



Government and External Affairs
1776 West Lakes Parkway, Suite 400
West Des Moines, IA 50266
unitypoint.org

October 31, 2022

The Honorable Ami Bera, M.D.
172 Cannon House Office Building
Washington, DC

The Honorable Larry Bucshon, M.D.
2313 Rayburn House Office Building
Washington, DC

The Honorable Kim Schrier, M.D.
1123 Longworth House Office Building
Washington, DC

The Honorable Michael Burgess, M.D.
2161 Rayburn House Office Building
Washington, DC

The Honorable Earl Blumenauer
1111 Longworth House Office Building
Washington, DC

The Honorable Brad Wenstrup, D.P.M.
2419 Rayburn House Office Building
Washington, DC

The Honorable Bradley Schneider
300 Cannon House Office Building
Washington, DC

The Honorable Mariannette Miller-Meeks, M.D.
1716 Longworth House Office Building
Washington, DC

RE: MACRA Request for Information (RFI)

Submitted electronically via macra.rfi@mail.house.gov

Dear Representatives Bera, Bucshon, Schrier, Burgess, Blumenauer, Wenstrup, Schneider, and Miller-Meeks,

UnityPoint Health appreciates the opportunity to provide comments on this MACRA request for information (RFI). UnityPoint Health is one of the nation's most integrated health care systems. Through more than 32,000 employees and our relationships with more than 480 physician clinics, 40 hospitals in urban and rural communities and 14 home health agencies throughout our 9 regions, UnityPoint Health provides care throughout Iowa, central Illinois, and southern Wisconsin. On an annual basis, UnityPoint Health hospitals, clinics, and home health agencies provide a full range of coordinated care to patients and families through more than 8.4 million patient visits.

In addition, UnityPoint Health is committed to payment reform and are actively engaged in numerous initiatives that support population health and value-based care. UnityPoint Accountable Care is the accountable care organization (ACO) affiliated with UnityPoint Health and has value-based contracts with multiple payers, including Medicare. UnityPoint Accountable Care currently participates in the Center for Medicare and Medicaid Innovation's Global and Professional Direct Contracting Model, which serves more than 100,000 beneficiaries and includes providers that have participated in the Next Generation

ACO Model, the Medicare Shared Savings Program (MSSP), and the Pioneer ACO Model. Over the years, UnityPoint Health through our hospitals and home health agencies have expanded upon this Medicare value-based portfolio and participated in several Bundled Payments for Care Improvement episodes, the Home Health Value-Based Purchasing (HHVBP) Model, and the Medicare Care Choices Model.

UnityPoint at Home appreciates the Congressional outreach to explore MACRA and opportunities for improvement. **As a member of The Academy Advisors and the Value-Based Care Coalition, UnityPoint Health was also involved in the development of their formal comment letters submitted to this RFI and supports the sentiments expressed within.** Within this context, UnityPoint at Home respectfully offers the following input.

MACRA Feedback

This RFI seeks feedback on actions Congress could take to stabilize the Medicare payment system, without dramatic increases in Medicare spending, while ensuring successful value-based care incentives are in place. Responses may address: (1) MACRA effectiveness; (2) regulatory, statutory, and implementation barriers for MACRA to increase value in the U.S. health care system; (3) provider participation uptake in value-based payment models; and (2) MIPS and APM programs opportunities for improvement.

Comment: Whether MACRA has been effective is a loaded question. While the 2015 bipartisan MACRA law was intended to replace the Sustainable Growth Rate (SGR) payment formula, this has not materialized, the availability of value-based Medicare payment models has lagged, existing Alternative Payment Models (APMs) lack attribution and payment transparency creating overlap confusion, APM rules are in a constant state of flux (hampering participation and financial planning), and Congress has been reinserted into the annual fee-for-service rate-setting process. That said, **UnityPoint Health has been an early adopter of value-based care, voluntarily starting in Medicare value-based models in 2012, and we remain committed to this journey.** Over the years, UnityPoint Health has offered fairly consistent input on the future of value-based care. In our comment letter to the MACRA proposed rule in 2016, UnityPoint Health's response remains true (with the exception of physician uptake projected by the CMS Office of the Actuary):

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].”

Since the passage of MACRA and adoption of regulations, UnityPoint Health has continued to offer suggestions / recommendations for improvement. Rather than repeating those comments, select portions have been attached as addendums to this letter (MACRAProposed2016, CMMIDirection2017, DirectProviderContracting2018, PatientsOverPaperwork2019, MandatorySpecialtyModels2019, and PhysicianFeeSchedule2019). As you consider how to further the adoption of value-based care, **we respectfully request that Congress continue include Section 4 of the Value in Health Care Act (H.R. 4587) in an end-of-year legislative package.** This bipartisan legislation would extend the 5 percent Alternative Payment Model (APM) incentive payments and allow CMS to adjust qualifying thresholds to achievable Qualifying APM Participant levels in the coming years. This will recognize those providers that have already committed to value and encourage them to continue, while Congress is re-evaluating this path.

We are pleased to provide input on this RFI and its impact on our hospitals and health system, our patients, and communities served. To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons, Executive Director, Government & External Affairs at cathy.simmons@unitypoint.org or 319-361-2336.

Sincerely,



Cathy Simmons
Executive Director, Government & External Affairs



UnityPoint Health

UnityPoint Health

Department of Government and External Affairs
1776 West Lakes Parkway, Suite 400
West Des Moines, IA 50266
unitypoint.org

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*

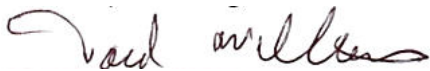
collection of self-reported data is significant as providers either must extract information manually or via specially built EHR reports.

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,



David Williams, M.D., C.P.E.
CEO
UnityPoint Health Partners



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



1776 West Lakes Parkway, Suite 400
West Des Moines, IA 50266
unitypoint.org

November 20, 2017

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Centers for Medicare & Medicaid Services (CMS): Innovation Center New Direction Request for Information

Submitted electronically via CMMI_NewDirection@cms.hhs.gov

Dear Ms. Verma,

UnityPoint Health (UPH) appreciates the opportunity to provide comments on the Request for Information (RFI) regarding the CMS Innovation Center (Innovation Center). 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, 38 hospitals in the 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 6.2 million patient visits. In addition, UPH is actively engaged in numerous initiatives which support population health and value-based care.

UPH is an early adopter of innovative value-based models and has partnered in Innovation Center demonstrations for seven years. UPH participates in Innovation Center contracts under the Bundled Payment for Care Improvement Model 2, the Home Health Value-Based Purchasing Model, and the Medicare Care Choices Model. In addition, UnityPoint Accountable Care (UPAC) is the ACO affiliated with UPH and has value-based contracts with multiple payers, including Medicare. UPAC is the largest ACO participating in the Next Generation ACO Model with roughly 80,000 beneficiaries attributed to this program and has received first-year savings. Historically, UPAC has providers that have participated in the Medicare Shared Savings Program as well as providers from the Trinity Pioneer ACO, which was the most rural ACO and achieved two years of savings.

We appreciate CMS' outreach to stakeholders, including the provider community, as it seeks to build upon the work at the Innovation Center. We respectfully offer the following comments.

INNOVATION CENTER AUTHORITY TO TEST INNOVATION

Prior to addressing the issues raised in this Request for Information, we feel compelled to dispel the believe that “CMMI exceeded statutory authority by issuing broad, compulsory models, like the Part B Drug Payment Model and Episode Payment Model (EPM) models.”¹ ***Our home health agency, UnityPoint at Home, is licensed and practices in the one of the nine states that is mandatorily participating in the Innovation Center’s Home Health Value-Based Purchasing Model (HHVBP).*** Within our ACO, we rank as one of the largest Next Generation ACOs, are one of the most rural ACOs, and have specialists as more than 40% of our participating providers, including behavioral health providers. ***We do not agree that the Innovation Center exceeded its authority and, in fact, believe that this discretion is necessary in order to instill timely flexibility and adjustments within an otherwise rigid payment construct.*** Under the Affordable Care Act (ACA), Congress established the Innovation Center to “test innovative payment and service delivery models to reduce program expenditures under the applicable titles while preserving or enhancing the quality of care furnished to individuals under such titles. In selecting such models, the Secretary shall give preference to models that also improve the coordination, quality, and efficiency of health care services furnished to” Fee-for-Service Medicare beneficiaries, Medicaid enrollees, or Medicare-Medicaid beneficiaries.²

While we do not always agree with the timing and technical issues related to Innovation Center initiatives, we believe that Congress granted the Innovation Center definite authority to proceed with mandatory initiatives under its Expansion of Models authority. The statute reads:

- (c) Taking into account the evaluation under subsection (b)(4), the Secretary may, through rulemaking, expand (including implementation on a nationwide basis) the duration and the scope of a model that is being tested under subsection (b) or a demonstration project under section 1866C, to the extent determined appropriate by the Secretary, if—
 - (1) the Secretary determines that such expansion is expected to—
 - (A) reduce spending under applicable title without reducing the quality of care; or
 - (B) improve the quality of care and reduce spending; and
 - (2) the Chief Actuary of the Centers for Medicare & Medicaid Services certifies that such expansion would reduce program spending under applicable titles.³

This provision allows the Innovation Center to disseminate best practices, including nationwide implementation, of models that balance cost and quality concerns and have been certified by the CMS Chief Actuary. This provision was put in place to expedite rulemaking and implementation for promising

¹ RFI comment letter in response to this RFI dated November 15, 2017, from 113 organizations – the first listed organization is Advocates for Responsible Care (ARxC).

² 42 USC 1315A(a)(1)

³ 42 USC 1315A(c)

and innovative ideas. ***As an early adopter of Innovation Center ACO and other voluntary models, as well as a current participant in the mandatory HHVBP model, we appreciate CMS' efforts to move from volume to value and recognize the importance of agency discretion to facilitate change.*** As CMS works to implement the aggressive timeframe enacted by the bi-partisan MACRA legislation and offer options for provider reimbursement and enhanced service delivery, CMS should demonstrate restraint when curbing authority intended by Congress to support healthcare innovation.

GUIDING PRINCIPLES

As an early adopter, we are invested in the basic tenets of the Innovation Center to reduce costs and improve quality for Medicare and Medicaid beneficiaries. As for the guiding principles, which mark a new chapter for the Innovation Center, we are pleased with the focus and the high bar it sets for ensuring high quality care at a reduced cost.

1) **Choice and competition in the market** – As an organization that operates in three Midwest states, UPH is a firm believer in improving choice for beneficiaries and promoting a competitive marketplace. We hope to work with the Innovation Center to ***improve geographic disparities by increasing access and competition within rural areas.***

2) **Provider Choice and Incentives** – We are supportive of the Innovation Center's efforts to improve provider choice and incentives, especially as it relates to ***reducing unnecessarily burdensome regulations.*** We are pleased with the focus on models with defined control groups or comparison populations, and encourage the Innovation Center to promote data sharing to inform participating entities in strengthening models.

3) **Patient-centered care** – We support the Innovation Center's emphasis on flexibility and empowering beneficiaries to take ownership of their health. We agree that "beneficiaries should be empowered as consumer[s]," and ***recommend that both CMS and the Innovation Center make all APM performance data available to the public as soon as "final" data has been released by the agency after the data review and/or approval period provided to model Participants.*** We want to assure that data released to the public is not only timely but accurate to avoid beneficiary confusion. UPH believes improved data sharing can improve outcomes for beneficiaries while informing participating entities in strengthening models.

4) **Benefit design and price transparency** – UPH supports greater price transparency to ensure cost-effective care and improves outcomes. In this arena, UPH supports the recommendation of The Conference Board (*Adjusting the Prescription: Committee for Economic Development Recommendations for Health Care Reform*) to ***repurpose the ACA's Independent Payment Advisory Board (IPAB) to provide information for the physician-patient relationship.*** This would include data gathering and research to inform both patients and providers in their decision-making process. With the importance of data, a centralized structure for its release and dissemination should be prioritized.

