed rules do not address fraud and abuse regulatory waivers.

Comment: *Since the enactment of the physician self-referral law in 1989 and the original enactment of the Anti-Kickback statute in 1972, the delivery of health care services and the payment for those services – among all payers, both government and private - has changed dramatically. By intent and design, Stark physician self-referral law (“Stark”) separates entities that are furnishing designated health services from physicians who are providing care to Medicare beneficiaries. UPH and other health care professionals face the challenge of trying to achieve system-wide clinical and financial integration to lower costs and improve health access and outcomes, while simultaneously complying with Stark, Anti-Kickback, and other laws and regulations that create care silos. There are many activities and relationships that are necessary to achieve successful clinical and financial integration that remain prohibited outside of specific payment models. Health care providers need flexibility, in the context of appropriate fraud and abuse safeguards, to collaborate and manage care in ways that would otherwise be prohibited – exactly the policy intent of MACRA.*

While the ACA legislated a pathway for regulatory waivers to be developed and applied to its risk-based models, no such legislative language was included in MACRA. The final rule for the Medicare Shared Savings Program (MSSP) ACO waivers will presumably be applicable to health care providers who elect to use the MSSP ACO model to qualify for the APM track. However, it is the intent of MACRA, and also in line with current CMS value-based payment goals, for new risk-based payment models to be developed. These new innovative payment models - as recommended by the Physician-Focused Payment Model Technical Advisory Committee, developed by CMS, or enacted by future legislation - will need regulatory accommodation to create the alignment necessary for health care providers to assume risk and deliver coordinated care.

One specific approach to accommodate innovative payment models is the creation of a new exception for innovative payment methodologies. This new exception would include the following:

- *Amend the §1877(e) compensation arrangements exception to add a new provision for innovative payment methodologies that promote and advance accountability for quality, cost/risk, care coordination, patient experience and outcomes.*
- *In order to qualify for the exception, the arrangements would need to meet conditions that are already used to qualify ACOs and other risk sharing arrangements under the Stark and anti-kickback statutes. These safeguards include written agreements, transparency, and provider accountability, as well as prohibitions on double billing or shifting costs to federal health care payers.*

The new innovative payment methodology exception would permit payers and providers to experiment with models that encourage collaboration, care coordination and the reduction or elimination of duplicative services. Under current interpretations, Stark arguably prohibits even commercial payers from entering into innovative arrangements with hospitals and physicians to promote quality, care coordination and cost reduction. This new exception would be instrumental in helping physicians, hospitals and other health care providers succeed under MACRA.

Also, the MACRA legislation requires the Secretary to undertake two studies relating to the promotion of alternative payment models. These include a study, in consultation with the Office of Inspector General (OIG), to examine and report to Congress on fraud related to APMs (APM Report) and another study, also in consultation with OIG, to recommend options for amending existing fraud and abuse laws and regulations through exceptions, safe harbors, or other narrowly tailored provisions to permit gainsharing arrangements that would otherwise be prohibited (Gainsharing Report). Through the Gainsharing Report, UPH is hopeful that CMS and OIG will acknowledge that, as financial and outcomes risk is assumed, the need to eliminate barriers to integration will be necessary for sustained success.

QUALITY MEASUREMENT, REPORTING AND VENDOR CERTIFICATION

CMS requires quality measures used in Advanced APMs to be comparable to the quality measures used in MIPS. Advanced APMs must also use at least one outcome measure, if available on the MIPS list for that specific performance period. CMS has been charged to eliminate the effect of geographic adjustments in payment rates and take into account risk factors, such as socioeconomic and demographic characteristics, ethnicity, and health status of individuals, in recognition that less healthy individuals may require more intensive interventions. Future rulemaking will re-examine risk adjustment for socioeconomic status on quality and resource use measures.

Comment: *UPH largely supports the collection and public reporting of valid and reliable quality data. Such quality data demonstrates value, underpins compliance, and provides structure for care delivery. Since MIPS is a stepping stone to Advanced APMs, UPH applauds CMS's efforts to align MIPS and APM reporting. To encourage MIPS professionals to transition to APMs, APM reporting should remain focused on innovative programming and MIPS should align but not increase Advanced APM reporting domain requirements. Consistent with our prior comments on the Draft CMS Quality Measure Development Plan, we generally agree with the CMS proposed process to adopt and retire evidence-based quality measures. UPH recommends a smaller core measure set with less reliance on self-reported measures. The administrative burden associated with the*

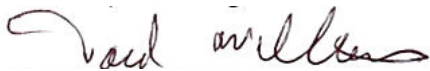
collection of self-reported data is significant as providers either must extract information manually or via specially built EHR reports.

Social determinants of health account for as much as 40% of health outcomes. UPH is pleased that CMS will be reviewing and incorporating the IMPACT Act report recommendations anticipated in October 2016. We look forward to providing comment during future rulemaking on this vital aspect of population health.

Lastly, we appreciate CMS' efforts in move to evidence-based, outcome measures. These measures have multiple forums to be vetted, seek provider input, and provide adequate notice of anticipated changes. As CMS continues to revise measure sets, we request that consideration be given to the infrastructure, time and expense incurred by providers (and software developers) to adequately develop, validate and field train for these measures.

We appreciate the opportunity to provide comments to the proposed rule and its impact on our integrated health system and our patients. To discuss our comments or for additional information on any of the addressed topics, please contact Sabra Rosener, Vice President and Government Relations Officer, Public Policy and External Affairs at Sabra.Rosener@unitypoint.org or 515-205-1206.

Sincerely,



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UnityPoint Health Partners



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