December 19, 2016

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

RE: CMS–5517–FC: 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 final rule related to MIPS and APM Incentives published in the Federal Register on November 4, 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 72,000 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.

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 (APMs)

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. As the largest ACO participating in the Next Generation ACO model, UnityPoint Health Partners has a keen interest in assuring that MACRA requirements both recognize our providers for their commitment to voluntarily assume heightened risk and support delivery system flexibility required to drive innovation and high quality care.

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. While we support the introduction of new models to qualify as Advanced APMs, we also caution CMS to consider their impact on current Advanced APMs. For instance, when crafting another MSSP Track (i.e. MSSP Track 1+) to meet Advanced APM eligibility, CMS should clearly differentiate this new track from current MSSP Tracks 2 and 3 as well as the Next Generation ACO Model and consider whether there are sufficient benefits in these greater risk-bearing models to maintain a heightened level of commitment or instead whether this new model will introduce migration of early innovators to lower risk models.

Advanced APM QP Determination and Performance Period

For purposes of determining Qualified Professionals (QP), the Final Rule establishes 3 snapshot dates throughout the performance period to allow new providers that join an Advanced APM to be eligible as QPs for that year. In addition, the QP Performance Period for Advanced APMs has been defined as January 1 through August 31.

Comment: We appreciate the revisions from the Proposed Rule that provide some relief in determining QP status. Although the snapshots and performance year definition establish further clarity around QP status eligibility and reporting consequences, there remains a significant time gap in which providers may join Advanced APMs, and Advanced APMs will be required to maintain dual quality reporting systems – Advanced APM reporting and MIPS reporting. For instance, under the Next Generation ACO model, there is a 6-month lag between when a Next Generation ACO must submit its participant list to CMS for a given performance year and the start of that performance year (i.e., an Next Generation ACO must submit its participant list for 2017 in mid-June 2016). If a physician joins the ACO July 1, 2016, he or she would be ineligible to receive an Advanced APM bonus until 2020 and may potentially be subject to MIPS reporting for 2017. We request that CMS align its Next Generation ACO process with MACRA reporting and institute a process whereby “late calendar year ACO joiners” (i.e. preferred providers within ACO participation TINs) are exempt from MIPS reporting and eligible for the Advanced APM incentive payment. The present time gap effectively discourages providers from joining the Next Generation ACO during this time and can hamper timely ACO recruitment and operations.

Advanced APM Nominal Revenue-Based Threshold

The Final Rule added a revenue-based threshold on 8 percent of an APM Entity’s Medicare Part A and B revenue. This 8% threshold was established for performance periods 2017 and 2018, and CMS is seeking comment related to increasing this amount for performance periods 2019 and beyond.
Comment: We applaud the addition of this additional threshold alternative. Similar to our concerns with the graduated threshold schedule for QP determination (below), we believe that this 8% level should remain static until time and data to suggest an increase is needed. This increase in nominal risk seems premature and may serve to discourage rather than encourage providers to assume more risk without evidence that such behavior is occurring and is successful.

Advanced APM Bonus Calculation
The Final Rule sets forth that only supplemental service payments meeting specific criteria will be included in the calculation of the APM Incentive Payment amount.

Comment: This regulation appears contrary to the goals of population-based payment models that strive to decrease traditional spending through care coordination and alternative care delivery approaches. When ACO providers lower spending, the Advanced APM bonus calculation penalizes them by also lowering their bonus amount. We urge CMS to include ACO shared savings payments as supplemental service payments in the calculation of the Advanced APM incentive payment amount.

Advanced APM Medicare Only QP Threshold and All-Payer Combination QP Threshold
MACRA progressively increases the revenue percentage for QPs within Advanced APMs from 25% to 50% (starting in 2019) to 75% (starting in 2021). Additionally an All-Payer Option is available in 1919 to permit revenue from other sources, such as Medicaid, MA, and commercial plans, to be included in the revenue threshold calculation.

Comment: We are concerned with the graduated schedule of heightened thresholds. The Final Rule has left in place this drastic percentage increase over a short period of time which will not only discourage further Advanced APM participation, but also jeopardize QPs that may have achieved Advanced APM status in the past. We would recommend that the 25% threshold remain constant for the Medicare Only threshold, and that for the All-Payer Option, the threshold remain constant at 50% with the 25% Medicare portion of this option being able to recognize MA revenue as needed. These percentages are sufficiently steep and recognize that Advanced APMs exist in local markets in which there are insufficient levels of risk arrangements outside Medicare. As participation in Advanced APMs increases, CMS can re-evaluate these thresholds to encourage greater migration to value-based arrangements.

Other Payer Advanced APMs
The Final Rule includes Medicaid as a potential Other Payer as well as Medicare Advantage and commercial health plans. Eligible Other Payers must meet specific Advanced APM requirements.

Comment: We support the alignment of state-based Medicaid strategies with MACRA goals and their ability to be classified as Advanced APMs. As an organization that operates in three Midwest states, UPH encourages the establishment of minimum constructs for Medicaid programming to meet Advanced APM criteria. For consistency of provider implementation across state lines, CMS should consider establishing flexibility to recognize value-based payment innovation, including the following:
Different types of Value-Based Payment options, including total cost of care for the general population, voluntary bundled care arrangements, and total care for special needs populations;

Graduated levels of risk for providers, including fee-for-service with bonus, fee-for-service with upside only, fee-for-service with risk sharing – both upside and downside risk, and global capitation;

Innovator programs for provider ready to assume more risk;

Medicaid quality program that aligns with and qualifies for Medicare programming incentives;

Input from providers in the form of steering committees and/or clinical advisory groups; and

Clear delineation of State Value-Based Payment objectives in MCO contracts.

As we stated in our comments to the Proposed Rule, we support the multipayer concept in theory, but have concerns related to the willingness of commercial payers to support value-based arrangements with Advanced APMs. At a minimum, as multi-payer initiatives are explored and implemented, we encourage federal, state and commercial payers to share full claims data feeds with providers. For the All-Payer Option to calculate QPs for Advanced APMs, participating payers should be required to share claims data. Ideally, this data feed should resemble the CMS data feed or be placed in an All-Payers Database that uploads to a common data framework. The timely sharing of claims data promotes transparency and quality care.

Advanced APM Participation by Rural Health Clinics (RHCs)
The Final Rule reaffirms that 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. In addition, RHC payments are not considered part of the amount upon which the APM 5% incentive payment is based.

Comment: UnityPoint Health Partners 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.

**PHYSICIAN SELF-REFERRAL (Stark Law) UPDATES - FRAUD AND ABUSE WAIVERS**

The Final Rule does not address fraud and abuse regulatory waivers.

**Comment:** We are disappointed that the Final Rule does not address Stark Law protections. 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 is instrumental in helping physicians, hospitals and other health care providers succeed under MACRA and we urge your consideration of this regulatory language.

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,

Sabra Rosener, J.D.
VP / Government Relations Officer
UnityPoint Health