5) **Transparent model design and evaluation** – UPH is encouraged by the Innovation Center’s focus on transparent design and evaluation methods, especially as it relates to collaborations with public stakeholders. The Innovation Center has actively released Requests for Information to stakeholders and the public; however, it would be ***helpful if the Innovation Center would release summaries of feedback that is received from the RFI process.*** These summaries would not need to reflect each commentator, but it would be beneficial to learn response rates and general feedback themes. This information would also aid in understanding the patchwork of national innovation as well as future payment direction. In terms of model design and evaluation, we understand the desire to implement multipayer models; however, we have concerns with commercial payer participation, which leaves out some geographies due to payer reluctance. This effectively omits feedback from providers in those regions and similarly prioritizes feedback from a select group of payers. ***We request that multi-payer models in the public payer arena be afforded the same weight as multi-payer models including private payers.***

6) **Small Scale Testing** – We support Innovation Center efforts to test smaller scale models that may meet requirements for expansion. Under the ACA, Congress established the Innovation Center to test innovative payment and service delivery models. This provision allows the Innovation Center to disseminate best practices, including nationwide implementation, of models that balance cost and quality concerns and have been certified by the CMS Chief Actuary. This provision expedites rulemaking and implementation for promising and innovative ideas. ***As a current Participant in several Innovation Center models, including a mandatory model, and with aggressive MACRA timeframes, we strongly support CMS’ authority to test and disseminate new models and discourage undue restraint in this area.***

In addition to the guiding principles, we would like to raise the issue of sustainability as it relates to the various demonstration models. UPH has embraced the Innovation Center’s focus and priorities, which have resulted in improved outcomes at a lower cost across several models that we’ve participated in. We’ve seen firsthand how organizations like UPH can work with CMS and States to become laboratories of innovation – and we remain firmly committed to that effort. However, there are stages in the process that lead to great uncertainty for the provider and/or organization, such as whether a various model will continue. This uncertainty creates a disincentive to participate. We are particularly concerned with other commentators suggest limiting demonstrations to five years.⁴ While we understand that demonstrations should eventually reach conclusion and either migrate to a permanent status, be revised, or be dissolved, we are concerned that a 5-year timeframe does not and should not adequately represent all demonstrations. By inserting such a timeframe, this period may become a de facto timeframe for all projects; instead agency discretion should be utilized in conjunction with stakeholder input to determine appropriate model duration, scope and spread. Generally, the Innovation Center should examine steps to provide certainty for beneficiaries, providers and organizations that are looking at alternative methods of providing high-quality care over the short- and long-term. ***While sustainability may be implied within the***

⁴ Letter referenced in Footnote 1

guiding principles listed above, we believe that it should be elevated to a stand-alone principle and added to this list.

POTENTIAL PAYMENT REFORM MODELS

In response to CMS' search for feedback and guidance, the framework outlined below incorporates and expands upon the Innovation Center's guiding principles to new design models.

EXPANDED OPPORTUNITIES FOR PARTICIPATION IN ADVANCED APMS

Established by the passage of MACRA, APMs were developed with the goal of reforming Medicare's Part B payment method. Coupled with the delivery of high-quality and cost-efficient care, qualified participants have demonstrated an integral role in building upon the lay APM foundation. Currently participating in the Next Generation ACO demonstration, UnityPoint Health is proud to lead by example. A subsidiary of UnityPoint Health, UnityPoint Accountable Care (UPAC) has received more than \$28 million in shared savings from value-based contracting efforts; of which \$10.5 million stem from participation in the Medicare Next Generation ACO Model and \$18.2 million from various commercial payers. The shared savings from the participating in the Medicare Next Generation ACO Model were tied to performance on both quality and cost. The results reflect the continued commitment of UPH to transition away from the traditional Fee-For-Service payment model while building on its track record as a national leader in managing patient populations.

As the nation's largest Next Generation ACO demonstration model with a history of demonstrated savings, UPH firmly believes the delivery of value-based care continues to generate significant progress. **The Innovation Center should establish a hierarchy of demonstrations that provide a stepwise approach for providers to accept various degrees of risk in exchange for heightened levels of Part B compensation under MACRA as well as demonstration payment incentives and regulatory and operational flexibilities. To increase opportunities for eligible clinicians to participate in Advanced APMs (A-APMs) and achieve QP participation threshold, UPH encourages CMS to:**

(1) Simplify incentives; (2) Focus on chronic care management; (3) Support MA participation as a contributory means to achieve QP state; and (4) Encourage models emphasizing rural provider participation; and (5) Promote continued participation in A-APMs by early adopters.

As a step to simplify incentives, ***bonuses and small fee schedule increases should be generated in all APM frameworks, incorporating those participants operating under MSSP Track 1 in which providers have taken on increased investment risk.*** In following this step, providers electing to not participate in APMs should not incur a fee increase. To fund this measure, we propose to reallocate the MIPS exceptional performance bonus dollars to be utilized within the context of this framework. Focal to program success and sustainability, we highlight the systematic integrity of bridging proportional risk to incentives. We ask

the Administration to consider, as program frameworks are proposed, whether there are sufficient benefits in heightened risk-bearing models to maintain an elevated level of commitment or instead whether models with reduced risk will introduce migration of early innovators to lower risk models.

To achieve long-term health objectives established by CMS, ***encouraging chronic care management in demonstrations should be a focal step*** in aligning with the guiding principle of patient-centered care. We support an emphasis in the creation of holistic population health models, as opposed to models limited to specific disease states and their episodes of care. UPH further ***encourages avenues in which rural populations are a focal feature of proposed models***. MIPS has extensively excluded many rural providers through the rule making process and there is little incentive for these providers to aspire to A-APM participation. As a distinguished early adopter, ***UPH believes engagement amongst the early adoption community should be further explored***. When possible, we urge the Innovation Center to continue the use of payment tracks within demonstrations to promote a glide path to capitated payment, such as that available under the Next Generation ACO. We are also encouraged by the joint efforts of the Innovation Center with States to test global payments, including the Maryland All-Payer Model, the Vermont All-Payer ACO Model and the Pennsylvania Rural Health Model. Our concern with all-payer models is that the dissemination potential is limited by a disinterest and general refusal of commercial payers to share claims data, not to mention participation in larger multipayer reform efforts. We recommend that the Innovation Center engage in multiple payer efforts involving public payers (so as not to limit those regions with limited commercial payer interest) and that all demonstrations require timely sharing of summary and raw claims data with providers. Once a public payer model is successful, there will be better success at encouraging private participation; however, this should not be a limiting factor in areas with interested and willing provider groups and State agencies.

As a means of transitioning from Fee-For-Service constructs, global payments promote provider flexibility and capture the removal of restrictive regulations presently afflicting care decisions. ***We strongly encourage the Innovation Center to continue offering global payment models that correspond to heightened regulatory flexibility***. Our goal with global payments is to free our providers from the arbitrary confines of Fee-For-Service reimbursement and, when applied at an ACO level, it enables patient-centered care to prevail and eliminates siloed provider (business unit) targets in favor of enterprise-wide targets. For services outside the ACO, it enables the ACO to contract for those services outside Fee-For-Service constraints and ideally within sub-capitated arrangements that are market based and with willing participants. Theoretically, global payments should simplify regulatory concerns by eliminating Stark and Anti-kickback concerns, medically necessary determinations (similar to the PACE program), burdensome waiver processes, and referral requirements. Within this transition, the Innovation Center should consider a model for Medicare block grant funding directly to A-APM entities, based on the national average per beneficiary. We are concerned that regional performance benchmarks are not as attractive to warrant continued participation by high performers.

To increase responsiveness to eligible clinicians and their patients, as well as potentially expediting the process for providers that seek to join A-APMs, UPH encourages the Administration to consider the following measures:

(1) Prospective Attribution development; (2) Tax incentives; (3) Stark Law exceptions; (4) Expanded Waiver authorities; (5) Statutory recognition of A-APMs; (6) Financial incentives for beneficiaries; (7) All payer database mandate; (8) Clarification of overlapping program rules; (9) Comprehensive healthcare system risk-sharing solutions; and (10) Value payments.

To avoid the churn of retrospective attribution, a durable perception of the target population will be quintessential to the Administration's ability to meaningfully respond to eligible clinicians and their patients. **When participating in MSSP, our retrospective attribution churn rate was approximately 25% per quarter and undermined efforts at targeted care coordination and quality improvement initiatives. It also created confusion for beneficiaries.** The comprehensive risk and resources required to participate as an A-APM significantly effects clinician engagement and participation. **Tax incentives act as a channel to address current participation barriers amongst clinicians and reward those physicians whom have already transitioned to A-APM models.** Incentives could take form as tax-free retained earnings, retained by the physician practices, which could exclusively be utilized as infrastructure development and risk reserve offsets to assist in the transition to an APM model. Distributed incentive earnings should not be considered as a loan and should not require physicians to match funds. We also recognize consumer participation in demonstration models may currently be acting as a barrier for physicians participating in A-APMs. To further entice beneficiary participation, **we recommend the institution of financial benefits to beneficiaries.** Maintaining a voluntary program mindset, the utilization of shared savings models enable payers and providers to share benefits; beneficiary incentives could take form as wellness performance benefits, not copayment waivers.

In furthering the Agency's goal, **we strongly encourage the Administration to act within its power to institute Stark Law exceptions for providers within a population-based risk-bearing A-APM model.** We would further suggest the expansion of waiver authority as an avenue the Administration should explore, which would have positive impacts on the agency's desire to both expedite the process for providers looking to join A-APMs and increase clinician and patient responsiveness.

As with risk, the future of a model deters potential eligible clinician populations from transitioning to the A-APM framework; to correct the gray area encompassing A-APM participation, **UPH strongly recommends the Administration make formal recommendations to statutorily recognize A-APM models upon completion of a demonstration period.** With appropriate modifications, the Next Generation Model ACO (referencing a second iteration of the Pioneer ACO Model) should graduate from the Innovation Center lab into the mainstream healthcare model market, where the model will be able to function similarly to comparable risk-bearing models or provider-owned Medicare Advantage plans.

Current regulatory overlaps have muddled program rule clarity and are increasingly viewed as a disincentive for providers to take heightened risk for total populations. Current overlap rules fail to recognize the totality of population health programming and incentivize siloed, episodic care (whether procedures or condition-based) based upon Fee-For-Service constructs over total population health programming. For instance, Oncology Care Model, Comprehensive ESRD Care Model, and Bundled Payments for Care Improvement (BPCI) beneficiaries are removed from the Next Generation ACO for

purposes for these episodic procedures, yet the Next Generation ACO remains responsible for the overall outcomes and costs of their care. These rules allow new episodic programs and their providers to skim off ACO infrastructure investments, do not require notice of attribution among programs nor inter-program care coordination, and impose a narrow 60- or 90-day treatment timeframe misaligned to holistic care (i.e., a significant number of BPCI episodes, such as congestive heart failure, chronic obstructive pulmonary disease, and diabetes, require lengthy aftercare and are subject to co-morbidities). To address the entanglement, ***we encourage a hierarchical approach to CMS / Innovation Center model overlap, in which precedence is given to population health risk-bearing entities.*** We would suggest that CMS use the existing payment model classification framework refined by the Health Care Payment Learning & Action Network (LAN) as a basis for its overlap policy. Within this framework for payment models, CMS can offer a hierarchy of the various delivery models. For example, if a bundled payment were being proposed in a geographic area in which there is a prevalent ACO, the ACO should drive patient attribution and performance goals to incorporate specialty care within the patient’s care plan. As for reimbursement, these payments would be included within the ACO financial framework and, for ACOs under a capitated model, the ACO could convert the bundles into sub-capitation arrangements. Such approach would prioritize holistic patient care, engage specialists, leverage ACO infrastructure investments, and provide model certainty for ACOs and high performing networks as they consider and participate in innovative payment approaches.

UPH recommends that CMS consider the following measures to capture appropriate data to drive the design of innovation payment models and initiatives to encourage A-APM participation amongst the eligible clinician population:

(1) Streamlined data reporting; (2) Formation of an all payer database; and (3) Integration of Part D data.

As an early adopter of payment innovation and care delivery transformation, perhaps our biggest learning involved working with data and becoming a truly data-driven organization. We cannot understate the importance of EHR and claims data and the ability to synthesize and proactively analyze this data for our patients. We also have come to realize that collecting data for purely reporting purposes is not productive. In terms of data reporting, ***we support the genesis of the CMS Meaningful Measures initiative.*** In our response to the Draft CMS Quality Measure Development Plan⁵, UPH conducted a cursory review of quality measure sets listed in the Table below. Although a year old, this Table still illustrates the point that CMS collects disparate data under differing quality domains. Future models should strive to require streamlined data under common domains, particularly when payment is tied to quality/value.

| MA | NGACO | ACO / PCMH Consensus Core* | MIPS** | PQRS |
|--|---------------------------|-------------------------------|---------------|----------------------------------|
| Managing Chronic (Long Term) Conditions (12) | At Risk Population (7) | Cardiovascular Care (4) | Clinical Care | Effective Clinical Care (145) |
| | | Diabetes (5) | | |
| | | Behavioral Health (2) | | |
| | | Pulmonary (2) | | |

⁵ UPH letter dated March 1, 2016, and submitted via MACRA-MDP@hsag.com

| | | | | |
|--|--|--|----------------------------------|---|
| | Care Coordination / Patient Safety (9) | Care Coordination / Patient Safety (1) | Safety Care Coordination | Patient Safety (43) Communication and Care Coordination (42) |
| Member Experience with Health Plan (6) Member Complaints and Changes in the Health Plan's Performance (4) Health Plan Customer Service (3) | Patient/Caregiver Experience (8) | Patient Experience (3) | Patient and Caregiver Experience | Person and Caregiver-Centered Experience (16) |
| Staying Healthy: Screenings, Tests and Vaccines (7) | Preventive Health (9) | Prevention and Wellness (6) | Population Health and Prevention | Community / Population Health (15) |
| | | Utilization & Cost / Overuse (1) | Efficiency and Cost Reduction | Efficiency and Cost Reduction (20) |

* Measure counts exclude future areas identified for measure development

**Released Consensus Core Measure Sets for: (A) ACO and PCMH / Primary Care - 22 measures; (B) Cardiovascular - 31 measures; (C) Gastroenterology - 8 measures; (D) HIV - Hep C - 8 measures; (E) Medical Oncology - 14 measures; and (F) OB-GYN - 11 measures

In terms of data sharing, we do not want to miss an opportunity to encourage a more robust system to share claims data. **We are supportive of sharing both raw claims-level data and claims summary data.** We have used claims data to monitor trends and pinpoint areas where care practice improvement is appropriate as well as to assess cost drivers. **This claims data should not be subject in an opt-in process,** but rather should be routinely available and provided, which allows and encourages providers / organizations to access and utilize this information. The untimely receipt of data and any variance from standardized formats has hindered our ability to drive innovation within payment models and measures. We encourage CMS to advance the following concepts within its models:

- **Access to All-Payer administrative claims data.**
- **Access to substance abuse records by treating providers.**
- **Permit the sharing of patient medical information within a clinically integrated care setting.** HIPAA currently restricts the sharing of a patient’s medical information for “health care operations.”

Further, we request that the Administration consider the sharing of Part D data for lives attributed to certain population health entities, namely down-side risk ACOs. Drug information would enhance an ACO’s ability to manage and coordinate patient care. This data would provide insight into prescribing patterns, use of Generics, and patient refills and missed refills. We believe this powerful data itself would serve as an incentive for providers to transition to these advanced risk-bearing models. With the opioid crisis, the data would also enhance an ACO’s ability to clinically manage this emergency.

Upon piloting Part D data access, the Innovation Center could then choose to expand this data sharing beyond down-side risk ACOs.

MEDICARE ADVANTAGE INNOVATION MODELS

Medicare Advantage (MA) provides an important option for Medicare beneficiaries to access coordinated care and greater benefits. We support CMS efforts to provide MA plans with flexibility to innovate and achieve better outcomes. The more MA can be divorced from Fee-For-Service limitations, the better they will be able to innovate. We believe there are variety ways CMS can further these goals, such as increasing choice and reducing cost in ways that incentivize both the beneficiary and provider group.

We are encouraged by plans from CMS in implementing the Medicare Advantage Value-Based Insurance Design (VBID) model, which represents how CMS is exploring alternative payment models in the MA program under its existing 1115A authority. To that end, ***we encourage CMS to pursue more models in the MA plan space that go beyond Fee-For-Service and MA for paying for care delivery.*** One such option would be a demonstration that empowers ACOs with third-party administration (TPA) capabilities to compete with MA plans. UPH believes that A-APMs such as Next Generation ACOs are uniquely positioned to step up involvement in the MA space given their experience in support of population health and value-based care.

STATE-BASED AND LOCAL INNOVATION, INCLUDING MEDICAID-FOCUSED MODELS

States play an important role in delivering high-quality care in Medicaid that meet the needs of their residents. Health care providers are vital to those efforts and work with CMS to test models based on state plans and local innovation initiatives. UPH values our Medicaid patients and is highly engaged with our States in assuring that our patients receive high-value care. We have responded in the Innovation Center's Request for Information processes for both the State Innovation Model (SIM) Concepts in October 2016⁶ and the Pediatric Alternative Payment Model Concepts in April 2017⁷. UPH also had representatives participate in the State Planning process for the Iowa SIM grant.

In general, ***we support CMS' interest in providing States with more flexibility and encouraging the use of value-based arrangements.*** The nature of the value-based arrangements can be flexible to reflect different maturity levels related to capabilities and networks, such as bundled or episodic care payments, total cost of care payments for special needs population, and/or total costs of care payments for the general population. Additionally, payment scope can be combined with varying levels of provider risk – Fee-For-Service with bonuses; Fee-For-Service with upside only risk; Fee-For-Service with two-sided risk; and Global capitation. Within these constructs, there are some low hanging fruits; we believe that States

⁶ UPH letter dated October 28, 2016, and submitted via SIM.RFI@cms.hhs.gov

⁷ UPH letter dated April 6, 2017, and submitted via HealthyChildrenandYouth@cms.hhs.gov

should re-envision the use of referral networks, pilot pediatric payment alternatives, and permit ACOs to compete alongside MCOs in the Medicaid space.

For providers that are ready to assume more risk (either two-sided risk based on Fee-For-Service or global capitation), ***the Innovation Center should offer, or encourage States to offer, a voluntary Innovator Program***, similar to that created in New York. The Innovator Program in New York rewards providers with up to 95% of premium pass-through for total risk arrangements as the prime program benefit. The pass-through percentage is determined by analyzing the amount of the risk and administrative tasks taken on by the providers: more delegation results in higher percentage of premium (between 90% and 95%). The providers are required to pass a strict set of criteria to be deemed an 'innovator' and once they have reached Innovator status, all MCOs are required to participate in these arrangements. If adopted, we would recommend that the specifics of an Innovator Program should be outlined in any VBP contract.

We also believe the ***Innovation Center should pursue a cross continuum Social Determinants of Health model that combines attributes of, and effectively partners, the Accountable Care Community model and down-side risk ACOs***. The combination of these models would address the heterogenous medical needs of a Medicaid population that is often exacerbated by social determinants of health requiring wrap around and after-care services.

MENTAL AND BEHAVIORAL HEALTH MODELS

The Substance Abuse and Mental Health Services Administration (SAMHSA) developed the Primary and Behavioral Health Care Integration (PBHCI) Program. It provides support to communities to coordinate and integrate primary care services into publicly funded, community-based behavioral health settings. UnityPoint Health - Berryhill Center, a Community Mental Health Center (CMHC) in Fort Dodge, Iowa, is participating in the eighth cohort and this primary care and behavioral health care integration has improved outcomes for our patients. Selected clinical outcomes are:

- Blood Pressure 39.2% of the population has improved with 23.4% no longer at risk against targets;
- Waist circumference was 60.3% outcome improved with 11.0% no longer at risk; and
- Cholesterol – HDL 52.9% improved with 4.3% no longer at risk, LDL 47.7% improved with 9.2% no longer at risk and Tri-glycerides 45.7% outcome improved with 10.0% no longer at risk.

While the SAMHSA grant has focused on care delivery and quality outcomes, it raises issues related to a sustainable payment model. Among our recurring sustainability concerns is the retention of a primary care provider. ***We request that the Innovation Center work with Health Resources and Services Administration and SAMSHA to consider a pilot that enables CMHCs to utilize Federally Qualified Health Center (FQHC) payment mechanisms for the integration of primary care services***. While FQHCs are supported to provide behavioral health services in-house, the same is generally not true for CMHCs. Sustainable payment modeling is vital. We believe that there should be no wrong door for behavioral health services and that patients with Severe Mental Illness (SMI) should be supported in an environment in which they are currently receiving services and have a familiarity and comfort level.

We appreciate the opportunity to provide comments on the “new direction” of the Innovation Center and its impact on our integrated health system and our patients. UnityPoint Health is passionate about our value-based work and its future. We are encouraged by the suggested topics and look forward to continuing our relationship and dialogue with the Innovation Center as the nation moves from healthcare reimbursement volume to holistic value. To discuss our comments or for additional information on any of the addressed topics, please contact Sabra Rosener, Vice President and Government Relations Officer, Government and External Affairs at Sabra.Rosener@unitypoint.org or 515-205-1206.

Sincerely,

A handwritten signature in blue ink that reads "Sabra Rosener".

Sabra Rosener, JD

Vice President, Government and External Affairs



1776 West Lakes Parkway, Suite 400
West Des Moines, IA 50266
unitypoint.org

May 25, 2018

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Centers for Medicare & Medicaid Services (CMS): Direct Provider Contracting Models Request for Information

Submitted electronically via DPC@cms.hhs.gov

Dear Ms. Verma,

UnityPoint Health (UPH) appreciates the opportunity to provide comments regarding the Direct Provider Contracting Models Request for Information. 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, 38 hospitals in the 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 6.2 million patient visits. In addition, UPH is actively engaged in numerous initiatives which support population health and value-based care.

UPH is an early adopter of innovative value-based models and has partnered in CMS Innovation Center demonstrations for seven years. UPH participates in Innovation Center contracts under the Bundled Payment for Care Improvement Model 2, the Home Health Value-Based Purchasing Model, and the Medicare Care Choices Model. In addition, UnityPoint Accountable Care (UAC) is the ACO affiliated with UPH and has value-based contracts with multiple payers, including Medicare. UAC is the largest ACO participating in the Next Generation ACO Model with roughly 83,000 beneficiaries attributed to this program and has received first-year savings. Historically, UAC has providers that have participated in the Medicare Shared Savings Program (MSSP) as well as providers from the Trinity Pioneer ACO, which was the most rural ACO and achieved two years of savings.

It is from our ACO experience that we respectfully offer the following input.

In general, UPH is supportive of new payment and service delivery models that advance providers from volume to value. With the passage of MACRA, there is an urgency for CMS and the Innovation Center to develop more Advanced Alternative Payment Models (A-APMs). As these models are considered and developed, we are encouraged that CMS is seeking stakeholder input and that this Request For Information (RFI) is specifically exploring options for direct provider contracting. We also are pleased that the RFI recognizes that the CMS already offers some robust A-APMs that fit into a DPC model, such as ACOs, CPC+ and BPCI. If new DPC models are developed, we urge the Innovation Center to establish a clear hierarchy of demonstrations that provide a stepwise approach for providers to accept various degrees of risk in exchange for heightened levels of Part B compensation under MACRA. As risk is increased, so should the opportunity for demonstration payment incentives and regulatory and operational flexibilities. We ask CMS to consider, as program frameworks are proposed, whether there are sufficient benefits in heightened risk-bearing models to maintain an elevated level of commitment or instead whether models with reduced risk will introduce migration of early innovators to lower risk models.

PROVIDER/STATE PARTICIPATION

- 1. How can a DPC model be designed to attract a wide variety of practices, including small, independent practices, and/or physicians? Specifically, is it feasible or desirable for practices to be able to participate independently or, instead, through a convening organization such as an ACO, physician network, or other arrangement?*

The most effective approach to facilitate greater participation by a wide variety of practices is to reduce and eventually eliminate the MIPS exemptions. MIPS has extensively excluded many rural providers through the rulemaking process and there is little incentive for these providers to aspire to A-APM participation. Additionally, the MACRA framework should simplify incentives with bonuses and small fee schedule increases generated in all APM frameworks (including MSSP Track 1). Focal to program success and sustainability, we encourage CMS to systematically bridge proportional risk to greater incentives. Instead of penalties, providers electing to not participate in APMs should not obtain a fee increase. To fund this measure, we propose the reallocation of the MIPS exceptional performance bonus dollars to be utilized within the context of this framework.

There is also substantial and comprehensive risk and resources required to participate as an A-APM, which significantly effects clinician engagement and participation. Tax incentives may serve as a channel to address current participation barriers amongst clinicians and reward those physicians whom have already transitioned to A-APM models. Incentives could take the form of tax-free retained earnings, retained by the physician practices, which could exclusively be utilized as infrastructure development and risk reserve offsets to assist in the transition to an A-APM model. Distributed incentive earnings should not be considered as a loan and should not require physicians to match funds.

BENEFICIARY PARTICIPATION

8. *The Medicare program, specifically Medicare Part B, has certain beneficiary cost-sharing requirements, including Part B premiums, a Part B deductible, and 20 percent coinsurance for most Part B services once the deductible is met. Are these types of incentives necessary to test a DPC initiative?*

We agree that consumer participation in demonstration models may currently be acting as a barrier for physicians participating in A-APMs. To further entice beneficiary participation, we support the institution of direct financial benefits to beneficiaries. Maintaining a voluntary program mindset, the utilization of shared savings models enables payers and providers to share benefits; beneficiary incentives could take the form of wellness performance benefits, not just copayment waivers. We believe that these incentives should be tied to risk-bearing models and we encourage CMS to take a comprehensive look across all A-APM models and demonstrations to make these tools available in a standardized fashion.

GENERAL MODEL DESIGN

14. *Should quality performance of DPC-participating practices be determined and benchmarked in a different way under a potential DPC model?*

CMS has made measuring quality performance too complex, and each model varies. Instead of creating additional performance measures, we believe that any future models should strive to require streamlined quality data measurement under common domains and with a focus on outcomes, particularly when payment is tied to quality/value. We do not agree with the current and ever-expanding MIPS measurement approach that silos measurement within provider specialty, as we believe this dilutes any emphasis on population health and total cost of care.

15. *Are there other direct contracting arrangements in the commercial sector and/or with Medicare Advantage plans that CMS should consider testing in FFS Medicare and/or Medicaid?*

Medicare Advantage (MA) provides an important option for Medicare beneficiaries to access coordinated care and greater benefits. We support efforts to encourage provider-based MA plans with added flexibility to innovate and achieve better outcomes. The more MA governance is infused with providers and its payment structure can be divorced from Fee-For-Service limitations, the better MA plans will be able to drive innovation, better quality and outcomes, and lower costs. One such option would be a demonstration that enables high-value ACOs with third-party administration (TPA) capabilities to compete with MA plans. We believe this option has tremendous potential to achieve the greatest savings, highest quality and best patient experience as providers will be equipped with an aligned economic incentive to control costs and provide quality care with top patient experience.

As for Medicaid, we support providing States with more flexibility and encouraging the use of value-based arrangements. The nature of the value-based arrangements can be flexible to reflect different maturity

levels related to capabilities and networks, such as bundled or episodic care payments, total cost of care payments for special needs population, and/or total costs of care payments for the general population. For providers that are ready to assume more risk (either two-sided risk based on Fee-For-Service or global capitation), we urge CMS to consider a voluntary Innovator Program, similar to that created in New York. The Innovator Program in New York rewards providers with up to 95% of premium pass-through for total risk arrangements as the prime program benefit. The pass-through percentage is determined by analyzing the amount of the risk and administrative tasks taken on by the providers: more delegation results in higher percentage of premium (between 90% and 95%). The providers are required to pass a strict set of criteria to be deemed an 'innovator' and once they have reached Innovator status, all Managed Care Organization (MCOs) are required to participate in these arrangements. If adopted, we would recommend that the specifics of an Innovator Program should be outlined in any VBP contract.

EXISTING ACO INITIATIVES

21. How can we strengthen such initiatives to potentially attract more physician practices and/or enable a greater proportion of practices to accept two-sided financial risk? What additional waivers would be necessary? Are there refinements and/or additional provisions that CMS should consider adding to existing initiatives?

Greater Participation: To attract more providers and encourage two-sided financial risk, we recommend that CMS strengthen the current testing environment by providing certainty for those participating in demonstrations and that these demonstrations continue to include phased entry options.

UPH believes engagement amongst the early adoption community should be further explored. It is through the successes of these early adopters that others will be encouraged to follow. It also accelerates change as developed and tested by providers. That said, the uncertain future of models developed by the Innovation Center deters potential eligible clinician populations from transitioning to the A-APM framework. To correct the gray area encompassing A-APM participation, UPH strongly recommends that CMS make formal recommendations to statutorily recognize A-APM models upon completion of a demonstration period. With appropriate modifications, the Next Generation Model ACO (referencing a second iteration of the Pioneer ACO Model) should graduate from the Innovation Center lab into the mainstream healthcare model market, where the model will be able to function similarly to comparable risk-bearing models or provider-owned Medicare Advantage plans.

Further, current regulatory overlaps have muddled program rule clarity and are increasingly viewed as a disincentive for providers to take heightened risk for total populations. Current overlap rules fail to recognize the totality of population health programming and incentivize siloed, episodic care (whether procedures or condition-based) based upon Fee-For-Service constructs over total population health programming. For instance, Oncology Care Model, Comprehensive ESRD Care Model, and Bundled Payments for Care Improvement (BPCI) beneficiaries are removed from the Next Generation ACO for purposes for these episodic procedures, yet the Next Generation ACO remains responsible for the overall outcomes and costs of their care. These rules allow new episodic programs and their providers to skim off ACO infrastructure investments, do not require notice of attribution among programs nor inter-program

care coordination, and impose a narrow 60- or 90-day treatment timeframe misaligned to holistic care (i.e., a significant number of BPCI episodes, such as congestive heart failure, chronic obstructive pulmonary disease, and diabetes, require lengthy aftercare and are subject to co-morbidities). To address the entanglement, we encourage a hierarchical approach to CMS / Innovation Center model overlap, in which precedence is given to population health risk-bearing entities. We would suggest that CMS use the existing payment model classification framework refined by the Health Care Payment Learning & Action Network (LAN) as a basis for its overlap policy. Within this framework for payment models, CMS should offer a hierarchy of the various delivery models. For example, if a bundled payment were being proposed in a geographic area in which there is a prevalent ACO, the ACO should drive patient attribution and performance goals to incorporate specialty care within the patient's care plan. As for reimbursement, these payments would be included within the ACO financial framework and, for ACOs under a capitated model, the ACO could convert the bundles into sub-capitation arrangements. Such approach would prioritize holistic patient care, engage specialists, leverage ACO infrastructure investments, and provide model certainty for ACOs and high performing networks as they consider and participate in innovative payment approaches.

In recognition that participation in value-based care is a continuum, we urge CMS when possible to continue the use of payment tracks within demonstrations to promote a glide path to capitated payment, such as that available under MSSP or the Next Generation ACO model.

Additional Waivers: We strongly encourage CMS to act within its power to institute Stark Law exceptions for providers within a population-based risk-bearing A-APM model. We cannot understate the impact of this expanded waiver authority to expedite the process for providers looking to join A-APMs and increase clinician and patient responsiveness.

Program Refinements: We suggest that CMS develop more opportunities or tracks with global payments and associated flexibilities as well as strengthen data sharing in support of population health objectives and total cost of care.

As a means of transitioning from Fee-For-Service constructs, global payments promote provider flexibility and capture the removal of restrictive regulations presently afflicting care decisions. We strongly encourage CMS to continue offering global payment models that correspond to heightened regulatory flexibility. The goal with global payments is to free providers from the arbitrary confines of Fee-For-Service reimbursement and, when applied at an ACO level, it enables patient-centered care to prevail and eliminates siloed provider (business unit) targets in favor of enterprise-wide targets. For services outside the ACO, it enables the ACO to contract for those services outside Fee-For-Service constraints and ideally within sub-capitated arrangements that are market based and with willing participants. Theoretically, global payments should simplify regulatory concerns by eliminating Stark and Anti-kickback concerns, medically necessary determinations (similar to the PACE program), burdensome waiver processes, and referral requirements.

As for data sharing, we encourage a more robust system to share claims data. We are supportive of sharing both raw claims-level data and claims summary data. We have used claims data to monitor trends and pinpoint areas where care practice improvement is appropriate as well as to assess cost drivers. This claims data should not be subject in an opt-in process, but rather should be routinely available and provided, which allows and encourages providers to assess and utilize this information. The untimely receipt of data and any variance from standardized formats has hindered our ability to drive innovation within payment models and measures. We encourage CMS to advance the following concepts within its models:

- Access to All-Payer administrative claims data.
- Access to substance abuse records by treating providers.
- Permit the sharing of patient medical information within a clinically integrated care setting. HIPAA currently restricts the sharing of a patient's medical information for "health care operations."

We also request that CMS consider the sharing of Part D data for lives attributed to certain population health entities, namely down-side risk ACOs. Drug information would enhance an ACO's ability to manage and coordinate patient care. This data would provide insight into prescribing patterns, use of Generics, and patient refills and missed refills. We believe this powerful data itself would serve as an incentive for providers to transition to these advanced risk-bearing models. With the opioid crisis, the data would also enhance an ACO's ability to clinically manage this emergency. Upon piloting Part D data access, CMS could then choose to expand this data sharing beyond down-side risk ACOs.

We appreciate the opportunity to provide input on this Request For Information. To discuss our comments or for additional information on any of the addressed topics, please contact Sabra Rosener, Vice President and Government Relations Officer, Government & External Affairs at Sabra.Rosener@unitypoint.org or 515-205-1206.

Sincerely,



Sabra Rosener, JD
Vice President, Government & External Affairs



CMS-6082-NC
UnityPoint Health

1776 West Lakes Parkway, Suite 400
West Des Moines, IA 50266
unitypoint.org

August 12, 2019

Administrator Seema Verma
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-6082-NC
P.O. Box 8016
Baltimore, MD 21244-1816

RE: CMS-6082-NC - Request for Information; Reducing Administrative Burden To Put Patients Over Paperwork; published at Vol. 84, No. 112 Federal Register 27070-27072 on June 11, 2019.

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

Dear Administrator Verma,

UnityPoint Health (“UPH”) appreciates this opportunity to provide input on the Patients Over Paperwork request for information. UPH is one of the nation’s most integrated healthcare systems. Through more than 32,000 employees and our relationships with more than 310 physician clinics, 39 hospitals in metropolitan and rural communities and 19 home health agencies throughout our 9 regions, UPH provides care throughout Iowa, central Illinois and southern 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 6.2 million patient visits.

In addition, UPH is committed to payment reform and is actively engaged in numerous initiatives which support population health and value-based care. UnityPoint Accountable Care (UAC) is the ACO affiliated with UPH and has value-based contracts with multiple payers, including Medicare. UAC is a current Next Generation ACO, and it contains providers that have participated in the Medicare Shared Savings Program (MSSP) as well as providers from the Pioneer ACO Model. UnityPoint Health also participates in a Medicare Advantage provider-sponsored health plan through HealthPartners UnityPoint Health.

We appreciate CMS’s past efforts under the Patients Over Paperwork initiative. UPH respectfully offers the following comments for future efforts.

REDUCING ADMINISTRATIVE BURDEN TO PUT PATIENTS OVER PAPERWORK

CMS is soliciting public comments to: (1) Modify or streamline reporting requirements, documentation requirements, or processes to monitor compliance to CMS rules and regulations; (2) align Medicare, Medicaid and other payer coding, payment and documentation requirements, and processes; (3) enable operational flexibility, feedback mechanisms, and data sharing that would enhance patient care, support

who are providing care to Medicare beneficiaries. Advanced APMs 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. ***We encourage regulatory flexibility to enhance patient care, support the clinician-patient relationship, and facilitate individual preferences.***

- **New Stark law exception to accommodate innovative payment models.** The exception¹ would address innovative value-based payment models that establish networks involving designated health services entities and referring physicians to assume financial risk and provide high-value services. We would also suggest harmonizing language² to provide clarity within existing Stark Law exceptions for value-based arrangements.

VALUE-BASED SERVICE DELIVERY

Insurance companies, along with the federal and state governments, have traditionally borne the risk for the cost of health care. Under Medicare Advantage (MA), health plans provide managed care to beneficiaries based on a monthly capitated fee. The MACRA legislation gives providers “skin in the game” by mandating that providers assume risk for the cost of care of their patients to receive preferred reimbursement. For the most part, these risk programs are administered by the Center for Medicare and Medicaid Innovation (CMMI). ***To improve the accessibility and presentation of CMS requirements, we would recommend that Advanced APMs have common benefits and that Advanced APM requirements be achievable so as to encourage greater uptake to value-based service delivery by providers.***

- **MACRA Advanced Alternative Payment Models (Advanced APMs) regulatory flexibility.** *Risk-bearing A-APMs should be afforded greater administrative flexibility. For A-APMs that bear risk to total populations, these A-APMs will ultimately compete with MA plans, infuse competition into the market, eliminate the middle man and provide more patient-centric care.* Common ground rules for participation should include:
 - **Exemption from MIPS reporting for all Advanced APM Participants at the Participant TIN level.** This would eliminate the need by innovative and high-performing provider organizations to support two quality reporting systems for the underlying Advanced APM program and MIPS;
 - **Voluntary enrollment** for beneficiaries;
 - Eligible A-APMs should operate under **partial or capitated risk arrangements**, as shared savings is a flawed methodology;
 - Ability to **waive beneficiary co-payments and deductibles** for preventive care and chronic care management;
 - A-APMs need the option to refer to **preferred providers**; and
 - **Stark law should be waived** for entities participating in partial or capitated risk.

¹ StarkRFI_UPH_08-24-18.pdf submitted via Regulations.gov at comment tracking number: 1k2-9515-eahs; See Appendix A: New Value Based Arrangements Exception

² StarkRFI_UPH_08-24-18.pdf submitted via Regulations.gov at comment tracking number: 1k2-9515-eahs; See Appendix B: Other Modifications to Existing Exceptions

- **MACRA revenue threshold levels for Qualified Participants (QPs) within Advanced APMs.** MACRA progressively increases these threshold level. CMS should evaluate the capacity of A-APMs to meet current threshold levels and make recommendations to Congress alter this structure to retain current A-APMs and to encourage further A-APM establishment. We encourage CMS to seek stakeholder input when offering alternatives that uphold a transition to value-based services from volume.
- **Taxation treatment of population health infrastructure.** Tax regulations should permit independent physician groups to retain earnings tax free for the purpose of funding losses on at-risk contracts or investing in population health infrastructure that directly support success in at-risk contracts.

ACCOUNTABLE CARE ORGANIZATIONS (ACOs)

As an early adopter of ACO models (having participated in Medicare ACO models since 2012), UnityPoint Accountable Care (UAC) has and is participating in Medicare ACO models as a glide path to assuming greater risk while enhancing overall population health. UAC is one of the largest ACO participating in the Next Generation ACO Model and has received two-years of shared savings with performance results pending for the third year. Historically, UAC has providers that have participated in the MSSP as well as providers from the Trinity Pioneer ACO, which was the most rural Pioneer Model ACO and achieved two years of shared savings. In our opinion, Medicare ACO models have succeeded in offering a differentiated patient experience through enhanced provider engagement and testing benefit enhancements and programmatic waivers. The following are recommendations to enable operational flexibility, feedback mechanisms and data sharing to promote innovation, provider transition to value and enhanced patient experience:

- **Remove new beneficiary notification requirements.** ACOs must notify beneficiaries at the point of care about voluntary alignment, its participating in the MSSP and the opportunity to decline claims data sharing. This notice is in addition to current posting requirements and the availability of written notices upon request. Since MSSP had retired a similar past notification procedure due in part to beneficiary confusion and provider burden, we encourage CMS to discontinue its use again.
- **Clarify program overlap with preference for global population models.** Current regulatory overlaps have muddled program rule clarity and are increasingly viewed as a disincentive for providers to take heightened risk for total populations. These overlap rules fail to recognize the totality of population health programming and incentivize siloed, episodic care (whether procedures or condition-based) based upon Fee-For-Service constructs over total population health programming. For instance, Oncology Care Model, Comprehensive ESRD Care Model, and Bundled Payments for Care Improvement (BPCI) beneficiaries are removed from the Next Generation ACO for purposes for these episodic procedures, yet the Next Generation ACO remains responsible for the overall outcomes and costs of their care. These rules allow new episodic programs and their providers to skim off ACO infrastructure investments, do not require notice of attribution among programs nor inter-program care coordination, and impose a narrow 60- or 90-day treatment timeframe misaligned to holistic care (i.e., a significant number of BPCI

episodes, such as congestive heart failure, chronic obstructive pulmonary disease, and diabetes, require lengthy aftercare and are subject to co-morbidities). With the advent of direct contracting entity models and a new round of mandatory bundles and ESRD programming forthcoming, this issue needs resolution. To address the entanglement, ***we encourage a hierarchical approach to CMS / Innovation Center model overlap, in which precedence is given to population health risk-bearing entities.*** We would suggest that CMS use the existing payment model classification framework refined by the Health Care Payment Learning & Action Network (LAN) as a basis for its overlap policy. Within this framework for payment models, CMS can offer a hierarchy of the various delivery models. For example, if a bundled payment were being proposed in a geographic area in which there is a prevalent ACO, the ACO should drive patient attribution and performance goals to incorporate specialty care within the patient's care plan. As for reimbursement, these payments would be included within the ACO financial framework and, for ACOs under a capitated model, the ACO could convert the bundles into sub-capitation arrangements. Such approach would prioritize holistic patient care, engage specialists, leverage ACO infrastructure investments, and provide model certainty for ACOs and high performing networks as they consider and participate in innovative payment approaches.

- **Allow two-sided ACOs a “zero year” within their contract performance periods.** This voluntary “zero year” would enable ACOs to adapt their business constructs to the new ACO model, to test pilots and to receive performance data. This zero year recognizes that CMS often does not announce model participants more than 3 months prior to the start of the contract and data lag is often three to six months in arrears. We believe CMS should include zero year provisions for new two-sided risk models.
- **Provide valuable and actionable real-time data needed for successful care coordination.** CMS does provide Medicare ACOs with claims data and performance reports, and we appreciate CMS's leadership in providing access to claims data. In the realm of real-time data, we would urge CMS to similarly lead the industry in efforts to make such data available. As a starting point, CMS incentivize hospitals to participate in electronic notifications of hospital admissions, discharges, and transfers (ADTs). CMS could consider some potential penalty/incentive frameworks which may include a new attestation process with associated penalties; revisions to one of the hospital quality programs to include participation as an offset/bonus; or, for those hospitals who choose to participate, affording hospitals some regulatory flexibility, such as expanded use of telehealth. In addition, CMS could make Health Insurance Portability and Accountability Act (HIPAA) Eligibility Transaction System (HETS) feeds available to ACOs and Medicare providers participating in Advanced APMs.
- **Make transparent the Qualified Participant (QP) calculation within the Quality Payment Program (QPP).** QPP thresholds are based on revenue or beneficiary counts for the ratio of attributed beneficiaries over attribution-eligible beneficiaries. These counts different from ACO assigned and assignable beneficiaries, and ACO reports cannot be used to project QP scores. We encourage CMS to make QP calculations transparent and even consider using the same definitions as within the ACO programs to promote definition consistency, enable providers to gauge QP status and encourage further transition to value and risk-based arrangements.

- **Address ongoing concerns with NGACO risk adjustment.** Simply put, the current 3-percent cap across a five-year agreement is inadequate and pales in comparison to Medicare Advantage plans. We encourage CMS to revisit this cap to promote further transition to value-based arrangements.
- **Permit ACOs to appeal a payment or alignment determination.** There is presently no provision to allow ACOs to appeal a CMS payment determination made in error. Likewise, ACOs cannot appeal a provider (TIN) misalignment – for instance, a provider TIN exits an MSSP ACO and joins an NGACO, the NGACO timely adds the provider TIN to the NGACO list, but the MSSP ACO does not timely remove the provider TIN from the MSSP list. In this instance, the MSSP ACO retains the provider TIN and the NGACO has no appeal rights. We urge CMS to revamp its appeals process to address these issues.
- **Expand opportunities to increase beneficiary engagement.** CMS should work with ACOs to permit flexibility in this arena and enable beneficiaries to be rewarded for high-value care choices. One example would be to reinstate incentives for Annual Wellness Visits. Another example would be creative methods to reduce telehealth co-pays.
- **Allow ACOs direct access to CMS program integrity to report suspected fraud and abuse.**
- **Simplify ACO marketing requirements.** We request that CMS eliminate the requirement for ACOs to submit internal provider facing materials.
- **Timing of annual Quality Payment Program (QPP) Proposed Rule.** We would suggest that CMS consider moving the QPP Proposed Rule to a notice and comment period earlier in the calendar year. By placing within the annual Physician Fee Schedule update, it is unlikely that the Final Rule will be released before November leaving only 2 months to operationalize changes. We would suggest that the QPP update occur during a timeframe that is more aligned to the annual Inpatient Prospective Payment System update (Proposed Rule in the spring and Final Rule in the summer).
- **Streamline QualityNet access to permit system level secure file exchange access for integrated health systems.** QualityNet houses reports to monitor performance under various CMS quality programs including the Inpatient and Outpatient Quality Reporting, Value Based Purchasing Program, HAC Reduction Program, and Hospital Readmission Reduction Program. UPH regularly uses QualityNet reports, such as (1) Overall Hospital Star Rating Hospital Specific Reports, (2) Hospital Value-Based Purchasing (VBP) Percentage Payment Summary Report (PPSR); (3) Hospital-Acquired Condition Reduction Program Hospital Specific Reports; (4) Medicare Spending per Beneficiary Hospital Specific Reports; (5) Public Reporting Preview Reports; and (6) Hospital Readmission Reduction Program Hospital Specific Reports. While each UPH hospital can access these reports through the QualityNet secure file exchange, our centralized UPH analytics personnel **with** approved QualityNet Healthcare System level access **cannot** receive these same reports. This requires duplicative steps by our centralized analytics team to request these reports from each hospital, which is both unnecessary and time consuming and defeats any efficiency efforts to centralize reporting functions.
- **Flexibility in Web Interface submission requirements** for Next Generation ACO quality reporting. In 2018, CMS changed the reporting format from an xml format to an Excel format. The new Excel file template was provided, including 146 columns to capture data for all measures in one spreadsheet and drop-down lists to help ensure only valid data was submitted in each cell. While

this format might be helpful for an organization that manually abstracts their data into the spreadsheet, it was and is very burdensome for organizations that have automated this process to pull directly from their EHR. UAC had been required to use the xml format since its participation in the Pioneer ACO Model in 2012. We would request that CMS consider reinstating the xml format for early adopters and also suggest that in the future CMS work with stakeholders as it considers “upgrading” reporting systems to consider timing and impact.

MEDICAID REFORM

The growth of Medicaid managed care is well documented. We believe that this trend has generally resulted in states turning over their regulatory keys concerning some of their most vulnerable residents to private health plans with little accountability and virtually no avenue for public input. We have significant concerns that loose federal parameters for Medicaid managed care usurps decision-making authority that should appropriately lie with, and be maintained by, taxpayers and the federal and state governments. In this arena, we suggest that Patients Over Paperwork should focus efforts on maintaining clear guidelines that assure single sources of regulatory truth and enable stakeholder input, including input from consumers and providers. CMS regulations should:

- **Encourage multi-payer state-based strategies to align with MACRA goals.** Specifically UPH highly supports multi-payer strategies in which **states align with existing Medicare models**, instead of encouraging state-specific new payer models. UPH recommends that value-based payments models include 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.
- **Require Medicaid Managed Care Organizations (MCOs) to honor copayments for dual eligible beneficiaries in Advanced APMs.**
- **Encourage the streamlining and alignment of quality measures** when feasible to Medicare Quality Payment Program constructs and the Meaningful Measures Initiative.
- **Adopt uniform standards for Medicaid managed care** that create a third-party appeal process for providers, improve the prior authorization process, mandate timely data sharing, enforce contractual obligations and institute a centralized credentialing process.
- **Enable funding of inpatient substance use disorder (SUD) treatment.** The Medicaid Institutions for Mental Diseases (IMD) exclusion prohibits the use of federal Medicaid financing for care provided to most patients in mental health and substance use disorder residential treatment

facilities larger than 16 beds. With the opioid crisis, this funding is even more vital. Although not a comprehensive solution, we encourage CMS to consider excluding SUD from the definition of mental disease for the purposes of determining if a treatment facility is an IMD. This would enable states to draw down federal funds for SUD treatment provided in inpatient settings with more than 16 beds if less than 50 percent of patients had cooccurring mental illnesses that required an inpatient level of care.

TELEHEALTH AND BROADBAND SUPPORT

Telehealth is a vital service delivery modality that enables access to services for patients with distance or transportation barriers, mobility issues and/or provider shortages. At UPH, telehealth visits are up 41% compared to the same period last year, and 45% of telehealth visits are attributed to Medicare or Medicaid patients (although these patients comprise more than 60% of our payor mix). ***Regulatory barriers prevent further use of telehealth to enhance patient care, support the clinician-patient relationship, and facilitate individual preferences.*** We would recommend that CMS:

- **Examine the elimination of geographic restrictions imposed on originating sites.** This geographic limitation draws arbitrary service eligibility lines, which do not necessarily correlate to patient barriers to care but do restrict service delivery options and preferences and hamper population health initiatives. In particular CMS should
 - Advocate to Congress to outright eliminate geographic restrictions imposed by Section 1834(m);
 - Lift this rural limitation for providers participating in risk-bearing arrangements (i.e. participation in an Advanced Alternative Payment Model under the Quality Payment Program); and
 - Redefine originating sites to include patient homes, schools, long-term care hospitals, hospice centers, and employer work sites.
- **Revise the CMS telehealth regulatory approval process.** Currently regulatory approval process for Medicare reimbursement of telehealth is on a case-by-case basis, which results in a small percentage of services being reimbursed. We request that CMS reverse this process and instead have a presumption that Medicare-covered services are reimbursed when delivered via telehealth, unless a case-by-case exception prohibiting its use is in place.

HOSPITALS

Hospitals have been closing at an alarming rate and, for non-profit hospitals, operating margins have experienced a downward trend. We would request that CMS consider regulatory relief in the targeted areas below:

- **Exempt hospitals in a Medicare two-sided ACO from RAC audits.** This is an unnecessary expense for ACO Participants who are already trying to limit their Medicare spend.
- **Eliminate utilization review regulations around intensity of services and qualifying days for Medicare patients after meeting Admission criteria.** Since payment is based on DRGs, the scrutiny and regulations focused on appropriate documentation and coding are sufficient.

Program of All-inclusive Care for the Elderly (PACE) provides comprehensive medical and social services to certain frail, community-dwelling elderly individuals, most of whom are dually eligible for Medicare and Medicaid benefits. To assist with seamless administration of this program and encourage program awareness by beneficiaries, we encourage the following actions:

- **Continue progress toward implementing the PACE pilots** that would allow PACE organizations to serve new populations. The PACE Innovation Act (a) allows CMS to develop pilots using the PACE model to serve those under 55 years of age and those at risk of needing a nursing home, and (b) encourages CMS to allow operational flexibilities that would support adaptation of the PACE model for new populations and promote PACE growth, efficiency and innovation. In particular, the pilots rely on the waiver authorities of CMMI.
- **Require training for Medicaid Options Counselors on PACE.** PACE regulations have restrictions on marketing by PACE Organizations. To increase PACE awareness by beneficiaries, especially in PACE services areas, we would encourage CMS to require training for Options Counselors on this program.

We are pleased to provide input in response to this request for information and to offer suggestions to reduce administrative burden which impacts our integrated health system and the individuals and communities we serve. To discuss our comments or for additional information on any of the addressed topics, please contact Sabra Rosener, Vice President, Government & External Affairs at sabra.rosener@unitypoint.org or 515-205-1206.

Sincerely,



Sabra Rosener, JD

VP, Government & External Affairs



UnityPoint Health

Government & External Affairs
1776 West Lakes Parkway, Suite 400
West Des Moines, IA 50266
www.unitypoint.org

September 16, 2019

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5527-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: CMS-5527-P – Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures; published in Vol. 84, No. 138 Federal Register 34478-34595 on July 19, 2019.

Submitted electronically via www.regulations.gov

Dear Administrator Verma:

UnityPoint Health (“UPH”) appreciates the opportunity to provide comments in response to the Centers for Medicare & Medicaid Services’ (CMS) proposed rule to establish two mandatory specialty care models. Through more than 32,000 employees, our relationships with more than 310 physician clinics, 39 hospitals in metropolitan and rural communities and 19 home health agencies throughout our 9 regions, UPH provides care throughout Iowa, western Illinois and southern 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 6.2 million patient visits.

As an integrated healthcare system, UPH believes that patient-centered care is best supported by a value-based payment structure that enables healthcare providers to focus on population health instead of volume-based episodic care. UPH’s commitment to population health and value-based care is evidenced by our status as an early adopter of an Accountable Care Organization (ACO) framework. UnityPoint Health Accountable Care (UAC) is the ACO affiliated with UPH and has value-based contracts with multiple payers, including Medicare. UAC is a current Next Generation ACO, and it contains providers that have participated in the Medicare Shared Savings Program as well as providers from the Pioneer ACO Model. UPH also has had regional participation in other Centers for Medicare and Medicaid Innovation (CMMI) Medicare models, including the Bundled Payments for Care Improvement (BPCI) Initiative and the Medicare Care Choices Model. Our home health agency, UnityPoint at Home, is licensed and practices in the one of the nine states that is mandatorily participating in the Innovation Center’s Home Health Value-Based Purchasing Model (HHVBP).

UnityPoint Health respectfully offers the following comments to the proposed regulatory framework.

GENERAL PROVISIONS

CMS is proposing that both new mandatory models be subject to certain beneficiary protections and common requirements, including provisions related to model evaluation, audits and record retention, monitoring and compliance, remedial action, limitations on review and rights in data and intellectual property.

Comment:

Mandatory Models: UPH agrees that the CMMI has the authority to proceed with mandatory initiatives under its Expansion of Models authority.¹ We appreciate CMS’s efforts to move from volume to value and recognize the importance of agency discretion to facilitate change. While we do not always agree with the timing and technical issues of CMMI models, we believe that the discretion to make models mandatory is necessary in order to disseminate best practices, including nationwide implementation, of models that balance cost and quality concerns and to instill timely flexibility and adjustments within an otherwise rigid payment construct. Additionally, we urge CMS to continue the formal rule-making process for the release of mandatory models, so that stakeholders can participate in the development of model parameters.

Selected Geographic Regions: In this proposed rule, CMS indicates that each model will use a random sampling methodology to select model participants. The actual geographic regions subject to these models have not been identified in this proposed rule. In the past, CMS has rationalized, in part, the nondisclosure of regions during this rule-making phase as necessary to assure that CMS receives stakeholder input from the entire nation, instead of just those selected regions. We understand this rationale; however, this timing disadvantages providers, in that mandatory models often have aggressive implementation timeframes and when geographic regions are “revealed” in the final rule, there is often less than 90 days until go live. This is the case with both proposed Specialty Care Models, which are set for implementation on January 1, 2020. **We would request that CMS always allow at least a 90-day period prior to implementation, and perhaps more time dependent upon the model, to facilitate operational success and beneficiary satisfaction.** These initiatives require additional beneficiary notice, workflow revisions and, in many cases, external support to incorporate infrastructure / software changes. Until a final rule is released, it is not practical or efficient for providers to prepare to operationalize these models.

Overlap Treatment: With the increasing speed at which new APMs are released, **we continue to be concerned that the lack of a strict overlap structure undermines the financial integrity of early adopters in high-risk Advanced APM models.** In the absence of an established overlap framework that incorporates both CMS and CMMI value-based programming, CMS is effectively creating a disincentive for providers to voluntarily bear heightened risk for a total population. Now as CMS is encouraging providers to enter into Direct Contracting models, providers are not equipped with enough information to evaluate the potential effect of specialty and other episodic models on global payments and total cost of care. When provider organizations commit to bear risk for the health care

¹ 42 USC 1315A(c)

of populations, there is a finite opportunity for those organizations to reduce costs while maintaining access and quality. For instance, when an ACO is in a market, new episodic models and their providers have been permitted to piggy back off ACO infrastructure investments, are not required to provide notice of attribution among programs nor inter-program care coordination, and impose narrow 60- or 90-day treatment timeframes that are misaligned to holistic care. Without an overall framework, at-risk providers must review each model to determine impact on population health strategies and financial opportunities and many times, as with these Specialty Care Models, the rules are unclear.

To address this entanglement, **we encourage a hierarchical approach to CMS / CMMI model overlap**, in which precedence is given to population health risk-bearing entities. **We would suggest that CMS use the existing payment model classification framework refined by the Health Care Payment Learning & Action Network (LAN) as a basis for its overlap policy.** Within this framework for payment models, CMS should offer a hierarchy of the various delivery models. For example, if a bundled payment were being proposed in a geographic area in which there is a prevalent ACO, the ACO should drive patient attribution and performance goals to incorporate specialty care within the patient’s care plan. As for reimbursement, these payments would be included within the ACO financial framework and, for ACOs under a capitated model, the ACO could convert the bundles into sub-capitation arrangements. Such approach would prioritize holistic patient care, engage specialists, leverage ACO infrastructure investments, and provide model certainty for ACOs and high performing networks as they consider and participate in innovative payment approaches.

When developing an overlap framework, we offer the following suggestions:

- **Risk-bearing population health models should take precedence over episodic care models for attribution and financial modeling.** Population health models with prospective attribution are particularly disadvantaged when population health programming, care coordination efforts, and financial modeling are undercut through the “partial” transfer of beneficiaries for episodic care. Instead, contracting with episodic care providers should be at the discretion of the population health model participant (such as an ACO) to allow the ACO service delivery flexibility.
- **Population health models should take precedence over Fee-For-Service models for attribution and financial modeling.** This appropriately incentivizes transition to value and risk-bearing. Fee-For-Service models still ultimately reward service volume and may inappropriately incent hospitalizations or high-cost placements. The population health model participant should not be allowed to manage care for their population with minimal carve-outs, particularly carve-outs for Fee-For-Service models.
- **Risk-bearing population health model participants should be allowed to opt out of participation in mandatory model demonstrations.** CMS should reward providers that voluntarily choose to accept risk. By granting population health models participants the discretion to opt out, these model participants can innovate based on the needs and priorities of their beneficiaries and control the flow of funds within their service delivery model.
- **CMS should develop a mandatory decision support tool that encompasses all payment reform models to assign attribution and financial modeling.** We urge CMS to develop a tool to clarify the pecking order for beneficiary attribution and financial implications (i.e. order in which models receives payment). We would also suggest that, upon the release of each new model,

CMS and/or CMMI incorporate each model into the decision support tool.

RADIATION ONCOLOGY (RO) MODEL

The mandatory RO Model would test prospective site-neutral, episode-based payments for specified professional and technical radiotherapy (RT) services furnished during a 90-day episode to Medicare fee-for-service (FFS) beneficiaries diagnosed with certain cancer types. Specific to the RO Model, the model is proposed for five performance years starting either January 1, 2020 or April 1, 2020. Proposed participants include Hospital Outpatient Provider Departments (HOPDs), physician group participants and freestanding radiation therapy centers. The proposed pricing methodology includes withholds related to incomplete episodes, quality, and beneficiary experience. This model is intended to meet qualifications for an Advanced APM and would require four quality measures and collection of a CAHPS survey.

Comment: Without regard to overlap magnitude (both beneficiaries and provider/suppliers), the RO Model in principle and reality overlaps populations attributed to, and participating in, global models. **As a Next Generation ACO Participant, our ACO is impacted as this not only affects financial modeling and benchmarks, but it impacts our strategy in establishing an ACO provider network and our overall population health care strategy.** For providers subject to this overlap, this implicates additional quality reporting and payment parameters outside those under the Next Generation ACO. We would recommend that CMS develop an overlap framework as suggested in our *Overlap Treatment* narrative.

In general, this is a site-neutral payment model associated with specific quality measures. The concept of site neutrality is an attempt to “fix” inequities in the Fee-For-Service payment structure. Consistent with prior input to CMS, **UPH has general concerns related to how this concept fits with access to care and within the constructs of two-sided risk models.**

In general, we question CMS’s role in site of service delivery decisions for organizations engaged in two-sided risk models. While the intent of site neutral policies is to allow healthcare decisions to focus on delivery instead of payment, we do not believe that this can be effectively accomplished under Fee-For-Service parameters. Site neutrality is based on the assumption that this payment structure will curb excess use; however, access to care in the Midwest and in rural areas is primarily driven by geography and efficiencies and not cost. We would recommend that CMS encourage value-based programs and allow providers through shared decision-making with their patients to determine appropriate and convenient delivery options.

We also believe that there are unintended consequences to “resetting the table” in this fashion. Namely, this approach fails to recognize that independent (free-standing) and for-profit entities will strategize to cherry pick certain lower-acuity patients to increase their operating margins and erode already fragile provider-based department operating margins for Midwest providers. Without developing a holistic payment approach that takes into consider all payments, fee schedules will continue to drive healthcare builds and infrastructure. We wholeheartedly urge CMS to focus on population health objectives and the path to value within this and all Medicare payment regulations and to promote regulatory and payment flexibility for providers who engage in financial risk.

ESRD TREATMENT CHOICES (ETC) MODEL

The mandatory ETC Model would test the effectiveness of adjusting certain Medicare payments to ESRD facilities and Managing Clinicians to encourage greater utilization of home dialysis and kidney transplantation. In particular, the model proposes to adjust payments for home dialysis claims with claim-through dates from January 1, 2020, through December 31, 2022 through a Home Dialysis Payment Adjustment (HDP), and to assess the rates of home dialysis and kidney transplant among beneficiaries attributed to ETC Participants during the period beginning January 1, 2020, and ending June 30, 2025, with a Performance Payment Adjustment (PPA) based on those rates applying to claims for dialysis and dialysis-related services with claim-through dates beginning January 1, 2021, and ending June 30, 2026. This model does not qualify as an Advanced APM and requires two quality measures - the Standardized Mortality Ratio and the Standardized Hospitalization Ratio.

Comment: Generally, UPH is supportive of movement to home dialysis, methodology that supports peritoneal dialysis and involves a more graduated approach to hemodialysis, accelerated pathways to kidney transplantation and an overall emphasis on patients making informed choices, rather than decisions based on provider convenience. While we are pleased that CMS recognizes that this model needs to be tested in rural areas, we would encourage CMS to assure payment equity for treating rural patients that takes into account geographic distance from dialysis facilities.

For our attributed Next Generation ACO beneficiaries, less than 1% have an ESRD diagnosis and these beneficiaries are highly concentrated but dispersed around 10 cities with dialysis facilities. For our ACO, the relative overlap potential (both beneficiaries and provider/suppliers) between models will be small. **While we anticipate that our Next Generation ACO will benefit from reduced costs under the ETC Model, we are still concerned with the lack of details in the proposed rule related to overlap treatment**, including additional work effort or reporting that this may entail. Although the ETC Model does not include quality measures for clinicians at this point, if providers are included within a total cost of care Advanced APM, we would encourage CMS to consider exempting them from ETC Model reporting. We would reiterate our recommendation that CMS develop an overlap framework as suggested in our *Overlap Treatment* narrative.

We are pleased to provide comments to the proposed regulations and their impact on our integrated healthcare system. To discuss our comments or for additional information on any of the addressed topics, please contact Sabra Rosener, Vice President and Government Relations Officer, Government and External Affairs at sabra.rosener@unitypoint.org or 515-205-1206.

Sincerely,



Sabra Rosener, JD
VP, Government & External Affairs
UnityPoint Health



UnityPoint Health

Government & External Affairs
1776 West Lakes Parkway, Suite 400
West Des Moines, IA 50266
www.unitypoint.org

September 27, 2019

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1715-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: CMS-1715-P – Medicare Program; CY 2020 Revisions to 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; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations; published in Vol. 84, No. 157 Federal Register 40482-41289 on August 14, 2019.

Submitted electronically via www.regulations.gov

Dear Administrator Verma:

UnityPoint Health (“UPH”) appreciates the opportunity to provide comments in response to the Centers for Medicare & Medicaid Services’ (CMS) proposed rule for the 2019 Physician Fee Schedule and Part B reimbursement. Through more than 32,000 employees, our relationships with more than 310 physician clinics, 39 hospitals in metropolitan and rural communities and 19 home health agencies throughout our 9 regions, UPH provides care throughout Iowa, western Illinois and southern 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 6.2 million patient visits. In addition, UPH is committed to payment reform and is actively engaged in numerous initiatives which support population health and value-based care. UnityPoint Health Accountable Care (UAC) is the ACO affiliated with UPH and has value-based contracts with multiple payers, including Medicare. UAC is a current Next Generation ACO, and it contains providers that have participated in the Medicare Shared Savings Program as well as providers from the Pioneer ACO Model.

UnityPoint Health respectfully offers the following comments to the proposed regulatory framework.

While the request for public comment was limited to the physician notification, we would like to use this opportunity to request that CMS provide clarification on the following:

- Availability of Professional Services: Among the required services, professional services must be available on a 7-day-a-week, 24-hour-a-day basis in order to ensure that patients have access to expert clinical knowledge and advice in the event of an urgent or emergent infusion-related situation. **We would request that CMS further clarify this availability of professional services requirement to include professional services provided “on-call” as well as extending beyond nursing services.**
- Infusion Drug Administration Calendar Day: We request that CMS revisit this definition, which triggers when a supplier can bill for home infusion therapy services. **We would suggest adoption of this revised definition: Infusion drug administration calendar day means the day on which home infusion therapy services are furnished in the individual’s home on the day of infusion drug administration.** This eliminates a burdensome and unnecessary requirement that skilled professionals (i.e. nurses) be physically present in an individual’s home on the day the infusion drug is administered for payment to occur. For instance, in many cases, subcutaneous IVIG tier 2 and tier 3 medications are self-administered after training is received from healthcare professionals. Our suggested revised definition recognizes standard industry practice, which rely on patients to self-administer these drugs without a physical presence requirement. In addition, the revised definition aligns with the statute’s plain language and Congressional intent and eases demands on workforce shortages, particularly in rural areas.
- Home Infusion Drug: Both statute and regulation define this term as “a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment.” The billing commentary states “Each visit reported would include the length of time in which professional services were provided (in 15 minute increments).” **We encourage CMS to further clarify in regulation or guidance how the 15-minute duration for reimbursement purposes is operationalized.** We would request that the clarification include that the 15-minute duration applies to both intravenous and subcutaneous administration, and that administration time should be rounded up in 15-minute intervals. This recommendation will address that administration reimbursement will not be pro-rated or denied for increments less than 15 minutes and that this timeframe does not solely apply to subcutaneous administration.

BUNDLED PAYMENT OPPORTUNITIES

CMS is seeking comments on opportunities to expand the concept of bundling to recognize efficiencies among physicians’ services paid under the PFS and better align Medicare payment policies with CMS’s broader goal of achieving better care for patients, better health for our communities, and lower costs through improvement in our health care system.

Comment: While we appreciate that CMS is seeking provider input on value-based, episodic care payments, **we continue to be concerned that the lack of a strict overlap structure undermines the financial integrity of early adopters in high-risk Advanced APM models.** Through UnityPoint Accountable Care, UnityPoint Clinic is an ACO Participant in the Next Generation ACO Model. In the

absence of an established overlap framework that incorporates both CMS and CMMI value-based programming, CMS is effectively creating a disincentive for providers to voluntarily bear heightened risk for a total population. Now as CMS is encouraging providers to enter into Direct Contracting models, providers are not equipped with enough information to evaluate the potential effect of bundled payments and other episodic models on global payments and total cost of care. When provider organizations commit to bear risk for the health care of populations, there is a finite opportunity for those organizations to reduce costs while maintaining access and quality. For instance, when an ACO is in a market, new episodic models and their providers have been permitted to piggy back off ACO infrastructure investments, are not required to provide notice of attribution among programs nor inter-program care coordination, and impose narrow 60- or 90-day treatment timeframes that are misaligned to holistic care. Without an overall framework, at-risk providers must review each model to determine impact on population health strategies and financial opportunities and many times, the rules are unclear.

Prior to expanding bundled payment models or other Advanced APMs, **we encourage a hierarchical approach to CMS / CMMI model overlap**, in which precedence is given to population health risk-bearing entities. **We would suggest that CMS use the existing payment model classification framework refined by the Health Care Payment Learning & Action Network (LAN) as a basis for its overlap policy.** Within this framework for payment models, CMS should offer a hierarchy of the various delivery models. For example, if a bundled payment were being proposed in a geographic area in which there is a prevalent ACO, the ACO should drive patient attribution and performance goals to incorporate specialty care within the patient’s care plan. As for reimbursement, these payments would be included within the ACO financial framework and, for ACOs under a capitated model, the ACO could convert the bundles into sub-capitation arrangements. For ACOs, the most appropriate bundles are those involving surgical procedures. Such approach would prioritize holistic patient care, engage specialists, leverage ACO infrastructure investments, and provide model certainty for ACOs and high performing networks as they consider and participate in innovative payment approaches.

When developing an overlap framework, we offer the following suggestions:

- **Risk-bearing population health models should take precedence over episodic care models for attribution and financial modeling.** Population health models with prospective attribute are particularly disadvantaged when population health programming, care coordination efforts, and financial modeling are undercut through the “partial” transfer of beneficiaries for episodic care. Instead, contracting with episodic care providers should be at the discretion of the population health model participant (such as an ACO) to allow the ACO service delivery flexibility.
- **Population health models should take precedence over Fee-For-Service models for attribution and financial modeling.** This appropriately incentivizes transition to value and risk-bearing. Fee-For-Service models still ultimately reward service volume and may inappropriately incent hospitalizations or high-cost placements. The population health model participant should not be allowed to manage care for their population with minimal carve-outs, particularly carve-outs for Fee-For-Service models.
- **Risk-bearing population health model participants should be allowed to opt out of participation in mandatory model demonstrations.** CMS should reward providers that

voluntarily choose to accept risk. By granting population health models participants the discretion to opt out, these model participants can innovate based on the needs and priorities of their beneficiaries and control the flow of funds within their service delivery model.

- **CMS should develop a mandatory decision support tool that encompasses all payment reform models to assign attribution and financial modeling.** We urge CMS to develop a tool to clarify the pecking order for beneficiary attribution and financial implications (i.e. order in which models receives payment). We would also suggest that, upon the release of each new model, CMS and/or CMMI incorporate the model into the decision support tool.

MEDICAID PROMOTING INTEROPERABILITY PROGRAM

CMS is proposing to maintain the continuous 90-day period with the calendar year to demonstrate meaningful use for the first time. For Objective 1: Protect Patient Health Information, Medicaid EPs may conduct a security risk analysis at any time during CY 2021, even if the EP conducts the analysis after the EP attests to meaningful use of CEHRT to the state.

Comment: As this program winds down, **we are extremely concerned with the reporting period requirement for Medicaid EPs who have demonstrated meaningful use in a prior year.** A minimum of any continuous 274-day period creates a situation in which organizations are expected to submit data by October 1 (the 275th day) essentially mandating zero turn around to create reports, validate data, and submit data before the close of the reporting window. This reporting period is challenging and should be reconsidered.

MEDICARE SHARED SAVINGS PROGRAM (MSSP) QUALITY MEASURES

CMS is proposing to align the MSSP quality measure set with proposed changes to the Web Interface measure set under MIPS, change claims-based measures and correct a cross-reference to the skilled nursing facility (SNF) 3-day rule waiver. For Performance Year 2020, ACO-14 Preventive Care and Screening Influenza Immunization would no longer be reported and replaced by ACO-47 Adult Immunization Status. CMS discusses moving to all claims-based measures and implementing a core measure set that applied to populations and public health conditions. CMS is also seeking comment on aligning the MSSP quality score with the MIPS quality performance category score.

Comment: UPH participates in the Next Generation ACO Model through UnityPoint Accountable Care. As such, Next Generation ACOs use the MSSP quality measure set. Historically, UPH has been supportive of the Meaningful Measures initiative and has applauded CMS efforts to streamline data collection and reporting. Last year, the current MSSP measure set was reduced from 31 to 24 and transitioned to a focus on outcome-based measures, including patient experience of care.

As for proposed changes to specific measures in this rule, CMS is proposing the removal of ACO-14 (Preventive Care and Screening Influenza Immunization) and its replacement with ACO-47 (Adult Immunization Status) for PY 2020. **We do not support the removal of ACO-14 until ACO-47 has gone live in a reporting only status for at least one year.** ACO-47 is a composite measure that includes routine vaccines for influenza; tetanus and diphtheria (Td) or tetanus, diphtheria and acellular pertussis (Tdap); zoster; and pneumococcal. There are several challenges to this proposed change related to timeframe, measure components and measure scoring. As a composite measure, we believe that ACO-47 will be complicated to collect and measure. There are four different age groups that comprise five denominators and each numerator has a different schedule. It is unclear how ACO-

47 will be scored. Additionally, we believe that the inclusion of the shingles vaccine should be monitored, as this vaccine is more costly and has been subject to shortages. We are concerned that providers may be inadvertently penalized for immunizations that are subject to noncompliance due to accessibility issues. Overall, we recommend that CMS retain ACO-14 until ACO-47 is ready for pay-for-performance status. If ACO-14 is removed in PY 2020, this will also result in other metrics within the prevention / patient safety category increasing in weight, at least on a temporary basis.

We support the transition to pay-for-performance status in PY 2019 for ACO-17 (Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention). **We also support pay-for-reporting status in both PY 2020 and PY 2021 for ACO-43** (Ambulatory Sensitive Condition Acute Composite (AHRQ Prevention Quality Indicator (PQI) #91)).

We would request that CMS revisit the general process as well as the measures contained within the Patient / Caregiver Experience domain. Currently 10 measures (43% of the MSSP measure set) are located within the Patient/Caregiver Experience domain, while the other domains have between three and six measures each. **We would request that CMS reduce the number of measures within this domain with the goal of more equal distribution across domains.** In addition, we have general concerns about the CAHPS survey methodology. Foremost, this survey is very subjective (being based on the patients perception of their health) and is not necessarily anything that providers can impact. Other concerns include: (1) Sample size of 860 is the same regardless of actual ACO size; (2) sampled patients do not represent the full population we serve (when comparing our own CG-CAHPS data comparing Next Generation ACO patients to non-Next Generation ACO patients, Next Generation ACO patients consistently score us higher in almost every domain); (3) providers cannot supplement response rates (while we have a low response rate and high number of surveys returned for bad addresses, we aren't able to supplement with more accurate contact information in effort to reach more of the sampled patients); and (4) surveys are administered once annually.

In terms of aligning the MSSP quality score with the MIPS quality score, we understand the stated goal, but we urge caution with this approach. While we appreciate the sentiment to keep measurement and scoring simple and aligned across programs, we would respectfully suggest that APM measures should lead and not follow MIPS. As MIPS continues to be populated with specialty driven measures, this does not encourage transition to APM constructs. We do not support the MIPS measures dictating the standards for APMs. Case in point, we are concerned about the addition of the MIPS All-Cause Unplanned Admission for Patients with Multiple Chronic Conditions (MCC) measure to the MIPS quality performance category in PY 2021 and its potential impact on APMs.

QUALITY PAYMENT PROGRAM (QPP)

CMS is proposing numerous changes to the QPP, which consists of two participation pathways – the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (Advanced APMs). CMS will apply a new MIPS Value Pathways (MVPs) framework to future proposals beginning with the 2021 MIPS Performance Year and seeks public comment. In addition, Qualified Clinical Data Registry (QCDR) measure standards are strengthened and the cost category adds new episode-based measures for specialist care and revises both the total per capita cost and the Medicare Spending Per Beneficiary (MSPB) measures. In terms of APMs, revisions will align other payer Medical Home models and marginal risk definitions. CMS also provides overall estimates of APM incentive payments and MIPS payment adjustments.

Comment:

- **MIPS Value Pathways (MVP):** CMS is proposing a new framework for MIPS – MIPS Value Pathways (MVP). We do not support the MVP proposal in concept, as we believe CMS should target its work efforts on providing more APM options. Enhancing MIPS and potentially making it more attractive does not necessarily assist in the overall transition to value-based services and population health and it diverts resources and rewards from providers who have been early adopters of care delivery innovation.
- **MIPS Changes To Cost Performance Category:** CMS is proposing significant changes to the cost category in an attempt to populate this measurement domain as its category weight increases. CMS is adding 10 episode-based measures for specialist cost of care and revising the total per capita cost measure and the Medicare Spending Per Beneficiary (MSPB) measure. Given the significant changes to this category, we would request that new metrics receive initial pay-for-reporting status. In this category, **we oppose the policy direction CMS is taking and believe that it is counter to overall population health objectives.**

First, we generally disagree with establishing separate definitions for attribution, cost and other key terms between MIPS and Advanced APM programs. This permits providers to game the system to whatever program provides the greatest short-term incentives. CMS should try, when possible, to align measures and definitions, rather than creating parallel models that may or may not align. To encourage transition to APMs and population health, we believe CMS efforts should concentrate on incenting specialists to APMs and not MIPS.

Second, excluding specialists from the primary care provider cost measures is contrary to the overall goals of reducing costs in the Medicare population. Specialty care is a major driver of cost in Medicare, so exempting specialists from overall responsibility for cost doesn't seem to align with the overall goals of the program. Additionally, that change would further erode the cross-continuum care networks that align primary care providers and specialists to improve quality and reduce costs. We continue to oppose recent programmatic changes and rules that seem to create adversarial relationships between providers rather than incenting collaboration and eroding total cost of care models.

Finally, as Advanced APM thresholds continue to increase, this misalignment presents a major risk if Advanced APM entities fail to meet the Advanced APM targets in the future. The changeover burden, in both effort and cost, becomes greater as the measures start to evolve separately. Additionally, there is no guarantee that the factors that are part of the ACO measures will align with the MIPS measures, creating additional performance risk.

- **Promoting Interoperability RFIs.** CMS is seeking stakeholder input on a variety of promoting interoperability topics.
 - **RFI: Metric to Improve Efficiency of Providers within EHR:** Overall, as an integrated healthcare system participating in numerous value-based arrangements, efficiency is already being tackled on a daily basis. Instead of having an efficiency measurement mandated by CMS, we would prefer that health care organizations be allowed flexibility to target activities that are most beneficial to our patients and organizational goals.

Related to efficient health care processes, we believe the addition of a PI measure would just muddy the waters. Because there is no single definition of efficiency, we are concerned that any measure will have unintended consequences dependent upon a provider's scope of practice, clinical responsibilities and organizational structure. There is also the potential for adverse incentives. For instance, PI efficiency may prioritize speed over time spent with patients, including those with complex needs. Patient care should be dictated by an individual's health care needs and the provider's scope of practice. Lastly, we fear that a PI measure may prioritize EHR improvements over larger systematic issues. The EHR is a tool and should not be the focus on efficiency, although it can be part of a solution.

In terms of measuring efficiency through cost reduction and resource utilization, there are other programs and measures that address these concerns. Medicare ACO programs encourage cost reduction. Appropriate Use Criteria is already in place and requires consultation of qualified clinical decision support to reduce avoidable advanced imaging services. The Hospital Value-Based Purchasing program incentivizes improving the quality of care for hospital patients while reducing costs.

- *RFI: Provider to Patient Exchange Objective:* This objective is noble but doesn't sufficiently recognize that EHRs are still struggling to share data with each other due to variance in set up and configuration. To be successful, **we believe that CMS should first focus on better national standards for data exchange and facilitating engagement in data exchanges by various care settings and community-based services.** We support the inclusion of ambulatory providers, post-acute care providers, pharmacies, dental providers and community-based services. We know that health IT adoption rates are depressed in care settings that were not subject to the EHR Incentive Programs. We also know that, as providers try to maintain patients within community settings, it is important that patient records are comprehensive and follow the patient across care settings. The need for further standardize interoperability and to increase participation cannot be understated. We would also suggest that CMS include payers within these efforts.

We should also highlight the importance of timing of access to information and the need for reasonable and targeted standards in the area. Immediate electronic access to information, such as laboratory results, without provider review or consult has consequences and has the potential to add stress and confusion for patients and providers. Information regarding pathology and cytology can be detrimental to a patient if they have not heard this news from a provider first. While patients can see test results, providers may need to explain that not all abnormal results are bad or that not all normal results are good. When establishing timeframes between result finalization and release to the patient, this process needs to be targeted. While we believe it may be possible to further condense these timeframes, we would not support further reductions for pathology and cytology due to the highly complex and sensitive nature of results. In addition to patient concerns, health plans and payers often demand immediate access to information to start processing. Often providers wait for various laboratory tests and results to be returned prior to completing documentation. Health plans and payers often want documentation to

support charges, and such documentation may not be done due to this workflow regarding the wait for results. For payers, we believe that access should be defined by standards of when documentation should be completed in a patient chart. Again, clear standards related to information access are needed.

To promote record accuracy, standards that promote patient matching should be prioritized. Among initiatives that could be undertaken include:

- Standardize processes and/or formats for data collection, such as the use of standardizing conventions for naming newborns (e.g. use of legal name);
- Additional data elements, such as patient email addresses; and
- Standardize patient addresses into USPS format that includes a verification process.

We would also suggest that CMS engage a stakeholder group to seek feedback and build consensus on data elements to be collected and the preferred format.

- *RFI: Integration of Patient-Generated Health Data into EHRs using CEHRT:* Although we support initiatives to empower patients to be engaged in their health care, **we have concerns with the role that providers should have in this area and whether it is an appropriate PI measure.** In the initial definition of Meaningful Use Stage 3, a patient-generated health data (PGHD) measure was included but subsequently removed when the program transitioned to an interoperability focus. We question what has changed to warrant its inclusion now. As for the role of the provider, incorporating PGHD requires action on the part of patients. Providers cannot force patients to take steps to improve their generated data. We are opposed to any such measures that would penalize providers if their patients choose to not engage in applications or portals that allow submission of data. Should CMS develop a PGHD measure, it would need to be well defined and allow adequate time for implementation and training of patients to complete.
- *RFI: Engaging In Activities that Promote EHR Safety:* This topic is not new. Our health care system is heavily engaged in security risk analysis and mitigation plans related to our EHR and technology implementation and, given that CMS has deemed additional clinical decisions support tools for safety to be "topped out," we assume that this is true of most hospitals. **We do believe that increased standardization for interoperability and requiring agencies, such as state departments of health, to meet the same security requirements will enhance EHR safety.** As CMS explores this issue, **we would suggest additional work surrounding HIPAA and cybersecurity definitions for where patient accountability begins, and health care organizations accountability ends.**

While attesting to security measures, such as those within SAFER Guides, could be beneficial, we do not have enough information to provide a judgment at this point. We are uncertain about overall reporting burden, whether these attestations represent more topped out activities and whether additional infrastructure costs are associated. As this is developed, we would suggest any proposal undergo future rulemaking to solicit more feedback.

- **APM Partial QP Determinations:** For PY 2020, CMS is restricting Partial Qualifying APM Participant (QP) status to the Tax ID (TIN)/National Provider Identifier (NPI) combination through which the Partial QP status is attained. As a result, Partial QPs would be subject to MIPS reporting and MIPS

payment adjustments for TIN/NPI combinations outside the APM Entity, and their APM Entity would still elect whether to participate in MIPS for the TIN(s) associated with the APM Entity. This is a step backwards. We urge CMS to permit Partial QPs to opt out of MIPS reporting for their non-Advanced APM TIN(s).

- **Advanced APM Thresholds:** Perhaps the biggest impediment to Advanced APM status and growth is an issue that CMS choose not to address – Advanced APM participation thresholds. ***We reiterate our past position that Advanced APM participation thresholds for Medicare-only revenue or patient count should be eliminated altogether or kept at 2017 and 2018 performance year levels.*** The Proposed Rule maintains the MACRA thresholds which progressively increase the revenue percentage for QPs within Advanced APMs from 25% to 50% (starting in 2019) to 75% (starting in 2021) and the patient counts from 20% to 35% to 50%. We are concerned with the graduated schedule of heightened thresholds. In particular, these thresholds:
 - Discourage future Advanced APM participation from clinicians struggling to meet current thresholds.
 - Jeopardize clinicians that have already achieved Advanced APM status.
 - Disfavor rural providers, as the limited number of rural patients makes thresholds more difficult to achieve than in urban areas. In rural areas, ACOs may participate in every available risk arrangement but still fall short on the number of covered lives.

In addition, the thresholds incorrectly assume that accelerated growth in value-based arrangements is achievable over a very short term. The thresholds fail to adequately consider:

- Levels of risk arrangements outside Part B Medicare, which are often insufficient in Advanced APM local markets
- Inherent attribution limits. There are a limited number of primary care providers (PCPs) or PCP-like specialists that are not employed by competitive health systems or, as the only major specialist group in the community, are willing to align directly with one health system versus another health system.
- Diminishing return constructs within Advanced APMs. The objective is to deploy programs and resources to lower the overall costs while maintaining access and quality. As a result, there is a decrease in overall revenue from value-based arrangements.

As participation in Advanced APMs increases, we urge CMS to re-evaluate these thresholds to encourage greater migration to value-based arrangements. Instead of MACRA thresholds, Advanced APM status should rely on the underlying eligibility requirements for those Advanced APM demonstrations or programs appearing on the QPP website list. If thresholds are not eliminated, we would suggest that revenue threshold remain constant at the 25% revenue or 20% patient count Medicare-only thresholds with one caveat – Medicare-only should also recognize MA revenue or patient count as needed for MA relationships that share “more than nominal risk” with clinicians.

- **Other APM Flexibilities:** We respectfully request CMS to consider the below recommendations to enable operational flexibility to promote innovation, provider transition to value and enhanced patient experience:
 - **Make transparent the Qualified APM Participant (QP) calculation within the QPP.** QPP thresholds are based on revenue or beneficiary counts for the ratio of attributed

- beneficiaries over attribution-eligible beneficiaries. These counts different from ACO assigned and assignable beneficiaries, and ACO reports cannot be used to project QP scores. We encourage CMS to make QP calculations transparent and even consider using the same definitions as within the ACO programs to promote definition consistency, enable providers to gauge QP status and encourage further transition to value and risk-based arrangements.
- Timing of annual QPP Proposed Rule. We would suggest that CMS consider moving the QPP Proposed Rule to a notice and comment period earlier in the calendar year. By placing within the annual Physician Fee Schedule update, it is unlikely that the Final Rule will be released before November leaving only 2 months to operationalize changes. We would suggest that the QPP update occur during a timeframe that is more aligned to the annual Inpatient Prospective Payment System update (Proposed Rule in the spring and Final Rule in the summer).
 - Streamline QualityNet access to permit system level secure file exchange access for integrated health systems. QualityNet houses reports to monitor performance under various CMS quality programs including the Inpatient and Outpatient Quality Reporting, Value Based Purchasing Program, HAC Reduction Program, and Hospital Readmission Reduction Program. UPH regularly uses QualityNet reports, such as (1) Overall Hospital Star Rating Hospital Specific Reports; (2) Hospital Value-Based Purchasing (VBP) Percentage Payment Summary Report (PPSR); (3) Hospital-Acquired Condition Reduction Program Hospital Specific Reports; (4) Medicare Spending per Beneficiary Hospital Specific Reports; (5) Public Reporting Preview Reports; and (6) Hospital Readmission Reduction Program Hospital Specific Reports. While each UPH hospital can access these reports through the QualityNet secure file exchange, our centralized UPH analytics personnel **with** approved QualityNet Healthcare System level access **cannot** receive these same reports. This requires duplicative steps by our centralized analytics team to request these reports from each hospital, which is both unnecessary and time consuming and defeats any efficiency efforts to centralize reporting functions.
 - Flexibility in Web Interface submission requirements for Next Generation ACO quality reporting. In 2018, CMS changed the reporting format from an xml format to an Excel format. The new Excel file template was provided, including 146 columns to capture data for all measures in one spreadsheet and drop-down lists to help ensure only valid data was submitted in each cell. While this format might be helpful for an organization that manually abstracts their data into the spreadsheet, it was and is very burdensome for organizations that have automated this process to pull directly from their EHR. UAC had been required to use the xml format since its participation in the Pioneer ACO Model in 2012. We have invested time and infrastructure to support this reporting format. We would request that CMS consider reinstating the xml format for early adopters and also suggest that in the future CMS work with stakeholders as it considers “upgrading” reporting systems to consider timing and impact.

We are pleased to provide comments to the proposed regulations and their impact on our integrated

healthcare system. To discuss our comments or for additional information on any of the addressed topics, please contact Sabra Rosener, Vice President and Government Relations Officer, Government and External Affairs at sabra.rosener@unitypoint.org or 515-205-1206.

Sincerely,



Dan Allen, MD
Chief Medical Officer
UnityPoint Clinic



Sabra Rosener, JD
VP, Government & External Affairs
UnityPoint Health